

Level 8, 261 George Street Sydney NSW 2000 Tel: (61-2) 9247 8212 Fax: (61-2) 9247 3932

E-mail: pnightingale@biotron.com.au Website: www.biotron.com.au

27 June 2006

The Manager Companies Australian Stock Exchange Limited 20 Bridge Street Sydney NSW 2000

(21 pages by email)

Dear Madam

#### **RE: PRESENTATION OF COMPANY ACTIVITIES**

I attach a presentation updating the Company's activities.

For further information, please contact Dr. Michelle Miller, CEO, on (61-2) 61258001.

Yours sincerely

Peter J. Nightingale Company Secretary

pjn3546



Dr. Michelle Miller
June 2006

### **BIOTRON LTD**

- Developing new generation antiviral drugs with large, expanding world markets.
- Current major focus on drugs to treat HIV-1 and Hepatitis C virus.

### HIV - HIGH GROWTH MARKET

- 37.8 million people with HIV/AIDS at end of 2003
- 4.8 million people were newly infected with HIV in 2003
- In 2003 2.9 million people died of HIV/AIDS-related causes
- US market alone worth >US\$3.3 billion p.a.

### NEW TREATMENTS NEEDED

- Development of resistant viral strains is a main cause of antiretroviral therapy failure
- Most patients develop resistance to existing HIV drugs
  - ~ 26% newly diagnosed patients have resistant strains of virus
  - ~ 78% of late-stage patients develop resistance to existing therapies
- FDA approved HIV therapies include 1 Entry Inhibitor, 17 Reverse Transcriptase Inhibitors and 10 Protease Inhibitors
- Unmet need for new drugs suitable for HAART\* therapy that attack the virus in new ways and

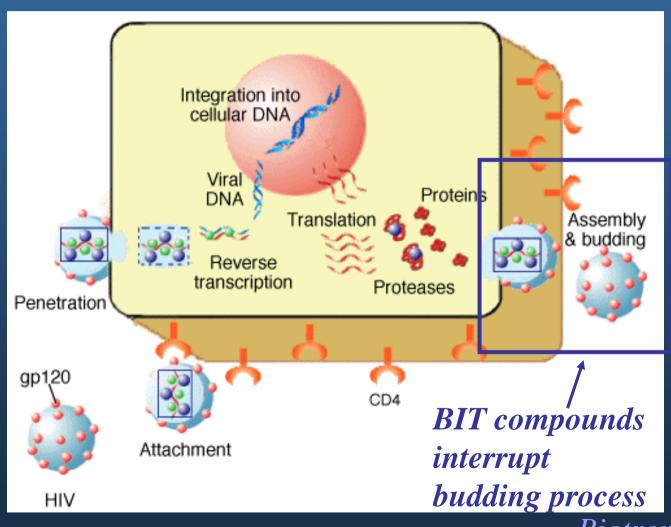
# BIOTRON'S HIV DRUG DEVELOPMENT PROGRAM

- Designed and synthesised library of ~250 compounds to target Viral Protein U (Vpu)
  - − >70% active against target
- Developed bacterial cell-based assay for target screening
- Selected subset for detailed studies to determine "druggability" profiles
- In late 2005 selected BIT225 as lead compound to take to the clinic

### BIT 225 –A NOVEL APPROACH

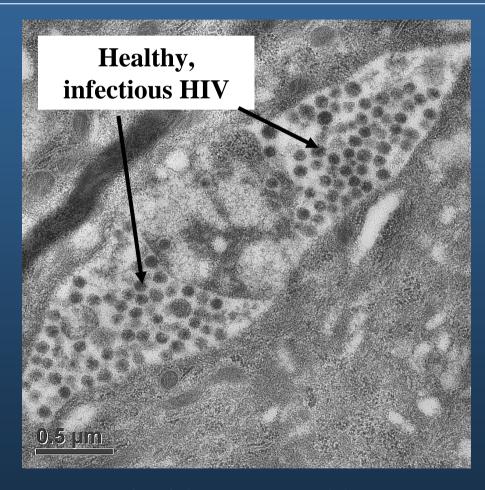
- BIT-225 is a Viral Protein U (Vpu) inhibitor
- No existing drugs target HIV Vpu protein novel mode of action
- Disturbs formation of new virus particles through budding process
- Reduces infectivity of virus produced by infected cells

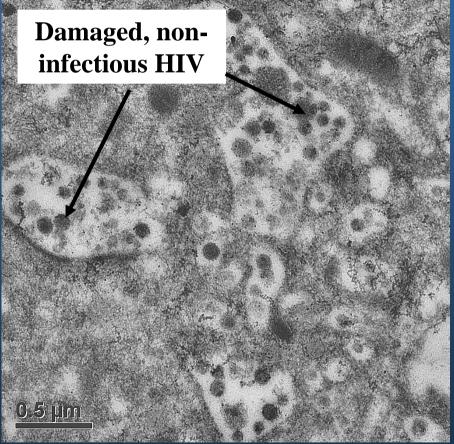
# BIT- 225 TARGETS DIFFERENT STAGE OF HIV LIFE CYCLE



