BIOTRON LIMITED
(ASX:BIT)

AGM
24 November, 2015

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.

Biotron Snapshot

- Leader in developing viroporin inhibitors for the treatment of viral infections
  - Viroporin targets include influenza (M2), HIV-1 (Vpu), Hep C (p7), Dengue (M), SARS (E), RSV (SH) and others
    - Crucial for viral pathogenesis
  - Rapid proprietary primary bacterial cell-based screening assays
  - *Designed library of compounds to target these viroporins*
- Pipeline of internally-generated, first-in-class small molecule viroporin inhibitors for key markets
  - BIT225 derived from Biotron's compound library
  - Demonstrated clinical activity against HIV-1, and HCV G1 and GT3
- Focused on clinical development of BIT225, but next generation inhibitor is ready to progress to IND-enabling studies

BIT225 demonstrates that Biotron's viroporin-targeting approach to drug development works

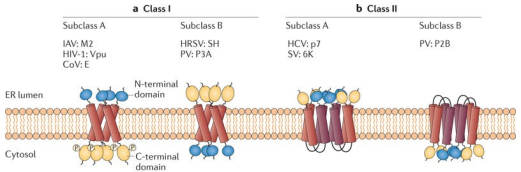
Biotron's Core Technology & Pipeline

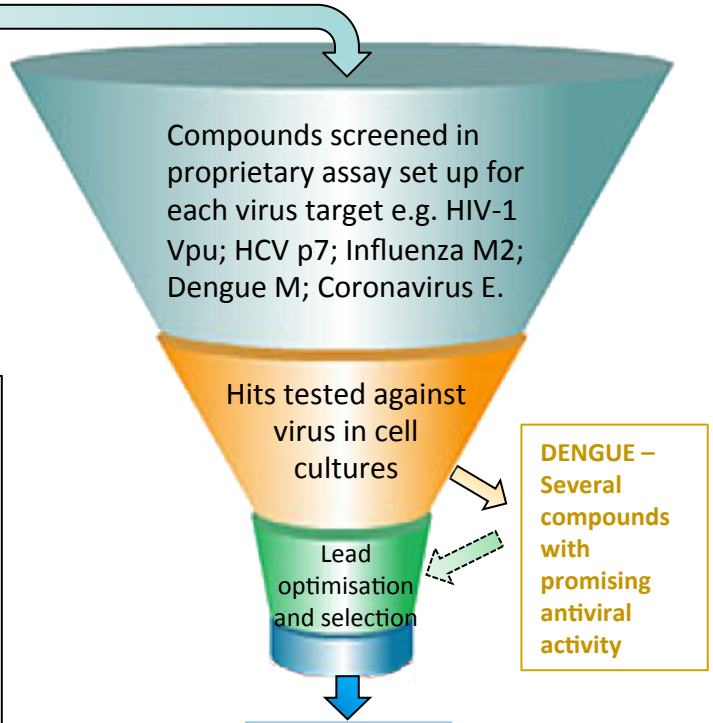
Designed library of compounds to target **viroporins**:

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

VIROPORINS

- New class of viral proteins
- Key roles in production and release of infectious virus





DENGUE – Several compounds with promising antiviral activity

BIT314 (HCV)

BIT225 (HIV-1 and HCV)

OTHER "HITS" IN LIBRARY include:

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

BIT225 is a representation of the value that resides within Biotron's core expertise

Biotron

BIT225 - Proven Clinical Track Record

- Over 200 patients and healthy volunteers dosed with BIT225 to date
- Promising clinical efficacy against HIV-1 and HCV
  - HCV GT1 (BIT225-005) – 100% receiving 400mg BID for 28 days in combination with 48 weeks IFN/RBV (per protocol) were virus-free at 48 weeks
  - HIV-1/HCV GT3 (BIT225-006) – 100% receiving 300mg BID for 28 days in combination with 48 weeks IFN/RBV (per protocol) achieved SVR12 i.e. cured of HCV infection
  - BIT225 increases the rate at which HCV is cleared
  - BIT225 efficiently inhibits HIV-1 replication in macrophage reservoir cells *in vitro* and *in vivo* (BIT225-004)
- Patent position over compound and its uses
- Compound is relatively easy to make and very stable

BIT225 – Positioning Within HCV Landscape

- Aim has been to generate data for positioning of BIT225 for partnerships
- Focus has been on:
  - Defining genotype activity *in vitro* and *in vivo*
  - Generating pharmacokinetic (PK) data on BIT225
  - Generating supporting toxicology and non-clinical data package
  - **Generating safety data to support combination trials with other HCV drugs**
- As a result, a solid, IND-supporting data package for BIT225 has been generated

