biota

Biota Holdings Limited ACN 006 479 081

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30 August 2004

Commentary on Group Results for the Year Ended 30 June 2004

Biota Holdings Limited (ASX:BTA) announced its results today for the year ended 30 June 2004, reporting a significant improvement over the prior year's performance. The year was important from an operational and strategic perspective.

Significant events

Milestones during the year included:

- Biota executed an agreement with Sankyo, one of Japan's largest pharmaceutical companies, to collaborate on the development and partnering of long-acting neuraminidase inhibitors (LANI). Under the alliance, the companies cross-licensed their relevant patents which covered Biota's second generation FLUNET[™] compounds and Sankyo's LANI compound. Subsequently, the companies formed a Licensing Committee to jointly offer the combined pipeline of second generation flu drugs to prospective licensing partners for development and marketing. This committee has been actively pursuing partnering opportunities.
- Biota's common cold candidate drug, BTA798, passed preliminary toxicological testing and was cleared to commence preclinical development.
- The Company offered its first Share Purchase Plan (SPP) and received a positive response from shareholders, raising \$8.4m. Approximately 14% of eligible shareholders participated, well in excess of normal SPP take-up rates.
- Development at the Company's new site in Notting Hill, Victoria has progressed well. The building, which will house laboratories and offices, will be the new Australian headquarters for Biota. It is intended that all global research activities will be consolidated into this facility when it becomes available in October 2004, as the new capacity will allow for the combined Australian and USA research activities to be conducted at this location. This integration of global research will lead to more efficient and effective management of the programs, as well as yield significant cost savings.
- Biota negotiated profit share rights to a new influenza diagnostic product, manufactured by Thermo Electron in the USA. In addition to profit share from the current FLU OIA[®] diagnostic product, Biota now receives profit share revenue from the FLU OIA A/B diagnostic product. Combined profit share from the two products during the year was \$3.5m, boosted by an influenza epidemic in the USA.
- Biota received a two year, \$2.7m AusIndustry R&D Start grant to support development of a small
 molecule RSV treatment and preventative, leveraging the Company's long-standing expertise in structure
 based drug design. During the year, all the research milestones under that grant were achieved and the
 Company continues to progress research towards a preclinical candidate that could be positioned for
 human clinical trials in two to three years. The grant is scheduled to conclude in June 2005.
- In May 2004, Biota announced that it had filed a suit in the Victorian Supreme Court claiming damages from GlaxoSmithKline (GSK) for past and future lost royalties on Relenza[™], arising from GSK's decisions to withdraw support for the product shortly after its worldwide launch in 1999/00. The Company will vigorously pursue this claim during the 2005 financial year and is confident of the merits of its case.

Results of operations

For 2004, the Company reported a loss attributable to members of \$7.8m (2003: \$10.3m). This improvement was due to strong revenues and expense savings arising from the USA operations.

Revenues of \$8.0m grew by 8% from the prior period (2003: \$7.4m). This was primarily due to increased profit share revenues from diagnostic sales by Thermo Electron of \$3.5m, up 117% from 2003. Profit share was generated by sales of the FLU OIA diagnostic product, as well as a new FLU OIA A/B diagnostic recently added to the range, and was boosted by the influenza epidemic in the USA during the northern hemisphere winter.

Relenza royalties of \$0.6m fell by almost 50% from the prior period payment (2003: \$1.1m), due to the ongoing decline in global sales of this product despite a very significant growth in the overall flu treatment and prevention market.

Operating expenses of \$16.1m decreased by 12% from the prior period (2003: \$18.4m), largely due to reduced R&D costs in the US. As a result of restructuring of the US operations and careful cost management across all research operations, R&D expenses declined to \$7.8m (2003: \$10.8m). Marketing and Business Development expenses rose to \$2.3m (2003: \$1.3m) with the progression of certain research programs into development activities.

In Australia, the Company commenced litigation against GlaxoSmithKline for breaches of contract and fiduciary duties for failing to promote and support Relenza. Expenses of \$1.0m were incurred during the year in preparing and commencing the litigation.

