# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 20-F

**(Mark one)**

☐ **Registration statement pursuant to Section 12(b) or (g) of the Securities Exchange Act of 1934**

**or**

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**For the Fiscal Year ended June 30, 2016**

**or**

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**or**

☐ **Shell company report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Commission file number: 001-37518**

# Benitec Biopharma Limited

**(Exact name of Registrant as specified in its charter)**

**Australia**
**(Jurisdiction of incorporation or organization)**

**99 Mount Street, Suite 1201**
**North Sydney, NSW, 2060, Australia**
**(Address of principal executive offices)**

**Greg West**
**Chief Executive Officer**
**99 Mount Street, Suite 1201**
**North Sydney, NSW, 2060, Australia**
**Tel: +61 2 9555 6986**
**Fax: +612 9818 2238**
**(Name, telephone, e-mail and/or facsimile number and address of company contact person)**

**Securities registered or to be registered pursuant to Section 12(b) of the Act:**
**None**

**Securities registered or to be registered pursuant to Section 12(g) of the Act:**

| Title of each class | Name of each exchange on which registered |
|---|---|
| **American Depositary Shares, each representing twenty Ordinary Shares*** | **The NASDAQ Capital Market** |
| **Warrants, each exercisable for one American Depositary Share** | **The NASDAQ Capital Market** |

*** Not for trading, but only in connection with the registration of American Depositary Shares.**

**Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:**
**None**

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Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the date of the close of the period covered by the annual report.

**146,529,096 Ordinary Shares at June 30, 2016**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) for the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☐ Yes ☒ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☐ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

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## 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 US$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 Annual Report on Form 20-F contains translations of some Australian dollar amounts into U.S. dollars at specified rates. Except as otherwise stated in this Annual Report on Form 20-F, all translations from Australian dollars to U.S. dollars are based on the rate published by the Reserve Bank of Australia on the date indicated. See Item 3.A "Key Information—Selected Financial Data." No representation is made that the Australian dollar amounts referred to in this Annual Report on Form 20-F could have been or could be converted into U.S. dollars at such rate.

Unless otherwise noted, all industry and market data in this Annual Report on Form 20-F, including information provided by independent industry analysts, are presented in U.S. dollars. Unless otherwise noted, all other financial and other data related to Benitec Biopharma Limited in this Annual Report on Form 20-F are presented in Australian dollars. All references to "$" in this Annual Report on Form 20-F refer to Australian dollars or U.S. dollars, as the context requires based on the foregoing. All references to "A$" in this Annual Report on Form 20-F mean Australian dollars. All references to "US$" in this Annual Report on Form 20-F mean U.S. 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 Annual Report on Form 20-F have been prepared in accordance with International Accounting Standards 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. See Item 3.A "Key Information—Selected Financial Data."

## TRADEMARKS AND TRADENAMES

We have proprietary and licensed rights to trademarks used in this Annual Report on Form 20-F which are important to our business, many of which are registered under applicable intellectual property laws. These trademarks are as follows:

- BENITEC BIOPHARMA®
- BENITEC®
- SILENCING GENES FOR LIFE®
- Tribetarna®
- Hepbarna®
- Nervarna®

Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 20-F appear without the "®" or "™" symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent possible under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. Each trademark, trade name or service mark of any other company appearing in this Annual Report on Form 20-F is the property of its respective holder.

## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F contains forward looking statements that are subject to a number of risks and uncertainties, many of which are beyond our control. All statements, other than statements of historical fact included in this Annual Report on Form 20-F, regarding our strategy, future operations, financial position, projected costs, prospects, plans and objectives of management are forward looking statements. When used in this Annual Report on Form 20-F, the words "could," "believe," "anticipate," "intend," "estimate," "expect," "may," "continue," "predict," "potential," "project," or the negative of these terms, and similar expressions are intended to identify forward looking statements, although not all forward looking statements contain such identifying words. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report on Form 20-F, we caution you that these statements are based on a combination of facts and important factors currently known by us and our expectations of the future, about which we cannot be certain.

Forward-looking statements may include statements about:

- our plans to develop and potentially commercialize our product candidates;
- the timing of the initiation and completion of preclinical studies and clinical trials;
- the timing of patient enrollment and dosing in any future clinical trials;
- the timing of the availability of data from clinical trials;
- the timing of expected regulatory filings;
- the development of novel AAV vectors;
- expectations about the plans of licensees of our technology;
- the clinical utility and potential attributes and benefits of ddRNAi and our product candidates, including the potential duration of treatment effects and the potential for a "one shot" cure;
- potential future out-licenses and collaborations;
- our expectations regarding expenses, ongoing losses, future revenue, capital needs and needs for additional financing;
- the length of time over which we expect our cash and cash equivalents, including the proceeds from our U.S. initial public offering, to be sufficient; and
- our intellectual property position and the duration of our patent portfolio.

All forward-looking statements speak only as of the date of this Annual Report on Form 20-F. You should not place undue reliance on these forward-looking statements. Although we believe that our plans, objectives, expectations and intentions reflected in or suggested by the forward-looking statements we make in this Annual Report on Form 20-F are reasonable, we can give no assurance that these plans, objectives, expectations or intentions will be achieved. We disclose important factors that could cause our actual results to differ materially from our expectations under Item 3.D "Key Information—Risk Factors" and elsewhere in this Annual Report on Form 20-F.

The forward-looking statements made in this Annual Report on Form 20-F relate only to events or information as of the date on which the statements are made in this Annual Report on Form 20-F. 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.

## PART I

### Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

### Item 2. Offer Statistics and Expected Timetable

Not applicable.

### Item 3. Key Information

#### A. *Selected Financial Data.*

The following tables set forth summary historical financial data for the periods indicated.

The consolidated statement of profit or loss and other comprehensive income data and consolidated statement of financial position data for and as of the fiscal years ended June 30, 2014, 2015 and 2016 are derived from the audited consolidated financial statements included in this Annual Report on Form 20-F. In our management's opinion, these financial statements include all adjustments necessary for the fair presentation of our financial condition as of such dates and our results of operations for such periods.

Our financial statements have been prepared in Australian dollars and in accordance with International Financial Reporting Standards. Our financial statements comply with IFRS, as issued by the IASB.

You should read the selected consolidated financial data in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 20-F, including Item 5. "Operating and Financial Review and Prospects" and "Item 18. Financial Statements." Our historical results do not necessarily indicate our expected results for any future periods.

| (in thousands, except per share data) | For the year ended June 30, | | |
|---|---|---|---|
| | 2016 | 2015 | 2014 |
| **Statement of Profit or Loss and Other Comprehensive Income Data:** | | | |
| Revenue: | | | |
| Revenue | A$ 464 | A$ 1,081 | A$ 598 |
| Other income | 3,590 | 2,891 | 776 |
| Total revenue | 4,054 | 3,972 | 1,374 |
| Costs and expenses: | | | |
| Royalties and license fees | (139) | (40) | (193) |
| Research and development | (13,287) | (6,228) | (3,758) |
| Employment related | (6,283) | (3,425) | (2,444) |
| Share based expenses | (1,746) | (1,503) | (355) |
| Travel related expenses | (1,023) | (1,039) | (585) |
| Consultants costs | (1,020) | (882) | (653) |
| Occupancy costs | (718) | (275) | (122) |
| Corporate expenses | (1,211) | (1,018) | (646) |
| Net loss foreign exchange | (414) | — | (111) |
| IPO costs | (1,191) | (1,071) | — |
| Write-off of clinical trial prepayment | (1,800) | — | — |
| Loss before income tax | (24,778) | (11,509) | (7,493) |
| Income tax benefit | — | — | 454 |
| Loss for the period | A$ (24,778) | A$ (11,509) | A$ (7,039) |
| Loss per share, basic and diluted | A$ 0.1741 | A$ (0.0996) | A$(0.0778) |
| Weighted-average shares outstanding, basic and diluted | 142,312,486 | 115,507 | 90,432 |

**(in thousands)**

| | As of June 30, | | |
|---|---|---|---|
| | 2016 | 2015 | 2014 |
| **Statement of Financial Position Data:** | | | |
| Cash and cash equivalents | A$18,230 | A$21,787 | A$31,359 |
| Total current assets | 19,384 | 25,064 | 34,448 |
| Total assets | 19,890 | 25,520 | 34,496 |
| Total current liabilities | 1,035 | 1,642 | 955 |
| Total liabilities | 1,053 | 1,642 | 955 |
| Total equity | 18,837 | 23,878 | 33,541 |

**Exchange Rate Information**

The Australian dollar is convertible into U.S. dollars at freely floating rates. There are no legal restrictions on the flow of Australian dollars between Australia and the United States. Any remittances of dividends or other payments by us to persons in the United States are not and will not be subject to any exchange controls.

Our financial statements are prepared and presented in Australian dollars.

The table below sets forth for the periods identified the number of U.S. dollars per Australian dollar as published by the Reserve Bank of Australia. We make no representation that any Australian dollar or U.S. dollar amounts could have been, or could be, converted into U.S. dollars or Australian dollars, as the case may be, at any particular rate, the rates stated below, or at all. On October 24, 2016, the Australian dollar/U.S. dollar exchange rate was 0.7615.

| | At Period End (1) | Average Rate (2) | High (3) | Low (4) |
|---|---|---|---|---|
| **Fiscal year ended June 30,** | | | | |
| 2016 | 0.7426 | 0.7272 | 0.7812 | 0.6867 |
| 2015 | 0.7680 | 0.8293 | 0.9458 | 0.7590 |
| 2014 | 0.9420 | 0.9187 | 0.9672 | 0.8716 |
| 2013 | 0.9275 | 1.0271 | 1.0593 | 0.9202 |
| 2012 | 1.0191 | 1.0362 | 1.1026 | 0.9453 |
| **Month ended:** | | | | |
| September 30, 2016 | 0.7630 | 0.7595 | 0.7698 | 0.7469 |
| August 31, 2016 | 0.7514 | 0.7630 | 0.7711 | 0.7514 |
| July 31, 2016 | 0.7522 | 0.7526 | 0.7626 | 0.7436 |
| June 30, 2016 | 0.7426 | 0.7396 | 0.7533 | 0.7239 |
| May 31, 2016 | 0.7242 | 0.7322 | 0.7607 | 0.7160 |
| April 30, 2016 | 0.7655 | 0.7662 | 0.7812 | 0.7535 |

(1) Determined by the published rate on the last trading day of the month.
(2) Determined by averaging the published rate on the last day of each full month during the fiscal year indicated or by averaging the published rates for all trading days during the month indicated, as applicable.
(3) Determined by the highest published rate during the month.
(4) Determined by the lowest published rate during the month.

**B.** ***Capitalization and Indebtedness.***

Not applicable.

**C.** ***Reasons for the Offer and Use of Proceeds.***

Not applicable.

**D.** ***Risk Factors.***

*An investment in the ADSs involves significant risks. You should carefully consider the risks described below and the other information in this Annual Report on Form 20-F. If any of the following risks actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected, the trading price of the ADSs could decline and you could lose all or part of your investment.*

**Risks Related to Our Financial Condition and Capital Requirements**

***We have incurred significant net losses. We anticipate that we will continue to incur significant net losses for the foreseeable future and we may never achieve or maintain profitability.***

We are a biotechnology company and have not yet generated significant revenue. We have incurred losses of A$7.0 million, A$11.5 million and A$24.8 million for the fiscal years ended June 30, 2014, 2015 and 2016, respectively. We have not generated any revenues from sales of any of our product candidates.

As of June 30, 2016, we had accumulated losses of A$131.4 million. We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities. To date, we have financed our operations primarily through the issuance of equity securities, research and development grants from the Australian government and payments from our collaboration partners. We have not generated, and do not expect to generate, any significant revenue for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies and clinical trials and the regulatory approval process for product candidates. The amount of our future net losses is uncertain and will depend, in part, on the rate of our future expenditures. Our ability to continue operations will depend on, among other things, our ability to obtain funding through equity or debt financings, strategic collaborations or additional grants.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our research and preclinical development of our product candidates;

- expand the scope of our current preclinical studies for our product candidates or initiate clinical, additional preclinical or other studies for product candidates;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials;
- further develop the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies, which may or may not include those related to our ddRNAi technology and delivery vectors for our therapeutic candidates;
- maintain, protect and expand our intellectual property portfolio;
- create additional infrastructure to support our operations as a public company in the United States and our product development and future commercialization efforts; and
- experience any delays or encounter issues with any of the above.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause the price of the ADSs to decline.

***We have never generated any revenue from product sales and may never be profitable.***

Our ability to generate significant revenue and achieve profitability depends on our ability to, alone or with strategic collaboration partners, successfully complete the development of and obtain the regulatory approvals for our product candidates, to manufacture sufficient supply of our product candidates, to establish a sales and marketing organization or suitable third-party alternative for the marketing of any approved products and to successfully commercialize any approved products on commercially reasonable terms. All of these activities will require us to raise sufficient funds to finance business activities. We do not expect any milestone payments from our collaborative partners to be significant in the foreseeable future. In addition, we do not anticipate generating revenue from commercializing product candidates for the foreseeable future, if ever. Our ability to generate future revenues from commercializing product candidates depends heavily on our success in:

- establishing proof of concept in preclinical studies and clinical trials for our product candidates;
- successfully initiating and completing clinical trials of our product candidates;
- obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials;
- maintaining, protecting and expanding our intellectual property portfolio, and avoiding infringing on intellectual property of third parties;
- establishing and maintaining successful licenses, collaborations and alliances with third parties;
- developing a sustainable, scalable, reproducible and transferable manufacturing process for our product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide products and services adequate, in amount and quality, to support clinical development and commercialization of our product candidates, if approved;

- launching and commercializing any product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;
- obtaining market acceptance of any product candidates that receive regulatory approval as viable treatment options;
- obtaining favorable coverage and reimbursement rates for our products from third-party payors;
- addressing any competing technological and market developments;
- identifying and validating new product candidates; and
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter.

The process of developing product candidates for ddRNAi-based therapeutics contains a number of inherent risks and uncertainties. For example, it may not be possible to identify a target region of a disease-associated gene that has not been previously identified and/or patented by others, resulting in restrictions on freedom to operate for that target sequence. Silencing the target gene may not ultimately result in curing the disease as there may be more factors contributing to the development of the disease than the target gene. Silencing the target gene using ddRNAi may lead to short-term or long-term adverse effects that were not predicted or observed in preclinical studies. The delivery of the DNA construct to the target cells may not be possible, or complete or adequate to provide sufficient therapeutic benefit.

Even if one or more of our product candidates is approved for commercial sale, we may incur significant costs associated with commercializing any approved product candidate. As one example, our expenses could increase beyond expectations if we are required by the Food and Drug Administration, or FDA, or other regulatory agencies, domestic or foreign, to perform clinical and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations, which could have an adverse effect on our business, financial condition, results of operations and prospects.

***We will need to continue our efforts to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or discontinue our product development efforts or other operations.***

Developing ddRNAi products is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates in preclinical studies and in future clinical trials and as we undertake preclinical studies of new product candidates.

As of June 30, 2016, our cash and cash equivalents were A$18.2 million. We estimate that our cash and cash equivalents will be sufficient to fund our operations until approximately the fourth calendar quarter of calendar 2017. However, our 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, through public or private equity or debt financings, government grants or other third-party funding, strategic alliances and licensing arrangements or a combination of these approaches. In addition, because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. In any event, we will require additional capital to obtain regulatory approval for our product candidates and to commercialize any product candidates that receive regulatory approval.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may compromise our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders, and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ordinary shares, ADSs and Warrants to decline. If we incur indebtedness we may be required to agree to restrictive

covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could compromise our ability to conduct our business. We could also seek financing through arrangements with collaborative partners at an earlier stage than would otherwise be desirable and we may be required to relinquish rights to some or all of our technologies or product candidates or otherwise agree to terms unfavorable to us.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any approved product candidates.

***We will be unable to conclude clinical trials for our product candidates for hepatitis B, AMD and OPMD if we are unable to raise additional financing.***

We plan to develop our pipeline of product candidates using our ddRNAi technology to deliver therapeutics for a number of life-threatening conditions. We intend to advance our product candidates for hepatitis B, AMD and OPMD through clinical trials, but we will need additional financing to do so. In order to complete the planned preclinical proof-of-concept studies for our lead product candidates and to build the infrastructure that we believe will be necessary to commercialize our lead product candidates, we will require substantial additional funding. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs for these product candidates.

***We receive Australian government research and development grants. If we lose funding from these research and development grants, we may encounter difficulties in the funding of future research and development projects, which could harm our operating results.***

We have historically received, and expect to continue to receive, grants through the Australian federal government's Research and Development Tax Incentive program, under which the government provides a cash refund for the 43.5% (reduced from 45% at July 1, 2016) of eligible research and development expenditures by small Australian entities, which are defined as Australian entities with less than A$20 million in revenue, having a tax loss. The Research and Development Tax Incentive grant is made by the Australian federal government for eligible research and development purposes based on the filing of an annual application. We received Research and Development Tax Incentive grants in the fiscal years ended June 30, 2014, 2015 and 2016 of A$0.8 million, A$2.3 million and A$3.6 million, respectively. This grant is available for our research and development activities in Australia, as well as activities in the United States to the extent such U.S.-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. To the extent our research and development expenditures are deemed to be "ineligible," then our grants would decrease. In addition, the Australian government may in the future decide to modify the requirements of, reduce the amounts of the grants available under, or discontinue the Research and Development Tax Incentive program. For instance, the Australian government recently released findings and a panel recommendation that if implemented would reduce the amount of the grants available to small companies such as Benitec to a maximum of A$2 million per annum. Any such change in the Research and Development Tax Incentive program could have a material adverse effect on our future cash flows and financial position.

**Risks Related to the Product Development and Regulatory Approval of Our Product Candidates**

***Our product candidates are based on ddRNAi technology. Currently, no product candidates utilizing ddRNAi technology have been approved for commercial sale and our approach to the development of ddRNAi technology may not result in safe, effective or marketable products.***

We have concentrated our product research and development efforts on our ddRNAi technology, and our future success depends on successful clinical development of this technology. We plan to develop a pipeline of product candidates using our ddRNAi technology and deliver therapeutics for a number of chronic and life-threatening conditions, including hepatitis B, age-related macular degeneration and OPMD.

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 may be unable to reach agreement on favorable terms, or at all, with providers of vectors needed to optimize delivery of our product candidates to target disease cells and we may also experience unanticipated problems or delays in expanding our manufacturing capacity or transferring our manufacturing process to commercial partners, any of which may prevent us from completing our preclinical trials, initiating clinical trials or commercializing our products on a timely or profitable basis, if at all.

Only a few product candidates based on RNAi or ddRNAi have been tested in either animals or humans, and a number of clinical trials conducted by other companies using other forms of RNAi technologies have not been successful. We may discover that application of ddRNAi does not possess properties required for a therapeutic benefit, such as the ability to continually express shRNAs for the period of time required to be maximally effective or the ability of viral vectors or other technologies to effectively deliver ddRNAi constructs to target cells in therapeutically relevant concentrations. In addition, application of ddRNAi-based products in humans may result in safety problems. We currently have only limited data, and no conclusive evidence, to suggest that we can effectively produce effective therapeutic treatments using our ddRNAi technology.

***We are early in our product development efforts and all of our current product candidates are still in preclinical development. We may not be able to obtain regulatory approvals for the commercialization of some or all of our product candidates.***

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of biologics is subject to extensive regulation by the FDA and other regulatory authorities, and these regulations differ from country to country. We do not have any products on the market and are early in our development efforts. All of our product candidates are in preclinical development. All of our current and future product candidates are subject to the risks of failure typical for development of biologics. The development and approval process is expensive and can take many years to complete, and its outcome is inherently uncertain. In addition, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results.

We have not submitted an application, or received marketing approval, for any of our product candidates and will not submit any applications for marketing approval for several years. We have limited experience in conducting and managing clinical trials necessary to obtain regulatory approvals, including approval by the FDA. To receive approval, we must, among other things, demonstrate with evidence from clinical trials that the product candidate is both safe and effective for each indication for which approval is sought, and failure can occur in any stage of development. Satisfaction of the approval requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we might receive regulatory approvals for any of our product candidates currently under development.

The FDA and foreign regulatory authorities also have substantial discretion in the pharmaceutical product approval process. The numbers, types and sizes of preclinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, and there may be varying interpretations of data obtained from preclinical studies or clinical trials, any of which may cause delays or limitations in the approval or the decision not to approve an application. Regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of any future clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of any future clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the patients recruited for a particular clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;

- the results of any future clinical trials may not confirm the positive results from earlier preclinical studies or clinical trials;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from any future clinical trials of our product candidates may not be sufficient to the satisfaction of FDA or comparable foreign regulatory authorities to support the submission of a biologics license application, or BLA, or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may only agree to approve a product candidate under conditions that are so restrictive that the product is not commercially viable;
- regulatory agencies might not approve or might require changes to our manufacturing processes or facilities; or
- regulatory agencies may change their approval policies or adopt new regulations in a manner rendering our clinical data insufficient for approval.

Any delay in obtaining or failure to obtain required approvals could materially and adversely affect our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact the price of the ADSs and Warrants. Furthermore, any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. These limitations may limit the size of the market for the product.

We are not permitted to market our product candidates in the United States or in other countries until we receive approval of a BLA from the FDA or marketing approval from applicable regulatory authorities outside the United States. Obtaining approval of a BLA can be a lengthy, expensive and uncertain process. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States, which will significantly impair our ability to generate any revenues. In addition, failure to comply with FDA and non-U.S. regulatory requirements may, either before or after product approval, if any, subject us to administrative or judicially imposed sanctions, including:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending BLAs or supplements to approved BLAs.

Even if we do receive regulatory approval to market a product candidate, any such approval may be subject to limitations on the indicated uses for which we may market the product. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us or our collaborators to commence product sales. Any delay in obtaining, or an inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability.

***Because our product candidates are based on a novel technology, it is difficult to predict the time and cost of product candidate development as well as subsequently obtaining regulatory approval.***

The clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other pharmaceutical product candidates. The FDA and comparable foreign regulatory authorities have relatively limited experience with ddRNAi-based therapeutics, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States or other countries. We and our current collaborators, or any future collaborators, may never receive approval to market and commercialize any product candidate. Even if we or a collaborator obtain regulatory approval, the approval may be for disease indications or patient populations that are not as broad as we intended or desired and may require labeling that includes significant use or distribution restrictions or safety warnings.

Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. For example, the FDA has established the Office of Tissues and Advanced Therapies (formerly Office of Cellular, Tissue and Gene Therapies) within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the United States National Institutes of Health, or the NIH, are also subject to review by the NIH Office of Biotechnology Activities' Recombinant DNA Advisory Committee, or the RAC. Although the FDA decides whether individual gene therapy protocols may proceed, the RAC review process can delay the initiation of a clinical trial, even if the FDA has reviewed the trial design and details and approved its initiation. Conversely, the FDA can put a proposed biological product on clinical hold even if the RAC has provided a favorable review of the product. Also, before a clinical trial can begin at any institution, that institution's institutional review board, or IRB, and its institutional biosafety committee, or IBC, if it has one, have to review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or comparable foreign regulatory bodies to change the requirements for approval of any of our product candidates.

These committees and advisory groups and the new guidelines they promulgate and new requirements they may impose may lengthen the clinical development and regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory committees and advisory groups, and comply with applicable guidelines and requirements as they may change from time to time. If we fail to do so, we may be required to delay or discontinue development of our product candidates. These additional processes may result in a development, review and approval process that is longer than we otherwise would have expected for our product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market would delay or prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability.

***Positive results from preclinical studies of our product candidates are not necessarily predictive of the results of our planned clinical trials of our product candidates.***

Positive results in preclinical proof-of-concept and animal studies of our product candidates may not result in positive results in clinical trials in humans. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in preclinical development or early stage clinical trials, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused

by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or other regulatory authority approval. If we fail to produce positive results in our clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be negatively impacted.

***Issues that may impact ddRNAi delivery to the cell could adversely affect or limit our ability to develop and commercialize product candidates.***

Successful clinical development of ddRNAi-based therapeutics is largely dependent on using the appropriate vectors to obtain therapeutically relevant concentrations of the DNA constructs that express the shRNAs in the appropriate target cells. To develop effective product candidates, we will need to license delivery technologies from third parties or develop delivery technologies with research collaborators. Although delivery technologies, including AAV vectors, have been identified and are well defined for specific tissue types, we continue to seek vectors with ideal delivery properties for other indications we are pursuing, including OPMD. The tissue tropism and other physical properties of AAV vectors are limited and may not be effective for other product candidates or delivery into a wide array of tissues types. AAV vectors can also trigger immune responses in some patients, and those patients will not derive clinical benefit from administration of a product candidate unless steps are taken to clinically address the issue. If we or our collaborators are not successful in identifying effective vectors for our product candidates, we may not succeed in developing marketable products. In addition, if we are unable to reach agreement on favorable terms, or at all, with providers of any effective vectors that we do identify, we may not succeed in completing our clinical trials or commercializing our products on a timely or profitable basis, if at all. We have only one such agreement in place that allows us to use a vector both for clinical trials and for commercialization, and that agreement is with respect to our program for the treatment of AMD.

We use AAV vectors as part of our ddRNAi approach for several indications. As such, we require licenses and the ability to manufacture large quantities of AAV particles under the FDA's current good manufacturing practices, or cGMP, requirements and those of comparable foreign regulatory authorities in order to commercialize a product candidate using an AAV vector.

***We may find it difficult to enroll patients in our clinical trials, and patients could discontinue their participation in any future clinical trials, which could delay or prevent any future clinical trials of our product candidates and make those trials more expensive to undertake.***

Identifying and qualifying patients to participate in any future clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates. Patients may be unwilling to participate in any future clinical trials because of negative publicity from adverse events in the biotechnology, RNAi or gene therapy industries. Patients may be unavailable for other reasons, including competitive clinical trials for similar patient populations, and the timeline for recruiting patients, conducting trials and obtaining regulatory approval of potential products may be delayed. If we have difficulty enrolling a sufficient number of patients to conduct any future clinical trials as planned, we may need to delay, limit or discontinue those clinical trials. Clinical trial delays could result in increased costs, slower product development, setbacks in testing the effectiveness of our technology or discontinuation of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a trial, to complete any future clinical trials in a timely manner. Patient enrollment is affected by factors including:

- finding and diagnosing patients;
- severity of the disease under investigation;
- design of the clinical trial protocol;
- size and nature of the patient population;

- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- clinicians' and patients' perceptions of the potential advantages of the product being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

For example, we experienced some difficulties in enrolling patients in our clinical trial of TT-034, which was discontinued for commercial reasons. These difficulties were due to several factors, including sudden changes in patients' viral load, liver enzymes and other clinical parameters immediately prior to their dosing, as well as late withdrawal due to personal reasons. We believe the increased availability of new and effective therapies such as Sovaldi and Harvoni, which were recently approved for treatment of the hepatitis C virus, and the fact that the early lower-dose cohort patients receive a sub-therapeutic dose of TT-034, may also have been contributing factors. We may face similar difficulties enrolling patients in clinical trials for other product candidates for these and other reasons.

We or our collaborators plan to seek initial marketing approval for our product candidates in the United States, Australia and Europe. We may not be able to initiate or continue any future clinical trials in a timely manner if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA or comparable foreign regulatory agencies. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with contract research organizations, or CROs, clinical sites and physicians;
- different standards for the conduct of clinical trials;
- our inability to locate and engage qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments.

In addition, patients enrolled in any future clinical trials may discontinue their participation at any time during the trial as a result of a number of factors, including experiencing adverse events, which may or may not be judged related to our product candidates under evaluation. The discontinuation of patients in any one of our trials may cause us to delay or discontinue our clinical trial, or cause the results from that trial not to be positive or sufficient to support either partnering with a pharmaceutical company to further develop and commercialize the product candidate or filing for regulatory approval of the product candidate.

***We may encounter substantial delays in any future clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.***

None of our proprietary product candidates are currently in clinical trials. Before obtaining marketing approval from regulatory authorities for the sale of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical trials are expensive and time-consuming, and their outcome is uncertain. We cannot guarantee that any clinical trials will be initiated or conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology or other data to support the initiation of human clinical trials;

- delays in reaching consensus with regulatory agencies on trial design;
- identifying, recruiting and training suitable clinical investigators;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining required IRB or IBC approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials;
- imposition of a clinical hold by regulatory agencies, including after an inspection of our clinical trial operations or trial sites;
- failure by our CROs, other third parties or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's good clinical practices, or GCP, or applicable regulatory requirements in other countries;
- inability to manufacture, test, release, import or export for use sufficient quantities of our product candidates for use in clinical trials;
- failure to manufacture our product candidate in accordance with cGMP requirements or applicable regulatory guidelines in other countries;
- delays in the testing, validation and manufacturing of our product candidates;
- delays in the delivery of our product candidates to the clinical trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites dropping out of a trial;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical trial protocols; or
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or discontinue product development programs.

Further, a clinical trial may be suspended or discontinued by us, our collaborators, the IRBs or the IBCs at the sites in which such trials are being conducted, the data safety monitoring board, or DSMB, for such trial, or by the FDA or comparable foreign regulatory authorities due to a number of factors, including the imposition of a clinical hold or termination of a trial due to failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, unforeseen safety issues or adverse side effects of our product candidate, or a product candidate from another company that shares similar properties, failure to demonstrate adequate benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience discontinuation of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates may be eliminated or delayed. Furthermore, many of the factors that lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In addition, if we or our third-party collaborators make significant manufacturing or formulation changes to our product candidates, we or they may need to conduct additional studies to bridge the modified product candidates to earlier versions to ensure comparability and safety of the two different product candidates.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to commercialize our programs and product candidates. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates.

If the results of any future clinical trials are inconclusive or if there are safety concerns or adverse events associated with our product candidates, we may:

- fail to obtain, or be delayed in obtaining, marketing approval for our product candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- need to change the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their marketing approval of the product after granting it;
- have regulatory authorities impose restrictions on distribution of the product in the form of a risk evaluation and mitigation strategy, or REMS, or modified REMS, that limit our ability to commercialize the product;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued and held liable for harm caused to patients; or
- experience damage to our reputation.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our product candidates.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of any particular study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any BLA we submit to the FDA or any comparable foreign regulating authorities. Any such delay or rejection could prevent us from commercializing our product candidates.

***Our product candidates and the process for administering our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any potential marketing approval.***

Treatment with our product candidates may produce undesirable side effects or adverse reactions or events. For example, the AAV vector and related capsid protein, which we are currently using to deliver most of our ddRNAi product candidates, could cause adverse immunological side effects due to preexisting and/or recall

responses to the naturally occurring virus from which the vector is engineered, or to the DNA construct product itself. These responses may also interfere with therapeutic efficacy if not identified and managed optimally. Preexisting immune responses to AAV manifesting as neutralizing antibodies are common within the general population and may be a limitation to the enrollment of patients in gene therapy clinical trials using AAV vectors, the successful use of AAV vectors in gene therapy clinical trials and the market acceptance of product candidates, if approved, that are delivered using AAV vectors. Patients with neutralizing antibodies to AAV will not derive clinical benefit from administration of such a product candidate unless steps are taken to clinically address the issue and those treatments themselves may cause adverse effects. In previous clinical trials undertaken by other companies involving systemic administration of AAV viral vectors for gene therapy, some subjects experienced adverse events, including the development of a negative T cell response against the AAV capsid protein. If our vectors cause similar adverse events, we may be required to delay or discontinue further clinical development of our product candidates. It is also possible that we may discover new adverse events related to AAV or other vectors, which could potentially enhance the risk to patients who use our product candidates delivered with that vector.

If any such adverse events occur, any future clinical trials could be suspended or discontinued and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidates for any or all targeted indications. The product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial. If we elect or are required to delay, suspend or discontinue any clinical trial of any of our product candidates, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if any of our product candidates receive marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of the product outweigh its risks, which may include, among other things, a medication guide outlining the risks of gene therapies for distribution to patients and a communication plan to patients and healthcare practitioners. Other elements to assure safe use in a mandated REMS could include, but are not limited to, restrictions upon distribution and prescribing, additional prescriber training, establishment of patient registries and other measures that could limit commercialization of the product. Comparable foreign regulating authorities might require adoption of measures similar to a REMS. Furthermore, if we or others later identify undesirable side effects caused by our product candidate, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could significantly harm our business, prospects, financial condition and results of operations.

***If we are unable to successfully develop related diagnostics for our therapeutic product candidates, or experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of our therapeutic product candidates.***

We may develop related diagnostics for some of our therapeutic product candidates. Such related diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval or clearance prior to commercialization. Marketing approval or clearance of the diagnostic will require sufficient data to support its safety and efficacy. In addition, at least in some cases, the FDA and comparable foreign regulatory authorities may require the development and regulatory approval or clearance of a related diagnostic as a condition to approving our therapeutic product candidates. While we have

some, limited experience in developing diagnostics, we plan to rely in large part on third parties to perform these functions. We may seek to enter into arrangements with one or more third parties to create a related diagnostic for use with our current or future product candidates.

If we, or any third parties that we engage to assist us, are unable to successfully develop or obtain marketing approval or clearance for related diagnostics for our therapeutic product candidates, or experience delays in doing so:

- the development of relevant product candidates may be delayed or impaired altogether if we are unable to appropriately select patients for enrollment in our clinical trials;
- our relevant therapeutic product candidate may not receive marketing approval if its effective use depends on a related diagnostic in the regulatory authority's judgment; and
- we may not realize the full commercial potential of any therapeutic product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients with the specific genetic alterations targeted by our therapeutic product candidates.

If any of these events were to occur, our business would be harmed.

***Even if we complete the necessary preclinical studies and clinical trials, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate or the approval may be for a more narrow indication than we expect.***

We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or comparable foreign regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Regulatory agencies also may approve a treatment candidate for fewer or more limited indications than requested, may not approve the price we intend to charge for our product candidate, may limit our ability to promote the product, may impose significant limitations upon the approval of the product, including, but not limited to, narrow indications, significant warnings, precautions or contraindications with respect to conditions of use, or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. The FDA or comparable foreign regulatory authorities may impose a REMS or other conditions upon our approval that limit our ability to commercialize the product candidate.

***Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.***

Even if we obtain regulatory approval in a jurisdiction, the regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the holder of an approved BLA is obligated to monitor and report to the FDA adverse events and any failure of a product to meet the specifications in the BLA. FDA guidance advises that patients treated with some types of gene therapy undergo follow-up observations for potential adverse events for as long as 15 years. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable foreign, federal and state laws.

In addition, product manufacturers and their establishments, products and applications are subject to payment of user fees and continual review and periodic inspections by the FDA and comparable foreign regulatory authorities for compliance with cGMP and comparable foreign requirements, and adherence to commitments made in the BLA. If we or a regulatory agency discover previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to permit government reimbursement of our product by government-sponsored third-party payors;
- refuse to approve a pending BLA or supplements to a BLA submitted by us for other indications or new product candidates;
- seize our product; or
- refuse to allow us to enter into or continue supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenues.

***Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval for our product candidates outside of the United States, which would limit our market opportunities and adversely affect our business.***

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of our product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries must also approve the manufacturing and marketing of the product candidates in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Even if a product candidate is approved, the FDA or comparable regulatory authorities in other countries, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States also have requirements for approval of product candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Regulatory approval of a product candidate in one country does not ensure approval in any other country, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in other countries. Also, regulatory approval for any of our product candidates may be withdrawn based on adverse events reported or regulatory decisions made in other countries. If we fail to comply with the regulatory requirements in international markets and/or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be compromised and our business may be adversely affected.

***Our future prospects are also dependent on our or our collaborators' ability to successfully develop a pipeline of additional product candidates, and we and our collaborators may not be successful in efforts to use our platform technologies to identify or discover additional product candidates.***

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our platform technology. We do not have any products on the market and are early in our development efforts. All of our product candidates are in preclinical development. Our product candidates derived from our platform technology may not successfully complete IND-enabling studies, and our research programs may fail to identify other potential product candidates for clinical development for a number of reasons. Our and our collaborators' research methodology may be unsuccessful in identifying potential product candidates, our potential product candidates may not demonstrate the necessary preclinical outcomes to progress to clinical studies, or our product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

If any of these events occur, we may be forced to discontinue our development efforts for a program or programs. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

***We may not be able to obtain orphan drug exclusivity for our product candidates.***

Of our current product candidates, the only one designed for treatment of an indication that would likely qualify for rare disease status is our ddRNAi therapeutic for the treatment of OPMD. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs or biological products for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a product intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. The FDA may also designate a product as an orphan drug if it is intended to treat a disease or condition of more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product candidate. Under the European Union orphan drug legislation, a rare disease or condition means a disease or condition which affects not more than five in ten thousand persons in the European Union at the time of the orphan drug designation application.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for such indication for that time period. During the marketing exclusivity period, in the European Union, the European Medicines Agency, or the EMA, is precluded from approving a similar drug with an identical therapeutic indication. The applicable period is seven years in the United States and ten years in the European Union. The European Union exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition, and the same drug could be approved for a different condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug, made by a competitor, for the same condition if the FDA concludes that the competitive product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the European Union, the EMA can approve a competitive product if the orphan drug no longer meets the criteria for orphan designation (including sufficient profitability), if the competitive product is safer, more effective or otherwise clinically superior, or if the orphan drug cannot be supplied in sufficient quantities.

**Risks Related to Our Reliance on Third Parties**

***Our prospects for successful development and commercialization of our products are dependent to varying degrees upon the research, development, commercialization, and marketing efforts of our collaborators.***

We rely on third parties for certain aspects of the research, development, commercialization and marketing of our current and any future product candidates. Other than as provided for in our collaboration agreements, we have no control over the resources, time and effort that our collaborators may devote to the development of product candidates using our ddRNAi technology. We are dependent on our collaborators to conduct some aspects of the research and development of each of our product candidates, and expect to need access to them to facilitate and/or to complete the regulatory process. We will likely rely on a pharmaceutical company for the successful marketing and commercialization of any such product candidates for which they/we receive approval, if any. There can be no guarantee at this stage that we will conclude a partnership with such a company on favorable terms, or at all, nor even if we do so, that success will be achieved.

Our ability to recognize revenues from successful collaborations may be impaired by multiple factors including:

- a collaborator may shift its priorities and resources away from our programs due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- a collaborator may cease development in an area that is the subject of a collaboration agreement;
- a collaborator may change the success criteria for a particular program or product candidate in development, thereby delaying or ceasing development of such program or product candidate in development;
- a collaborator with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaborator with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a collaborator may exercise its rights under the agreement to discontinue our collaboration;
- a dispute may arise between us and a collaborator concerning the development and commercialization of a product candidate in development, resulting in a delay in milestones, royalty payments, or discontinuation of a program and possibly resulting in costly litigation or arbitration that may divert management attention and resources;
- a collaborator may not adequately protect the intellectual property rights associated with a product candidate; and
- a collaborator may use our proprietary information or intellectual property in such a way as to expose us to litigation from a third party.

If our collaborators do not perform in the manner we expect or fulfill their responsibilities in a timely manner, or at all, the development, regulatory and commercialization process could be delayed or discontinued or otherwise be unsuccessful. Conflicts between us and our collaborators may arise. In the event of discontinuation of one or more of our collaboration agreements, it may become necessary for us to assume the responsibility for any such product candidates at our own expense or seek new collaborators. In that event, we likely would be required to limit the size and scope of one or more of our independent programs or increase our expenditures and seek additional funding, which may not be available on acceptable terms or at all, and our business may be harmed.

***We rely on third parties to conduct our preclinical studies and expect to rely on third parties to conduct any future clinical trials. If these third parties do not meet our deadlines or otherwise conduct the studies as required, we may be delayed in progressing, or ultimately may not be able to progress, product candidates to clinical trials, our clinical development programs could be delayed or unsuccessful, and we may not be able to commercialize or obtain regulatory approval for our product candidates when expected, or at all.***

We do not have the ability to conduct all aspects of our preclinical testing or any future clinical trials ourselves. We are dependent on third parties to conduct the preclinical studies for our product candidates and will depend on third parties to conduct any future clinical trials for our product candidates, and therefore the timing of the initiation and completion of these trials and studies is reliant on third parties and may occur at times substantially different from our estimates or expectations.

In the case of clinical trials, we expect to rely on CROs and third-party collaborators to conduct any future clinical trials in accordance with our clinical protocols and regulatory requirements. We expect our CROs, investigators and third-party collaborators will play a significant role in the conduct of these trials and subsequent collection and analysis of data. There is no guarantee that any CROs, investigators or the other third-party collaborators on which we rely for administration and conduct of any future clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fails to meet expected deadlines, fails to adhere to our clinical protocols, fails to meet regulatory requirements or otherwise performs in a substandard manner, any future clinical trials may be extended, delayed or terminated. If any of our future clinical trial sites terminates for any reason, we may lose all of the information on subjects enrolled in any such clinical trials.

If we cannot contract with acceptable third parties on commercially reasonable terms, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed or discontinued.

In all events, we are responsible for ensuring that each of our preclinical studies and any future clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires clinical trials to be conducted in accordance with current GCP, including for conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements, and any failure to satisfy these responsibilities and requirements, whether caused by us or by third parties upon whom we rely, could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Because we rely on third-party manufacturing and supply partners, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.***

We rely on third-party supply and manufacturing partners to manufacture and supply the materials for our research and development and preclinical and clinical study supplies. We do not own manufacturing facilities or supply sources for such materials.

There can be no assurance that our supply of research and development, preclinical and clinical development biologics and other materials will not be limited, interrupted or restricted in certain geographic regions, be of satisfactory quality or continue to be available at acceptable prices. Replacement of a third-party manufacturer could require significant effort, cost and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMP. In the event that any of our suppliers or manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves or enter into an agreement with another third party, which would be costly and delay any future clinical trials.

In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills or technology to another third party. These factors increase our reliance on our manufacturers and may require us to obtain a license from a manufacturer in order to have another third-party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines of the FDA and comparable foreign regulatory authorities. The delays and costs associated with the verification of a new manufacturer could increase our costs and delay the development of our product candidates.

We expect to continue to rely on third-party manufacturers for preclinical and clinical grade product candidates and if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements could adversely affect our business in a number of ways, including:

- an inability to conduct necessary preclinical studies to progress our product candidates to clinical trials;
- an inability to initiate or continue any future clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of a collaborator;
- subjecting our product candidates to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

***We and our collaborators may disagree over our right to receive payments under our collaboration agreements, potentially resulting in costly litigation and loss of reputation.***

Our ability to receive payments under our collaboration agreements depends on our ability to clearly delineate our rights under those agreements. We have out-licensed portions of our intellectual property to our collaborators with the intent that our collaborators will develop product candidates based on our ddRNAi technology to address specific conditions, including HIV/AIDS, certain cancers, ocular diseases and genetic diseases and intractable neuropathic pain. However, a collaborator may use our intellectual property without our permission, dispute our ownership of intellectual property rights, or argue that our intellectual property does not cover, or add value to, any product candidates they develop. If a dispute arises, it may result in costly patent office procedures and litigation, and our collaborator may refuse to pay us while the dispute is ongoing. Furthermore, regardless of any resort to legal action, a dispute with a collaborator over intellectual property rights may damage our relationship with that collaborator and may also harm our reputation in the industry. Even if we are entitled to payments from our collaborators, we may not actually receive these payments, or we may experience difficulties in collecting the payments to which we believe we are entitled. After our collaborators launch commercial products containing our licensed traits, we will need to rely on the good faith of our collaborators to report to us the sales they earn from these products and to accurately calculate the payments we are entitled to, a process that will involve complicated and difficult calculations. Although we seek to address these concerns in our collaboration agreements by reserving our right to audit financial records, such provisions may not be effective.

***We have only limited experience in regulatory affairs and intend to rely on consultants and other third parties for regulatory matters, which may affect our ability or the time we require to obtain necessary regulatory approvals.***

We have limited experience in filing and prosecuting the applications necessary to gain regulatory approvals for gene therapy or ddRNAi product candidates. Moreover, the product candidates that are likely to result from our development programs are based on novel technologies that have not been extensively tested in humans. The regulatory requirements governing these types of product candidates may be less well defined or more rigorous than for conventional products. As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals of any products that we develop. We intend to rely on independent consultants for purposes of our regulatory compliance and product development and approvals in the United States and elsewhere. Any failure by our consultants to properly advise us regarding, or properly perform tasks related to, regulatory compliance requirements could compromise our ability to develop and seek regulatory approval of our product candidates.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we rely on third parties to manufacture our product candidates, and because we collaborate with various organizations and academic institutions on the advancement of our technology and product candidates, we may, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by potential competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, discovery by a third party of our trade secrets or other unauthorized use or disclosure would impair our intellectual property rights and protections in our product candidates.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us. In other cases we may share these rights with other parties. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication.

**Risks Related to Commercialization of Our Product Candidates**

***We have not entered into agreements with any third-party manufacturers to support commercialization of our product candidates. Additionally, no manufacturers have experience producing our product candidates at commercial levels, and any manufacturer that we work with may not achieve the necessary regulatory approvals or produce our product candidates at the quality, quantities, locations and timing needed to support commercialization.***

We have not yet secured manufacturing capabilities for commercial quantities of our product candidates or established facilities in the desired locations to support commercialization of our product candidates.We intend to rely on third-party manufacturers for commercialization, but have not entered into any agreements with such manufacturers to support our product candidates currently in development. We may be unable to negotiate agreements with third-party manufacturers to support our commercialization activities on commercially reasonable terms.

We may encounter technical or scientific issues related to manufacturing or development that we may be unable to resolve in a timely manner or with available funds. Currently, we do not have the capacity to manufacture our product candidates on a commercial scale. In addition, our product candidates are novel, and no manufacturer currently has experience producing our product candidates on a large scale. If we are unable to engage manufacturing partners to produce our product candidates on a larger scale on reasonable terms, our commercialization efforts will be harmed.

Even if we timely develop a manufacturing process and successfully transfer it to the third-party manufacturers of our product candidates, if such third-party manufacturers are unable to produce the necessary quantities of our product candidates, or do so in compliance with cGMP or with pertinent foreign regulatory requirements, and within our planned time frame and cost parameters, the development and sales of our product candidates, if approved, may be impaired.

***If we are unable to enter into agreements with third parties to commercialize our product candidates or establish sales and marketing capabilities to market and sell our product candidates, we may be unable to generate any revenues.***

We currently have no sales and marketing organization and have no experience selling and marketing pharmaceutical products. To successfully commercialize any product candidates that may be approved, we will need to develop these capabilities, either through our relationships with collaborators or our own. We may seek to enter into collaborations with other entities to utilize their marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If our future collaborators do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. The establishment and development of our own sales force or the establishment of a contract sales force to market any products we may develop will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

***Physicians, patients, third-party payors or others in the medical community may not be receptive to our product candidates, and we may not generate any future revenue from the sale or licensing of our product candidates.***

Even if we obtain approval for a product candidate, we may not generate or sustain revenue from sales of the product if the product cannot be sold at a competitive cost or if it fails to achieve market acceptance by physicians, patients, third-party payors or others in the medical community. These market participants may be hesitant to adopt a novel treatment based on ddRNAi technology, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. Market acceptance of our product candidates will depend on, among other factors:

- the safety and efficacy of our product candidates;
- our ability to offer our products for sale at competitive prices;
- the relative convenience and ease of administration of our product candidates;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- the terms of any approvals and the countries in which approvals are obtained;
- limitations or warnings contained in any labeling approved by the FDA or comparable foreign regulatory authorities;
- conditions upon the approval imposed by FDA or comparable foreign regulatory authorities, including, but not limited to, a REMS;
- the willingness of patients to try new treatments and of physicians to prescribe these treatments;
- the availability of government and other third-party payor coverage and adequate reimbursement; and
- availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

Since we are focused on the emerging therapeutic modality of ddRNAi, these risks may increase if new competitors are able to market ddRNAi-based therapeutics or if these treatments become less favored in the commercial marketplace. In addition, we believe that one of the benefits of our ddRNAi technology is the expected length of time of its effect. If our treatments do not have a long-term effect after administration, such a development would likely significantly and adversely affect market acceptance of our product candidates, if approved.

Additional risks apply in relation to any disease indications we pursue which are classified as rare diseases and allow for orphan drug designation by regulatory agencies in major commercial markets, such as the United States or European Union. If pricing is not approved or accepted in the market at an appropriate level for any approved product for which we pursue and receive an orphan drug designation, such product may not generate enough revenue to offset costs of development, manufacturing, marketing and commercialization despite any benefits received from the orphan drug designation, such as market exclusivity, for a period of time. Orphan exclusivity could temporarily delay or block approval of one of our products if a competitor obtains orphan drug designation for its product first. However, even if we obtain orphan exclusivity for one of our products upon approval, our exclusivity may not block the subsequent approval of a competitive product that is shown to be clinically superior to our product.

Market size is also a variable in disease indications not classified as rare. Our estimates regarding potential market size for any indication may be materially different from what we discover to exist at the time we commence commercialization, if any, for a product, which could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.

***We face competition from entities that have developed or may develop product candidates for our target disease indications, including companies developing novel treatments and technology platforms based on modalities and technology similar to ours. If these companies develop technologies or product candidates more rapidly than we do or their technologies, including delivery technologies, are more effective, our ability to develop and successfully commercialize product candidates may be compromised.***

The development and commercialization of pharmaceutical products is highly competitive. We compete with a variety of multinational pharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. Our competitors have developed, are developing or could develop product candidates and processes competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community, patients and third-party payors, and any new treatments that enter the market.

We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are developing, and may in the future try to develop, product candidates.

This increasingly competitive landscape may compromise the development of our product candidates. For example, improvements in the efficacy, delivery and success rates of competitors' product candidates, in conjunction with a reduction in the price and duration of their treatments, diminished partnering interest from pharmaceutical companies in our product candidate TT-034 for the treatment of HCV. This caused us to announce in February 2016 the discontinuation of our program to develop TT-034 before the conclusion of its clinical trial.

We are aware of multiple companies that are working in the field of RNAi therapeutics, including Alnylam, Arbutus, Arrowhead, Silence Therapeutics plc, RXi Pharmaceuticals Corporation, Quark Pharmaceuticals, Inc., Marina Biotech, Inc. and Dicerna. Arrowhead, Arbutus and Alnylam are all developing siRNA-based therapeutics for HBV. All of our current product candidates, if approved, would compete with approved and currently marketed treatments.

In addition, our product candidates would compete with antisense and other RNA-based pharmaceutical products currently under development. Like RNAi therapeutics, antisense products target mRNA with the objective of suppressing the activity of specific genes. The development of antisense products is more advanced than that of RNAi therapeutics, and antisense technology may become the preferred technology for products that target mRNAs.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources and experience than we have. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position.

Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or non-competitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

***A variety of risks associated with international operations could hurt our business.***

If any of our product candidates are approved for commercialization, it is our current intention to market them on a worldwide basis, either alone or in collaboration with others. In addition, we conduct development activities in various jurisdictions throughout the world. We expect that we will be subject to additional risks related to engaging in international operations, including:

- different regulatory requirements for approval of pharmaceutical products in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in Australia or the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

***The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain coverage and adequate reimbursement for any of our product candidates that are approved could limit our ability to market those products and compromise our ability to generate revenue.***

The availability of coverage and adequate reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both in the United States and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the reimbursement amounts approved by third-party payors may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products.

The intended use of a pharmaceutical product by a physician can also affect pricing. For example, CMS could initiate a National Coverage Determination administrative procedure, by which the agency determines which uses of a therapeutic product would and would not be reimbursable under Medicare. This determination process can be lengthy, thereby creating a long period during which the future reimbursement for a particular product may be uncertain.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries is likely to put pressure on the pricing and usage of any of our product candidates that may be approved for marketing in the future. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems can be substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and other third-party payors, in the United States and abroad, to cap or reduce healthcare costs, resulting in legislation and reforms such as, in the United States, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care Education Reconciliation Act, or the ACA. The ACA may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. In addition, other legislative changes have been adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year effective April 2013 that, due to subsequent legislative amendments to the statute, will stay in effect through 2024 unless additional Congressional action is taken. Additionally, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could negatively affect coverage or reduce the reimbursement for any of our product candidates that receive regulatory approval.

We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription pharmaceutical products and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on pharmaceutical product pricing. Such reforms could depress pricing for any product candidates that we may successfully develop and for which we may obtain regulatory approval and may negatively affect our overall financial condition and ability to develop additional product candidates.

***Our relationships with third-party payors, healthcare professionals and customers in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to significant penalties.***

Our relationships with third-party payors, healthcare professionals and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute any pharmaceutical products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program, created under the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to payments or other transfers of value made to physicians and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members by the 90th day of each subsequent calendar year, and disclosure of such information will be made by CMS on a publicly available website; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require pharmaceutical manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

***Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our product candidates or compromise our ability to conduct our business or obtain regulatory approvals for our product candidates.***

Gene therapy remains a novel technology and no gene therapy product utilizing ddRNAi has been approved to date in the United States. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Our product candidates, including our viral delivery systems, could produce adverse events. Adverse events in our clinical trials or following approval of any of our product candidates, even if not ultimately attributable to our product candidates, could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

**Risks Related to Our Business Operations**

***We may not successfully engage in strategic transactions or enter into new collaborations, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expenses and present significant distractions to our management.***

From time to time, we may consider additional strategic transactions, such as collaborations, acquisitions, asset purchases or sales and out- or in-licensing of product candidates or technologies. In particular, we will evaluate and, if strategically attractive, seek to enter into additional collaborations, including with major biotechnology or pharmaceutical companies. The competition for collaborators is significant, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new or existing collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the collaborator discontinues the collaboration. Any such collaboration, or other strategic transaction, may require us to incur non-recurring or other charges, increase our expenditures, pose significant integration or implementation challenges or disrupt our management or business.

These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material adverse effect on our business, results of operations, financial condition and prospects. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay and make more expensive the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

***Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan.***

Our success largely depends on the continued service of key management and other specialized personnel, including Mr. Gregory West (Chief Executive Officer), Dr. David Suhy, PhD (Chief Scientific Officer), Dr. Cliff Holloway (Chief Business and Operating Officer), and Ms. Georgina Kilfoil (Chief Clinical and Development Officer). The loss of one or more members of our management team or other key employees or advisors could delay or increase the cost of our research and development programs and materially harm our business, financial

condition, results of operations and prospects. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel because of the highly technical nature of our product candidates and the specialized nature of the regulatory approval process for our product candidates. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty. We do not maintain key person life insurance policies on any of our management team members or key employees. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations.