The BIT225-008 (3-month dosing trial) was central to providing essential safety and PK data

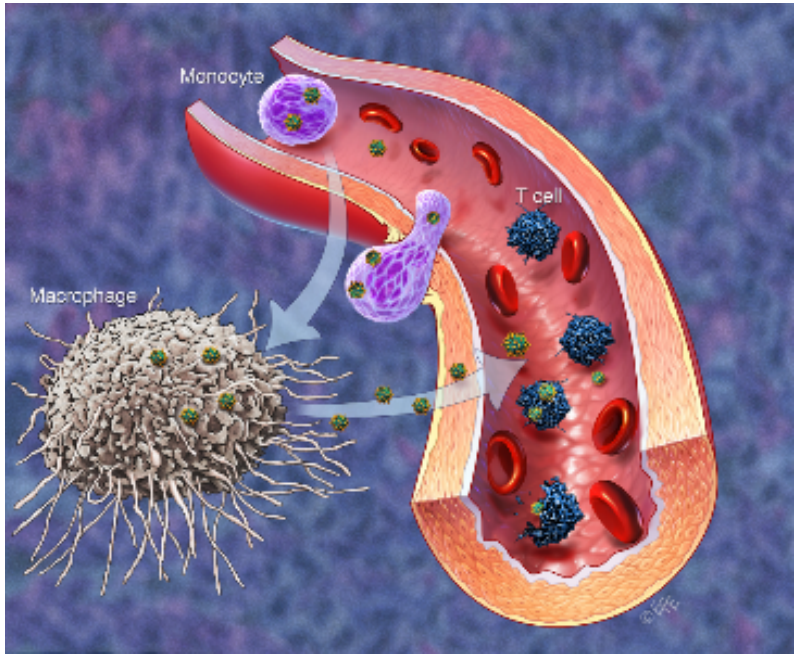
Focus is on partnering the HCV program for combination trials

BIT225-008 Trial

- Preliminary data from HCV GT3 cohort:
  - Response to IFN/RBV was much higher than historical controls had indicated
    - Rates influenced by age, gender, liver damage, genetics, etc
    - High SVR12 rate in control arm means cannot show a BIT225 effect
  - BUT we have data demonstrating pan-genotypic *in vitro* activity plus 005 and 006 trial data
  - GT1 SVR12 data is due in 1Q16
  - Prime aim of the trial:
    - **Now have safety data with the new capsule formulation out to 12 week dosing**
    - i.e. sufficient for dosing studies with new HCV drugs

BIT225 remains a promising new antiviral drug for HIV and HCV infections

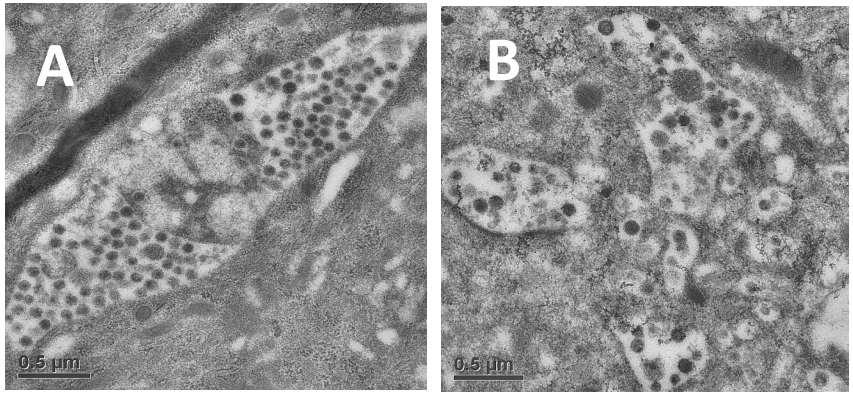
HIV-1 – Towards a Cure



- Infection rates in Australia are at 20 year high
- Over 1.1 million people living with HIV-1 in the USA, with 1 in 6 unaware of diagnosis
- US$11.9 bn sales in US, Europe and Japan in 2013; expected to grow to US$16.8 bn by 2020
- HIV-1 patients need to stay on antiretroviral drugs (cART) to keep virus levels under control
- Despite reducing viral loads, cART does not fully restore health
- New mode of actions drugs are needed to eradicate or cure HIV-1 infection

