biota

Biota Holdings Limited
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For Immediate Release

Melbourne, Australia — 15 February 2012

Half year report

Summary

- The BARDA laninamivir contract has progressed well. Revenue of $4.3 million was recognised in the first half.
- Inavir royalties of $0.7 million. A further prophylaxis trial has been commenced in Japan.
- Relenza royalties of $0.7 million.
- Enrolment for the Phase IIb Human Rhinovirus study has been completed. Full study results are anticipated early in Q2 2012.
- Net loss of $11 million.
- Cash of $56.5 million at 31 December 2011.

Biota Holdings Limited (ASX: BTA) today announced a half year loss of $11 million compared to a net loss of $15.9 million in the corresponding half year.

Total revenue was $7.8 million, compared to $8.1 million in 1H F2011. Revenue included $0.7 million of Relenza royalties (1H F11: $3.3m) and $0.7 million (1H F11: $1.2m) of royalties from laninamivir (Inavir). Revenue under the BARDA contract was $4.3 million (1H F11: Nil) and the first three contract milestones have been delivered.

Commenting on the results today, Biota CEO Peter Cook said *"The key business focus has been to ensure progress under the BARDA contract and manage cash and costs until the restocking of government neuraminidase inhibitor stockpiles improve Relenza royalty income.*

It is pleasing to see the very successful advance of all our programs, although the short term focus will be on the HRV Phase IIb results to be announced in early Q2 2012".

Total expenses were $19.4 million (1H F11: $24.8m).

The Company's cash at $56.5 million confirms a slow down in cash use, a trend which is expected to continue over the next six months. The business will continue to balance its programs' demands against the availability of cash from its royalty streams.

Significant Events

- The main activities under the BARDA contract have been the recruitment of staff with experience in advanced clinical development and manufacturing, the appointment of suppliers and the transfer of the manufacturing know-how from Japan to the USA.

  Key achievements are:

  - Submission of the first 3 contract milestones;
  - Synthesis of the first batch of laninamivir (active pharmaceutical ingredients or API) to be produced outside of Japan; and
  - Injection moulding of inhalers using US approved polymers.

  In parallel, the clinical team are planning for two Phase I studies that are expected to commence around June 2012.

- Inavir royalties were $ 0.7 million. Prior to the recent heavy influenza outbreak in Japan, Daiichi Sankyo indicated that sales of Inavir were forecasted to be US$125 million and achieve a 33% share of the Japanese market, this season.
- Daiichi Sankyo has initiated a further prophylaxis trial in Japan. The trial intends to recruit 1,500 subjects to evaluate Inavir's ability to prevent transmission of influenza A and B within families with a confirmed sufferer.
- Relenza royalties were subdued at $0.7 million and thus far have not included any significant replacement of expired inventory in government stockpiles.
- The Phase IIb clinical study of the HRV antiviral BTA798 in asthmatic subjects has completed recruitment ahead of schedule. Results are expected to be available in early Q2 2012. BTA798 has been allocated the generic name of "vapendavir" by the World Health Organisation.
- Considerable progress has been made on the RSV, HCV-NN and GYR programs. Biota expects to have nominated a lead candidate for each of these preclinical programs by mid-year.
- The Board has made solid progress on how best to secure long term value recognition from laninamivir and Biota's other products, in conjunction with our advisor Piper Jaffray. Directors expect to be in a position to take a proposal to shareholders by mid 2012.

About Biota

Biota is a leading anti-infective drug development company based in Melbourne Australia, with key expertise in respiratory diseases, particularly influenza. Biota developed the first-in-class neuraminidase inhibitor, zanamivir, subsequently marketed by GlaxoSmithKline as Relenza. Biota research breakthroughs include a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease and Hepatitis C (HCV) virus infections. Biota has clinical trials underway with its lead compound for human rhinovirus (HRV) infection in patients with compromised respiration or immune systems.

In addition, Biota and Daiichi Sankyo co-own a range of second generation influenza antivirals, of which the lead product Inavir®, is marketed in Japan. Biota holds a contract from the US Office of Biomedical Advanced Research and Development Authority (BARDA) for the advanced development of laninamivir in the USA.

Relenza™ is a registered trademark of the GlaxoSmithKline group of companies.
Inavir® is registered to Daiichi Sankyo.

