



**BENITEC LIMITED**

ABN 64 068 943 662

**PRELIMINARY FINAL REPORT**

(Appendix 4E)

**FOR THE YEAR ENDED**

**30 JUNE 2008**

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**Results for announcement to the market  
For the Year Ended 30 June 2008**

	30 June 2008 \$000's	30 June 2007 \$000's	Percentage increase/ (decrease)
Revenue from continuing operations	560	486	15.2%
Loss from continuing operations after tax	(2,775)	(2,008)	38.2%
Loss from discontinued operations after tax	-	(739)	n/a
Loss for the period attributable to members	(2,775)	(2,747)	1.0%
	30 June 2008 Cents per share	30 June 2007 Cents per share	Percentage increase/ (decrease)
Earnings per share	(0.96)	(1.29)	(25.6)%
Net tangible asset backing per ordinary share	0.5	1.3	(61.5)%

No dividends were paid during the financial year and none are proposed to be paid.

A commentary on the financial results is contained on page 4.

This Preliminary Final Report is based on financial statements that are in the process of being audited, and therefore no audit report has been attached.

## **Commentary on Results**

This Preliminary Final Report is made to the Australian Stock Exchange Limited ("ASX") pursuant to Listing Rule 4.3A and Appendix 4E. The information contained in this report has been derived from the full Financial Report of Benitec Limited ("Benitec"), which is currently subject to audit. The Preliminary Financial Report comprises the results of Benitec and its controlled entities.

### **Financial Results**

Benitec's net loss for the year ended 30 June 2008 was \$2,774,690 compared to a net loss of \$2,746,753 for the previous financial year.

Operating revenue from continuing operations for the 12 months to 30 June 2008 was \$482,969, up from \$485,957 in the previous financial year. Other income during the year was \$76,725, compared to \$nil in the previous financial year. The decrease in operating revenue was due primarily to the transfer of certain royalty revenues to CSIRO in part contribution to the patent costs as per the August 2006 agreements and the one-off effect of the Sigma-Aldrich initial payment of US\$2 million in October 2005.

Operating expenses relating to continuing operations for the financial year were \$3,334,384 down from \$2,494,313 in the previous year. The net cost of discontinued operations was \$nil as compared to \$738,397 in the previous financial year, which addressed both the unsustainable costs being incurred in the US operation and significant overheads at a corporate level.

Benitec's current assets balance at 30 June 2008 was \$2,006,210 (2007: \$5,208,050), with current liabilities of \$662,193 (2007: \$1,572,659).

Net tangible assets have fallen to 0.5 cents per share from 1.3 cents per share last year.

The decrease in net tangible assets reflected the decision to suspend the proposed rights issue in May 2008. This capital raising, which was expected to raise \$5 million, would have resulted in a significant increase in the Company's net assets and provided sufficient cash to fund the operations for a further two years. It is expected that this raising will be reactivated once the current CSIRO negotiations have been completed.

### **Overview of Operations**

The past year has continued the major rebuilding of the Company although progress with major issues has been varied.

We have successfully strengthened the Benitec team during the past year. In July 2007, our CEO Sue MacLeman was appointed a Director of the Company in recognition of the significant contribution she has made and continues to make to Benitec. In October 2007 Mel Bridges joined the Board as a Non-Executive Director. Mel is well known for his outstanding and successful contribution to the Australian biotech sector and we are reaping the benefits of his substantial industry knowledge and experience.

At around the same time, we were also successful in obtaining the services of Dr Jason Smythe as Chief Scientific Officer. Jason has an extremely impressive international CV and he has proved to be a valuable addition to the team with his extensive knowledge and experience in Benitec's field.

## **Overview of Operations (continued)**

### **Litigation Update**

In July 2007, the Company was advised that the US Federal Circuit had issued its decision in the *Benitec v. Nucleonics* appeal, affirming the initial US District Court decision to dismiss the Nucleonics' challenge for lack of subject matter jurisdiction.

Nucleonics then filed in the US Supreme Court to have the matter heard. However in April 2008, the US Supreme Court denied this request thus ending nearly four years of litigation in the US courts.