***Our collaborations with outside scientists and consultants may be subject to restriction and change.***

We work with medical experts, chemists, biologists and other scientists at academic and other institutions, and consultants who assist us in our research, development and regulatory efforts, including the members of our scientific advisory board. In addition, these scientists and consultants have provided, and we expect that they will continue to provide, valuable advice regarding our programs and regulatory approval processes. These scientists and consultants are not our employees and may have other commitments that would limit their future availability to us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, we are limited in our ability to prevent them from establishing competing businesses or developing competing products. For example, if a key scientist acting as a principal investigator in any of our future clinical trials identifies a potential product or compound that is more scientifically interesting to his or her professional interests, his or her availability to remain involved in any future clinical trials could be restricted or eliminated.

***We may experience difficulties in managing our growth and expanding our operations.***

We have limited experience in development and commercialization of pharmaceutical products. As our product candidates continue to advance through preclinical studies and any future clinical trials and potentially toward regulatory approval and commercial sale, we will need to expand our development, regulatory, manufacturing and sales capabilities or contract with other organizations to provide these capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

***Our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and comparable foreign regulators, provide accurate information to the FDA and comparable foreign regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of any future clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.***

The use of our product candidates in clinical trials and the sale of any products for which we may in the future obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates, if approved for commercial sale; and
- increased cost, or impairment of our ability, to obtain or maintain product liability insurance coverage.

We carry combined public and products liability (including human clinical trials extension) insurance of A$20 million per occurrence with a A$20 million aggregate limit. We believe our product liability insurance coverage is sufficient in light of our current clinical programs. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any product candidates, we intend to expand our insurance coverage to include the sale of commercial products, but we may not be able to obtain or maintain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded against other pharmaceutical companies in class action lawsuits based on pharmaceutical products, or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause the price of the ADSs and Warrants to decline and, if judgments exceed our insurance coverage, could materially and adversely affect our financial position.

During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or discontinue our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our product candidate, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may harm our reputation, delay our regulatory approval process, limit the type of regulatory approvals our product candidates receive or maintain, and compromise the market acceptance of any of our product candidates that may in the future receive regulatory approval. As a result of these factors, a product liability claim, even if successfully defended, could hurt our business and impair our ability to generate revenue.

***We and our development partners, third-party manufacturers and suppliers use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.***

We and our development partners, third-party manufacturers and suppliers may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. National, state and local laws and regulations in the United States, Australia and other countries govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development and commercialization efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and any future clinical trials, regulatory approvals or product commercialization progress could be suspended.

***We may use our limited financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a collaboration arrangement.

***Our internal computer and information technology systems, or those of our collaborators and other development partners, third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a disruption of our product development programs.***

Despite the implementation of security measures, our internal computer and information technology systems and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to damage from computer viruses, cyber-attacks, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruptions of our operations. While we have not experienced any material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. For example, the loss of clinical trial data from ongoing or future clinical trials or data from preclinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture our product candidates and will rely on third parties to conduct future clinical trials, and similar events relating to their computer systems could also have similar consequences to our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed and become more expensive.

***Our current laboratory operations are concentrated in one location and any events affecting this location may seriously compromise our ability to operate our business and continue the development of our product candidates.***

Our current laboratory operations are located in our facility situated in Hayward, California. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize the facility, may compromise our ability to operate our business, particularly on a daily basis, cause us financial losses and inhibit or delay our continued development of our product candidates. Loss of access to this facility may result in increased costs, delays in the development of our product candidates or interruption of our business operations. As part of our risk management policy, we maintain insurance coverage at levels that we

believe are appropriate for our business. However, in the event of an accident or incident at this facility, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facility is unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material adverse effect on our business, financial position, results of operations and prospects.

***The investment of our cash and cash equivalents is subject to risks which may cause losses and affect the liquidity of these investments.***

As of June 30, 2016, we had A$18.2 million in cash and cash equivalents. We historically have invested substantially all of our available cash and cash equivalents, including the net proceeds of our U.S. initial public offering, in cash deposits meeting the criteria of our investment policy, which is focused on the preservation of our capital. These investments are subject to general credit, liquidity, market and interest rate risks. We may realize losses in the fair value of these investments, which would have a negative effect on our financial results. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. The market risks associated with our investment portfolio may have an adverse effect on our results of operations, liquidity and financial condition.

***Our ability to utilize our net operating losses and certain other tax attributes may be limited.***

We have substantial carried forward tax losses which may not be available to offset any future assessable income. In order for an Australian corporate taxpayer to carry forward and utilize tax losses, the taxpayer must pass either the continuity of ownership test, or COT, or, if it fails the COT, the same business test, or SBT, in respect of relevant tax losses.

We have not carried out any analysis as to whether we have met the COT or, failing the COT, the SBT over relevant periods. In addition, future shareholding changes may result in a significant ownership change for us. It is therefore uncertain as to whether any of our tax losses carried forward as of June 30, 2016 will be available to be carried forward and available to offset our assessable income, if any, in future periods.

**Risks Related to Our Intellectual Property**

***If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to obtain exclusivity for our product candidates or prevent others from developing similar competitive products.***

We rely upon a combination of patents, know-how, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file, and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors or licensees, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, our patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, patent term adjustments, etc., although we are unaware of any such defects. If we or our current licensors or licensees, or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current licensors or licensees, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or other jurisdictions. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has

been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. For example, three of our European patents licensed from CSIRO that expire in 2019 have been subject to oppositions before the European Patent Office (EPO), and these oppositions have resulted in appealable decisions to maintain one of the European patents and to revoke two others. Each of those EPO decisions has been appealed. One of the appeals filed by CSIRO has been dismissed and the relevant European patent was revoked. The remaining two appeals are still underway and we cannot know whether these appeals, if carried through, will be decided favorably for us. Furthermore, even if our patents and patent applications are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties.

If the patent applications we hold or have in-licensed with respect to our programs or product candidates fail to issue, or are revoked, if the breadth or strength of our patent protection is threatened, or if our patent portfolio fails to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize future products. Any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications before March 16, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications on or after March 16, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including biosimilar or generic medications. This risk is material in light of the length of the development process of our products and lifespan of our current patent portfolio.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. What constitutes a trade secret and what protections are available for trade secrets varies from state to state in the United States and country by country worldwide. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets can be difficult to detect, could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets

and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, the laws of some foreign countries such as India and China do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our markets.

***We rely on license relationships with a number of third parties for portions of our intellectual property, including platform technology patents relating to our ddRNAi technology. This arrangement could restrict the scope and enforcement of our intellectual property rights and limit our ability to successfully commercialize current and future product candidates.***

We have in-licensed certain ddRNAi-related intellectual property from third-party licensors. We rely on some of these third parties to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights we license, and therefore cannot guarantee that these patents and applications will be prosecuted or enforced in a manner consistent with the best interests of our business. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Additionally, we may not be able to control the publication or other disclosures of research carried out by our licensors relating to technology that could otherwise prove patentable. Pursuant to the terms of some of our license agreements with third parties, some of our third-party licensors have the right, but not the obligation, to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors, and cannot guarantee that we would receive it and on what terms. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, our competitive position and our financial condition could suffer.

***Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.***

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter partes review proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any DNA constructs formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

***We may not be successful in obtaining or maintaining necessary rights to gene therapy product components and processes for our development pipeline through acquisitions and in-licenses.***

Presently we have rights to intellectual property to develop our current gene therapy product candidates. However, our product candidates may require specific formulations to work effectively and efficiently and rights to such formulations may be held by others. In addition, we may need additional intellectual property rights as we develop future therapy product candidates. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify on terms that we find acceptable, or at all. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

***We may enter into license agreements with third parties, and if we fail to comply with our obligations in such agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.***

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates.

In many cases, patent prosecution of our in-licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In some cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under any collaboration relationships we might enter into in the future;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

***We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful, and issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.***

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

For example, in patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation, amendments to our patent claims or statements being made on the record such that our claims may no longer be construed to cover our product candidates. For example, three of our European patents licensed from CSIRO have been subject to oppositions before the European Patent Office (EPO), and these oppositions have resulted in appealable decisions to maintain one European patent and to revoke two others. Each of those EPO decisions has been appealed. One of the appeals filed by CSIRO has been dismissed and the relevant European patent was revoked. The remaining two appeals are still underway. Outcomes or statements on the record in one country could have a disadvantageous effect on prosecution or enforcement of a patent or patent application in another country. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that no invalidating prior art exists or that the patent examiner was aware of all material prior art during prosecution. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce or defend the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted, enforced and defended in a manner consistent with the best interests of our business. If a

defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have a material adverse impact on our business. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, enforcement of a favorable decision by a court can depend on cooperation of a governmental authority which may or may not be available in every jurisdiction. There could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could depress the market price of our ADSs and Warrants. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

For our patents and patent applications filed in the United States before March 16, 2013, interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may result in a decision adverse to our interests and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could cause the trading price of our ADSs and Warrants to fall.

***Our results of operations will be affected by the level of royalty payments that we are required to pay to third parties.***

We are a party to license agreements that require us to remit royalty payments and other payments related to in-licensed intellectual property. Under our in-license agreements, we may pay up-front fees and milestone payments and be subject to future royalties. We cannot precisely predict the amount, if any, of royalties we will owe in the future, and if our calculations of royalty payments are incorrect, we may owe additional royalties, which could negatively affect our results of operations. As our product sales increase, we may, from time to time, disagree with our third-party collaborators as to the appropriate royalties owed, and the resolution of such disputes may be costly, may consume management's time, and may damage our relationship with our collaborators. Furthermore, we may enter into additional license agreements in the future, which may also include royalty, milestone and other payments.

***The licenses we grant to our collaborators to use our ddRNAi technology are exclusive to the development of product candidates for certain conditions.***

Some of the out-licenses we grant to our collaborators to use our ddRNAi technology are exclusive to the development of product candidates for certain conditions, so long as our collaborators comply with certain requirements. That means that once our ddRNAi technology is licensed to a collaborator for a specified condition, we are generally prohibited from developing product candidates for that condition and from licensing the ddRNAi to any third party for that condition. The limitations imposed by these exclusive licenses could prevent us from expanding our business and increasing our development of product candidates with new collaborators, both of which could adversely affect our business and results of operations.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

Certain of our key employees and personnel are or were previously employed at universities, medical institutions or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary

information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. Furthermore, universities or medical institutions who employ some of our key employees and personnel in parallel to their engagement by us may claim that intellectual property developed by such person is owned by the respective academic or medical institution under the respective institution intellectual property policy or applicable law. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs, be a distraction to management and other employees, and damage our relationships with the academic and medical institutions.

***We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may in the future have ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various corresponding governmental patent agencies outside of the United States require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and it therefore is costly, time-consuming and inherently uncertain. In addition, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation.

An important change introduced by the Leahy-Smith Act is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Among some of the other changes introduced by the Leahy-Smith Act are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding

sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Recent U.S. Supreme Court rulings such as Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad I); BRCA1- &BRCA2-Based Hereditary Cancer Test Patent Litig. (Myriad II); and Promega Corp. v. Life Technologies Corp. have also narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in some situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

***Our success depends, in part, on our ability to protect our intellectual property and our technologies outside the United States. We may not be able to protect our intellectual property rights throughout the world.***

Our commercial success depends, in part, on our ability to obtain and maintain patent and trade secret protection for our technologies, our traits, and their uses, as well as our ability to operate without infringing upon the proprietary rights of others outside the United States. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

Filing, prosecuting and defending patents on product candidates in all countries around the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. In addition, we may at times in-license third-party technologies for which limited international patent protection exists and for which the time period for filing international patent applications has passed. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Potential competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, if approved, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

**Risks Related to the ADSs and Warrants**

***The market price and trading volume of the ADSs and Warrants may be volatile and may be affected by economic conditions beyond our control.***

The market price of the ADSs and Warrants may be highly volatile and subject to wide fluctuations. In addition, the trading volume of the ADSs and Warrants may fluctuate and cause significant price variations to occur. If the market price of the ADSs or Warrants declines significantly, you may be unable to resell your ADSs or Warrants at or above your purchase price, if at all. We cannot assure you that the market price of the ADSs or Warrants will not fluctuate or significantly decline in the future.

Some specific factors that could negatively affect the price of the ADSs and Warrants or result in fluctuations in their price and trading volume include:

- actual or expected fluctuations in our operating results;
- changes in market valuations of similar companies;
- changes in our key personnel;
- changes in financial estimates or recommendations by securities analysts;
- trading prices of our ordinary shares on the ASX;
- changes in trading volume of ADSs or Warrants on The NASDAQ Capital Market, or NASDAQ, and of our ordinary shares on the ASX;
- sales of the ADSs or Warrants or ordinary shares by us, our executive officers or our shareholders in the future; and
- conditions in the financial markets or changes in general economic conditions.

***An active trading market for the ADSs or Warrants may not continue to develop or may not be liquid enough for you to sell your ADSs or Warrants quickly or at market price.***

Prior to our recent U.S. initial public offering, our securities were not listed on any U.S. stock exchange, we were not a reporting company under the Exchange Act and there had been only a limited public market in the United States for the ADSs and no public market in the United States for the Warrants. Although the ADSs and Warrants are listed on The NASDAQ Capital Market, if an active public market in the United States for the ADSs and Warrants does not continue to develop, the market price and liquidity of the ADSs and Warrants may be adversely affected. The initial public offering price for the ADSs and Warrants was determined by negotiation between us and the underwriter. The price at which the ADSs are traded has declined below the initial public offering price, and the price at which the Warrants are traded has not exceeded the Warrant exercise price. The ADS price and/or the Warrant price may continue to decline, which means you may experience a decrease in the value of your ADSs and Warrants regardless of our operating performance or prospects. In the past, following periods of volatility in the market price of a company's securities, shareholders often instituted securities class action litigation against that company. If we were involved in a class action suit, it could divert the attention of senior management and, if adversely determined, could cause us significant financial harm.

***The dual listing of our ordinary shares and the ADSs and Warrants may adversely affect the liquidity and value of the ADSs and Warrants.***

Our ADSs and Warrants are listed on NASDAQ, and our ordinary shares are listed on the ASX. We cannot predict the continued effect of this dual listing on the value of our ordinary shares, ADSs and Warrants. However, the dual listing of our ordinary shares, ADSs and Warrants may dilute the liquidity of these securities in one or both markets and may impair the development of an active trading market for the ADSs and Warrants in the United States. The trading price of the ADSs and Warrants could also be adversely affected by trading in our ordinary shares on the ASX.

***As a foreign private issuer, we are permitted and we expect to follow certain home country corporate governance practices in lieu of certain NASDAQ requirements applicable to domestic issuers. This may afford less protection to holders of the ADSs and Warrants.***

As a foreign private issuer whose ADSs and Warrants are listed on NASDAQ, we will be permitted to follow certain home country corporate governance practices in lieu of certain NASDAQ requirements. For example, we may follow home country practice with regard to the composition of the board of directors and quorum requirements applicable to shareholder meetings. A foreign private issuer must disclose in its annual reports filed with the SEC the requirements with which it does not comply followed by a description of its applicable home country practice. The Australian home country practices described above may afford less protection to holders of the ADSs and Warrants than that provided under NASDAQ rules. See 10.B "Additional Information – Memorandum and Articles of Association" and Item 16G "Corporate Governance."

***As a foreign private issuer, we are permitted to file less information with the SEC than a company incorporated in the United States. Accordingly, there may be less publicly available information concerning us than there is for companies incorporated in the United States.***

As a foreign private issuer, we are exempt from certain rules under the Exchange Act, that impose disclosure requirements as well as procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as a company that files as a U.S. company whose securities are registered under the Exchange Act, nor are we required to comply with the SEC's Regulation FD, which restricts the selective disclosure of material non-public information. Accordingly, there may be less information publicly available concerning us than there is for a company that files as a domestic issuer.

***We are an emerging growth company as defined in the JOBS Act and the reduced disclosure requirements applicable to emerging growth companies may make the ADSs or Warrants less attractive to investors and, as a result, adversely affect the price of the ADSs or Warrants and result in a less active trading market for the ADSs or Warrants.***

We are an emerging growth company as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. For example, we rely on an exemption from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act relating to internal control over financial reporting, and we will not provide such an attestation from our auditors for so long as we qualify as an emerging growth company.

We may avail ourselves of these disclosure exemptions until we are no longer an emerging growth company. We cannot predict whether investors will find the ADSs or Warrants less attractive because of our reliance on some or all of these exemptions. If investors find the ADSs or Warrants less attractive, it may cause the trading price of the ADSs or Warrants to decline and there may be a less active trading market for the ADSs or Warrants.

We will cease to be an emerging growth company upon the earliest of:

- the end of the fiscal year in which the fifth anniversary of completion of our initial public offering in the United States occurs, or June 30, 2021;
- the end of the first fiscal year in which the market value of our ordinary shares held by non-affiliates exceeds US$700 million as of the end of the second quarter of such fiscal year;
- the end of the first fiscal year in which we have total annual gross revenues of at least US$1.0 billion; and
- the date on which we have issued more than US$1.0 billion in non-convertible debt securities in any rolling three-year period.

***If we fail to establish and maintain proper internal financial reporting controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.***

Section 404(a) of the Sarbanes-Oxley Act requires that, beginning with our second annual report after the completion of our initial public offering in the United States, our management assess and report annually on the effectiveness of our internal controls over financial reporting and identify any material weaknesses in our internal controls over financial reporting. Although Section 404(b) of the Sarbanes-Oxley Act requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal controls over financial reporting, we rely on the exemption provided in the JOBS Act, and consequently will not be required to comply with SEC rules that implement Section 404(b) of the Sarbanes-Oxley Act until such time as we are no longer an emerging growth company.

Our first Section 404(a) assessment will take place beginning with our second annual report after the completion of our initial public offering in the United States (i.e., our annual report for the year ending June 30, 2016). The presence of material weaknesses could result in financial statement errors which, in turn, could lead to errors in our financial reports and/or delays in our financial reporting, which could require us to restate our operating

results. We might not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404(a) of the Sarbanes-Oxley Act. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control.

If we are unable to conclude that we have effective internal controls over financial reporting, investors may lose confidence in our operating results, the price of the ADSs or Warrants could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, the ADSs and Warrants may not be able to remain listed on NASDAQ.

***ADS holders and Warrant holders may be subject to additional risks related to holding ADSs and Warrants rather than ordinary shares.***

ADS holders and Warrant holders do not hold ordinary shares directly and, as such, are subject to, among others, the following additional risks:

- As an ADS holder, we will not treat you as one of our shareholders and you will not be able to exercise shareholder rights, except through the ADR depositary as permitted by the deposit agreement. As a Warrant holder, you will have no rights as an ADS holder until you exercise your Warrant.
- Distributions, if any, on the ordinary shares represented by your ADSs will be paid to the ADR depositary, and before the ADR depositary makes a distribution to you on behalf of your ADSs, any withholding taxes that must be paid will be deducted. Additionally, if the exchange rate fluctuates during a time when the ADR depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.
- We and the ADR depositary may amend or terminate the deposit agreement without the ADS holders' consent in a manner that could prejudice ADS holders. We may also amend the ADS Warrant Agent Agreement without the consent of any Warrant holder for the purpose of curing any ambiguity, or curing, correcting or supplementing any defective provision contained in the ADS Warrant Agent Agreement or adding or changing any other provisions with respect to matters or questions arising under that agreement as we and the Warrant Agent deem shall not adversely affect the interest of the Warrant holders. We may also modify or amend the ADS Warrant Agent Agreement in other respects with the vote or written consent of the holders of at least 65% of the then outstanding Warrants.

***The Warrants are a risky investment. You may be unable to exercise your Warrants for a profit.***

The value of the Warrants will depend on the value of our ADSs, which will depend on factors related and unrelated to the success of our commercialization and product development activities, and cannot be predicted at this time, as well as the factors described herein that may affect the value of our ordinary shares. The Warrants have an exercise period of 5 years.

If the price of our ADSs does not increase to an amount sufficiently above the exercise price of the Warrants during the exercise period of the Warrants, you may be unable to recover any of your investment in the Warrants. In addition, because we are an Australian corporation whose ordinary shares are listed on the ASX, the anti-dilution adjustments included in the Warrants are limited to those permitted by the rules of the ASX. As a result, the Warrants do not include any value-weighted average price or similar adjustment provision for issuances of ADSs at a price below the exercise price of the Warrants or the market price of our ADSs or ordinary shares. There can be no assurance that any of the factors that could impact the trading price of our ADSs will result in the trading price increasing to an amount that will exceed the exercise price or the price required for you to achieve a positive return on your investment in the Warrants.

***You must act through the ADR depositary to exercise your voting rights and, as a result, you may be unable to exercise your voting rights on a timely basis. Holders of Warrants will have no rights as ADS holders until they acquire ADSs.***

As a holder of ADSs (and not the ordinary shares underlying your ADSs), we will not treat you as one of our shareholders, and you will not be able to exercise shareholder rights. The ADR depositary will be the holder of the ordinary shares underlying your ADSs, and ADS holders will be able to exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the deposit agreement relating to the ADSs. There are practical limitations on the ability of ADS holders to exercise their voting rights due to the additional procedural steps involved in communicating with these holders. For example, holders of our ordinary shares will receive notice of shareholders' meetings by mail and will be able to exercise their voting rights by either attending the shareholders meeting in person or voting by proxy. ADS holders, by comparison, will not receive notice directly from us. Instead, in accordance with the deposit agreement, we will provide notice to the ADR depositary of any such shareholders meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date. If we so instruct, the ADR depositary will mail to holders of ADSs the notice of the meeting and a statement as to the manner in which voting instructions may be given by holders as soon as practicable after receiving notice from us of any such meeting. To exercise their voting rights, ADS holders must then instruct the ADR depositary as to voting the ordinary shares represented by their ADSs. Due to these procedural steps involving the ADR depositary, the process for exercising voting rights may take longer for ADS holders than for holders of ordinary shares. The ordinary shares represented by ADSs for which the ADR depositary fails to receive timely voting instructions will not be voted.

Until you acquire ADSs upon exercise of the Warrants, you will have no rights with respect to our ADSs or the ordinary shares underlying the ADSs, including the right the receive dividend payments, vote or respond to tender offers. Upon exercise of your Warrants, you will be entitled to exercise the rights of ADS holders as to matters for which the record date occurs after the exercise date.

***Although we are required to use our reasonable best efforts to have an effective registration statement covering the issuance of the ADSs underlying the Warrants at the time that holders of our Warrants exercise their Warrants, we cannot guarantee that a registration statement will be effective, in which case holders of our Warrants may not be able to receive freely tradable ADSs upon exercise of the Warrants.***

Holders of our Warrants will be able to exercise the Warrants and receive freely tradable shares only if (i) a current registration statement under the Securities Act relating to the ADSs underlying the Warrants is then effective, or an exemption from such registration is available, and (ii) such ADSs are qualified for sale or exempt from qualification under the applicable securities laws of the states in which the various holders of Warrants reside, as further described in the ADS Warrant Agent Agreement. Although we have undertaken in the ADS Warrant Agent Agreement, and therefore have a contractual obligation, to use our reasonable best efforts to maintain a current registration statement covering the ADSs underlying the Warrants to the extent required by federal securities laws, we may not be able to do so. If we are not able to do so, holders will not be able to exercise their Warrants and receive freely tradable ADSs but rather will have the exercise price for the Warrants returned to them. The value of the Warrants may be greatly reduced if a registration statement covering the ADSs issuable upon exercise of the Warrants is not kept current.

***The Warrants may not have any value.***

The Warrants will expire on August 21, 2020, the 5 year anniversary of the closing of our U.S. initial public offering. In the event the price of the ADSs does not exceed the exercise price of the Warrants during the period in which the Warrants are exercisable, the Warrants may not have any value.

***If we are classified as a "passive foreign investment company," then our U.S. shareholders could suffer adverse tax consequences as a result.***

Generally, if, for any taxable year, at least 75% of our gross income is passive income or at least 50% of the average quarterly value of our gross assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If

we are characterized as a PFIC, a U.S. holder of our ordinary shares or ADSs may suffer adverse U.S. tax consequences, including having gains realized on the sale of our ordinary shares or ADSs treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares or ADSs by individuals who are U.S. holders, and having interest charges added to their tax on distributions from us and on gains from the sale of our ordinary shares or ADSs. See Item 10.E "Additional Information – Taxation."

While we believe we were not a PFIC for fiscal 2015, it is likely that we were a PFIC for fiscal 2016. This arose due to the decline in the value of our shares and the fact that the applicable PFIC rules treat our working capital as a passive asset for purposes of the PFIC asset test.

We do not intend to provide U.S. holders with the information that would permit such investors to make a qualified electing fund ("QEF") election. However, U.S. holders may be able to make a timely "mark-to-market" election that would mitigate some of the adverse U.S. tax consequences associated with our PFIC status. U.S. holders should discuss this with their tax advisors.

We also note that U.S. holders in a PFIC are subject to additional U.S. information reporting rules. If a U.S. holder owns ordinary shares or ADSs or warrants during any year in which we are a PFIC, the U.S. holder generally will be required to file an IRS Form 8621 ("Information Return by a Shareholder of a PFIC or Qualified Electing Fund"), generally with the U.S. holder's federal income tax return for that year. Since our fiscal year ends June 30, calendar year U.S. holders would typically need to make the mark-to-market election and file the IRS Form 8621 with their 2016 U.S. federal tax return.

**We strongly urge U.S. holders to discuss this matter with their tax advisors.**

***Currency fluctuations may adversely affect the price of our ordinary shares, ADSs and Warrants.***

Our ordinary shares are quoted in Australian dollars on the ASX and the ADSs and Warrants are quoted in U.S. dollars on NASDAQ. Movements in the Australian dollar/U.S. dollar exchange rate may adversely affect the U.S. dollar price of the ADSs and Warrants. In the past year the Australian dollar has generally weakened against the U.S. dollar. However, this trend may not continue and may be reversed. If the Australian dollar weakens against the U.S. dollar, the U.S. dollar price of the ADSs and Warrants could decline, even if the price of our ordinary shares in Australian dollars increases or remains unchanged.

***We have never declared or paid dividends on our ordinary shares and we do not anticipate paying dividends in the foreseeable future.***

We have never declared or paid cash dividends on our ordinary shares. For the foreseeable future, we currently intend to retain all available funds and any future earnings to support our operations and to finance the growth and development of our business. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to compliance with applicable laws and covenants under current or future credit facilities, which may restrict or limit our ability to pay dividends, and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. We do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. As a result, a return on your investment in the ADS and the Warrants will only occur if our ADS price appreciates.

***You may not receive distributions on our ordinary shares represented by the ADSs or any value for such distribution if it is illegal or impractical to make them available to holders of ADSs.***

While we do not anticipate paying any dividends on our ordinary shares in the foreseeable future, if such a dividend is declared, the depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit the distribution of the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have a material adverse effect on the value of your ADSs.

***Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares, ADSs or Warrants.***

We are incorporated in Australia and are subject to the takeover laws of Australia. Among other things, we are subject to the Australian Corporations Act 2001, or the Corporations Act. Subject to a range of exceptions, the Corporations Act prohibits the acquisition of a direct or indirect interest in our issued voting shares if the acquisition of that interest will lead to a person's voting power in us increasing to more than 20%, or increasing from a starting point that is above 20% and below 90%. Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares. This may have the ancillary effect of entrenching our board of directors and may deprive or limit our shareholders', ADS holders' or Warrant holders' opportunity to sell their ordinary shares, ADSs or Warrants and may further restrict the ability of our shareholders, ADS holders and Warrants holders to obtain a premium from such transactions. See Item 10.A "Additional Information—Share Capital."

***Our Constitution and Australian laws and regulations applicable to us may adversely affect our ability to take actions that could be beneficial to our shareholders.***

As an Australian company, we are subject to different corporate requirements than a corporation organized under the laws of the states of the United States. Our Constitution, as well as the Australian Corporations Act, set forth various rights and obligations that are unique to us as an Australian company. These requirements may operate differently than those of many U.S. companies. You should carefully review the summary of these matters set forth under Item 10.B "Additional Information – Memorandum and Articles of Association."

## Item 4. Information on Benitec

### A. *History and Development of the Company*.

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 we were incorporated in Australia in 1995, we have devoted the majority of our resources to development efforts relating to 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 of which equaled US$13.8 million. We have also been awarded research and development grants from the Australian federal government, totaling A$2.3 million in fiscal 2015 and A$3.6 million in fiscal 2016. We have earned licensing revenue from licensing our ddRNAi technology to five biopharmaceutical companies, totaling A$0.3 million in fiscal 2015 and A$0.2 million in fiscal 2016.

In October 2012, we acquired Tacere Therapeutics, Inc., or Tacere, an RNA interference therapeutics company based in California with a development program focused on hepatitis C. 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 U.S. initial public offering in which we issued 30,000,000 ordinary shares (represented by 1,500,000 ADSs) and 575,000 Warrants. The ADSs and Warrants are listed on The NASDAQ Capital Market.

Our headquarters are located at 99 Mount Street, Suite 1201, North Sydney, New South Wales, 2060 Australia. Our telephone number is +61 2 9555 6986. Our website address is www.benitec.com. Our agent for service of process in the United States is Tacere Therapeutics, Inc., 3940 Trust Way, Hayward, CA 94545.

### B. *Business Overview*.

#### Overview

We are a biotechnology company developing a novel, proprietary therapeutic technology platform that combines gene silencing and gene therapy with a goal of providing sustained, long-lasting silencing of disease-causing genes from a single administration. We believe our technology has the potential to be a “one shot” cure for a wide range of diseases that are currently addressed by strict ongoing treatment regimens or that have no effective treatment or only palliative care options. We are using our technology, called DNA-directed RNA interference, or ddRNAi, to develop our pipeline of product candidates for the treatment of several chronic and life-threatening human diseases, such as hepatitis B, age-related macular degeneration, or AMD and oculopharyngeal muscular dystrophy, or OPMD. We will require additional financing to conduct clinical trials for our product candidates for hepatitis B, AMD and OPMD. These diseases have large patient populations, with the exception of OPMD which is a rare disease. In addition, we have licensed our ddRNAi technology to other biopharmaceutical companies whose pipeline programs are progressing towards, or are in, clinical development for applications including HIV/AIDS, retinitis pigmentosa, Huntington’s disease, cancer immunotherapy and intractable neuropathic pain.

Many diseases are known to be caused by the inappropriate expression of a gene or multiple genes. It has been observed since 1998 that RNA interference, or RNAi, is a mechanism that can potentially be used to specifically turn off, or silence, genes whose sequences are known. Thus, RNAi can potentially be used to treat or cure diseases with a genetic basis by targeting a specific region of the molecular sequence of the disease-causing gene. RNAi is potentially applicable to over 20,000 human genes and a large number of disease-causing microorganism-specific genes. The mechanism of action of RNAi involves the introduction of short interfering RNA, or siRNA, into a cell. The siRNA’s sequence is constructed to match a short region of the target gene. The

siRNA is processed by the cell's own enzymes to destroy the target gene's messenger RNA, or mRNA, thus preventing the disease-causing gene from being expressed. This occurs as long as the siRNA remains prevalent in the cell.

Our approach differs from the standard RNAi approach, which is commonly referred to as siRNA and is being developed by a number of other companies, including Alnylam Pharmaceuticals, Inc., or Alnylam, Arbutus Biopharma Corporation, or Arbutus (formerly known as Tekmira Pharmaceuticals Corporation before its name change and integration with OnCore BioPharma), and Dicerna Pharmaceuticals, Inc., or Dicerna. In this standard RNAi approach, double-stranded siRNA is produced synthetically and subsequently introduced into the target cell either by chemical modification of the RNA or by a range of other delivery methods. While clinical efficacy has been demonstrated for a number of indications utilizing this approach, it has a number of limitations, which include:

- Once administered, siRNA levels within cells are finite and limited to the initial amount delivered. Extended therapeutic benefit requires repeated administration for multiple cycles.
- Patient adherence challenges due to dosing frequency and treatment duration.
- Therapeutic concentrations of siRNA are not stably maintained because the levels of synthetic siRNA in the cells decrease over time.
- Delivery of siRNA into the appropriate target cells has been a considerable challenge. Unmodified siRNA is unstable in the bloodstream, can cause an adverse immune response and does not readily cross membranes to enter cells. Therefore, novel chemical modifications or the use of novel delivery materials are required to introduce the siRNA into the target cells, making it complicated to develop therapeutics.
- Because the liver acts to clear foreign contaminants from the bloodstream, current systemic delivery of siRNA molecules is limited primarily to targeting the liver. As a result, the majority of siRNA pipeline drugs have been restricted to liver diseases.
- When injected into the body, siRNA is recognized as a foreign contaminant and can cause an adverse immune response, or interferon response, potentially resulting in serious adverse effects.
- There are multiple target disease-causing genes in some diseases, including certain viral infections and certain types of cancer. siRNA-based applications typically involve multiple siRNA molecules, one for each gene desired to be silenced, and may require specialized delivery formulations to ensure distribution of each molecule in the target cells. This delivery challenge makes it more difficult to develop treatments for diseases that implicate multiple genes.
- siRNA only acts to silence genes, but cannot be used to replace defective genes with normally functioning genes.

Our ddRNAi technology is designed to utilize the specificity and gene silencing effect of RNA interference while overcoming many of the limitations associated with the ongoing administration of siRNA. Our ddRNAi approach combines RNA interference with gene therapy. Unlike siRNA, our ddRNAi technology starts with a DNA construct. Gene therapy vectors, which are carrier molecules, often viruses, that deliver genetic material into the cell, are used to deliver the DNA construct to the nucleus of the targeted cells. The DNA construct then generates double-stranded short hairpin RNAs, or shRNAs, which are processed by the cell into siRNAs, which in turn silence the disease-associated genes. Advantages of our ddRNAi approach include:

- ddRNAi is designed to produce sustained, long-lasting silencing of the disease-causing gene, following a single administration, leading to the potential for "one shot" cures for a wide range of diseases, which could eliminate the requirement for patient compliance to take regular doses of medicine for long-term management of their disease.

- ddRNAi technology can potentially use any clinically validated gene therapy vector, enabling it to target a wide range of tissues, including, but not limited to, the liver.
- Because ddRNAi uses the cell's own transcriptional mechanisms to produce shRNA, a constant level of shRNA can potentially be produced so that intracellular levels of siRNA do not fall below threshold levels required for disease suppression.
- The level of shRNA in the cells can potentially be fine-tuned to achieve optimal concentrations.
- Off-tissue effects can be minimized by using tissue specific promoters that are designed to restrict expression of shRNA to only the target tissue.
- The DNA constructs are shielded in gene therapy vectors that are designed to avoid activating the interferon response.
- ddRNAi provides the option to both silence the defective gene and replace the defective gene with a normal version, using the same gene therapy vector. Thus silencing and replacement of the mutant gene occurs in the same cell. We believe this "silence and replace" strategy is ideally suited to developing therapeutics for a number of genetic disorders.
- ddRNAi can be designed to express multiple siRNAs in the same cell, targeting either a single gene at several different sites to minimize the risk of viral resistance, or multiple genes in distinct cellular pathways, potentially enabling treatment of complex genetic diseases such as cancer, diabetes and heart disease.
- ddRNAi can elicit long-term response by continued expression of siRNA from a single administration, potentially preventing viral reinfection.

Our strategy is to discover, develop and commercialize treatments that leverage the capabilities of ddRNAi. We intend to do so by progressing our pipeline of ddRNAi-based therapeutics designed to treat and cure a number of human diseases, thereby demonstrating the broad clinical application of ddRNAi.

Proceeds from our initial public offering in the United States, with our pre-existing cash and cash equivalents, will advance our product candidates for hepatitis B, AMD and OPMD. Additional financing will be needed to advance our product candidates for hepatitis B, AMD and OPMD through clinical trials.

We are developing BB-103 and BB-101 (previously known as Hepbarna), which are currently in preclinical studies, for the treatment of the hepatitis B virus, or HBV. We plan to file an investigational new drug, or IND, application late in 2017 for either BB-103 or BB-101. HBV is a small DNA virus that, according to the WHO, infects up to 240 million people worldwide, resulting in up to 780,000 deaths per year. Infection with HBV occurs in phases ranging from a silent, acute phase that can be resolved by the immune system to a persistent chronic infection requiring life-long therapy. In the case of a chronic HBV infection, the presence of viral particles and proteins, particularly the s-antigen, causes hepatic inflammation leading to liver dysfunction, acute hepatic failure, cirrhosis or hepatocellular carcinoma. Patients suffering from HBV have limited treatment options from therapies consisting of antivirals and, less commonly, interferon therapy. These treatments require adherence to strict recurrent treatment regimens, may cause the hepatitis B virus to mutate and develop antiviral drug resistance, and may only provide viral suppression through the course of administration, and not a cure. The long-term use of interferon, particularly in high doses, may also be associated with significant side effects, including nausea, vomiting, shortness of breath, dizziness and fatigue, that can cause patients to deviate from the course of treatment. BB-103 and BB-101 are both designed to be single administration ddRNAi-based therapies that are delivered using a gene therapy vector that targets the liver and inhibits viral replication and s-antigen production on a long-term basis. Both BB-103 and BB-101 could be used either as monotherapies or, more likely, in combination with another antiviral compound.

In March 2016, Benitec announced results of its recent *in vivo* study of BB-101. Key findings of the *in vivo* study indicate that a single BB-101 treatment in the PhoenixBio (PXB) mouse model can result in suppression of HBV. The *in vivo* experiment supports the *in vitro* findings previously observed in human hepatocytes isolated from the PXB mouse model, announced in December 2015. We believe these results demonstrate the potential utility of an approach that combines RNAi with gene therapy to treat HBV, and we intend to advance the HBV program towards the clinic. A follow on *in vivo* study is currently being conducted in the PXB chimeric mouse model. In this study, BB-101 and BB-103 are applied to HBV infected animals as monotherapy or in combination with either Entecavir or Pegylated Interferon, two anti-viral medications described under See Item 4.B "Information on Benitec –Current Hepatitis B Treatments".

In addition to BB-103 and BB-101 for HBV, we are focusing on developing product candidates to treat AMD and OPMD. We will require additional financing to conduct clinical trials for our product candidates for HBV, AMD and OPMD. For selected product candidates, at the appropriate stage, we may collaborate with large pharmaceutical companies to further develop and, if approved, commercialize them to achieve broad product distribution. For certain products we deem to be outside of our immediate focus, we will continue to out-license, where appropriate, applications of our ddRNAi technology for the development of a range of therapeutics. During calendar 2017 we expect to complete our *in vivo* proof of concept studies and initiate IND-enabling work with all three of our lead product candidates.

We have completed a Phase I/IIa clinical trial for our now discontinued product candidate, TT-034, which we were developing to treat patients chronically infected with the most common genotype of the hepatitis C virus, or HCV, before winding down the program for commercial reasons. We believe the clinical trial results for TT-034 provide support for the safety of our platform technology.

**Our Strengths**

We believe that the combination of our proprietary ddRNAi technology and our deep expertise and know-how in designing and clinical development of ddRNAi-based therapeutics will enable us to achieve and maintain a leading position in gene silencing for treatment of human disease. Our key strengths include:

- A first mover advantage for ddRNAi-based therapeutics;
- Exclusive rights to a novel, proprietary ddRNAi technology platform that is potentially the basis of single-administration therapies with sustained, long-term silencing of disease-causing genes;
- A pipeline of programs focused on life threatening or chronic diseases with either large patient populations, including hepatitis B and AMD, or rare disease status potentially supporting an orphan drug classification, including OPMD;
- Collaborations with third parties to expand the technology platform and develop additional expertise in DNA delivery technologies, in scalable manufacturing, in DNA construct design and in developing related diagnostics to help identify the most appropriate patient populations to benefit from these novel treatments;
- Out-licensing agreements with third parties utilizing our ddRNAi technology to develop therapies outside of our core research areas, which we believe could provide further validation of our technology's potential to address numerous diseases;
- Our development team has significant experience in designing and developing ddRNAi therapeutics and includes founding scientists in the ddRNAi field; and
- Rights to intellectual property that includes a patent portfolio protecting our ddRNAi technology platform in numerous jurisdictions through 2019, and a growing portfolio of patents protecting improvements to our ddRNAi technology and product candidates in numerous jurisdictions through at least 2025.

**Our Strategy**

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**. We are pursuing early preclinical research in HBV, AMD and OPMD and plan to submit IND applications for those product candidates. During 2017 we expect to complete preclinical *in vivo* proof of concept studies with our product candidates and to initiate IND-enabling work.
- **Continue our leadership position in ddRNAi-based therapeutics**. We believe we are the only company to date to have advanced into a clinical trial an RNAi therapeutic for systemic administration by gene therapy vectors.The clinical trial of our now discontinued TT-034 product candidate indicated that TT-034 caused no treatment-related serious adverse events among the nine patients dosed. Although there was no reduction in viral load seen, the biopsy data from the nine patients dosed showed transduction of hepatic tissues. We have developed significant experience in ddRNAi through our work on HCV, HBV, AMD and OPMD. We have strong relationships with key opinion leaders in the field and will continue to engage with the medical and scientific community to communicate the potential therapeutic value of ddRNAi.
- **Further develop and improve our ddRNAi platform technology and its associated intellectual property position.** In addition to progressing our pipeline of product candidates, we will further develop and improve our ddRNAi platform technology and its associated intellectual property through in-house development and in-licensing of complementary technologies. One such example is our relationship with 4D Molecular Therapeutics LLC, or 4DMT, a company that is developing a vector to deliver our ddRNAi constructs to the retinal cells of the eye from an intravitreal injection to treat patients with AMD.
- **Develop drugs in our core disease areas and partner selectively to commercialize and expand our pipeline**. The adaptability of our platform also presents an opportunity for us to selectively form collaborations to expand our capabilities and product offerings into a range of diseases and potentially to accelerate the development and commercialization of ddRNAi therapeutics more broadly. We will continue to advance programs in core disease areas to appropriate stage of proof of concept before proposing to commercialise with pharmaceutical companies. Where appropriate we will seek to progress one or more programs through to commercialization. For example, our pipeline program to treat an orphan indication, OPMD, is seen as a candidate for this approach. We will also continue to out-license use of ddRNAi for applications and therapeutics outside of our immediate focus to expand our franchise of ddRNAi-based therapeutics.
- **Pursue indications with high unmet medical need or large patient populations**. Each of our three current core indications are severe diseases with high unmet medical need or large patient populations. We believe there is a strong rationale for treating these diseases and other diseases that have well-characterized gene targets that can be silenced, thus preventing the disease-causing gene from being expressed. Given the poor prognosis and limited treatment options for most of these diseases, we believe our ddRNAi-based product candidates may offer a potential single-treatment

alternative for these patients. Our ddRNAi-based product candidates, if successful, may offer a potentially superior long-term value proposition for our patients and the healthcare system more broadly, which we believe will allow us to derive premium value while delivering patients life-altering treatments. We also intend to develop ddRNAi applications in novel technologies including immunotherapy, such as chimeric antigen receptor T cells, or CAR T, for a range of additional disease areas, subject to our ability to obtain additional financing apart from our initial public offering in the United States.

**Our Technology—ddRNAi**

Our proprietary technology platform is called DNA-directed RNA interference, or ddRNAi, which is designed to produce long-term silencing of disease-causing genes, by combining RNA interference, or RNAi, with delivery agents typically associated with gene therapy.

Standard gene therapy is normally used to compensate for abnormal or malfunctioning genes or to make a beneficial protein to address a defect. If a mutated gene causes a necessary protein to be faulty or missing, gene therapy is used to introduce a wild type, or normal, copy of the gene to restore the function of the protein. This is the approach to gene therapy taken by a number of other companies to date.

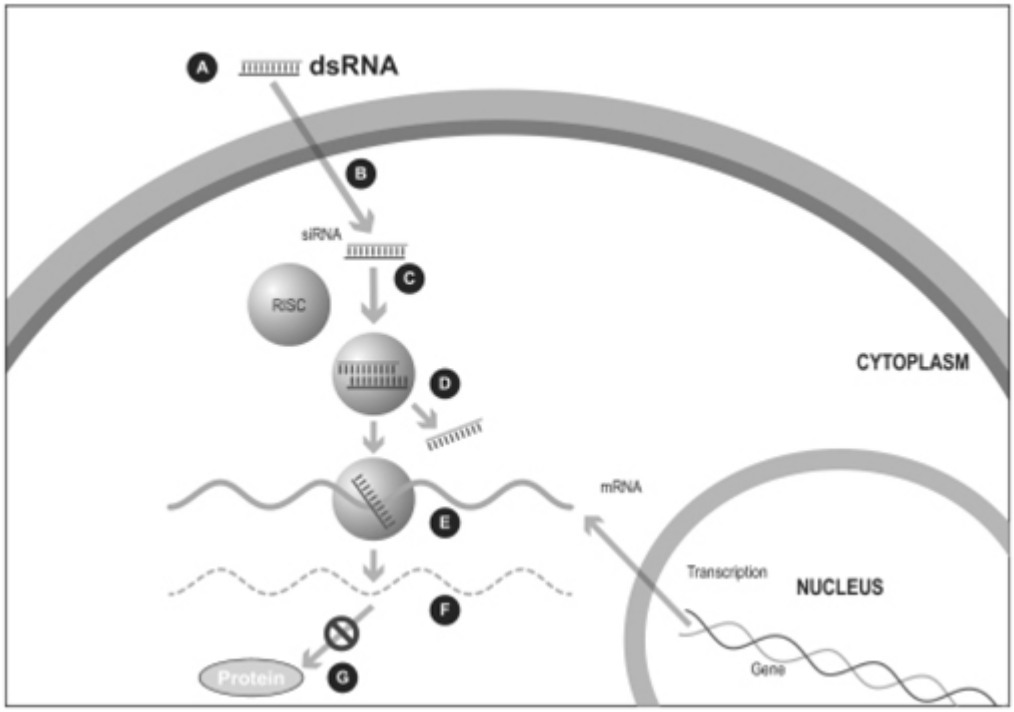
With our ddRNAi approach, gene therapy vectors are used to deliver a DNA construct that produces shRNAs, which are processed by the cell into siRNAs, which then silence the disease-associated genes.

***Overview of RNAi and siRNA approach***

Many diseases are known to be caused by the inappropriate expression of a gene or multiple genes. These disease-associated genes can be turned off, or silenced, by the use of RNAi, resulting in a treatment or cure of the disease. Thus, RNAi provides the ability to develop therapeutics against diseases caused by inappropriate gene expression, by targeting a specific region of the molecular sequence of the disease-causing gene. RNAi is potentially applicable to over 20,000 human genes and a large number of disease-causing microorganism-specific genes.

The mechanism of action of RNAi involves the introduction of siRNA into a cell. The siRNA's sequence is constructed to match a short region of the target gene. The siRNA is processed by the cell's own enzymes to destroy the target gene's mRNA, thus preventing the disease-causing gene from being expressed. This occurs as long as the siRNA remains prevalent in the cell. In the standard RNAi approach, siRNA is produced synthetically in the laboratory and introduced into the target cell either by chemical modification of the RNA or by a range of delivery materials. A number of other companies, including Alnylam, Arbutus, and Dicerna, utilize this approach in their RNAi product candidates.

**Figure 1. The siRNA approach.**




**A small double stranded RNA, or dsRNA, molecule (A), comprising one strand known as the sense strand and another strand known as the antisense strand, which are complementary to each other, is synthesized in the laboratory. These small dsRNAs are called small interfering RNAs, or siRNAs. The sequence of the sense strand corresponds to a short region of the target gene mRNA. The siRNA is delivered to the target cell (B), where a group of enzymes, referred to as the RNA Interference Specificity Complex, or RISC, process the siRNA (C), where one of the strands (usually the sense strand) is released (D). RISC uses the antisense strand to find the mRNA that has a complementary sequence (E) leading to the cleavage of the target mRNA (F). As a consequence, the output of the mRNA (protein production) does not occur (G).**

***Our Approach to Gene Silencing—ddRNAi***

Our ddRNAi technology is designed to utilize the specificity and gene silencing effect of RNAi while overcoming many of the limitations of siRNA. Our ddRNAi approach combines RNA interference with gene therapy vectors to deliver a DNA compound to the target diseased tissue in order to silence the disease-associated genes.

*Gene therapy*

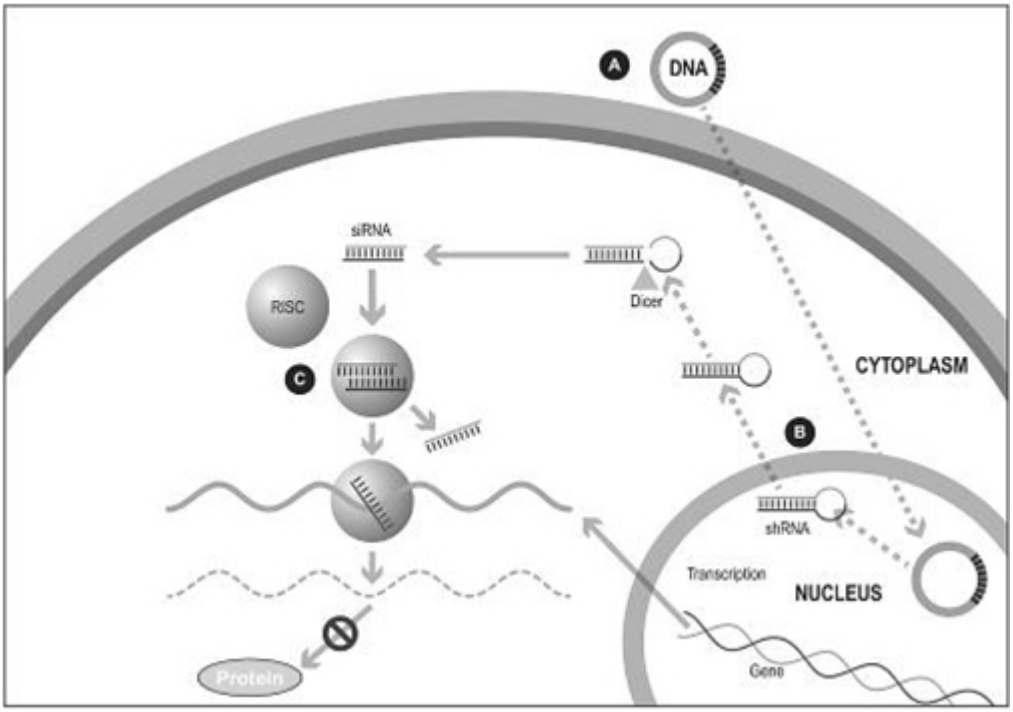
Gene therapy is designed to introduce genetic material into cells, usually to compensate for abnormal or malfunctioning genes or to make a beneficial protein to address a defect. If a mutated gene causes a necessary protein to be faulty or missing, gene therapy is used typically to introduce a normal copy of the gene to restore the function of the protein. Genetic material that is inserted directly into a cell usually does not function. Instead, a carrier called a vector is genetically engineered to deliver the gene. Certain viruses are often used as vectors because they can deliver the new gene by infecting the cell. The vector viruses are designed not to cause disease when used in people. Some types of vector viruses, such as lentivirus, integrate their genetic material, including the new gene, into a chromosome in the human cell. Other vector viruses, such as adenoviruses and adeno-associated viruses, or AAV, introduce their DNA into the nucleus of the cell, but the DNA of the vector virus is not integrated into a chromosome; only the therapeutic gene is integrated. Most of our ddRNAi programs utilize AAV as the delivery vector. A number of viral vectors can produce gene expression for months or years following a single administration, depending on the target tissue.

The vector can be given intravenously or injected directly into a specific tissue in the body, where it enters individual cells. Alternatively, a sample of the patient's cells can be removed and exposed to the vector in a laboratory setting. The cells containing the vector are then returned to the patient where they produce the expressed RNA or protein.

*ddRNAi*

Our ddRNAi technology utilizes DNA as the therapeutic molecule designed to generate shRNAs continuously in the target cell. A range of viral and non-viral gene therapy vectors can be used to deliver the DNA construct into the cell's nucleus. Once delivered, the DNA sequence codes for specific shRNAs, which are then processed by the cell's endogenous machinery into siRNA. The siRNA created by the cell then completes the RNAi cycle described above by cleaving the mRNA of the target gene thus preventing the disease-causing gene from being expressed.

**Figure 2. The ddRNAi approach.**

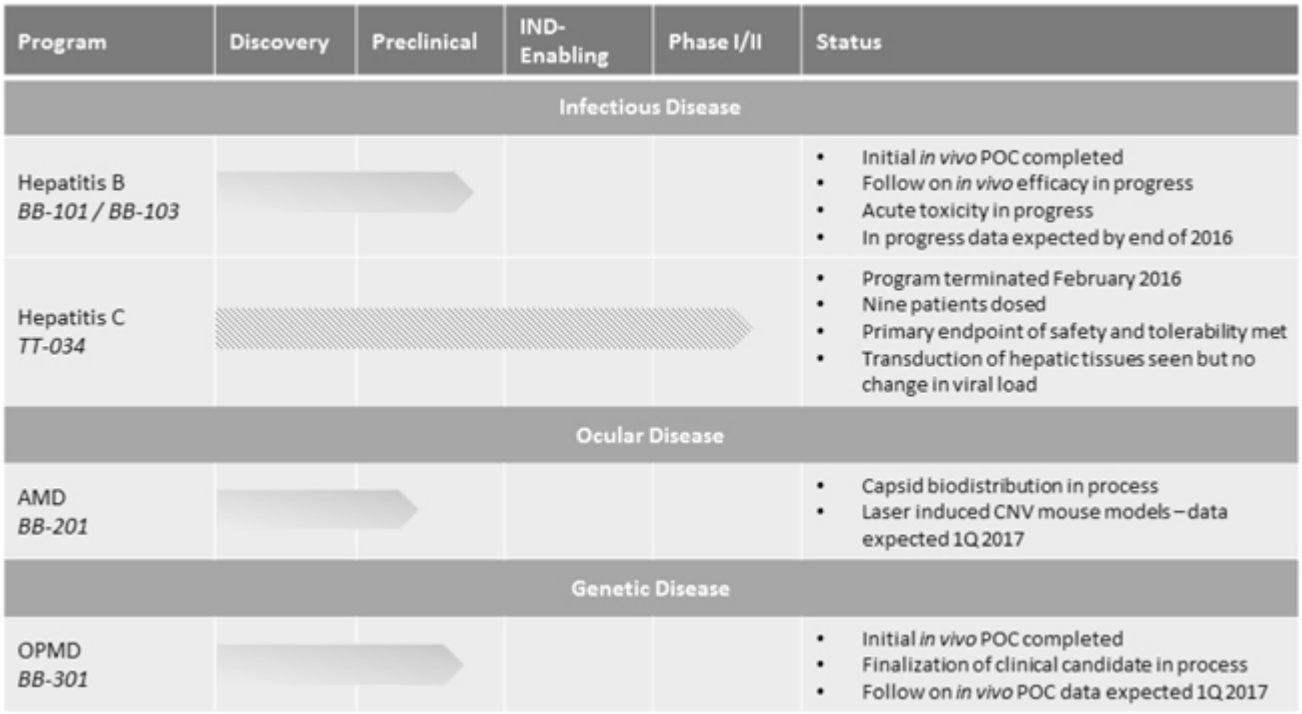



**A DNA construct is delivered to the target cell's nucleus by a gene therapy vector (A) such as an AAV. Once in the nucleus, the DNA construct continuously produces shRNAs (B) which are processed by an enzyme called Dicer into siRNAs (C). The processed siRNA is incorporated into RISC and silences the target gene using the same mechanism shown in Figure 1.**

**Our Pipeline**

We are developing a portfolio of product candidates based on our proprietary ddRNAi gene silencing technology focused on chronic and life threatening conditions with disease-associated genes.