Cash reserves held by the Company increased during the period to \$22.9m (2003: \$21.6m). The operating cash outflow was \$6.0m but due to support of shareholders, a Share Purchase Plan raised \$8.4m in October 2003.

About Biota

Biota is a world-leading antiviral drug discovery company with its headquarters in Melbourne, Australia. Biota's first breakthrough was the discovery of zanamivir, subsequently marketed by GlaxoSmithKline as Relenza. In partnership with Thermo Electron, Biota markets the FLU OIA diagnostics for the rapid detection of influenza. In partnership with Sankyo, Biota is engaged in the development and commercialisation of second generation flu therapies (LANI or long-acting neuraminidase inhibitors). Biota also has active discovery and development programs aimed at new therapies for diseases caused by Human Rhinovirus (common cold), RSV (Respiratory Syncytial Virus), HIV, and hepatitis C.

For further information please contact:

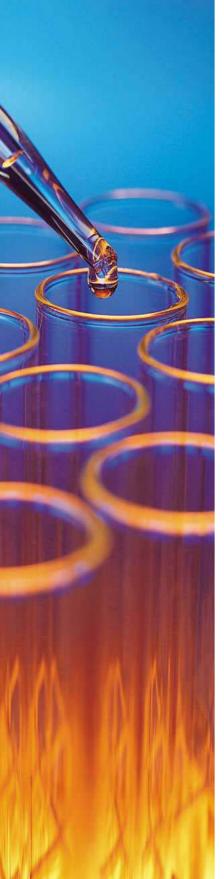
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™ FLUNET is a registered trademark of Biota Scientific Management Pty Ltd

[™]Relenza is a registered trademark of the GlaxoSmithKline group of companies

[®]FLU OIA is a registered trademark of Thermo Electron Corporation

Biota Holdings Limited ABN 28 006 479 081



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ASX Preliminary Final Report – 30 June 2004

Lodged with the ASX under Listing Rule 4.3A

This information should be read in conjunction with the 30 June 2004 Annual Report.

Biota Holdings Limited Level 4, 616 St Kilda Road Melbourne VIC 3004 Australia T: +61 3 9529 2311 F: +61 3 9529 2261 www.biota.com.au

Corporate Directory

Directors

John R Grant (Chairman) Peter L Molloy (Chief Executive Officer) Barbara J Gibson Ian D Gust Andrew M S Tyndale

Company Secretary

Andrew J Macdonald

Registered & Corporate Office

Registered office at the date of this report:

Level 4, 616 St Kilda Road Melbourne VIC 3004, Australia T: +61 3 9529 2311 F: +61 3 9529 2261 E: info@biota.com.au W: www.biota.com.au

With effect from 31 October 2004, Biota's registered office and principal place of business will be:

10/585 Blackburn Road Notting Hill VIC 3168, Australia

Share Registry

ASX Perpetual Registrars Limited GPO Box 1736 Melbourne VIC 3001 T: 1300 554 474 (within Australia) T: +61 3 9615 9999 (outside Australia) F: +61 3 9615 9900 E: <u>registrars@asxperpetual.com.au</u> W: <u>www.asxperpetual.com.au</u>

Stock Exchange

Australia Biota Holdings Limited is a public company listed with the Australian Stock Exchange Limited. ASX:BTA

USA

Biota's American Depositary Receipts (ADRs) trade in the United States on the pink sheets at a ratio of three shares to each ADR. ADR:BTAHY



Biota Holdings Limited ABN 28 006 479 081 Year ended 30 June 2004

(Previous corresponding period: Year ended 30 June 2003)

Results for announcement to the market

				A\$'000
Revenue from ordinary activities	up/ down	8.1%	То	\$8,048
Loss from ordinary activities after tax attributable to members	up /down	24.6%	То	\$7,771
Net loss for the period attributable to members	up /down	24.6%	То	\$7,771

	Amount p	er security	Franked amount per security		
Dividends	Current period	Previous corresponding period	Current period	Previous corresponding period	
Final dividend	Nil cents	Nil cents	Nil cents	Nil cents	
Interim dividend	Nil cents	Nil cents	Nil cents	Nil cents	

Record date for determining entitlements to the dividend

Not applicable

Amounts in the Preliminary Final Report have been rounded off to the nearest thousand dollars, unless otherwise stated.



