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22 November 2011

The Manager Companies  
ASX Limited  
20 Bridge Street  
SYDNEY NSW 2000

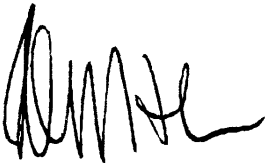
(19 pages by email)

Dear Madam,

**PRESENTATION TO ANNUAL GENERAL MEETING**

I attach a PowerPoint presentation which is to be delivered to the shareholders present at today's Annual General Meeting which is convened to be held at 11.00 am.

Yours faithfully



Peter J. Nightingale  
Company Secretary

pjn6370

***Biotron*** *ASX:BIT*

**AGM 22 November 2011**

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# Forward Looking Statements

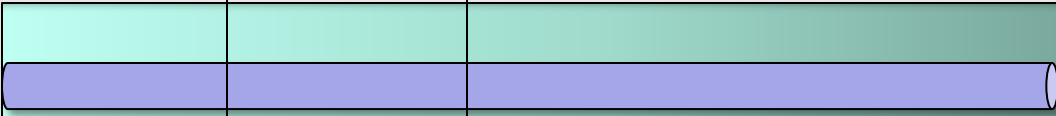
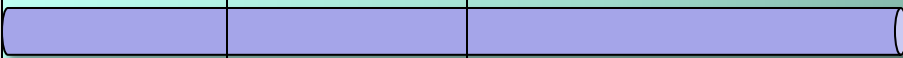

This presentation may contain forward-looking statements with respect to the financial condition, results and business achievements/performance of Biotron Limited and certain of the plans and objectives of its management. These statements are statements that are not historical facts. Words such as “should”, “expects”, “anticipates”, “estimates”, “believes” or similar expressions, as they relate to Biotron Limited, are intended to identify forward-looking statements. By their nature, forward-looking statements involve risk and uncertainty because they reflect Biotron’s current expectations and assumptions as to future events and circumstances that may not prove accurate. There is no guarantee that the expected events, trends or results will actually occur. Any changes in such assumptions or expectations could cause actual results to differ materially from current expectations.

# Key Highlights for 2010/2011

- HCV Program
  - Successful completion of Phase 2a clinical trial (BIT225-005) of BIT225 in HCV-infected patients in combination with standard of care
- HIV Program
  - Finalisation of design of Phase Ib/2a trial (BIT225-004) of BIT225 in HIV-infected patients
  - Ethics and regulatory approvals of BIT225-004
  - Commencement of BIT225-004 in Thailand
- Initiation and successful completion of a \$2.4 million capital raising via a rights issue and share placement

# Biotron's Pipeline

- Two clinical phase programs:
  - Hepatitis C virus and HIV

Project	Target	Discovery	Preclinical	Clinical Trials			
				Phase Ia	Ph Ib	Ph 2a	Ph 2b
Hep C	p7						
HIV	Vpu						
Dengue	M protein						

# Hepatitis C Virus – The Silent Killer

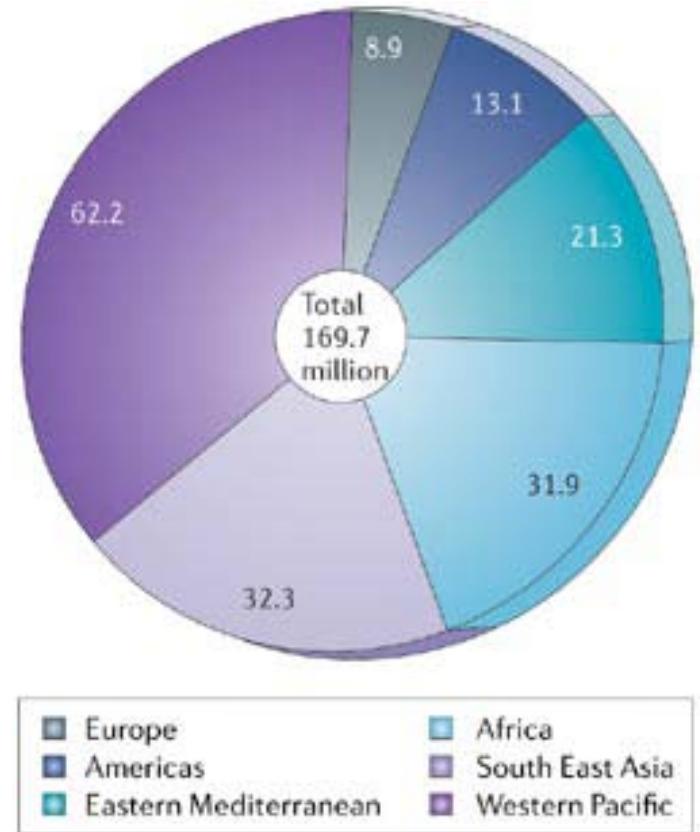
- Leading cause of chronic liver disease and transplants
- 180 m people infected worldwide (3% world population); 130 m are chronically infected
- 4 m patients in US (2.7 m chronically infected)
  - 70% will develop liver diseases including cirrhosis and liver cancer
  - Currently only 2.6% are treated each year
- Standard of care is interferon and ribavirin
  - Up to 50% patients don't respond to current treatment
  - Significant side effect profile – high drop out rate
  - Documented need for new, safer drugs



# Hep C – An Expanding Market

Worldwide market ~US\$2.8 billion;  
predicted to expand to >US\$10 billion as  
new, safer drugs enter the market.

USA and Europe represent major markets  
but other, larger markets are emerging.