### **Patent Activities**

#### *Patent Reexamination - USA*

One of the key issues for the Company is the ongoing patent reexamination in the US. Nucleonics initiated a third party Reexamination at the U.S. Patent and Trademark Office ("USPTO") on 4 October 2004, providing the USPTO with art it asserted invalidated U.S. Patent No. 6,573,099 ("099 Patent"). The USPTO rejected the claims based on the provided art. Benitec successfully overcame the references, and the USPTO withdrew all rejections but instituted new rejections on additional art it had uncovered. Benitec then filed a response, which it believed overcame the rejections of Record.

Nucleonics then requested a second Reexamination, adding art it asserted invalidated the '099 Patent. The USPTO merged the two Reexaminations and sent out an Office Action completely withdrawing most of the earlier rejections it made, modifying other rejections, and adding rejections based on the art Nucleonics provided in its second Reexamination request.

Benitec reviewed this new material and believes it does not raise any issues that would preclude patentability of the invention disclosed in the '099 Patent. Benitec also believes it has strong arguments for overcoming the art of record. Benitec responded to the rejections found in the merged Reexaminations in April 2007. During an interview with the Examiner in early July 2007, the Company had the opportunity to discuss confusing aspects of the evidence antedating the Fire patent and removing it as prior art.

On 15 August 2007, Nucleonics' counsel filed a third-party submission to enter an Examination Report from the European Patent Office for a patent application claiming priority to the '099 Patent under re-examination. Benitec considered this submission to be improper and to have the potential to confuse the issues involved in the '099 Patent Reexamination. Consequently, Benitec has confronted the issue directly and submitted a request to preclude entry of the improper material.

In April 2008 a non final office action was received by the USPTO in response to Benitec's response filed in April 2007. Benitec filed a response to this non final office action on 11 July 2008. This was after a meeting on 10 June 2008 with Examiner Celsa, Examiner Ponnaluri, and Supervisory Examiner Jones to clarify the art and respond to questions regarding the science.

A follow up meeting is planned with the Examiner in the next few months to discuss this response in more detail and to include Examiner Schultz, who is the supervisor of the art unit handling all RNAi technology. The second interview is intended to work through any further questions about the claims. As we have experienced working with Examiner Celsa, we can't say with any certainty what the next steps in this process will be. He is not restricted in the time to address the response, or the timing of his review.

## **Overview of Operations (continued)**

### *Other Patent Matters*

In the last 12 months progress has also been made with the BLT fully owned patent families and in July 2008 the New Zealand Patent Office granted Patent no. 543815 (W02004/106517) focused on producing "Double-Stranded Nucleic Acid constructs for therapeutic and related applications of RNA interference (RNAi)". Examination is continuing for the two patent families that recently entered national phase: "Multiple promoter expression cassettes for simultaneous delivery of RNAi agents" and "RNAi expression constructs".

### **R&D Progress**

In the last 12 months Benitec has established a high-level network of potential collaborators in the fields of gene therapy, gene silencing and RNAi research and development.

Key research relationships (formal and informal) currently exist with the following groups in the areas of target identification and delivery technology:

- Division of Molecular Biology: City of Hope (Duarte, California USA);
- Gene & Stem Cell Therapy Group: Centenary Institute of Cancer Medicine and Cell Biology (NSW Australia);
- Gene Therapy Research Unit: Childrens Medical Research Institute & Westmead Children's Hospital (NSW Australia);
- Centre for Reproduction and Development: Monash Institute of Medical Research (Victoria Australia);
- The WHO Collaborating Centre for Virus Reference and Research (Victoria Australia); and
- Division of Basic Science and Vaccine Research: Institute of Human Virology (Maryland USA).

### *City of Hope HIV Stem cell Project*

In 2006 the estimated number of people living with HIV had increased to approximately 39.5 million. In the same year there were approximately 2.9 million deaths due to AIDS and 4.3 million new HIV infections. Of these cases in 2006 approximately 2.14 million people with HIV lived in the US and Western and Central Europe.

The HIV/AIDS market is currently valued at \$6.8 billion and is projected to grow to at least \$10 billion by 2014. Although current treatment regimens may slow the replication rate of the HIV virus they are not curative, and the emergence of drug resistant HIV virus continues to be a major clinical problem.

