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# Biota



**Leading anti-infective drug  
development company**

BioCentury Future Leaders Conference  
8 April 2010

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## Forward looking statement

*This presentation contains forward looking statements that involve risks and uncertainties. Although we believe that the expectations reflected in the forward looking statements are reasonable at this time, Biota can give no assurance that these expectations will prove to be correct.*

*Actual results could differ materially from those anticipated. Reasons may include risks associated with drug development and manufacture, risks inherent in the regulatory processes, delays in clinical trials, risks associated with patent protection, future capital needs or other general risks or factors.*

*Relenza<sup>®</sup> is a registered trademark of GlaxoSmithKline.*

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# Overview




- Small molecule drug discovery company focused on infectious diseases
  - Listed on the ASX as BTA in 1985
  - Based in Melbourne, Australia with 90 employees
  - Profitable
- Steady income stream from partnered programs and cash flow from lead influenza asset (Relenza®) for 5 more years
- Influenza franchise succession products:
  - LANI (laninamivir) expected to be on the market in Japan for the 2011 influenza season
  - LANI adult Phase III demonstrated a single inhaled dose of laninamivir was shown as effective as 75mg oseltamivir twice a day for 5 days
  - 3<sup>rd</sup> generation in development
- Robust and balanced pipeline, includes HRV & RSV

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# Early licensing allows corporate growth

- Ensures portfolio approach
- Provides early collaboration income and cash milestones
  - Engage Big Pharma early
    - Expertise and resources
  - Reduces development and commercialization risk
  - Allows deeper investment in appropriate opportunities
- Current strategic objective
  - Achieve 2 to 3 royalty generating products in market near-term

# Broad infectious disease pipeline

	Preclinical	Phase 1	Phase 2	Phase 3	Marketed	Licensee
<b>Influenza Franchise</b>	<b>Relenza® (zanamivir)</b>	██████████	██████████	██████████	██████████	
	<b>Long Acting NIs 2<sup>nd</sup> Generation - Laninamivir</b>					
	Japan - Therapy	██████████	██████████	██████████	JNDA Filed	
	Japan - Prophylaxis	██████████	██████████	██████████		
	Rest of World	██████████	██████████	██████████		
<b>Long Acting NIs 3rd Generation</b>						
FLUNET	██████████					
<b>Other Programs</b>	<b>Human Rhinovirus BTA798 (HRV)</b>	██████████	██████████	IIa complete		
	<b>RSV, PPAT, Gyrase, HCV-NN</b>	██████████				

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# Influenza Overview

Products

Seasonal Market

Stockpile Market

# Managing influenza is a multi-prong approach

## VACCINES

### *Prevention Only*

- MOA: Vaccines stimulate production of the body's own antibodies to combat future exposure
- Inexpensive
- Limitations
  - Must be **on strain**
  - Enough people need to be vaccinated to contain the spread in the population (70%). Only about 30% of the U.S. population is vaccinated annually.
- Pandemic swine flu has required duplication of vaccination
  - TWO shots required this season: one pandemic and one for seasonal strains
  - Inadequate supply for the entire population in 2009/10