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Biota Holdings Limited
(ABN 28 006 479 081)

Interim report
for the half year ended 31 December 2011

Biota Holdings Limited
ABN 28 006 479 081

Corporate Directory

Directors
Jim Fox (Chairman)
Paul R Bell
Peter C Cook (CEO & Managing Director)
Jeff Errington
Ian D Gust AO
Richard Hill

Company Secretary
Damian Lismore (Chief Financial Officer)

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

United States
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

Interim report – half year ended 31 December 2011
(Previous corresponding period: half year ended 31 December 2010)

Results for announcement to the market

		% change		A$'000
Revenue from ordinary activities	Down	3%	To	$7,814
Loss from ordinary activities after tax attributable to members	Down	31%	To	$10,996
Net loss for the period attributable to members	Down	31%	To	$10,996

Dividends	**Amount per security**		**Franked amount per security**	
	Current period	Previous corresponding period	Current period	Previous corresponding period
Final dividend	Nil	Nil	Nil	Nil
Interim dividend	Nil	Nil	Nil	Nil

Record date for determining entitlements to the dividend. Not applicable

Amounts in the interim report have been rounded off to the nearest thousand dollars, unless otherwise stated.

Biota Holdings Limited
ABN 28 006 479 081

Interim report – 31 December 2011
Commentary on Group Results for the half year ended 31 December 2011

Explanation of revenue and expenses

Total revenues were $7,814 (2010: $8,062). The main elements were:

- Royalty income was $1,415 (2010: $4,491). Royalties from sales of Relenza were $727 (2010: $3,328) and royalties from sales of Inavir was $688 (2010: $1,163).
- Income associated with the BARDA contract was $4,336 (2010: Nil).

Total expenses for the period were $19,440 (2010: $24,783) comprising:

- Research and development expenses of $8,124 (2010: $12,948);
- Product development expenses of $7,769 (2010: $8,410) includes the HRV Phase IIb clinical trial costs which commenced in 2010 and includes costs associated with the BARDA contract in 2011; and
- Sub royalty amortisation of $606 (2010: $621).

Explanation of net loss after income tax

The Loss after income tax was $10,996 (2010: loss of $15,946). The income tax credit was $630 (2010:$775).

Explanation of assets, liabilities and equities – December 2011 & December 2010

Cash balances were $56,540 (2010: $77,518).

Receivables at $7,292 (2010: $6,814) include:

- Relenza royalties' receivable at 31 December 2011 of $2,496 (2010: $4,223), which are due prior to 30 June 2012; and
- Funds receivable from BARDA of $2,473 (2010: Nil).

Plant and equipment principally is the investment in the fit-out of the laboratories and offices at 585 Blackburn Road, Notting Hill.

Deferred tax assets represent deductible temporary differences.

Intangible assets of $2,394 (2010: $3,581) principally represents $2,240 (2010: $3,436) in respect of the agreement with CSIRO and Victorian College of Pharmacy where the parties agreed to exchange variable royalty payments in relation to intellectual property, for a fixed amount less accumulated amortisation. This amount will continue to be progressively expensed over the Relenza patent life.

Deferred revenue of $486 (2010: $1,532) represents NIH grant funds received in advance. This amount is expected to be progressively released to revenue over subsequent reporting periods.

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

Biota Holdings Limited
ABN 28 006 479 081

Interim report – 31 December 2011

Table of Contents

This interim 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 2011 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.

Directors' report
31 December 2011

Your Directors present their report on the consolidated entity, consisting of Biota Holdings Limited ("the Company") and the entities it controlled at the end of, or during, the half year ended 31 December 2011.

Directors

The following persons were Directors of Biota Holdings Limited during the reporting period and up to the date of this report: Jim Fox (Chair), Paul Bell, Peter Cook, Jeff Errington, Ian Gust and Richard Hill.

Review of operations

A review of operations of the consolidated entity during the half year is attached to this report under the title of "Commentary on Group Results for the half year ended 31 December 2011".

Auditors' independence

A copy of the auditors' independence declaration as required under section 307C of the *Corporations Act 2001* is set out on page 2.

Rounding of amounts to nearest thousand dollars

The Company is of a kind referred to in Class Order 98/0100 issued by the Australian Securities and Investments Commission, relating to the "rounding off" of amounts in the Directors' report and financial report. Amounts in the Directors' report and financial report have been rounded off to the nearest thousand dollars in accordance with that Class Order.

