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20 November 2017

The Manager Companies ASX Limited 20 Bridge Street SYDNEY NSW 2000

(19 pages by email)

Dear Madam,

#### PRESENTATION TO ANNUAL GENERAL MEETING

I attach an address by the Chairman and a PowerPoint presentation which are to be delivered to the shareholders present at today's Annual General Meeting which is convened to be held at 11.30 am.

Yours faithfully

Peter J. Nightingale Company Secretary

pjn9169



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My Fellow Shareholders

#### CHAIRMAN'S ADDRESS TO THE AGM

In recent weeks, Biotron has taken a giant step towards demonstrating that eradication of HIV is possible. The 36<sup>th</sup> and final patient in the Company's Phase 2 HIV trial completed treatment. The trial was designed to demonstrate the Company's lead compound, BIT225, benefits patients above and beyond current anti-HIV treatments. Analysis of trial data is, by necessity, frustratingly slow so we have little choice but to impatiently await final results. Nevertheless, we remain confident. For the many millions of patients destined to live with this disease, there is hope, and for the thousands of shareholders of this Company maybe, just maybe, there is light at the end of a very long tunnel.

This is the 9<sup>th</sup> clinical trial conducted by Biotron. The previous eight trials successfully provided sound stepping stones along the clinical development pathway for BIT225. The latest trial caps off our determination to demonstrate sound science and proven results add credence to our belief in the significance of the Company's platform. The only way to achieve the commercial outcomes that are desired by shareholders is by patiently delivering quality data from clinical trials and supporting studies.

Much has been achieved during the past 12 months, as will be outlined in the CEO's presentation.

Looking ahead, we have every reason to be optimistic. Close focus on our core assets is presenting new opportunities. Biotron should not be viewed as a single asset company. Our diversity offers a strong portfolio of possibilities capable of delivering sustainable shareholder value.

Importantly, BIT225 is only one of hundreds of Biotron compounds. A substantial volume of evidence now supports the belief that many opportunities reside in the Company's compound library, likely to be beneficial against additional viral targets.

A disciplined and focused approach to capital management is embedded in our operating model. Our priority is to retain flexibility in the development of growth opportunities aligned, of course, to our lead product.

I would like to take this opportunity to thank our small but dedicated staff for their determination and productive efforts during the past12 months. I would also like to thank my fellow directors for their equally dedicated participation and support.

In particular, I should single out Denis Wade for his enduring contribution and dedication to the Company since he joined the Board in 2010.

For personal reasons, Denis steps down from the Board today. Denis' advice and insight have been of enormous value to me personally and to the entire Board. He departs with a mix of our regret and gratitude. I am relieved to report he won't be going far. Denis will retain an ongoing advisory role with the Company.

I would now like to invite our CEO, Michelle Miller, to address the meeting.

Michael J. Hoy

Chairman

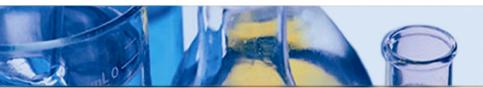


# Annual General Meeting 20<sup>th</sup> November 2017



## **Forward Looking Statements**

This presentation may contain forward looking statements with respect to the financial condition, results and business achievements/performance of Biotron Limited (ACN 086 399 144) 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.





## **Investment Highlights**

- Biotron is designing, developing and commercialising a platform of antiviral drugs with a novel mode of action – able to target a wide variety of viral infections
- Pipeline of programs in high value, high need markets
- Progress in clinical lead program (BIT225) provides strong validation for entire platform





## **Biotron Limited – Snap Shot**

#### **BROAD PLATFORM WITH NEW CLASS OF ANTIVIRAL DRUGS**

#### **HIV-1 ERADICATION**

- Targeting HIV-1 in long-lived reservoirs
- Phase 2 trial in progress during 2017; dosing complete

#### **HEPATITIS C VIRUS (HCV)**

- New class of HCV drug
- Phase 2 completed
- Seeking partnerships in China

#### **HBV & EARLY STAGE PROGRAMS**

- Pipeline of early stage programs, including:
  - Hepatitis B virus
  - Respiratory viruses
  - Flaviviruses (e.g. Dengue)

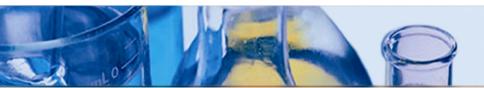
ROBUST CLINICAL VALIDATION – COMPLETED 8 CLINICAL TRIALS WITH STRONG SAFETY & EFFICACY OUTCOMES





## **Key Achievements FY 2017**

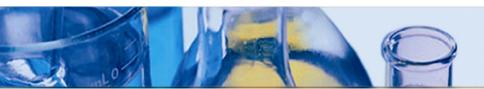
- Commenced Phase 2 clinical trial of BIT225 and Combination Antiretroviral Therapy (cART) in Feb'17
  - Fully recruited in July '17; Dosing with BIT225/placebo completed; data pending
- Demonstrated significant and accelerated reduction in HIV-1 viral load following addition of BIT225 in humanised mouse study in Feb '17
- Independent Nature publication validated Biotron's approach of targeting HIV-1 in macrophages as a key step in HIV-1 eradication in May '17
- Appointed Lynx Financial as Corporate Advisor for China assisting with executing HCV regional partnering strategy in June '17
- Raised \$1.56 million via rights issue in June '17
- Received \$1.6 million R&D tax refund in Nov '17 (post-end of FY)