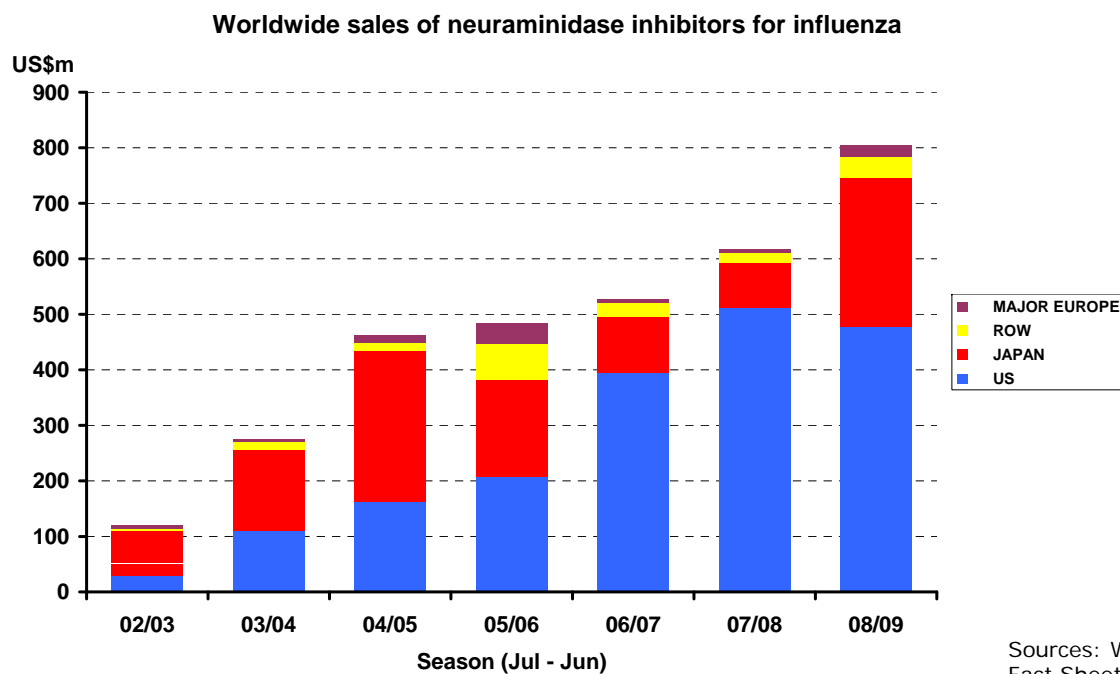
## NEURAMINIDASE INHIBITORS

### *Treatment & Prevention*

- MOA: Neuraminidase Inhibitors (NIs) block the enzyme that releases virions from the host lung cell, following replication.
  - The neuraminidase enzyme is common to all influenzas
  - Relenza (zanamivir) was the first in class NI
  - NIs both treat and prevent infection from the influenza virus
- NIs are the **ONLY** treatment option
- Neuraminidase Inhibitors can be used for prophylaxis

# Seasonal Market

- Seasonal or prescription market ~US\$800m annually
  - Occurs annually during autumn and winter in temperate regions
  - Circulates between hemispheres with two peaks in tropical countries
  - Approx 3-5 million cases of severe illness worldwide
    - Approx 250,000 to 500,000 deaths mostly in the very young and over 65s
  - Significant Relenza growth in Japan in 2008/09
  - Distribution channel – prescription and pharmacy



# Stockpile Market

- Stockpile or government market ~ US\$8b built over 4-5 years
  - Governments' inventories stockpiled for an epidemic or pandemic
  - Pandemics spread worldwide and infect a large proportion of the population
    - Occur irregularly approximately 3 each century for the last 300 years
    - Major outbreaks: 1918 Spanish Flu, 1957 Asian Flu, 1968 Hong Kong flu, 2009 Swine Flu
    - Can cause high mortality, Spanish Flu killed 50 million people
    - Typically occur when a new strain is transmitted to humans from another species
  - Distribution channel – direct sale business to government
- Stockpile initiated in 2004 by World Health Organization (WHO)
  - Approx 60 countries intend to/or carry stockpiles
  - One course for 25% of population
  - U.S. stockpile has not achieved that target, currently ~22%; c.f. France 33%, UK 35% (intention to 50%), Australia 55%.
  - WHO recommends increasing percentage coverage of the population as capacity/funding permits

# Why Relenza

- Relenza's percentage of the stockpile has been increasing due to:
  - Drug interactions and side effects with oseltamivir
  - Concerns of oseltamivir resistance
    - To date, 28 H1N1 pandemic viruses resistant to oseltamivir have been detected and characterized worldwide
    - All of these viruses show the same H275Y mutation that confers resistance to oseltamivir, but not to zanamivir
  - Rebalancing from 15:85 Relenza:Tamiflu towards 50:50
  - Replenishment US\$1bn
    - 5-7 year shelf life
- Device delivers drug directly to the primary site of infection on the lungs

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## Biota's influenza portfolio