This report is made in accordance with a resolution of the Directors.

Jim Fox
Director

Peter Cook
Director

Melbourne
14 February 2012

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Auditor's Independence Declaration

As lead auditor for the review of Biota Holdings Limited for the half year ended 31 December 2011, I declare that to the best of my knowledge and belief, there have been:

a) no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the review; and

b) no contraventions of any applicable code of professional conduct in relation to the review.

This declaration is in respect of Biota Holdings Limited and the entities it controlled during the period.

Nadia Carlin
Partner
PricewaterhouseCoopers

14 February 2012

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Consolidated income statement
For the half year ended 31 December 2011

	Notes	Half year 2011 $'000	Half year 2010 $'000
Revenues from continuing operations	3	7,565	6,984
Other income	3	249	1,078
Expenses:			
Research and development		(8,124)	(9,997)
-Amortisation of antibacterial programs acquired		-	(2,951)
Product development		(7,769)	(8,410)
Business development		(489)	(399)
Sub-royalty amortisation		(606)	(621)
Corporate – head office		(2,452)	(2,405)
Loss before income tax		(11,626)	(16,721)
Income tax credit/(expense)		630	775
Loss for the half-year		**(10,996)**	**(15,946)**
Other comprehensive (expense)/income			
Exchange differences on translation of foreign operations		16	(607)
Other comprehensive income/(expense) for the half-year, net of tax		16	(607)
Total comprehensive (expense)/income for the half year		(10,980)	(16,553)
Loss is attributable to:			
Owners of Biota Holdings Limited		(10,996)	(15,946)
Total comprehensive (expense)/income for the half-year is attributable to:			
Owners of Biota Holdings Limited		(10,980)	(16,553)
Loss per share from continuing operations and attributable to the ordinary equity holders of the Company		**Cents**	**Cents**
Basic loss per share		(6.1)	(8.9)
Diluted loss per share		(6.0)	(8.8)

The consolidated income statement should be read in conjunction with the accompanying notes.

Consolidated balance sheet

As at 31 December 2011

	Notes	31 December 2011 $'000	30 June 2011 $'000
Current assets			
Cash and cash equivalents		56,540	70,011
Trade and other receivables		7,292	4,060
Total current assets		63,832	74,071
Non-current assets			
Plant and equipment		5,411	5,457
Deferred tax assets		1,692	1,062
Intangible assets		2,394	2,971
Total non-current assets		9,497	9,490
Total assets		73,329	83,561
Current liabilities			
Trade and other payables		4,428	4,090
Deferred revenue		486	143
Provisions		1,710	2,152
Total current liabilities		6,624	6,385
Non-current liabilities			
Provisions		468	320
Total non-current liabilities		468	320
Total liabilities		7,092	6,705
Net assets		66,237	76,856
Equity			
Contributed equity	4	147,922	147,583
Reserves		246	208
Retained losses		(81,931)	(70,935)
Total equity		66,237	76,856

The consolidated balance sheet should be read in conjunction with the accompanying notes.

Consolidated statement of changes in equity

For the half year ended 31 December 2011

	Contributed equity $'000	Reserves $,000	Retained losses $,000	Total equity $'000
Balance at 1 July 2010	146,375	1,366	(42,845)	104,896
Loss for the half-year	-	-	(15,946)	(15,946)
Exchange differences on translation of foreign operations	-	(607)	-	(607)
Total comprehensive income for the half-year	**-**	**(607)**	**(15,946)**	**(16,553)**
Transactions with owners in their capacity as owners:				
Contributions of equity, net of transaction costs	747	-	-	747
Payments for treasury shares	(781)	-	-	(781)
Employee share options expensed	-	559	-	559
Transfer from share based payment reserve for employee options exercised	751	(751)	-	-
	717	(192)	-	525
Balance at 31 December 2010	**147,092**	**567**	**(58,791)**	**88,868**
Balance at 1 July 2011	147,583	208	(70,935)	76,856
Loss for the half-year	-	-	(10,996)	(10,996)
Exchange differences on translation of foreign operations	-	16	-	16
Total comprehensive income for the half-year	**-**	**16**	**(10,996)**	**(10,980)**
Transactions with owners in their capacity as owners:				
Employee share options expensed	-	361	-	361
Transfer from share based payment reserve for employee options exercised	339	(339)	-	-
	339	22	-	361
Balance at 31 December 2011	**147,922**	**246**	**(81,931)**	**66,237**