***In-House Programs***




Proceeds from our initial public offering in the United States, with our pre-existing cash and cash equivalents, will advance our product candidates for hepatitis B, AMD and OPMD. Additional financing will be needed to advance our product candidates for hepatitis B, AMD and OPMD through clinical trials. As depicted and described in the image above and as discussed elsewhere in this report, our Hepatitis C program was terminated in February 2016.

**BB-103 and BB-101 for the Treatment of Hepatitis B**

We are developing BB-103 and BB-101 for the treatment of HBV. Ultimately, only one of the two compounds will be a candidate to enter into testing in human clinical studies. BB-103 is our lead candidate; any final decision for moving one or the other into the clinic will follow efficacy and acute toxicity studies. We are targeting completion of the *in vivo* proof-of-concept preclinical studies that couple BB-103 and BB-101 with approved therapeutics to treat individuals infected with HBV in the fourth quarter of calendar 2016. Results of recent *in vivo* and *in vitro* studies, from March 2016 and December 2015, respectively, have, we believe, demonstrated the potential utility of an approach that combines RNAi with gene therapy to treat HBV, and we intend to advance the HBV program towards the clinic. However, we will need to seek additional financing to proceed with clinical trials for either BB-103 or BB-101.

We have completed a Phase I/IIa clinical trial for our now discontinued product candidate, TT-034, which we were developing to treat patients chronically infected with the most common genotype of HCV. The trial achieved its primary end point of safety of TT-034 in HCV patients, based on safety within the liver and other organs of the nine patients that were dosed in the study. There was one serious adverse event observed, a pulmonary embolism resulting from a fall, and it was classified as unrelated to the therapy. That event was resolved within four weeks. Three other adverse events (diarrhoea, light-headedness and bradycardia) were also observed and considered possibly treatment related. All of those events were mild in nature and resolved completely. No adverse event met the pre-defined criteria for a dose-limiting toxicity. In addition, no T-cell capsid response was seen in any of the subjects, as has been previously reported at similar high-dose levels in other companies' systemic trials with AAV. While transduction of hepatic tissues was seen, there was no reduction in viral load in treated patients, which was a secondary endpoint of the study. We believe that our experience with the TT-034 clinical trial will be of value in designing and implementing our other programs, in particular HBV, as both HBV and HCV replicate in the liver. We have designed certain aspects of BB-103 to mimic the design elements of TT-034.

The human hepatitis B virus is a small DNA virus that, according to the WHO, infects up to 240 million people worldwide, resulting in up to 780,000 deaths per year. Infection with HBV occurs in phases ranging from a silent, acute phase that can be resolved by the immune system to a persistent chronic infection requiring life-long therapy. In the case of a chronic HBV infection, the presence of viral proteins, particularly the s-antigen, causes hepatic inflammation leading to liver dysfunction, acute hepatic failure, cirrhosis or hepatocellular carcinoma.

***Current Hepatitis B Treatments***

HBV predominantly exists as eight genotypes, designated A through H, with distinct geographic distribution. We believe the keys to developing a successful HBV therapeutic are to stop viral replication and to prevent production of or clear specific antigens generated by the virus, in particular the HBV surface antigen, or HBsAg.

According to GlobalData, a market research firm, the global hepatitis B therapeutics market was worth $2.4 billion in 2014, and is expected to reach a total of $3.0 billion by 2024 at a Compound Annual Growth Rate of 2.4% (GlobalData, 2016). The current therapies used as standard of care for HBV consist of antivirals composed of nucleotide and nucleoside analogues, or NUCs, and, less commonly, interferon therapy.

The most common anti-viral medications are taken as tablets each day for a year or longer and primarily act to inhibit viral replication:

- Lamivudine (Zeffix). There are almost no side effects to Lamivudine, however a significant concern is the possible development of hepatitis B virus mutations and antiviral drug resistance after long-term use.
- Adefovir (Hepsera). Adefovir is often used for people who have developed a hepatitis B virus mutation after taking Lamivudine. There are almost no side effects except for the possibility of developing hepatitis B virus mutations and antiviral drug resistance.
- Entecavir (Baraclude). Entecavir has potent activity against chronic hepatitis B. There are almost no side effects except for the possibility of developing hepatitis B virus mutations and antiviral drug resistance.
- Tenofovir (Viread). Tenofovir has potent activity against chronic hepatitis B. It is particularly useful in patients who have developed drug resistance to other medications.
- Pegylated Interferon (Pegasys). Interferon is given by injection once a week, usually for six months to a year. The drug has many potential side effects, such as flu symptoms and depression, but is reported to control the hepatitis B virus in a third of patients without need for long-term medication.

Most of these therapies can provide long-term viral load suppression but have low cure rates and have the additional risk of drug-resistant mutations. The long-term use of interferon, particularly in high doses, may also be associated with significant side effects, including nausea, vomiting, shortness of breath, dizziness and fatigue, adding to issues with patient compliance for the course of treatment. We believe that there is significant unmet medical need for HBV treatment due to the following factors:

- Inability of existing therapies to address the risk of recurrence of the infection, once an antiviral therapeutic is removed, due to the persistence of HBV covalently closed circular DNA, or cccDNA. cccDNA is a supercoiled DNA molecule that is present in the nucleus of HBV-infected cells and acts as a reservoir for further HBV infectivity. cccDNA is responsible for persistence of infection in the natural course of chronic HBV infection and during prolonged antiviral therapy.

- Mutations in the HBV genome conferring resistance to existing therapies.
- Long treatment regimens and, in some cases, significant debilitating side effects associated with current therapies, which lead to a risk of patient non-compliance.

A problem inherent to all of the current HBV antiviral treatment approaches is their inability to achieve a curative outcome. According to a study published in the *Journal of Viral Hepatitis* in 2014, HBsAg clearance occurs in only 3% of patients treated with NUCs and 7.8% of patients treated with interferon. Sustained suppression of HBV cccDNA by treatment with NUCs is only possible with continued treatment for many years, and clear-cut guidelines on when to stop treatment are not yet available. The authors concluded that there is a need for alternative therapeutic approaches such as drugs that can preferentially target stages in the life cycle of HBV, referred to as direct acting anti-virals, or DAAs, as well as new immunotherapeutic approaches. We believe that our ddRNAi-based therapeutic for HBV has characteristics of both of these approaches.

***Hepatitis B Treatments in Development***

*DAAs*

DAAs are chemicals that have been used to inhibit HBV replication by targeting one of the various stages of the viral life cycle. Use of DAAs may prove ineffective in clearing infected hepatocytes, and thus elimination of the cccDNA pool may be problematic. Accordingly, we believe combination treatments involving immunotherapeutic approaches may be necessary. Immunotherapeutic approaches that are being developed include DNA-based vaccines and molecules that are designed to activate immune responses to the hepatitis B virus. These approaches are not yet in clinical development.

*Cytotoxics*

TetraLogic Pharmaceuticals Corporation, or TetraLogic, has conducted preclinical studies to evaluate the potential development of the chemotherapeutic drug birinapant as a hepatitis B therapeutic to stimulate apoptosis, or programmed cell death, in HBV-infected liver cells. Using a mouse model of HBV infection, TetraLogic reported that birinapant was observed to have activity in the clearance of liver cells infected with HBV. The clearance was additive when given in combination with Entecavir. Birinapant caused a decline in HBsAg, whereas Entecavir alone did not, implying that birinapant exerts its effect on apoptosis via a different mechanism of action.

*siRNA*

Several therapeutics based on siRNA are in late preclinical stages or clinical stages of development at companies such as Arbutus, Arrowhead and Alnylam. The most advanced of these therapies is Arrowhead's drug candidate, ARC-520, which consists of two siRNAs targeting HBV mRNAs. Using transient and transgenic mouse models, it was observed that a single injection of ARC-520 resulted in a 3–4 log reduction in HBV-DNA and viral antigens. In addition, 95% reduction in HBV-DNA levels and approximately 90% reduction in HBsAg levels were observed after two doses of ARC-520 in a chimpanzee chronically infected with HBV. Arrowhead is currently testing ARC-520 in hepatitis B patients in a Phase II clinical study.

In addition, ARB-1467, an Arbutus drug candidate, has progressed to a Phase II multiple-dosing study initiated in December 2015 and ongoing. ARB-1467 uses a three-trigger siRNA design with a goal to facilitate the loss of HBsAg expression in chronic HBV patients. Using chimeric mouse models, ARB-1467 showed inhibition of HBsAg and HBeAg, as well as a reduction in viral DNA and cccDNA.

We believe these results highlight the potential of RNAi to have a therapeutic effect on chronic HBV infection. However, like NUCs and DAAs, siRNA-based therapeutics for HBV rely on ongoing treatment to be effective and they are subject to the other limitations of siRNA described above. Some of these limitations may have contributed to the modest efficacy of ARC-520 in their Phase I/IIa clinical trial announced by Arrowhead in 2014.

***Our ddRNAi-Based Hepatitis B Therapeutic—BB-103***

We are developing BB-103 to address many of the limitations of therapeutics for HBV currently on the market and those in development. BB-103 is designed to be a single administration ddRNAi-based therapy that is delivered using an AAV vector that targets the liver and expresses three shRNAs that target highly conserved regions on the HBV genome to inhibit both viral replication and viral protein, including s-antigen, production on a long-term basis. BB-103 could be used either as a monotherapy or, more likely, in combination with another antiviral compound.

We have designed certain components of BB-103 to mimic our now discontinued product candidate for HCV, TT-034, as both HBV and HCV replicate in the liver. The same AAV vector is used in both therapeutic candidates, designed to achieve the same biodistribution and liver transduction properties. The AAV vector is expected to be delivered by a single administration therapy. The AAV vector will target the liver and express three shRNAs that target three separate conserved regions of the genome. The most significant change is the replacement of the three anti-HCV shRNAs of TT-034 with three anti-HBV shRNAs in BB-103 as well as modeling the anti-HBV shRNAs into a miRNA backbone for more efficient expression. Though we have discontinued our clinical trial for TT-034 for commercial reasons, we believe the clinical results of TT-034 provide support for the safety of our platform technology.

Despite the discontinuation of the TT-034 Phase I/IIa trial, we believe useful information was obtained from the trial which should be beneficial for the clinical development of BB-103, the IND-enabling studies, the design and regulatory approval pathway for initial clinical trials, and potentially the starting clinical dose, in light of the similarities between TT-034 and BB-103.

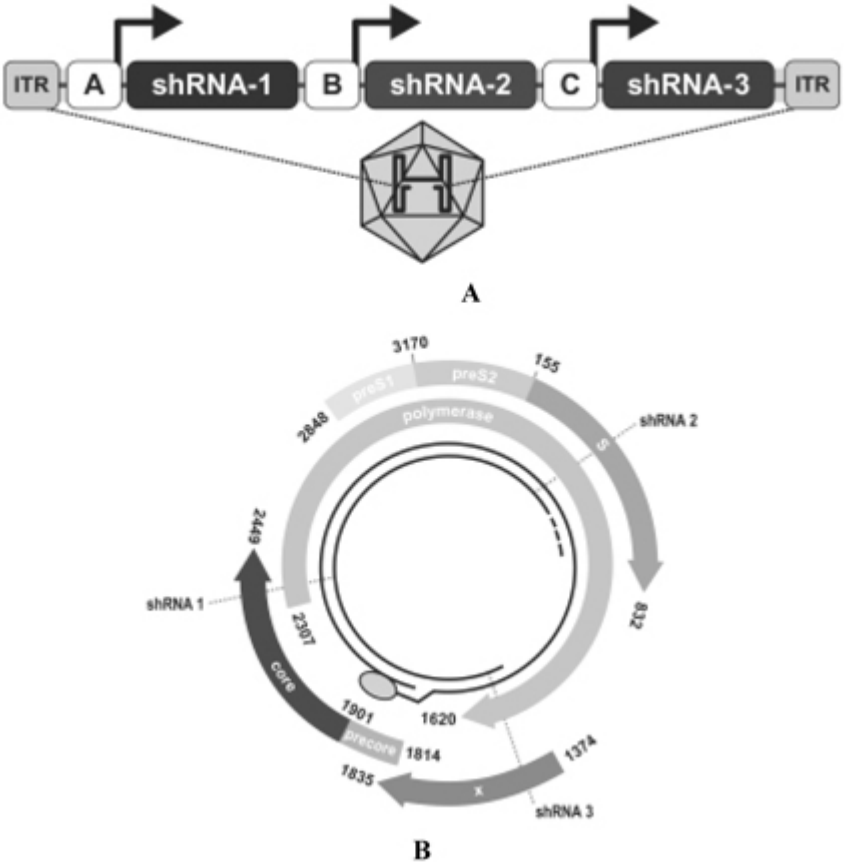
*BB-103—Design and Mechanism of Action*

The design of the BB-103 DNA construct takes advantage of the structure of the HBV genome. The hepatitis B virus is a small DNA virus with four overlapping open reading frames, meaning several genes are produced from the same DNA sequence by shifting the starting point of the translation process *(Figure 3)*. These four genes are known as the core, surface, X and polymerase genes. The core gene encodes the core nucleocapsid protein, which is important in viral packaging and thought to help stabilize cccDNA, and hepatitis B e-antigen. The surface gene encodes proteins, including s-antigen. The X gene encodes the X protein, which has properties that may be important in liver carcinogenesis. The polymerase gene encodes a large protein with functions critical for viral packaging and replication. Although HBV is a DNA virus, it replicates through an RNA intermediate. BB-103 targets the viral mRNA at three overlapping regions of the genome *(Figure 3)*, simultaneously silencing the surface, X, core and polymerase genes. As a result, we believe that the long-term suppression of HBV viral replication, through silencing of the polymerase gene and targeting the HBV RNA used for replication, the inhibition of HBV viral proteins production, including the s-antigen production, through silencing of the surface gene, and the inhibition of the cccDNA, through silencing of the core protein gene, could lead to eradication of HBV infection in patients by a single administration of BB-103.

***In vitro Development Highlights***

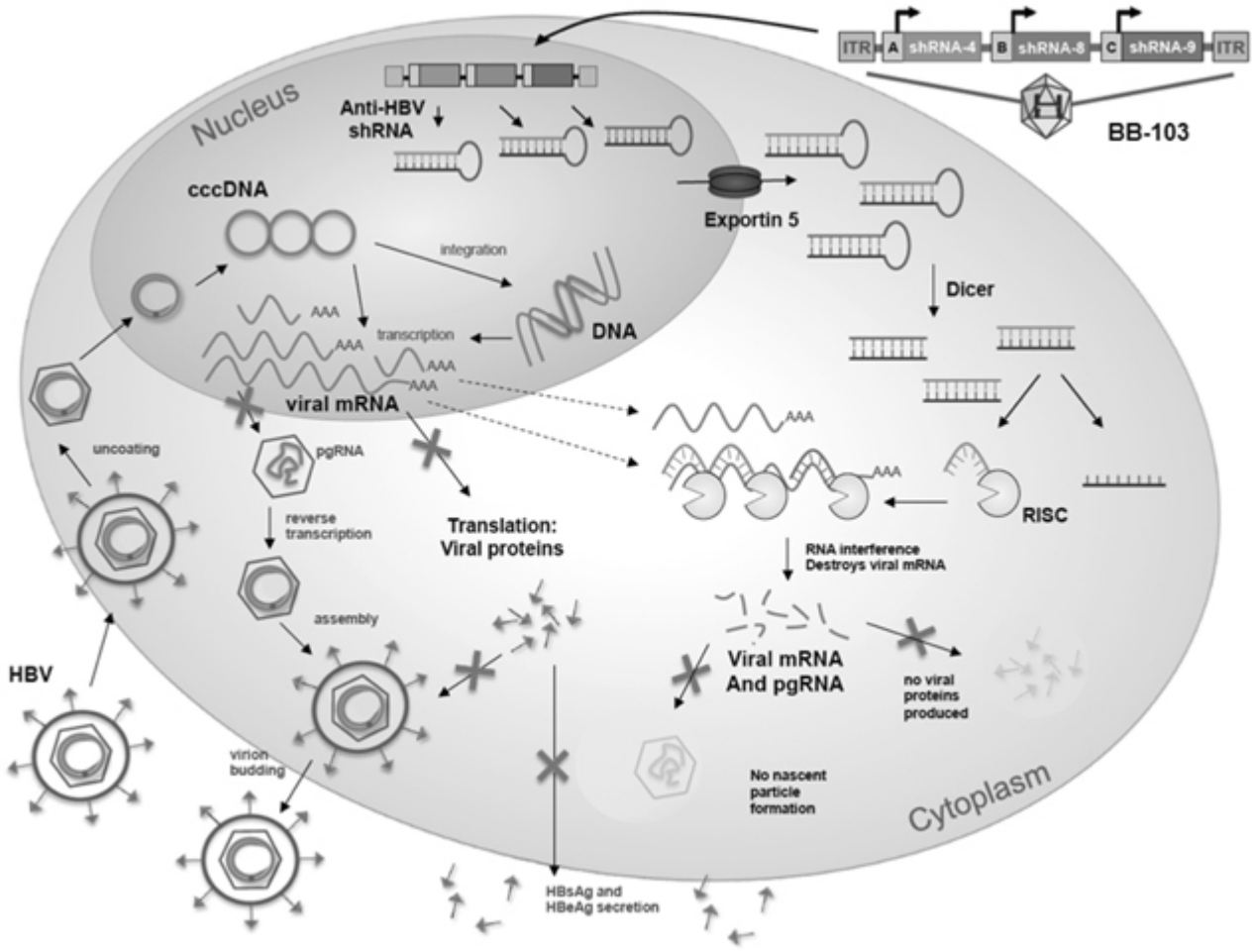
Our bioinformatics analysis of the major HBV genotypes, A through H, has identified several well-conserved regions of the genome for targeting with ddRNAi therapeutics. We have designed numerous shRNAs to target these regions, and we have identified lead candidates based on several factors, including activity, hyperfunctionality, meaning the highest activity at lowest levels, and the ability of the shRNA strand to be incorporated into the cell's natural RNA processing mechanism. The final clinical construct we have chosen is illustrated in Figure 3.

**Figure 3. The design for BB-103**




**The design for BB-103 is based on the design of TT-034, utilizing an AAV capsid and a triple construct targeting three separate conserved regions on the HBV mRNA (A); The shRNAs target regions on the overlapping reading frames of the HBV genome (B), allowing simultaneous targeting of the mRNAs that express viral proteins including DNA polymerase, s-antigen and core proteins.**

**Figure 4. The mechanism of action of BB-103**




**The DNA construct is delivered to the nucleus of hepatocytes via an AAV vector. Upon reaching the nucleus the construct expresses three different types of shRNAs (B) that are processed by the cell's endogenous machinery to produce siRNAs that cleave the HBV mRNA and thus prevent the virus from replicating and producing viral proteins.**

***In vivo Development Highlights and Ongoing Development Plan for BB-103***

Our development plan for BB-103 is focused on demonstrating clinical proof of concept in a Phase I/IIa clinical trial. We expect to complete *in vivo* proof-of-concept studies in the fourth quarter of calendar 2016.

Initial *in vitro* data from preclinical results in December 2015 demonstrated the efficacy of BB-102, a first generation compound expressing similar anti-HBV shRNA, to suppress multiple aspects of HBV in infected human liver cells. The *in vitro* data was supported by *in vivo* experiment in the chimeric mouse model results reported in March 2016, which demonstrated suppression of HBV *in vivo* in a mouse model following a single administration. Key findings from the *in vivo* study indicated that a single BB-102 treatment:

- reduced serum HBV DNA by 1.83 logs, equivalent to 98.5% elimination of circulating HBV;
- reduced intracellular liver HBV DNA by 94.9%;
- suppressed serum antigens, HBsAg and HBV envelope antigen (HBeAg), by 97.6% and 92.5%, respectively; and
- significantly decreased levels of HBV viral RNA and cccDNA.

**BB-201 and BB-202 for the Treatment of Age-Related Macular Degeneration**

***Overview***

We are developing two ddRNAi-based therapies, one for the treatment of wet AMD, which is designated BB-201, and the other potentially for both wet and dry AMD, which is designated BB-202. The delivery vector for both BB-201 and BB-202 is comprised of a novel AAV capsid is being developed in collaboration with 4DMT. The aim of this program is to develop a therapeutic that provides long-term treatment of AMD from a single intravitreal injection. We believe this could replace the need for regular intravitreal injections of protein based therapeutics into the eye, which is the current standard of care.

AMD is the deterioration of the eye's macula. The macula is a small area in the retina that is responsible for central vision. AMD is the leading cause of blindness and visual impairment in older adults, often involving blood vessel overgrowth and damage to the retina resulting in the loss of vision in the central visual field. The vascular endothelial growth factor, or VEGF-A, is responsible for stimulating the new blood vessel growth. The disease occurs in two forms, wet and dry. Dry AMD is the most common type of macular degeneration and affects 85% to 90% of the people with AMD. Dry AMD often develops into wet AMD.

In the dry form, there is a breakdown of retinal pigment epithelial cells in the macula. These cells support the light-sensitive photoreceptor cells that are critical for vision. Generally, the damage caused by the dry form is not as severe or rapid as that of the wet form. However, over time, it can cause profound vision loss. There are currently no approved treatments for dry AMD.

Wet AMD is the more advanced type of AMD. In wet AMD, which is also called exudative, or neovascular, AMD, the Bruch's membrane underlying the retina thickens, then breaks. The oxygen supply to the macula is disrupted and, as a result, new abnormal blood vessels grow through the subretinal membrane towards the macula, often raising the retina. The blood vessels are fragile, and often leak fluids that damage the macula. VEGF-a is a key molecule known to stimulate the new blood vessel growth in wet AMD. Although the wet form of the disease affects only 10% to 15% of those who have AMD, wet AMD accounts for 90% of the severe vision loss caused by macular degeneration.

According to a study published in JAMA Ophthalmology, AMD is the leading cause of irreversible vision loss in the United States, affecting an estimated 1.75 million people. It is estimated that 196 million people will be affected by AMD worldwide by 2020 according to a study published in Lancet Global Health.

There are a number of treatments currently available for wet AMD. According to GlobalData, the annual wet AMD treatment market across the United States, the United Kingdom, Germany, France, Spain, Italy and Japan will almost double from US$5.1 billion in 2013 to US$10.1 billion by 2023.

***Current AMD Treatments***

According to GlobalData, the global AMD treatment market is dominated by anti-VEGF drugs, including Lucentis, Avastin and Eylea, which together accounted for 98% of sales for AMD in 2013.

- Lucentis (ranibizumab) is an antibody fragment, or macromolecule, that directly inhibits VEGF-a by binding to it and thus preventing its binding to the corresponding receptor in the retina. The main challenge for Lucentis is that it requires frequent administration, typically monthly or bimonthly, via intravitreal injections.
- Avastin (bevacizumab) is a monoclonal antibody that also binds to VEGF-a. Although approved only for use in colon cancer, it is used off label for AMD. It is also injected intravitreally and requires ongoing regular injections to maintain its effect.

- Eylea (aflibercept) is a recombinant fusion protein consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1. It is recommended to be injected intravitreally every four weeks for the first three months and every eight weeks thereafter. Eylea is thought to work by inhibiting VEGF-a, VEGF-b and PGF.
- Macugen (pegaptanib) is an RNA aptamer that is directed against VEGF-a. It is recommended to be injected intravitreally every six weeks.

All four treatments have similar risks and potential for adverse events, due primarily to their use of frequent intravitreal injection. Risks of intravitreal injections include increase in intra-ocular pressure, retinal detachment and endophthalmitis, or inflammation of the internal chambers of the eye. Patients and doctors dislike ocular injections and tend to prefer treatments that require these injections less frequently. The use of VEGF inhibitors can also cause blood clots.

A number of companies are developing gene therapy-based treatments for AMD. In general, these approaches involve the delivery of genes expressing proteins that are designed to inhibit new blood vessel formation, which is one of the hallmarks of the disease. The genes that are being developed include genes that express VEGF inhibitors in addition to other factors that activate new blood vessel formation. In contrast, our approach is designed to directly silence the gene responsible for producing VEGF-a. We believe this could be more effective than other gene therapy approaches as our approach is to design ddRNAi-based therapeutics to prevent the production of VEGF-a rather than to deliver a new gene that expresses a new protein to inhibit VEGF-a after it has been produced. Furthermore, we believe that most of the other gene therapy approaches are delivered using subretinal injections. This route of administration presents challenges, including the requirement for hospitalization as a result of general anesthesia and the length of time required to complete the complicated surgical procedure.

***Our ddRNAi-Based AMD Therapeutics—BB-201 and BB-202***

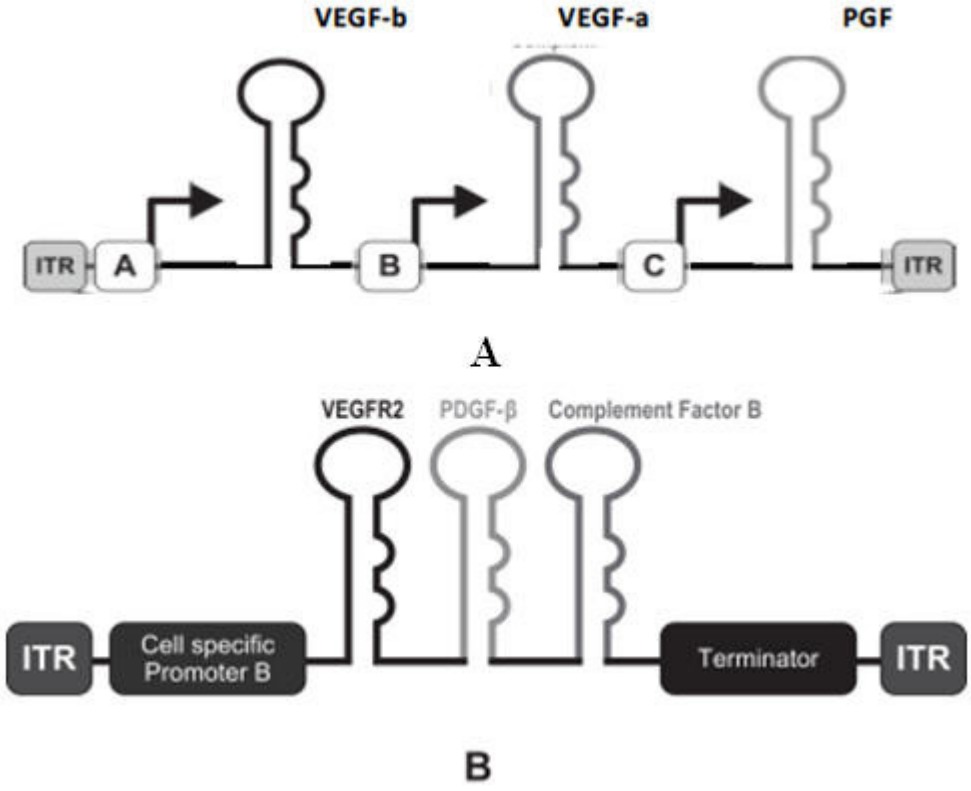
There are several challenges in the development of AMD therapeutic market and we believe that our ddRNAi technology has the potential to address and overcome a number of these challenges, including:

- The relatively short half-life of current standard-of-care therapies results in the need for regular administration by intravitreal injection every 4 to 8 weeks. We believe our ddRNAi-based therapeutics have the potential for sustained inhibition of disease progression, possibly for months or years, from a single intravitreal injection.
- AMD therapeutic programs under development at a number of other gene therapy companies focus on administering the product to target cells by subretinal injection. We are co-developing with 4DMT AAV vectors to target the subretinal cells following intravitreal injection, which we believe is a more commercially viable and less invasive route of administration and is the route used in most current anti-VEGF therapies.
- There are no approved treatments for dry AMD. We have designed and tested a ddRNAi construct that we believe has potential to address this unmet market need.

*BB-201 and BB-202- Design and Mechanism of Action*

- We are developing two ddRNAi-based product candidates, one for wet AMD, called BB-201, and one for both wet and dry AMD, called BB-202, that are designed to address many of the limitations for therapeutics for AMD currently on the market or under development.
- BB-201 is a ddRNAi construct expressing a three independent shRNAs designed to inhibit the expression of genes that encode for the VEGF-a, VEGF-b and PGF (*Figure 5A*). VEGF-A is responsible for stimulating the new blood vessel growth in wet AMD.
- BB-202 is our second generation product candidate designed to express three shRNAs, which target three different genes, VEGF receptor 2, PDGF-beta receptor and human complement factor B, which all play a role in the progression of AMD *(Figure 5B)*. VEGFR2 is the receptor known to bind VEGF-a, so silencing that receptor should prevent it from functioning to stimulate new blood vessel growth. The PDGF-beta receptor has a known role in recruiting cells that stabilize newly formed blood vessels for long term-persistence. Human complement factor B is a known component of ocular drusen.

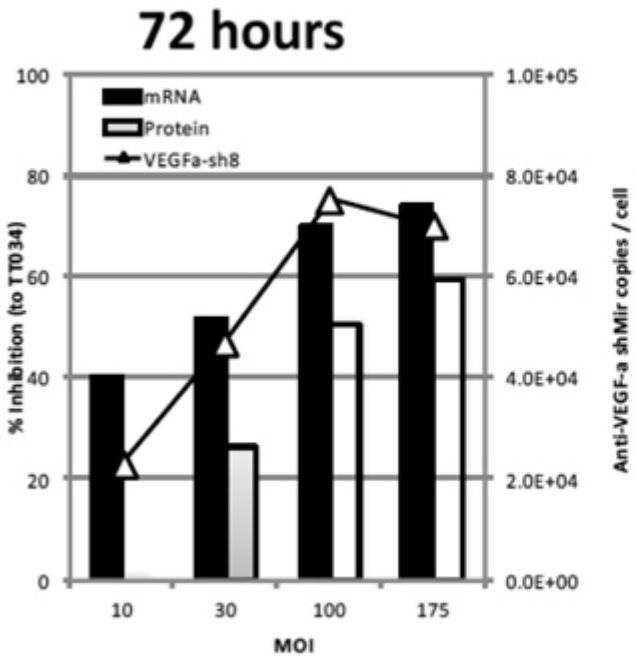
**Figure 5. Our AMD ddRNAi constructs**

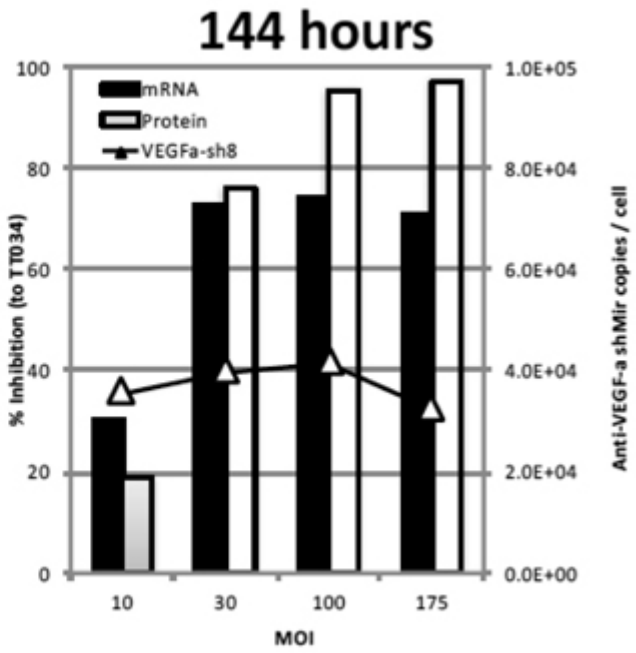



**BB-201 is a construct that uses three independent promoters to drive the expression of short hairpin RNA that target VEGF-a, VEGF-b and PGF and is intended for use in subjects with wet AMD (A); and BB-202 is a ddRNAi construct that uses one promoter to drive the expression of shRNA that target VEGFR2, PDGF-ßR, and Human Complement Factor B, three genes shown to have a role in both wet and dry AMD (B).**

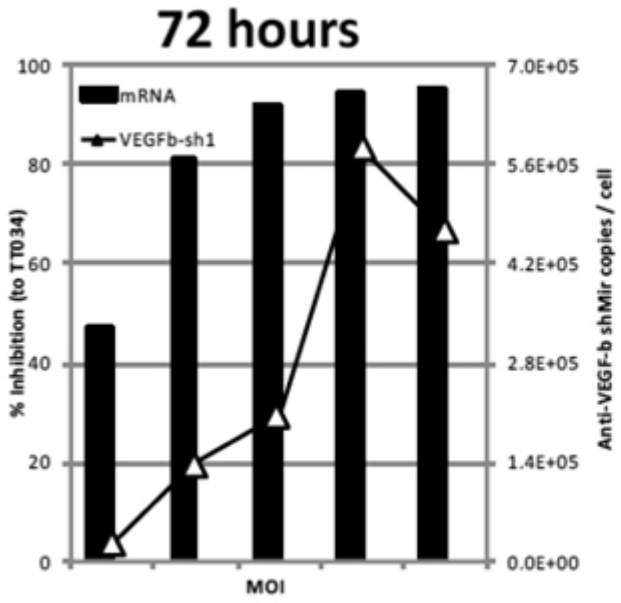
We have observed in *in vitro* studies that both BB-201 (*Figure 6*) and BB-202 (*Figure 7*) are effective at silencing the target genes.

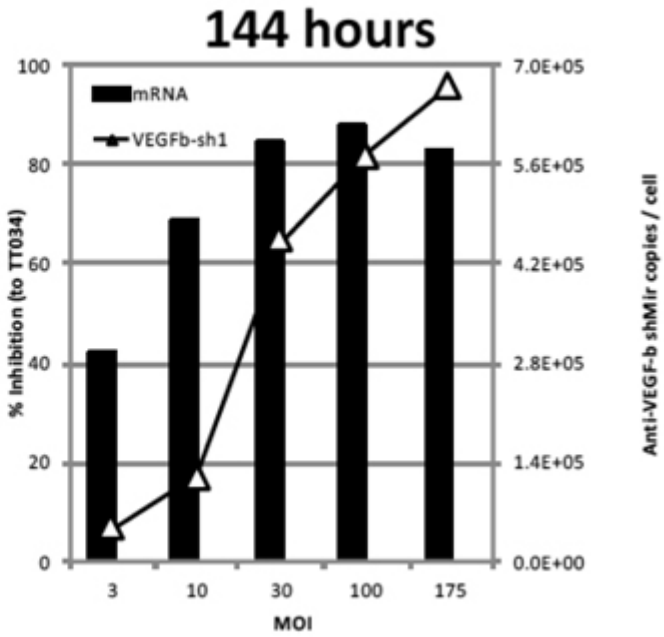
**Figure 6. Effects of BB-201 on VEGF-a, VEGF-b and PGF *in vitro*.**



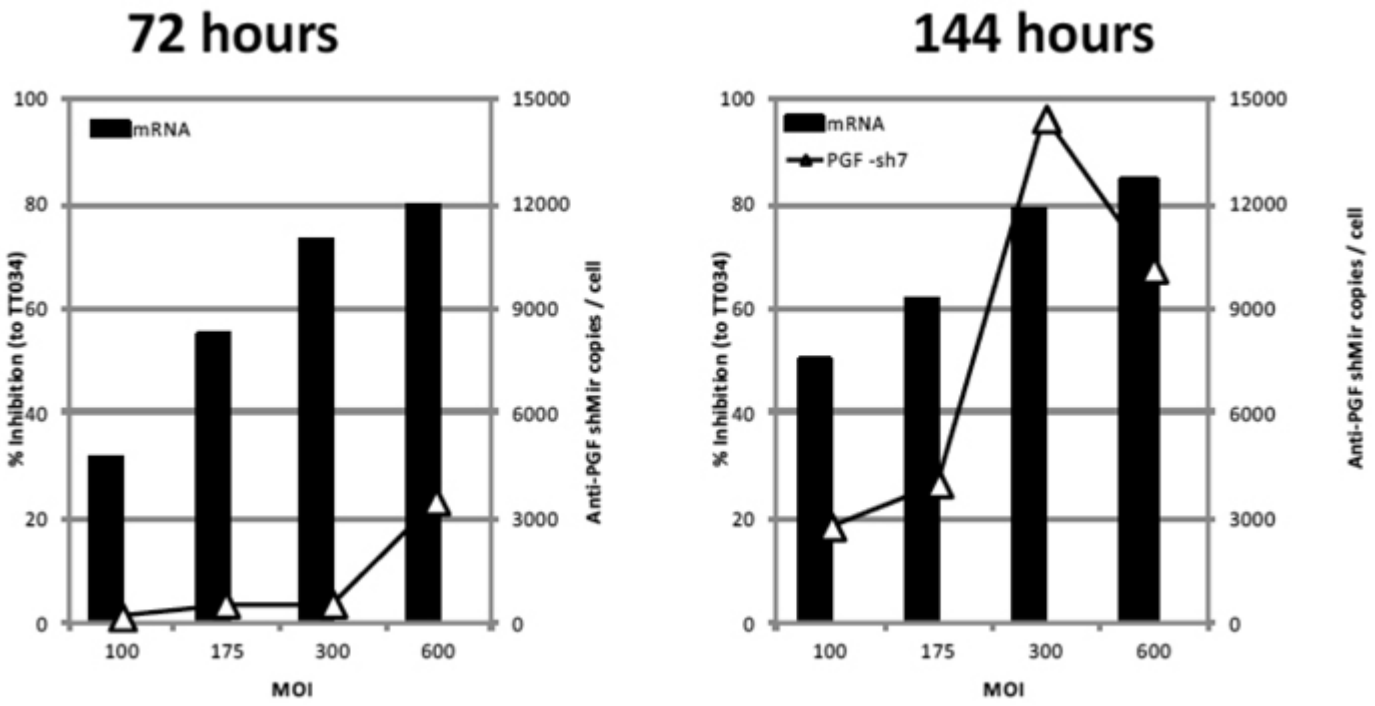




**VEGF-a**




**VEGF-b**

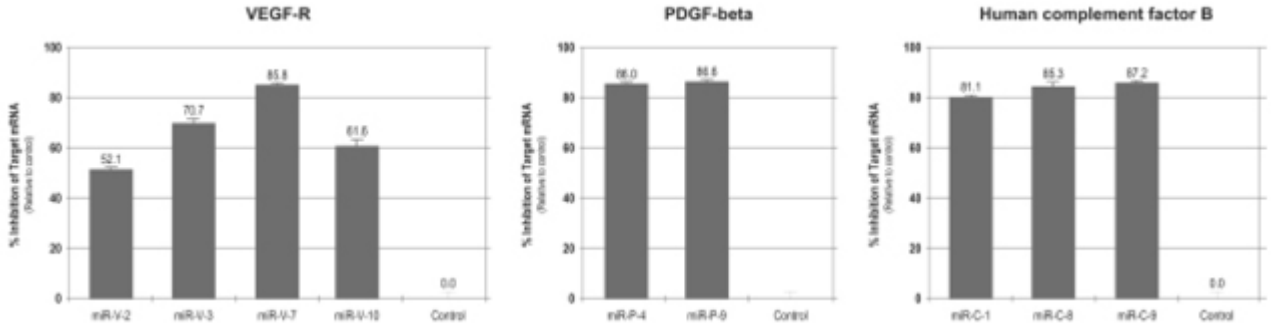



**PGF**

**A retinal pigment epithelial cell line cultured *in vitro* was treated with adenovirus harboring the BB-201 expression construct and monitored for up to 144 hours for inhibition of protein (light bars) and mRNA (black bars) as well as expression of the shRNA produced (triangles). "MOI" represents the multiplicity of infection. The production of anti-VEGF-a, VEGF-b and PGF shRNAs inside of the cells correlated with significant silencing of the respective target mRNA.**

**Figure 7. Effects of BB-202.**

**Figure 7. Effects of BB-202.**



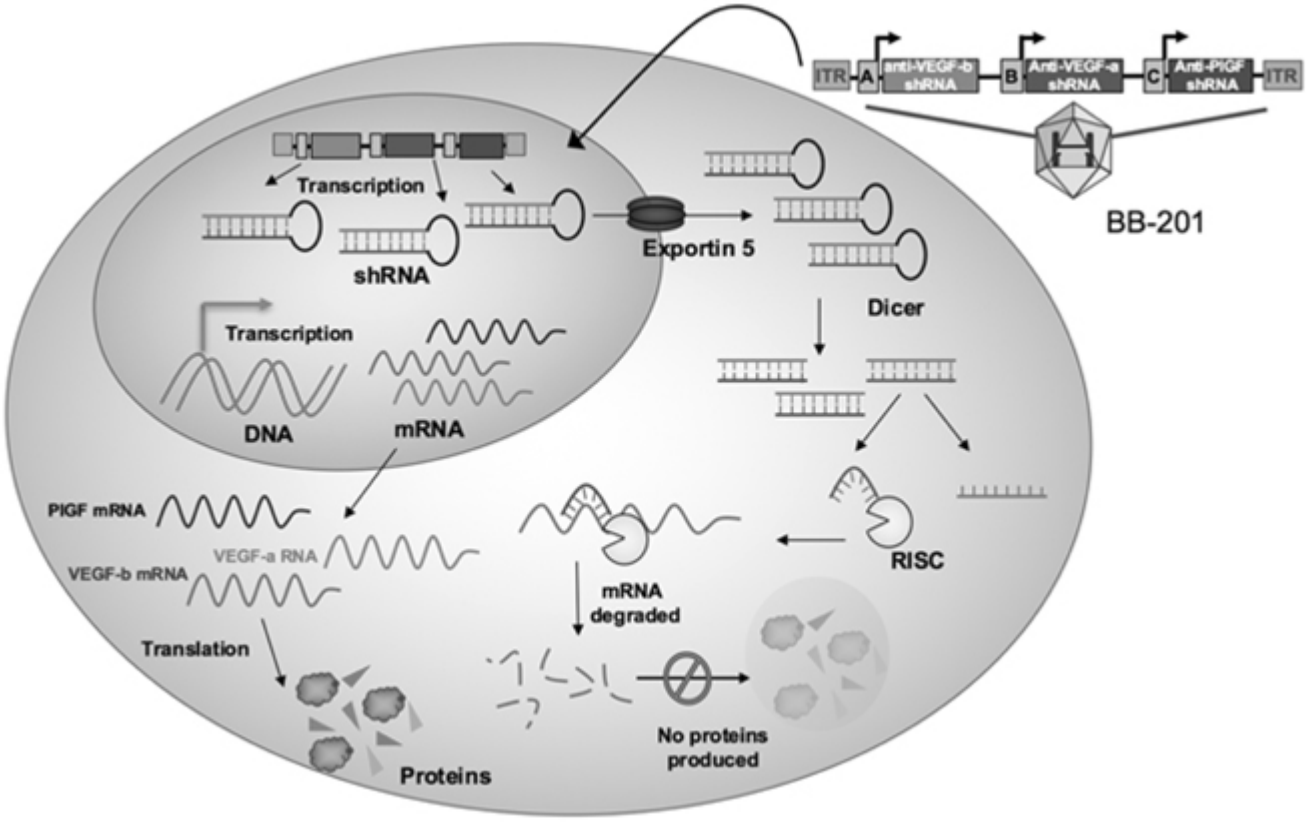

**In *in vitro* studies in retinal pigment epithelial cells, BB-202 inhibited target mRNA levels of VEGF-receptor, PDGF-beta and human complement factor B.**

***Ongoing Development Plan for AMD – Development of Novel Delivery Vector***

We have engaged 4DMT to develop a novel AAV capsid that, when delivered by intravitreal injection, will deliver our ddRNAi constructs to the retinal cells of the eye. 4DMT has developed novel AAV vectors with desirable physical properties, such as enhanced tissue attractions, or tropisms, and reduced immunogenicity using a technique called directed evolution. This involves sequential passaging of a starting AAV library *in vivo* to isolate

those variants that have the highest affinity for the target tissue. The sequential passaging for our AMD program is being conducted in non-human primates to enable identification of vectors expected to be suitable for the complex human eye structure. Preliminary results have evidenced the presence of AAV particles in the retina from intravitreal administration of the starting AAV library. We expect that we will select an AAV vector candidate by the fourth quarter of calendar 2016 for use in our *in vivo* studies of BB-201 following biodistribution studies. Upon production of the vector, we will initiate *in vivo* proof-of-concept studies in which the 4DMT vector will be used to deliver the BB-201 DNA construct that expresses an shRNA designed to silence VEGF-a, VEGF-b and PGF in a non-human primate model in which AMD has been induced by the treatment of the retina with a laser. We believe that the construct will silence the VEGF-a gene in the retinal cells by the mechanism shown in Figure 8.

**Figure 8. The expected mechanism of action of BB-201**




**Following an intravitreal injection, the DNA construct is delivered to the nucleus of retinal cells via an AAV vector (A). Upon reaching the nucleus, the construct expresses three types of shRNAs that are processed by the cell's endogenous machinery to produce siRNAs that cleave the VEGF-a, VEGF-b and PGF mRNA and prevent the corresponding proteins from being expressed and thus preventing it from stimulating the growth of new blood vessels.**

Although we expect to complete *in vivo* preclinical proof-of-concept studies in 2017, we will need to seek additional financing to proceed with clinical trials for our product candidates for AMD.

**BB-301 for Treatment of Oculopharyngeal Muscular Dystrophy**

We are developing BB-301 (previously known as Pabparna) for the treatment of OPMD, 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, or dysphagia, and eyelid

drooping, or ptosis, due to specific effects on the pharyngeal and cricopharyngeal muscle, which is located at the top of the esophagus. The disease is caused by a specific mutation in the poly(A)-binding protein nuclear 1, or PABPN1, gene. The main pathological characteristic of OPMD is the presence of dense intranuclear inclusions of mutated PABPN1 protein.

BB-301utilizes a "silence and replace" approach designed to silence the mutant PABPN1 gene with a ddRNAi construct and replace the mutant gene with the normal PABPN1 gene, delivered with an AAV vector.

Results from *in vivo* studies in an animal model of OPMD support proof of concept of this approach in BB-301 individual components. In conjunction with collaborators, we are working to optimize the *in vivo* delivery of BB-301 and, assuming successful results, we plan to develop BB-301 through IND-enabling studies, and subsequent submission of an IND application.

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 commercialization of BB-301, if it is approved. The largest OPMD cluster is in the French-Canadian population, with estimated prevalence of one in every one thousand people, and its highest prevalence is among Bukhara Jews living in Israel, where it affects one in six hundred people. In Europe, the estimated prevalence is one in one hundred thousand people. The relatively low abundance of patients afflicted by this disease allows this indication to be characterized as a rare disease, potentially supporting an orphan drug designation.

***Current OPMD Treatments and Products in Development***

The therapies for OPMD currently available and under development consist of a symptomatic surgical intervention called cricopharyngeal myotomy, an intravenous trehalose injection, Cabaletta, and cell transplantation. Each of these therapies has treatment limitations.

Cricopharyngeal myotomy is used to address ptosis and improve swallowing in moderate-to-severely affected individuals. It is the only current treatment to improve swallowing in OPMD patients but does not correct the progressive degradation of the pharyngeal musculature, which often leads to death from swallowing difficulties and choking.

Bioblast Pharma Ltd., an Israeli biotechnology company, is developing Cabaletta. It is currently being tested in Phase II/III clinical trials in Israel and Canada. Cabaletta is a solution of trehalose administered intravenously and we believe that it will require ongoing re-administration to remain effective.

The Institut de Myologie in Paris has undertaken a Phase I/II trial of a cell transplantation therapy, grafting autologous myoblasts isolated from spared muscles into the pharyngeal muscle. This is a significantly invasive procedure requiring surgery in two different sites of a patient's body.

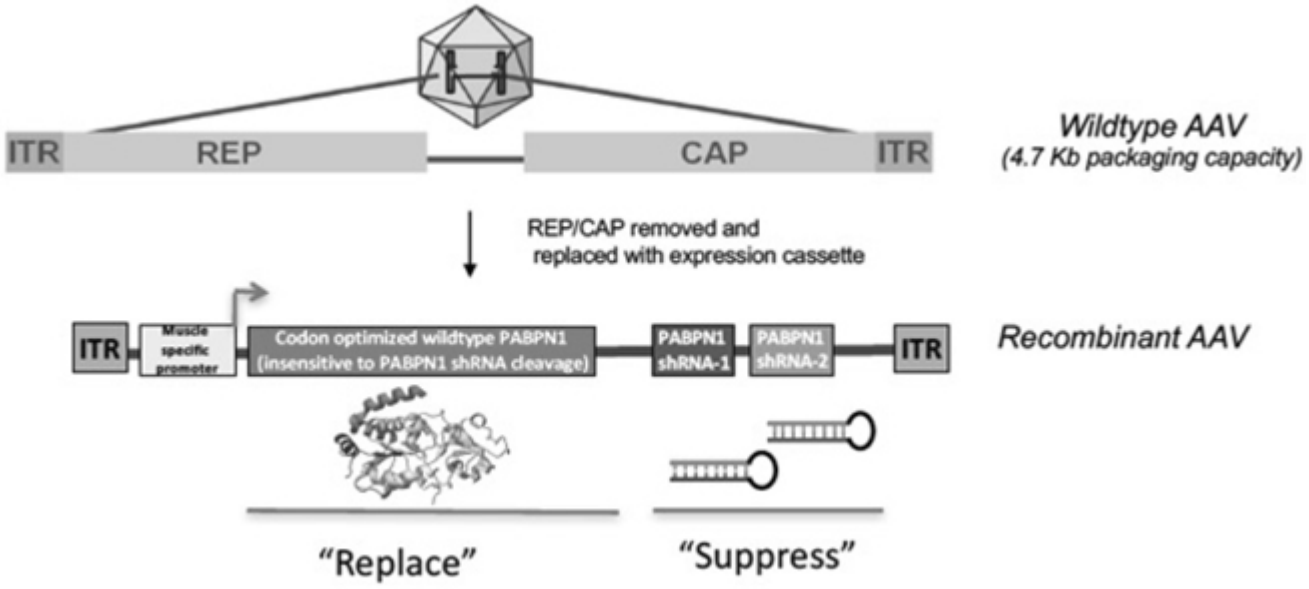
***Our ddRNAi-Based OPMD Therapeutic—BB-301***

We are developing BB-301, a single administration ddRNAi-based gene therapy, to correct the gene defect which causes the disease and to address many of the limitations of therapeutic approaches currently available and those in development for OPMD. BB-301 is a monotherapy delivered using an AAV vector and is designed to silence the expression of the mutant PABPN1 gene in esophageal muscle cells of OPMD patients while simultaneously introducing a silencing-resistant normal form of the gene. We believe OPMD is well suited for this "silence and replace" approach since the genetic mutation is well characterized and the target tissue is relatively small. Once validated, we believe a similar approach could be applied to other inherited disorders.

*BB-301—Design and Mechanism of Action*

BB-301 is designed to target three distinct regions of the PABPN1 mRNA, by generating three separate shRNAs from a single DNA construct, and to express a silencing-resistant version of the normal PABPN1 gene *(Figure 9)*.

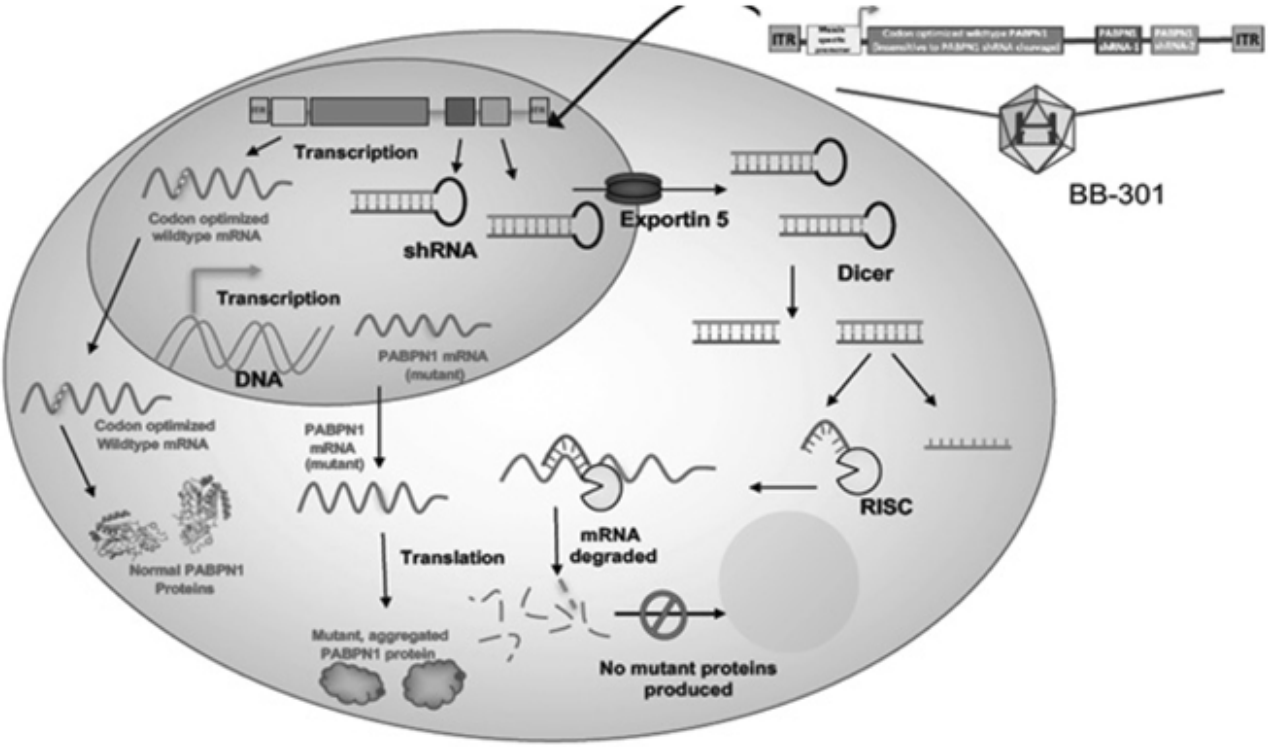
**Figure 9. BB-301 AAV "silence and replace" combination vector**




**BB-301 is comprised of a ddRNAi DNA construct expressing three separate shRNAs targeting three separate regions of the PABPN1 gene, designed to silence the defective PABPN1 gene in OPMD patients, combined with a gene expression construct that produces a silencing-resistant version of the normal PABPN1 gene, delivered using an AAV vector.**

In collaboration with researchers at the Royal Holloway University of London and the Institut de Myologie in Paris we have observed effective silencing of the PABPN1 gene *in vitro* by the ddRNAi construct. Furthermore, we have generated a gene expression construct that produces a silencing-resistant version of the normal PABPN1 gene. The mechanism of action of BB-301 is shown in Figure 10.

