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26 February 2010

The Manager Companies ASX Limited 20 Bridge Street SYDNEY NSW 2000

(18 pages by email)

Dear Madam,

## **HALF YEAR REPORTS**

In accordance with Listing Rule 4.2A, I attach the Company's Appendix 4D and Interim Financial Report for the half year ended 31 December 2009. This Interim Financial Report should be read in conjunction with the Company's 30 June 2009 Annual Report.

Yours sincerely

Peter J. Nightingale Company Secretary

pjn5263

# **Appendix 4D**

## **Half Year Report**

Name		

## **BIOTRON LIMITED** Financial year ended ('current period') ABN or equivalent company reference **31 DECEMBER 2009** 60 086 399 144

Results for announcement to the market				
Revenues from ordinary activities	Down	87%	to	6,467
Loss from ordinary activities after tax attributable to members	Down	5%	to	827,513
Net loss for the period attributable to members	Down	5%	to	827,513
Dividends (distributions)	Amount per	security	Franl	ked amount per security
Final dividend Interim dividend	Nil¢ Nil¢		Nil¢ Nil¢	
Previous corresponding period				
Final dividend Interim dividend	Nil¢ Nil¢			Nil¢ Nil¢
Record date for determining entitlements to the dividend.				
Brief explanation of any of the figures reported above and s of importance not previously released to the market:	hort details of ar	ny bonus o	r cash issu	e or other item(s)
Refer attached reports.				
NTA backing	Current p	eriod	Previo	us corresponding period
Net tangible asset backing per ordinary security	0.01 ce	nts		0.90 cents

A.B.N. 60 086 399 144

## INTERIM FINANCIAL REPORT FOR THE HALF YEAR ENDED 31 DECEMBER 2009

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## **DIRECTORS' REPORT**

Your Directors have pleasure in submitting their report together with the interim financial report of Biotron Limited ('the Company') for the half year ended 31 December 2009 and the review report thereon.

#### **Directors**

The names of the Directors of the Company in office during or since the end of the half year are:

## Mr Michael J. Hoy Independent and Non-Executive Chairman

Mr Hoy has more than 30 years' corporate experience in Australia, the United Kingdom, USA and Asia. He is Chairman of CityPrint Holdings Pty Limited, Chairman of Tellesso Technologies Limited and a former director of John Fairfax Holdings Limited and FXF Trust.

He has been a director since 7 February 2000 and Chairman since 16 March 2000.

## Dr Michelle Miller, BSc, MSc, PhD, GCertAppFin (Finsia) Managing Director

Dr Miller has worked for over 20 years in the bioscience industry, with extensive experience in managing commercial bioscience research. She completed her PhD in the Faculty of Medicine at Sydney University investigating molecular models of cancer development. Her experience includes a number of years at Johnson and Johnson developing anti-HIV gene therapeutics through preclinical research to clinical trials. She has experience in early-stage start-ups from time spent as Investment Manager with a specialist bioscience venture capital fund.

She was appointed as Managing Director on 21 June 2002.

## Dr Michael S. Hirshorn, OAM, MBA, MBBS, FFin Independent and Non-Executive Director

Dr Hirshorn has a 30 years career of founding, building, managing and investing in technology companies. He played a major role in all commercial aspects of Cochlear Limited's development, was a founding director of Resmed Inc., and Chief Executive Marketing for Polartechnics Limited.

He has over eight years of private equity experience, raising a fund and investing and developing companies. He has served on numerous government advisory committees, including the Start IT and T Committee, the Start Grants Biological Sciences Committee of the Department of Industry, Science and Resources. He is currently a director of Dynamic Hearing and TGR BioSciences.

Dr Hirshorn was appointed as a director on 16 March 2000.

## Mr Bruce Hundertmark Independent and Non-Executive Director

Mr Hundertmark is an independent businessman and company director with a wide range of experience in diverse business operations. He has specialised in recent years in high technology based company start-up operations and in promoting the formation of venture capital companies including News Datacom Research Limited in Israel, News Datacom Limited in Hong Kong and both PT Indo Bio Products and PT Indo Bio Fuels in Indonesia.