Biota Holdings Limited For the year ended 30 June 2004

Review of Operations

		2004 \$'000			2003 \$'000	
	Australia	USA	Total	Australia	USA	Total
Revenues						
Royalties	565		565	1,115	-	1,115
Research and license fees	16	1,780	1,796	-	3,686	3,686
Diagnostic sales revenues	3,490		3,490	1,609	-	1,609
and profit share						
Research grant	1,131	74	1,131	-	-	-
Interest/other	995	71	1,066	917	115	1,032
Total revenues	6,197	1,851	8,048	3,641	3,801	7,442
Operating expenses						
Royalties	81	-	81	159	-	159
Research and development	3,266	4,677	7,943	3,985	6,801	10,786
Marketing and business development	1,399	887	2,286	579	751	1,330
Corporate and administration	3,022	849	3,871	3,672	719	4,391
Depreciation and amortisation expense	587	1,247	1,834	248	1,301	1,549
Borrowing cost expenses	-	145	145	-	229	229
Total expenses	8,355	7,805	16,160	8,643	9,801	18,444
Operating loss	(2,158)	(5,954)	(8,112)	(5,002)	(6,000)	(11,002)
Income tax attributable to operating loss	-	-	-	-	-	-
Operating loss after income tax	(2,158)	(5,954)	(8,112)	(5,002)	(6,000)	(11,002)
Net loss attributable to outside equity interest		-	(341)		-	(694)
Loss attributable to the members of Biota Holdings Limited		_	(7,771)		=	(10,308)

Explanation of revenue and expenses

The operating revenues for the period were \$6,982 (2003: \$6,410).

 As a result of the influenza epidemic in the USA during the winter, Australian profit share from sales of the FLU OIA and FLU OIA A/B diagnostics by our partner, Thermo Electron, were \$3,490 (2003: \$1,609). The FLU OIA A/B product, a differentiated test for influenza strains A and B, was released to the market by Thermo Electron during the 2004 year.



- USA research fees were \$1,780 (2003: \$1,840). These fees were paid by GlaxoSmithKline (GSK) under a two year collaboration agreement which expired in August 2004. No license fees were received in the period.
- Grant funds received from the RSV Start grant project revenues were \$1,131 (2003: \$0). The Start grant commenced in April 2003 and is scheduled to conclude in June 2005.
- Royalties received from GSK on global sales of Relenza during the year were \$565 (2003: \$1,115).

Other revenues for the period, predominantly interest income, were \$1,066 (2003: \$1,032).

Total expenses for the period were \$16,160 (2003: \$18,444).

- Research expenses, excluding depreciation, were \$7,943 (2003: \$10,786). Expense savings were achieved in the USA due to restructuring conducted in December 2003 and general cost saving measures adopted across all research operations.
- Marketing and Business Development expenses were \$2,286 (2003: \$1,330). Costs associated with the
 FLUNET compounds have been transferred from research to marketing and business development given
 that the LANI program is now into active partnering. These expenses include legal and patent costs, as
 well as contract chemistry and other external costs.
- Corporate expenses, excluding depreciation, were \$3,871 (2003: \$4,994). In May 2004, the Company commenced litigation against GSK, claiming breaches of contract and fiduciary duties by GSK for failing to promote and support Relenza. Expenses of \$968 were incurred during the year preparing for, and commencing, the litigation. Subject to the period of litigation, it is expected that further costs will occur during the 2005 financial year and possibly into the following financial year.
- Deprecation and amortisation expenses were \$1,834 (2003: \$1,549). These expenses include amortisation of development costs (\$399) associated with the FLU OIA A/B product. Total development costs were \$1,108.