Despite the tremendous success of the highly active antiretroviral treatment (HAART) regimens for the treatment of HIV infection there remain significant deficiencies in current therapies.

In response to this pressing need for new therapeutic paradigms the Benitec / City of Hope (COH) research program was initiated in 2004.

Benitec has had a long-standing relationship with researchers at the COH biomedical research and treatment centre located in California, USA. Benitec has joined with the COH team as a collaborator (not a clinical trial sponsor) in the current pilot study of the rHIV7-shI-TAR-CCR5RZ lentivirus construct in late stage HIV-1 infected patients undergoing bone marrow ablation and auto-transplantation for lymphoma.

A Pilot Study of the Safety and Feasibility of Stem Cell Therapy for AIDS Lymphoma using Stem Cells Treated with a Lentiviral Vector-encoding Multiple anti-HIV RNA's is still ongoing at the City of Hope in Duarte, California.

This project represents Benitec's first clinical activity in the field of RNAi therapeutics. The clinical study is proposed to be fully recruited by the end of 2008. The primary objective of the study is to determine the safety and feasibility of treating AIDS patients with an antiviral

construct in conjunction with autologous haematopoietic stem cell transplantation for intermediate to high-grade AIDS-related lymphoma.

The rHIV7-shI-TAR-CCR5RZ construct contains three distinct antiviral agents, namely;

- i. a ribozyme against mRNA for the HIV-1 receptor protein CCR5 (CCR5RZ);
- ii. a TAR RNA decoy (to sequester HIV-1 Tat protein); and
- iii. a ddRNAi molecule targeted to the common HIV Tat / Rev exon (shI).

Data from the human pilot HIV Lymphoma stem cell study has been presented by Dr John Rossi at the Keystone RNAi, MicroRNA and Non-Coding RNA conference (March 2008, Whistler) and Dr John Zaia at the ASGT Conference (May 2008, Boston). A further update will be provided at the RNAi meeting in Boston in October 2008.

The IND Annual Report on this clinical study was submitted to the US FDA on August 26<sup>th</sup> 2008 confirming (i) that there have been no serious adverse events or reactions with the two patients treated to date (currently in follow-up) and (ii) that the remaining three patients will have completed their treatment by end-December 2008.

#### *T cell Programme*

Benitec is also involved in a collaboration with the City of Hope for a T cell HIV/AIDS project. This consortium program involves five collaborative partners, namely:

- i. Beckman Research Institute, COH (BRICOH, Duarte CA);
- ii. Colorado State University (CSU, Fort Collins, CO);
- iii. Fred Hutchinson Cancer Research Centre (FHCRC/WU, Seattle WA);
- iv. International Therapeutics Inc (ITI, Seattle, WA); and
- v. University of Pennsylvania (UPENN, Philadelphia, PA).

This program is a multi-project effort centred at COH to investigate HIV-based vector delivery of anti-HIV RNA (initially pHIV7-shI-TAR-CCR5RZ) to CD4<sup>+</sup> peripheral blood T-cells (as opposed to the CD34<sup>+</sup> stem cells targeted in the clinical pilot study above) as a clinical modality.

The IPCP Program is funded by a US\$7 million National Institutes of Health (USA) grant awarded specifically to fund development of this vector (pHIV7-shI-TAR-CCR5RZ). This funding will conclude in August 2008. The IND proposal is expected to be submitted in Q3 2008 and the trial to commence by Q1 2009.

In addition to the above projects the internal Benitec programme is expected to be expanded once the capital raising has been completed. This will allow the Scientific Advisory Board endorsed Science Operational Plan to be implemented including the establishment of fully operational R&D Labs and Facilities, recruitment of Senior Scientific staff & Research Assistant staff and progression of internal projects including the Hepatitis B and cancer projects.

