

Biota

**Leading anti-infective drug
development company**

RBS Morgans Life Science Conference
Sydney, 4 May 2010

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® is a registered trademark of GlaxoSmithKline.

Topics

- Brief Introduction to Biota
- Influenza
 - Relenza
 - Laninamivir
- Human Rhinovirus
 - Target markets
 - Future development
- Financial Summaries for H1 F2010

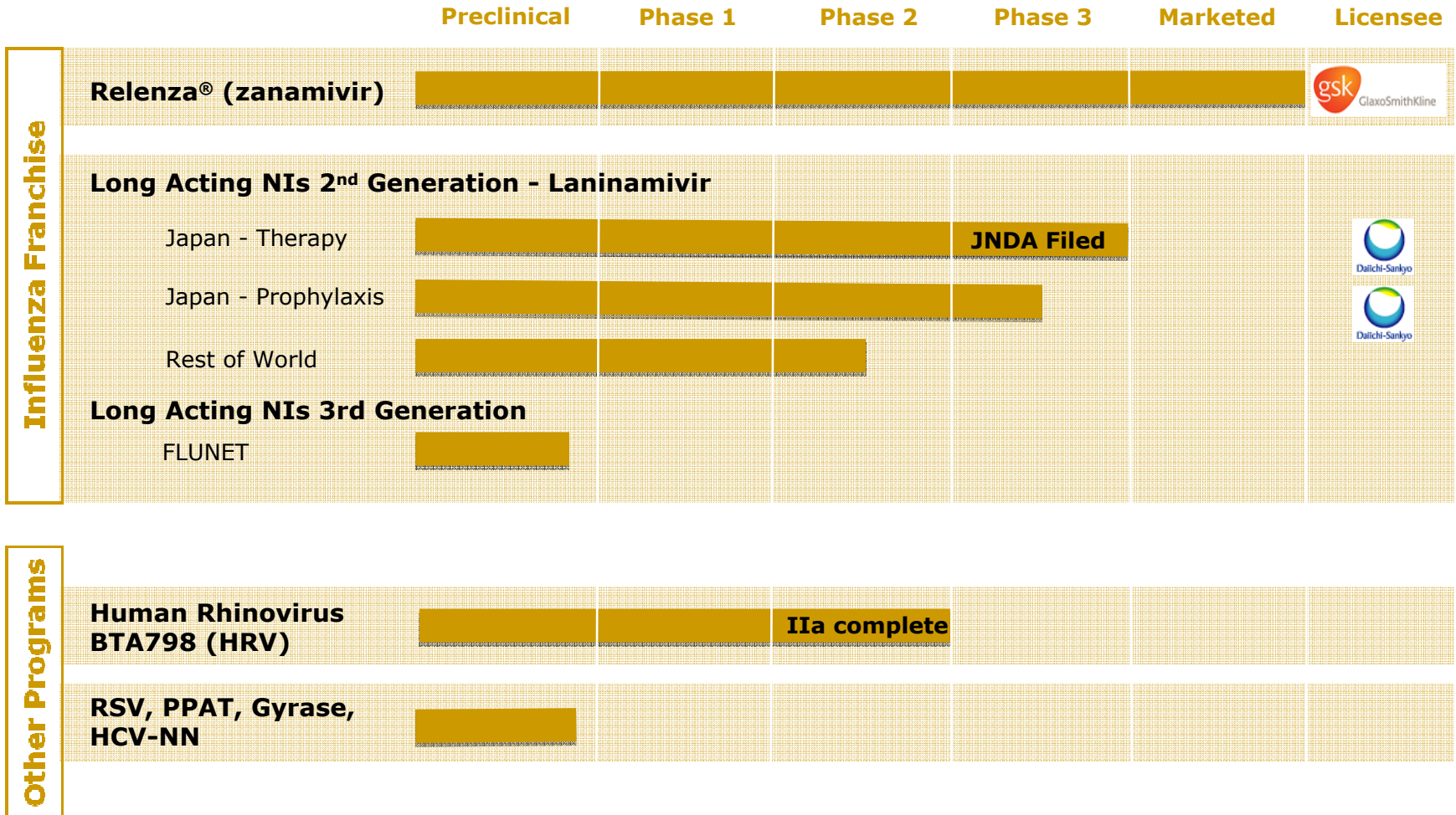
Overview

- 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 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
 - 3rd generation in development
- HRV completed proof of concept in humans
- Deep and balanced preclinical pipeline in antivirals and antibacterials

Corporate strategy

- Adopt a portfolio approach
- Licence early to provide collaboration income and cash milestones
 - Engage Big Pharma early
 - Expertise and resources
 - Reduces development and commercialization risk
 - Allows deeper investment where appropriate on selected opportunities
- Strategic objective
 - Achieve 2 to 3 royalty generating products in market near-term