Biotron Limited

### BIOTRON'S HIV DRUG IN ACTION





HIV inside untreated human cells

HIV inside human cells treated with BIT-225

Biotron Limited

# BIT- 225 ACTIVE IN VIRAL RESERVOIR CELLS

HIV-infected monocytes move out of the blood stream to set up reservoirs of infection in surrounding tissues



- Eradication of HIV from reservoirs is essential to prevent development of AIDS
- Current HIV drugs cannot eradicate the underlying seat of infection (termed the viral reservoir)

BIT225 is the first of a new class of HIV drugs that target the viral reservoir cells

### BIT-225 PROFILE

- High oral bioavailability (~68%)
- Good stability and half-life in vivo
- Excellent safety profile in animals
- Good activity against HIV in vitro
- Active against resistant strains of HIV
- Synergistic with leading current HIV therapies
- Simple chemistry for manufacture
- Novel compound new mechanism of action

  Biotron Limited

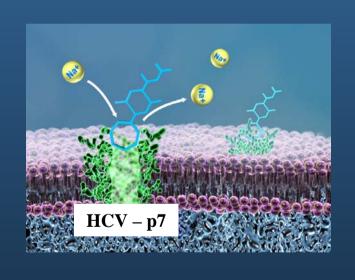
### **BIT- 225 CURRENT STATUS**

- Manufacture of drug to cGMP standards underway
  - Dr Reddy's Laboratories, India
- Formal preclinical safety and toxicity studies in progress
  - A leading European contract research organisation
- Finalising Phase I/IIa trial site and design
  - Melbourne
- Phase I/IIa human trial due to commence end 06

# HEPATITIS C VIRUS (HCV) MARKET

- 4x more prevalent than HIV
- 4m patients in US (2.7m chronic infection); 170m worldwide
- Worldwide market ~US\$2.8 billion currently predicted to expand to >US\$10b
- US surgeon general considers hepatitis C is one of the most significant public health threats facing US.
- Existing therapies ineffective and toxic

### **BIOTRON – TARGETING HCV P7**



- No existing drugs target HCV p7
- p7 target is essential for production of infectious HCV
- p7 and Vpu belong to same class of viral proteins called *viroporins*

### **BIOTRON'S HCV PROGRAM**

- Developed proprietary assays to screen drugs for anti-HCV activity
- Identified several lead candidates targeting HCV-p7 from Biotron compound library
- Commenced a lead optimization program
- Collaborations with Prof Eric Gowans at Burnet Institute, Melbourne and the NIH, USA
- Potential to fast-track to clinic based on preclinical data generated for HIV program

# ANTICIPATED MILESTONES 2006/07

#### BIT225 HIV Program:

•	Completion of BIT225 scale-u	p Q2 06
---	------------------------------	---------

• Completion of BIT225 preclin	nical Q4 06
and formulation work; regula	itory
/ethics approvals filed	

•	Commencement of Phase I/IIa	Q4 06
	clinical trial in humans	

•	Results of	of Phase	I/IIa clini	cal trial	Q2 07
---	------------	----------	-------------	-----------	-------

Biotron Limited

# **ANTICIPATED MILESTONES 2006/07**

### **HCV Program:**

<ul> <li>Results of screens for anti-HCV activity</li> </ul>	Q3 06
Selection of lead compound	Q4 06
<ul> <li>Commencement of preclinical work on selected lead</li> </ul>	Q1 07
<ul> <li>Completion of preclinical studies</li> </ul>	Q3 07
<ul> <li>Commencement of Phase I/IIa clinical trial for HCV</li> </ul>	Q4 07

Biotron Limited

### **CORPORATE STRATEGY**

- Increase shareholder value through technology platform focused on small molecule antiviral drugs
- Progress BIT-225 to the clinic as fast as possible for proof-of-concept human trial against HIV
- Identify lead compound for HCV and progress to the clinic
- Seek non-equity finance e.g. NIH grants for further development
- Partner at a stage to maximise value for shareholders

## FINANCIAL SUMMARY

• Shares on issue: 89.7m

• Unlisted options: 5.85m (average strike 46 cents, average exercise date Dec 2009)

• Cash: \$0.86m (as of 31 Mar 06)

• Historical cash burn per month \$0.2m

- Raised \$4.2m via rights issue in April 06
- Sufficient capital on hand to fund two Phase I/IIa human clinical trials (HIV & HCV)

### INVESTMENT SUMMARY

- First-in-class, patent protected, anti-HIV and anti-HCV drugs
  - Clinical trials with BIT225 due to commence late 2006
  - Potential for second-generation follow-up drugs
  - Lead selection in progress for HCV
  - Due to reach clinic in 2007
- Antiviral programs for Influenza and Dengue viruses
- Antivirals higher chance of successful development through the clinic and to market
- Positioned to gain maximum value over next 12 months



Dr Michelle Miller

Chief Executive Officer

02 6125 8001

mmiller@biotron.com.au

www.biotron.com.au