#### **New Licensing and Opportunities**

In January 2008, the Company's licensee Tacere Therapeutics, Inc. announced that it had entered into a collaboration and license agreement with pharmaceutical company Pfizer Inc to develop and commercialise its Hepatitis C virus (HCV) compound TT-033. This deal is a validation of the Benitec ddRNAi "expressed" approach for treating chronic infectious diseases from the world's biggest pharmaceutical company. It is the first expressed RNAi drug to be partnered with a major pharmaceutical company and it is a resounding commercial validation of Benitec's technology. This deal is significant for the Company as it holds an equity stake in Tacere and will also receive milestone and royalty payments from Tacere upon the commercialisation of this drug.

In March 2008, Tacere announced a further license agreement, this time with Oncolys BioPharma Inc (Tokyo) to develop and commercialise Tacere's RNA interference (RNAi)-based hepatitis C virus (HCV) compound TT-033 throughout Asia. The potential benefits to the Company are similar to the Pfizer deal.

### **Roadshows and Presentations**

The Company has been very active over the past year making a number of presentations to both potential investors and major international conferences. These include BioPartnering Europe (October 2007, London), the Intersuisse Asia Pacific LifeScience Forum (October 2007, London), the AusBiotech National Conference "Smart Targeting in Global Markets" (October 2007, Brisbane), BioPartnering North America (February 2008, Vancouver) and Bio08 (June 2008, San Diego). Data from the human pilot HIV Lymphoma stem cell study being conducted by the City of Hope using Benitec technology has also been presented by Dr John Rossi at the Keystone RNAi, MicroRNA and Non-Coding RNA conference (March 2008, Whistler) and Dr John Zaia at the ASGT Conference (May 2008, Boston). A further update from this study will be provided at the RNAi meeting in Boston in October 2008.

### **CSIRO Negotiations**

The renegotiation of terms with CSIRO in a way that benefits both parties and to improve opportunities for collaboration moving forward has been a long ongoing process. The delays in these negotiations have contributed to a decline in the Company's share price and we understand that this has distressed many shareholders. The Company is hopeful that these negotiations will be resolved soon.

### **Capital Raising**

Both the loan from Dr Chris Bremner and the Promega Convertible Note were converted into equity in October 2007, demonstrating strong support from two of the Company's major shareholders.

In May 2008, the Company announced a proposed fully underwritten non-renounceable rights issue to raise approximately \$5.1 million before costs. Unfortunately the rights issue was subsequently suspended after feedback from the market and the underwriter that the CSIRO Agreements needed adjustment before further significant investment or merger and acquisition transactions could be transacted in the market. As noted above, negotiations with CSIRO are continuing and the Company expects to reinstate this capital raising upon the successful conclusion of these negotiations.

**Income Statement**  
**For the Year Ended 30 June 2008**

	Note	Economic Entity 2008 \$	2007 \$
Revenue	1	482,969	485,957
Other income	1	76,725	-
		<u>559,694</u>	<u>485,957</u>
Royalties & licence fees		(115,625)	(116,061)
Research and development		(595,012)	(741,482)
Employment related expenses		(1,353,299)	(913,618)
Travel related costs		(163,603)	(160,448)
Consultants costs		(270,139)	(206,411)
Occupancy costs		(114,240)	(69,146)
Corporate expenses		(696,214)	(335,646)
Foreign currency translation		(26,252)	48,499
		<u>(3,334,384)</u>	<u>(2,494,313)</u>
Loss before income tax		(2,774,690)	(2,008,356)
Income tax expense		-	-
Loss from continuing operations		<u>(2,774,690)</u>	<u>(2,008,356)</u>
Loss from discontinued operations	2	-	(738,397)
Loss for year attributable to members of the parent entity		<u>(2,774,690)</u>	<u>(2,746,753)</u>
<i>Earnings per Share (cents per share)</i>			
Basic and diluted	9	(0.96)	(1.29)
Basic and diluted from continuing operations	9	(0.96)	(0.94)