Broad infectious disease pipeline



Broad infectious disease pipeline

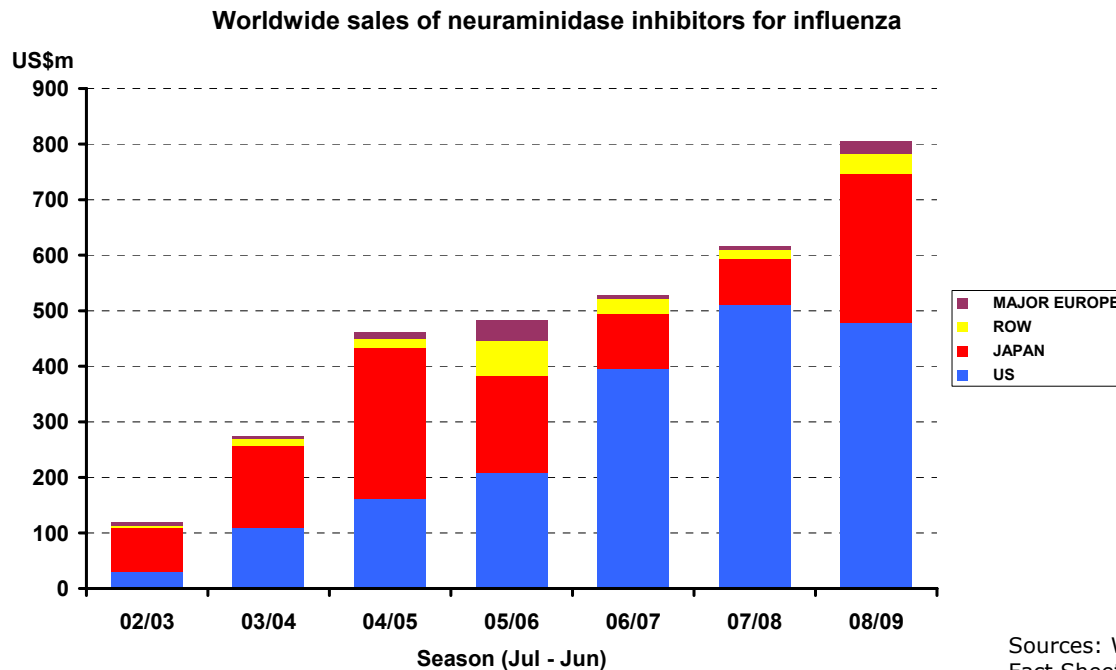
- Influenza
 - 2 markets
- Relenza
 - Growth
 - Relenza royalties
- Laninamivir
 - Japanese and Western clinical studies
 - Registration and investment timetables
 - Licensing

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

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

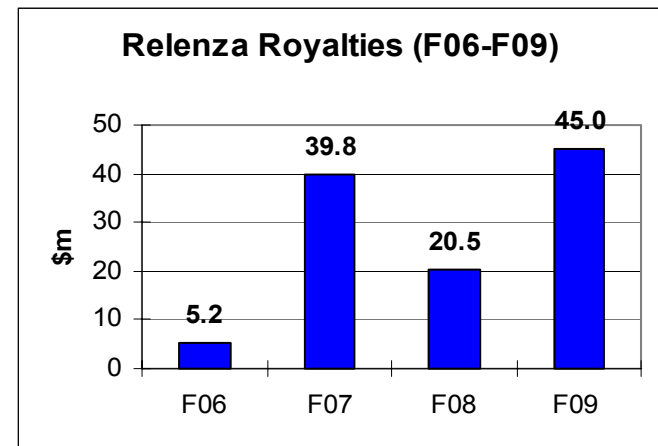
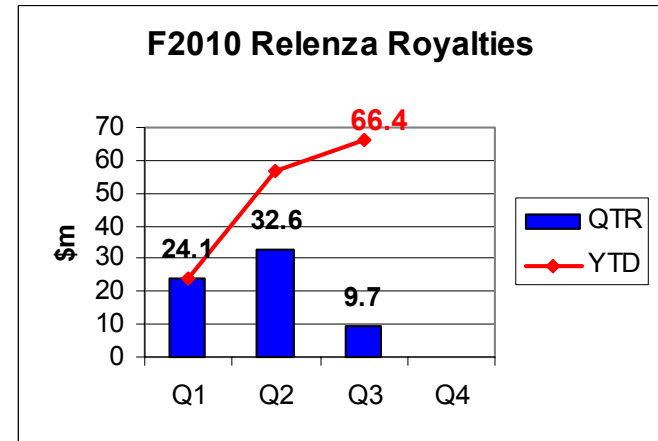


Why Relenza

- Relenza's percentage of the market 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
- Device delivers drug directly to the primary site of infection on the lungs