Relenza<sup>®</sup>

Laninamivir

FLUNET

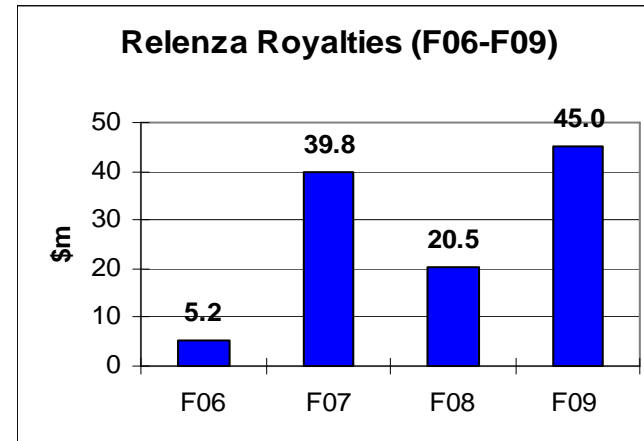
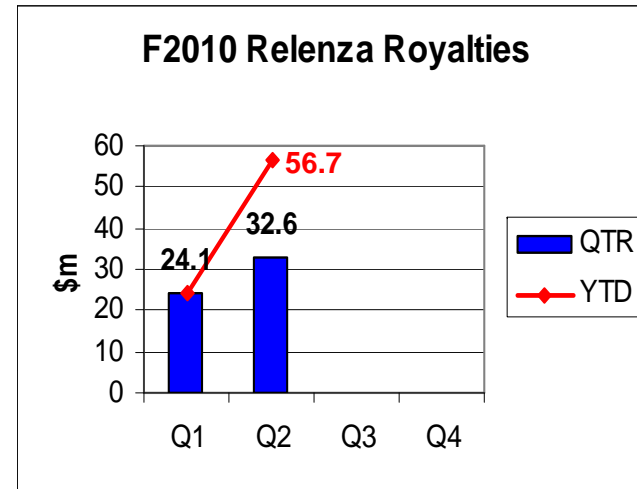
# Relenza® (zanamivir) profile

- History
  - 1980s - Biota acquired CSIRO's IP on the NI site and initiated a rational drug design program with the VCP
  - 1990 - Licensed to GlaxoSmithKline
  - 1999 - Launched worldwide
- MOA: neuraminidase inhibitor
- *Diskhaler*® delivers drug directly to the primary site of infection on the lungs
  - 10mg twice daily for five days
- Broad strain antiviral efficacy (H5N1, H1N1)
- Approved for:
  - Treatment of influenza A and B virus infection (7 years and older)
  - Prevention of influenza A and B virus infection (5 years and older)
- One of only two recommended treatments for Swine Flu



# Relenza royalties

- Royalty to Biota is 7% net
  - Paid 30 June, 12 months in arrears to 30 April
- GSK's approach to influenza market
  - Prioritizing government orders
  - Created Pandemic Centre of Excellence for influenza
  - Announced production capacity increases
    - 60m courses (announced 1 May 2009)
    - 90m Diskhaler, 100m Rotahaler\* by Dec 2009 (announced 22 Jul 2009)



*Fiscal Year ends 30 June*

# Laninamivir (LANI): Second generation influenza antiviral

- MOA: neuraminidase inhibitor; administered as a pro-drug CS8958 and converted to the active species, laninamivir, in the lung
- Co-owned with Daiichi-Sankyo
- Broad strain antiviral efficacy (4AH5N1,9AH1N1)
- Novel, easy to use, disposable inhaler
- Significant dosing advantage should lead to enhanced compliance
- Once only 40mg inhaled dose compared with
  - zanamivir: 10 mg twice daily for 5 days
  - oseltamivir: 75 mg twice daily for 5 days
- Once weekly for prophylaxis; once only for therapy



# LANI Current Status

- Japan trial summary
  - Adult Phase III treatment demonstrated a single inhaled dose of laninamivir as effective as 75mg oseltamivir twice a day for 5 days
  - Pediatric II/III study demonstrated both doses of laninamivir were equivalent to oseltamivir and were well tolerated
  - Conducted by Daiichi-Sankyo in Japan, Taiwan, Hong Kong and Korea
- Western studies
  - US \$5.6m NIH funding for 3 Phase I western trials - complete
  - Two Phase III trials (treatment & prophylaxis) likely for approval
    - Anticipated cost \$200-\$250m combined
    - Both trials can be completed in one flu season
    - Minimal risk given Japan trials and patient exposure
- Status
  - Daiichi Sankyo to market LANI in Japan – royalties to Biota
  - NDA filed in Japan in Feb 2010 – Approval expected in 3-12 months
  - Phase III prophylaxis commenced in Japan Nov 2009
- Actively seeking ROW pharmaceutical partner, co-owners to share commercial returns