He has been a director of numerous private and publicly listed companies including News International PLC, Sky Television PLC, Prudential Cornhill Insurance Limited, Harris Scarfe Limited, Bernkastel Wines Limited, Codan Limited, Samic Limited and Investment & Merchant Finance Corporation Limited.

Mr Hundertmark was appointed as a director on 16 March 2000.

## **DIRECTORS' REPORT**

### Mr Peter G. Scott Non-Executive Director

Mr Scott is a founding director of Biotron Limited with more than 30 years of commercial and entrepreneurial experience in Australia.

He is a director of Scott's Acorn Pty Ltd and was formerly Chairman and Managing Director of Scottcom Pty Ltd and Managing Director of ICAM Pty Ltd, audio visual and multimedia companies.

Mr Scott has been a director since 23 February 1999.

## Peter J. Nightingale Company Secretary

Mr Nightingale graduated with a Bachelor of Economics degree from the University of Sydney and is a member of the Institute of Chartered Accountants in Australia. He has worked as a chartered accountant in both Australia and the USA.

As a director or company secretary Mr Nightingale has, for the past 23 years, been responsible for the financial control, administration, secretarial and in-house legal functions of a number of private and public listed companies in Australia, the USA and Europe including Pangea Resources Limited, Timberline Minerals Inc., Perseverance Corporation Limited, Valdora Minerals N.L., Mogul Mining NL, Bolnisi Gold NL and Palmarejo Silver and Gold Corporation. Mr Nightingale is currently a director of Cockatoo Coal Limited, Planet Gas Limited and Callabonna Uranium Limited.

Mr Nightingale has been Company Secretary since 23 February 1999.

## **Review of Operations**

The period under review has seen significant advances on clinical progression of Biotron's antiviral drug development program, with continued focus on clinical development of the Company's lead drug, BIT225, in its HIV and Hepatitis C virus (HCV) programs.

Significant events achieved in this half year period include:

- Successful conclusion of a Phase Ib/IIa clinical trial of Biotron's lead drug, BIT225, in Hepatitis C virus (HCV) infected subjects. This marked a major milestone for the Company,
- Demonstration that BIT225 can limit the spread of HIV in cells taken from HIV-infected patients,
- Presentation of data from the Company's HIV and HCV programs at international scientific conferences.

In December 2009, the Company initiated a capital raising via an option issue, which was fully underwritten by Bell Potter and Martin Place Securities. The issue closed, over-subscribed, in early January 2010, raising \$2.1 million.

#### Clinical Development of BIT225

Biotron has an impressive pipeline of world-class clinical programs developing new drugs to treat significant viral diseases including HCV and HIV. To date Biotron has successfully completed two human trials of its lead drug BIT225 - an investigational, orally-administered, novel antiviral compound in development by Biotron for treatment of HIV and HCV infections. These include a 48 person first-in-human safety study in healthy volunteers in late 2007, and more recently a Phase Ib/IIa trial of the drug in people infected with HCV.

During the half-year period under review, Biotron completed the Phase Ib/IIa study in HCV-infected patients. This was the first study of the drug in a patient population, with 18 infected patients randomly assigned to receive either one of two doses of BIT225, or placebo, taking the drug twice daily for 7 days.

## **DIRECTORS' REPORT**

The study was successfully completed, with preliminary analysis indicating that the drug was safe and well tolerated, and most importantly, showed that BIT225 can reduce levels of the HCV in the treated patients. This was an important and exciting result, and supports the on-going development of the Company's drug.

The next stage of development of BIT225 is to test it in combination with the currently approved HCV drugs in patients infected with HCV, which, given that antiviral drugs cannot be used on their own to treat chronic infections due to development of drug resistance, is how BIT225 will most likely to be used in a clinical setting. These existing drugs (interferon alpha and ribavirin) are often associated with severe side effects, and have limited benefit in a large percentage of patients.