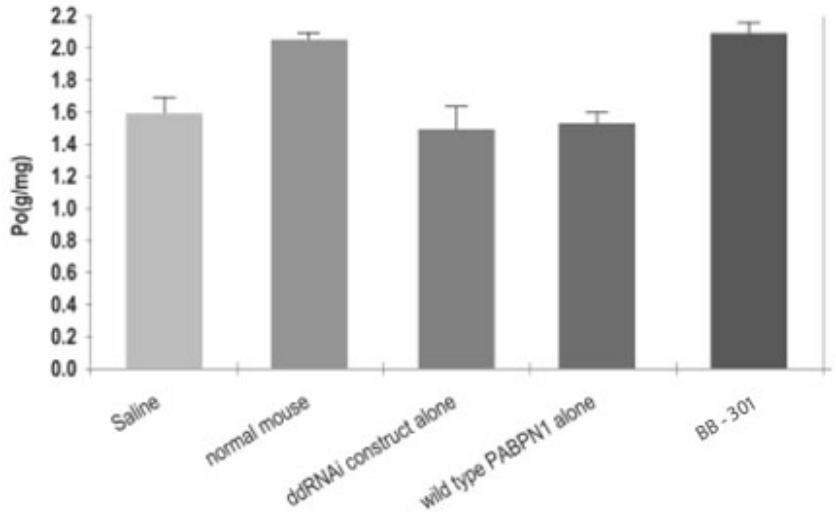
**Figure 10. The mechanism of action of BB-301**




**The DNA construct is delivered to the affected muscle cells via an AAV vector. Upon reaching the nucleus, the construct expresses one or two independent shRNAs that are processed by the cell's endogenous machinery to produce siRNAs that cleave the mutant PABPN1 mRNA and silence the expression of the mutant gene. In addition, the PABPN1 gene expression construct expresses a silencing-resistant version of the normal PABPN1 gene, which we believe may promote restoration of muscle function to the cell.**

In *in vivo* studies using a transgenic mouse model of OPMD at the Royal Holloway University of London and the Institut de Myologie, we observed normalization of muscle strength following administration of the ddRNAi and gene expression constructs (*Figure 11*).

**Figure 11. Restoration of muscle function *in vivo* following gene silencing and replacement**



**Restoration of muscle function *in vivo* following suppression of the mutant PABPN1 and replacement with the normal PABPN1 gene, with muscle function measured by specific tetanic force (Po). Neither the expression of a triple hairpin construct to down-regulate the mutant form of the PABPN1 protein, nor the expression of the normal protein, was sufficient by itself to restore specific force levels. The combination of the silencing of the mutant gene with the triple hairpin construct and replacement with the normal gene was observed to restore specific force capacity to healthy levels.**

***Ongoing Development Plans for BB-301***

Our development plan for BB-301 is focused on investigating options for the optimal delivery of the combined constructs that comprise BB-301. The options include combining the two constructs into a single AAV vector (*Figure 9*) and testing that combination vector *in vivo* in the OPMD mouse model, and generating and testing lentivirus-based combination vectors and testing their ability to produce gene modified autologous muscle stem cells *in vitro*.

Successful results from these studies may inform the design of later translational studies in dogs moving towards a clinical trial in OPMD patients initially via local administration of AAV vectors. We have completed initial preclinical proof-of-concept studies using the chosen clinical construct and plan to have follow on proof-of-concept data in the first quarter of calendar 2017.

**TT-034 for the Treatment of Hepatitis C**

Hepatitis C is a complex public health problem, characterized by a high prevalence of chronic infection by an RNA virus, an increasing burden of HCV-associated disease, low rates of testing and treatment, and the prospect of increasing incidence associated with injectable drug abuse. According to the WHO, over 170 million individuals worldwide have chronic hepatitis C. Chronic infection can result in cirrhosis and death in 20% of patients due to end-stage liver disease or hepatocellular carcinoma. We had been developing a ddRNAi-based therapeutic, TT-034, for the treatment of the most common genotype of the human hepatitis C virus. We began a Phase I/IIa first-in-human clinical trial of TT-034 in January 2014. Following the commencement of the clinical trial of TT-034, a number of new and effective therapeutics were approved for the treatment of HCV. Subsequently, competitors' products showed improvements in the efficacy, delivery and success rate of treatments for HCV while, at the same time, reducing the price and duration of their treatments.

As a result of the increasingly competitive landscape, in February 2016 we 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 our resources beyond completion of the existing patients.

The phase I/IIa clinical trial of TT-034 enrolled nine patients who received a single intravenous infusion of TT-034 at escalating doses of 4 x $10^{10}$, 1.25 × $10^{11}$, 4 × $10^{11}$ and 1.25 × $10^{12}$ vg/kg. Patients were monitored for safety and efficacy assessments over 24 weeks following the administration of TT-034. A liver biopsy, collected 21 days post dosing, was used to assess hepatic TT-034 DNA levels and shRNA expression.

These results show the administered doses of TT-034 to be well tolerated with no treatment related serious adverse events observed. In the nine patients dosed, one serious adverse event, a pulmonary embolism resulting from a fall, was observed and classified as unrelated to the therapy. That event was resolved within four weeks. Three other adverse events (diarrhoea, light-headedness and bradycardia) were also observed and considered possibly treatment related. All of those events were mild in nature and resolved completely. No adverse event met the pre-defined criteria for a dose-limiting toxicity. In addition, no T-cell capsid response was seen in any of the subjects, as has been previously reported at similar high dose levels in other companies' systemic trials with AAV. The patients dosed with TT-034 will be followed in a pre-planned follow-up study where they will have annual health checks for four and one-half years following completion of the study.

While transduction of hepatic tissues was seen, the assessment of TT-034 treatment on viral load, a secondary endpoint of the study, showed no reduction in viral load in the treated subjects.

We believe the data collected from this clinical trial will have a positive impact not only on Benitec's other therapeutic programs, but also for the field of gene therapy as a whole. This is the first time DNA transduction and transgene expression could be measured directly in hepatic tissues following systemic administration. We are using the data from this study to implement design changes in our clinical constructs and to benefit our other therapeutics programs benefit from this study.

**Tribetarna for the Treatment of Drug-Resistant Non-Small Cell Lung Cancer**

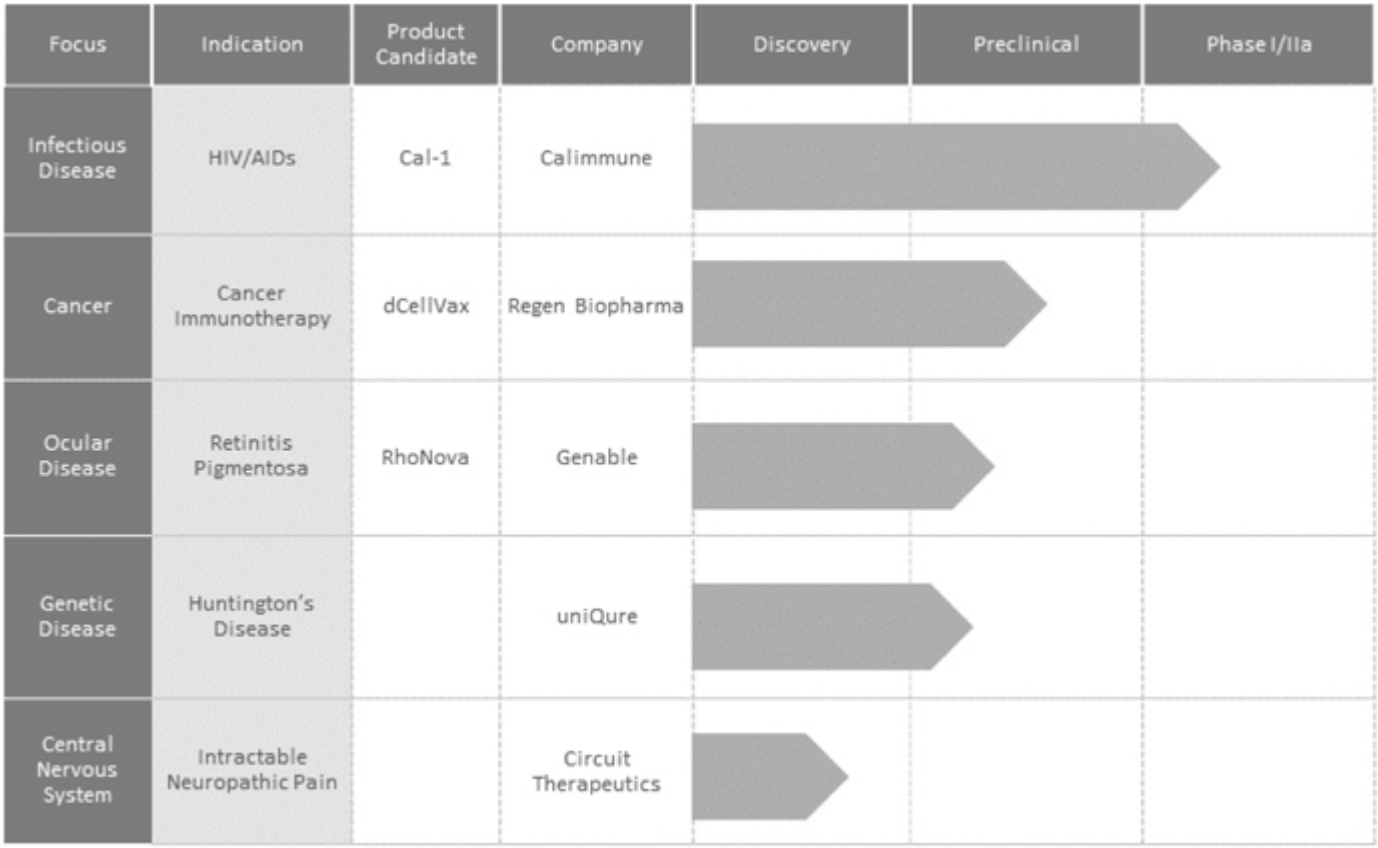
Lung cancer, including drug-resistant non-small cell lung cancer, or NSCLC, and small cell lung carcinoma, or SCLC, is the most common form of human cancer, and about 80% of diagnosed lung cancer cases are categorized as NSCLC. We had been developing a ddRNAi therapeutic, which we called Tribetarna, to target drug-resistant NSCLC and re-sensitize the tumors to chemotherapy by silencing the TUBB3 gene. We undertook preclinical proof-of-concept studies for Tribetarna in collaboration with researchers at the University of New South Wales, or UNSW, who were one of the first groups to demonstrate a link between TUBB3 expression and chemoresistance in NSCLC cells.

As a result of feedback from potential commercial partners, we decided to terminate the NSCLC program, allowing us to focus our resources on developing other preclinical programs which have attracted stronger interest from potential commercial partners and investors. We are in discussions with the UNSW to determine the best use of the data gathered to date. The program has provided insights into optimizing ddRNAi design and delivery.

**Our Out-Licensed Programs**

We have licensed our ddRNAi technology to companies who are developing therapeutic programs in five disease areas. These licenses expand the areas and number of ddRNAi-based therapeutics being developed. 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. Under these agreements, we have received aggregate payments of A$307,310 and A$247,000 for the fiscal years ended June 30, 2015 and June 30, 2016, respectively. We do not expect that any milestone payments we may receive in the future will be significant to our business.

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




***HIV/AIDS***

In March 2012, we granted a non-exclusive, royalty-bearing, worldwide license to a U.S.-based biotechnology company, Calimmune, Inc., or 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.

The license provides for modest upfront and milestone payments and single-digit percentage royalty payments on net sales. In addition, we receive a percentage of any sub-licensing revenues received. Unless terminated at an earlier date, the license agreement continues until the expiration or termination of all patents subject to the license. We may terminate the license agreement in the event of certain breaches by Calimmune or if Calimmune commences an action or proceeding with respect to the patent rights that are the subject of the license. Calimmune may terminate the license agreement at will.

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. Calimmune has 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.

***Retinitis Pigmentosa***

In July 2012, we granted an exclusive, royalty-bearing, worldwide license to an Ireland-based biotechnology company, Genable Technologies Limited, or Genable, to use, develop or commercialize 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.

The license provides for modest upfront and milestone payments and single-digit percentage royalty payments on net sales. In addition, we receive a percentage of any sub-licensing revenues received. Unless terminated at an earlier date, the license agreement continues until the expiration or termination of all patents subject to the license. We may terminate the license agreement in the event of certain breaches or if Genable commences an action or proceeding with respect to the patent rights that are the subject of the license. Genable may terminate the license agreement at will.

In October 2014, the European Medicines Agency, or 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, or Spark, had acquired the company for a combination of cash and common stock. Spark has indicated support for continuing the development of RhoNova.

***Huntington's Disease***

In December 2012, we granted a non-exclusive, royalty-bearing, worldwide license to a Netherlands-based biotechnology company, uniQure biopharma B.V., or 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.

The license provides for modest upfront and milestone payments and single-digit percentage royalty payments on net sales. In addition, we receive a percentage of any sub-licensing revenues received. Under the agreement, uniQure has an option to convert the license to an exclusive license depending upon achievement of certain preclinical milestones, and also to acquire additional licenses to our ddRNAi technology for other specific diseases. Unless terminated at an earlier date, the license agreement continues until the expiration of either all patents subject to the license or regulatory exclusivity, whichever is longer. We may terminate the license agreement in the event of certain breaches or if uniQure has not met a defined sales milestone or commences an action or proceeding with respect to the patent rights that are the subject of the license. uniQure may terminate the license agreement at will. In addition, certain rights and licenses granted to uniQure pursuant to the license agreement will automatically terminate in the event that our license of technology from Galapagos NV expires or is terminated.

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.

***Cancer Immunotherapy***

In August 2013, we granted an exclusive, royalty-bearing, worldwide license to a U.S.-based biotechnology company, Regen Biopharma Inc., or 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 ddRNAi 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.

The license provides for modest upfront and milestone payments, payable in cash or stock of Regen's parent company at Regen's discretion, and single-digit percentage royalty payments on net sales. In addition, we receive a percentage of any sub-licensing revenues received. Unless terminated at an earlier date, the license agreement continues until the expiration or termination of all patents subject to the license. We may terminate the license agreement in the event of certain breaches or if Regen has not met a defined sales milestone or commences an action or proceeding with respect to the patent rights. Regen may terminate the license agreement, in whole or in part, at will.

September 2016, Regen announced it had submitted a revised IND application to the FDA to support a clinical trial with dCellVax. The clinical trial involves generation of patient-specific immune stimulatory cells termed "dendritic cells" that are modified by gene-silencing so as to lose expression of the immune checkpoint gene IDO. Ten patients with advanced breast cancer will be treated in the proposed clinical trial.

***Intractable Neuropathic Pain***

In November 2014, we granted an exclusive, royalty-bearing, worldwide license to a U.S.-based biotechnology company, Circuit Therapeutics, Inc., or 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, a sodium ion channel that is exclusively expressed in certain sensory nerves and is critical for generation of pain.

The license provides for modest upfront and milestone payments and single-digit percentage royalty payments on net sales. In addition, we receive a percentage of any sub-licensing revenues received. Unless terminated at an earlier date, the license agreement continues until the expiration or termination of all patents subject to the license. We may terminate the license agreement in the event of certain breaches or if Circuit Therapeutics commences an action or proceeding with respect to the patent rights. We may also terminate the license agreement if Circuit Therapeutics has not met certain sales and development milestones. Circuit Therapeutics may terminate the license agreement at will.

**New Areas for ddRNAi Application**

We believe the applicability of ddRNAi to disease treatment could be further expanded using a number of strategies that are in the early stages of development. These strategies include:

| Program | Discovery | Preclinical | IND-Enabling | Phase I/II | Phase III | Status |
|---|---|---|---|---|---|---|
| **Immunotherapy** | | | | | | |
| CAR-T | | | | | | • In vitro proof of concept underway |
| **New Technologies** | | | | | | |
| Non-Viral Delivery | | | | | | • In vitro proof of concept underway |
| **Cell Therapy** | | | | | | |
| Stem Cells | | | | | | • Program terminated |

***Immunotherapies***

One approach to immunotherapy involves engineering patients' own immune cells to recognize and attack their tumors. This approach is called adoptive cell transfer, or ACT. ACT utilizes T cells. After isolation from a

patient's blood, the T cells are genetically engineered to produce special receptors on their surface called chimeric antigen receptors, or CARs. CARs are proteins that enable T cells to recognize a specific protein, or antigen on tumor cells. These engineered CAR T cells are cultured and expanded in the laboratory and then infused into the patient. After the infusion, the technology relies on the T cells multiplying in the patient's body and, with guidance from their engineered receptor, recognize and kill cancer cells that harbor the antigen on their surfaces.

CAR T cell therapy can cause side effects, the most common being cytokine-release syndrome. The infused T cells release cytokines, chemical messengers that help the T cells function. With cytokine-release syndrome, there is a rapid and massive release of cytokines into the bloodstream, which can lead to dangerously high fevers and precipitous drops in blood pressure. In addition, the reliance on patient-derived stem cells requires a non-scalable manufacturing process that is complex, time consuming and expensive.

An important aim for next generation of CAR T therapies is to silence multiple genes known to be associated with cytokine release syndrome, including the T cell receptor, or TCR, and major histocompatibility complex, or MHC. We believe that ddRNAi technology could potentially be used to achieve this goal.

Most of the current CAR applications use lentivirus to deliver gene constructs expressing CARs. The packaging capacity of this vector allows the expression of several shRNA constructs along with the CAR in a single construct. Thus, the same cell population that is transduced to express the CAR can also be modified by the activity of shRNA expressed from the same vector.

In addition to silencing the TCR, we believe ddRNAi technology could potentially be used to enhance other properties of CAR T cells.

***Non-viral delivery of DNA constructs***

Efficient delivery of DNA constructs to tissues remains a principal challenge to the development of gene therapy based therapeutics. Most gene therapy strategies employ viral vectors. We are using AAV based vectors in our HBV program to deliver therapeutic ddRNAi constructs to hepatocytes. While AAV vectors can transduce livers with high efficiency and drive sustained expression of shRNAs, there are certain disadvantages with their use.

A proportion of patients possess neutralizing antibodies to AAV, and efficient liver transduction could consequently be inhibited in such patients. Treatment with AAV vectors could also induce an immune response in some patients, potentially limiting the ability to readminister therapeutic viral vectors to those patients. While strategies such as transient immune suppression might circumvent these issues, we believe the use of non-viral DNA delivery vectors, designed to be non-immunogenic, could offer intrinsic advantages for gene therapy. We are consequently investigating strategies to develop non-viral vectors for the delivery of therapeutic ddRNAi constructs.

Our initial work on the development of non-viral vectors is being undertaken in the context of the HBV program. We have prepared DNA constructs that show persistence of expression *in vivo* and have also demonstrated that ddRNAi constructs prepared in this manner can express HBV therapeutic shRNAs. We are attempting to complex these DNA constructs in nanoparticles to achieve efficient transduction of hepatocytes *in vivo* and achieve sustained expression of shRNAs.

***Ocular diseases***

We believe a number of ocular diseases beyond AMD, such as diabetic retinopathy, could be targeted by ddRNAi therapeutics, assuming the AAV vector selection program with 4DMT is successful. This program aims to produce an AAV vector that can target a broad range of ocular cells from an intravitreal injection. We have exclusive access to modified AAV vectors 4DMT for all ocular indications using ddRNAi.

***Cell Therapies***

ddRNAi could potentially be used to produce modified stem cells that express shRNA for enhanced therapeutic benefit. We had been researching this approach for some of our pipeline programs but have recently decided to ceased further development.

**Intellectual Property**

We actively seek to protect the intellectual property and proprietary technology that we believe are important to our business, which includes seeking and maintaining patents claiming our ddRNAi technology, and other inventions relating to our products in development, or otherwise commercially and/or strategically important to the development of our business. We also rely on know-how and trade secrets that may be important to the development of our business and actively seek to protect the confidentiality of such know-how and trade secrets.

Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. For more information, please see "Risk Factors—Risks Related to Our Intellectual Property."

As of September 2016, we own or co-own a total of thirteen patent families (12 owned and 1 co-owned), of which three are in the provisional phase and others have progressed to national prosecution. These families include granted patents in the United States (9), Europe (2), Australia (3), Canada (2) and New Zealand (3). We have more than 20 pending national/regional applications in a total of 15 jurisdictions (counting as one jurisdiction the member states of the European Patent Convention). This intellectual property portfolio for our ddRNAi technology, improvements to the technology and product-specific patents can be commercialized collectively or in individual product candidate programs.

We also have a portfolio of in-licensed patents relating to the ddRNAi platform technology. The license from Commonwealth Scientific & Industrial Research Organization, or CSIRO, includes irrevocable, exclusive rights in the field of human therapeutics to CSIRO's patents claiming ddRNAi. The license includes two patent families with patents in the United States (9), Europe (3), the United Kingdom (1), Australia (4) and Canada (1). The license also includes nine pending national/regional applications in a total of four jurisdictions.

The patent portfolios for the ddRNAi platform and our product candidate pipeline are summarized below. The expected expiration dates included in the summary below do not give effect to patent term extensions that may be available due to delays in the patent office or due to steps taken to obtain regulatory approvals.

***ddRNAi Platform Technology***

The two patent families exclusively licensed from CSIRO include different aspects of the ddRNAi technology. The first of these patent families relates to DNA constructs and methods for using DNA to deliver RNA molecules, particularly shRNA, directed to the target gene. The granted U.S. patents in this family include claims to the structure and design of the DNA constructs, as well as human, animal and plant cells containing such DNA constructs and methods of using these constructs to reduce expression of a target gene. We expect any patents granted in this patent family to expire in March 2019.

The second patent family is an extension of the first patent family, and relates to chimeric DNA and methods for using DNA to deliver RNA molecules, particularly shRNA. The granted U.S. patent in this family claims DNA constructs and methods for reducing expression of a target gene in a plant as well as plant cells, subject matter that is not within our current field of use. We expect any patents granted in this patent family to expire in April 2019.

In December 2009, we entered into a commercial license arrangement with CSIRO for these two patent families relating to ddRNAi technology. This worldwide license in the field of human therapeutics is exclusive and irrevocable. In exchange for the license, we issued ordinary shares to CSIRO, and we are required to pay CSIRO approximately A$300,000 in the event of corporate transactions such as a merger, sale, change of control, capital reconstruction or insolvency event relating to Benitec. Under the license agreement, following notice to us and receipt of our comments, if any, CSIRO has control over prosecution of patent applications and litigation, if any.

Two of the CSIRO patents in the first family are in European Patent Office opposition proceedings. The European Patent Office Opposition Board published decisions in these proceedings in July 2014 and July 2015.

In its July 2014 decision, the Board revoked the first of these two related European patents and, in its July 2015 decision, it revoked the second. CSIRO has appealed both decisions. The U.S. patent corresponding to the two currently revoked European patents was upheld, with modified claims, upon re-examination at the USPTO in 2011, but we cannot know whether the appeals regarding the revoked European patents, if undertaken and carried through, will be decided favorably for us. The Company believes that even if the two currently revoked European patents, which are scheduled to expire in 2019, are not restored upon appeal, such revocation should have no materially adverse effect upon our other owned and licensed patents and patent applications described below.

In the second patent family, one of the CSIRO patents is subject to opposition proceedings in the European Patent Office and one of the patent applications was subject to USPTO interference proceedings. In February 2015, the European Patent Office Opposition Board published its decision to uphold CSIRO's European patent in the second family. The opponents have appealed this decision. In October 2012, the USPTO issued its decision to refuse to grant CSIRO's claims involved in the interference proceedings. CSIRO appealed this decision to the United States Court of Appeals for the Federal Circuit which reversed the USPTO's decision and granted the relevant claims to CSIRO. On remand, the Patent Trial and Appeal Board cancelled the opposing party's involved claims. The opposing party had until the deadline of March 28, 2016 to petition the U.S. Supreme Court to review the Federal Circuit's decision but did not file such an appeal.

***Technology Improvements***

We own two patent families that relate to improvements to ddRNAi technology. The first patent family relates to compositions of matter and methods for delivering shRNA molecules to animal cells for a variety of target genes. As of September 2016, this patent family included patents granted in the United Kingdom, Singapore and South Africa. We expect any patents granted in this patent family to expire in March 2021.

The second patent family relates to nucleic acid constructs and methods for using DNA to produce hairpin RNA molecules that can target multiple genes within one molecule. As of September 2016, this patent family included patents granted in Australia, New Zealand, Singapore and South Africa. We expect any patents granted in this patent family to expire in June 2024.

***Targeting the Hepatitis Virus***

We own two patents in the United States that relate to liver-specific promoters or enhancers. The first claims an expression cassette with a synthetic enhancer and a particular liver-specific promoter that may be used to express a variety of genes in liver. The second claims ddRNAi expression constructs that include a liver-specific promoter and one or more RNAi constructs that provide RNAi agents that target hepatitis virus genes. These granted U.S. patents provide options for promoter and construct design based on the target regions in the hepatitis gene of interest. The first of these two patents is expected to expire in February 2026, and the second is expected to expire in March 2027.

***Our ddRNAi-based treatment for hepatitis B***

Our patent portfolio related to our ddRNAi-based treatment for hepatitis B includes one patent family relating to single-stranded RNA and shRNA sequences to a range of target regions of the hepatitis B viral genome. This patent family was jointly filed with Biomics Biotech Co., Ltd., or Biomics, and Biomics subsequently assigned its ownership interests in the patent to us. As of September 2016, this patent family includes a patents granted in the United States and Europe and pending applications in the United States, Europe, Australia, Brazil, Canada, China, India, Korea and Russia. We expect any patents granted in this patent family to have expired by October 2031.

This patent family is the outcome of a collaborative research agreement between us and Biomics which was commenced in August 2009. The arrangement provided for both parties to receive a share of any revenue generated from commercializing this patent family commensurate with our respective contributions to the intellectual property subject to the agreement, which contributions were equal. In July 2015, we entered into an earn-out agreement with Biomics pursuant to which we acquired all rights, title and interest in this patent family 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 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$6.0 million, we would pay Biomics 1.5% of licensing revenue on any such additional amounts.

A U.S. priority document has been filed by us to claim composition of matter and methods of using a range of RNA molecules in the treatment of hepatitis B. This new patent filing claims the shRNA sequences that are under development as the lead candidates for HBV, and also include other target and RNA sequences to different regions of the HBV genome. This new patent application names Benitec as the sole applicant.

***Our ddRNAi-based therapeutic candidates for AMD***

Our patent portfolio for AMD includes one patent family relating to the target genes for AMD. This patent family relates to the target gene sequences for our two ddRNAi-based therapeutic candidates for AMD. As of September 2016, this patent family included pending applications in the United States, Europe, Australia, Canada, China, India, Israel, Mexico, Singapore, Japan, South Africa, Korea and Russia. We expect any patents to grant in this patent family to expire in January 2034.

***TT-034—ddRNAi-based treatment for hepatitis C***

Our patent portfolio related to our now discontinued product candidate TT-034 includes two patent families relating primarily to the shRNA sequences of TT-034 and the expression cassette design of the therapeutic. The first patent family has claims for methods and genetic constructs that use the shRNA sequences of TT-034 in the treatment of hepatitis C. The patent family relates to a range of different shRNA sequences, and includes the three candidate shRNA sequences incorporated in TT-034, as well as using ddRNAi to deliver the shRNA. The design of the expression cassette in this patent family is for three shRNA sequences with independent promoters driving the expression of each shRNA. As of September 2016, this patent family included patents granted in the United States (3), Europe, Australia, Canada, China, Israel, Japan and Korea. We expect any patents granted in this patent family to expire in March 2025.

The second patent family also includes claims for methods and genetic constructs using the shRNA sequences of TT-034 in the treatment of hepatitis C. The design of the expression in this patent family is for a single promoter to drive the expression of multiple shRNA sequences. As of September 2016, this patent family included patents granted in the United States (3), Australia, China, Europe, Canada, New Zealand and Hong Kong. We expect any patents granted in this patent family to expire in February 2026.

***Tribetarna—our ddRNAi-based treatment for lung cancer***

Our patent portfolio related to our now discontinued lung cancer program, includes one patent family relating to methods of increasing the sensitivity of a tumor cell to DNA damaging agents (cisplatin) or tubulin-binding agents (paclitaxel) using nucleic acid constructs encoding a shRNA or siRNA directed to regions of the TUBB2A, TUBB2C, or TUBB3 tubulin genes and conjugated to polyethylenimine. This patent family is licensed exclusively from the University of New South Wales. As of September 2016, this patent family included patents granted in Australia, China, Hong Kong, Israel, Japan and Singapore. We expect any patents granted in this patent family to expire in March 2028.

In August 2013, we entered into a commercial license arrangement with NewSouth Innovations Pty Limited, or NSi, of University of New South Wales for this patent portfolio. The license was terminated in October 2016.

We have filed a U.S. priority document to claim composition of matter and methods of using the shRNA sequences of Tribetarna in the treatment of lung cancer. This new provisional patent filing claims the expression cassette with the triple shRNA sequences of Tribetarna. This new patent application names us as the sole applicant.

***Targeting the T-Cell Receptor***

We have filed a provisional patent application in the U.S. for the CAR-T program entitled "Reagents for Producing T-Cells with Non-Functional TCR Compositions Comprising Same and Use Thereof."

***Know-How***

In addition to patent protection of ddRNAi technology and our product candidates, we also rely on proprietary know-how that is not patentable or that we elect not to patent, as valuable intellectual property for our business. This know-how is related to the areas of, among others, identifying nucleic acid targets for ddRNAi technology and designing ddRNAi constructs for targeting preferred genes. We have implemented a number of security measures to safeguard our know-how including limiting access to our research facilities, databases and networks. We also protect know-how by way of confidentiality agreements when engaging with external providers for progressing our pipeline of therapeutic candidates.

***Laws and Regulations Regarding Patent Terms***

The term of individual patents depends upon the legal terms of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent term may be shortened if a patent is terminally disclaimed over another patent or as a result of delays in patent prosecution by the patentee. A patent's term may be lengthened by a patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent. The patent term of a European patent is 20 years from its filing date, which, unlike in the United States, is not subject to patent term adjustments.

The term of a patent that covers an FDA-approved biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the biologic is under clinical testing regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved biologic may be extended. Similar provisions are available in Europe and other jurisdictions to extend the term of a patent that covers an approved biologic although the eligibility requirements for any duration of such extension vary. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products.

***Trademarks***

Our trademarks include registrations for company branding and product names for our pipeline in development.

| Trade Mark (program) | Trade Mark Number | Filing date | Jurisdiction | Status |
|---|---|---|---|---|
| BENITEC® | 1103049 | 10 Mar 2006 | Australia | Registered |
| BENITEC™ | NA (Appln: 86795296) | 21 Oct 2015 | United States | Pending |
| BENITEC™ | 1728797 | 16 Sep 2015 | Australia | Pending |
| BENITEC™ | 14680003 | 16 Oct 2015 | Europe | Pending |
| BENITEC BIOPHARMA® | 1448046 | 13 Sep 2011 | Australia | Registered |
| BENITEC BIOPHARMA® | 4636053 | 11 Feb 2014 | United States | Registered |
| SILENCING GENES FOR LIFE® | 1448041 | 13 Sep 2011 | Australia | Registered |
| SILENCING GENES FOR LIFE® | 4807242 | 22 Dec 2014 | United States | Registered |
| Tribetarna® (Lung cancer) | 1526479 | 19 Nov 2012 | Australia | Registered |
| Hepbarna® (Hepatitis B) | 1526483 | 19 Nov 2012 | Australia | Registered |
| Nervarna® (Pain) | 1526478 | 19 Nov 2012 | Australia | Registered |

**Manufacturing**

The manufacture of the complex biological products required for gene therapy is complex and difficult. We do not currently own or operate manufacturing facilities for the production of preclinical, clinical or commercial quantities of any of our product candidates. We are exploring long-term manufacturing alliances with a number of potential partners to investigate manufacturing processes in order to produce materials at reasonable scale and cost of goods to support future commercialization efforts. We do not have a long-term agreement with any third-party manufacturer, but we plan to establish such a relationship with an appropriate manufacturer to serve our long-term needs.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our contract manufacturing organizations manufacture our product candidates under cGMP, conditions. cGMP is a regulatory standard for the production of pharmaceuticals that will be used in humans.

**Sales and Marketing**

We have not yet established sales, marketing or product distribution operations because our product candidates are in preclinical or clinical development. If we receive marketing and commercialization approval for any of our product candidates, we intend to market the product through strategic alliances and distribution agreements with third parties. In certain cases we may market an approved product directly worldwide or in selected geographical segments. The ultimate implementation of our strategy for realizing the financial value of our product candidates is dependent on the results of clinical trials for our product candidates, the availability of funds and the ability to negotiate acceptable commercial terms with third parties.

**Competition**

The biopharmaceutical industry is characterized by intense and dynamic competition to develop new technologies and proprietary therapies.

Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. While we believe that our proprietary technology estate and scientific expertise in gene silencing using ddRNAi provide us with competitive advantages, we face potential competition from many different sources, including larger and better-funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions and governmental agencies and public and private research institutions that may develop potentially competitive products or technologies. We are aware of several companies focused on developing gene therapy or gene silencing product candidates, including:

- Alnylam, Arbutus and Arrowhead—developing siRNA-based therapeutics for hepatitis B;
- Avalanche Biotechnologies, Inc., Applied Genetic Technologies Corporation and Oxford Biomedica—developing gene therapies for wet AMD.

We are not aware of any companies developing a gene therapy or gene silencing approach for OPMD. There are other therapies either being marketed or currently in development for all of these diseases, some of which already have significant market share. Our product candidates, if approved, would also compete with treatments that have already been approved and accepted by the medical community, patients and third-party payors.

Many of our competitors and potential competitors, alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and the commercialization of those treatments. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and subject registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We anticipate that we will face intense and increasing competition as new products enter the market and advanced technologies become available. We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, we expect that our therapeutic products, if approved, will be priced at a significant premium over competitive products and our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of competitive products including biosimilar or generic products.

This increasingly competitive landscape may compromise the development of our product candidates. For example, improvements in the efficacy, delivery and success rates of competitors' product candidates, in conjunction with a reduction in the price and duration of their treatments, diminished partnering interest from pharmaceutical companies in our product candidate TT-034 for the treatment of HCV. This caused us to announce in February 2016 the discontinuation of our program to develop TT-034 before the conclusion of its clinical trial, despite the promising clinical results regarding the safety of that product candidate achieved to date.

**Government Regulation**

As a pharmaceutical and biological product company that wishes to conduct clinical trials and ultimately obtain marketing approval in the United States, we are subject to extensive regulation by the FDA, and other federal, state, and local regulatory agencies. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, the Public Health Service Act, or PHS Act, and their implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. A failure to comply explicitly with any requirements during the product development, approval, or post-approval periods, may lead to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an IRB, of a suspension on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution.

Although the discussion below focuses on regulation in the United States, we anticipate seeking approval for the testing and marketing of our products in other countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the European Union are addressed in a centralized way through the EMA, but country-specific regulation remains essential in many respects.

Government regulation may delay or prevent testing or marketing of our products and impose costly procedures upon our activities. The testing and approval process, and the subsequent compliance with appropriate statutes and regulations, requires substantial time, effort, and financial resources, and we cannot be certain that the FDA or any other regulatory agency will grant approvals for our products or any future products on a timely basis, if at all. The FDA's or any other regulatory agency's policies may change and additional governmental regulations may be enacted that could prevent or delay regulatory approval of our products or any future products or approval of new indications or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative, judicial, or administrative action, either in the United States or abroad.

***Recent Developments in Regulation of Gene Therapy***

Although the FDA has not yet approved any human gene therapy product for sale, it has provided guidance for the development of gene therapy products. For example, the FDA has established the Office of Tissues and Advanced Therapies (formerly Office of Cellular, Tissue and Gene Therapies) within CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its reviews. In addition, the FDA has issued a growing body of clinical guidelines, chemical, manufacturing and control, or CMC, guidelines and other guidelines, all of which are intended to facilitate industry's development of gene therapy products.

In 2012, the EMA approved a gene therapy product called Glybera, which is the first gene therapy product approved by regulatory authorities in the United States or the European Union. In May, 2016, the EMA approved a second gene therapy product called Strimvelis, the first approved *ex-vivo* stem cell gene therapy, to treat patients with a very rare disease called ADA-SCID (Severe Combined Immunodeficiency due to Adenosine Deaminase deficiency).

***Marketing Approval***

In the United States, for premarket approval purposes, the FDA regulates gene products as biologics under the FDC Act, the PHS Act and related regulations.

The steps required before a new biologic may be marketed in the United States generally include:

- nonclinical pharmacology and toxicology laboratory and animal tests according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission of an IND application which must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials according to GCPs and any additional requirements for the protection of human research subjects and their health information to establish the safety and efficacy of the investigational product for each targeted indication;
- submission of a biologics license application, or BLA, to the FDA;
- FDA's pre-approval inspection of manufacturing facilities to assess compliance with cGMPs and, if applicable, the FDA's good tissue practices, or GTPs, for the use of human cellular and tissue products to prevent the introduction, transmission, or spread of communicable diseases;
- FDA's audit of clinical trial sites that generated data in support of the BLA; and
- FDA approval of a BLA, which must occur before a product can be marketed or sold.

***Product Development Process***

Before testing any biologic in humans, the product enters the nonclinical, or preclinical, testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies to assess the potential safety and activity of the product. The conduct of nonclinical tests must comply with federal regulations and requirements including GLPs.

Where a gene therapy trial is conducted at, or sponsored by, institutions receiving NIH funding for recombinant DNA research, prior to the submission of an IND to the FDA, a protocol and related documentation is submitted to and the trial is registered with the NIH Office of Biotechnology Activities, or OBA, pursuant to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines.

***Guidelines***

Compliance with the NIH Guidelines is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA, however many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. The NIH is responsible for convening the RAC, a federal advisory committee, which discusses protocols that raise novel or particularly important scientific, safety or ethical considerations at one of its quarterly public meetings. The OBA will notify the FDA of the RAC's decision regarding the necessity for full public review of a gene therapy protocol. RAC proceedings and reports are posted to the OBA web site and may be accessed by the public.

The product sponsor then submits the results of the nonclinical testing, together with manufacturing information, analytical data, any available clinical data or literature, and a proposed clinical protocol, to the FDA in an IND, which is a request for authorization from the FDA to administer an investigational product to humans. Some nonclinical testing may continue even after the IND application is submitted. IND authorization is required before interstate shipping and administration of any new product to humans that is not the subject of an approved BLA. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA, within the 30-day

time period, raises concerns or questions about the conduct of the clinical trial and places the clinical trial on a clinical hold. In such case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. Further, an IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. If the site has an IBC, it may also have to review and approve the proposed clinical trial. Clinical trials involve the administration of the investigational product to patients under the supervision of qualified investigators following GCPs, requirements meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, investigators, and monitors. Clinical trials are conducted under protocols that detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, the parameters to be used in monitoring safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur, and the efficacy criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. The informed written consent of each participating subject is required and the form and content of the informed consent must be approved by each IRB.

The clinical investigation of an investigational product is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

- Phase I includes the initial introduction of an investigational product into humans. Phase I clinical trials may be conducted in patients with the target disease or condition or on healthy volunteers. These studies are designed to evaluate the safety, metabolism, pharmacokinetics and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase I clinical trials, sufficient information about the investigational product's pharmacokinetics and pharmacological effects may be obtained to permit the design of Phase II clinical trials. The total number of participants included in Phase I clinical trials varies, but is generally in the range of 20 to 80.
- Phase II includes the controlled clinical trials conducted to evaluate the effectiveness of the investigational product for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the product. Phase II clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants. Phase IIa trials provide information on the impact of dose ranging on safety, biomarkers and proof of concept, while Phase IIb trials are patient dose-ranging efficacy trials.
- Phase III clinical trials are controlled clinical trials conducted in an expanded patient population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the investigational product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product, and to provide an adequate basis for product approval. Phase III clinical trials usually involve several hundred to several thousand participants. In most cases, the FDA requires two adequate and well controlled Phase III clinical trials to demonstrate the efficacy of the product. FDA may accept a single Phase III trial with other confirmatory evidence in rare instances where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events; any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects; or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA typically recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by 10 years of annual queries, either in person or by questionnaire, of trial subjects.

The decision to terminate a clinical trial of an investigational biologic may be made by the FDA or other regulatory authority, an IRB, an IBC, or institutional ethics committee, or by a company for various reasons. The FDA may place a clinical hold and order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. If the FDA imposes a clinical hold, trials may not recommence without FDA and IRB authorization and then only under terms authorized by the FDA and IRB. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, or the clinical monitoring board or DSMB. This group provides authorization for whether or not a trial may move forward at designated check points. These decisions are based on the limited access to data from the ongoing trial. The suspension or termination of a clinical trial can occur during any phase of clinical trials if it is determined that the participants or patients are being exposed to an unacceptable health risk. In addition, there are requirements for the registration of ongoing clinical trials of drugs and biologics on public registries and the disclosure of certain information pertaining to the trials as well as clinical trial results after completion.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational product information is submitted to the FDA in the form of a BLA for a biologic to request marketing approval for the product in specified indications.

Human gene therapy products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of human gene therapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval. The NIH and the FDA have a publicly accessible database, the Genetic Modification Clinical Research Information System, which includes information on gene transfer trials and serves as an electronic tool to facilitate the reporting and analysis of adverse events on these trials. Over the last several years the FDA has issued helpful guidance on development of gene therapy products and shown a willingness to work closely with developers, especially with those working in orphan disease areas.

***Biologics License Application Approval Process***

In order to obtain approval to market a biologic in the United States, a BLA must be submitted to the FDA that provides data from nonclinical studies and clinical trials and manufacturing information establishing to the FDA's satisfaction the safety, purity, and potency or efficacy of the investigational product for the proposed indication. The BLA must be accompanied by a substantial user fee payment unless a waiver or exemption applies.

The FDA will initially review the BLA for completeness before it accepts it for filing. Under the FDA's procedures, the agency has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, which includes determining whether it is

effective for its intended use, and whether the product is being manufactured in accordance with cGMP, to assure and preserve the product's identity, safety, strength, quality, potency and purity, and in accordance with biological product standards. The FDA will inspect the facilities at which the product is manufactured to ensure the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. For a human cellular or tissue product, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue based products, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission, and spread of communicable disease. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure compliance with GCP.

If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information, or corrective action for a manufacturing facility. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the BLA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee. The FDA also may determine a REMS is necessary to assure the safe use of the biologic, in which case the BLA sponsor must submit a proposed REMS. The REMS may include, but is not limited to, a Medication Guide, a communications plan, and other elements to assure safe use, such as restrictions on distribution, prescribing, and dispensing.

After the FDA completes its initial review of a BLA, it will either license, or approve, the product, or issue a complete response letter to communicate that it will not approve the BLA in its current form and to inform the sponsor of changes that the sponsor must make or additional clinical, nonclinical or manufacturing data that must be received before the FDA can approve the application, with no implication regarding the ultimate approvability of the application. If a complete response letter is issued, the sponsor may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

The testing and approval process for both a drug and biologic requires substantial time, effort and financial resources and this process may take several years to complete. Data obtained from clinical trials are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product candidate intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product candidate. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product candidate that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar, but not identical, benefits.

***Expedited Development and Review Programs***

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic or drug may request the FDA to designate the biologic or drug as a fast track product at any time during the clinical development of the product. Unique to a fast track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological or drug product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Biological or drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a biological or drug product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Lastly, under the provisions of the new Food and Drug Administration Safety and Innovation Act, enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biological that is intended, alone or in combination with one or more other drugs or biological, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biological may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs and biologicals designated as breakthrough therapies are also eligible for accelerated approval and receive the same benefits as drugs and biologicals with Fast Track designation. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Fast Track designation, and priority review may expedite the product approval process, but do not change the standards for approval. Accelerated approval and breakthrough therapy designation do change the standards for product approval and thus may expedite the development and/or approval process.

***FDA Additional Requirements***

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 clinical trials may be made a condition to be satisfied for continuing drug and biologic approval. The results of Phase 4 clinical trials can confirm the efficacy of a product candidate and can provide important safety information. In addition, the FDA has express statutory authority to require sponsors to conduct post-market studies to specifically address safety issues identified by the agency.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of an onerous REMS, restrictions on distribution, or post-marketing study requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

***Medical device requirements***

Our contemplated diagnostics, for use with certain of our therapeutic products, are regulated by FDA as *in vitro* diagnostic, or IVD, medical devices. Such IVD devices must comply with applicable FDA IVD-specific regulations as well as FDA regulations applicable more broadly to medical devices. These FDA regulations include requirements for registering establishments with FDA; listing IVD devices with FDA; reporting certain adverse events related to IVD devices to FDA; complying with the Quality System Regulation (current good manufacturing practices for devices); labeling IVD devices; and obtaining premarket approval or clearance prior to marketing IVD devices (unless exempt). There are also regulations covering the requirements for investigational devices and the conduct of clinical investigations of devices. Like drugs and biologics, failure to comply with applicable device/IVD requirements can result in legal or administrative enforcement actions against an IVD device firm, its officers or employees, and/or its products.

***FDA Post-Approval Requirements***

Any products manufactured or distributed by us or on our behalf pursuant to FDA approvals are subject to continuing regulation by the FDA, including requirements for record-keeping, reporting of adverse experiences with the biologic or drug, and submitting biological product deviation reports to notify the FDA of unanticipated changes in distributed products. Manufacturers are required to register their facilities with the FDA and certain state agencies, and are subject to periodic announced or unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements, which impose certain quality processes, manufacturing controls and documentation requirements upon us and our third-party manufacturers in order to ensure that the product is safe, has the identity and strength, and meets the quality, purity and potency characteristics that it purports to have. In November 2013, the Drug Quality and Security Act, or DQSA, became law and establishes requirements to facilitate the tracing of prescription drug and biological products through the pharmaceutical supply distribution chain. This law includes a number of new requirements that will be implemented over time and will require us to devote additional resources to satisfy these requirements, including serializing the product and using new technology and data storage to electronically trace the product from manufacturer to dispenser. If our products are not covered by the serialization and tracing requirements of the DQSA, they may be subject to state pedigree and traceability

requirements. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, refuse to approve any BLA, force us to recall a product from distribution, shut down manufacturing operations or withdraw approval of the applicable BLA. Noncompliance with cGMP or other requirements can result in issuance of warning or untitled letters, civil and criminal penalties, seizures, and injunctive action.

The FDA and other federal and state agencies closely regulate the labeling, marketing and promotion of drugs and biologics. Government regulators, including the Department of Justice and the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities, recently have increased their scrutiny of the promotion and marketing of drugs and biologics. While doctors are free to prescribe any product approved by the FDA for any use, a company can only make claims relating to safety and efficacy of a product that are consistent with FDA approval, and the company is allowed to market a product only for the particular use and treatment approved by the FDA. In addition, any claims we make for our products in advertising or promotion must, among other things, be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning or untitled letters, corrective advertising, injunctions, potential civil and criminal penalties, criminal prosecution, and agreements with governmental agencies that materially restrict the manner in which a company promotes or distributes products.

***Pediatric Research Equity Act***

Under the Pediatric Research Equity Act, or PREA, as amended, a BLA or supplement must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Manufacturers must submit a pediatric study plan to the IND not later than 60 days after the end-of-phase 2 meeting with the FDA; if there is no such meeting, before the initiation of any phase 3 studies or a combined phase 2 and phase 3 study; or if no such study will be conducted, no later than 210 days before a marketing application or supplement is submitted. The intent of PREA is to compel sponsors whose products have pediatric applicability to study those products in pediatric populations, rather than ignoring pediatric indications for adult indications that could be more economically desirable. The FDA may grant deferrals for submission of data or full or partial waivers. By its terms, PREA does not apply to any product for an indication for which orphan designation has been granted, unless the FDA issues regulations stating otherwise. Because the FDA has not issued any such regulations, submission of a pediatric assessment is not required for an application to market a product for an orphan-designated indication.

***Patent Term Restoration and Marketing Exclusivity***

Depending on the timing, duration and specifics of FDA marketing approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within sixty days of approval of the biological. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

The Biologics Price Competition and Innovation Act of 2009, which was included within the Patient Protection and Affordable Care Act, created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product, and grants a reference biologic

twelve years of exclusivity from the time of first licensure. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months of exclusivity to be attached to any existing exclusivity, e.g., twelve year exclusivity, or patent protection for a drug. This six month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

***Government Regulation Outside the United States***

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a request for a clinical trial authorization, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product approval or licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of a biological product under European Union regulatory systems, we must submit a marketing authorization application. The application required in the European Union is similar to a BLA in the United States, with the exception of, among other things, country-specific document requirements. The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, a new biological generally receives eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a biosimilar application. During the additional two-year period of market exclusivity, a biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no biosimilar product can be marketed until the expiration of the market exclusivity. The innovator may obtain an additional one year of market exclusivity if the innovator obtains an additional authorization during the initial eight year period for one or more new indications that demonstrate significant clinical benefit over existing therapies. This data and market exclusivity regime in the European Union of a total of 10 or 11 years protects against generic competition, but does not protect against the launch of a competing product if the competitor, rather than referencing the clinical data of the originator, has conducted its own clinical trials to support its marketing authorization application.

Orphan drugs in the European Union are eligible for 10-year market exclusivity. This 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

***Pharmaceutical Coverage, Pricing and Reimbursement***

Sales of our products, when and if approved for marketing, will depend, in part, on the extent to which our products will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products, biologicals, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of interchangeable products. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor not to cover our product candidates could reduce physician usage of our products once approved and have a material adverse effect on our sales, results of operations and financial condition.

The containment of healthcare costs has become a priority of federal, state and foreign governments. Third-party payors are increasingly challenging the prices charged for drug products and medical services, examining the medical necessity and reviewing the cost effectiveness of drug products and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the ACA, was enacted. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

***Other Healthcare Laws***

Although we currently do not have any products on the market, we may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and other countries in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine and open payment laws and regulations, many of which may become more applicable to us if our product candidates are approved and we begin commercialization. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

**C.** ***Organizational Structure.***

We have four significant subsidiaries:

| Name | Country of Incorporation | Percentage Owned |
|---|---|---|
| Benitec Limited | U.K. | 100% |
| Benitec, Inc. | Delaware, U.S. | 100% |
| Tacere Therapeutics, Inc. | Delaware, U.S. | 100% |
| Benitec Australia Limited | Australia | 100% |

**D.** ***Property, Plants and Equipment.***

**Facilities**

Our corporate headquarters are located in Sydney, Australia and consist of approximately 1,350 square feet of leased office space that expires in September 2019. We relocated into this office space in October 2016. Our research and development facility is located in Hayward, California, and consists of approximately 4,750 square feet of leased office space under a lease that expires in May 2018.

We believe that our existing facilities are adequate for our current needs.

**Item 4A. Unresolved Staff Comments**

Not applicable.

**Item 5. Operating and Financial Review and Prospects**

**A.** ***Operating Results.***

We are a 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 is to validate that ddRNAi is safe and efficacious in a clinical setting. With this goal in mind, we are developing BB-103 and BB-101, which are currently in preclinical studies, as a therapy for hepatitis B. We plan

to file an IND application for either BB-103 or BB-101 late in 2017. Based on the potential market opportunity and interest from pharmaceutical companies, we plan to prioritize the HBV program as our next candidate for clinical development.

The success of preclinical studies and advancement to and successful completion of a clinical trial would be a key step in validating ddRNAi for therapeutic use, seeking regulatory approval of a product candidate based on ddRNAi and ultimately commercializing the product if it achieves approval. In the future, we expect to earn revenue primarily from licensing programs, strategic alliances and collaboration arrangements with pharmaceutical companies. 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.

We have incurred losses from operations in each year since inception. Our net losses were A$24.8 million, A$11.5 million, and A$7.0 million for the fiscal years ended June 30, 2016, 2015 and 2014, 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. 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 immunotherapy programs and non-viral delivery of DNA constructs through preclinical proof of concept;
- continue our research and development efforts of ddRNAi-based technology;
- seek regulatory approval for our product candidates; and
- add personnel and resources to support our product development and commercialization efforts.

As of June 30, 2016, we had cash and cash equivalents of A$18.2 million.

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.

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 commercialize 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 commercialize 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 favorable 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 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 43.5% (reduced from 45% at July 1, 2016) 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 U.S.-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 rather than the fiscal year to which they relate. To the extent our research and development expenditures are deemed to be "ineligible," then our grants would decrease. In addition, the Australian government may in the future decide to modify the requirements of, reduce the amounts of the grants available under, or discontinue the Research and Development Tax Incentive program. For instance, the Australian government recently released findings and a panel recommendation that if implemented would reduce the amount of the grants available to small companies such as Benitec to a maximum of A$2 million per annum. Any such change in the Research and Development Tax Incentive program could have a material adverse effect on our future cash flows and financial position.