Explanation of net loss after income tax

The 26.3% improvement in the net loss for the period, before allocation of outside equity interest, of \$8,112 (2003: \$11,002) was attributable to:

- Additional revenues of \$606, largely attributable to strong USA sales by Thermo Electron of the influenza diagnostic products;
- Savings achieved in the Australian and USA research operations of \$2,843;
- Unbudgeted legal and other expenditure relating to litigation against GSK of \$968.

Explanation of assets, liabilities and equities

In October 2003, additional capital of \$8,387 (net of expenses) was raised through a Share Purchase Plan.

Explanation of dividends

Directors have no expectation at this time of providing for, or paying, any dividend.



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This interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2004 and any public announcements made by Biota Holdings Limited during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.



1 Preliminary consolidated statement of financial performance

Biota Holdings Limited For the year ended 30 June 2004

		Consolidated
	2004 \$'000	2003 \$'000
Revenues from ordinary activities	8,048	7,442
Operating expenses		
Research and development Marketing and business development Corporate Borrowing cost expenses Depreciation and amortisation expense Royalties	(7,943) (2,286) (3,871) (145) (1,834) (81)	(10,786) (1,330) (4,391) (229) (1,549) (159)
Loss from ordinary activities before income tax	(8,112)	(11,002)
Income tax expense		<u> </u>
Loss from ordinary activities after income tax	(8,112)	(11,002)
Net loss attributable to outside equity interest	(341)	(694)
Net loss attributable to members of Biota Holdings Limited	(7,771)	(10,308)
Total changes in equity attributable to members of Biota Holdings Limited other than those resulting from transactions with owners as owners	(7,771)	(10,308)
Earnings/(loss) per share		
	Cents	Cents
Basic (loss)/earnings per share	(8.49)	(13.67)
Diluted (loss)/earnings per share	(8.49)	(13.67)

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



2 Preliminary consolidated statement of financial position

Biota Holdings Limited As at 30 June 2004

	2004 \$'000	2003 \$'000
Current assets		
Cash	22,896	21,643
Receivables Other	129 753	349 337
Total current assets	23,778	22,329
	20,770	22,020
Non-current assets		
Other	339	-
Plant and equipment	2,058	2,897
Total non-current assets	2,397	2,897
Total assets	26,175	25,226
Current liabilities		
Accounts payable	3,249	1,860
Interest bearing liabilities	443	416
Total current liabilities	3,692	2,276
Non-current liabilities		
Interest bearing liabilities	835	1,326
Provisions	28	36
_	863	1,362
Total liabilities	4,555	3,638
Net assets	21,620	21,588
Equity		
Parent entity interest		
Contributed equity	106,184	97,792
Foreign currency translation reserve	(1,112)	(892)
Accumulated losses	(82,169)	(73,854)
Total parent entity interest	22,903	23,046
Outside equity interest	(1,283)	(1,458)
Total equity	21,620	21,588

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



3 Preliminary consolidated statement of cash flows

Biota Holdings Limited For the year ended 30 June 2004

	2004 \$'000	2003 \$'000
	Inflows / (outflo	
Cash flows from operating activities		
Receipts from trade and other debtors (inclusive of goods and services tax)	7,409	6,457
Payments to suppliers and employees (inclusive of goods and services tax)	(14,243)	(15,755)
Interest expenses	(145)	(229)
Interest received	982	1,043
Net cash (outflow) from operating activities	(5,997)	(8,484)
Cash flows from investing activities		
Proceeds on maturity of money market investments	-	9,778
Payments for plant and equipment	(555)	(1,010)
Net cash (outflow)/inflow from investing activities	(555)	8,768
Cash flows from financing activities		
Repayments of interest bearing liabilities	(462)	(494)
Proceeds from issue and buyback of shares	8,419	2,531
Issue costs	(52)	-
Net cash (outflow)/inflow from financing activities	7,905	2,037
Net increase in cash held	1,353	2,321
Cash at the beginning of the financial year	21,643	20,339
Exchange rate adjustments	(100)	(1,017)
Cash at the end of the financial year	22,896	21,643

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



4 Notes to the preliminary consolidated financial statements

Biota Holdings Limited For the year ended 30 June 2004

4.1 Material factors affecting the assets, liabilities and equity of the consolidated entity for the current period

Additional capital of \$8,444 was raised from a Share Purchase Plan held in October 2003 and \$52 of issue costs were incurred. New assets of \$1,106 were purchased in Australia and the USA during the period.