BIT225 Targets HIV-1 in Reservoir Cells

- BIT225 inhibits assembly and budding of new virus
- Phase 2a trial (BIT225-004) showed that BIT225 can reduce HIV-1 levels in macrophage cells *in vivo*, paralleling *in vitro* studies
- Potential benefits on immune aging and HIV-associated dementia
- **Potential for use in future virus eradication treatment**
- **Progressing to pivotal Phase 2 HIV trial in 2016**
    - **Aim is to demonstrate clinical benefit to attract a partner**



(A) Untreated Controls *(B) BIT225 treated cells*

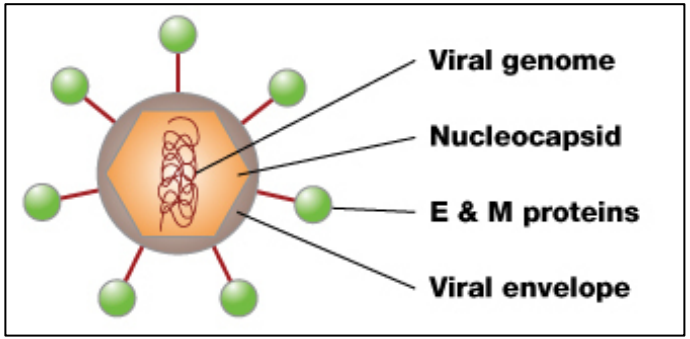
The non-clinical and clinical safety/PK package generated in the HCV program supports the HIV program for BIT225

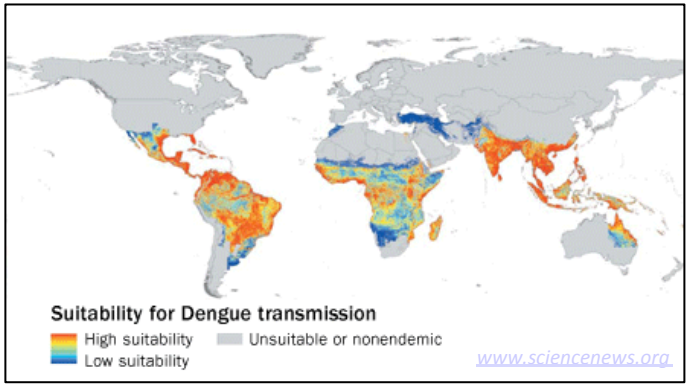
Unlocking Value in Compound Library

- Renewed interest in targeting viral diseases including
  - Respiratory syncytial virus (RSV)
  - Influenza (in particular drug resistant strains)
  - Hepatitis B virus
  - Tropical diseases including Dengue
- Ebola and MERS-CoV outbreaks have caused public health issues worldwide
- Aim - demonstrate utility of Biotron's drug development approach
  - Generating activity "heat map" of compound library
  - Characterising activity against key viruses of interest
  - Fund as much as possible with non-equity capital
- Main focus remains on commercialising the Company's HIV-1 and HCV programs, but essential that other opportunities are developed

Dengue Virus Program

- 2.5 billion people (40% world population) live in areas at risk of Dengue
- ~100 million people infected yearly
- A leading cause of illness and death in tropics and subtropics
- Transmission is by mosquito; most prevention programs target the vector
- No approved Dengue-specific therapeutic
- Vaccine trials have had disappointing results
- Biotron is targeting Dengue M protein – Similar target to HIV/ Vpu and HCV/p7
    - Several compounds with promising activity have been generated; tests are on-going





Investment Proposition

- HCV and HIV are high growth, multi-billion dollar markets
  - Treatment gaps remain
- BIT225 is a novel approach with demonstrated promising efficacy in Phase 2a/2 clinical trials
  - Represents a new class of direct-acting HCV drugs
  - Potential to fill significant HCV treatment gaps
    - Main focus is HCV Genotype 3
  - Potential to eradicate important HIV reservoirs, plus may impact on immune activation
  - Robust data package has been generated to support combination studies with potential partners
- Unique core expertise against novel viral targets
- Potential within compound library for significant other viral infections

Outlook for 2015/16

- Complete BIT225-008 HCV trial currently in progress
  - SVR12 for G1 due **1Q16**
- Investigational New Drug application (IND)
  - Finalise regulatory documentation containing an extensive data package
  - Partner for HCV combination studies
- Progress protocol and regulatory documentation for key Phase 2 HIV trial to commence in 1H16
- Expand earlier stage drug programs e.g. Dengue virus when funding available
- Continue commercialisation activities aimed at attracting partners
- Continue to promote company to local and international investment community