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

***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. No impairment was recorded in fiscal years 2016, 2015 or 2014.

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***

We pay 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, we 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$6.0 million, we would pay Biomics 1.5% of licensing revenue on any such additional amounts.

In August 2013, we 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 now discontinued therapeutic product candidate for NSCLC. In October 2016, the license was terminated.

**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 year-end 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.

The significant movement in the foreign currency translation reserve and foreign exchange transactional gain or loss in the fiscal year ended June 30, 2013 is due to historic intercompany loan balances between Benitec and its foreign subsidiaries that are eliminated on consolidation which were deemed to be non-repayable and were accordingly transferred to equity during fiscal 2014. As a result of the transfer of historical intercompany receivable and payable balances to equity, these balances are translated at a historical rate and no further foreign exchange translational reserve or transactional gain or loss on these balances was required at June 30, 2014. The significant appreciation of the U.S. dollar against the Australian dollar, along with a high U.S. dollar cash balance following an equity placement in 2014, contributed to the net foreign exchange gain of A$0.6 million in fiscal 2015.

**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 analyze 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 detailed in Note 1 to our consolidated financial statements for the fiscal year ended June 30, 2016 appearing elsewhere in this report. We have summarized 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 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. 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 GAAP**

IFRS differs from GAAP in a few respects. While we have not assessed the materiality of differences between IFRS and GAAP, we note in particular that IFRS permits the recording of finance income and research and development grants as revenue, unlike 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 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 Operation**

***Comparison of the fiscal years ended June 30, 2016 and 2015***

*Revenue*

| (in thousands) | For the fiscal year ended June 30, 2016 | 2015 | Increase (Decrease) |
|---|---|---|---|
| Revenue: | | | |
| Licensing revenue and royalties | A$ 247 | A$ 307 | (60) |
| Finance income—interest | 217 | 774 | (557) |
| Other income: | | | |
| Net foreign exchange fluctuation* | — | 573 | (573) |
| Total revenue and other income | A$ 464 | A$ 1,654 | (1,190) |

* The net foreign exchange fluctuation is due to our significant U.S. dollar cash balances (following an equity placement in April 2014 and our U.S. initial public offering in August 2015) and currency moves between the U.S. dollar and the Australian dollar.

Licensing revenue and royalties decreased from fiscal 2015 to fiscal 2016 primarily due to timing differences in the recognition of such revenue.

Finance income decreased from A$0.8 million in fiscal 2015 to A$0.2 million in fiscal 2016 as a result of holding cash in low yielding U.S. dollar bank accounts and lower cash balance in fiscal 2016.

*Expenses*

*Research and development expense.* Research and development expense increased by A$7.1 million, from A$6.2 million in fiscal 2015 to A$13.3 million in fiscal 2016, primarily due to:

- A$2.5 million as an initial payment to acquire the full rights to the patents underlying our preclinical ddRNAi-based hepatitis B therapeutic program that were jointly filed by Biomics and us;
- higher research and development activity in fiscal 2016, including the dosing of additional patients in our Phase I/IIa clinical trial for TT-034; and
- work under our agreement with 4D Molecular Therapeutics LLC to develop vectors.

*Employment related expenses.* Employment-related expenses increased by A$2.9 million in fiscal 2016 compared to fiscal 2015 due to increased staff levels, particularly at Tacere's laboratory, in fiscal 2016.

*Share based expenses.* Share based expenses increased by A$0.2 million, from A$1.5 million in fiscal 2015 to A$1.7 million in fiscal 2016, largely due to the share based expense costs for options granted to our directors in November 2015. 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 our directors 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 were relatively unchanged at A$1.0 million in fiscal 2015 and fiscal 2016 and primarily related to our U.S. initial public offering in August 2015, participation in international conferences and meetings with pharmaceutical companies.

*Consultants costs.* Consultants costs increased by A$0.1 million from A$0.9 million in fiscal 2015 to A$1.0 million in fiscal 2016. We retained specialist advisers in relation to our key product candidate programs and for media and shareholder relations capabilities.

*Occupancy costs.* Occupancy costs increased by A$0.4 million from A$0.3 million in fiscal 2015 to A$0.7 million in fiscal 2016 due to a new expanded lease for the laboratory in California and increased space under lease in Australia.

*Corporate expenses.* Corporate expenses increased by A$0.2 million from A$1.0 million in fiscal 2015 to A$1.2 million in fiscal 2016 due to an increase in the size of our company and consequent expenses.

*IPO costs.* We incurred legal, accounting and other costs of A$1.2 million during fiscal 2016 in relation to our U.S. initial public offering that was completed in August 2015.

*Write-off of clinical trial prepayment.* In 2013 we had contracted with a clinical research organization to manage the initial clinical development and trials for our non-small cell lung cancer therapeutic candidate. The expected cost of the clinical trial was paid in advance in order to secure favorable commercial terms. As a result of feedback from potential commercial partners and investors, we decided in fiscal 2016 to discontinue the non-small cell lung cancer program, allowing resources to be focused on developing other preclinical programs. In August 2016, we reached agreement for the return of A$0.9 million of the prepayment due to the cancellation of the program. The remaining A$1.8 million of the prepayment has been written off.

*Loss for the period*

As a result of the foregoing, our loss for the period after income tax benefit increased by A$13.3 million from A$11.5 million in fiscal 2015 to A$24.8 million in fiscal 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.

***Comparison of the fiscal years ended June 30, 2015 and 2014***

*Revenue*

| (in thousands) | For the fiscal year ended June 30, 2015 | 2014 | Increase (Decrease) |
|---|---|---|---|
| Revenue: | | | |
| Licensing revenue and royalties | A$ 307 | A$ 277 | 30 |
| Finance income—interest | 774 | 321 | 453 |
| Other income: | | | |
| Australian government research and development grants | 2,318 | 776 | 1,542 |
| Net foreign exchange gain | 573 | — | 573 |
| Total revenue and other income | A$ 3,972 | A$ 1,374 | 2,598 |

Licensing revenue and royalties increased very slightly from fiscal 2014 to fiscal 2015 primarily due to timing differences in the recognition of such revenue.

Grants from the Australian government increased A$1.5 million, from A$0.8 million in fiscal 2014 to A$2.3 million in fiscal 2015 due to a higher level of eligible research and development expense in fiscal 2015.

Finance income increased by A$0.5 million from A$0.3 million in fiscal 2014 to A$0.8 million in fiscal 2015, as a result of a private placement of ordinary shares to institutional investors and a shareholder purchase plan in February 2014 that raised A$39.6 million, thus providing for higher interest returns on increased bank account cash balances in fiscal 2015.

Net foreign exchange gain in fiscal 2015 was due to a high U.S. dollar cash balance following an equity placement in 2014, coupled with a significant appreciation of the U.S. dollar against the Australian dollar during fiscal 2015. There was no such gain in fiscal 2014.

*Expenses*

*Royalties and licence fees.* Royalties and licence fees decreased from approximately A$193,000 in fiscal 2014 to A$40,000 in fiscal 2015 due primarily to a one-off payment related to certain intellectual property in fiscal 2014.

*Research and development expense.* Research and development expense increased by A$2.4 million, from A$3.8 million in fiscal 2014 to A$6.2 million in fiscal 2015, primarily due to higher research and development activity in fiscal 2015, including the dosing of patients in our now discontinued Phase I/IIa clinical trial for TT-034 and an agreement with 4D Molecular Therapeutics LLC, or 4DMT, to develop vectors.

*Employment related expenses.* Employment-related expenses increased by A$1.0 million, or 40%, in fiscal 2015 compared to fiscal 2014, due to increased staff levels, particularly at Tacere's laboratory, in fiscal 2015.

*Share based expenses.* Share based expenses increased by A$1.1 million, from A$0.4 million in fiscal 2014 to A$1.5 million in fiscal 2015. 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$0.4 million from A$0.6 million in fiscal 2014 to A$1.0 million in fiscal 2015 due to an increase in staff levels and more participation in international conferences, in addition to meetings with pharmaceutical companies.

*Consultants costs.* Consultants costs increased slightly from A$0.7 million in fiscal 2014 to A$0.9 million in fiscal 2015, as we retained specialist advisers in relation to our key product candidate programs and built up our shareholder relations capabilities.

*Occupancy costs.* Occupancy costs increased slightly from A$0.1 million in fiscal 2014 to A$0.3 million in fiscal 2015 due to increased lease costs for the Tacere laboratory in California and increased space under lease in Australia.

*Corporate expenses.* Corporate expenses increased by A$0.4 million, or 58%, from A$0.6 million in fiscal 2014 to A$1.0 million in fiscal 2015 due to an increase in the size of our company and increases in consequent expenses.

*IPO costs.* We incurred legal, accounting and other costs of A$1.1 million in fiscal 2015 in relation to our U.S. initial public offering that was completed in August 2015, while no such costs had been incurred in fiscal 2014.

*Loss for the period*

As a result of the foregoing, our loss for the period after income tax benefit increased by A$4.5 million, or 64%, from A$7.0 million in fiscal 2014 to A$11.5 million in fiscal 2015.

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, 2016, we had accumulated losses of A$131.4 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 had no borrowings in fiscal 2014, fiscal 2015 or fiscal 2016 and do not currently have a credit facility.

As of June 30, 2016, we had cash and cash equivalents of A$18.2 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.

***Cash flows***

The following table sets forth the sources and uses of cash for each of the periods set forth below:

| | For the fiscal year ended June 30, | | |
|---|---|---|---|
| **(in thousands)** | **2016** | **2015** | **2014** |
| Net cash used in operating activities | A$(20,208) | A$(9,692) | A$ (9,271) |
| Net cash provided by (used in) investing activities | (342) | (505) | (32) |
| Net cash provided by financing activities | 17,510 | 52 | 39,076 |

*Operating activities.* Net cash used in operating activities for fiscal 2016, fiscal 2015 and fiscal 2014 was A$20.2 million, A$9.7 million and A$9.3 million, respectively. The use of net cash in all periods resulted from our net losses.

*Investing activities.* Net cash used in investing activities in fiscal 2016, 2015 and 2014 was A$0.3 million, A$0.5 million and A$0.03 million, respectively, and mostly related to purchases of equipment.

*Financing activities.* Net cash provided by financing activities was A$17.5 million, A$0.05 million and A$39.1 million for fiscal 2016, fiscal 2015 and fiscal 2014. All such cash from financing activities related to the issuance of ordinary shares, including our U.S. initial public offering in fiscal 2016 with gross proceeds of A$18.8 million (US$13.8 million) and A$39.5 million from private placements in fiscal 2014.

***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 expect that the net proceeds from our initial public offering in the United States together with our pre-existing cash and cash equivalents will be sufficient to enable us to complete planned preclinical proof-of-concept studies for certain of our product candidates until approximately August 2017. In order to complete the planned preclinical proof-of-concept studies for our lead product candidates and to build the infrastructure that we believe will be necessary to commercialize our lead product candidates, we will require substantial additional funding.

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, defense 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 centers, 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 enrollment 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 enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

Our research and development expenses, categorized by product candidate or program, in fiscal 2016, fiscal 2015 and fiscal 2014 were as follows:

| | For the year ended June 30, | | |
|---|---|---|---|
| **Product candidate or program** | **2016** | **2015** | **2014** |
| TT-034 for the treatment of HCV | A$ 3,248,758 | A$3,171,886 | A$2,475,086 |
| BB-103 and BB-101* for the treatment of HBV | 3,924,457 | 491,878 | — |
| BB-201 and BB-202 for the treatment of AMD** | 2,796,851 | 1,179,269 | 793 |
| BB-301 for treatment of OPMD*** | 817,494 | — | 40,299 |
| New Technologies | 175,226 | — | — |
| Tribetarna for the treatment of drug-resistant NSCLC | 390,530 | 761,047 | 752,683 |
| Intractable neuropathic pain | — | — | 1,688 |
| Other project related research and development costs (includes insurance, legal, IP and lab equipment costs) | 1,933,501 | 624,211 | 487,320 |
| Total | A$13,286,817 | A$6,228,291 | A$3,757,869 |

* formerly known as Hepbarna and BB-HB-331.
** formerly known as BB-AMD-211 and BB-AMD-231.
*** formerly known as Papbarna.

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.

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, AMD and OPMD through to completion of preclinical proof of concept studies and completion of pre-IND meetings with the FDA. Based on cash requirements and financing, we plan to continue to advance our product candidates for hepatitis B, AMD and OPMD through to submission of an IND application and potentially completion of clinical proof of concept studies. We will require additional financing to conduct clinical trials for our product candidates for hepatitis B, AMD and OPMD.

**E.** ***Off-Balance Sheet Arrangements*****.**

We did not have over the past three fiscal years, and we currently do not have, any off-balance sheet arrangements as defined in the rules and regulations of the Securities and Exchange Commission.

**F.** ***Tabular Disclosure of Contractual Obligations*****.**

The following table summarizes our contractual obligations as of June 30, 2016:

| | Payments due by period (A$ thousand) | | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 year | 1-3 years | 3-5 years | More than 5 years |
| Operating lease obligations | A$ 224 | A$ 126 | A$ 98 | A$ — | A$— |
| Obligations under contracts with clinical research organizations | 2,716 | 2,716 | — | — | — |
| Total | A$2,940 | A$2,842 | A$ 98 | A$ — | A$— |

## Item 6. Directors, Senior Management and Employees

### A. *Directors and Senior Management.*

The following table sets forth information covering our current directors and executive officers.

| Name | Position |
|---|---|
| Greg West | Chief Executive Officer and Company Secretary |
| Peter Francis | Chairman of the Board of Directors |
| David Suhy | Chief Scientific Officer |
| Cliff Holloway | Chief Business and Operating Officer |
| Bryan Dulhunty | Chief Financial Officer |
| Georgina Kilfoil | Chief Clinical and Development Officer |
| John Chiplin | Director |
| J. Kevin Buchi | Director |
| Megan Boston | Director |
| Jerel A. Banks | Director |

***Greg West*** has been our Chief Executive Officer since August 2016 and, prior to that was Interim Chief Executive Officer from December 2015. He was also our Chief Financial Officer from May 2011 until August 2016 and has been Company Secretary since May 2011. From May 2010 to January 2011, he was Chief Financial Officer at Immune Systems Therapeutics, Ltd., a medical diagnostic company. Mr. West is a Chartered Accountant. He is a Director and Audit Committee Chairman of each of UOWD Limited (a business arm of Wollongong University) and IDP Education Limited and Education Australia Limited. He worked at PricewaterhouseCoopers and has held finance executive roles with financial institutions, including BT Financial Group, Deutsche Bank AG and IAG New Zealand Limited.

***Peter Francis*** has been Chairman of our Board since February 2006. Since 1993, Mr. Francis has been a partner at Francis Abourizk Lightowlers, a firm of commercial and technology lawyers with offices in Melbourne, Australia. He is a legal specialist in the areas of intellectual property and licensing and provides legal advice to corporations and research bodies. Mr. Francis completed his studies in law and jurisprudence at Monash University.

***Dr. David Suhy*** was appointed as our Chief Scientific Officer in April 2015, prior to which he served as our Senior Vice President, Research & Development since October 2012. In April 2008, he joined Tacere Therapeutics, Inc. as Director of Research & Development and continued in that role until our acquisition of Tacere in October 2012. Previous roles include Associate Director of R&D at Clontech Laboratories, Inc. and Principal Scientist at Antara Biosciences Inc. He also led the Target Validation Group at PPD Discovery, a company with proprietary technology surrounding the use of genetic suppressor elements to identify "druggable" genomic targets for large pharmaceutical companies.

***Dr. Cliff Holloway*** has been our Chief Business and Operating Officer since August 2016. Prior to joining our company, Dr. Holloway served as CEO and Managing Director of Sienna Cancer Diagnostics Ltd since 2015. Dr. Holloway served as CEO and Managing Director of Immune System Therapeutics Ltd from 2012 to 2014 and CEO and Executive Director of Biosceptre International Ltd from 2010 to 2012. He has been a director of Newstar Ventures Pty Ltd. since 2014. He was formerly VP Business Development at ASX listed biotechnology company Arana Therapeutics Ltd, which was acquired by Cephalon Inc (now Teva Pharmaceuticals) in 2009. Dr. Holloway has extensive experience in biopharmaceutical and healthcare related technologies with a focus on commercialization and product development. He holds a Bachelor of Pharmacy and a PhD in Medicinal Chemistry from the University of Nottingham, United Kingdom.

***Bryan Dulhunty*** has been our Chief Financial Officer since August 2016. He previously served as executive chairman, director, managing director, chief financial officer and company secretary of a number of ASX-listed and non-listed biotech companies. For the period 2004 to 2012, Mr. Dulhunty held various roles with Viralytics Ltd, including non-executive director, executive chairman and managing director. Since 2012, Mr. Dulhunty has run his own consultancy business, CoSA Pty Ltd,

that provides financial and regulatory services to companies in the life science industry including Benitec. Mr. Dulhunty holds a Bachelor of Economics from the University of Sydney and is a Australian Chartered Accountant.

***Georgina Kilfoil*** was appointed as our Chief Clinical and Development Officer in April 2015 prior to which she served as Vice President, Clinical Operations since February 2015. Ms. Kilfoil initially provided services to Benitec in October 2014 in the role of Senior Drug Development Consultant. Prior to joining Benitec, Ms. Kilfoil was a business consultant from March 2013 to September 2014 and prior to that was Senior Vice President, Management and Development at Anthera Pharmaceuticals, Inc. from March 2010 to February 2013. Previous to this, Ms. Kilfoil served as Project Management Consultant at InClin, Inc. and Vice President of Project Management at Peninsula Pharmaceuticals, Inc. Ms. Kilfoil is a certified Project Management Professional, has a Bachelor of Science Degree in Pharmacology from the University of Bristol, United Kingdom, and a Masters of Business Administration from the Australian Graduate School of Management, Sydney, Australia.

***Dr. John Chiplin*** has been a Director since February 2010. Dr. Chiplin is a founder of and has served as a Managing Director of investment company, Newstar Ventures Ltd., since 1998. More recently, he has served as a director of Medistem, Inc. through its acquisition by Intrexon Corporation in 2014, as founding Chief Executive Officer of Arana Therapeutics Limited from 2006 through its acquisition by Cephalon, Inc. in 2009, as director of Domantis Ltd through its acquisition by GlaxoSmithKline plc in 2006, and as Managing Director of ITI Life Sciences Fund from 2003 to 2005. Dr. Chiplin currently serves on the board of directors of Adalta Pty Ltd, ScienceMedia Inc., Prophecy Inc., Batu Biologics Inc., The Coma Research Institute and Cynata Therapeutics Limited which is traded on the ASX. Dr. Chiplin's Pharmacy and PhD degrees are from the University of Nottingham, Nottingham, United Kingdom.

***J. Kevin Buchi*** has been a Director since April 2013. Since August 2013, he has served as Chief Executive Officer of TetraLogic Pharmaceuticals Corporation. Mr. Buchi served as Chief Executive Officer of Cephalon, Inc., or Cephalon, from December 2010 through its acquisition by Teva Pharmaceutical Industries Ltd., or Teva Pharmaceuticals, in October 2011. After the acquisition Mr. Buchi served as Corporate Vice President, Global Branded Products of Teva Pharmaceuticals. Mr. Buchi joined Cephalon in 1991 and held various positions, including Chief Operating Officer, from January 2010 to December 2010, Chief Financial Officer and Head of Business Development prior to being appointed Chief Executive Officer. Mr. Buchi currently serves as President and Chief Executive Officer and a member of the Board of Directors of TetraLogic Pharmaceuticals Corp. Mr. Buchi is also on the Board of Directors of Stemline Therapeutics, Inc., Forward Pharma A/S, Alexza Pharmaceuticals, Inc. and Epirus Biopharmaceuticals Inc. Mr. Buchi has a B.A. in chemistry from Cornell University and a Masters in Management from Kellogg Graduate School of Management at Northwestern University. He is also a Certified Public Accountant.

***Megan Boston*** has been a Director since August 16, 2016. From April 2014 to July 2016, she was Managing Director of Omni Market Tide Limited, an ASX-listed technology company and from April 2014 to June 2015, she was chief executive officer of GRT Exchange, an Australian technology company. Since 2010, Ms. Boston has been a Director or Deputy Chair of Adult Multicultural and Education Service in Australia and a Board member and Chair of the Audit and Risk Committee for the Victorian Human Rights and Equal Opportunity Commission. Previously Ms. Boston was a Board Member and Chair of the Finance, Audit and Risk Committee for Beyond Medical Education, a provider of General Practitioner training services in regional Victoria, Australia. Ms. Boston is a Chartered Accountant (Australia).

***Dr. Jerel A. Banks*** has been a Director since October 25, 2016. Dr. Banks is the Chief Investment Officer of Nant Capital, LLC. Prior to joining Nant Capital, LLC, Dr. Banks served as vice president, portfolio manager and research analyst for the Franklin Biotechnology Discovery Fund at Franklin Templeton Investments from 2012 to 2015. Dr. Banks currently serves as a Director of Genos Research, Inc. Prior to his tenure at Franklin Templeton Investments, he worked as a biotechnology equity research analyst at Sectoral Asset Management from 2011-2012. From 2008-2011, Dr. Banks worked as a biotechnology equity research analyst at Apothecary Capital, the healthcare investment management team for the family investment office of the Bass Family of Fort Worth, Texas. Dr. Banks began his career in investment management as a healthcare equity research associate at Capital Research Company where he was a member of the equity research team from 2006-2008. Dr. Banks earned an M.D. from the Brown University School of Medicine and a Ph.D. in Organic Chemistry from Brown University, and he holds an A.B. in Chemistry from Princeton University.

There are no family relationships among any of our directors or executive officers and no arrangements or understandings with major shareholders, customers, suppliers or others pursuant to which any of our directors or members of senior management was selected as such, except Dr. Banks was appointed as a Director following the acquisition by Nant Capital, LLC of approximately 19.9% of Benitec's outstanding ordinary shares. The business addresses for each of our directors and executive officers is Benitec Biopharma Limited, 99 Mount Street, Suite 1201, North Sydney, New South Wales, 2060 Australia.

**B.** ***Compensation*****.**

**Remuneration**

The remuneration policy of Benitec is to align director and executive objectives with shareholder and business objectives by providing a fixed remuneration component and typically offering long-term incentives based on key performance areas. Our board of directors believes the remuneration policy to be appropriate and effective in its ability to attract and retain the best executives and directors to run and manage the consolidated entity, as well as create goal congruence between directors, executives, and shareholders.

Our board of directors is responsible for determining the appropriate remuneration package for our Chief Executive Officer, and our Chief Executive Officer is in turn responsible for determining the appropriate remuneration packages for senior management.

Executives typically receive a base salary based on factors such as experience and comparable industry information, options and performance incentives. Our board of directors reviews our Chief Executive Officer's remuneration package, and our Chief Executive Officer reviews the other senior executives' remuneration packages, annually by reference to the consolidated entity's performance, executive performance, and comparable information within the industry.

The performance of executives is measured against criteria agreed annually with each executive and is based predominantly on the overall success of Benitec in achieving its broader corporate goals. Bonuses and incentives are linked to predetermined performance criteria. Our board of directors may, however, exercise its discretion in relation to approving incentives, bonuses, and options, and can recommend changes to our Chief Executive Officer's recommendations. The policy is designed to attract the highest caliber of executives and reward them for performance that results in long-term growth in shareholder wealth.

Executives may be invited to participate in the employee share option plan.

Australian executives or directors receive a superannuation guarantee contribution required by the government and do not receive any other retirement benefits.

All remuneration paid to directors and executives is valued at the cost to us and expensed. Options are valued using the Black-Scholes methodology. The board of directors' policy is to remunerate non-executive directors at market rates for comparable companies for time, commitment, and responsibilities. Our board of directors as a whole determines payments to the non-executive directors and reviews their remuneration annually, based on market practice, duties and accountability. The maximum aggregate amount of fees that can be paid to non-executive directors is subject to approval by shareholders at our annual general meeting. Fees for non-executive directors are not linked to the performance of the consolidated entity. However, to align directors' interests with shareholder interests, the directors are encouraged to hold our shares.

Our directors are paid remuneration for their services as directors (but excluding any remuneration payable to a director under any executive services contract with us or one of our related bodies corporate) which is determined in a general meeting of shareholders. The aggregate, fixed sum for directors' remuneration is to be divided among the directors in such proportion as the directors themselves agree and in accordance with our Constitution. The fixed sum remuneration for directors may not be increased except at a general meeting of shareholders and the particulars of the proposed increase are required to have been provided to shareholders in the notice convening the meeting. In addition, executive directors may be paid remuneration as employees of Benitec.

Fees payable to our non-executive directors must be by way of a fixed sum and not by way of a commission on or a percentage of profits or operating revenue. Remuneration paid to our executive directors must also not include a commission or percentage of operating revenue.

Pursuant to our Constitution, any director who performs services that in the opinion of our board of directors, are outside the scope of the ordinary duties of a director may be paid extra remuneration, which is determined by our board of directors.

In addition to other remuneration provided in our Constitution, all of our directors are entitled to be paid by us for reasonable travel accommodation and other expenses incurred by the directors in attending general meetings, board meetings, committee meetings or otherwise in connection with our business.

In addition, in accordance with our Constitution, a director may be paid a retirement benefit as determined by our board of directors subject to the limits set out in the Corporations Act and the ASX Listing Rules which broadly restrict our ability to pay our officers a termination benefit in the event of a change of control of the Company or our subsidiaries as well as impose requirements for shareholder approval to be obtained to pay certain retirement benefits to our officers.

***Performance Based Remuneration***

Each executive's remuneration package typically has a performance-based component. The intention of this approach is to facilitate goal congruence between executives with the business and shareholders. Generally, the executive's performance based remuneration is tied to Benitec's successful achievement of certain key milestones relating to its operating activities, as well as Benitec's overall financial position.

The remuneration policy has been tailored to align the goals of shareholders, directors, and executives. Two methods are applied in achieving this aim, the first being a performance-based bonus linked to achievement of key corporate milestones, and the second being the issuance of options to the majority of directors and executives to encourage the alignment of personal and shareholder interests.

***Details of Remuneration for fiscal 2016***

The following tables set forth all of the compensation awarded to, earned by or paid to each individual who served as director and executive officer in fiscal year 2016.

| | Short Term Benefits | | | Post-Employment Benefits | Long Term Benefits | Share-Based Payments | |
|---|---|---|---|---|---|---|---|
| | Cash Salary and Fees A$ | Cash Bonus A$ | Non-Monetary A$ | Super Annuation A$ | Employee Leave A$ | Options A$ | Total A$ |
| *Non-Executive Directors:* | | | | | | | |
| Peter Francis | 113,328 | — | — | 8,550 | — | 212,993 | 334,871 |
| Kevin Buchi | 78,488 | — | — | — | — | 127,796 | 206,284 |
| John Chiplin | 81,230 | — | — | — | — | 127,796 | 209,026 |
| Iain Ross** | 81,262 | — | — | — | — | 127,796 | 209,058 |
| *Executive Officers:* | | | | | | | |
| Peter French* | 503,379 | 120,000 | (90,256) | 9,024 | — | 172,237 | 714,384 |
| Greg West | 333,333 | 69,000 | 25,268 | 19,308 | 13,209 | 115,758 | 575,876 |
| David Suhy | 343,218 | 68,644 | 42,242 | — | — | 118,600 | 572,704 |
| Carl Stubbings*** | 263,583 | 27,500 | (11,676) | 18,748 | — | 8,875 | 307,030 |
| | 1,797,821 | 285,144 | (34,422) | 55,630 | 13,209 | 1,011,851 | 3,129,233 |

* No longer an executive officer since December 9, 2015.
** No longer a director since October 1, 2016.
*** No longer an officer since July 31, 2016.

The proportion of remuneration at risk and the fixed proportion are as follows:

| | Fixed remuneration | | At risk – STI (bonus) | | At risk – LTI (options) | |
|---|---|---|---|---|---|---|
| Name | 2016 | 2015 | 2016 | 2015 | 2016 | 2015 |
| *Non-Executive Directors:* | | | | | | |
| Peter Francis | 36% | 100% | — | — | 64% | — % |
| Kevin Buchi | 38% | 46% | — | — | 62% | 54% |
| John Chiplin | 39% | 100% | — | — | 61% | — % |
| Iain Ross** | 39% | 100% | — | — | 61% | — % |
| *Executive Officers:* | | | | | | |
| Peter French* | 59% | 82% | 17% | — | 24% | 18% |
| Greg West | 66% | 53% | 12% | — % | 22% | 47% |
| David Suhy | 67% | 57% | 12% | — % | 21% | 43% |
| Carl Stubbings*** | 88% | 66% | 9% | — % | 3% | 34% |
| Georgina Kilfoil | — % | 33% | — | — | — % | 67% |

* No longer an executive officer since December 9, 2015.
** No longer a director since October 1, 2016.
*** No longer an officer since July 31, 2016.

The proportion of the cash bonus paid/payable or forfeited is as follows:

| Name | Cash bonus paid/payable 2016 | Cash bonus paid/payable 2015 | Cash bonus forfeited 2016 | Cash bonus forfeited 2015 |
|---|---|---|---|---|
| *Executive Officers:* | | | | |
| Peter French* | 100% | — % | — % | — % |
| Greg West | 100% | — % | — % | — % |
| David Suhy | 100% | — % | — % | — % |
| Carl Stubbings*** | 50% | — % | 50% | — % |
| Georgina Kilfoil | — % | — % | — % | — % |

* No longer an executive officer since December 9, 2015.
*** No longer an officer since July 31, 2016.

There were no shares issued to directors and executive officers as part of compensation during the year ended June 30, 2016. The terms and conditions of each grant of options over ordinary shares affecting remuneration of directors and executive officers in this fiscal year or future reporting years is as follows:

| Grant date | No. granted | Expiry date | Exercise price | Fair value per option at grant date |
|---|---|---|---|---|
| 11/12/2015 | 6,720,000 | 11/12/2020 | A$ 0.77 | A$ 0.234 |

Details of options over ordinary shares granted, vested and lapsed for directors and executive officers as part of compensation during the year ended June 30, 2016 are set out below:

| Name | Number of options granted | Grant date | Value per option at grant date (A$) | Value of options at grant date (A$) | Number vested | Exercise price (A$) | Vested and first exercise date | Last exercise date |
|---|---|---|---|---|---|---|---|---|
| Peter Francis | 1,400,000 | 11/12/2015 | 0.234 | 328,161 | 466,666 | A$ 0.77 | 11/12/2015 | 11/12/2020 |
| Kevin Buchi | 840,000 | 11/12/2015 | 0.234 | 196,896 | 280,000 | A$ 0.77 | 11/12/2015 | 11/12/2020 |
| John Chiplin | 840,000 | 11/12/2015 | 0.234 | 196,896 | 280,000 | A$ 0.77 | 11/12/2015 | 11/12/2020 |
| Iain Ross** | 840,000 | 11/12/2015 | 0.234 | 196,896 | 280,000 | A$ 0.77 | 11/12/2015 | 11/12/2020 |
| Peter French* | 2,800,000 | 11/12/2015 | 0.234 | 656,319 | (2,800,000) | A$ 0.77 | — | — |

* All options granted lapsed on termination of employment on December 9, 2015.
** No longer a director since October 1, 2016.

**Employment Agreements with Executive Officers**

The key provisions of the employment agreements (other than remuneration) are set out below for each of our executive officers. None of these employment agreements have termination dates.

| Name of executive officer | Title of executive officer | Date employment agreement commenced | Notice period required to terminate without cause by either party |
|---|---|---|---|
| Greg West | Chief Executive Officer | August 10, 2016 | Six months |
| Cliff Holloway | Chief Business Officer | August 10, 2016 | Three months |
| Bryan Dulhunty | Chief Financial Officer | July 1, 2016 | Three months |
| David Suhy | Chief Scientific Officer | August 28, 2012 | At will |
| Georgina Kilfoil | Chief Clinical and Development Officer | September 19, 2014 | Three months |

**Consequences of Performance on Shareholder Wealth**

The earnings of Benitec and its subsidiaries for the five years ended June 30, 2016 are summarized below:

| | 2012 A$'000 | 2013 A$'000 | 2014 A$'000 | 2015 A$'000 | 2016 A$'000 |
|---|---|---|---|---|---|
| Loss after income tax | (4,113) | (3,488) | (7,039) | (11,509) | (24,778) |

The factors that are considered to affect total shareholders return are summarized below:

| | 2012 | 2013 | 2014 | 2015 | 2016 |
|---|---|---|---|---|---|
| Share price at financial year end (A$) | 0.43 | 0.38 | 1.15 | 0.69 | 0.98 |
| Basic earnings per share (cents per share) | (0.43) | (8.25) | (7.78) | (9.96) | (17.41) |

**Additional Disclosures Relating to Key Management Personnel**

The number of shares in Benitec held during fiscal 2016 by each director and executive officer, including their personally related parties, is set out below:

| | Balance at the start of the year | Received as part of remuneration | Exercise of options | Disposables / other | Balance at the end of the year |
|---|---|---|---|---|---|
| ***Ordinary shares*** | | | | | |
| Peter Francis | 424,174 | — | — | — | 424,174 |
| Kevin Buchi | 861,539 | — | — | — | 861,539 |
| John Chiplin | 200,000 | — | — | — | 200,000 |
| Iain Ross** | 66,364 | — | — | — | 66,364 |
| Peter French* | 591,785 | — | — | — | 591,785 |
| Carl Stubbings*** | 136,787 | — | — | — | 136,787 |
| | 2,280,649 | — | — | — | 2,280,649 |

* No longer an executive officer since December 9, 2015.
** No longer a director since October 1, 2016.
*** No longer an officer since July 31, 2016.

**Employee Share Option Plan**

We had an employee share option plan that was approved by our shareholders in November 2009 and was in effect until November 2014. Our shareholders approved a new Officers' and Employees' Option Plan at our 2015 Annual General Meeting in November 2015.

The following employee options to purchase ordinary shares of Benitec Biopharma Limited were outstanding as at June 30, 2016:

| | | *Share options outstanding at June 30, 2016* | |
|---|---|---|---|
| *Grant date* | *Expiry date* | *Exercise price* | *Number under option* |
| September 26, 2011 * | September 26, 2016 | $ 1.25 | 2,800,000 |
| November 17, 2011 ** | November 17, 2016 | $ 1.25 | 600,000 |
| February 7, 2012 ** | February 7, 2017 | $ 1.25 | 156,000 |
| November 16, 2012 ** | November 16, 2017 | $ 1.25 | 400,000 |
| November 10, 2013 * | May 18, 2018 | $ 0.62 | 400,000 |
| August 22, 2013 ** | August 22, 2018 | $ 1.25 | 480,000 |
| May 15, 2014 ** | May 15, 2019 | $ 1.50 | 180,000 |
| December 17, 2014 ** | December 17, 2019 | $ 1.25 | 2,634,000 |
| May 6, 2015 ** | May 6, 2020 | $ 1.25 | 650,000 |
| November 12, 2015* | November 12, 2020 | $ 0.77 | 3,920,000 |
| | | | 12,220,000 |

* Non-Executive Directors options.
** ESOP options.

No employee options were exercised during fiscal 2016.

**C. *Board Practices.***

**Board of Directors**

Our board of directors currently consists of five members. Our directors are elected at each annual general meeting of our shareholders and serve until their successors are elected or appointed, unless their office is earlier vacated. We believe that each of our directors has relevant industry experience. The membership of our board of directors is directed by the following requirements:

- our Constitution specifies that there must be a minimum of three directors and a maximum of 10, and our board of directors may determine the number of directors within those limits;
- as set forth in our Board Charter, the membership of the board of directors should consist of a majority of independent directors who satisfy the criteria recommended by the ASX Corporate Governance Principles and Recommendations;
- the Chairman of our Board should be an independent director who satisfies the criteria for independence recommended by the ASX Corporate Governance Principles and Recommendations; and
- our board of directors should, collectively, have the appropriate level of personal qualities, skills, experience, and time commitment to properly fulfill its responsibilities or have ready access to such skills where they are not available.

Our board of directors has delegated responsibility for the conduct of our businesses to the Chief Executive Officer, but remains responsible for overseeing the performance of management. Our board of directors has established delegated limits of authority, which define the matters that are delegated to management and those that require board of directors approval. Under the Corporations Act, at least two of our directors must be resident Australians. None of our directors have any service contracts with Benitec that provide for benefits upon termination of employment.

**Committees**

To assist our board of directors with the effective discharge of its duties, it has established a Remuneration and Nomination Committee and an Audit and Risk Committee, which committees operate under a specific charter approved by our board of directors.

***Remuneration and Nomination Committee.*** The members of our Remuneration and Nomination Committee are Peter Francis, Kevin Buchi and John Chiplin. Dr. John Chiplin acts as chairman of the committee. The committee's role involves:

- identifying, evaluating and recommending qualified nominees to serve on our board of directors;
- developing and overseeing our internal corporate governance processes;
- maintaining a management succession plan;
- evaluating, adopting and administering our compensation plans and similar programs advisable for us, as well as modifying or terminating existing plans and programs;
- establishing policies with respect to equity compensation arrangements; and
- overseeing, reviewing and reporting on various remuneration matters to our board of directors.

***Audit and Risk Committee.*** The members of our Audit and Risk Committee are Megan Boston and Kevin Buchi. Our board of directors has determined that each of them meets the criteria for independence of audit committee members set forth in Rule 10A-3(b)(1) under the Securities Exchange Act of 1934 and the applicable rules of The NASDAQ Capital Market and Rule 10A-3(b)(1)(iv)(2) under the Exchange Act. Each member of our audit committee meets the financial literacy requirements of the listing standards of The NASDAQ Capital Market. Megan Boston acts as the chairman of the audit committee and our board of directors has determined that Megan Boston is an audit committee "financial expert," as defined by Item 407(d) of Regulation S-K under the Securities Act.

Iain Ross was a member of our Audit and Risk Committee during fiscal 2016 and fiscal 2017 until September 30, 2016, when his resignation as a director became effective. As a result, Benitec is not currently in compliance with a NASDAQ rule that requires a company to maintain an audit committee of at least three members. We have notified NASDAQ of this deficiency and expect to cure it within 180 days from September 30, 2016, as permitted under NASDAQ Rule 5605(c)(4)(B), by appointing a new independent director to our Audit and Risk Committee.

The principal duties and responsibilities of our audit committee include:

- overseeing and reporting on various auditing and accounting matters to our board of directors, including the selection of our independent accountants, the scope of our annual audits, fees to be paid to the independent accountants, the performance of our independent accountants and our accounting practices;

- overseeing and reporting on various risk management matters to our board of directors.
- considering and approving or disapproving all related-party transactions;
- reviewing our annual and semi-annual financial statements and reports and discussing the statements and reports with our independent registered public accounting firm and management;
- reviewing and pre-approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services;
- evaluating the performance of our independent registered public accounting firm and deciding whether to retain their services; and
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters.

**Code of Conduct**

We have established a Code of Conduct, which sets out the standards of behavior that apply to every aspect of our dealings and relationships, both within and outside Benitec. The following standards of behavior apply to all directors, executive officers and employees of Benitec:

- comply with all laws that govern us and our operations;
- act honestly and with integrity and fairness in all dealings with others and each other;
- avoid or manage conflicts of interest;
- use our assets responsibly and in the best interests of Benitec; and
- be responsible and accountable for our actions.

The Code of Conduct is available on our website at www.benitec.com.

**D. *Employees*.**

As of June 30, 2016, we had 18 full-time employees, 12 of whom have a PhD or other post-graduate degrees. Of these full-time employees, 16 are engaged in research and development activities and 4.5 are engaged in finance, legal, human resources, facilities and general management. Our employees are located in Sydney, Australia and at our research and development facility located in Hayward, California. None of our employees is represented by any labor union.

**E.** ***Share Ownership.***

The chart below sets forth the number of shares held by directors and executive officers as of June 30, 2016:

| | Ordinary Shares Beneficially Owned | |
|---|---|---|
| **Shareholder** | **Number** | **Percent** |
| ***Officers and Directors*** | | |
| Peter Francis | 2,490,840(1) | 1.7 |
| Greg West | 706,666(2) | * |
| Carl Stubbings*** | 136,787(3) | * |
| David Suhy | 933,334(4) | * |
| Georgina Kilfoil | 400,000(5) | * |
| John Chiplin | 880,000(6) | * |
| Iain Ross** | 746,364(7) | * |
| J. Kevin Buchi | 1,541,539(8) | 1.1 |
| Officers and Directors as a group (8 persons) | 7,835,530 | 5.3% |

* Represents beneficial ownership of less than 1% of the outstanding ordinary shares of Benitec.

** No longer a director since October 1, 2016.

*** No longer an officer since July 31, 2016.

(1) Includes (i) 424,174 shares and (ii) 2,066,666 shares that Mr. Francis has the right to acquire pursuant to options that are exercisable as of June 30, 2016 or will become exercisable within 60 days of such date.

(2) Includes 706,666 shares that Mr. West has the right to acquire pursuant to options that are exercisable as of June 30, 2016 or will become exercisable within 60 days of such date.

(3) Includes (i) 136,787 shares.

(4) Includes 933,334 shares that Dr. Suhy has the right to acquire pursuant to options that are exercisable as of June 30, 2016 or will become exercisable within 60 days of such date.

(5) Includes 400,000 shares that Ms. Kilfoil has the right to acquire pursuant to options that are exercisable as of June 30, 2016 or will become exercisable within 60 days of such date.

(6) Includes (i) 200,000 shares and (ii) 680,000 shares that Dr. Chiplin has the right to acquire pursuant to options that are exercisable as of June 30, 2016 or will become exercisable within 60 days of such date.

(7) Includes (i) 66,364 shares and (ii) 680,000 shares that Mr. Ross has the right to acquire pursuant to options that are exercisable as of June 30, 2016 or will become exercisable within 60 days of such date.

(8) Includes (i) 861,539 shares and (ii) 680,000 shares that Mr. Buchi has the right to acquire pursuant to options that are exercisable as of June 30, 2016 or will become exercisable within 60 days of such date.

The number of options over ordinary shares in Benitec held during the financial year ended June 30, 2016 by each director and other executive officers, including their personally related parties, is set out below:

| | Balance at the start of the year | Granted | Exercised** | Expired /forfeited /other | Balance at the end of the year | Vested and exercisable | Vested and unexercisable |
|---|---|---|---|---|---|---|---|
| **Options over ordinary shares** | | | | | | | |
| Peter Francis | 1,696,924 | — | (96,924) | — | 1,600,000 | 1,600,000 | — |
| Peter French | 2,849,231 | — | (249,231) | — | 2,600,000 | 1,666,667 | — |
| Kevin Buchi | 646,154 | — | (246,154) | — | 400,000 | 266,666 | — |
| John Chiplin | 410,563 | — | — | (10,563) | 400,000 | 400,000 | — |
| Iain Ross | 407,500 | — | — | (7,500) | 400,000 | 400,000 | — |
| Mel Bridges* | 521,539 | — | — | (521,539) | — | — | — |
| Greg West | 400,000 | 600,000 | — | — | 1,000,000 | 413,333 | — |
| David Suhy | 600,000 | 600,000 | — | — | 1,200,000 | 533,333 | — |
| Carl Stubbings | 612,308 | 400,000 | (12,308) | — | 1,000,000 | 466,667 | — |
| Gerogina Kilfoil* | — | 600,000 | — | — | 600,000 | 200,000 | — |
| Michael Graham | 600,000 | 400,000 | — | (1,000,000) | — | — | — |
| | 8,744,219 | 2,600,000 | (604,617) | (1,539,602) | 9,200,000 | 5,946,666 | — |

* Non-executive directors options.
** ESOP options.

A new Officers' and Employees' Share Option Plan was approved by our shareholders at the Annual Meeting in November 2015. Shareholders approved the issue of options under the plan to Directors of the Company as follows:

| Director (and/or eligible nominee(s)) | Position | Number of Options | Value |
|---|---|---|---|
| Peter Francis | Non-Executive Chairman | 1,400,000 | A$ 455,560 |
| Peter French | Managing Director, CEO | 2,800,000 | A$ 911,120 |
| Kevin Buchi | Non-Executive Director | 840,000 | A$ 273,336 |
| John Chiplin | Non-Executive Director | 840,000 | A$ 273,336 |
| Iain Ross | Non-Executive Director | 840,000 | A$ 273,336 |
| | | 6,720,000 | A$2,186,688 |

One third of the options issued to a Director will vest upon issue, one third on the first anniversary of issue, and the balance on the second anniversary of issue, subject to accelerated vesting or cancellation as provided for in the Option Plan and terms of the options.

Each options entitles the holder to acquire one fully paid ordinary share in the capital of the Company upon exercise, and has an exercise price of seventy-seven cents (A$0.77) and an expiry date which is the fifth anniversary of the date of issue. The objectives of the option plan are to:

- provide eligible Directors and executive officers with an additional incentive to work to improve the performance of the Company;
- attract and retain eligible Directors and executive officers essential or desirable for the continued growth and development of the Company;
- promote and foster loyalty and support amongst eligible Directors and executive officers for the benefit of the Company; and
- enhance the relationship between the Company and eligible Directors and executive officers for the long term mutual benefit of all parties.

## Item 7. Major Shareholders and Related Party Transaction

### A. *Major Shareholders.*

The following table and accompanying footnotes present certain information regarding the beneficial ownership of our ordinary shares based on 146,529,096 ordinary shares outstanding as of June 30, 2016 by:

- each person known by us to be the beneficial owner of more than 5% of our ordinary shares;
- each of our directors and executive officers individually; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security, including options that are exercisable within 60 days of June 30, 2016. Information with respect to beneficial ownership has been furnished to us by each director, executive officer, or 5% or more shareholder, as the case may be. Ordinary shares subject to options currently exercisable or exercisable within 60 days of September 30, 2015 are deemed to be outstanding for computing the percentage ownership of the person holding these options and the percentage ownership of any group of which the holder is a member, but are not deemed outstanding for computing the percentage of any other person.

Based on information known to us, as of June 30, 2016, we had 107 shareholders in the United States. These shareholders held an aggregate of 32,894,938 of our outstanding ordinary shares, or approximately 22.45% of our outstanding ordinary shares. A large number of our ordinary shares are held by nominee companies so we cannot be certain of the identity of those beneficial owners.

Unless otherwise indicated, to our knowledge each shareholder possesses sole voting and investment power over the ordinary shares listed subject to community property laws, where applicable. None of our shareholders has different voting rights from other shareholders. Unless otherwise indicated, the address for each of the persons listed in the table below is Benitec Biopharma Limited, 99 Mount Street, Suite 1201, North Sydney, New South Wales, 2060 Australia.

| | Ordinary Shares Beneficially Owned [1] | |
|---|---|---|
| **Shareholder** | **Number** | **Percent** |
| ***5% Shareholders*** | | |
| Dr. Christopher Bremner | 8,133,547 | 5.5% |
| Sabby Management, LLC | 7,351,471 | 5.0% |

On October 24, 2016, Nant Capital, LLC acquired 29,305,819 ordinary shares, representing approximately 16.7% of our total share capital.

To our knowledge, there have not been any significant changes in the ownership of our ordinary shares by major shareholders over the past three years, except as follows (which is based upon substantial shareholder notices filed with the ASX):

- Nant Capital, LLC acquired approximately 19.9% of our existing ordinary shares (representing a 16.7% interest in our ordinary shares post-issuance) in October 2016 in connection with a private placement.
- Sabby Management, LLC increased its interest by 1.2%, from 7.54% in August 2015 to 8.67% of the total voting power as at December 31, 2015. Sabby Management, LLC beneficially owned an aggregate of 12,697,331 ordinary shares as of December 31, 2015, up from 11,000,000 aggregate ordinary shares acquired in August 2015 in connection with our initial public offering in the United States. Sabby Management, LLC controls the Sabby Healthcare Master Fund and the Sabby Volatility Warrant Master Fund, which beneficially owned 10,781,061 and 1,916,270 ordinary shares, respectively, as of December 31, 2015. Hal Mintz is the Manager of Sabby Mangement, LLC. In April 2016, Sabby Management, LLC reported that in March 2016 it sold 5,345,860 ordinary shares and, as at April 5, 2016, beneficially held an aggregate of 7,351,471 ordinary shares, or 5.02% of the total voting power.
- RA Capital Management, LLC, or RA Capital, and its associates became a substantial shareholder on February 28, 2014, when it reported that it held 7,009,345 ordinary shares, or 7.0%, of the total voting power as of that date. Between April 2014 and July 2015, RA Capital acquired an aggregate of 7,009,346 ordinary shares for A$7,500,000 and sold an aggregate of 3,589,366 ordinary shares for A$3,602,867. On July 1, 2015, RA Capital reported that it held 10,429,325 ordinary shares, or 9.00% of the total voting power, as of that date. In August 2015, RA Capital reported that it sold 5,454,582 ordinary shares and ceased to own more than 5% of Benitec's ordinary shares.
- Dalit Pty Ltd, or Dalit, became a substantial shareholder on July 23, 2013, when it reported that it held 4,545,455 ordinary shares, or 6.17%, of the total voting power as of that date. As a result of a capital raising in February 2014, it ceased to be a substantial shareholder.
- Irwin Biotech Nominees Pty Ltd atf BIOA Trust became a substantial shareholder on July 23, 2013 when it reported that it held 4,769,091 ordinary shares, or 6.47%, of the total voting power as of that date. On February 28, 2014, Irwin reported that it ceased to be a substantial shareholder (as a result of share dilution due to a capital raising).

- MJGD Nominees Pty Ltd atf BSMI Trust became a substantial shareholder on July 23, 2013 when it reported that it held 4,769,091 ordinary shares, or 6.47%, of the total voting power as of that date. On February 28, 2014, MJGD reported that it ceased to be a substantial shareholder (as a result of share dilution due to a capital raising).
- Commonwealth Scientific & Industrial Research Organisation, or CSIRO, became a substantial shareholder on January 11, 2010, when it reported that it held 40,097,026 ordinary shares, or 10%, of the total voting power as of that date. On February 28, 2014, CSIRO reported that it ceased to be a substantial shareholder (as a result of share dilution due to a capital raising).

**B.** ***Related Party Transactions.***

Other than as disclosed below, since July 1, 2013, we did not enter into any transactions or loans with any: (i) enterprises that directly or indirectly, through one or more intermediaries, control, are controlled by or are under common control with us; (ii) associates; (iii) individuals owning, directly or indirectly, an interest in our voting power that gives them significant influence over us, and close members of any such individual's family; (iv) executive officers and close members of such individuals' families; or (v) enterprises in which a substantial interest in our voting power is owned, directly or indirectly, by any person described in (iii) or (iv) or over which such person is able to exercise significant influence.

- Legal services at normal commercial rates totaling A$116,540 for fiscal 2016, A$143,684 for fiscal 2015 and A$108,913 for fiscal 2014 were provided by Francis Abourizk Lightowlers, a law firm in which Mr. Peter Francis is a partner and has a beneficial interest. In addition, Benitec temporarily rented office space in Melbourne from Francis Abourizk Lightowlers and the associated rental cost was A$11,102 during fiscal 2016.
- Consultancy fees were paid for services totaling A$165,983 for fiscal 2016, A$118,013 for fiscal 2015 and A$40,000 for fiscal 2014 provided by NewStar Ventures Ltd, a corporation in which Dr. John Chiplin and Cliff Holloway are directors and have beneficial interests.
- Annabel West, the wife of Greg West, our Chief Executive Officer, was employed by us as a part-time clerical and administrative assistant. Annabel West was paid wages of A$49,117 and A$43,583, respectively, for fiscal 2015 and fiscal 2016.
- Hannah Stubbings, daughter of our former Chief Business Officer, Carl Stubbings, was employed by us as a part-time intern from September 2013 until April 2014 and was paid wages of A$7,325.
- When Dr. Cliff Holloway was appointed our Chief Business and Operating Officer in August 2016, his wife, Sakura Holloway, was our Intellectual Property Counsel from May 2014 to October 2016.
- Genevieve French, daughter of our former Chief Executive Officer, Peter French, was employed by us as a part-time intern. Genevieve French was paid wages of A$4,125 and A$7,525, respectively, for fiscal 2015 and fiscal 2016.

Transactions between related parties are on normal commercial terms and the conditions no more favorable than those available to other non-related parties.

**C.** ***Interests of Experts and Counsel.***

Not applicable.

## Item 8. Financial Information

**A.** ***Consolidated Statements and Other Financial Information.***

Our financial statements are included in Item 18 "Financial Statements."

### Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, any such future litigation could have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

### Dividends

We have never declared or paid cash dividends on our ordinary shares. For the foreseeable future, we currently intend to retain all available funds and any future earnings to support our operations and to finance the growth and development of our business. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to compliance with applicable laws and covenants under current or future credit facilities, which may restrict or limit our ability to pay dividends, and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. We do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. Should we determine to pay dividends in the future, all dividends unclaimed for one year after having been declared may be invested or otherwise made use of by our board of directors for our benefit until claimed or otherwise disposed of in accordance with our Constitution.

**B.** ***Significant Changes.***

On October 24, 2016, Benitec entered into a strategic engagement with Nant Capital, LLC. The strategic engagement includes a scientific collaboration in clinical programs and an immediate private placement to Nant Capital, LLC of 29,305,819 ordinary shares in Benitec, representing approximately 19.9% of its then outstanding issued capital (for a post-issue holding of approximately 16.7%). The shares were priced at A$0.0895 per share, representing the 7-day volume weighted average price of the ordinary shares on the ASX prior to the execution of a share purchase subscription agreement.

Approval of shareholders will be sought for the issue of up to an additional 29,305,819 ordinary shares to Nant Capital, LLC within three months after Benitec's 2016 annual shareholders meeting (to be held on December 14, 2016) which, should the issue proceed, would result in Nant Capital, LLC holding approximately 28.6% of the issued capital of Benitec. The capital raised will be used to fund technology to be sublicensed from NantWorks, LLC and to fund our existing therapeutic candidate development programs. Nant Capital, LLC could only be required to purchase the additional ordinary shares if it has entered into a collaboration agreement with Benitec and the purchase price would be market price.