Development costs of \$1,018 were paid during the period to Thermo Electron for the new diagnostic product, FLU OIA A/B. These costs are being amortised over a three year period.

4.2 Segment information

Primary reporting - geographical segments

The consolidated entity has one business segment, being pharmaceutical and medical research, with operations in Australia, the home country of the Company, and the USA. The Australian and USA operations are conducted in Melbourne, Victoria, and Carlsbad, California, respectively.

			Inter-segment	
2004	Australia	USA	eliminations/unallocated	Consolidated
	\$'000	\$'000	\$'000	\$'000
Operating revenue	5,202	1,780	-	6,982
Interest revenue	991	19	-	1,010
Other revenue	4	52	-	56
Total segment revenue	6,197	1,851	-	8,048
Segment result	(2,158)	(5,809)	-	(7,967)
Net interest				(145)
Loss from ordinary activities before income tax expense				(8,112)

2003	Australia \$′000	USA \$'000	Inter-segment eliminations/unallocated \$'000	Consolidated \$'000
Operating revenue	2,724	3686	-	6,410
Interest revenue	867	44	-	911
Other revenue	50	996	(925)	121
Total segment revenue	3,641	4,726	(925)	7,442
Segment result	(5,002)	(5,771)	-	(10,773)
Net interest				(229)
Loss from ordinary activities before income tax expense				(11,002)



4.3 Revenues from ordinary activities

	Current period	Previous corresponding period
	\$'000	\$'000
Revenue from operations		<u>.</u>
Research revenues	1,796	1,840
License fee	-	1,846
Royalties	565	1,115
Diagnostics profit share	3,490	1,609
Grants	1,131	-
Total revenue from sales	6,982	6,410
Revenues – other		
Interest revenue	1,010	938
Other revenue	56	94
Total other revenue	1,066	1,032
Total revenues	8,048	7,442

4.4 Comparison of half year profits

	Current period \$'000	Previous corresponding period \$'000
Consolidated (loss) from ordinary activities after tax attributable to members reported for the 1st half yearly report	(2,867)	(5,230)
Consolidated (loss) from ordinary activities after tax attributable to members for the 2nd half year	(4,904)	(5,078)

4.5 Movements in ordinary share capital

Date	Details	Number of shares	Issue price \$	\$'000
1 July 2003 30 October 2003 10 March 2004	Opening balance Share placement Exercise of options	80,647,099 16,230,332 8,000	0.52 0.58	97,792 8,387 5
30 June 2004	Closing balance	96,885,431		106,184

\$52 of issue costs were incurred regarding the share placement. The increase in share capital shown above has been recorded net of these costs.



4.6 Accumulated losses

	Current period	Previous corresponding period
	\$'000	\$'000
Accumulated losses at the beginning of the financial year	(73,854)	(63,546)
Minority interest adjustment to accumulated losses opening balance	(544)	-
Loss attributable to members	(7,771)	(10,308)
Accumulated losses at end of financial year	(82,169)	(73,854)

4.7 Foreign currency translation reserve

	Current period	Previous corresponding period
	\$'000	\$'000
Accumulated reserves at the beginning of the financial year	(892)	-
Net exchange difference on translation of foreign controlled entity	(220)	(892)
Accumulated reserves at end of financial year	(1,112)	(892)

4.8 Reconciliation of cash

	Current period	Previous corresponding period
	\$'000	\$'000
Cash on hand and at bank	2,970	824
US Treasury bills	1,942	2,550
Certificates of deposit and promissory notes	17,984	18,269
Total cash at end of period	22,896	21,643

Treasury Bills were established in the USA as security for Letters of Credit for Biota Inc's finance and operating leases. These Bills currently have a 90 day term and yield between 0.92%-1.01% (2003: 0.83%-1.6%).