BIT225 has been shown to be highly synergistic with these drugs in preclinical laboratory testing, which means that greater reductions in virus levels can be achieved using smaller quantities of the drugs in combination than if they were used individually.

The combination study trial design is being finalised, clinical trial protocols are in development and it is anticipated that the trial will be underway within first half of 2010, and conclude before end of the calendar year.

BIT225 represents a first-in-class drug for treatment of HCV, targeting the p7 protein of HCV. It is estimated that in the USA alone, some 4 million people have been infected with Hepatitis C with 2.7 million suffering from chronic infection. Worldwide, 170 million people are infected. HCV causes inflammation of the liver, which may lead to fibrosis and cirrhosis, liver cancer and, ultimately, liver failure. Existing drugs for HCV have limited effectiveness and toxicity issues, leaving a significant need for new therapies. The worldwide market is currently almost US\$3.0 billion, but is estimated that this market will expand to over US\$10.0 billion as safe, effective therapies enter the market. The pharmaceutical industry is particularly interested in new drugs that specifically target the replication cycle of the Hepatitis C virus, and there is considerable interest in the outcomes of the combination trial that Biotron is currently setting up.

BIT225 also works against HIV, the virus that causes AIDS. BIT225 specifically targets HIV in reservoir cells and represents an opportunity to attack HIV at its source in the body. Current HIV therapies have little or no effect on HIV in the underlying reservoir of infected cells where the virus hides from the immune system. Late in 2009, Biotron scientists presented a paper at an international conference, reporting that BIT225 is able to limit the spread of virus in cells isolated from HIV-infected patients.

The Company proposes to progress BIT225 into a proof-of-concept Phase Ib/IIa trial in HIV-infected patients during 2010, subject to funding availability.

These trials in HIV and HCV patients are critical steps in the Company's development. Demonstration that BIT225 can attack these viruses in patients will be a major advance in terms of Company and technology valuations. The Company is focused on achieving a successful outcome, and has been progressing discussions with potential pharmaceutical companies in anticipation of finalising a deal once these trials have been completed. The proposed trials are designed to benefit shareholders through significantly increasing the value of Biotron in the market and to its future pharmaceutical company partners.

The level of interest by the international community in Biotron's antiviral programs was reflected by the selection of Biotron to participate in prestigious international scientific conferences over the last 6 months. In December 2009, Biotron was selected to present at the biannual HepDART conference in the USA as well as the International Workshop on HIV Persistence.

### **Subsequent Events**

The financial report has been prepared on a going concern basis. As is usual for a research and development company losses are being incurred in meeting the Company's objectives.

At 31 December 2009, the Company had a deficiency in net current assets of \$41,798. Subsequent to 31 December 2009 the Company raised \$2,100,000, and will continue to manage its expenditures in line with funds available to pursue its programs.

The \$2,100,000 was raised via the allotment of 114,537,315 new options via a fully underwritten non-renounceable issue to existing shareholders on the basis of 1 new option for every existing share held by the members at an issue price of \$0.02 per option.

## **DIRECTORS' REPORT**

The options have an exercise price of 10 cents and an expiry date 30 December 2011. Each new option carries an additional right whereby if a new option is exercised by 31 March 2010, one additional option to acquire one new fully paid ordinary share in the capital of the Company up to 30 March 2012 for \$0.20 will be issued to the optionholder for each new option exercised.

## Lead Auditor's Independence Declaration under Section 307C of the Corporations Act 2001

The lead auditor's independence declaration is set out on page 5 and forms part of the Directors' Report for the half year ended 31 December 2009.