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 the octanoate pro-drug 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 reduced stockpile/distribution costs and 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



Comparison of regional regulatory requirements

- Japan (PMDA)
 - Oseltamivir control
 - Confirmed influenza patients (POCT)
 - Drug product manufactured under Japanese GMP
- USA (FDA)
 - Placebo control
 - Symptomatic presumptive influenza patients
 - GMP

Regional development

Japan

4 phase I studies (Japan)
SAD/MAD, expanded populations



2 phase II POC studies
(Japan, Taiwan)
(controls: oseltamivir, placebo)

5 phase I & 2 phase II studies
(Japan)
Expanded populations



Phase III pivotal study (Japan)
3 supportive phase III studies
with devices, paed (Japan, Asia)



JNDA

Supporting
data for
ROW

US/ROW

Phase I study (UK)
single dose

Phase I study (UK)
single dose (elderly subjects)

Phase I study (UK)
multiple dose (every week)



Phase II Opening IND Study (US)
Treatment of influenza in adults

Phase III studies
(US/EU)

Phase I, II studies (US)
Expanded populations

Completed

Planned

Investment & timetable for ROW registration

	USD(m)	
	Cost	Cumulative
Phase II commencement	30	30
Phase III commencement	50	80
NDA submission treatment	100	180
NDA submission prophylaxis	70	250

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

LANI licensing

- Target Companies
 - Global pharmaceutical companies with infectious disease sales forces and government contracts
 - Licensee responsible for all ROW development
- Due diligence in progress
- Deal metrics forecasts should recognise
 - No more than Phase II completed in West
 - Only for western markets (Japan licensed to DS)
 - Upfronts and milestones potentially shared – Daiichi Sankyo, Hovione, Biota

Human rhinovirus

- Target markets
- HRV exacerbations in Asthma & CoPD
- Future development

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
 - Available to license

HRVs exacerbate respiratory illnesses

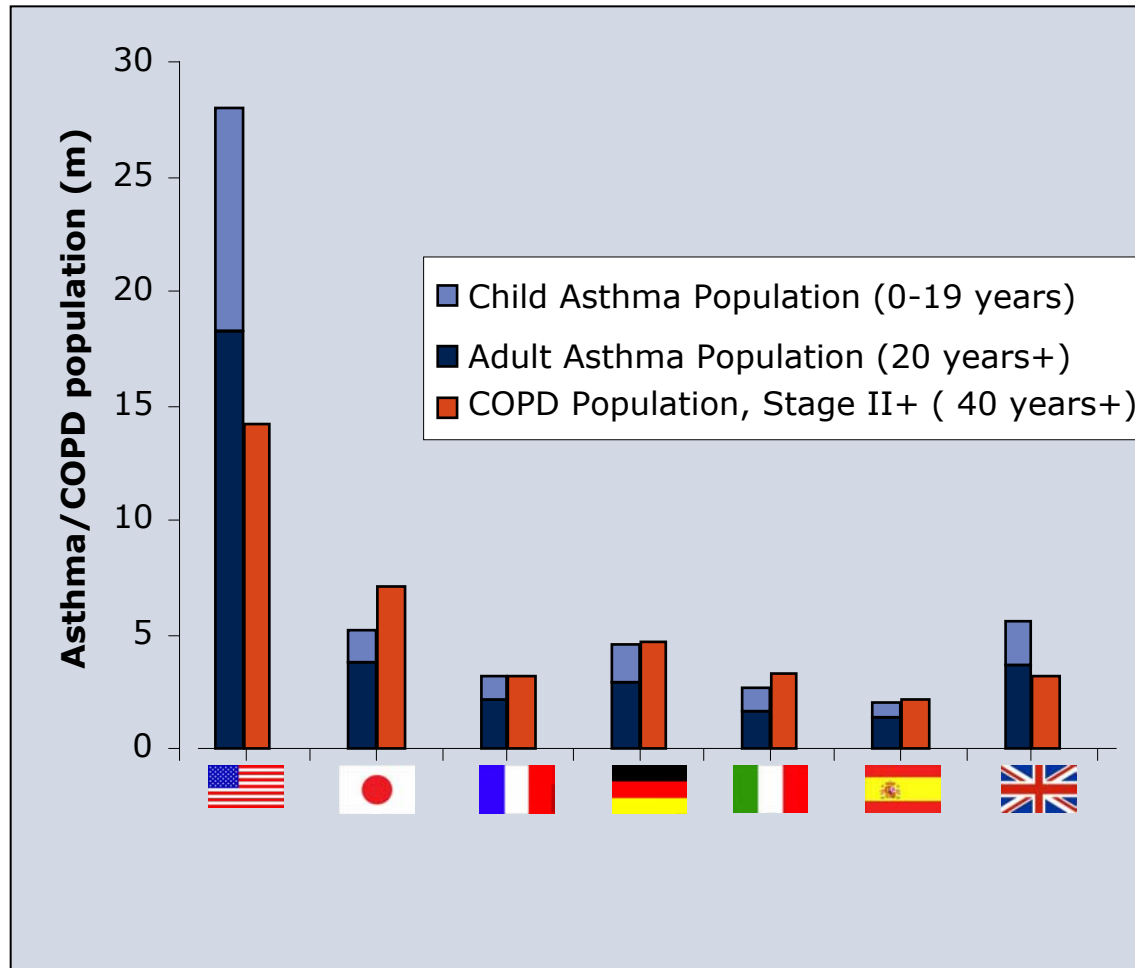
- Respiratory viruses strongly associated with asthma exacerbations in children (80-85%)¹ and adults (60%)²
- Associated with COPD exacerbations but less well studied³
 - 40% of COPD exacerbations associated with respiratory viruses⁴
- Causal relationship between human rhinovirus infection and exacerbations in COPD⁵ and asthma⁶ established in human challenge studies