## **Commercialisation – Key Focus**

- Three tactical priorities:
  - Partnering lead clinical program BIT225 for HIV-1 eradication
  - Partnering one or more preclinical programs e.g. HBV
  - Execute a regional licensing deal in China HCV program remains a great opportunity



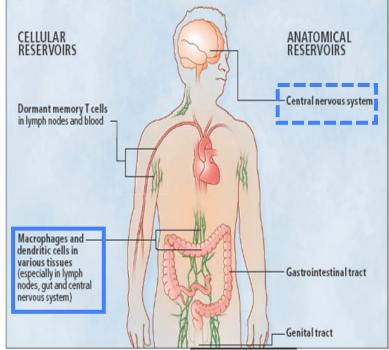


### **HIV-1 Eradication**

#### [WHERE THE VIRUS HIDES]

#### HIV'S MANY RESERVOIRS

Beyond lying in wait in dormant memory T cells, HIV may reproduce at a low rate in certain other immune system cells—particularly macrophages and dendritic cells that seem inherently able to ward off immune defenses and anti-HIV drugs to some extent. Further, HIV-infected cells in a few parts of the body may be physically shielded to a degree from the immune system and certain drugs. HIV made in cellular and anatomical reservoirs does not reach the blood readily in aggressively treated patients but might generate a vigorous infection if treatment stops.



#### **Current drugs do not eradicate HIV-1 virus**

- HIV-1 remains hidden in reservoirs, leading to chronic, life-long infection
  - Invisible to body's immune defenses
  - Not sensitive to anti-HIV-1 drugs
- New mode of actions drugs are needed to eradicate or cure HIV-1 infection

#### Why is HIV-1 eradication necessary?

- Long-term health implications e.g. HAND, immune activation, etc
- Cost of treatment
  - ~ \$20 billion p.a. world wide
  - Major burden on healthcare systems

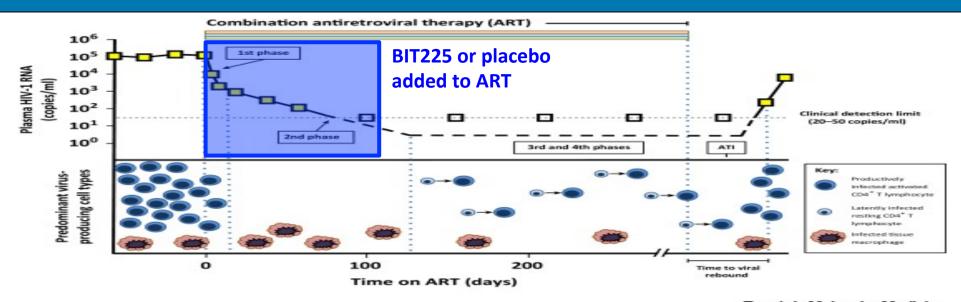
BIT225 has potential to be used in combination with other drugs to eradicate HIV-1 reservoirs

Mario Stevenson Scientific American **299**, 78 - 83 (2008)



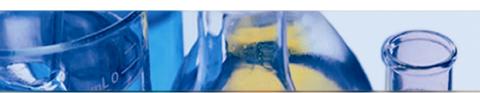


## **HIV-1 Eradication: BIT225-009 Trial**



Trends in Molecular Medicine

- 36 HIV-1<sup>+ve</sup>, treatment-naïve subjects commencing ART
- Randomised 2:1 (drug:placebo)
- BIT225 or placebo added to ART for first 12 weeks of treatment
- Read-out
  - Impact on virus levels; reduction of immune activation markers
- Fully recruited; completed dosing with BIT225/placebo; in follow-up period (ART alone)





## HIV-1 Eradication: BIT225-009 Trial

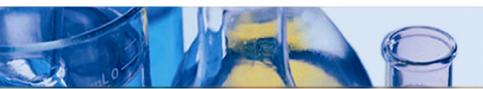
- Fully recruited July; last patient, last dose in mid-October
- Three month follow-up period post-dosing with BIT225/placebo
  - Additional samples collected from patients throughout this next 3 month period
- Post-trial laboratory analyses on samples from treatment period are in progress:
  - Virological Outcomes
  - Immunological Outcomes
- Post-dosing sample data also required to complete the analyses
  - E.g. Any rebound or change in parameters once drug ceased?
- All data is necessary to determine outcome of the trial





## **Commercialisation: BIT225 HIV-1 Eradication**

- Several pharmaceutical companies have active HIV-1 "Cure" Programs
- Identified and qualified potential partners
- Positive outcomes BIT225 clinical trial key to progressing commercialisation discussions
- Potential partners have defined their success criteria we are aligned!
- Communicating trial data as soon as available
- Follow up meetings with potential partners continue