Benitec and Nant Capital, LLC have agreed to use their reasonable efforts to enter into a scientific collaboration agreement (by December 30, 2016) designed to take Benitec back into the clinic. The collaboration would involve an antisense oligonucleotide ("ASO") sublicense from NantWorks, LLC for the treatment of squamous cell carcinoma associated with head and neck cancer ("SCCHN"), and the intended development of a ddRNAi program that would represent a second generation therapeutic for the treatment of SCCHN.

Benitec would sublicense the ASO asset from NantWorks, LLC with the intent to complete a follow-on clinical trial. This trial could encompass a Phase II/III study in which the ASO directed at epidermal growth factor receptor ("EGFR") would be coupled with Erbitux for treating patients. Sublicense terms are to be settled between Benitec and NantWorks, LLC. The ddRNAi program is

expected to be a second generation therapeutic for the treatment of SCCHN. The use of ddRNAi could provide the ability to target patients with a variant of EGFR, which can compromise up to 40% of SCCHN patients with malignant lesions. Benitec has modelled entry into the clinic for a Phase I/IIa study at the end of calendar year 2018, assuming a start date of early calendar 2017. Benitec would be the sponsor on record for the clinical trial.

Under the proposed collaboration agreement, Benitec would work with NantWorks, LLC scientists, clinicians and consultants to develop a regulatory strategy and clinical plan. Benitec would prepare a scientific development plan and budget as soon as possible with a targeted completion date of December 30, 2016. Benitec would fund the development plan in large part from equity issuances to Nant Capital, LLC and potentially other investors.

Upon completion of the initial placement of ordinary shares, Jerel A Banks, the Chief Investment Officer of Nant Capital, LLC, has been appointed to the Board of Directors of Benitec. Prior to joining NantWorks, LLC, Dr. Banks served as vice president, portfolio manager and research analyst for the Franklin Biotechnology Discovery Fund at Franklin Templeton Investments. Dr. Banks earned an M.D. from the Brown University School of Medicine and a Ph.D. in Organic Chemistry from Brown University, and he holds an A.B. in Chemistry from Princeton University.

**Item 9. The Offer and Listing.**

**A. *Listing Details.***

*The NASDAQ Capital Market*

Since August 18, 2015, our ordinary shares in the form of ADSs and Warrants have been trading on The NASDAQ Capital Market under the symbols "BNTC" and "BNTCW", respectively. The following table sets forth the high and low sales for our ADSs and Warrants for the periods indicated as reported on The NASDAQ Capital Market:

| | US$ High | US$ Low |
|---|---|---|
| *ADSs* | | |
| **Fiscal Year Ended** | | |
| June 30, 2016 | $ 9.00 | $ 1.22 |
| **Fiscal Year Ended June 30, 2016** | | |
| First Quarter 2016 (ended September 30, 2015) | $ 9.00 | $ 6.00 |
| Second Quarter 2016 (ended December 31, 2015) | $ 7.30 | $ 3.95 |
| Third Quarter 2016 (ended March 31, 2016) | $ 4.34 | $ 1.22 |
| Fourth Quarter 2016 (ended June 30, 2016) | $ 1.90 | $ 1.22 |
| **Fiscal Year Ending June 30, 2017** | | |
| First Quarter 2017 | $ 2.06 | $ 1.20 |
| Second Quarter 2017 (through October 24, 2016) | $ 1.78 | $ 1.36 |
| **Month Ended** | | |
| July 2016 | $ 2.00 | $ 1.20 |
| August 2016 | $ 2.06 | $ 1.50 |
| September 2016 | $ 1.82 | $ 1.31 |
| *Warrants* | | |
| **Fiscal Year Ended** | | |
| June 30, 2016 | $ 3.99 | $ 0.31 |
| **Fiscal Year Ended June 30, 2016** | | |
| First Quarter (ended September 30, 2015) | $ 3.99 | $ 2.01 |
| Second Quarter (ended December 31, 2015) | $ 3.50 | $ 1.75 |
| Third Quarter 2016 (ended March 31, 2016) | $ 2.50 | $ 0.31 |
| Fourth Quarter 2016 (through June 30, 2016) | $ 1.00 | $ 0.40 |
| **Fiscal Year Ending June 30, 2017** | | |
| First Quarter 2017 | $ 0.82 | $ 0.24 |
| Second Quarter 2017 (through October 24, 2016) | $ 0.34 | $ 0.08 |
| **Month Ended** | | |
| July 2016 | $ 0.47 | $ 0.47 |
| August 2016 | $ 0.82 | $ 0.24 |
| September 2016 | $ 0.34 | $ 0.24 |

*Australian Securities Exchange*

Our ordinary shares have been trading on the ASX since 1997. The following table presents, for the periods indicated, the high and low market prices for our ordinary shares reported on the ASX, under the symbol BLT. All prices are in Australian dollars.

| | High A$ | Low A$ |
|---|---|---|
| Annual: | | |
| *Fiscal year ended June 30,* | | |
| 2016 | 0.96 | 0.09 |
| 2015 | 1.32 | 0.52 |
| 2014 | 2.38 | 0.28 |
| 2013 | 0.50(1) | 0.25(1) |
| 2012 | 0.75(1) | 0.25(1) |
| Quarterly: | | |
| *Fiscal year ended June 30, 2017* | | |
| Second quarter (through October 24, 2016) | 0.08 | 0.13 |
| First quarter | 0.14 | 0.08 |
| *Fiscal year ended June 30, 2016* | | |
| Fourth quarter | 0.13 | 0.09 |
| Third quarter | 0.33 | 0.12 |
| Second quarter | 0.56 | 0.27 |
| First quarter | 0.96 | 0.69 |
| *Fiscal year ended June 30, 2015* | | |
| Fourth quarter | 0.89 | 0.67 |
| Third quarter | 1.08 | 0.71 |
| Second quarter | 1.07 | 0.52 |
| First quarter | 1.32 | 0.87 |
| *Fiscal year ended June 30, 2014* | | |
| Fourth quarter | 1.84 | 0.86 |
| Third quarter | 2.38 | 0.56 |
| Second quarter | 0.75 | 0.35 |
| First quarter | 0.41 | 0.25(1) |
| Most Recent Six Months: | | |
| September 2016 | 0.13 | 0.09 |
| August 2016 | 0.14 | 0.11 |
| July 2016 | 0.16 | 0.09 |
| June 2016 | 0.11 | 0.09 |
| May 2016 | 0.12 | 0.10 |
| April 2016 | 0.13 | 0.11 |

(1) Takes into account a 25:1 share consolidation that became effective in July 2013.

**B. *Plan of Distribution*.**

Not applicable.

**C. *Markets.***

On August 18, 2015 our ADSs and Warrants were listed on The NASDAQ Capital Market under the ticker symbols “BNTC” and “BNTCW,” respectively. Prior to our initial public offering in the United States, we did not list our ADSs on any other stock exchange.

**D. *Selling Shareholders.***

Not applicable.

**E. *Dilution*.**

Not applicable.

**Item 10. Additional Information.**

**A.** ***Share capital.***

Not applicable.

**B.** ***Memorandum and Articles of Association.***

Our Constitution is similar in nature to the bylaws of a U.S. corporation. It does not provide for or prescribe any specific objectives or purposes of Benitec. Our Constitution is subject to the terms of the ASX Listing Rules and the Corporations Act. It may be amended or repealed and replaced by special resolution of shareholders, which is a resolution passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution.

Under Australian law, a company has the legal capacity and powers of an individual both within and outside Australia. The material provisions of our Constitution are summarized below. This summary is not intended to be complete nor to constitute a definitive statement of the rights and liabilities of our shareholders, and is qualified in its entirety by reference to the complete text of our Constitution, a copy of which is on file with the Securities and Exchange Commission.

***Interested Directors***

A director may not vote in respect of any contract or arrangement in which the director has, directly or indirectly, any material interest according to our Constitution. Such director must not be counted in a quorum, must not vote on the matter and must not be present at the meeting while the matter is being considered. However, that director may execute or otherwise act in respect of that contract or arrangement notwithstanding any material personal interest.

Unless a relevant exception applies, the Corporations Act requires our directors to provide disclosure of certain interests or conflicts of interests and prohibits directors from voting on matters in which they have a material personal interest and from being present at the meeting while the matter is being considered. In addition, the Corporations Act and the ASX Listing Rules require shareholder approval of any provision of related party benefits to our directors.

***Directors' Compensation***

Our directors are paid remuneration for their services as directors (but excluding any remuneration payable to a director under any executive services contract with us or one of our related bodies corporate) which is determined in a general meeting of shareholders. The aggregate, fixed sum for directors' remuneration is to be divided among the directors in such proportion as the directors themselves agree and in accordance with our Constitution. The fixed sum remuneration for directors may not be increased except at a general meeting of shareholders and the particulars of the proposed increase are required to have been provided to shareholders in the notice convening the meeting. In addition, executive directors may be paid remuneration as employees of Benitec.

Fees payable to our non-executive directors must be by way of a fixed sum and not by way of a commission on or a percentage of profits or operating revenue. Remuneration paid to our executive directors must also not include a commission or percentage of operating revenue.

Pursuant to our Constitution, any director who performs services that in the opinion of our board of directors, are outside the scope of the ordinary duties of a director may be paid extra remuneration, which is determined by our board of directors.

In addition to other remuneration provided in our Constitution, all of our directors are entitled to be paid by us for reasonable travel accommodation and other expenses incurred by the directors in attending general meetings, board meetings, committee meetings or otherwise in connection with our business.

In addition, in accordance with our Constitution, a director may be paid a retirement benefit as determined by our board of directors subject to the limits set out in the Corporations Act and the ASX Listing Rules which broadly restrict our ability to pay our officers a termination benefit in the event of a change of control of the Company or our subsidiaries as well as impose requirements for shareholder approval to be obtained to pay certain retirement benefits to our officers.

***Borrowing Powers Exercisable by Directors***

Pursuant to our Constitution, the management and control of our business affairs are vested in our board of directors. Our board of directors has the power to raise or borrow money, and charge any of our property or business or any uncalled capital, and may issue debentures or give any other security for any of our debts, liabilities or obligations or of any other person, in each case, in the manner and on terms it deems fit.

***Retirement of Directors***

Pursuant to our Constitution and the ASX Listing Rules, one-third of our directors, other than the managing director, must retire from office at every annual general meeting. If the number of directors is not a multiple of three, then the number nearest, to but not exceeding, one-third must retire from office. The directors who retire in this manner are required to be the directors or director longest in office since last being elected. A director, other than the director who is the Chief Executive Officer, must retire from office at the conclusion of the third annual general meeting after which the director was elected. Retired directors are eligible for a re-election to the board of directors unless disqualified from acting as a director under the Corporations Act or our Constitution.

***Rights and Restrictions on Classes of Shares***

The rights attaching to our ordinary shares are detailed in our Constitution. Our Constitution provides that our directors may issue shares with preferred, deferred or other special rights, whether in relation to dividends, voting, return of share capital, or otherwise as our board of directors may determine. Subject to any approval which is required from our shareholders under the Corporations Act and the ASX Listing Rules (see "—Exemptions from Certain NASDAQ Corporate Governance Rules" and "—Change of Control"), any rights and restrictions attached to a class of shares, we may issue further shares on such terms and conditions as our board of directors resolve. Currently, our outstanding share capital consists of only one class of ordinary shares.

***Dividend Rights***

Our board of directors may from time to time determine to pay dividends to shareholders. All dividends unclaimed for one year after having been declared may be invested or otherwise made use of by our board of directors for our benefit until claimed or otherwise disposed of in accordance with our Constitution.

***Voting Rights***

Under our Constitution, and subject to any voting exclusions imposed under the ASX Listing Rules (which typically exclude parties from voting on resolutions in which they have an interest), the rights and restrictions attaching to a class of shares, each shareholder has one vote on a show of hands at a meeting of the shareholders unless a poll is demanded under the Constitution or the Corporations Act. On a poll vote, each shareholder shall have one vote for each fully paid share and a fractional vote for each share held by that shareholder that is not fully paid, such fraction being equivalent to the proportion of the amount that has been paid to such date on that share. Shareholders may vote in person or by proxy, attorney or representative. Under Australian law, shareholders of a public company are not permitted to approve corporate matters by written consent. Our Constitution does not provide for cumulative voting.

Note that ADS holders may not directly vote at a meeting of the shareholders but may instruct the depositary to vote the number of deposited ordinary shares their ADSs represent.

***Right To Share in Our Profits***

Pursuant to our Constitution, our shareholders are entitled to participate in our profits only by payment of dividends. Our board of directors may from time to time determine to pay dividends to the shareholders; however, no dividend is payable except in accordance with the thresholds set out in the Corporations Act.

***Rights to Share in the Surplus in the Event of Liquidation***

Our Constitution provides for the right of shareholders to participate in a surplus in the event of our liquidation, subject to the rights attaching to a class of shares.

***No Redemption Provision for Ordinary Shares***

There are no redemption provisions in our Constitution in relation to ordinary shares. Under our Constitution, any preference shares may be issued on the terms that they are, or may at our option be, liable to be redeemed.

***Variation or Cancellation of Share Rights***

Subject to the terms of issue of shares of that class, the rights attached to shares in a class of shares may only be varied or cancelled by a special resolution of Benitec, together with either:

- a special resolution passed by members holding shares in the class; or
- the written consent of members with at least 75% of the shares in the class.

***Directors May Make Calls***

Our Constitution provides that subject to the terms on which the shares have been issued directors may make calls on a shareholder for amounts unpaid on shares held by that shareholder, other than monies payable at fixed times under the conditions of allotment. Shares represented by the ADSs issued in our initial public offering in the United States were fully paid and are not subject to calls by directors.

**General Meetings of Shareholders**

General meetings of shareholders may be called by our board of directors. Except as permitted under the Corporations Act, shareholders may not convene a meeting. The Corporations Act requires the directors to call and arrange to hold a general meeting on the request of shareholders with at least 5% of the votes that may be cast at a general meeting or at least 100 shareholders who are entitled to vote at the general meeting. Notice of the proposed meeting of our shareholders is required at least 28 days prior to such meeting under the Corporations Act.

**Foreign Ownership Regulation**

There are no limitations on the rights to own securities imposed by our Constitution. However, acquisitions and proposed acquisitions of securities in Australian companies may be subject to review and approval by the Australian Federal Treasurer under the Foreign Acquisitions and Takeovers Act 1975, or the FATA, which generally applies to acquisitions or proposed acquisitions:

- by a foreign person (as defined in the FATA) or associated foreign persons that would result in such persons having an interest in 15% or more of the issued shares of, or control of 15% or more of the voting power in, an Australian company; and
- by non-associated foreign persons that would result in such foreign person having an interest in 40% or more of the issued shares of, or control of 40% or more of the voting power in, an Australian company, where the Australian company is valued above the monetary threshold prescribed by FATA.

However, no such review or approval under the FATA is required if the foreign acquirer is a U.S. entity and the value of the target is less than A$1,094 million.

The Australian Federal Treasurer may prevent a proposed acquisition in the above categories or impose conditions on such acquisition if the Treasurer is satisfied that the acquisition would be contrary to the national interest. If a foreign person acquires shares or an interest in shares in an Australian company in contravention of the FATA, the Australian Federal Treasurer may order the divestiture of such person's shares or interest in shares in that Australian company.

**Ownership Threshold**

There are no provisions in our Constitution that require a shareholder to disclose ownership above a certain threshold. The Corporations Act, however, requires a shareholder to notify us and the ASX once it, together with its associates, acquires a 5% interest in our ordinary shares, at which point the shareholder will be considered to be a "substantial" shareholder. Further, once a shareholder owns a 5% interest in us, such shareholder must notify us and the ASX of any increase or decrease of 1% or more in its holding of our ordinary shares, and must also notify us and the ASX on its ceasing to be a "substantial" shareholder. As we are now a U.S. public company, our shareholders are also subject to disclosure requirements under U.S. securities laws.

**Issues of Shares and Change in Capital**

Subject to our Constitution, the Corporations Act, the ASX Listing Rules and any other applicable law, we may at any time issue shares and grant options or warrants on any terms, with preferred, deferred or other special rights and restrictions and for the consideration and other terms that the directors determine.

Subject to the requirements of our Constitution, the Corporations Act, the ASX Listing Rules and any other applicable law, including relevant shareholder approvals, we may consolidate or divide our share capital into a larger or smaller number by resolution, reduce our share capital (provided that the reduction is fair and reasonable to our shareholders as a whole and does not materially prejudice our ability to pay creditors) or buy back our ordinary shares whether under an equal access buy-back or on a selective basis.

**Change of Control**

Takeovers of listed Australian public companies, such as Benitec, are regulated by the Corporations Act, which prohibits the acquisition of a "relevant interest" in issued voting shares in a listed company if the acquisition will lead to that person's or someone else's voting power in Benitec increasing from 20% or below to more than 20% or increasing from a starting point that is above 20% and below 90%, subject to a range of exceptions.

Generally, a person will have a relevant interest in securities if the person:

- is the holder of the securities;
- has power to exercise, or control the exercise of, a right to vote attached to the securities; or
- has the power to dispose of, or control the exercise of a power to dispose of, the securities, including any indirect or direct power or control.

If, at a particular time, a person has a relevant interest in issued securities and the person:

- has entered or enters into an agreement with another person with respect to the securities;

- has given or gives another person an enforceable right, or has been or is given an enforceable right by another person, in relation to the securities (whether the right is enforceable presently or in the future and whether or not on the fulfillment of a condition);
- has granted or grants an option to, or has been or is granted an option by, another person with respect to the securities; or
- the other person would have a relevant interest in the securities if the agreement were performed, the right enforced or the option exercised;

the other person is taken to already have a relevant interest in the securities.

There are a number of exceptions to the above prohibition on acquiring a relevant interest in issued voting shares above 20%. In general terms, some of the more significant exceptions include:

- when the acquisition results from the acceptance of an offer under a formal takeover bid;
- when the acquisition is conducted on market by or on behalf of the bidder under a takeover bid, the acquisition occurs during the bid period, the bid is for all the voting shares in a bid class and the bid is unconditional or only conditioned on prescribed matters set out in the Corporations Act;
- when shareholders of Benitec approve the takeover by resolution passed at general meeting;
- an acquisition by a person if, throughout the six months before the acquisition, that person or any other person has had voting power in Benitec of at least 19% and, as a result of the acquisition, none of the relevant persons would have voting power in Benitec more than three percentage points higher than they had six months before the acquisition;
- when the acquisition results from the issue of securities under a rights issue;
- when the acquisition results from the issue of securities under dividend reinvestment schemes;
- when the acquisition results from the issue of securities under underwriting arrangements;
- when the acquisition results from the issue of securities through operation of law;
- an acquisition that arises through the acquisition of a relevant interest in another listed company which is listed on a prescribed financial market or a financial market approved by ASIC;
- an acquisition arising from an auction of forfeited shares conducted on-market; or
- an acquisition arising through a compromise, arrangement, liquidation or buy-back.

Breaches of the takeovers provisions of the Corporations Act are criminal offenses. ASIC and the Australian Takeover Panel have a wide range of powers relating to breaches of takeover provisions, including the ability to make orders canceling contracts, freezing transfers of, and rights attached to, securities, and forcing a party to dispose of securities. There are certain defenses to breaches of the takeover provisions provided in the Corporations Act.

**Access to and Inspection of Documents**

Inspection of our records is governed by the Corporations Act. Any member of the public has the right to inspect or obtain copies of our registers on the payment of a prescribed fee. Shareholders are not required to pay a fee for inspection of our registers or minute books of the meetings of shareholders. Other corporate records, including minutes of directors' meetings, financial records and other documents, are not open for inspection by shareholders. Where a shareholder is acting in good faith and an inspection is deemed to be made for a proper purpose, a shareholder may apply to the court to make an order for inspection of our books.

**C.** ***Material Contracts.***

**Commonwealth Scientific & Industrial Research Organisation ("CSIRO") License Agreement**

In December 2009, we entered into a commercial license arrangement with CSIRO for two patent families relating to ddRNAi technology. This worldwide license in the field of human therapeutics is exclusive and irrevocable. In exchange for the license, we issued ordinary shares to CSIRO, and we are required to pay CSIRO approximately $300,000 in the event of corporate transactions such as a merger, sale, change of control, capital reconstruction or insolvency event relating to Benitec. Under the license agreement, following notice to us and receipt of our comments, if any, CSIRO has control over prosecution of patent applications and litigation, if any.

In January 2010, the Company reached a settlement with CSIRO to replace the existing Licence Agreement and Commercial Agreement with a new exclusive Licence Agreement for the use of intellectual property and the Capital Growth Agreement with the issue of ordinary shares. As part of the settlement, a Transition Agreement was put in place in order to facilitate the change from the old agreements to the new agreement and to deal with a number of other matters. Under the terms of the Transition Agreement, the Company agreed to pay CSIRO an amount of $297,293 for past patent costs only in the event of a trigger event, being either a corporate transaction or an insolvency event.

**Biomics Biotec Co., Ltd. ("Biomics") Research and Collaboration Agreement**

In August 2009, we entered into a collaborative agreement with 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$6.0 million, we would pay Biomics 1.5% of licensing revenue on any such additional amounts.

**NewSouth Innovations Ptd Limited Commercial License Agreement**

In August 2013, we 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 discontinued therapeutic product candidate for NSCLC. In October 2016, the license was terminated.

**4D Molecular Therapeutics, LLC ("4DMT") Collaborative Research and License Agreement**

In November 2014, we entered into a collaboration research and license agreement with 4DMT to develop a delivery vector for two ddRNAi-based therapies that we are developing, one for the treatment of wet AMD, which is designated BB-201, and the other potentially for both wet and dry AMD, which is designated BB-202.

**Strategic Relationship with Nant Capital, LLC**

On October 24, 2016, Benitec entered into a strategic engagement with Nant Capital, LLC. The strategic engagement includes a scientific collaboration in clinical programs and an immediate private placement to Nant Capital, LLC of 29,305,819 ordinary shares in Benitec, representing approximately 19.9% of its then outstanding issued capital (for a post-issue holding of approximately 16.7%). The shares were priced at $A0.0895 per share, representing the 7-day volume weighted average price of the ordinary shares on the ASX prior to the execution of a share purchase subscription agreement. Jerel A. Banks, the Chief Investment Officer of Nant Capital, LLC, was appointed to the Board of Benitec on October 25, 2016. See Item 8.B "Significant Changes."

**D.** ***Exchange Controls.***

The Australian dollar is convertible into U.S. dollars at freely floating rates. There are no legal restrictions on the flow of Australian dollars between Australia and the United States. Any remittances of dividends or other payments by Benitec to persons in the United States are not subject to any exchange controls.

**E.** ***Taxation*****.**

**U.S. Taxation**

This section describes the material U.S. federal income tax consequences to a U.S. holder of owning ordinary shares or ADSs or Warrants. It applies only to ordinary shares or ADSs or Warrants that are held as capital assets for tax purposes. This section does not apply to a holder of ordinary shares or ADSs or Warrants that is a member of a special class of holders subject to special rules, including a dealer in securities, a trader in securities who elects to use a mark-to-market method of accounting for its securities holdings, a tax-exempt organization, a life insurance company, a person liable for alternative minimum tax, a person who actually or constructively owns 10 per cent or more of the voting stock of the company, a person that holds ordinary shares or ADSs or Warrants as part of a straddle or a hedging or conversion transaction, a person that purchases or sells ordinary shares or ADSs or Warrants as part of a wash sale for tax purposes, or a person whose functional currency is not the U.S. dollar.

If a partnership holds the ordinary shares or ADSs or Warrants, the U.S. federal income tax treatment of a partner generally will depend on the status of the partner and the tax treatment of the partnership. A partner in a partnership holding the ordinary shares or ADSs or Warrants should consult its tax adviser with regard to the U.S. federal income tax treatment of an investment in the ordinary shares or ADSs or Warrants. This section is in part based on the representations of the Depositary and the assumption that each obligation in the deposit agreement and any related agreement will be performed in accordance with its terms.

In general, for U.S. federal income tax purposes, a holder of ADSs will be treated as the owner of the ordinary shares represented by those ADSs. Exchanges of ordinary shares for ADSs, and ADSs for ordinary shares generally will not be subject to U.S. federal income tax.

**Distributions**

Subject to the passive foreign investment company rules discussed below, U.S. holders generally will include as dividend income the U.S. dollar value of the gross amount of any distributions of cash or property (without deduction for any withholding tax), other than certain pro rata distributions of ordinary shares, with respect to ordinary shares to the extent the distributions are made from our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes. A U.S. holder will include the dividend income on the day actually or constructively received by the holder, in the case of ordinary shares, or by the depositary, in the case of ADSs. We do not intend to maintain calculations of earnings and profits, as determined for U.S. federal income tax purposes. Consequently, any distributions generally will be reported as dividend income.

Dividends paid to a non-corporate U.S. holder on shares or ADSs will generally be taxable at the preferential rates applicable to long-term capital gains provided (a) that certain holding period requirements are satisfied, (b) the U.S.-Australia income tax treaty is a qualified treaty and we are eligible for benefits under the treaty or our ordinary shares or ADSs are readily tradable on a U.S. securities market, and (c) provided that we were not, in the taxable year prior to the year in which the dividend was paid, and are not, in the taxable year in which the dividend is paid, a PFIC. The Treaty has been approved for the purposes of the qualified dividend rules and the ADSs and Warrants are listed on NASDAQ. We do not believe we were a PFIC in 2014 and do not expect to be a PFIC for 2015. However, our status in the current year and future years will depend in part upon our use of the funds from the U.S. initial public offering as well as our income and assets (which for this purpose depends in part on the market value of our shares) in those years. You should consult your tax adviser regarding the availability of the reduced tax rate on qualified dividends. In the case of a corporate U.S. holder, dividends on shares and ADSs are taxed as ordinary income and will not be eligible for the dividends received deduction generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations.

The amount of any cash distribution paid in any foreign currency will be equal to the U.S. dollar value of such currency, calculated by reference to the spot rate in effect on the date such distribution is received by the U.S. holder or, in the case of ADSs, by the Depositary, regardless of whether and when the foreign currency is in fact converted into U.S. dollars. If the foreign currency is converted into U.S. dollars on the date received, the U.S. holder generally should not recognize foreign currency gain or loss on such conversion. If the foreign currency is not converted into U.S. dollars on the date received, the U.S. holder will have a basis in the foreign currency equal to its U.S. dollar value on the date received, and generally will recognize foreign currency gain or loss on a subsequent conversion or other disposal of such currency. Such foreign currency gain or loss generally will be treated as U.S. source ordinary income or loss for foreign tax credit limitation purposes.

Dividends will be income from sources outside the United States, and generally will be "passive category" income or, for certain taxpayers, "general category" income, which are treated separately from each other for the purpose of computing the foreign tax credit allowable to a U.S. holder. In general, a taxpayer's ability to use foreign tax credits may be limited and is dependent on the particular circumstances. U.S. holders should consult their own tax advisers with respect to these matters.

**Sale, Exchange or other Disposition of Ordinary Shares or ADSs or Warrants**

Subject to the PFIC rules discussed below, a U.S. holder who sells or otherwise disposes of ordinary shares or ADSs or Warrants will recognize a capital gain or loss for U.S. federal income tax purposes equal to the difference between the U.S. dollar value of the amount realized and the holder's tax basis, determined in U.S. dollars, in those ordinary shares or ADSs or Warrants. The gain or loss will generally be income or loss from sources within the United States for foreign tax credit limitation purposes. The capital gain of a non-corporate U.S. holder is generally taxed at preferential rates where the holder has a holding period greater than 12 months in the shares or ADSs or Warrants sold. There are limitations on the deductibility of capital losses.

The U.S. dollar value of any foreign currency received upon a sale or other disposition of ordinary shares or ADSs or Warrants will be calculated by reference to the spot rate in effect on the date of sale or other disposal (or, in the case of a cash basis or electing accrual basis taxpayer, on the settlement date). A U.S. holder will have a tax basis in the foreign currency received equal to that U.S. dollar amount, and generally will recognize foreign currency gain or loss on a subsequent conversion or other disposal of the foreign currency. This foreign currency gain or loss generally will be treated as U.S. source ordinary income or loss for foreign tax credit limitation purposes.

**Passive Foreign Investment Company**

A non-U.S. corporation will be a PFIC for U.S. federal income tax purposes for any taxable year if either:

(a) 75 per cent or more of its gross income for such year is "passive income" which for this purpose generally includes dividends, interest, royalties, rents and gains from commodities and securities transactions and gains from assets that produce passive income (the "Income Test"); or

(b) 50 per cent or more of the value of its gross assets (based on an average of the quarterly values of the gross assets) during such year is attributable to assets that produce passive income or are held for the production of passive income (the "Asset Test").

We believe the Company qualified as a PFIC for fiscal 2016. This arose because of the decline in the Company's stock price coupled with the fact that the applicable PFIC rules treat working capital as a passive asset for purposes of the PFIC Asset Test. As a consequence, any gain realised on the sale or other disposition of ordinary shares or ADSs or warrant would in general not be treated as a capital gain. Instead, a U.S. holder would be treated as if it had realised such gain and certain "excess distributions" ratably over its holding period for the ordinary shares or ADSs or Warrants and would be taxed at the highest tax rate in effect for each such year to which the gain was allocated, together with an interest charge in respect of the tax attributable to each such year. In addition, dividends received with respect to ordinary shares or ADSs would not be eligible for the special tax rates applicable to qualified dividend income if the company were a PFIC either in the taxable year of the distribution or the preceding taxable year, but instead would be taxable under the tax rules described above. Assuming the shares or ADSs are "marketable stock", a U.S. holder may mitigate the adverse tax consequences described above by timely electing to be taxed annually on a mark-to-market basis with respect to such shares or ADSs.

Holders of PFIC stock are subject to additional U.S. information reporting rules. If a U.S. holder owns ordinary shares or ADSs or warrants during any year in which we are a PFIC, the U.S. holder generally will be required to file an IRS Form 8621 ("Information Return by a Shareholder of a PFIC or Qualified Electing Fund") with respect to the Company, generally with the U.S. holder's federal income tax return for that year.

**U.S. Holders should consult their tax advisors with respect to the Company's status as a PFIC, the availability and desirability of a mark-to-market election, and such U.S. Holder's information reporting obligations.**

**Australian Tax Considerations**

In this section, we discuss the material Australian income tax, stamp duty and goods and services tax considerations related to the acquisition, ownership and disposal by the absolute beneficial owners of the ordinary shares, ADSs or Warrants.

It is based upon existing Australian tax law as of the date of this registration statement, which is subject to change, possibly retrospectively. This discussion does not address all aspects of Australian tax law which may be important to particular investors in light of their individual investment circumstances, such as shares held by investors subject to special tax rules (for example, financial institutions, insurance companies or tax exempt organizations). In addition, this summary does not discuss any foreign or state tax considerations, other than stamp duty and goods and services tax.

Prospective investors are urged to consult their tax advisors regarding the Australian and foreign income and other tax considerations of the acquisition, ownership and disposition of the shares or warrants. As used in this summary a "Non-Australian Shareholder" is a holder that is not an Australian tax resident and is not carrying on business in Australia through a permanent establishment.

***Nature of ADSs for Australian Taxation Purposes***

Ordinary shares represented by ADSs held by a U.S. holder will be treated for Australian taxation purposes as held under a "bare trust" for such holder. Consequently, the underlying ordinary shares will be regarded as owned by the ADS holder for Australian income tax and capital gains tax purposes. Any dividends paid on the underlying ordinary shares will also be treated as dividends paid to the ADS holder, as the person beneficially entitled to those dividends. Therefore, in the following analysis we discuss the tax consequences to Non-Australian Shareholders of ordinary shares for Australian taxation purposes. We note that the holder of an ADS will be treated for Australian tax purposes as the owner of the underlying ordinary shares that are represented by such ADSs.

***Taxation of Dividends***

Australia operates a dividend imputation system under which dividends may be declared to be "franked" to the extent of tax paid on company profits. Fully franked dividends are not subject to dividend withholding tax. An exemption for dividend withholding tax can also apply to unfranked dividends that are declared to be conduit foreign income, or CFI, and paid to Non-Australian Shareholders. Dividend withholding tax will be imposed at 30%, unless a shareholder is a resident of a country with which Australia has a double taxation agreement and qualifies for the benefits of the treaty. Under the provisions of the current Double Taxation Convention between Australia and the United States, the Australian tax withheld on unfranked dividends that are not declared to be CFI paid by us to a resident of the United States which is beneficially entitled to that dividend is limited to 15% where that resident is a qualified person for the purposes of the Double Taxation Convention between Australia and the United States.

If a Non-Australian Shareholder is a company and owns a 10% or more interest, the Australian tax withheld on dividends paid by us to which a resident of the United States is beneficially entitled is limited to 5%. In limited circumstances the rate of withholding can be reduced to zero.

***Exercise of Warrants***

Any capital gain or loss on exercise of a warrant is disregarded. The amount paid to acquire the warrant, and the amount paid to exercise the warrant, are both included in the cost base and reduced cost base of the ordinary shares underlying the Warrants.

***Tax on Sales or other Dispositions of Shares or Warrants—Capital gains tax***

Non-Australian Shareholders will not be subject to Australian capital gains tax on the gain made on a sale or other disposal of ordinary shares or warrants (or recognise a capital loss on the lapse of a warrant), unless they, together with associates, hold 10% or more of our issued capital, at the time of disposal or for 12 months of the last 2 years prior to disposal.

Non-Australian Shareholders who own a 10% or more interest would be subject to Australian capital gains tax if more than 50% of our direct or indirect assets, determined by reference to market value, consists of Australian land, leasehold interests or Australian mining, quarrying or prospecting rights. The Double Taxation Convention between the United States and Australia is unlikely to limit Australia's right to tax any gain in these circumstances. Net capital gains are calculated after reduction for capital losses, which may only be offset against capital gains.

***Tax on Sales or other Dispositions of Shares or Warrants—Shareholders Holding Shares and Warrants on Revenue Account***

Some Non-Australian Shareholders may hold shares on revenue rather than on capital account for example, share traders. These shareholders may have the gains made on the sale or other disposal of the shares and/or warrants included in their assessable income under the ordinary income taxing provisions of the income tax law, if the gains are sourced in Australia.

Non-Australian Shareholders assessable under these ordinary income provisions in respect of gains made on shares and/or warrants held on revenue account would be assessed for such gains at the Australian tax rates for non-Australian residents, which start at a marginal rate of 32.5%. This rate does not include the Temporary Budget Repair Levy of 2% that applies in certain circumstances. Some relief from Australian income tax may be available to Non-Australian Shareholders under the Double Taxation Convention between the United States and Australia.

To the extent an amount would be included in a Non-Australian Shareholder's assessable income under both the capital gains tax provisions and the ordinary income provisions, the capital gain amount would generally be reduced, so that the shareholder would not be subject to double tax on any part of the income gain or capital gain.

***Dual Residency***

If a shareholder is a resident of both Australia and the United States under those countries' domestic taxation laws, that shareholder may be subject to tax as an Australian resident. If, however, the shareholder is determined to be a U.S. resident for the purposes of the Double Taxation Convention between the United States and Australia, the Australian tax would be subject to limitation by the Double Taxation Convention. Shareholders should obtain specialist taxation advice in these circumstances.

***Stamp Duty***

No stamp duty is payable by Australian residents or non-Australian residents on the issue and trading of shares or warrants that are quoted on the ASX or NASDAQ at all relevant times and the shares do not represent 90% or more of all of our issued shares.

***Australian Death Duty***

Australia does not have estate or death duties. As a general rule, no capital gains tax liability is realized upon the inheritance of a deceased person's shares. The disposal of inherited shares by beneficiaries may, however, give rise to a capital gains tax liability if the gain falls within the scope of Australia's jurisdiction to tax.

***Goods and Services Tax***

The issue or transfer of shares or warrants to a non-Australian resident investor will not incur Australian goods and services tax.

**F.** ***Dividends and Paying Agents.***

Not applicable.

**G.** ***Statement by Experts.***

Not applicable.

**H.** ***Documents on Display.***

Inspection of our records is governed by the Corporations Act. Any member of the public has the right to inspect or obtain copies of our registers on the payment of a prescribed fee. Shareholders are not required to pay a fee for inspection of our registers or minute books of the meetings of shareholders. Other corporate records, including minutes of directors' meetings, financial records and other documents, are not open for inspection by shareholders. Where a shareholder is acting in good faith and an inspection is deemed to be made for a proper purpose, a shareholder may apply to the court to make an order for inspection of our books.

We file periodic reports and information with the Securities and Exchange Commission. You may inspect a copy of these reports without charge at the Public Reference Room of the Securities and Exchange Commission at

100 F Street N.E., Washington, D.C. 20549 or at the Securities and Exchange Commission's regional offices 233 Broadway, New York, New York 10279 and 500 West Madison Street, Suite 1400, Chicago, Illinois 60661. The public may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission also maintains an Internet site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Securities and Exchange Commission. The Securities and Exchange Commission's World Wide Web address is http://www.sec.gov.

Our ADSs and Warrants are listed on The NASDAQ Capital Market. As a result, we are subject to the periodic reporting requirements of the Exchange Act and we file reports and other information with the Securities and Exchange Commission. These reports and other information and the registration statement and exhibits and schedules thereto may be inspected without charge at, and copies thereof may be obtained at prescribed rates from, the public reference facilities of the Securities and Exchange Commission and the electronic sources listed in the preceding paragraph.

We prepare annual and other reports. Our annual reports contain financial statements examined and reported upon, with opinions expressed by our independent auditors. Our consolidated financial statements included in these annual reports are prepared in conformity with IFRS. Our annual and other reports to our shareholders are posted on the "Investor Centre" page of our website at http://www.benitec.com. In furnishing our web site address in this report, however, we do not intend to incorporate any information on our web site into this report, and any information on our web site should not be considered to be part of this report.

We will also furnish the depositary with all notices of shareholder meetings and other reports and communications that are made generally available to our shareholders. The depositary, to the extent permitted by law, shall arrange for the transmittal to the registered holders of American Depositary Receipts of all notices, reports and communications, together with the governing instruments affecting our shares and any amendments thereto. Such documents are also available for inspection by registered holders of American Depositary Receipts at the principal office of the depositary.

**I.** ***Subsidiary Information*****.**

Not applicable.

**Item 11. Quantitative and Qualitative Disclosures About Market Risk.**

We are exposed to market risk related to changes in interest rates and exchange rates.

As of June 30, 2016, 2015 and 2014, we had cash and cash equivalents of A$18.2 million, A$21.8 million and A$31.4 million, respectively, primarily held in bank accounts and term deposits. Our primary exposure to market risk is interest rate sensitivity, which is affected primarily by changes in the general level of Australian interest rates. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% increase in interest rates would not have a material effect on the fair market value of our portfolio.

We are exposed to fluctuations in foreign currencies that arise from foreign currencies held in bank accounts and the translation of results from our operations outside Australia. Our foreign exchange exposure is primarily the U.S. dollar. Foreign currency risks arising from commitments in foreign currencies are managed by holding cash in that currency. Foreign currency translation risk is not hedged.

See Note 18 of our June 30, 2016 financial statements included in this Annual Report on Form 20-F for more detailed information on our financial risk management.

**Item 12. Description of Securities Other than Equity Securities.**

**A.** ***Debt Securities*****.**

Not applicable.

**B.** ***Warrants and Rights.***

Not applicable.

**C.** ***Other Securities.***

Not applicable.

**D.** ***American Depositary Shares.***

**Fees and Expenses**

| **Persons depositing or withdrawing ordinary shares or ADS holders must pay the depositary:** | **For:** |
|---|---|
| $5.00 (or less) per 100 ADSs (or portion of 100 ADSs) | • Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property<br>• Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates |
| $.05 (or less) per ADS | • Any cash distribution to you |
| A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs | • Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to you |
| $.05 (or less) per ADS per calendar year | • Depositary services |
| Registration or transfer fees | • Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares |
| Expenses of the depositary | • Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement)<br>• Converting foreign currency to U.S. dollars |
| Taxes and other governmental charges the depositary or the custodian have to pay on any ADS or share underlying an ADS, for example, stock transfer taxes, stamp duty or withholding taxes | • As necessary |
| Any charges incurred by the depositary or its agents for servicing the deposited securities | • As necessary |

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid. The depositary may collect any of its fees by deduction from any cash distribution payable to you that are obligated to pay those fees.

From time to time, the depositary may make payments to us to reimburse or share revenue from the fees collected from you, or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the ADS program. In performing its duties under the deposit agreement, the depositary may use brokers, dealers or other service providers that are affiliates of the depositary and that may earn or share fees or commissions.

## PART II

### Item 13. Defaults, Dividend Arrearages and Delinquencies

Not applicable.

### Item 14. Material Modifications to the Rights of Security Holders and the Use of Proceeds

**Use of Proceeds**

On August 24, 2015, we completed an initial public offering in the United States on The NASDAQ Capital Market of 1,500,000 American Depositary Shares (ADSs), representing 30,000,000 fully paid ordinary shares of Benitec, together with warrants to purchase 500,000 ADSs, representing 10,000,000 fully paid ordinary shares, pursuant to a Registration Statement on Form F-1, as amended (File No. 333-205135), which became effective on August 17, 2015. Maxim Group LLC was the sole underwriter. Each ADS represents 20 ordinary shares of Benitec. We granted the underwriter a 45-day option to purchase up to an additional 225,000 ADSs and/or 75,000 warrants to purchase ADSs to cover over-allotments, if any. Simultaneously with the closing, we issued and sold 75,000 warrants in connection with the underwriter's partial exercise of such option.

Pursuant to the initial public offering in the United States, we sold a total of 1,500,000 ADSs (including the ADSs sold pursuant to the over-allotment option) at a price of $9.21 per ADS and warrants to purchase 575,000 ADSs (including the warrants to purchase ADSs sold pursuant to the over-allotment option) at a price of $0.01 per warrant. The aggregate offering price of the ADSs and warrants to purchase ADSs (including the over-allotment option) was approximately $13.8 million. The total expenses of the offering, including underwriting discounts and commissions, were approximately $2.8 million. The net proceeds we received from the offering (including the over-allotment option) were approximately $11.0 million.

As of October 31, 2015, we have begun, and intend to continue, to use the net proceeds we received from our initial public offering as disclosed in our Registration Statement on Form F-1. None of proceeds from our initial public offering in the United States were used for direct or indirect payments to our directors, officers or their associates, or to persons owning 10% or more of our equity securities, or to our affiliates.

### Item 15. Controls and Procedures

**Disclosure Controls and Procedures**

As of June 30, 2016, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act).

Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective to provide reasonable assurance that the information we are required to disclose in the reports we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management to allow timely decisions regarding required disclosures.

There are inherent limitations to the effectiveness of any disclosure controls and procedures system, including the possibility of human error and circumventing or overriding them. Even if effective, disclosure controls and procedures can provide only reasonable assurance of achieving their control objectives.

**Management's Annual Report on Internal Control over Financial Reporting**

The Management of Benitec is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of June 30, 2016 based on the criteria set forth in "Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission" ("COSO 2013"). Based on our evaluation under the criteria set forth in COSO 2013, our management concluded that our internal control over financial reporting was effective as of June 30, 2016.

**Attestation Report of the Registered Public Accounting Firm**

Not applicable. As an emerging growth company, we are not required to provide an attestation report of the company's registered public accounting firm on management's assessment regarding internal control over financial reporting.

**Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting that occurred during the period covered by this annual report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 16A. Audit Committee Financial Expert**

Each member of our audit committee meets the financial literacy requirements of the listing standards of The NASDAQ Capital Market. Megan Boston acts as the chairman of the audit committee, and our board of directors has determined that Megan Boston is an audit committee "financial expert," as defined by Item 407(d) of Regulation S-K under the Securities Act.

**Item 16B. Code of Ethics**

We have established a Code of Conduct, which sets out the standards of behavior that apply to every aspect of our dealings and relationships, both within and outside Benitec. The Code of Conduct applies to all directors, executive officers and employees of Benitec. The Code of Conduct is available on our website at www.benitec.com. For additional information regarding our Code of Conduct, see Item 6.C., "Directors, Senior Management and Employees - Board Practices - Code of Conduct."

**Item 16C. Principal Accountant Fees and Services**

During the financial year the following fees were paid or payable for services provided by Grant Thornton Audit Pty Ltd, the auditor of the Company:

| | 2016 A$ | 2015 A$ |
|---|---|---|
| Audit Fees | 178,250 | 95,000 |
| Audit-Related Fees | 33,895 | — |
| Tax Fees | 22,250 | 20,050 |
| All Other Fees - IPO services | — | 180,000 |
| Total | 234,395 | 295,050 |

Our audit committee reviews and pre-approves all audit services and permitted non-audit services (including the fees and other terms) to be provided by our independent auditors.

**Item 16D. Exemptions from the Listing Standards for Audit Committees.**

Not applicable.

**Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

Not applicable.

**Item 16F. Changes in Registrant's Certifying Accountant**

Not applicable.

**Item 16G. Corporate Governance**

**Implications of Being an Emerging Growth Company**

Pursuant to The Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), we are classified as an "Emerging Growth Company." Under the JOBS Act, Emerging Growth Companies are exempt from certain reporting requirements, including the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. Under this exemption, our auditor will not be required to attest to and report on management's assessment of our internal controls over financial reporting during a five-year transition period. We may avail ourselves of these disclosure exemptions until we are no longer an emerging growth company.

Pursuant to the JOBS Act, we will remain an Emerging Growth Company until the earliest of:

- the end of the fiscal year in which the fifth anniversary of completion of our initial public offering in the United States;
- the end of the first fiscal year in which the market value of our ordinary shares held by non-affiliates exceeds US$700 million as of the end of the second quarter of such fiscal year;
- the end of the first fiscal year in which we have total annual gross revenues of at least US$1 billion; and
- the date on which we have issued more than US$1 billion in non-convertible debt securities in any rolling three-year period.

**Implications of Being a Foreign Private Issuer**

We are also considered a "foreign private issuer." In our capacity as a foreign private issuer, we are exempt from certain rules under the U.S. Securities Exchange Act of 1934, as amended (the "Exchange Act"), that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our ordinary shares. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

**Exemptions from Certain NASDAQ Corporate Governance Rules**

The NASDAQ listing rules allow for a foreign private issuer, such as Benitec, to follow its home country practices in lieu of certain of the NASDAQ's corporate governance standards. In connection with our NASDAQ Listing Application, we have relied on and expect to continue to rely on exemptions from certain corporate governance standards that are contrary to the laws, rules, regulations or generally accepted business practices in Australia. These exemptions are described below:

- Although the majority of our directors currently qualify as independent under the NASDAQ Listing Rules, we have relied on and expect in the future to continue to rely on an exemption from these independence requirements for a majority of our board of directors as prescribed by NASDAQ Listing Rules. The ASX Listing Rules do not require us to have a majority of independent directors although ASX Corporate Governance Principles and Recommendations do recommend a majority of independent directors. During fiscal 2015, we did, however, have a majority of directors who were "independent" as defined in the ASX Corporate Governance Principles and Recommendations, which definition differs from NASDAQ's definition. Accordingly, because Australian law and generally accepted business practices in Australia regarding director independence differ from the independence requirements under NASDAQ Listing Rules, we may seek to claim this exemption in the future.

- We have relied on and expect to continue to rely on an exemption from the requirement that our independent directors meet regularly in executive sessions under NASDAQ Listing Rules. The ASX Listing Rules and the Corporations Act do not require the independent directors of an Australian company to have such executive sessions and, accordingly, we seek to claim this exemption.
- We have relied on and expect to continue to rely on an exemption from the quorum requirements applicable to meetings of shareholders under NASDAQ Listing Rules. In compliance with Australian law, our Constitution provides that three shareholders present, in person or by proxy, attorney or a representative, shall constitute a quorum for a general meeting. NASDAQ Listing Rules require that an issuer provide for a quorum as specified in its by-laws for any meeting of the holders of ordinary shares, which quorum may not be less than $33^{1/3}$% of the outstanding shares of an issuer's voting ordinary shares. Accordingly, because applicable Australian law and rules governing quorums at shareholder meetings differ from NASDAQ's quorum requirements, we seek to claim this exemption.
- We will rely an exemption from the requirement that at least two members of a compensation committee be "independent" as defined in NASDAQ Rule 5605(a)(2). The ASX Listing Rules and Australian law do not require an Australian company to establish a compensation committee, known in Australia as a remuneration committee, which is comprised solely of non-executive directors if the company is not included in the S&P/ASX300 Index at the beginning of its fiscal year. Benitec was not included on the S&P/ASX300 Index at the beginning of its last fiscal year and, hence, is not required under ASX Listing Rules to have a remuneration (compensation) committee. The ASX Corporate Governance Principles and Recommendations contain a non-binding recommendation that all ASX-listed companies should have a remuneration committee comprised of at least three members, a majority of whom (including the chair) are "independent". While these recommendations contain guidelines for assessing independence, ASX-listed entities are able to adopt their own definitions of an independent director for this purpose and is different from the definition in NASDAQ Rule 5605(a)(2). That being said, Benitec has, and expects to continue to have, a Remuneration and Nominations Committee consisting of three non-executive directors.

We have relied on and expect to continue to rely on an exemption from the requirement prescribed by NASDAQ Listing Rules that issuers obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions, private placements of securities, or the establishment or amendment of certain stock option, purchase or other compensation plans. Applicable Australian law and the ASX Listing Rules differ from NASDAQ requirements, with the ASX Listing Rules providing generally for prior shareholder approval in numerous circumstances, including (i) issuance of equity securities exceeding 15% of our issued share capital in any 12-month period (but, in determining the 15% limit, securities issued under an exception to the rule or with shareholder

approval are not counted), (ii) issuance of equity securities to related parties (as defined in the ASX Listing Rules) and (iii) issuances of securities to directors or their associates under an employee incentive plan. Due to differences between Australian law and rules and the NASDAQ shareholder approval requirements, we seek to claim this exemption.

**Item 16H. Mine Safety Disclosure**

Not applicable.

## PART III

### Item 17. Financial Statements

Refer to “Item 18 – Financial Statements” below

### Item 18. Financial Statements

Our Consolidated Financial Statements commencing on page F-1, as set forth in the following index, are hereby incorporated herein by reference. These Consolidated Financial Statements are filed as part of this Annual Report.

## INDEX TO FINANCIAL STATEMENTS

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**BOARD OF DIRECTORS AND SHAREHOLDERS**
**BENITEC BIOPHARMA LIMITED**

We have audited the accompanying consolidated statement of financial position of Benitec Biopharma Limited and subsidiaries (the "Group") as of June 30, 2016 and 2015, and the related consolidated statement of profit or loss and other comprehensive income, changes in equity, and cash flows for each of the two years in the period ended June 30, 2016. These financial statements are the responsibility of the Group's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Group's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Benitec Biopharma Limited and subsidiaries as of June 30, 2016 and 2015, and the results of their operations and their cash flows for each of the two years in the period ended June 30, 2016 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

GRANT THORNTON AUDIT PTY LTD
Chartered Accountants
Sydney, NSW, Australia

October 28, 2016

**Statement of profit or loss and other comprehensive income**
**For the year ended 30 June 2016**

| | Note | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|---|
| **Revenue** | 4 | 464 | 1,081 |
| Other income | 5 | 3,590 | 2,891 |
| **Expenses** | | | |
| Royalties and licence fees | | (139) | (40) |
| Research and development | 6 | (13,287) | (6,228) |
| Employee benefits expense | | (6,283) | (3,425) |
| Share-based expense | | (1,746) | (1,503) |
| Travel related costs | | (1,023) | (1,039) |
| Consultants costs | | (1,020) | (882) |
| Occupancy costs | | (718) | (275) |
| Corporate expenses | | (1,211) | (1,018) |
| Net loss foreign exchange | | (414) | — |
| IPO costs | | (1,191) | (1,071) |
| Writeoff of clinical trial prepayment | 10 | (1,800) | — |
| **Loss before income tax benefit** | | (24,778) | (11,509) |
| Income tax benefit | 7 | — | — |
| **Loss after income tax benefit for the year attributable to the owners of Benitec Biopharma Limited** | 16 | (24,778) | (11,509) |
| **Other comprehensive income** | | | |
| *Items that may be reclassified subsequently to profit or loss* | | | |
| Foreign currency translation | | (19) | 6 |
| **Total comprehensive income for the year attributable to the owners of Benitec Biopharma Limited** | | (24,797) | (11,503) |
| | | **Cents** | **Cents** |
| Basic earnings per share | 28 | (17.41) | (9.96) |
| Diluted earnings per share | 28 | (17.41) | (9.96) |

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

**Statement of financial position**
**As at 30 June 2016**

| | Note | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|---|
| **Assets** | | | |
| **Current assets** | | | |
| Cash and cash equivalents | 8 | 18,230 | 21,787 |
| Trade and other receivables | 9 | 977 | 123 |
| Other current assets | 10 | 177 | 3,154 |
| Total current assets | | 19,384 | 25,064 |
| **Non-current assets** | | | |
| Property, plant and equipment | 11 | 506 | 456 |
| Total non-current assets | | 506 | 456 |
| **Total assets** | | 19,890 | 25,520 |
| **Liabilities** | | | |
| **Current liabilities** | | | |
| Trade and other payables | 12 | 833 | 1,449 |
| Provisions | 13 | 202 | 193 |
| Total current liabilities | | 1,035 | 1,642 |
| **Non-current liabilities** | | | |
| Provisions | | 18 | — |
| Total non-current liabilities | | 18 | — |
| **Total liabilities** | | 1,053 | 1,642 |
| **Net assets** | | 18,837 | 23,878 |
| **Equity** | | | |
| Issued capital | 14 | 147,641 | 129,631 |
| Reserves | 15 | 2,565 | 2,038 |
| Accumulated losses | 16 | (131,369) | (107,791) |
| **Total equity** | | 18,837 | 23,878 |

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

**Statement of changes in equity**
**For the year ended 30 June 2016**

| Consolidated | Issued capital $'000 | Reserves $'000 | Accumulated losses $'000 | Total equity $'000 |
|---|---|---|---|---|
| Balance at 1 July 2014 | 129,186 | 641 | (96,286) | 33,541 |
| Loss after income tax benefit for the year | — | — | (11,509) | (11,509) |
| Other comprehensive income for the year, net of tax | — | 6 | — | 6 |
| Total comprehensive income for the year | — | 6 | (11,509) | (11,503) |
| *Transactions with owners in their capacity as owners:* | | | | |
| Contributions of equity, net of transaction costs | 337 | — | — | 337 |
| Share-based payments | — | 1,503 | — | 1,503 |
| Transfer of expired share-based payments | — | (4) | 4 | — |
| Transfer to share capital for options exercised | 108 | (108) | — | — |
| Balance at 30 June 2015 | 129,631 | 2,038 | (107,791) | 23,878 |

| Consolidated | Issued capital $'000 | Reserves $'000 | Accumulated losses $'000 | Total equity $'000 |
|---|---|---|---|---|
| Balance at 1 July 2015 | 129,631 | 2,038 | (107,791) | 23,878 |
| Loss after income tax benefit for the year | — | — | (24,778) | (24,778) |
| Other comprehensive income for the year, net of tax | — | (19) | — | (19) |
| Total comprehensive income for the year | — | (19) | (24,778) | (25,797) |
| *Transactions with owners in their capacity as owners:* | | | | |
| Contributions of equity, net of transaction costs (note 14) | 18,010 | — | — | 18,010 |
| Share-based payments (note 29) | — | 1,746 | — | 1,746 |
| Transfer of expired share-based payments | — | (1,200) | 1,200 | — |
| Balance at 30 June 2016 | 147,641 | 2,565 | (131,369) | 18,837 |

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

**Statement of cash flows**
**For the year ended 30 June 2016**

| | Note | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|---|
| **Cash flows from operating activities** | | | |
| Receipts from customers (inclusive of GST) | | 340 | 307 |
| Research and development grants | | 3,590 | 2,318 |
| Interest received | | 217 | 774 |
| Payments to suppliers and employees (inclusive of GST) | | (24,355) | (13,091) |
| Net cash used in operating activities | 27 | (20,208) | (9,692) |
| **Cash flows from investing activities** | | | |
| Purchase of property, plant and equipment | 11 | (342) | (505) |
| Net cash used in investing activities | | (342) | (505) |
| Cash flows from financing activities | | | |
| Proceeds from issue of shares | | 19,462 | 385 |
| IPO and share issue transaction costs | | (1,952) | (333) |
| Net cash from financing activities | | 17,510 | 52 |
| Net decrease in cash and cash equivalents | | (3,040) | (10,145) |
| Cash and cash equivalents at the beginning of the financial year | | 21,787 | 31,359 |
| Effects of exchange rate changes on cash and cash equivalents | | (517) | 573 |
| Cash and cash equivalents at the end of the financial year | 8 | 18,230 | 21,787 |

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

**Notes to the financial statements**
**30 June 2016**

**Note 1. Significant accounting policies**

The principal accounting policies adopted in the preparation of the financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

**New, revised or amending Accounting Standards and Interpretations adopted**

In the current year, the Group has applied two amendments to AASBs issued by the Australian Accounting Standards Board (AASB) that are mandatorily effective for an accounting period that begins on or after 1 July 2015, and therefore relevant for the current year end.