Smith Nature Reviews Drug Discovery 5, 715–716 (September 2006)

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Nature Reviews | Drug Discovery

**Biotron**

# BIT225 and Hepatitis C – Phase 1a

- New investigational oral drug for treating HCV infection
- First in class; targets p7 protein – essential for virus assembly and release
- Phase 1a (BIT225-001) – single dose study (35 – 600 mg) in healthy volunteers.
  - Completed 2007
  - 48 subjects
  - BIT225 well-tolerated at doses up to 600mg
  - Good bioavailability and half-life



# BIT225 and Hepatitis C – Phase 1b

- Phase 1b (BIT225-003) – 7-day dosing with drug or placebo in 18 HCV-infected patients.
  - Completed 2009
  - 18 subjects
  - Different genotypes and past-treatment history
  - BIT225 significantly reduced HCV levels compared to placebo ( $p=0.0002$ )
  - First indication that BIT225 could target HCV *in vivo*

# BIT225 and Hepatitis C – Phase 2a

Ph II Trial Period			<i>Trial design</i>	
0	2	4	Weeks	44 wks
8 pts	Placebo		Interferon + Ribavirin	
8 pts	BIT225 (200 mg) + IFN/rib		Interferon + Ribavirin	
8 pts	BIT225 (400 mg) + IFN/rib		Interferon + Ribavirin	

- Protocol BIT225-005
- Pts randomly assigned to receive either placebo or BIT225 twice daily for 28 days commencement of standard combination therapy for Hep C (IFN/ribavirin)
- Patients continue after 28 days just on IFN/ribavirin as part of their standard treatment (external to Phase II trial)
- 24 patients, genotype 1
- Trial commenced Sept 2010 in Thailand; Completed Aug 2011

# BIT225 and Hepatitis C – Phase 2a (cont)

- Preliminary results released Oct 2011
  - BIT225 treatment resulted in ~1 log (i.e.10-fold) improvement in viral load reduction over and above IFN and ribavirin over the 28 days of treatment
    - **Clear demonstration that this first in class, direct-acting antiviral drug has good antiviral activity**
    - **Confirmed preclinical efficacy studies that demonstrated synergism with IFN and ribavirin**
    - **Data to be presented at HepDART in early December**

# BIT225 Commercialisation Strategy – Hepatitis C

- Documented need for new antiviral drugs; licensing space is still very active
  - 18 Oct 2011 - Roche acquired Anadys (NASDAQ:ANDS), with Phase 2b and Phase 1 HCV programs, for US\$230 million
- BIT225 is well-positioned
  - First in class drug
  - Potential to be used with either IFN/ribavirin i.e. current treatment, or
  - To be combined with other new direct-acting antiviral drugs for HCV treatment in new, yet to be approved cocktails
- Currently conferring with clinical and industry experts to determine most suitable next steps in development of BIT225 as an anti-HCV drug



# BIT225 and HIV

- Current international focus on strategies for elimination or cure of HIV
  - Current HIV treatments do not completely eliminate virus from the body
- Biotron is well positioned with its HIV drug targeting virus in the reservoir cells
  - ***Prevents production of infectious virus in reservoir cells***
  - ***Potential to eliminate this long-lived source of virus in the body***
- Commenced a Phase 1b/2a trial in HIV-positive patients in September 2011
- Anticipate completion of enrolment in 1Q2012

# BIT225 and HIV – Phase 1b/2a Trial

	Days		
	0	10	20
8 pts	Placebo	Drug-free follow-up	
16 pts	400 mg BIT225	Drug-free follow-up	

- Protocol BIT225-004
- 24 subjects to be enrolled
- Treatment-naïve, high virus load and relatively high T-cell counts
- Trial designed to demonstrate proof-of-concept i.e. can reduce HIV loads in HIV-infected reservoir cells in man



# BIT225 Commercialisation Strategy – HIV

- 39.5 million people living with HIV/AIDS
- 4.3 million people newly infected with HIV p.a.
- 2.9 million people die of HIV/AIDS-related causes p.a.
- US market alone worth >US\$3.3 billion p.a.; global market is worth >US\$9 billion p.a.
- Reservoir elimination field is still in its infancy
  - Most programs are still at research/university stage of development
  - Biotron's approach is novel and relatively advanced
- If successful, anticipate that BIT225 could be used in combination with existing anti-retroviral therapies

# BIT225 Commercialisation Strategy – HIV/HCV Co-infected

- The US and European regulatory agencies (FDA and EMEA) have clearly stated their enthusiasm for trialing and developing new HCV drugs in hard to treat populations
- These include the HIV/HCV co-infected population
  - Up to 30% of HIV-infected are also HCV-infected
  - Have a worse prognosis and outcome
  - No other drugs target both viruses
  - Biotron has a unique position as BIT225 works on both HIV and HCV



# Update on Early Stage Antiviral Programs

- HIV
  - BIT225 has shown activity in dendritic cells – the first cells to be exposed to HIV at the point of infection
  - Exploring whether BIT225 could be used to prevent establishment of HIV infection (oral microbicide)
  
- Dengue
  - Research program with Universities of Wollongong and Canberra (ARC Linkage Grant scheme)
  - Targeting M protein of Dengue (new target)
  - Designing, synthesising and testing new compounds targeting Dengue virus
  - Aim to use data from this current project to leverage funding for extended studies



# (Near) Future Directions

- Formulation studies of BIT225 into capsule/tablet format
- 3-month toxicology studies in animals
- Investigate potential trial design(s) for next trial(s)
  - 3-month dosing with SOC (+/-IFN)
  - Studies against other genotypes
  - Combination with other new classes of anti-HCV drugs
  - Studies in difficult to treat populations especially HIV/HCV co-infected
- **Aim is to continue to add value to programs as proceed towards commercialisation**

# *Biotron* ASX:BIT

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