# Influenza antiviral treatment landscape

Trade Name	Generic/ Code Name	Company Name	Type	H5N1 Avian	2008/09 Seasonal	2009 Pandemic A H1N1	Status
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## Not recommended for seasonal flu:

generic	amantadine		Oral	x	x	✓	Marketed
generic	rimantidine		Oral	x	x	✓	Marketed

## Marketed neuraminidase inhibitors:

Relenza®	zanamivir	Biota/GSK	Inhaled	✓	✓	✓	Marketed
Tamiflu®	oseltamivir	Gilead/Roche	Oral	✓	x	✓	Marketed

## Development pipeline:

	Ianinamivir	Biota/ Daiichi Sankyo	Inhaled	✓	✓	✓	Japan NDA Filed for Therapy, Feb 2010
	Ianinamivir	Biota/ Daiichi Sankyo	Inhaled	✓	✓	✓	Japan Phase III Prophylaxis ongoing
	FLUNET	Biota/ Daiichi Sankyo	Inhaled	✓	Untested	Untested	Preclinical
	peramivir	BioCryst	IV	✓	x	✓	Phase III US Emergency use only Japan approved
	favipiravir (T-705)	Toyama	Oral	✓	Unknown	✓	Phase III initiated
	A-315675	Abbott	Unknown	Unknown	Unknown	✓	Preclinical

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## **Selected infectious disease programs**

Human rhinovirus  
Respiratory syncytial virus

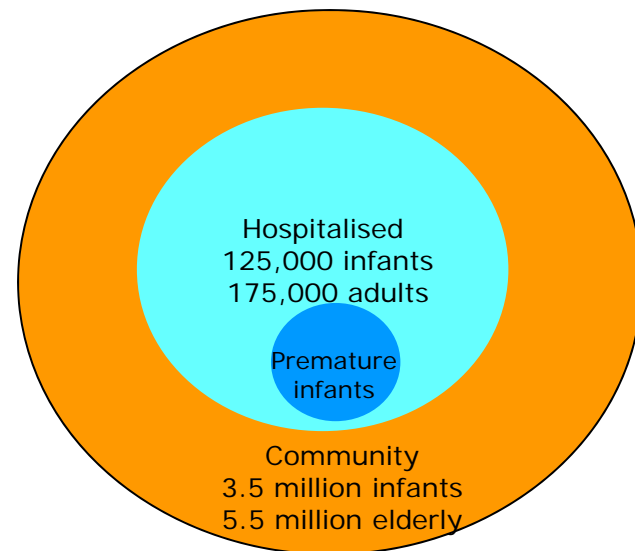
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# Human rhinovirus: BTA798

- HRV is the most frequent cause of the common cold
- MOA: capsid inhibitor
- Oral delivery
- No approved antiviral treatment available for patients with underlying respiratory issues
- Target markets
  - Serious complications in patients with COPD, Asthma, Cystic Fibrosis
  - Patients with compromised immune systems (chemotherapy, transplants)
- Status
  - Phase Ia proved safe and well-tolerated in healthy volunteers at all single and multiple doses
  - Phase IIa successfully demonstrated proof-of-concept in humans
  - Designing multiple Phase IIb trials
  - Available to license

# Respiratory syncytial virus (RSV)

- Synonym: bronchiolitis
- MOA: fusion inhibitor
- Oral delivery
- Product advantages for unserved infant and elderly markets
- Potential small molecule antiviral market estimated >US\$1b (Total Market >US\$8b)
  - MedImmune (AZ) dominates market with Synagis >US\$1B
  - Synagis – monoclonal antibody by injection and limited reimbursement scope
- Therapeutic & prophylactic indications
- Phase I initiation expected in 2011



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## **Corporate overview**

Management team

Financials

F2010 Outlook

# Management team

## Management

<b>Peter Cook</b> , M.Pharm., FRMIT, PhC., MPS, MRACI, C.Chem., MAICD	Managing Director and Chief Executive Officer Member of the Board of Directors
<b>Damian Lismore</b> BA (Hons), FCA, MAICD	Chief Financial Officer and Company Secretary
<b>Jane Ryan</b> BSc (Hons), PhD	Vice President, Product Development
<b>Leigh Farrell</b> BSc (Hons), FAICD, PhD	Vice President, Business Development
<b>Simon Tucker</b> BSc (Hons), PhD	Vice President, Research
<b>John Lambert</b> BSc (Hons), MRACI, C.Chem., PhD	Principal Director, Product Development Operations