AASB 2015-3 'Amendments to Accounting Standards arising from the Withdrawal of AASB 1031 Materiality'

This amendment completes the withdrawal of references to AASB 1031 in all Australian Accounting Standards and Interpretations, Australian allowing that Standard to effectively be withdrawn.

AASB 2015-4'Amendments to Accounting Financial Requirements Australian Groups with Foreign Parent'

The amendments to AASB 128 align the relief available in AASB 10 and AASB 128 in respect of the financial reporting requirements for Australian groups with a foreign parent. The amendments require Standards that the ultimate Australian entity shall apply the equity method in reporting accounting for interests in associates and joint ventures if either the Australian entity or the group is a reporting entity, or both the entity and group a are reporting entities.

The application of these amendments does not have any material impact on the disclosures or the amounts recognised in the Group's consolidated financial statements.

**New Accounting Standards and Interpretations not yet mandatory or early adopted**

Certain new accounting standards and interpretations have been published that are not mandatory for 30 June 2016 reporting periods and have not been early adopted by the group. The group's assessment of the impact of these new standards and interpretations is set out below.

- AASB 9 *Financial Instruments* - addresses the classification, measurement and derecognition of financial assets and financial liabilities and introduces new rules for hedge accounting. In December 2014, the AASB made further changes to the classification and measurement rules and also introduced a new impairment model. These latest amendments now complete the new financial instruments standard.
- Impact - The entity is yet to undertake a detailed assessment of the impact of AASB 9. However, based on the entity's preliminary assessment, the Standard is not expected to have a material impact on the transactions and balances recognised in the financial statements when it is first adopted for the year ending 30 June 2019.

  Mandatory application date / Date of adoption by group - Must be applied for financial years commencing on or after 1 January 2018.

  Based on the transitional provisions in the completed IFRS 9, early adoption in phases was only permitted for annual reporting periods beginning before 1 February 2015. After that date, the new rules must be adopted in their entirety.
- AASB 15 Revenue from Contracts with Customers - The AASB has issued a new standard for the recognition of revenue. This will replace AASB 118 which covers contracts for goods and services. The new standard is based on the principle that revenue is recognised when control of a good or service transfers to a customer; so the notion of control replaces the existing notion of risks and rewards.

**Note 1. Significant accounting policies (continued)**

- Impact - The entity is yet to undertake a detailed assessment of the impact of AASB 15. However, based on the entity's preliminary assessment, the Standard is not expected to have a material impact on the transactions and balances recognised in the financial statements when it is first adopted for the year ending 30 June 2019.

  The standard permits a modified retrospective approach for the adoption. Under this approach, entities will recognise transitional adjustments in retained earnings on the date of initial application (eg 1 July 2017), ie without restating the comparative period. They will only need to apply the new rules to contracts that are not completed as of the date of initial application.

  Mandatory application date / Date of adoption by group - commencing on or after 1 January 2018. Expected date of adoption by the group: 1 July 2018

- AASB 16 *Leases* - The AASB has issued a new standard for the recognition of leases. This will replace AASB 117: *Leases*. The new standard introduces a single lessee accounting model that no longer requires leases to be classified as operating or financing.

  Other major changes include, the recognition of a right-to-use asset and liability, depreciation of right-to-use assets in line with AASB 116: *Property Plant and Equipment*, variable lease payments that depend on an index or rate are included in the initial measurement of lease liability, option for lessee to not separate non-lease components and account for all components as a lease, and additional disclosure requirements.

- Impact - The entity is yet to undertake a detailed assessment of the impact of AASB 16. However, based on the entity's preliminary assessment, the Standard is not expected to have a material impact on the transactions and balances recognised in the financial statements when it is first adopted for the year ending 30 June 2020.

  Mandatory application date / Date of adoption by group - Must be applied for financial years commencing on or after 1 January 2019.Expected date of adoption by the group: 1 July 2019.

There are no other standards that are not yet effective and that would be expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

**Going concern**

The directors have prepared the financial statements on a going concern basis after taking into consideration the net loss for the year of $25,678,000 (2015: $11,509,000) and the cash and cash equivalents balance of $18,230,000 (2015: $21,787,000). The directors have recognised the capital raisings in the last 2 years, performed a review of the cash flow forecasts, considered the cash flow needs of the Group, and believe that the strategies in place are appropriate to generate funding which will be sufficient to maintain the going concern status of the Group. If these strategies are unsuccessful then the Group may need to realise its assets and extinguish liabilities other than in the ordinary course of business and at amounts different to those disclosed in the financial report.

**Basis of preparation**

These general purpose financial statements have been prepared in accordance with Australian Accounting Standards and Interpretations issued by the Australian Accounting Standards Board ('AASB') and the Corporations Act 2001, as appropriate for for-profit oriented entities. These financial statements also comply with International Financial Reporting Standards as issued by the International Accounting Standards Board ('IASB').

*Historical cost convention*

The financial statements have been prepared under the historical cost convention.

**Note 1. Significant accounting policies (continued)**

*Critical accounting estimates*

The preparation of the financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the financial statements, are disclosed in note 2.

**Parent entity information**

In accordance with the Corporations Act 2001, these financial statements present the results of the Group only. Supplementary information about the parent entity is disclosed in note 24.

**Principles of consolidation**

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of Benitec Biopharma Limited ('Company' or 'parent entity') as at 30 June 2016 and the results of all subsidiaries for the year then ended. Benitec Biopharma Limited and its subsidiaries together are referred to in these financial statements as the 'Group'.

Subsidiaries are all those entities over which the Group has control. The Group controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date that control ceases. The Companies 100% owned subsidiary, Tacere Therapeutics, Inc. has a 31 December year end. The Company is reviewing the appropriate time to align the subsidiary year end to the parent's year end. For consolidation purposes Tacere prepares financial statements for the 12 month period ended 30 June that are used to consolidate into the group accounts.

Intercompany transactions, balances and unrealised gains on transactions between entities in the Group are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of the impairment of the asset transferred. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

The acquisition of subsidiaries is accounted for using the acquisition method of accounting. A change in ownership interest, without the loss of control, is accounted for as an equity transaction, where the difference between the consideration transferred and the book value of the share of the non-controlling interest acquired is recognised directly in equity attributable to the parent.

Where the Group loses control over a subsidiary, it derecognises the assets including goodwill, liabilities and non-controlling interest in the subsidiary together with any cumulative translation differences recognised in equity. The Group recognises the fair value of the consideration received and the fair value of any investment retained together with any gain or loss in profit or loss.

**Operating segments**

Operating segments are presented using the 'management approach', where the information presented is on the same basis as the internal reports provided to the Chief Operating Decision Makers ('CODM'). The CODM is responsible for the allocation of resources to operating segments and assessing their performance.

**Foreign currency translation**

The financial statements are presented in Australian dollars, which is Benitec Biopharma Limited's functional and presentation currency.

**Note 1. Significant accounting policies (continued)**

*Foreign currency transactions*

Foreign currency transactions are translated into Australian dollars using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at financial year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in profit or loss.

*Foreign operations*

The assets and liabilities of foreign operations are translated into Australian dollars using the exchange rates at the reporting date. The revenues and expenses of foreign operations are translated into Australian dollars using the average exchange rates, which approximate the rates at the dates of the transactions, for the period. All resulting foreign exchange differences are recognised in other comprehensive income through the foreign currency reserve in equity.

The foreign currency reserve is recognised in profit or loss when the foreign operation or net investment is disposed of.

**Revenue recognition**

Revenue is recognised when it is probable that the economic benefit will flow to the Group and the revenue can be reliably measured. Revenue is measured at the fair value of the consideration received or receivable.

*Licensing revenue and royalties*

Revenue from the granting of licenses is recognised in accordance with the terms of the relevant agreements and is usually recognised on an accruals basis, unless the substance of the agreement provides evidence that it is more appropriate to recognise revenue on some other systematic rational basis.

*Interest*

Interest revenue is recognised as interest accrues using the effective interest method. This is a method of calculating the amortised cost of a financial asset and allocating the interest income over the relevant period using the effective interest rate, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to the net carrying amount of the financial asset.

**Government research and development grants**

Government grants are recognised at fair value where there is reasonable assurance that the grant will be received and all grant conditions will be met. Grants relating to expense items are recognised as income over the periods necessary to match the grant costs they are compensating. Grants relating to assets are credited to deferred income at fair value and are credited to income over the expected useful life of the asset on a straight-line basis.

Research and development grant revenue is recognised as income when a reliable estimate can be made of the amounts receivable

**Income tax**

The income tax expense or benefit for the period is the tax payable on that period's taxable income based on the applicable income tax rate for each jurisdiction, adjusted by the changes in deferred tax assets and liabilities attributable to temporary differences, unused tax losses and the adjustment recognised for prior periods, where applicable.

Deferred tax assets and liabilities are recognised for temporary differences at the tax rates expected to be applied when the assets are recovered or liabilities are settled, based on those tax rates that are enacted or substantively enacted, except for:

- When the deferred income tax asset or liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting nor taxable profits; or
- When the taxable temporary difference is associated with interests in subsidiaries, associates or joint ventures, and the timing of the reversal can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future.

**Note 1. Significant accounting policies (continued)**

Deferred tax assets are recognised for deductible temporary differences and unused tax losses only if it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

The carrying amount of recognised and unrecognised deferred tax assets are reviewed at each reporting date. Deferred tax assets recognised are reduced to the extent that it is no longer probable that future taxable profits will be available for the carrying amount to be recovered. Previously unrecognised deferred tax assets are recognised to the extent that it is probable that there are future taxable profits available to recover the asset.

Deferred tax assets and liabilities are offset only where there is a legally enforceable right to offset current tax assets against current tax liabilities and deferred tax assets against deferred tax liabilities; and they relate to the same taxable authority on either the same taxable entity or different taxable entities which intend to settle simultaneously.

Benitec Biopharma Limited (the 'head entity') and its wholly-owned Australian subsidiaries have formed an income tax consolidated group under the tax consolidation regime. The head entity and each subsidiary in the tax consolidated group continue to account for their own current and deferred tax amounts. The tax consolidated group has applied the 'separate taxpayer within group' approach in determining the appropriate amount of taxes to allocate to members of the tax consolidated group. No tax sharing agreement has been entered between entities in the tax consolidated group.

In addition to its own current and deferred tax amounts, the head entity also recognises the current tax liabilities (or assets) and the deferred tax assets arising from unused tax losses and unused tax credits assumed from each subsidiary in the tax consolidated group.

**Current and non-current classification**

Assets and liabilities are presented in the statement of financial position based on current and non-current classification.

An asset is classified as current when: it is either expected to be realised or intended to be sold or consumed in normal operating cycle; it is held primarily for the purpose of trading; it is expected to be realised within 12 months after the reporting period; or the asset is cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current.

A liability is classified as current when: it is either expected to be settled in normal operating cycle; it is held primarily for the purpose of trading; it is due to be settled within 12 months after the reporting period; or there is no unconditional right to defer the settlement of the liability for at least 12 months after the reporting period. All other liabilities are classified as non-current.

Deferred tax assets and liabilities are always classified as non-current.

**Cash and cash equivalents**

Cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

**Trade and other receivables**

Other receivables are recognised at amortised cost, less any provision for impairment.

**Note 1. Significant accounting policies (continued)**

**Investments and other financial assets**

Investments and other financial assets are initially measured at fair value. Transaction costs are included as part of the initial measurement, except for financial assets at fair value through profit or loss. They are subsequently measured at either amortised cost or fair value depending on their classification. Classification is determined based on the purpose of the acquisition and subsequent reclassification to other categories is restricted.

Financial assets are derecognised when the rights to receive cash flows from the financial assets have expired or have been transferred and the Group has transferred substantially all the risks and rewards of ownership.

*Loans and receivables*

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are carried at amortised cost using the effective interest rate method. Gains and losses are recognised in profit or loss when the asset is derecognised or impaired.

*Impairment of financial assets*

The Group assesses at the end of each reporting period whether there is any objective evidence that a financial asset or group of financial assets is impaired. Objective evidence includes significant financial difficulty of the issuer or obligor; a breach of contract such as default or delinquency in payments; the lender granting to a borrower concessions due to economic or legal reasons that the lender would not otherwise do; it becomes probable that the borrower will enter bankruptcy or other financial reorganisation; the disappearance of an active market for the financial asset; or observable data indicating that there is a measurable decrease in estimated future cash flows.

The amount of the impairment allowance for loans and receivables carried at amortised cost is the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted at the original effective interest rate. If there is a reversal of impairment, the reversal cannot exceed the amortised cost that would have been recognised had the impairment not been made and is reversed to profit or loss.

**Property, plant and equipment**

Plant and equipment is stated at historical cost less accumulated depreciation and impairment. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Depreciation is calculated on a straight-line basis to write off the net cost of each item of property, plant and equipment (excluding land) over their expected useful lives as follows:

| | |
|---|---|
| Leasehold improvements | period of the lease term |
| Plant and equipment | 3-7 years |

The residual values, useful lives and depreciation methods are reviewed, and adjusted if appropriate, at each reporting date.

An item of property, plant and equipment is derecognised upon disposal or when there is no future economic benefit to the Group. Gains and losses between the carrying amount and the disposal proceeds are taken to profit or loss.

**Leases**

The determination of whether an arrangement is or contains a lease is based on the substance of the arrangement and requires an assessment of whether the fulfilment of the arrangement is dependent on the use of a specific asset or assets and the arrangement conveys a right to use the asset.

A distinction is made between finance leases, which effectively transfer from the lessor to the lessee substantially all the risks and benefits incidental to the ownership of leased assets, and operating leases, under which the lessor effectively retains substantially all such risks and benefits.

**Note 1. Significant accounting policies (continued)**

Operating lease payments, net of any incentives received from the lessor, are charged to profit or loss on a straight-line basis over the term of the lease.

**Impairment of non-financial assets**

Other intangible assets that have an indefinite useful life are not subject to amortisation and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other non-financial assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount.

Recoverable amount is the higher of an asset's fair value less costs of disposal and value-in-use. The value-in-use is the present value of the estimated future cash flows relating to the asset using a pre-tax discount rate specific to the asset or cash-generating unit to which the asset belongs. Assets that do not have independent cash flows are grouped together to form a cash-generating unit.

**Trade and other payables**

These amounts represent liabilities for goods and services provided to the Group prior to the end of the financial year and which are unpaid. Due to their short-term nature they are measured at amortised cost and are not discounted. The amounts are unsecured and are usually paid within 30 days of recognition.

**Employee benefits**

*Short-term employee benefits*

Liabilities for wages and salaries and other employee benefits expected to be settled within 12 months of the reporting date are measured at the amounts expected to be paid when the liabilities are settled.

*Other long-term employee benefits*

Employee benefits not expected to be settled within 12 months of the reporting date are measured as the present value of expected future payments to be made in respect of services provided by employees up to the reporting date using the projected unit credit method. Consideration is given to expect future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the reporting date on corporate bonds with terms to maturity and currency that match, as closely as possible, the estimated future cash outflows.

*Defined contribution superannuation expense*

Contributions to defined contribution superannuation plans are expensed in the period in which they are incurred.

*Share-based payments*

Equity-settled share-based compensation benefits are provided to directors and senior executives. The plan currently in place to provide these benefits is the Employee Share Option Plan ('ESOP').

Equity-settled transactions are awards of shares, or options over shares that are provided to employees in exchange for the rendering of services.

The cost of equity-settled transactions are measured at fair value on grant date. Fair value is independently determined using Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the impact of dilution, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk free interest rate for the term of the option, together with non-vesting conditions that do not determine whether the Group receives the services that entitle the employees to receive payment. No account is taken of any other vesting conditions.

**Note 1. Significant accounting policies (continued)**

The cost of equity-settled transactions are recognised as an expense with a corresponding increase in equity over the vesting period. The cumulative charge to profit or loss is calculated based on the grant date fair value of the award, the best estimate of the number of awards that are likely to vest and the expired portion of the vesting period. The amount recognised in profit or loss for the period is the cumulative amount calculated at each reporting date less amounts already recognised in previous periods.

Market conditions are taken into consideration in determining fair value. Therefore any awards subject to market conditions are considered to vest irrespective of whether or not that market condition has been met, provided all other conditions are satisfied.

If equity-settled awards are modified, as a minimum an expense is recognised as if the modification has not been made. An additional expense is recognised, over the remaining vesting period, for any modification that increases the total fair value of the share-based compensation benefit as at the date of modification.

If the non-vesting condition is within the control of the Group or employee, the failure to satisfy the condition is treated as a cancellation. If the condition is not within the control of the Group or employee and is not satisfied during the vesting period, any remaining expense for the award is recognised over the remaining vesting period, unless the award is forfeited.

If equity-settled awards are cancelled, it is treated as if it has vested on the date of cancellation, and any remaining expense is recognised immediately. If a new replacement award is substituted for the cancelled award, the cancelled and new award is treated as if they were a modification.The dilutive effect, if any, of outstanding options is reflected as additional share dilution in the computation of earnings per share.

**Fair value measurement**

When an asset or liability, financial or non-financial, is measured at fair value for recognition or disclosure purposes, the fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date; and assumes that the transaction will take place either: in the principal market; or in the absence of a principal market, in the most advantageous market.

Fair value is measured using the assumptions that market participants would use when pricing the asset or liability, assuming they act in their economic best interests. For non-financial assets, the fair value measurement is based on its highest and best use. Valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, are used, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

**Issued capital**

Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

Costs related to an initial offering are expensed in the statement of profit or loss and other comprehensive income.

**Earnings per share**

*Basic earnings per share*

Basic earnings per share is calculated by dividing the profit attributable to the owners of Benitec Biopharma Limited, excluding any costs of servicing equity other than ordinary shares, by the weighted average number of ordinary shares outstanding during the financial year, adjusted for bonus elements in ordinary shares issued during the financial year.

**Note 1. Significant accounting policies (continued)**

*Diluted earnings per share*

Diluted earnings per share adjusts the figures used in the determination of basic earnings per share to take into account the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares and the weighted average number of shares assumed to have been issued for no consideration in relation to dilutive potential ordinary shares.

**Goods and Services Tax ('GST') and other similar taxes**

Revenues, expenses and assets are recognised net of the amount of associated GST, unless the GST incurred is not recoverable from the tax authority. In this case it is recognised as part of the cost of the acquisition of the asset or as part of the expense.

Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the tax authority is included in other receivables or other payables in the statement of financial position.

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to the tax authority, are presented as operating cash flows.

Commitments and contingencies are disclosed net of the amount of GST recoverable from, or payable to, the tax authority.

**Comparative figures**

When required by accounting standards, comparative figures have been adjusted to conform to changes in the presentation for the current financial year.

**Rounding of amounts**

The Parent entity has applied the relief available to it under ASIC Corporations (Rounding in Financial/Directors' Reports). Instrument 2016/191 and accordingly amounts in the financial statements and Directors Report have been rounded off to the nearest $1,000, or in certain cases, to the nearest dollars.

**Note 2. Critical accounting judgements, estimates and assumptions**

The preparation of the financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts in the financial statements. Management continually evaluates its judgements and estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgements, estimates and assumptions on historical experience and on other various factors, including expectations of future events, management believes to be reasonable under the circumstances. The resulting accounting judgements and estimates will seldom equal the related actual results. The judgements, estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities (refer to the respective notes) within the next financial year are discussed below.

*Research and development expenses*

Management does not consider the development programs to be sufficiently advanced to reliably determine the economic benefits and technical feasibility to justify capitalisation of development costs. These costs have been recognised as an expense when incurred.

Research and development expenses relate primarily to the cost of conducting clinical and pre-clinical trials. Clinical development costs are a significant component of research and development expenses. Estimates have been used in determining the expense liability under certain clinical trial contracts where services have been performed but not yet invoiced. Generally the costs, and therefore estimates, associated with clinical trial contracts are based on the number of patients, drug administration cycles, the type of treatment and the outcome being measured. The length of time before actual amounts can be determined will vary depending on length of the patient cycles and the timing of the invoices by the clinical trial partners.

**Note 2. Critical accounting judgements, estimates and assumptions (continued)**

The Group accounts for the federal government research and development grants tax incentive when a reliable estimate of the amounts receivable can be made.

*Share-based payment transactions*

The Group measures 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 by using either the Black-Scholes model taking into account the terms and conditions upon which the instruments were granted. The accounting estimates and assumptions relating to equity-settled share-based payments would have no impact on the carrying amounts of assets and liabilities within the next annual reporting period but may impact profit or loss and equity.

*Recovery of deferred tax assets*

Deferred tax assets are recognised for deductible temporary differences only if the Group considers it is probable that future taxable amounts will be available to utilise those temporary differences and losses. Given the Company's and each individual entities' history of recent losses, the Group has not recognised a deferred tax asset with regard to unused tax losses and other temporary differences, as it has not been determined whether the Company or its subsidiaries will generate sufficient taxable income against which the unused tax losses and other temporary differences can be utilised.

*Costs of capital raising*

Costs directly attributable to an equity transaction are held in the statement of financial position until the completion of the transaction. On completion, the costs will be applied against issued capital. Costs associated with abandoned or sub-optimal equity transactions are expensed to profit or loss in the year the transaction is determined to no longer be viable under existing conditions.

**Note 3. Operating segments**

*Identification of reportable operating segments*

The Group has only one operating segment during the financial year, being the global commercialisation by licensing and partnering of patents and licences in biotechnology, more specifically in functional genomics, with applications in biomedical research and human therapeutics. This operating segment is based on the internal reports that are reviewed and used by the Board of Directors (who are identified as the Chief Operating Decision Makers ('CODM')) in assessing performance and in determining the allocation of resources.

The information reported to the CODM is on at least a monthly basis.

The group sources some of its revenue from the United States of America and therefore presents the split by geographical region.

*Geographical information*

| | Sales to external customers | | Geographical total assets | |
|---|---|---|---|---|
| | 2016 $'000 | 2015 $'000 | 2016 $'000 | 2015 $'000 |
| Australia | 247 | 307 | 19,076 | 25,070 |
| United States of America | — | — | 814 | 450 |
| | 247 | 307 | 19,890 | 25,520 |

## Note 4. Revenue

| | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|
| *Sales revenue* | | |
| Licensing revenue and royalties | 247 | 307 |
| *Other revenue* | | |
| Interest | 217 | 774 |
| Revenue | 464 | 1,081 |

## Note 5. Other income

| | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|
| Net foreign exchange gain | — | 573 |
| Federal government research and development grants received for year ended 2015. (Income from previous period related to year ended 2014). | 3,590 | 2,318 |
| Other income | 3,590 | 2,891 |

## Note 6. Expenses

| | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|
| Loss before income tax includes the following specific expenses: | | |
| *Depreciation* | | |
| Leasehold improvements | 205 | 10 |
| Plant and equipment | 85 | 87 |
| Total depreciation | 290 | 97 |
| *Research and development* | | |
| Project expenses | 12,240 | 4,983 |
| Other IP related expenses | 1,047 | 1,245 |
| Total research and development | 13,287 | 6,228 |
| *Rental expense relating to operating leases* | | |
| Minimum lease payments | 265 | 179 |
| *Superannuation expense* | | |
| Defined contribution superannuation expense | 280 | 128 |
| *Employee benefits expense excluding superannuation* | | |
| Employee benefits expense excluding superannuation | 6,003 | 3,297 |

**Note 7. Income tax benefit**

| | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|
| ***Income tax benefit*** | | |
| Current tax | — | — |
| Aggregate income tax benefit | — | — |
| ***Numerical reconciliation of income tax benefit and tax at the statutory rate*** | | |
| Loss before income tax benefit | (24,778) | (11,509) |
| Tax at the statutory tax rate of 30% | (7,433) | (3,453) |
| Tax effect amounts which are not deductible/(taxable) in calculating taxable income: | | |
| Legal expenses | 59 | 15 |
| Share-based payments | 524 | 451 |
| Capital items deductible | (476) | (487) |
| Sundry items | 500 | 472 |
| | (6,826) | (3,002) |
| Deferred tax asset not brought to account | 6,826 | 3,002 |
| Income tax benefit | — | — |
| ***Tax losses not recognised*** | | |
| Unused tax losses for which no deferred tax asset has been recognised | 64,182 | 53,866 |
| Potential tax benefit @ 30% | 19,255 | 16,160 |
| Capital unused tax losses for which no deferred tax asset has been recognised | 1,272 | 1,272 |
| Potential tax benefit at statutory tax rates | 382 | 382 |

The above potential tax benefit has not been recognised in the statement of financial position. These tax losses are recognised only if the consolidated entity considers it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

There was a prior period reduction to tax losses of $12,434,000 for the consolidated group due to adjustments to carried forward losses not realised on lodgement of tax returns for the period. The effect was to decrease the tax losses of the consolidated group from $5,866,000 to $41,432,000 for the year ending 30 June 2015.

| | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|
| *Deferred tax assets not recognised* | | |
| Deferred tax assets not recognised comprises temporary differences attributable to: | | |
| Others | 39 | 58 |
| Total deferred tax assets not recognised | 39 | 58 |

The above potential tax benefit, which excludes tax losses, for deductible temporary differences has not been recognised in the statement of financial position as the recovery of this benefit is uncertain.

**Note 8. Current assets - cash and cash equivalents**

| | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|
| Cash at bank | 552 | 916 |
| Cash on deposit | 17,678 | 20,871 |
| | 18,230 | 21,787 |

**Note 9. Current assets - trade and other receivables**

| | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|
| Settlement receivable* | 900 | 123 |
| Other receivables | 13 | — |
| BAS receivable | 64 | 123 |
| | 977 | 123 |

* On the 26 August 2016 a settlement agreement was reached for the return of $900,000 of the $2.7million clinical trial prepayment due to the cancellation of the small cell lung cancer program. See Note 10 for further details.

There is no receivable balance that is either past due or impaired.

**Note 10. Current assets - other**

| | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|
| Prepayments | 149 | 74 |
| Prepaid clinical trials* | — | 2,700 |
| IPO costs *** | — | 285 |
| Other current assets | 28 | 95 |
| | 177 | 3,154 |

* The Group announced on 3 June 2013 that it had committed to moving its non-small cell lung cancer therapeutic, into clinical development. The Group is using European-based clinical research organisation Clinical Trials Group ('CTGCRO') to manage both the initial clinical development and trials. The expected full cost of the clinical trial was paid in advance. This prepayment was made to secure favourable commercial terms with CTGCRO for the conduct of the trials. As at the 30 June 2015 the trials had still not commenced.

As a result of feedback from pharma companies and investors, the Company 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 Group reached an agreement on the 26 August 2016 for the return of $900,000 of the prepayment due to the cancellation of the program. Funds are due to be received prior to 31 December 2016. Refer Note 9. The remaining $1,800,000 has been included as an impairment charge in the profit and loss statement.

*** 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. Refer to note 14 for further details.

## Note 11. Non-current assets - property, plant and equipment

| | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|
| Leasehold improvements - at cost | 264 | 252 |
| Less: Accumulated depreciation | (220) | (15) |
| | 44 | 237 |
| Plant and equipment - at cost | 877 | 544 |
| Less: Accumulated depreciation | (415) | (325) |
| | 462 | 219 |
| | 506 | 456 |

*Reconciliations*

Reconciliations of the written down values at the beginning and end of the current and previous financial year are set out below:

| Consolidated | Leasehold improvement $'000 | Plant and equipment $'000 | Total $'000 |
|---|---|---|---|
| Balance at 30 June 2014 | 8 | 40 | 48 |
| Additions | 239 | 266 | 505 |
| Depreciation expense | (10) | (87) | (97) |
| FX loss | — | — | — |
| Balance at 30 June 2015 | 237 | 219 | 456 |
| Additions | 12 | 330 | 342 |
| Depreciation expense* | (205) | (85) | (290) |
| FX loss | — | (2) | (2) |
| Balance at 30 June 2016 | 44 | 462 | 506 |

***** Deprecation of leasehold assets was accelerated to match the life of the head office lease.

## Note 12. Current liabilities - trade and other payables

| | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|
| Trade payables | 538 | 760 |
| Other payables | 295 | 689 |
| | 833 | 1,449 |

## Note 13. Current liabilities - provisions

| | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|
| Employee benefits | 202 | 193 |

## Note 14. Equity - issued capital

| | Consolidated 2016 Shares | Consolidated 2015 Shares | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|---|---|
| Ordinary shares - fully paid | 146,529,096 | 115,881,763 | 147,641 | 129,631 |

*Movements in ordinary share capital*

| Details | Date | Shares | Issue price | $'000 |
|---|---|---|---|---|
| Balance | 30 June 2015 | 115,881,763 | | 129,631 |
| Biomics issue* | 15 July 2015 | 647,333 | 0.7724 | 500 |
| IPO issue | 15 August 2015 | 30,000,000 | 0.6488 | 19,463 |
| IPO and share issue transaction costs | | | | (1,953) |
| Balance | 30 June 2016 | 146,529,096 | | 147,641 |
| The weighted average number of shares on issue during the twelve months to June 30, 2016 was | | 142,312,486 | | |

* During the year Benitec acquired full rights to its pre-clinical hepatitis B program from its collaborator, Biomics Biotechnologies, to enable the independent progression of the product candidate and simplify partnering negotiations. In order to acquire full rights to the hepatitis B program that was previously developed by Joint Venture with Biomics, Benitec paid the JV partner $2.5million in upfront payments ($2million cash, $500k shares), with a further $3.5million and single digit royalties payable to Biomics upon successful commercialization of the program. (consistent with ASX announcement of 9 July 2015).

### Issued capital

*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.

## Note 14. Equity - issued capital (continued)

*Capital risk management*

The Group's objectives when managing capital is to safeguard its ability to continue as a going concern, so that it can provide returns for shareholders and benefits for other stakeholders and to maintain an optimum capital structure to reduce the cost of capital.

The capital structure of the Group consists of cash and cash equivalents and equity attributable to equity holders. Operating globally, the Group develops speciality pharmaceutical products. The overall strategy of the Group is to continue its drug development programs, which depends on selling assets and raising additional equity to fund the activities.

The capital risk management policy remains unchanged from the 2015 Annual Report.

## Note 15. Equity - reserves

| | Consolidated | |
|---|---|---|
| | 2016 $'000 | 2015 $'000 |
| Foreign currency reserve | (1,319) | (1,300) |
| Share-based payments reserve | 3,884 | 3,338 |
| | 2,565 | 2,038 |

*Foreign currency reserve*

The reserve is used to recognise exchange differences arising from the translation of the financial statements of foreign operations to Australian dollars.

*Share-based payments reserve*

The reserve is used to recognise the value of equity benefits provided to employees and directors as part of their remuneration, and other parties as part of their compensation for services.

*Movements in reserves*

Movements in each class of reserve during the current and previous financial year are set out below:

| Consolidated | Foreign currency $'000 | Share-based payments $'000 | Total $'000 |
|---|---|---|---|
| Balance at 30 June 2014 | (1,306) | 1,947 | 641 |
| Foreign currency translation | 6 | — | 6 |
| Share-based payments | — | 1,503 | 1,503 |
| Transfer of expired share-based payments | — | (4) | (4) |
| Transfer to share capital for options exercised | — | (108) | (108) |
| Balance at 30 June 2015 | (1,300) | 3,338 | 2,038 |
| Foreign currency translation | (19) | — | (19) |
| Share-based payments | — | 1,746 | 1,746 |
| Transfer of expired share-based payments | — | (1,200) | (1,200) |
| Balance at 30 June 2016 | (1,319) | 3,884 | 2,565 |

**Note 16. Equity - accumulated losses**

| | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|
| Accumulated losses at the beginning of the financial year | (107,791) | (96,286) |
| Loss after income tax benefit for the year | (24,778) | (11,509) |
| Transfer from share-based payment reserve for expired options | 1,200 | 4 |
| Accumulated losses at the end of the financial year | (131,369) | (107,791) |

**Note 17. Equity - dividends**

There were no dividends paid, recommended or declared during the current or previous financial year.

**Note 18. Financial instruments**

***Financial risk management objectives***

The Group's activities expose it to a variety of financial risks: market risk (including foreign currency risk and interest rate risk) and liquidity risk. The Group's principal financial instruments comprise receivables, payables, cash and short-term deposits. The Group manages its exposure to key financial risks, including interest rate and currency risk in accordance with the Company financial risk management policy. The objective of the policy is to protect the assets and provide a solid return.

| | Consolidated 2016 $'000 | Consolidated 2015 $'000 |
|---|---|---|
| Financial Assets | | |
| Cash and cash equivalents | 18,230 | 21,787 |
| Trade and other receivables | 977 | 123 |
| Total Financial Assets | 19,307 | 21,910 |
| Financial Liabilities | | |
| Trade and other payables | 833 | 1,499 |
| Total Financial Liabilities | 833 | 1,499 |

***Market risk***

*Foreign currency risk*

The Group undertakes certain transactions denominated in foreign currency and is exposed to foreign currency risk through foreign exchange rate fluctuations.

Foreign exchange risk arises from future commercial transactions and recognised financial assets and financial liabilities denominated in a currency that is not the entity's functional currency. The risk is measured using sensitivity analysis and cash flow forecasting.

At the 30 June 2016 the Company held USD cash or cash equivalents of AUD$8.8m and trade payables and accruals of $300k. Net USD exposure in AUD of $8.5m. Each 1 cent movement in the AUD/USD exchange rate has an +/- effect of AUD $88k on profit and net assets of the Company.

*Interest rate risk*

The Group generates income from interest on surplus funds. At reporting date, the Group had the following assets exposed to Australian variable interest rate risk that are not designated in cash flow hedges:

**Note 18. Financial instruments (continued)**

As at the reporting date, the Group had the following variable rate cash and cash equivalents outstanding:

| | 2016 | | 2015 | |
|---|---|---|---|---|
| **Consolidated** | **Weighted average interest rate %** | **Balance $'000** | **Weighted average interest rate %** | **Balance $'000** |
| Cash and cash equivalents | 1% | 18,230 | 3.26% | 21,787 |
| Net exposure to cash flow interest rate risk | | 18,230 | | 21,787 |

An analysis by remaining contractual maturities in shown in 'liquidity and interest rate risk management' below.

***Credit risk***

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to the Group. The maximum exposure to credit risk at the reporting date to recognised financial assets is the carrying amount, net of any provisions for impairment of those assets, as disclosed in the statement of financial position and notes to the financial statements. The Group does not hold any collateral.

***Liquidity risk***

Vigilant liquidity risk management requires the Group to maintain sufficient liquid assets (mainly cash and cash equivalents) to be able to pay debts as and when they become due and payable.

The Group manages liquidity risk by maintaining adequate cash reserves and available borrowing facilities by continuously monitoring actual and forecast cash flows and matching the maturity profiles of financial assets and liabilities.

*Remaining contractual maturities*

The following tables detail the Group's remaining contractual maturity for its financial instrument liabilities. The tables have been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the financial liabilities are required to be paid.

| **Consolidated - 2016** | Weighted average interest rate % | 1 year or less $'000 | Between 1 and 2 years $'000 | Between 2 and 5 years $'000 | Over 5 years $'000 | Remaining contractual maturities $'000 |
|---|---|---|---|---|---|---|
| *Non-derivatives* | | | | | | |
| Non-interest bearing | | | | | | |
| Trade payables | -% | 538 | — | — | — | 538 |
| Other payables | -% | 295 | — | — | — | 295 |
| Total non-derivatives | | 833 | — | — | — | 833 |

| **Consolidated - 2015** | Weighted average interest rate % | 1 year or less $'000 | Between 1 and 2 years $'000 | Between 2 and 5 years $'000 | Over 5 years $'000 | Remaining contractual maturities $'000 |
|---|---|---|---|---|---|---|
| *Non-derivatives* | | | | | | |
| Non-interest bearing | | | | | | |
| Trade payables | -% | 760 | — | — | — | 760 |
| Other payables | -% | 689 | — | — | — | 689 |
| Total non-derivatives | | 1,449 | — | — | — | 1,449 |

**Note 18. Financial instruments (continued)**

The cash flows in the maturity analysis above are not expected to occur significantly earlier than contractually disclosed above.

***Fair value of financial instruments***

Unless otherwise stated, the carrying amounts of financial instruments reflect their fair value.

**Note 19. Key management personnel disclosures**

*Compensation*

The aggregate compensation made to directors and other members of key management personnel of the Group is set out below:

| | Consolidated | |
|---|---|---|
| | **2016** | **2015** |
| | **$** | **$** |
| Short-term employee benefits | 2,048,543 | 1,735,847 |
| Post-employment benefits | 55,630 | 96,353 |
| Long-term benefits | 13,209 | — |
| Share-based payments | 1,011,851 | 1,036,123 |
| | 3,129,233 | 2,868,323 |

**Note 20. Remuneration of auditors**

During the financial year the following fees were paid or payable for services provided by Grant Thornton Audit Pty Ltd, the auditor of the Company:

| | Consolidated | |
|---|---|---|
| | **2016** | **2015** |
| | **$** | **$** |
| *Audit services - Grant Thornton Audit Pty Ltd* | | |
| Audit or review of the financial statements | 178,250 | 95,000 |
| Other audit services | | |
| - F1 review | 23,695 | — |
| - S8 review | 10,200 | — |
| *Other services - Grant Thornton Audit Pty Ltd* | | |
| Tax compliance and corporate advisory services | 22,250 | 20,050 |
| IPO services | — | 180,000 |
| | 22,250 | 200,050 |
| | 234,395 | 295,050 |

**Note 21. 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 long term patient follow-up through 2016 and beyond.

**Note 21. Contingent liabilities and commitments (continued)**

While the Company announced on February 20, 2016 that is was terminating the HCV program, Benitec is committed to completing the study and the company's estimate of the cost, assuming all patients remain in the study and the follow-up continues to 2021 is a maximum of $1.0 million. The scenario of all patients remaining in the study to 2021 is most unlikely and the actual cost is likely to be far less than the nominated contingency of $1 million.

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 optimised 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.

On June 28, 2016, the Group signed a contract with PhoenixBio Co., Ltd to conduct a study evaluating the anti-HBV efficacy of its HBV preclinical asset in combination with standard of care therapies in HBV GT C infected PXB-mice.

The Group has contracted for scientific work on the therapeutic programs, as described above, and payments due within the next 12 month's total approximately $2,716,000. (2015: $2,892,000)

In addition, Benitec during the year acquired full rights to its pre-clinical hepatitis B program from its collaborator, Biomics Biotechnologies, to enable the independent progression of the product candidate and simplify partnering negotiations. In order to acquire full rights to the hepatitis B program that was previously developed by Joint Venture with Biomics, Benitec paid the JV partner $2.5million in upfront payments ($2million cash, $500k shares), with a further $3.5million and single digit royalties that may be payable to Biomics, in the instance that constructs developed during the joint venture are commercialised. Commercialisation is uncertain at this time.

**Note 22. Commitments**

| | Consolidated | |
|---|---|---|
| | **2016 $'000** | **2015 $'000** |
| *Lease commitments - operating* | | |
| Committed at the reporting date but not recognised as liabilities, payable: | | |
| Within one year | 126 | 118 |
| One to five years | 98 | 378 |
| | 224 | 496 |

Operating lease commitments includes contracted amounts for offices under non-cancellable operating leases expiring within 3 years with, in some cases, options to extend. The leases have various escalation clauses. On renewal, the terms of the leases are renegotiated.

*Parent entity*

Benitec Biopharma Limited is the parent entity.

*Subsidiaries*

Interests in subsidiaries are set out in note 25.

*Key management personnel*

Disclosures relating to key management personnel are set out in note 19 and the remuneration report in the directors' report.

## Note 23. Related party transactions

*Transactions with related parties*

The following transactions occurred with related parties:

| | Consolidated 2016 $ | Consolidated 2015 $ |
|---|---|---|
| Payment for other expenses: | | |
| Legal services paid / payable to Francis Abourizk Lightowlers, a law firm in which Mr Peter Francis is a partner and has a beneficial interest. | 116,540 | 143,684 |
| Consultancy fees for executive duties paid/payable to NewStar Ventures Ltd, a corporation in which Dr John Chiplin is a director and has a beneficial interest. | 165,983 | 118,013 |

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*

There were no loans to or from related parties at the current and previous reporting date.

*Terms and conditions*

All transactions were made on normal commercial terms and conditions and at market rates.

## Note 24. Parent entity information

Set out below is the supplementary information about the parent entity.

*Statement of profit or loss and other comprehensive income*

| | Parent 2016 $'000 | Parent 2015 $'000 |
|---|---|---|
| Loss after income tax | (25,917) | (9,562) |
| Total comprehensive income | (25,917) | (9,562) |
| *Statement of financial position* | | |
| Total current assets | 18,948 | 26,763 |
| Total assets | 20,237 | 27,108 |
| Total current liabilities | 845 | 1,574 |
| Total liabilities | 863 | 1,574 |
| Equity | | |
| Issued capital | 147,641 | 129,631 |
| Share-based payments reserve | 3,884 | 3,338 |
| Accumulated losses | (132,151) | (107,435) |
| Total equity | 19,374 | 25,534 |

**Note 24. Parent entity information (continued)**

*Guarantees entered into by the parent entity in relation to the debts of its subsidiaries*

The parent entity had no guarantees in relation to the debts of its subsidiaries as at 30 June 2016 and 30 June 2015.

*Contingent liabilities*

The parent entity had no contingent liabilities as at 30 June 2016 (2015: nil), other than the contingent liabilities described in note 21.

*Capital commitments - Property, plant and equipment*

The parent entity had no capital commitments for property, plant and equipment as at 30 June 2016 and 30 June 2015.

*Significant accounting policies*

The accounting policies of the parent entity are consistent with those of the Group, as disclosed in note 1, except for the following:

- Investments in subsidiaries are accounted for at cost, less any impairment, in the parent entity.
- Dividends received from subsidiaries are recognised as other income by the parent entity and its receipt may be an indicator of an impairment of the investment.

**Note 25. Interests in subsidiaries**

The consolidated financial statements incorporate the assets, liabilities and results of the following subsidiaries in accordance with the accounting policy described in note 1:

| Name | Principal place of business / Country of incorporation | Ownership interest 2016 % | Ownership interest 2015 % |
|---|---|---|---|
| Benitec Australia Limited | Australia | 100.00% | 100.00% |
| Benitec Biopharma Limited | United Kingdom | 100.00% | 100.00% |
| Benitec, Inc. | USA | 100.00% | 100.00% |
| Benitec LLC | USA | 100.00% | 100.00% |
| RNAi Therapeutics, Inc. | USA | 100.00% | 100.00% |
| Tacere Therapeutics, Inc.* | USA | 100.00% | 100.00% |

* Note Tacere year end is 31 December which was the year end date when the Company was acquired.

**Note 26. Events after the reporting period**

**Restructuring of Senior Executive team**

Benitec announced a restructure of its executive team with appointment of Mr Greg West as permanent CEO, Dr Cliff Holloway as Chief Business and Operating Officer, and Mr Bryan Dulhunty as Chief Financial Officer. The changes signify an important new era for the Company and strengthens its core capabilities with their combined expertise in global biotechnology and biopharmaceutical sectors. Benitec remains committed to its articulated strategy to develop and enhance its ddRNAi technology platform, establish co-development and collaboration arrangements for non-pipeline projects, and to out-license ddRNAi to companies that are developing therapeutic programs independently.

On appointment of Mr West as CEO, Mr West was granted 2.2million options vesting over 3 years and expiring in 5 years. The exercise price is 16.65 cents per option.

**Note 26. Events after the reporting period (continued)**

**Appointment of new Audit and Risk Committee Chair**

Benitec announced the appointment of Ms Megan Boston as Director of the Company and Chair of the Audit and Risk Committee on the 16 of August 2016. Ms Boston has significant experience in finance, audit, risk management, compliance and corporate governance sectors with listed entities and government organisations in Australia. Mr. Iain Ross step down as Chair of the Audit and Risk Committee on the appointment of Miss Boston.

On August 23, 2016, Ms. Sakura Holloway was appointed Joint Company Secretary. Subsequently Ms. Holloway left the Company on October 11, 2016. Mr. Greg West remains as the Company Secretary.

On September 30, 2016, Mr. Iain Ross resigned from the Board of Benitec.

On October 24, 2016, Benitec entered into a strategic engagement with Nant Capital, LLC. The strategic engagement includes a scientific collaboration in clinical programs and an immediate private placement to Nant Capital, LLC of 29,305,819 ordinary shares in Benitec, representing approximately 19.9% of its then outstanding issued capital (for a post-issue holding of approximately 16.7%). The shares were priced at A$0.0895 per share, representing the 7-day volume weighted average price of the ordinary shares on the ASX prior to the execution of a share purchase subscription agreement. Jerel A. Banks, the Chief Investment Officer of Nant Capital, LLC, has been appointed to the Board of Benitec.

Approval of shareholders will be sought for the issue of up to an additional 29,305,819 ordinary shares to Nant Capital, LLC within three months after Benitec's 2016 annual shareholders meeting (to be held on December 14, 2016) which, should the issue proceed, would result in Nant Capital, LLC holding approximately 28.6% of the issued capital of Benitec. The capital raised will be used to fund technology to be sublicensed from NantWorks, LLC and to fund our existing therapeutic candidate development programs. Nant Capital, LLC could only be required to purchase the additional ordinary shares if it has entered into a collaboration agreement with Benitec and the purchase price would be market price.

Benitec and Nant Capital, LLC have agreed to use their reasonable efforts to enter into a scientific collaboration agreement (by December 30, 2016) designed to take Benitec back into the clinic. The collaboration would involve an antisense oligonucleotide ("ASO") sublicense from NantWorks, LLC for the treatment of squamous cell carcinoma associated with head and neck cancer ("SCCHN"), and the intended development of a ddRNAi program that would represent a second generation therapeutic for the treatment of SCCHN.

No other matter or circumstance has arisen since 30 June 2016 that has significantly affected, or may significantly affect the Group's operations, the results of those operations, or the Group's state of affairs in future financial years.

**Note 27. Reconciliation of loss after income tax to net cash used in operating activities**

| | Consolidated | |
|---|---|---|
| | 2016 $'000 | 2015 $'000 |
| Loss after income tax benefit for the year | (24,778) | (11,509) |
| Adjustments for: | | |
| Accrued provision Promega | 60 | — |
| Depreciation and amortisation | 290 | 97 |
| Share-based payments | 1,746 | 1,503 |
| Unrealised Foreign exchange | 506 | (567) |
| Issue of ordinary shares to Biomics * | 500 | — |
| Impairment of prepayment | 1,800 | — |
| Change in operating assets and liabilities: | | |
| (Increase) in trade and other receivables | (854) | (1) |
| Decrease in other current assets | 1,178 | 98 |
| (Decrease)/increase in trade and other payables | (683) | 661 |
| Increase in employee benefits | 27 | 26 |
| Net cash used in operating activities | (20,208) | (9,692) |

* During the year Benitec acquired full rights to its pre-clinical hepatitis B program from its collaborator, Biomics Biotechnologies, to enable the independent progression of the product candidate and simplify partnering negotiations. In order to acquire full rights to the hepatitis B program that was previously developed by Joint Venture with Biomics, Benitec paid the JV partner $2.5million in upfront payments ($2million cash, $500k shares), with a further $3.5million and single digit royalties payable to Biomics upon successful commercialization of the program. (consistent with ASX announcement of 9 July 2015).

**Note 28. Earnings per share**

| | Consolidated | |
|---|---|---|
| | **2016 $'000** | **2015 $'000** |
| Loss after income tax attributable to the owners of Benitec Biopharma Limited | (24,778) | (11,509) |
| | **Number** | **Number** |
| Weighted average number of ordinary shares used in calculating basic earnings per share | 142,312,486 | 115,507,308 |
| Weighted average number of ordinary shares used in calculating diluted earnings per share | 142,312,486 | 115,507,308 |

**Note 28. Earnings per share (continued)**

| | Cents | Cents |
|---|---|---|
| Basic earnings per share | (17.41) | (9.96) |
| Diluted earnings per share | (17.41) | (9.96) |

Outstanding options to acquire ordinary shares are not considered dilutive for the years ended 30 June 2016 and 30 June 2015.

On 15 July 2015 the, Company issued 647,333 ordinary shares for acquisition of IP rights, refer note 14.On 15 August 2015, the Company issued 30,000,000 ordinary shares and 10,000,000 options refer note 14.

**Note 29. Share-based payments**

**Benitec Biopharma Limited Employees Share Option Plan (ESOP):**

*Description of plan*

The Group may from time to time issue employee's options to acquire shares in the parent at a fixed price. Each option when exercised entitles the option holder to one share in the Parent Company. Options are exercisable on or before an expiry date, do not carry any voting or dividend rights and are not transferable except on death of the option holder.

The following table shows the number and weighted average exercise price (WAEP) of share options issued under the ESOP:

| | 2016 Number | 2016 WAEP | 2015 Number | 2015 WAEP |
|---|---|---|---|---|
| Outstanding at the beginning of the year | 12,500,000 | 1.234 | 8,608,000 | 1.229 |
| Granted during the year | 6,720,000 | 0.77 | 4,284,000 | 1.250 |
| Exercised during the year | — | — | (320,000) | 0.521 |
| Lapsed or forfeited during the year | (7,000,000) | 1.06 | (72,000) | 1.250 |
| Outstanding at the end of the year | 12,220,000 | 1.079 | 12,500,000 | 1.234 |
| Options exercisable at the end of the year | 8,292,000 | | 7,734,334 | |

*Details of ESOP share options outstanding as at end of year:*

| Grant date | Expiry date | Exercise price | 2016 Number | 2015 Number* |
|---|---|---|---|---|
| 26/09/2011 | 26/09/2016 | 1.25 | 2,800,000 | 2,800,000 |
| 17/11/2011 | 17/11/2016 | 1.25 | 600,000 | 1,800,000 |
| 07/02/2012 | 07/02/2017 | 1.25 | 156,000 | 156,000 |
| 18/07/2012 | 18/07/2017 | 1.25 | — | 400,000 |
| 16/11/2012 | 16/11/2017 | 1.25 | 400,000 | 400,000 |
| 22/08/2013 | 22/08/2018 | 1.25 | 480,000 | 2,080,000 |
| 10/11/2013 | 18/05/2018 | 0625 | 400,000 | 400,000 |
| 15/05/2014 | 15/05/2019 | 1.50 | 180,000 | 180,000 |
| 17/12/2014 | 17/12/2019 | 1.25 | 2,634,000 | 3,334,000 |
| 06/05/2015 | 06/05/2020 | 1.25 | 650,000 | 950,000 |
| 12/11/2015 | 12/11/2020 | 0.77 | 3,920,000 | — |
| | | | 12,220,000 | 12,500,000 |

**Note 29. Share-based payments (continued)**

* The prior year options numbers initially only included shares issued under the employee share option plan. The note this year includes both shares issued under the employee share option scheme and the directors option scheme.

The weighted average remaining life of the options issued under the ESOP at 30 June 2016 was 2 years and 7 months (2015: 3 years and 4 months).

For the options granted during the year, the valuation model inputs used to determine the fair value at the grant date are as follows

| Grant date | Expiry date | Share price at grant date | Exercise price | Expected * volatility | Dividend yield | Risk-free interest rate | Fair value at grant date |
|---|---|---|---|---|---|---|---|
| 12/11/2015 | 17/12/2020 | $ 0.40 | $ 0.77 | 88.35% | -% | 2.4% | $ 0.2344 |

Total expenses arising from share-based payment transactions recognised during the period as part of employee benefit expense were $1,745,947 (2015: $1,502,726).