## **Commercialisation: Preclinical Programs – HBV**

- Hepatitis B virus (HBV) therapeutic space has significant interest from pharma & biotech companies
- Biotron's HBV program is eliciting early interest from potential partners
  - In vitro data on several candidate compounds includes evidence of reduction of industry recognised markers
  - Novel mechanism is very attractive in combination approaches to treatment of HBV
- Expands Biotron's partnering opportunities potential for early stage co-development / collaboration agreement





## Commercialisation: Regional Licensing – China, HCV Program

- The new HCV drugs (e.g. Solvadi) may cause reactivation of HBV in HCV/HBV coinfected patients
  - Resulted in US FDA "Black Box" Warning on new HCV drugs
- 30 million HCV-infected people in China, compared to 3-5 million in USA
- 93 million chronically infected with HBV in China, compared to 2.2 million in USA
  - High HCV/HBV co-infection rate in China (estimated to be 10 million)
  - Reactivation of HBV in people undergoing HCV treatment with these new HCV drugs has potential to be a major health & economic issue in China
- BIT225 has been shown in clinical trials to significantly improve clinical outcome in HCV GT1-infected patients in combination with Interferon & Ribavirin (IFN/RBV)
- IFN/RBV have several potential advantages over new HCV drugs in some settings
  - IFN/RBV is significantly cheaper than the new HCV drugs
  - HBV reactivation is less common and less severe in HCV/HBV co-infected patients with IFN/RBV





## Commercialisation: Regional Licensing – China, HCV Program

- Seeking partnerships for commercialisation of BIT225 for the treatment of HCV in China
- Appointed a Shanghai-based corporate advisor with extensive experience in cross-border transactions in the healthcare space
- Developed a well qualified prospect list
- Presented to potential licensees all with capacity to finalise commercial development and launch of BIT225 in China
- Discussions are on-going





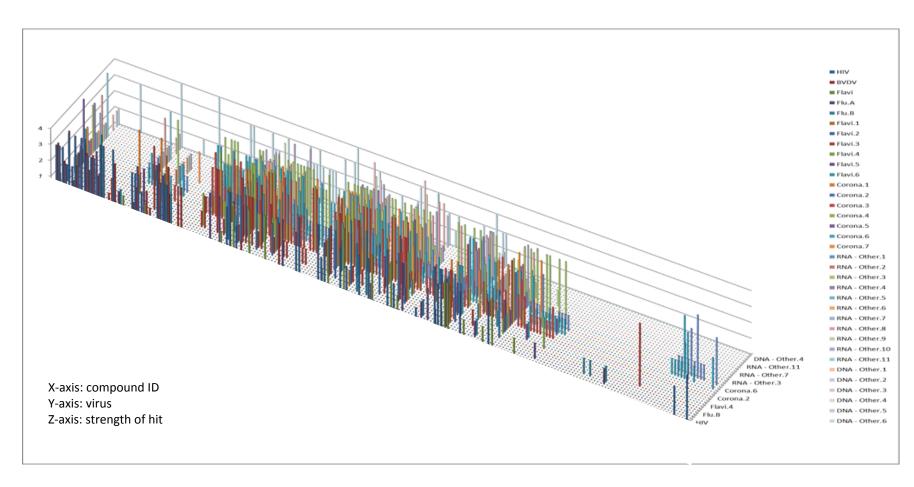
## **Unlocking Value for Other Virus Targets**

## Library of compounds designed to target viroporins found in some viruses:

Initially >250 compounds designed and synthesised; library now ~350

#### **OTHER "HITS" IN LIBRARY include:**

- Influenza A and B
- Hepatitis B virus (HBV)
- Coronaviruses (Including SARS)
- Epstein-Barr virus (EBV)
- Zika virus
- others







## **Unlocking Value for Other Virus Targets**

Biotron's Viroporin approach enables the targeting of a wide range of viral diseases; examples include:

- Respiratory Viruses such as Respiratory Syncytial Virus (RSV), Influenza, & Coronaviruses (leading cause of "common cold")
- Flaviviruses such as Zika Virus and Dengue
- Transplant viruses such as BK virus
- Epstein Barr virus (EBV) particular interest in Asia where it is causative agent of Nasopharyngeal
  Carcinoma

Biotron's Viroporin platform has the potential to become an important tool in the development of antiviral therapies

Potential for establishing early stage collaborations with pharmaceutical companies utilising Biotron's approach





## **Summary**

#### HIV Eradication

- Engaged with the right potential partners
- Waiting for data from trial but continue to engage with pharma

#### Preclinical Programs

- HBV has promise as a preclinical candidate for joint development. HBV therapeutic space is very hot.
- BIT225 results validate the platform; potential to facilitate funded developments by partners for "other" viral diseases

#### Regional Licensing

• HCV in China remains a significant development opportunity — "cost-conscious" market combined with the high rate of co-infection HCV & HBV requires different approach than used in the USA

Success in any or all of these strategies will be a "company maker" increasing the value for Biotron stakeholders