## Board of Directors (non-executives)

<b>James Fox</b> BE M.Eng Sci, PhD <b>Chairman</b>	Director of Air New Zealand and Isoft; Former CEO of Vision Systems
<b>Paul Bell</b> BA, MA (Hons)	Director of Cochlear; Former member of Merck & Co.'s Management Committee and President of their Asia Pacific Human Health Division
<b>Prof Jeffery Errington</b> FRS, FMedSci	Director of the Institute for Cell and Molecular Biosciences and Centre for Bacterial Cell Biology at Newcastle University; Royal Society Fellow
<b>Prof Ian Gust</b> AO. MD, MBS, BSc, DipBact(Lond), FRCPA, FRACP, MASM, FTS	Professorial Fellow at the University of Melbourne; Former director of R&D at CSL
<b>Richard Hill</b> BA,LL.B,LL.M	Chairman of Sirtex Medical and Calliden Group; Director of Pelorus Property Group; Founding Partner of Hill Young & Associates
<b>Grant Latta</b> AM B.Bus, MBA, CPA, FAICD, FAIM, AAMI, Cert. Eng 	Director of Austrade; Dep Chairman of Food Sciences Australia and Export Finance and Insurance and Development Corporation; Member of Australian Competition Tribunal

# Solid Financial Position

- 2010 Half Year Financial Summary\*
  - Cash on hand A \$52 million
  - Profit before tax A \$41.4 million
  - Profit after tax A \$33.5 million
  - Revenues A \$61.7 million
    - Relenza royalties \$56.7m (1H FY09: \$3.8m)
  - Expenses A \$20 million
- Projected gross expenses A \$50 million per year
- Shares\*\* (ASX: BTA)
  - Outstanding 179 million
  - Current Price A \$2.27
  - Market Cap A \$410 million

\* Fiscal Year ends 30 June

\*\* As of 31 March 2010

USD/AUD approximately \$0.90

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## Compelling F2010 outlook

- Record first half; Second half on track
  - H1 PAT \$33.5m, Cash \$52m
  - Minimum of A\$62m receivable on 30 June on YTD 31 December
- Valuable pipeline
  - Increasing Relenza royalties
  - Considerable progress with LANI
    - NDA filed in Japan, expected approval 3-12 months
    - ROW licensing opportunity
  - Licensing opportunities with HRV
    - Completed proof of concept (Phase IIa)

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## Further information

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# Biota

**Additional Financial information  
– 6 months to 31 December 2009**



## Profit & loss for half year to 31 December 2009

	H1 F09	H1 F10
	\$m	\$m
<b>Revenue</b>	<b>33.5</b>	<b>61.6</b>
Expenses		
Medicinal chemistry and research	6.3	10.7
Product and clinical development	6.0	4.8
Business development	0.4	0.6
Sub royalty	0.8	2.0
Corporate	2.1	2.2
GSK litigation	7.3	-
Finance costs	0.4	-
	<b>23.3</b>	<b>20.2</b>
<b>PBT</b>	<b>10.1</b>	<b>41.4</b>
<b>PAT</b>	<b>7.2</b>	<b>33.5</b>

- Relenza royalties \$56.7m (FY09: \$3.8m)
- Collaboration income \$1.4m (FY09: \$6.7m)
- Sub-royalty: amortisation of CSIRO & VCP buyout
  - \$6.0m remaining by Dec 2014

## Balance sheets at 31 December 2009

	H1 F09	H1 F10
	\$m	\$m
Cash	55.4	52.0
Receivables	6.9	64.0
Plant & equipment	7.2	6.9
Intangible assets	11.4	14.7
Deferred tax assets	2.2	1.0
	<u>83.1</u>	<u>138.5</u>
Payables	1.9	2.5
Deferred revenue	7.3	3.5
Current tax liability	-	7.3
Provisions & Performance payment	8.0	3.5
	<u>17.2</u>	<u>16.9</u>
<b>Net assets/Net equity</b>	<b><u>65.9</u></b>	<b><u>121.6</u></b>

- Receivables: includes \$62.9m of Relenza royalties
- Intangible assets: outstanding amount to be amortised from
  - CSIRO & VCP royalty buyout (\$6.0m)
  - IP purchased from Prolysis (\$8.4m)
- Deferred revenue: upfront payments and funds received in advance
- Current tax liability \$7.3m – provision for payment in late 2010 assuming all tax losses recovered (\$39.6m)
- Provisions & Performance payment: performance payment to VCP (\$2.1m)