This report has been signed in accordance with a resolution of the Directors and is dated 26 February 2010:

Michael J. Hoy Director



# Lead Auditor's Independence Declaration under Section 307C of the Corporations Act 2001 to the Directors of Biotron Limited

I declare that, to the best of my knowledge and belief, in relation to the review for the half year ended 31 December 2009, there have been:

- (i) no contraventions of the auditor independence requirements as set out in the Corporations Act 2001 in relation to the review; and
- (ii) no contraventions of any applicable code of professional conduct in relation to the review.

**KPMG** 

W. E. Austin Partner

26 February 2010 Brisbane

## INTERIM STATEMENT OF COMPREHENSIVE INCOME FOR THE HALF YEAR ENDED 31 DECEMBER 2009

	Notes	31 December 2009 \$	31 December 2008 \$
Other income		-	5,000
Administration and consultants' expenses		(133,839)	(124,544)
Depreciation .		(11,561)	(20,807)
Direct research and development expenses		(396,046)	(483,247)
Employee and director expenses		(197,835)	(195,759)
Legal expenses		(416)	(4,768)
Rent and outgoings expenses		(28,682)	(27,720)
Other expenses from ordinary activities		(65,601)	(61,209)
Operating loss before financing income		(833,980)	(913,054)
Interest income		6,467	45,664
Net finance income		6,467	45,664
Loss before tax		(827,513)	(867,390)
Income tax expense		<u> </u>	
Loss for the period		(827,513)	(867,390)
Other comprehensive income for the period			
Total comprehensive loss for the period		(827,513)	(867,390)
Basic loss per share attributable to ordinary equity holders	6	(0.72) cents	(0.83) cents
Diluted loss per share attributable to ordinary equity holders	6	(0.72) cents	(0.83) cents

The interim statement of comprehensive income is to be read in conjunction with the notes to the interim financial statements set out on pages 10 to 11.

# INTERIM BALANCE SHEET AS AT 31 DECEMBER 2009

	Notes	31 December 2009 \$	30 June 2009 \$
Current assets			
Cash and cash equivalents		79,361	950,581
Trade and other receivables		25,065	27,520
Other	_	47,612	18,385
Total current assets		152,038	996,486
Non-current assets			
Plant and equipment	_	55,791	67,352
Total non-current assets	<u>-</u>	55,791	67,352
Total assets		207,829	1,063,838
Current liabilities			
Trade and other payables		96,693	136,397
Employee entitlements	_	97,143	85,935
Total current liabilities	<u>-</u>	193,836	222,332
Total liabilities	-	193,836	222,332
Net assets	=	13,993	841,506
Equity			
Issued capital		19,920,593	19,920,593
Reserves		359,608	359,608
Accumulated losses	_	(20,266,208)	(19,438,695)
Total equity	=	13,993	841,506

The interim balance sheet is to be read in conjunction with the notes to the interim financial statements set out on pages 10 to 11.

## INTERIM STATEMENT OF CASH FLOWS FOR THE HALF YEAR ENDED 31 DECEMBER 2009

Cash flows from operating activities	31 December 2009 \$	31 December 2008 \$
Cash receipts in the course of operations	-	3,910
Payments for research and development	(443,883)	(558,741)
Cash payments in the course of operations	(435,379)	(571,511)
Cash absorbed by operations	(879,262)	(1,126,342)
Interest received  Net cash used in operating activities	8,042 (871,220)	54,175 (1,072,167)
Cash flows from investing activities		
Proceeds from sale of plant and equipment	-	5,000
Net cash used in investing activities	-	5,000
Net decrease in cash and cash equivalents	(871,220)	(1,067,167)
Cash and cash equivalents at 1 July	950,581	2,063,596
Cash and cash equivalents at 31 December	79,361	996,429

The interim statement of cash flows is to be read in conjunction with the notes to the interim financial statements set out on pages 10 to 11.