4.9 Non-cash financing and investing activities

The major non-cash transactions that occurred during the period were \$455 regarding additions to property, plant and equipment that remained unpaid at the year end and \$391 relating to the impairment of USA based leasehold improvements.



4.10 Reconciliation of profit/(loss) after income tax to net cash flows from operating activities

	Current period \$'000	Previous corresponding period \$'000
Cash flow information		
Operating (loss) after income tax	(8,112)	(11,002)
Depreciation	1,834	1,549
Net exchange difference	(110)	343
Changes in assets and liabilities		
(Increase)/decrease in trade debtors and other debtors	144	214
Increase/(decrease) in trade creditors and other liabilities	255	411
Increase/(decrease) in provisions	(8)	1
Net cash inflows/(outflows) from operating activities	(5,997)	(8,484)

4.11 Earnings per share

		Previous
	Current period	corresponding period
	\$'000	\$'000
	Cents	Cents
Basic earnings/(loss) per share (EPS)	(8.49)	(13.67)
Diluted earnings/(loss) per share (EPS)	(8.49)	(13.67)
Losses used to calculate EPS	(7,771)	(10,308)
	Number	Number
Weighted average shares used to calculate basic EPS	91,499,422	75,407,375
Weighted average shares used to calculate diluted EPS	91,499,492	75,407,375

Options granted by the Company to directors and employees are considered to be potential ordinary shares but are not dilutive in the current period or the previous corresponding period and have not been included in the determination of diluted earnings per share.

4.12 Contingent liabilities

During the period, the Company has entered into commercially sensitive contractual arrangements with external parties in regard to the provision of legal and consulting services associated with litigation against GSK. These arrangements could potentially give rise to a future liability under certain circumstances. During the year, expenses of \$968 were incurred in preparing for, and commencing, the litigation.



4.13 Events occurring after reporting date

The following significant events have occurred since the reporting date:

- The Company has entered into a contract for the building of new laboratory and office facility at its site in Notting Hill, Australia. These works are expected to be completed during October 2004.
- A USA subsidiary of the Company (Biota Inc) has chosen to outsource its research program to an Australian subsidiary (Biota Scientific Management Pty Ltd) during the 2005 financial year and consolidate research operations at its new Australian laboratory and office facility. Accordingly, Biota Inc will be closing its laboratory facility in the USA.

4.14 Audit

This report is based on accounts which are in the process of being audited.



5 Supplementary appendix 4E information

Biota Holdings Limited For the year ended 30 June 2004

5.1 NTA backing

	Current period	Previous
		corresponding period
Net tangible asset backing per ordinary share	22.3 cents per share	28.6 cents per share

5.2 Individually significant items

During the period, a Share Purchase Plan for shareholders raised \$8,387 (net of costs) with 16,230,332 shares being issued at 52 cents per share.

5.3 Biota Inc

In February 2004, Biota Inc, a subsidiary of the Company, bought back shares from a minority shareholder. As a result, the Company now holds a 92.3% interest in Biota Inc (formerly 88%) and continues to provide funding to the subsidiary.



6 Basis of preparation of preliminary final report

This general purpose financial report for the reporting period ended 30 June 2004 has been prepared in accordance with Accounting Standard AASB1029 *Interim Financial Reporting*, other mandatory professional reporting requirements (Urgent Issues Group Consensus Views), other authoritative pronouncements of the Australian Accounting Standards Board and the *Corporations Act 2001*.

This preliminary final financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2004 and any public announcements made by Biota Holdings Limited during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

The accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period.

This preliminary final report including the commentary on Group results was approved by a resolution of the board of directors on 27 August 2004.

Andrew J Macdonald Company Secretary 30 August 2004