*The accompanying notes form part of these financial statements*

**Balance Sheet**  
**As at 30 June 2008**

	Note	Economic Entity 2008 \$	2007 \$
<b>Current Assets</b>			
Cash and cash equivalents	3	1,844,226	4,960,351
Trade and other receivables	4	116,618	241,508
Other current assets	5	45,366	6,191
<b>Total Current Assets</b>		<b>2,006,210</b>	<b>5,208,050</b>
<b>Non-Current Assets</b>			
Property, plant and equipment	6	14,018	8,002
<b>Total Non-Current Assets</b>		<b>14,018</b>	<b>8,002</b>
<b>Total Assets</b>		<b>2,020,228</b>	<b>5,216,052</b>
<b>Current Liabilities</b>			
Trade and other payables	8	607,671	1,541,894
Provisions		54,522	30,765
<b>Total Current Liabilities</b>		<b>662,193</b>	<b>1,572,659</b>
<b>Total Liabilities</b>		<b>662,193</b>	<b>1,572,659</b>
<b>Net Assets</b>		<b>1,358,035</b>	<b>3,643,393</b>
<b>Equity</b>			
Issued capital		72,728,840	72,475,990
Reserves		2,411,191	2,174,709
Accumulated losses		(73,781,996)	(71,007,306)
<b>Total Equity</b>		<b>1,358,035</b>	<b>3,643,393</b>

*The accompanying notes form part of these financial statements.*

**Statement of Changes in Equity  
For the Year Ended 30 June 2008**

	Issued Capital	Share Based Payment Reserve	Retained Losses	Total
	\$	\$	\$	\$
Balance at 1 July 2006	66,229,567	2,093,624	(68,260,553)	<b>62,638</b>
Loss attributable to members of parent entity	-	-	(2,746,753)	<b>(2,746,753)</b>
Fair value of options vested during the period	-	81,085	-	<b>81,085</b>
Share issues, net of transaction costs	6,246,423	-	-	<b>6,246,423</b>
Balance 30 June 2007	<u>72,475,990</u>	<u>2,174,709</u>	<u>(71,007,306)</u>	<u><b>3,643,393</b></u>
Loss attributable to members of parent entity	-	-	(2,774,690)	<b>(2,774,690)</b>
Fair value of options vested during the period	-	236,482	-	<b>236,482</b>
Share issues, net of transaction costs	252,850	-	-	<b>252,850</b>
Balance 30 June 2008	<u>72,728,840</u>	<u>2,411,191</u>	<u>(73,781,996)</u>	<u><b>1,358,035</b></u>

*The accompanying notes form part of these financial statements*

**Cash Flow Statement**  
**For the Year Ended 30 June 2008**

	Economic Entity	
	2008	2007
	\$	\$
Cash Flow from Operating Activities		
Receipts from customers	380,632	730,847
Payments to suppliers and employees	(3,663,821)	(2,708,111)
Net cash used in operating activities	(3,283,189)	(1,977,264)
Cash Flows from Investing Activities		
Interest received	196,674	82,209
Purchase of non-current assets	(10,803)	(9,030)
Net cash provided by investing activities	185,871	73,179
Cash Flows from Financing Activities		
Proceeds from issue of shares	14,117	4,984,464
Proceeds from borrowings	-	1,000,000
Net cash provided by financing activities	14,117	5,984,464
Net increase/(decrease) in cash held	(3,083,201)	4,080,379
Exchange rate changes	(32,924)	(20,768)
Cash at beginning of financial year	4,960,351	900,740
Cash at end of financial year	<b>3</b> 1,844,226	4,960,351

*The accompanying notes form part of these financial statements*

**Notes to the Financial Statements  
For the Year Ended 30 June 2008**

	Economic Entity	
	2008	2007
	\$	\$
1. Revenue and Other Income		
Revenue from continuing operations comprises:		
Revenue		
- licensing revenue and royalties	287,373	402,589
- finance income - interest received	195,596	83,368
	482,969	485,957
Other income		
- doubtful debt recovery	55,775	-
- realised gain on foreign currency translation	20,013	
- sundry income	937	-
	76,725	-
Total revenue and other income	559,694	485,957
2. Discontinued Operations		
On April 17 and 22 June 2006 the economic entity announced its intention to scale back and ultimately close its in-house clinical program based in the United States. Office equipment and other items were divested prior to 30 June 2006. Certain activities were relocated to Australia during the 2007 financial year.		
The financial performance of the discontinued operations to the closure date which is included in the loss from discontinued operations per the income statement is as follows:		
Other revenue	-	-
Expenses from ordinary activities	-	(738,397)
Loss on sale or write down of equipment	-	-
Loss before income tax	-	(738,397)
Income tax expense	-	-
Loss attributable to members of the parent entity	-	(738,397)
Basic and diluted earnings per share for loss from discontinued operations attributable to ordinary equity holders of the parent	cents	cents
	-	(0.35)