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

Consolidated cash flow statement
For the half year ended 31 December 2011

	Half year 2011 $'000	2010 $'000
Cash flows from operating activities		
Receipts from customers (inclusive of GST)	3,826	19
Payments to suppliers and employees (inclusive of GST)	(18,140)	(25,676)
	(14,314)	(25,658)
Other revenue and income		
Interest received	1,675	2,493
Income tax paid	-	(3,674)
Net cash outflow from operating activities	(12,639)	(26,838)
Cash flows from investing activities		
Payments for plant and equipment	(844)	(459)
Net cash outflow from investing activities	(844)	(459)
Cash flows from financing activities		
Proceeds from issue of shares	-	747
Payments for treasury shares	-	(781)
Net cash outflow from financing activities	-	(34)
Net decrease in cash and cash equivalents	(13,483)	(27,331)
Cash and cash equivalents at the beginning of the half year	70,011	104,867
Effects of exchange rate changes on cash and cash equivalents	12	(18)
Cash and cash equivalents at the end of the half year	56,540	77,518

The consolidated cash flow statement should be read in conjunction with the accompanying notes.

1. Summary of significant accounting policies

Basis of preparation of half year report

This general purpose financial report for the interim half year reporting period ended 31 December 2011 has been prepared in accordance with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Act 2001*.

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 2011 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.

2. Segment information

Description of segments

Management has determined the operating segments based on the reports reviewed by the strategic steering committee that are used to make strategic decisions.

The committee reviews the business from a divisional perspective (ie Research, Product Development and Corporate) and on a project basis. All projects are anti-infective drug discovery and clinical development activities and so represent one reportable business segment. The Group operates globally in developing its projects and has laboratories in Australia and England. The divisions of the business have therefore been determined as reportable segments.

(a) Segment information provided to the strategic steering committee

The segment information provided to the strategic steering committee for the reportable segments for the half year ended 31 December 2011 is as follows:

Divisions	Research		Product Development		Corporate		Intersegment elimination		Total	
	2011 $'000	2010 $'000	2011 $'000	2010 $'000	2011 $'000	2010 $'000	2011 $'000	2010 $'000	2011 $'000	2010 $'000
Total segment revenue	198	1,544	4,455	1,005	5,754	9,012	(2,593)	(3,499)	7,814	8,062
Intersegment revenue	-	(1,451)	-	-	(2,593)	(2,048)	2,593	3,499	-	-
External revenue	198	93	4,455	1,005	3,161	6,964	-	-	7,814	8,062
Adjusted EBITDA	(8,279)	(10,350)	(4,355)	(7,994)	1,100	3,803	-	-	(11,534)	(14,541)
Depreciation & amortisation	797	3,787	19	4	653	675	-	-	1,469	4,466

The chief operating decision maker reviews assets and liabilities on a consolidated basis monthly. Therefore, no measure of segment assets and liabilities is separately disclosed in this report.

Whilst the group advances its programs globally, it has assets in two geographical locations. The following table sets out the value of the group's non current assets by location:

	Australia		England		Total	
	2011 $'000	2010 $'000	2011 $'000	2010 $'000	2011 $'000	2010 $'000
Non current assets	9,270	11,124	227	292	9,497	11,416

All revenue is generated by the Group's Australian based operations, although counterparties may be in other countries.

2. Segment information (continued)

(c) Other segment information

(i) Segment revenue

Sales between segments are carried out at arm's length and are eliminated on consolidation. The revenue from external parties reported to the strategic steering committee is measured in a manner consistent with that in the income statement. Revenues from external customers are derived from royalty on sales, grants for institutions and funding agreements with partners.

Segment revenue reconciles to total revenue from continuing operations in note 3.