# INTERIM STATEMENT OF CHANGES IN EQUITY FOR THE HALF YEAR ENDED 31 DECEMBER 2009

Attributable to equity holders of the Company				
	Share capital \$	Equity compensation reserve \$	Retained losses \$	Total \$
Balance at 1 July 2008  Total comprehensive income for the period	19,146,365	359,608	(17,662,596)	1,843,377
Loss	-	-	(867,390)	(867,390)
Other comprehensive income	<u>-</u>	-	<u> </u>	<u> </u>
Balance at 31 December 2008	19,146,365	359,608	(18,529,986)	975,987
Balance at 1 July 2009 Total comprehensive income for the period	19,920,593	359,608	(19,438,695)	841,506
Loss	-	-	(827,513)	(827,513)
Other comprehensive income		-	-	-
Balance at 31 December 2009	19,920,593	359,608	(20,266,208)	13,993

The interim statement of changes in equity is to be read in conjunction with the notes to the interim financial statements set out on pages 10 to 11.

## NOTES TO THE INTERIM FINANCIAL STATEMENTS FOR THE HALF YEAR ENDED 31 DECEMBER 2009

#### 1. REPORTING ENTITY

Biotron Limited (the 'Company') is a company domiciled in Australia.

The annual financial report of the Company as at and for the year ended 30 June 2009 is available upon request from the Company's registered office at Level 2, 66 Hunter Street, Sydney, NSW, 2000 or at www.biotron.com.au.

#### 2. STATEMENT OF COMPLIANCE

The interim financial report has been prepared in accordance with AASB 134 *Interim Financial Reporting* and the Corporations Act 2001.

The Company's interim financial report does not include all of the information required for a full annual financial report, and should be read in conjunction with the 30 June 2009 annual financial report and any public announcements by the Company during the half year in accordance with continuous disclosure obligations arising under the Corporations Act 2001.

The interim financial report was authorised for issue by the Directors on 26 February 2010.

#### 3. SIGNIFICANT ACCOUNTING POLICIES

Except as described below, the accounting policies applied by the Company in this interim financial report are the same as those applied by the Company in its financial report as at and for the year ended 30 June 2009.

## Presentation of Financial Statements

The Company applies revised AASB 101 *Presentation of Financial Statements (2007)*, which became effective as of 1 January 2009. As a result, the Company presents in the statement of changes in equity, all owner changes in equity, whereas all non-owner changes in equity are presented in the statement of comprehensive income. This presentation has been applied in these interim financial statements as of and for the six month period ended on 31 December 2009.

Comparative information has been re-presented so that it also is in conformity with the revised standard. Since the change in accounting policy only impacts presentation aspects, there is no impact on earnings per share.

Determination and presentation of operating segments

From 1 July 2009, the Company determines and presents operating segments based on the information that internally is provided to the Managing Director, who is the Company's chief operating decision maker. This change in accounting policy is due to the adoption of AASB 8 Operating Segments. Previously, operating segments were determined and presented in accordance with AASB 14 Segment Reporting. The new accounting policy in respect of operating segment disclosures is presented as follows.

An operating segment is a component of the Company that engages in business activities from which it may earn revenues and incur expenses, including revenues and expenses that relate to transactions with any of the Company's other components. An operating segment's operating result is reviewed regularly by the Managing Director to make decisions about resources to be allocated to the segment and assess its performance, and for which discrete financial information is available.

There is no change to operating segment disclosures as a result of this change in accounting policy.

## NOTES TO THE INTERIM FINANCIAL STATEMENTS FOR THE HALF YEAR ENDED 31 DECEMBER 2009

#### 4. ESTIMATES

The preparation of the interim financial report requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, income and expenses. Actual results may differ from these estimates.

In preparing this interim financial report, the significant judgements made by management in applying the Company's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the financial report as at and for the year ended 30 June 2009.

#### 5. SUBSEQUENT EVENTS

The financial report has been prepared on a going concern basis. As is usual for a research and development company losses are being incurred in meeting the Company's objectives.

At 31 December 2009 the Company had a deficiency in net current assets of \$41,798. Subsequent to 31 December 2009 the Company raised \$2,100,000, and will continue to manage its expenditures in line with funds available to pursue its programs.