1. Johnston, SL et al *Br. Med. J.*, **1995**, 310:1225
2. Nicholson et al. *BMJ.*, **1993**, 307:982
3. Papi A et al., *Am. J. Resp. & Crit. Care Med.* **2006**, 173:1114
4. Seemungal, T et al *Am. J. Respir. Crit. Care Med.* 2001,164:1618
5. Mallia P, et al., *Resp. Research.*, **2006**, 7:116
6. Message SD, et al., *PNAS*, **2008**, 105:13562



Asthma and COPD are major diseases: 90m patients across the seven major markets (7MM)

- 51 million adults and children suffer from asthma in 7MM
- Nearly 38 million adults have COPD Stage II or higher
- Asthma prevalence is believed to have stabilized
 - Significant variation across countries
 - Greatest prevalence of physician diagnosed childhood asthma in the UK (13%)
 - Highest adult prevalence in the US (8%)
- COPD prevalence, Stage II or higher is estimated to be about 10% across the seven major markets, and continues to rise with aging populations



Asthma/COPD Rx sales in 2008

Market	2008 Sales (US\$ billion)
United States	15
Japan	2
Five major EU Markets	7
TOTAL	24

HRV & Asthma

- Characteristics of asthma exacerbation and respiratory virus infection
 - Predominantly HRV¹
 - Loss of control of asthma
 - Inflammation
 - Decreased lung function
- Increased sensitivity to HRV in asthmatics
 - Increased severity and duration of lower respiratory symptoms²
 - Greater reductions in lung function
 - Impaired IFN production in asthmatics strongly related to severity of exacerbation, virus load, airway inflammation³

1. Newcomb DC, et al., *Proc. Am Thorac. Soc.*, **2009**, 6:266
2. Corne, JM et al, *Lancet*, **2002** 359(9309):831
3. Contoli, M et al *Nat Med.* **2006** 12:1023



HRV & COPD

- Epidemiologic association between respiratory virus infection and COPD exacerbations established¹
 - Predominantly HRV
- Experimental HRV16 infection demonstrated impact on COPD exacerbations²
 - URT symptom onset day 4
 - Peak LRT symptoms days 7-14
 - Lung function nadir days 9-20
- Proposed that antiviral intervention at onset of URT symptoms may be beneficial

1. Seemungal T, et al., *Am. J. Resp. & Crit. Care Med.* **2001**, 164:1618

2. Mallia P, et al., *Resp. Research*, **2006**, 7:116

Future development: Phase II

- Natural infection study – cost \$25-30m
- Outcome measures
 - Reduction in cold symptoms
 - Viral load; symptom scores (WURSS-21, Jackson score)
 - Asthma clinical outcomes¹
 - β_2 -agonist use, lung function (FEV1, PEF), asthma index²
 - Oral corticosteroid use, hospitalisation
 - Biological outcomes
 - FENO, cytokines, virology

1. Reddel, HK., *Am. J. Respir. Crit. Care Med.*, **2009**, Vol 180, 59–99

2. Sorkness, RL., *JACI*, **Oct 2008**, 838

Financials

- Profit & Loss H1 F2010
- Balance Sheet H1 F2010

Profit & loss for half year to 31 December 2009

	H1 F09	H1 F10
	\$m	\$m
Revenue	33.5	61.6
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	-
	23.3	20.2
PBT	10.1	41.4
PAT	7.2	33.5

- Relenza royalties \$56.7m (FY09: \$3.8m)
- Collaboration income \$1.4m (FY09: \$6.7m)
- Sub-royalty: amortisation of CSIRO & VCP buyout
 - \$6.0m to be amortised 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>
Net assets/Net equity	<u>65.9</u>	<u>121.6</u>

- 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)

Near-term milestones

- 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
 - 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)

Further information

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