(ii) Adjusted EBITDA

A reconciliation of adjusted EBITDA to reported loss after income tax is provided as follows:

	Half year	
	2011	**2010**
	$'000	**$'000**
Adjusted EBITDA	**(11,534)**	**(14,541)**
Interest revenue	1,769	2,486
Depreciation	(863)	(894)
Amortisation of antibacterial programs and sub-royalty	(606)	(3,572)
Share options expense	(392)	(200)
Income tax credit	630	775
Loss after income tax from continuing operations	**(10,996)**	**(15,946)**

3. Revenues from ordinary activities and other income

	Half year	
	2011	**2010**
	$'000	**$'000**
Revenues from continuing operations		
Royalties	1,415	4,491
Revenue under BARDA contract	4,336	-
Interest revenue	1,769	2,486
Other revenue	45	7
Total revenues from continuing operations	7,565	6,984
Other income		
Grant income	249	1,078
Total other income	249	1,078
Total revenues and other income	7,814	8,062

4. Contributed equity

	Half year		Half year	
	2011 Shares	2010 Shares	2011 $'000	2010 $'000
Issue of ordinary shares				
At start of period	181,417,556	179,209,987	148,616	146,575
Issue of shares	-	813,021	-	747
Options exercised	286,155	782,557	339	751
At end of period	181,703,711	180,805,565	148,955	148,073
Treasury shares held in Trust			(1,033)	(981)
			147,922	147,092

5. Loss per share

	Half year 2011	Half year 2010
	Cents	**Cents**
Basic loss per share (EPS)	(6.1)	(8.9)
Diluted loss per share (EPS)	(6.0)	(8.8)
	$'000	**$'000**
Loss used to calculate EPS	(10,996)	(15,946)
Weighted average shares used to calculate	**Number**	**Number**
Basic EPS	181,627,507	180,023,219
Diluted EPS	182,187,265	183,987,820

Options granted by the Company to employees are considered to be potential ordinary shares.

6. Tax audit

The Australian Taxation Office (ATO) has been conducting an audit in respect to income and expenditures associated with the litigation against GlaxoSmithKline (GSK). On 19 December 2011, the ATO issued a position paper. The ATO's preliminary conclusion is that having accepted the legal costs as deductible, the settlement sum received of $20 million is ordinary income (and not a capital gain). If the latter is sustained, this would result in an additional income tax assessment of approximately $2 million after utilisation of previously unrecognised tax losses.

The ATO position paper invites a response where there is a disagreement of the facts or interpretation by the ATO. Biota (with its advisors, Deloitte) disagrees with the conclusion reached in respect of the settlement sum received and have prepared a response to the ATO position paper. Accordingly, no liability has been recognised in this regard.

7. Events occurring after balance sheet date

No other matter or circumstance has arisen since 31 December 2011 that has significantly affected, or may significantly affect:

- The Group's operations in future financial years; or
- The results of those operations in future financial years; or
- The Group's state of affairs in future financial years.

8. Net tangible asset backing

	31 December 2011	30 June 2011
Net tangible asset backing per ordinary share	35 cents	41 cents

Directors' declaration

In the Directors' opinion:

a) the financial statements and notes set out on pages 3 to 9 are in accordance with the *Corporations Act 2001,* including:

   (i) complying with Accounting Standards, the *Corporations Regulations 2001* and other mandatory professional reporting requirements; and

   (ii) giving a true and fair view of the consolidated entity's financial position as at 31 December 2011 and of its performance for the half year ended on that date; and

b) there are reasonable grounds to believe that Biota Holdings Limited will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the Directors.

For and on behalf of the Board.

Jim Fox
Director

Peter Cook
Director

Melbourne
14 February 2012

Independent auditor's review report to the members of Biota Holdings Limited

Report on the Half-Year Financial Report

We have reviewed the accompanying half-year financial report of Biota Holdings Limited, which comprises the balance sheet as at 31 December 2011, and the income statement, statement of changes in equity and statement of cash flows for the half-year ended on that date, selected explanatory notes and the directors' declaration for the Biota Holdings Limited Group (the consolidated entity). The consolidated entity comprises both Biota Holdings Limited (the company) and the entities it controlled during that half-year.

Directors' responsibility for the half-year financial report

The directors of the company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards (including the Australian Accounting Interpretations) and the *Corporations Act 2001* and for such control as the directors determine is necessary to enable the preparation of the half-year financial report that is free from material misstatement whether due to fraud or error.

Auditor's responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of an Interim Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the financial report is not in accordance with the *Corporations Act 2001* including: giving a true and fair view of the consolidated entity's financial position as at 31 December 2011 and its performance for the half-year ended on that date; and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001.* As the auditor of Biota Holdings Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a half-year 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.*

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Conclusion

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

(a) giving a true and fair view of the consolidated entity's financial position as at 31 December 2011 and of its performance for the half-year ended on that date; and

(b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*

PricewaterhouseCooper

Nadia Carlin
Partner

14 February 2012