The \$2,100,000 was raised via the allotment of 114,537,315 new options via a fully underwritten non renounceable issue to existing shareholders on the basis of 1 new option for every existing share held by the members at an issue price of \$0.02 per option.

The options have an exercise price of 10 cents and an expiry date 30 December 2011. Each new option carries an additional right whereby if a new option is exercised by 31 March 2010, one additional option to acquire one new fully paid ordinary share in the capital of the Company up to 30 March 2012 for \$0.20 will be issued to the optionholder for each new option exercised.

### 6. LOSS PER SHARE

Basic and diluted loss per share have been calculated using:	31 December 2009 \$	31 December 2008 \$
Net loss for the six months ended 31 December	827,513	867,390
Weighted average number of ordinary shares	114,537,315	104,443,565

## **DIRECTORS' DECLARATION**

In the opinion of the directors of Biotron Limited:

- (a) the financial statements and notes, set out on pages 6 to 11, are in accordance with the Corporations Act 2001, including:
  - (i) giving a true and fair view of the Company's financial position as at 31 December 2009 and of its performance for the half year ended on that date; and
  - (ii) complying with Australian Accounting Standard AASB 134 *Interim Financial Reporting* and the Corporations Regulations 2001; and
- (b) there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

This report has been signed in accordance with a resolution of the directors and is dated 26 February 2010:

Michael J. Hoy Director



## INDEPENDENT AUDITOR'S REVIEW REPORT TO THE MEMBERS OF BIOTRON LIMITED

We have reviewed the accompanying interim financial report of Biotron Limited (the 'Company'), which comprises the interim balance sheet as at 31 December 2009, statement of comprehensive income, statement of changes in equity and statement of cash flows for the half year ended on that date, a description of significant accounting policies and other explanatory notes 1 to 6, and the directors' declaration.

#### Directors' Responsibility for the Interim Financial Report

The directors of the Company are responsible for the preparation and fair presentation of the interim financial report in accordance with Australian Accounting Standards (including the Australian Accounting Interpretations) and the *Corporations Act 2001*. This responsibility includes establishing and maintaining internal control relevant to the preparation and fair presentation of the interim financial report that is free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

#### Auditor's Responsibility

Our responsibility is to express a conclusion on the interim financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of Interim and Other Financial Reports Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the interim financial report is not in accordance with the *Corporations Act 2001* including: giving a true and fair view of the Company's financial position as at 31 December 2009 and its performance for the half year ended on that date; and complying with Australian Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*. As auditor of Biotron Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

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

## Independence

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

#### Conclusion

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

- a) giving a true and fair view of the Company's financial position as at 31 December 2009 and of its performance for the half year ended on that date; and
- b) complying with Australian Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001.

**KPMG** 

26 February 2010 Brisbane W.E. Austin

Partner

## **CORPORATE DIRECTORY**

## **Directors:**

Mr Michael J. Hoy (Chairman)
Dr Michelle Miller (Managing Director)
Dr Michael S. Hirshorn
Mr Bruce Hundertmark
Mr Peter G. Scott

## **Company Secretary:**

Mr Peter J. Nightingale

## **Registered Office:**

Level 2, 66 Hunter Street SYDNEY NSW 2000

Phone: 61-2 9300 3344 Fax: 61-2 9221 6333

E-mail: enquiries@biotron.com.au Homepage: www.biotron.com.au

## **Share Registrar:**

Computershare Investor Services Pty Limited PO Box 523 BRISBANE QLD 4001

Phone: 61-7 3237 2100 Fax: 61-7 3229 9860

### **Auditors:**

KPMG Level 16, Riparian Plaza 71 Eagle Street BRISBANE QLD 4000

## Home Exchange:

ASX Limited 20 Bridge Street SYDNEY NSW 2000

## Solicitors:

Minter Ellison 88 Phillip Street SYDNEY NSW 2000

Biotron Limited, incorporated and domiciled in Australia, is a publicly listed company limited by shares.