* expected volatility was determined by reference to Bloomberg for the Benitec share price based on historical volatility

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**BOARD OF DIRECTORS AND SHAREHOLDERS**
**BENITEC BIOPHARMA LIMITED**

We have audited the accompanying consolidated statements of financial position of Benitec Biopharma Limited and subsidiaries (the "Group") as of June 30, 2015 and 2014, and the related consolidated statements of profit or loss and other comprehensive income, changes in equity, and cash flows for each of the two years in the period ended June 30, 2015. These financial statements are the responsibility of the Group's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Group's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Benitec Biopharma Limited and subsidiaries as of June 30, 2015 and 2014, and the results of their operations and their cash flows for each of the two years in the period ended June 30, 2015 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

GRANT THORNTON AUDIT PTY LTD
Chartered Accountants
Sydney, NSW, Australia

November 16, 2015

**Benitec Biopharma Limited**
**Statement of profit or loss and other comprehensive income**
**For the years ended 30 June 2015 and 2014**

| | Note | Consolidated 2015 $'000 | Consolidated 2014 $'000 |
|---|---|---|---|
| **Revenue** | 4 | 1,081 | 598 |
| Other income | 5 | 2,891 | 776 |
| **Expenses** | | | |
| Royalties and licence fees | | (40) | (193) |
| Research and development | 6 | (6,228) | (3,758) |
| Employee benefits expense | | (3,425) | (2,444) |
| Share-based expense | | (1,503) | (355) |
| Travel related costs | | (1,039) | (585) |
| Consultants costs | | (882) | (653) |
| Occupancy costs | | (275) | (122) |
| Corporate expenses | | (1,018) | (646) |
| Net loss foreign exchange | | — | (111) |
| IPO costs | | (1,071) | — |
| **Loss before income tax benefit** | | (11,509) | (7,493) |
| Income tax benefit | 7 | — | 454 |
| **Loss after income tax benefit for the year attributable to the owners of Benitec Biopharma Limited** | 16 | (11,509) | (7,039) |
| **Other comprehensive income** | | | |
| *Items that may be reclassified subsequently to profit or loss* | | | |
| Foreign currency translation | | 6 | 8 |
| Other comprehensive income for the year, net of tax | | 6 | 8 |
| **Total comprehensive income for the year attributable to the owners of Benitec Biopharma Limited** | | (11,503) | (7,031) |
| | | **Cents** | **Cents** |
| Basic earnings per share | 28 | (9.96) | (7.78) |
| Diluted earnings per share | 28 | (9.96) | (7.78) |

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

**Benitec Biopharma Limited**
**Statement of financial position**
**As at 30 June 2015 and 2014**

| | Note | Consolidated 2015 $'000 | Consolidated 2014 $'000 |
|---|---|---|---|
| **Assets** | | | |
| **Current assets** | | | |
| Cash and cash equivalents | 8 | 21,787 | 31,359 |
| Trade and other receivables | 9 | 123 | 122 |
| Other | 10 | 3,154 | 2,967 |
| Total current assets | | 25,064 | 34,448 |
| **Non-current assets** | | | |
| Property, plant and equipment | 11 | 456 | 48 |
| Total non-current assets | | 456 | 48 |
| **Total assets** | | 25,520 | 34,496 |
| **Liabilities** | | | |
| **Current liabilities** | | | |
| Trade and other payables | 12 | 1,449 | 788 |
| Provisions | 13 | 193 | 167 |
| Total current liabilities | | 1,642 | 955 |
| **Total liabilities** | | 1,642 | 955 |
| **Net assets** | | 23,878 | 33,541 |
| **Equity** | | | |
| Issued capital | 14 | 129,631 | 129,186 |
| Reserves | 15 | 2,038 | 641 |
| Accumulated losses | 16 | (107,791) | (96,286) |
| **Total equity** | | 23,878 | 33,541 |

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

**Benitec Biopharma Limited**
**Statement of changes in equity**
**For the years ended 30 June 2015 and 2014**

| Consolidated | Issued capital $'000 | Reserves $'000 | Accumulated losses $'000 | Total equity $'000 |
|---|---|---|---|---|
| Balance at 1 July 2013 | 89,609 | 278 | (89,247) | 640 |
| Loss after income tax benefit for the year | — | — | (7,039) | (7,039) |
| Other comprehensive income for the year, net of tax | — | 8 | — | 8 |
| Total comprehensive income for the year | — | 8 | (7,039) | (7,031) |
| *Transactions with owners in their capacity as owners:* | | | | |
| Contributions of equity, net of transaction costs (note 14) | 39,577 | — | — | 39,577 |
| Share-based payments (note 29) | — | 355 | — | 355 |
| Balance at 30 June 2014 | 129,186 | 641 | (96,286) | 33,541 |

| Consolidated | Issued capital $'000 | Reserves $'000 | Accumulated losses $'000 | Total equity $'000 |
|---|---|---|---|---|
| Balance at 1 July 2014 | 129,186 | 641 | (96,286) | 33,541 |
| Loss after income tax benefit for the year | — | — | (11,509) | (11,509) |
| Other comprehensive income for the year, net of tax | — | 6 | — | 6 |
| Total comprehensive income for the year | — | 6 | (11,509) | (11,503) |
| *Transactions with owners in their capacity as owners:* | | | | |
| Contributions of equity, net of transaction costs (note 14) | 337 | — | — | 337 |
| Share-based payments (note 29) | — | 1,503 | — | 1,503 |
| Transfer of expired share-based payments | — | (4) | 4 | — |
| Transfer to share capital for options exercised | 108 | (108) | — | — |
| Balance at 30 June 2015 | 129,631 | 2,038 | (107,791) | 23,878 |

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

**Benitec Biopharma Limited**
**Statement of cash flows**
**For the years ended 30 June 2015 and 2014**

| | Note | Consolidated 2015 $'000 | Consolidated 2014 $'000 |
|---|---|---|---|
| **Cash flows from operating activities** | | | |
| Receipts from customers (inclusive of GST) | | 307 | 260 |
| Research and development grants | | 2,318 | 776 |
| Interest received | | 774 | 321 |
| Income taxes refunded (paid) | | — | 454 |
| Payments to suppliers and employees (inclusive of GST) | | (13,091) | (11,082) |
| Net cash used in operating activities | 27 | (9,692) | (9,271) |
| **Cash flows from investing activities** | | | |
| Payments for property, plant and equipment | 11 | (505) | (32) |
| Net cash used in investing activities | | (505) | (32) |
| **Cash flows from financing activities** | | | |
| Proceeds from issue of shares | | 385 | 39,076 |
| IPO and share issue transaction costs | | (333) | — |
| Net cash from financing activities | | 52 | 39,076 |
| Net (decrease)/increase in cash and cash equivalents | | (10,145) | 29,773 |
| Cash and cash equivalents at the beginning of the financial year | | 31,359 | 1,587 |
| Effects of exchange rate changes on cash and cash equivalents | | 573 | (1) |
| Cash and cash equivalents at the end of the financial year | 8 | 21,787 | 31,359 |

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

## Note 1. Significant accounting policies

The principal accounting policies adopted in the preparation of the financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

### New, revised or amending Accounting Standards and Interpretations adopted

The Group has adopted all of the new, revised or amending Accounting Standards and Interpretations issued by the International Accounting Standards Board ('IASB') that are mandatory for the current reporting period. The adoption of these Accounting Standards and Interpretations did not have any significant impact on the financial performance or position of the Group.

Any new, revised or amending Accounting Standards or Interpretations that are not yet mandatory have not been early adopted.

The following Accounting Standards and Interpretations are most relevant to the Group:

- Amendments to IAS 32: Offsetting Financial Assets and Financial Liabilities;
- Amendments to IAS 36: Recoverable Amount Disclosures for Non-Financial Assets; and
- Annual improvements to IFRS: 2010-2012 cycle.

### Going concern

The directors have prepared the financial statements on a going concern basis after taking into consideration the net loss for the year of $11,509,000 (2014: $7,039,000) and the cash and cash equivalents balance of $21,787,000 (2014: $31,359,000).

The Company announced the closing of its U.S. initial public offering of 1,500,000 American Depositary Shares (ADSs)1, representing 30,000,000 fully paid ordinary shares of Benitec, together with warrants to purchase 500,000 ADSs, representing 10,000,000 fully paid ordinary shares. Each ADS represents 20 ordinary shares of Benitec. At the time of pricing, Benitec granted the underwriter a 45-day option to purchase up to an additional 225,000 ADSs and/or 75,000 warrants to purchase ADSs to cover over-allotments, if any. This was not ultimately exercised. Simultaneously with the closing, Benitec issued and sold 75,000 warrants in connection with the underwriter's partial exercise of such option. The gross proceeds from the offering were $18,844,000 (US$13,820,000), 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.

### Basis of preparation

The financial report covers Benitec Biopharma Limited and its subsidiaries as a consolidated entity ("Group"). Benitec Biopharma Limited is a listed public company, incorporated and domiciled in Australia. All amounts are stated in Australian dollars.

The consolidated general purpose financial statements of the Group have been prepared in accordance with the requirements of the *Corporations Act 2001*, International Accounting Standards and other authoritative pronouncements of the International Accounting Standards Board. Compliance with International Accounting Standards results in full compliance with the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). Benitec Biopharma Limited is a for-profit entity for the purpose of preparing financial statements.

The consolidated financial statements have been prepared using the measurement bases specified by International Accounting Standards for each type of asset, liability, income and expense. The measurement bases are more fully described in the accounting policies below.

The consolidated financial statements for the year ended 30 June 2015 were approved and authorized for issue by the Board of Directors on 16 November 2015.

*Historical cost convention*

The financial statements have been prepared on an accrual basis on historical costs modified by the revaluation of selected non-current assets and financial instruments for which the fair value basis of accounting has been applied.

*Critical accounting estimates*

The preparation of the financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the financial statements, are disclosed in note 2.

**Parent entity information**

In accordance with the Corporations Act 2001, these financial statements present the results of the Group only. Supplementary information about the parent entity is disclosed in note 24.

**Principles of consolidation**

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of Benitec Biopharma Limited ('Company' or 'parent entity') as at 30 June 2015 and the results of all subsidiaries for the year then ended. Benitec Biopharma Limited and its subsidiaries together are referred to in these financial statements as the 'Group'.

**Note 1. Significant accounting policies (continued)**

Subsidiaries are all those entities over which the Group has control. The Group controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date that control ceases.

Intercompany transactions, balances and unrealised gains on transactions between entities in the Group are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of the impairment of the asset transferred. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

The acquisition of subsidiaries is accounted for using the acquisition method of accounting. A change in ownership interest, without the loss of control, is accounted for as an equity transaction, where the difference between the consideration transferred and the book value of the share of the non-controlling interest acquired is recognised directly in equity attributable to the parent.

Where the Group loses control over a subsidiary, it derecognises the assets including goodwill, liabilities and non-controlling interest in the subsidiary together with any cumulative translation differences recognised in equity. The Group recognises the fair value of the consideration received and the fair value of any investment retained together with any gain or loss in profit or loss.

**Operating segments**

Operating segments are presented using the 'management approach', where the information presented is on the same basis as the internal reports provided to the Chief Operating Decision Makers ('CODM'). The CODM is responsible for the allocation of resources to operating segments and assessing their performance.

**Foreign currency translation**

The financial statements are presented in Australian dollars, which is Benitec Biopharma Limited's functional and presentation currency.

*Foreign currency transactions*

Foreign currency transactions are translated into Australian dollars using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at financial year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in profit or loss.

*Foreign operations*

The assets and liabilities of foreign operations are translated into Australian dollars using the exchange rates at the reporting date. The revenues and expenses of foreign operations are translated into Australian dollars using the average exchange rates, which approximate the rates at the dates of the transactions, for the period. All resulting foreign exchange differences are recognised in other comprehensive income through the foreign currency reserve in equity.

The foreign currency reserve is recognised in profit or loss when the foreign operation or net investment is disposed of.

**Revenue recognition**

Revenue is recognised when it is probable that the economic benefit will flow to the Group and the revenue can be reliably measured. Revenue is measured at the fair value of the consideration received or receivable.

*Licensing revenue and royalties*

Revenue from the granting of licenses is recognised in accordance with the terms of the relevant agreements and is usually recognised on an accruals basis, unless the substance of the agreement provides evidence that it is more appropriate to recognise revenue on some other systematic rational basis.

*Interest*

Interest revenue is recognised as interest accrues using the effective interest method. This is a method of calculating the amortised cost of a financial asset and allocating the interest income over the relevant period using the effective interest rate, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to the net carrying amount of the financial asset.

**Note 1. Significant accounting policies (continued)**

**Government research and development grants**

Government grants are recognised at fair value where there is reasonable assurance that the grant will be received and all grant conditions will be met. Grants relating to expense items are recognised as income over the periods necessary to match the grant costs they are compensating. Grants relating to assets are credited to deferred income at fair value and are credited to income over the expected useful life of the asset on a straight-line basis.

Research and development grant revenue is recognised as income when it is received.

**Income tax**

The income tax expense or benefit for the period is the tax payable on that period's taxable income based on the applicable income tax rate for each jurisdiction, adjusted by the changes in deferred tax assets and liabilities attributable to temporary differences, unused tax losses and the adjustment recognised for prior periods, where applicable.

Deferred tax assets and liabilities are recognised for temporary differences at the tax rates expected to be applied when the assets are recovered or liabilities are settled, based on those tax rates that are enacted or substantively enacted, except for:

- When the deferred income tax asset or liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting nor taxable profits; or
- When the taxable temporary difference is associated with interests in subsidiaries, associates or joint ventures, and the timing of the reversal can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred tax assets are recognised for deductible temporary differences and unused tax losses only if it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

The carrying amount of recognised and unrecognised deferred tax assets are reviewed at each reporting date. Deferred tax assets recognised are reduced to the extent that it is no longer probable that future taxable profits will be available for the carrying amount to be recovered. Previously unrecognised deferred tax assets are recognised to the extent that it is probable that there are future taxable profits available to recover the asset.

Deferred tax assets and liabilities are offset only where there is a legally enforceable right to offset current tax assets against current tax liabilities and deferred tax assets against deferred tax liabilities; and they relate to the same taxable authority on either the same taxable entity or different taxable entities which intend to settle simultaneously.

Benitec Biopharma Limited (the 'head entity') and its wholly-owned Australian subsidiaries have formed an income tax consolidated group under the tax consolidation regime. The head entity and each subsidiary in the tax consolidated group continue to account for their own current and deferred tax amounts. The tax consolidated group has applied the 'separate taxpayer within group' approach in determining the appropriate amount of taxes to allocate to members of the tax consolidated group. No tax sharing agreement has been entered between entities in the tax consolidated group.

In addition to its own current and deferred tax amounts, the head entity also recognises the current tax liabilities (or assets) and the deferred tax assets arising from unused tax losses and unused tax credits assumed from each subsidiary in the tax consolidated group.

**Current and non-current classification**

Assets and liabilities are presented in the statement of financial position based on current and non-current classification.

An asset is classified as current when: it is either expected to be realised or intended to be sold or consumed in normal operating cycle; it is held primarily for the purpose of trading; it is expected to be realised within 12 months after the reporting period; or the asset is cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current.

A liability is classified as current when: it is either expected to be settled in normal operating cycle; it is held primarily for the purpose of trading; it is due to be settled within 12 months after the reporting period; or there is no unconditional right to defer the settlement of the liability for at least 12 months after the reporting period. All other liabilities are classified as non-current.

**Note 1. Significant accounting policies (continued)**

**Cash and cash equivalents**

Cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

**Trade and other receivables**

Other receivables are recognised at amortised cost, less any provision for impairment.

**Investments and other financial assets**

Investments and other financial assets are initially measured at fair value. Transaction costs are included as part of the initial measurement, except for financial assets at fair value through profit or loss. They are subsequently measured at either amortised cost or fair value depending on their classification. Classification is determined based on the purpose of the acquisition and subsequent reclassification to other categories is restricted.

Financial assets are derecognised when the rights to receive cash flows from the financial assets have expired or have been transferred and the Group has transferred substantially all the risks and rewards of ownership.

*Loans and receivables*

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are carried at amortised cost using the effective interest rate method. Gains and losses are recognised in profit or loss when the asset is derecognised or impaired.

*Impairment of financial assets*

The Group assesses at the end of each reporting period whether there is any objective evidence that a financial asset or group of financial assets is impaired. Objective evidence includes significant financial difficulty of the issuer or obligor; a breach of contract such as default or delinquency in payments; the lender granting to a borrower concessions due to economic or legal reasons that the lender would not otherwise do; it becomes probable that the borrower will enter bankruptcy or other financial reorganisation; the disappearance of an active market for the financial asset; or observable data indicating that there is a measurable decrease in estimated future cash flows.

The amount of the impairment allowance for loans and receivables carried at amortised cost is the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted at the original effective interest rate. If there is a reversal of impairment, the reversal cannot exceed the amortised cost that would have been recognised had the impairment not been made and is reversed to profit or loss.

**Property, plant and equipment**

Plant and equipment is stated at historical cost less accumulated depreciation and impairment. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Depreciation is calculated on a straight-line basis to write off the net cost of each item of property, plant and equipment (excluding land) over their expected useful lives as follows:

| | |
|---|---|
| Leasehold improvements | 3-10 years |
| Plant and equipment | 3-7 years |

The residual values, useful lives and depreciation methods are reviewed, and adjusted if appropriate, at each reporting date.

An item of property, plant and equipment is derecognised upon disposal or when there is no future economic benefit to the Group. Gains and losses between the carrying amount and the disposal proceeds are taken to profit or loss.

**Leases**

The determination of whether an arrangement is or contains a lease is based on the substance of the arrangement and requires an assessment of whether the fulfilment of the arrangement is dependent on the use of a specific asset or assets and the arrangement conveys a right to use the asset.

**Note 1. Significant accounting policies (continued)**

A distinction is made between finance leases, which effectively transfer from the lessor to the lessee substantially all the risks and benefits incidental to the ownership of leased assets, and operating leases, under which the lessor effectively retains substantially all such risks and benefits.

Finance leases are capitalised. A lease asset and liability are established at the fair value of the leased assets, or if lower, the present value of minimum lease payments. Lease payments are allocated between the principal component of the lease liability and the finance costs, so as to achieve a constant rate of interest on the remaining balance of the liability.

Leased assets acquired under a finance lease are depreciated over the asset's useful life or over the shorter of the asset's useful life and the lease term if there is no reasonable certainty that the Group will obtain ownership at the end of the lease term.

Operating lease payments, net of any incentives received from the lessor, are charged to profit or loss on a straight-line basis over the term of the lease.

**Impairment of non-financial assets**

Other intangible assets that have an indefinite useful life are not subject to amortisation and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other non-financial assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount.

Recoverable amount is the higher of an asset's fair value less costs of disposal and value-in-use. The value-in-use is the present value of the estimated future cash flows relating to the asset using a pre-tax discount rate specific to the asset or cash-generating unit to which the asset belongs. Assets that do not have independent cash flows are grouped together to form a cash-generating unit.

**Trade and other payables**

These amounts represent liabilities for goods and services provided to the Group prior to the end of the financial year and which are unpaid. Due to their short-term nature they are measured at amortised cost and are not discounted. The amounts are unsecured and are usually paid within 30 days of recognition.

**Employee benefits**

*Short-term employee benefits*

Liabilities for wages and salaries and other employee benefits expected to be settled within 12 months of the reporting date are measured at the amounts expected to be paid when the liabilities are settled.

*Other long-term employee benefits*

Employee benefits not expected to be settled within 12 months of the reporting date are measured as the present

value of expected future payments to be made in respect of services provided by employees up to the reporting date using the projected unit credit method. Consideration is given to expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the reporting date on corporate bonds with terms to maturity and currency that match, as closely as possible, the estimated future cash outflows.

*Defined contribution superannuation expense*

Contributions to defined contribution superannuation plans are expensed in the period in which they are incurred.

*Share-based payments*

Equity-settled share-based compensation benefits are provided to directors and senior executives. The plan currently in place to provide these benefits is the Employee Share Option Plan (‘ESOP’).

Equity-settled transactions are awards of shares, or options over shares, that are provided to employees in exchange for the rendering of services.

**Note 1. Significant accounting policies (continued)**

The cost of equity-settled transactions are measured at fair value on grant date. Fair value is independently determined using Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the impact of dilution, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk free interest rate for the term of the option, together with non-vesting conditions that do not determine whether the Group receives the services that entitle the employees to receive payment. No account is taken of any other vesting conditions.

The cost of equity-settled transactions are recognised as an expense with a corresponding increase in equity over the vesting period. The cumulative charge to profit or loss is calculated based on the grant date fair value of the award, the best estimate of the number of awards that are likely to vest and the expired portion of the vesting period. The amount recognised in profit or loss for the period is the cumulative amount calculated at each reporting date less amounts already recognised in previous periods.

Market conditions are taken into consideration in determining fair value. Therefore any awards subject to market conditions are considered to vest irrespective of whether or not that market condition has been met, provided all other conditions are satisfied.

If equity-settled awards are modified, as a minimum an expense is recognised as if the modification has not been made. An additional expense is recognised, over the remaining vesting period, for any modification that increases the total fair value of the share-based compensation benefit as at the date of modification.

If the non-vesting condition is within the control of the Group or employee, the failure to satisfy the condition is treated as a cancellation. If the condition is not within the control of the Group or employee and is not satisfied during the vesting period, any remaining expense for the award is recognised over the remaining vesting period, unless the award is forfeited.

If equity-settled awards are cancelled, it is treated as if it has vested on the date of cancellation, and any remaining expense is recognised immediately. If a new replacement award is substituted for the cancelled award, the cancelled and new award is treated as if they were a modification.

The dilutive effect, if any, of outstanding options is reflected as additional share dilution in the computation of earnings per share.

**Fair value measurement**

When an asset or liability, financial or non-financial, is measured at fair value for recognition or disclosure purposes, the fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date; and assumes that the transaction will take place either: in the principal market; or in the absence of a principal market, in the most advantageous market.

Fair value is measured using the assumptions that market participants would use when pricing the asset or liability, assuming they act in their economic best interests. For non-financial assets, the fair value measurement is based on its highest and best use. Valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, are used, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

**Issued capital**

Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

Costs related to an initial offering are expensed in the statement of profit or loss and other comprehensive income.

**Earnings per share**

*Basic earnings per share*

Basic earnings per share is calculated by dividing the profit attributable to the owners of Benitec Biopharma Limited, excluding any costs of servicing equity other than ordinary shares, by the weighted average number of ordinary shares outstanding during the financial year, adjusted for bonus elements in ordinary shares issued during the financial year.

**Note 1. Significant accounting policies (continued)**

*Diluted earnings per share*

Diluted earnings per share adjusts the figures used in the determination of basic earnings per share to take into account the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares and the weighted average number of shares assumed to have been issued for no consideration in relation to dilutive potential ordinary shares.

**Goods and Services Tax ('GST') and other similar taxes**

Revenues, expenses and assets are recognised net of the amount of associated GST, unless the GST incurred is not recoverable from the tax authority. In this case it is recognised as part of the cost of the acquisition of the asset or as part of the expense.

Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the tax authority is included in other receivables or other payables in the statement of financial position.

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to the tax authority, are presented as operating cash flows.

Commitments and contingencies are disclosed net of the amount of GST recoverable from, or payable to, the tax authority.

**Comparative figures**

When required by accounting standards, comparative figures have been adjusted to conform to changes in the presentation for the current financial year.

**Rounding of amounts**

Amounts in this report have been rounded to the nearest thousand dollars, or in certain cases, the nearest dollar.

**New Accounting Standards and Interpretations not yet mandatory or early adopted**

Accounting Standards and Interpretations that have recently been issued or amended but are not yet mandatory, have not been early adopted by the Group for the annual reporting period ended 30 June 2015. The Group's assessment of the impact of these new or amended Accounting Standards and Interpretations, most relevant to the Group, are set out below.

*IFRS 9 Financial Instruments*

This standard is applicable to annual reporting periods beginning on or after 1 January 2018. The standard replaces all previous versions of IFRS 9 and completes the project to replace IAS 39 'Financial Instruments: Recognition

and Measurement'. IFRS 9 introduces new classification and measurement models for financial assets. New simpler hedge accounting requirements are intended to more closely align the accounting treatment with the risk management activities of the entity. New impairment requirements will use an 'expected credit loss' ('ECL') model to recognise an allowance. The Group will adopt this standard from 1 July 2018 but the impact of its adoption is yet to be assessed. The impact on the Group is however likely to be immaterial.

*IFRS 15 Revenue from Contracts with Customers*

This standard is currently applicable to annual reporting periods beginning on or after 1 January 2018. The standard provides a single standard for revenue recognition. The core principle of the standard is that an entity will recognise revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services). It is expected that the Group will adopt this standard from 1 July 2018. The impact of adoption is likely to be immaterial, however a full impact assessment has yet to be undertaken.

## Note 2. Critical accounting judgements, estimates and assumptions

The preparation of the financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts in the financial statements. Management continually evaluates its judgements and estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgements, estimates and assumptions on historical experience and on other various factors, including expectations of future events, management believes to be reasonable under the circumstances. The resulting accounting judgements and estimates will seldom equal the related actual results. The judgements, estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities (refer to the respective notes) within the next financial year are discussed below.

*Research and development expenses*

Management does not consider the development programs to be sufficiently advanced to reliably determine the economic benefits and technical feasibility to justify capitalisation of development costs. These costs have been recognised as an expense when incurred.

Research and development expenses relate primarily to the cost of conducting clinical and pre-clinical trials. Clinical development costs are a significant component of research and development expenses. Estimates have been used in determining the expense liability under certain clinical trial contracts where services have been performed but not yet invoiced. Generally the costs, and therefore estimates, associated with clinical trial contracts are based on the number of patients, drug administration cycles, the type of treatment and the outcome being measured. The length of time before actual amounts can be determined will vary depending on length of the patient cycles and the timing of the invoices by the clinical trial partners.

The Group accounts for the federal government research and development grants tax incentive on cash basis due to the difficulty in making a reasonable estimation as at year end.

**Note 2. Critical accounting judgements, estimates and assumptions (continued)**

*Share-based payment transactions*

The Group measures 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 by using either the Black-Scholes model taking into account the terms and conditions upon which the instruments were granted. The accounting estimates and assumptions relating to equity-settled share-based payments would have no impact on the carrying amounts of assets and liabilities within the next annual reporting period but may impact profit or loss and equity.

*Recovery of deferred tax assets*

Deferred tax assets are recognised for deductible temporary differences only if the Group considers it is probable that future taxable amounts will be available to utilise those temporary differences and losses. Given the Company's and each individual entities' history of recent losses, the Group has not recognised a deferred tax asset with regard to unused tax losses and other temporary differences, as it has not been determined whether the Company or its subsidiaries will generate sufficient taxable income against which the unused tax losses and other temporary differences can be utilised.

*Costs of capital raising*

Costs directly attributable to an equity transaction are held in the statement of financial position until the completion of the transaction. On completion, the costs will be applied against issued capital.

Costs associated with an initial public offering or abandoned or sub-optimal equity transactions are expensed to profit or loss in the year the transaction is determined to no longer be viable under existing conditions.

**Note 3. Operating segments**

*Identification of reportable operating segments*

The Group has only one operating segment during the financial year, being the global commercialisation by licensing and partnering of patents and licences in biotechnology, more specifically in functional genomics, with applications in biomedical research and human therapeutics. This operating segment is based on the internal reports that are reviewed and used by the Board of Directors (who are identified as the Chief Operating Decision Makers ('CODM')) in assessing performance and in determining the allocation of resources.

*Geographical information*

| | Sales to external customers | | Geographical non-current assets | |
|---|---|---|---|---|
| | 2015 $'000 | 2014 $'000 | 2015 $'000 | 2014 $'000 |
| Australia | 307 | 274 | 456 | 48 |
| United States of America | — | 3 | — | — |
| | 307 | 277 | 456 | 48 |

**Note 4. Revenue**

| | Consolidated | |
|---|---|---|
| | 2015 $'000 | 2014 $'000 |
| *Sales revenue* | | |
| Licensing revenue and royalties | 307 | 277 |
| *Other revenue* | | |
| Interest | 774 | 321 |
| Revenue | 1,081 | 598 |

## Note 5. Other income

| | Consolidated 2015 $'000 | Consolidated 2014 $'000 |
|---|---|---|
| Net foreign exchange gain | 573 | — |
| Federal government research and development grants | 2,318 | 776 |
| Other income | 2,891 | 776 |

## Note 6. Expenses

| | Consolidated 2015 $'000 | Consolidated 2014 $'000 |
|---|---|---|
| Loss before income tax includes the following specific expenses: | | |
| *Depreciation* | | |
| Leasehold improvements | 10 | 2 |
| Plant and equipment | 87 | 11 |
| Total depreciation | 97 | 13 |
| *Research and development* | | |
| Project expenses | 4,983 | 3,310 |
| Other IP related expenses | 1,245 | 448 |
| Total research and development | 6,228 | 3,758 |
| *Rental expense relating to operating leases* | | |
| Minimum lease payments | 179 | 59 |
| *Superannuation expense* | | |
| Defined contribution superannuation expense | 128 | 89 |
| *Employee benefits expense excluding superannuation* | | |
| Employee benefits expense excluding superannuation | 3,297 | 2,355 |

## Note 7. Income tax benefit

| | Consolidated 2015 $'000 | Consolidated 2014 $'000 |
|---|---|---|
| *Income tax benefit* | | |
| Current tax | — | (454) |
| Aggregate income tax benefit | — | (454) |
| *Numerical reconciliation of income tax benefit and tax at the statutory rate* | | |
| Loss before income tax benefit | (11,509) | (7,493) |
| Tax at the statutory tax rate of 30% | (3,453) | (2,248) |
| Tax effect amounts which are not deductible/(taxable) in calculating taxable income: | | |
| Legal expenses | 15 | 16 |
| Share-based payments | 451 | 107 |
| Non-assessable foreign currency translation provision | — | (2) |
| Capital items deductible | (487) | (232) |
| Sundry items | 472 | 24 |
| | (3,002) | (2,335) |
| Deferred tax asset not brought to account | 3,002 | 2,335 |
| Income tax paid/(refund) from an overseas subsidiary | — | (454) |
| Income tax benefit | — | (454) |

| | Consolidated 2015 $'000 | Consolidated 2014 $'000 |
|---|---|---|
| *Tax losses not recognised* | | |
| Unused tax losses for which no deferred tax asset has been recognised | 53,866 | 43,677 |
| Potential tax benefit @ 30% | 16,160 | 13,103 |
| Capital unused tax losses for which no deferred tax asset has been recognised | 1,272 | 1,272 |
| Potential tax benefit at statutory tax rates | 382 | 382 |

The above potential tax benefit have not been recognised in the statement of financial position. These tax losses are recognised only if the consolidated entity considers it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

| | Consolidated | |
|---|---|---|
| | 2015 $'000 | 2014 $'000 |
| *Deferred tax assets not recognised* | | |
| Deferred tax assets not recognised comprises temporary differences attributable to: | | |
| Others | 58 | 50 |
| Total deferred tax assets not recognised | 58 | 50 |

The above potential tax benefit, which excludes tax losses, for deductible temporary differences has not been recognised in the statement of financial position as the recovery of this benefit is uncertain.

## Note 8. Current assets - cash and cash equivalents

| | Consolidated 2015 $'000 | Consolidated 2014 $'000 |
|---|---|---|
| Cash at bank | 916 | 289 |
| Cash on deposit | 20,871 | 31,070 |
| | 21,787 | 31,359 |

## Note 9. Current assets - trade and other receivables

| | Consolidated 2015 $'000 | Consolidated 2014 $'000 |
|---|---|---|
| Other receivables | — | 28 |
| BAS receivable | 123 | 94 |
| | 123 | 122 |

There is no receivable balance that is either past due or impaired.

## Note 10. Current assets - other

| | Consolidated 2015 $'000 | Consolidated 2014 $'000 |
|---|---|---|
| Prepayments | 74 | 27 |
| Prepaid clinical trials* | 2,700 | 2,700 |
| IPO costs ** | 285 | — |
| Other current assets | 95 | 240 |
| | 3,154 | 2,967 |

* The Group announced on 3 June 2013 that it had committed to moving its non-small cell lung cancer therapeutic, into clinical development. The Group is using European-based clinical research organisation Clinical Trials Group ('CTGCRO') to manage both the initial clinical development and trials. The prepayment was made to secure favourable commercial terms with CTGCRO for the conduct of the trials. As at the 30 June 2015 the trials had still no commenced.

** 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. Refer to note 26 for further details.

## Note 11. Non-current assets - property, plant and equipment

| | Consolidated | |
|---|---|---|
| | **2015 $'000** | **2014 $'000** |
| Leasehold improvements - at cost | 252 | 13 |
| Less: Accumulated depreciation | (15) | (5) |
| | 237 | 8 |
| Plant and equipment - at cost | 544 | 278 |
| Less: Accumulated depreciation | (325) | (238) |
| | 219 | 40 |
| | 456 | 48 |

*Reconciliations*

Reconciliations of the written down values at the beginning and end of the current and previous financial year are set out below:

| **Consolidated** | Leasehold improvement $'000 | Plant and equipment $'000 | Total $'000 |
|---|---|---|---|
| Balance at 1 July 2013 | 10 | 18 | 28 |
| Additions | — | 33 | 33 |
| Depreciation expense | (2) | (11) | (13) |
| Balance at 30 June 2014 | 8 | 40 | 48 |
| Additions | 239 | 266 | 505 |
| Depreciation expense | (10) | (87) | (97) |
| Balance at 30 June 2015 | 237 | 219 | 456 |

## Note 12. Current liabilities - trade and other payables

| | Consolidated | |
|---|---|---|
| | **2015 $'000** | **2014 $'000** |
| Trade payables | 760 | 573 |
| Other payables | 689 | 215 |
| | 1,449 | 788 |

Refer to note 18 for further information on financial instruments.

**Note 13. Current liabilities - provisions**

| | Consolidated | |
|---|---|---|
| | 2015 $'000 | 2014 $'000 |
| Employee benefits | 193 | 167 |

## Note 14. Equity - issued capital

| | Consolidated | | | |
|---|---|---|---|---|
| | 2015 Shares | 2014 Shares | 2015 $'000 | 2014 $'000 |
| Ordinary shares - fully paid | 115,881,763 | 114,898,993 | 129,631 | 129,186 |

*Movements in ordinary share capital*

| Details | Date | Shares | Issue price | $'000 |
|---|---|---|---|---|
| Balance | 1 July 2013 | 46,076,562 | | 89,609 |
| Placement of shares | 23 July 2013 | 27,629,089 | $ 0.280 | 7,618 |
| Share Purchase Plan issue | 6 August 2013 | 10,254,696 | $ 0.280 | 2,820 |
| Release of Tacere escrow shares | 30 October 2013 | 955,002 | $ 0.370 | 357 |
| Placement of shares | 28 February 2014 | 14,717,995 | $ 1.070 | 15,748 |
| Placement of shares | 15 April 2014 | 14,717,999 | $ 1.070 | 15,749 |
| Options exercised | 13 October 2013 | 197,540 | $ 0.325 | 64 |
| Options exercised | 14 January 2014 | 43,077 | $ 0.325 | 14 |
| Options exercised | 29 January 2014 | 49,464 | $ 0.325 | 16 |
| Options exercised | 10 February 2014 | 160,000 | $ 0.325 | 52 |
| Options exercised | 27 February 2014 | 32,000 | $ 0.325 | 11 |
| Options exercised | 20 March 2014 | 61,539 | $ 0.325 | 20 |
| Options exercised | 15 April 2014 | 3,468 | $ 2.500 | 9 |
| Remaining consolidation of shares on a 25:1 basis | | 562 | $ 0.000 | — |
| Transaction costs | | — | $ 0.000 | (2,901) |
| Balance | 30 June 2014 | 114,898,993 | | 129,186 |
| Transfer from share based payments for options exercised | | — | $ 0.000 | 108 |
| Options exercised | 30 July 2014 | 200,000 | $ 0.510 | 102 |
| Options exercised | 30 July 2014 | 60,000 | $ 0.570 | 34 |

| | | | | |
|---|---|---|---|---|
| Options exercised | 11 August 2014 | 60,000 | $0.570 | 34 |
| Options exercised | 28 November 2014 | 258,462 | $0.325 | 84 |
| Options exercised | 23 December 2014 | 86,155 | $0.325 | 28 |
| Options exercised | 13 January 2015 | 40,000 | $0.325 | 13 |
| Options exercised | 9 February 2015 | 61,538 | $0.325 | 20 |
| Options exercised | 17 February 2015 | 93,538 | $0.325 | 30 |
| Options exercised | 19 February 2015 | 123,077 | $0.325 | 40 |
| IPO and transaction costs | | — | $0.000 | (48) |
| Balance | 30 June 2015 | 115,881,763 | | 129,631 |

*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.

*Capital risk management*

The Group's objectives when managing capital is to safeguard its ability to continue as a going concern, so that it can provide returns for shareholders and benefits for other stakeholders and to maintain an optimum capital structure to reduce the cost of capital.

**Note 14. Equity - issued capital (continued)**

The capital structure of the Group consists of cash and cash equivalents and equity attributable to equity holders. Operating globally, the Group develops speciality pharmaceutical products. The overall strategy of the Group is to continue its drug development programs, which depends on selling assets and raising additional equity to fund the activities.

The capital risk management policy remains unchanged from the 2014 Annual Report.

**Note 15. Equity - reserves**

| | Consolidated | |
|---|---|---|
| | **2015 $'000** | **2014 $'000** |
| Foreign currency reserve | (1,300) | (1,306) |
| Share-based payments reserve | 3,338 | 1,947 |
| | 2,038 | 641 |

*Foreign currency reserve*

The reserve is used to recognise exchange differences arising from the translation of the financial statements of foreign operations to Australian dollars.

*Share-based payments reserve*

The reserve is used to recognise the value of equity benefits provided to employees and directors as part of their remuneration, and other parties as part of their compensation for services.

*Movements in reserves*

Movements in each class of reserve during the current and previous financial year are set out below:

| **Consolidated** | Foreign currency $'000 | Share-based payments $'000 | Total $'000 |
|---|---|---|---|
| Balance at 1 July 2013 | (1,314) | 1,592 | 278 |
| Foreign currency translation | 8 | — | 8 |
| Share-based payments | — | 355 | 355 |
| Balance at 30 June 2014 | (1,306) | 1,947 | 641 |
| Foreign currency translation | 6 | — | 6 |
| Share-based payments | — | 1,503 | 1,503 |
| Transfer of expired share-based payments | — | (4) | (4) |
| Transfer to share capital for options exercised | — | (108) | (108) |
| Balance at 30 June 2015 | (1,300) | 3,338 | 2,038 |

**Note 16. Equity - accumulated losses**

| | Consolidated | |
|---|---|---|
| | 2015 $'000 | 2014 $'000 |
| Accumulated losses at the beginning of the financial year | (96,286) | (89,247) |
| Loss after income tax benefit for the year | (11,509) | (7,039) |
| Transfer from share-based payment reserve | 4 | — |
| Accumulated losses at the end of the financial year | (107,791) | (96,286) |

## Note 17. Equity - dividends

There were no dividends paid, recommended or declared during the current or previous financial year.

## Note 18. Financial instruments

***Financial risk management objectives***

The Group's activities expose it to a variety of financial risks: market risk (including foreign currency risk and interest rate risk) and liquidity risk. The Group's principal financial instruments comprise receivables, payables, cash and short-term deposits. The Group manages its exposure to key financial risks, including interest rate and currency risk in accordance with the Company financial risk management policy. The objective of the policy is to protect the assets and provide a solid return.

***Market risk***

*Foreign currency risk*

The Group undertakes certain transactions denominated in foreign currency and is exposed to foreign currency risk through foreign exchange rate fluctuations.

Foreign exchange risk arises from future commercial transactions and recognised financial assets and financial liabilities denominated in a currency that is not the entity's functional currency. The risk is measured using sensitivity analysis and cash flow forecasting.

*Interest rate risk*

The Group generates income from interest on surplus funds. At reporting date, the Group had the following assets exposed to Australian variable interest rate risk that are not designated in cash flow hedges:

As at the reporting date, the Group had the following variable rate cash and cash equivalents outstanding:

| | 2015 | | 2014 | |
|---|---|---|---|---|
| **Consolidated** | **Weighted average interest rate %** | **Balance $'000** | **Weighted average interest rate %** | **Balance $'000** |
| Cash and cash equivalents | 3.26% | 21,787 | 3.67% | 31,359 |
| Net exposure to cash flow interest rate risk | | 21,787 | | 31,359 |

An analysis by remaining contractual maturities in shown in 'liquidity and interest rate risk management' below.

***Credit risk***

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to

the Group. The maximum exposure to credit risk at the reporting date to recognised financial assets is the carrying amount, net of any provisions for impairment of those assets, as disclosed in the statement of financial position and notes to the financial statements. The Group does not hold any collateral.

***Liquidity risk***

Vigilant liquidity risk management requires the Group to maintain sufficient liquid assets (mainly cash and cash equivalents) and available borrowing facilities to be able to pay debts as and when they become due and payable.

The Group manages liquidity risk by maintaining adequate cash reserves and available borrowing facilities by continuously monitoring actual and forecast cash flows and matching the maturity profiles of financial assets and liabilities.

**Note 18. Financial instruments (continued)**

*Remaining contractual maturities*

The following tables detail the Group's remaining contractual maturity for its financial instrument liabilities. The tables have been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the financial liabilities are required to be paid.

| Consolidated - 2015 | Weighted average interest rate % | 1 year or less $'000 | Between 1 and 2 years $'000 | Between 2 and 5 years $'000 | Over 5 years $'000 | Remaining contractual maturities $'000 |
|---|---|---|---|---|---|---|
| **Non-derivatives** | | | | | | |
| *Non-interest bearing* | | | | | | |
| Trade payables | — % | 760 | — | — | — | 760 |
| Other payables | — % | 688 | — | — | — | 688 |
| Total non-derivatives | | 1,448 | — | — | — | 1,448 |

| Consolidated - 2014 | Weighted average interest rate % | 1 year or less $'000 | Between 1 and 2 years $'000 | Between 2 and 5 years $'000 | Over 5 years $'000 | Remaining contractual maturities $'000 |
|---|---|---|---|---|---|---|
| **Non-derivatives** | | | | | | |
| *Non-interest bearing* | | | | | | |
| Trade payables | — % | 573 | — | — | — | 573 |
| Other payables | — % | 215 | — | — | — | 215 |
| Total non-derivatives | | 788 | — | — | — | 788 |

The cash flows in the maturity analysis above are not expected to occur significantly earlier than contractually disclosed above.

***Fair value of financial instruments***

Unless otherwise stated, the carrying amounts of financial instruments reflect their fair value.

**Note 19. Key management personnel disclosures**

*Compensation*

The aggregate compensation made to directors and other members of key management personnel of the Group is set out below:

| | Consolidated 2015 $ | Consolidated 2014 $ |
|---|---|---|
| Short-term employee benefits | 1,735,847 | 1,884,781 |
| Post-employment benefits | 96,353 | 71,100 |
| Share-based payments | 1,036,123 | 348,014 |
| | 2,868,323 | 2,303,895 |

## Note 20. Remuneration of auditors

During the financial year the following fees were paid or payable for services provided by Grant Thornton Audit Pty Ltd, the auditor of the Company:

| | Consolidated 2015 $ | Consolidated 2014 $ |
|---|---|---|
| *Audit services - Grant Thornton Audit Pty Ltd* | | |
| Audit or review of the financial statements | 95,000 | 73,238 |
| *Other services - Grant Thornton Audit Pty Ltd* | | |
| Tax compliance and corporate advisory services | 20,050 | 24,000 |
| IPO services | 180,000 | — |
| | 200,050 | 24,000 |
| | 295,050 | 97,238 |

## Note 21. Contingent liabilities and commitments

In January 2010, the Group reached a settlement with the CSIRO to replace the existing Licence Agreement and Commercial Agreement with a new exclusive Licence Agreement for the use of intellectual property and the Capital Growth Agreement with the issue of ordinary shares. As part of the settlement, a Transition Agreement was put in place in order to facilitate the change from the old agreements to the new agreement and to deal with a number of other matters.

Under the terms of the Transition Agreement, the Group agreed to pay CSIRO an amount of $297,000 for past patent costs only in the event of a trigger event, being either a corporate transaction or an insolvency event.

### Scientific work on the therapeutic programs

On 18 December 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 USA. The Group has negotiated a contract with favourable commercial terms, in some instances requiring prepayment, for Synteract to continue to manage the clinical trials throughout 2014, 2015 and 2016.

On 3 June 2014, the Group announced plans to progress its non-small cell lung cancer (‘NSCLC’) therapeutic candidate, Tribetarna advising it had reached agreement to use European-based clinical research organisation CTGCRO to manage clinical trials, and subsequently negotiated favourable commercial terms, which included prepayments covering the clinical trial and consulting services.

On 11 November 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 $2,892,000.

## Note 22. Commitments

| | Consolidated 2015 $'000 | Consolidated 2014 $'000 |
|---|---|---|
| *Lease commitments - operating* | | |
| Committed at the reporting date but not recognised as liabilities, payable: | | |
| Within one year | 118 | 116 |
| One to five years | 378 | 109 |
| | 496 | 225 |

Operating lease commitments includes contracted amounts for offices under non-cancellable operating leases expiring within 3 years with, in some cases, options to extend. The leases have various escalation clauses. On renewal, the terms of the leases are renegotiated.

## Note 23. Related party transactions

*Parent entity*

Benitec Biopharma Limited is the parent entity.

*Subsidiaries*

Interests in subsidiaries are set out in note 25.

*Key management personnel*

Disclosures relating to key management personnel are set out in note 19 and the remuneration report in the directors' report.

*Transactions with related parties*

The following transactions occurred with related parties:

| | Consolidated 2015 $ | Consolidated 2014 $ |
|---|---|---|
| Payment for other expenses: | | |
| Legal services paid / payable to Francis Abourizk Lightowlers, a law firm in which Mr Peter Francis is a partner and has a beneficial interest. | 143,684 | 108,913 |
| Consultancy fees for executive duties paid/payable to NewStar Ventures Ltd, a corporation in which Dr John Chiplin is a director and has a beneficial interest. | 118,013 | 40,000 |

*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*

There were no loans to or from related parties at the current and previous reporting date.

*Terms and conditions*

All transactions were made on normal commercial terms and conditions and at market rates.

## Note 24. Parent entity information

Set out below is the supplementary information about the parent entity.

*Statement of profit or loss and other comprehensive income*

| | Parent | |
|---|---|---|
| | 2015 $'000 | 2014 $'000 |
| Loss after income tax | (9,562) | (7,037) |
| Total comprehensive income | (9,562) | (7,037) |

*Statement of financial position*

| | Parent | |
|---|---|---|
| | 2015 $'000 | 2014 $'000 |
| Total current assets | 26,763 | 34,386 |
| Total assets | 27,108 | 34,568 |
| Total current liabilities | 1,574 | 1,312 |
| Total liabilities | 1,574 | 1,312 |
| Equity | | |
| Issued capital | 129,631 | 129,186 |
| Share-based payments reserve | 3,338 | 1,947 |
| Accumulated losses | (107,435) | (97,877) |
| Total equity | 25,534 | 33,256 |

*Guarantees entered into by the parent entity in relation to the debts of its subsidiaries*

The parent entity had no guarantees in relation to the debts of its subsidiaries as at 30 June 2015 and 30 June 2014.

*Contingent liabilities*

The parent entity had no contingent liabilities as at 30 June 2015 (2014: nil), other than the contingent liabilities described in note 21.

*Capital commitments - Property, plant and equipment*

The parent entity had no capital commitments for property, plant and equipment as at 30 June 2015 and 30 June 2014.

*Significant accounting policies*

The accounting policies of the parent entity are consistent with those of the Group, as disclosed in note 1, except for the following:

- Investments in subsidiaries are accounted for at cost, less any impairment, in the parent entity.
- Dividends received from subsidiaries are recognised as other income by the parent entity and its receipt may be an indicator of an impairment of the investment.

## Note 25. Interests in subsidiaries

The consolidated financial statements incorporate the assets, liabilities and results of the following subsidiaries in accordance with the accounting policy described in note 1:

| Name | Principal place of business / Country of incorporation | Ownership interest 2015 % | Ownership interest 2014 % |
|---|---|---|---|
| Benitec Australia Limited | Australia | 100.00% | 100.00% |
| Benitec Biopharma Limited | United Kingdom | 100.00% | 100.00% |
| Benitec, Inc. | USA | 100.00% | 100.00% |
| Benitec LLC | USA | 100.00% | 100.00% |
| RNAi Therapeutics, Inc. | USA | 100.00% | 100.00% |
| Tacere Therapeutics, Inc. | USA | 100.00% | 100.00% |

## Note 26. Events after the reporting period

On 9 July 2015, the Group announced that it had acquired the full rights to the pre-clinical ddRNAi-based hepatitis B (HBV) therapeutic program, Hepbarna® from Biomics Biotechnologies, which was previously under development as a joint venture between the two companies. The Company will pay $2,500,000 upfront with a further $3,500,000 upon successful commercialisation of the program and right to royalty on net sales. 647,333 ordinary shares in the Company were issued on 22 July 2015 as consideration.

On 22 July 2015, the Company's shareholders at a General Meeting passed a resolution to issue up to 115,000,000 new shares through an initial public offer, which would be represented by American Depositary Shares for trading on Nasdaq.

On 20 August 2015, the Company has successfully completed an initial public offer in the United States and the associated listing on the NASDAQ Global Select Market. Benitec issued 30,000,000 ordinary shares (converted to 1,500,000 NASDAQ ADS: BNTC) and 10,000,000 options (converted to 500,000 NASDAQ warrants: BNTCW representing 20 options for each warrant) through the initial public offer and raised $18,844,000 (US$13,820,000) under the IPO. Benitec intends to use the net proceeds of the IPO to advance the programs for its therapies, for working capital and for general corporate purposes.

No other matter or circumstance has arisen since 30 June 2015 that has significantly affected, or may significantly affect the Group's operations, the results of those operations, or the Group's state of affairs in future financial years.

**Note 27. Reconciliation of loss after income tax to net cash used in operating activities**

| | Consolidated | |
|---|---|---|
| | 2015 $'000 | 2014 $'000 |
| Loss after income tax benefit for the year | (11,509) | (7,039) |
| Adjustments for: | | |
| Depreciation and amortisation | 97 | 13 |
| Share-based payments | 1,503 | 355 |
| Foreign exchange differences | (567) | 9 |
| Change in operating assets and liabilities: | | |
| Increase in trade and other receivables | (1) | (17) |
| Decrease/(increase) in other operating assets | 98 | (2,937) |
| Increase in trade and other payables | 661 | 277 |
| Increase in employee benefits | 26 | 68 |
| Net cash used in operating activities | (9,692) | (9,271) |

## Note 28. Earnings per share

| | Consolidated | |
|---|---|---|
| | 2015 $'000 | 2014 $'000 |
| Loss after income tax attributable to the owners of Benitec Biopharma Limited | (11,509) | (7,039) |
| | **Number** | **Number** |
| Weighted average number of ordinary shares used in calculating basic earnings per share | 115,507,308 | 90,432,177 |
| Weighted average number of ordinary shares used in calculating diluted earnings per share | 115,507,308 | 90,432,177 |
| | **Cents** | **Cents** |
| Basic earnings per share | (9.96) | (7.78) |
| Diluted earnings per share | (9.96) | (7.78) |

Outstanding options to acquire ordinary shares are not considered dilutive for the years ended 30 June 2015 and 30 June 2014.

On 20 August 2015, the Company issued 30,000,000 ordinary shares and 10,000,000 options as detailed on note 25 events after the reporting period.

## Note 29. Share-based payments

### Benitec Biopharma Limited Employees Share Option Plan (ESOP):

*Description of plan*

The Group may from time to time issue employees options to acquire shares in the parent at a fixed price. Each option when exercised entitles the option holder to one share in the Company. Options are exercisable on or before an expiry date, do not carry any voting or dividend rights and are not transferable except on death of the option holder.

The following table shows the number and weighted average exercise price (WAEP) of share options issued under the ESOP:

| | 2015 Number | 2015 WAEP | 2014 Number | 2014 WAEP |
|---|---|---|---|---|
| Outstanding at the beginning of the year | 5,288,000 | 1.229 | 3,028,000 | 1.200 |
| Granted during the year | 4,284,000 | 1.250 | 2,260,000 | 1.270 |
| Exercised during the year | (200,000) | 0.510 | — | — |
| Lapsed or forfeited during the year | (72,000) | 1.250 | — | — |
| Outstanding at the end of the year | 9,300,000 | 1.250 | 5,288,000 | 1.229 |
| Options exercisable at the end of the year | 4,670,667 | | 2,178,667 | |

*Details of ESOP share options outstanding as at end of year:*

| Grant date | Expiry date | Exercise price | 2015 Number | 2014 Number |
|---|---|---|---|---|
| 13/07/2010 | 19/08/2014 | 0.51 | — | 260,000 |
| 17/11/2011 | 17/11/2016 | 1.25 | 1,800,000 | 1,800,000 |
| 07/02/2012 | 07/02/2017 | 1.25 | 156,000 | 168,000 |
| 18/07/2012 | 18/07/2017 | 1.25 | 400,000 | 400,000 |
| 16/11/2012 | 16/11/2017 | 1.25 | 400,000 | 400,000 |
| 22/08/2013 | 22/08/2018 | 1.25 | 2,080,000 | 2,080,000 |
| 15/05/2014 | 15/05/2019 | 1.50 | 180,000 | 180,000 |
| 17/12/2014 | 17/12/2019 | 1.25 | 3,334,000 | — |
| 06/05/2015 | 06/05/2020 | 1.25 | 950,000 | — |
| | | | 9,300,000 | 5,288,000 |

The weighted average remaining life of the options issued under the ESOP at 30 June 2015 was 3 years and 4 months (2014: 3 years and 3 months).

For the options granted during the current financial year, the valuation model inputs used to determine the fair value at the grant date, are as follows:

| Grant date | Expiry date | Share price at grant date | Exercise price | Expected * volatility | Dividend yield | Risk-free interest rate | Fair value at grant date |
|---|---|---|---|---|---|---|---|
| 17/12/2014 | 17/12/2019 | $0.840 | $1.250 | 95.00% | — % | 2.35% | $0.563 |
| 06/05/2015 | 06/05/2020 | $0.810 | $1.250 | 95.00% | — % | 2.35% | $0.534 |

* expected volatility was determined by reference to Bloomberg for the Benitec share price based on historical volatility

Total expenses arising from share-based payment transactions recognised during the period as part of employee benefit expense were $1,502,726 (2014: $355,116).