**Notes to the Financial Statements  
For the Year Ended 30 June 2008**

		Economic Entity	
		2008	2007
		\$	\$
3.	Cash and cash equivalents		
	Cash at bank	207,782	4,700,121
	Deposits at call	1,636,444	260,230
		<u>1,844,226</u>	<u>4,960,351</u>
4.	Trade and other receivables		
	Sundry debtors	<u>116,618</u>	<u>241,508</u>
5.	Other financial assets		
	Prepayments	36,194	589
	Other current assets	9,172	5,602
		<u>45,366</u>	<u>6,191</u>
6.	Property, plant and equipment		
	Plant and equipment – at cost	20,941	10,138
	Accumulated depreciation	(6,923)	(2,136)
		<u>14,018</u>	<u>8,002</u>
7.	Controlled Entities		
		Percentage Owned	
		2008	2007
	Country of Incorporation		
	Parent entity:		
	Benitec Limited	Australia	
	Controlled entities of Benitec Limited:		
	Benitec Australia Limited	Australia	100%
	Benitec Limited	UK	100%
	RNAI Therapeutics, Inc.	USA	100%
	Benitec, Inc.	USA	100%
	Benitec, LLC.	USA	100%

**Notes to the Financial Statements  
For the Year Ended 30 June 2008**

	Economic Entity	
	2008	2007
	\$	\$
8. Trade and other payables		
CURRENT		
Trade creditors	204,242	769,700
Sundry creditors and accrued expenses	403,429	532,677
Unsecured Loan Dr C. Bremner	-	52,980
Promissary Note - Promega Corporation	-	186,537
	<u>607,671</u>	<u>1,541,894</u>
9. Earnings per share		
Loss used in the calculation of basic and dilutive earnings per share	(2,774,690)	(2,746,753)
Weighted average number of ordinary shares outstanding during the year used in the calculation of basic and dilutive earnings per share	<u>290,278,098</u>	<u>213,592,676</u>

## **Other Information**

There is no dividend reinvestment plan in operation.

No entities were acquired or disposed of during the reporting period. However the activities of the wholly owned subsidiary Benitec LLC were discontinued in the previous reporting period as noted in the commentary above and in Note 2 to the Financial Statements.

The Company does not have any interests in joint ventures.

The economic entity operates predominately in one business and geographic segment, being the global commercialisation of patents and licenses developed in the area of biotechnology.

This financial report has been prepared on a going concern basis, which assumes sufficient funding from capital raising, and completion of income generating commercial agreements or, if necessary, reduction in activities or action to realise asset value. In common with start-up biotechnology companies:

- i. the Company's operations are subject to considerable risks due primarily to the nature of the development and commercialisation being undertaken; and
- ii. to allow the Company to execute its longer term plans, it will be necessary to raise additional capital in the near future.

The Directors cannot be certain of the success of the intended fund raising activities. However, in May 2008 the Company announced a proposed fully underwritten non-renounceable rights issue to raise approximately \$5.1 million before costs. The rights issue was suspended after feedback from the market and the underwriter that the CSIRO Agreements needed renegotiation before the capital raising could be transacted. Negotiations with CSIRO are continuing and the Company expects to reinstate the fully underwritten capital raising upon the successful conclusion of these negotiations.

In the meantime the Directors plan to continue the Company's operations on the basis of matters referred to above. In light of the above, it is their belief that sufficient funds will be raised, together with the existing net assets, for the Company to operate in its normal manner for a period of not less than twelve months from the date of this report. In the event that such arrangements are not entered into, there is significant uncertainty as to whether the Company and the consolidated entity will continue as going concerns and, therefore, whether they will realise their assets and extinguish their liabilities in the normal course of business and at the amounts stated in the financial report.

This financial report takes no account of the consequences, if any, of the effects of unsuccessful product development or commercialisation, nor of the inability of the Company to obtain adequate funding.

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