

**BIOTRON LIMITED**  
**(ASX:BIT)**

**Mid-Clinical Stage Antiviral  
Drug Development Company**

**Investor Update**  
**20 August 2015**

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A decorative horizontal strip at the bottom of the slide features a close-up, shallow depth-of-field photograph of laboratory glassware. On the left, a blue pipette tip is visible. In the center, a glass vial contains a yellow liquid. To the right, a small glass dish or well plate is partially visible. The background is a soft, out-of-focus light blue.

# 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.

# Financial Information

## Key Financial Metrics

Ticker Code	ASX: BIT
Share Price (19 Aug 2015)	A \$0.10
Market cap	A \$31.3 million
12 Month Trading Range	A \$0.0864 – 0.1832
Shares Outstanding	313 million
Options (BITO)	50.7 million \$0.12 expiry 30/09/16
Cash Position (06/2015)	A \$6.5 million

## Board

Michael Hoy	Non-executive Chairman
Michelle Miller	Managing Director
Susan Pond	Non-executive Director
Rob Thomas	Non-executive Director
Denis Wade	Non-executive Director

## 12 Month Share Price Performance



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# BIT225 Snapshot

- First in class drug and new drug target for treatment of HIV and Hepatitis C virus (HCV)
- Seven clinical trials completed; another is fully recruited
- Demonstrated clinical activity against HCV G1 and G3
- Independently shown to have HCV pan-genotype activity *in vitro*
- Efficiently inhibits HIV replication in monocyte/macrophage reservoir cells *in vitro* and *in vivo*
- Patent position over compound and its uses
- Compound is relatively easy to make and formulate; very stable at room temperature – important for supply chains
- Significantly undervalued compared to other HCV drugs = potential for considerable upside

# Significant Progress During Last 12 Months

ACTIVITY	STATUS/OUTCOME
Phase 2 HIV/HCV co-infected trial	100% SVR12 data reported for HIV/HCV G3
Phase 2a HIV trial	Impact on immune activation reported
Phase 2, three-month dosing HCV G1 & G3 trial	Fully recruited; SVR12 G3 3Q15; SVR12 G1 1Q16
Development of BIT225 capsules	Improves delivery of BIT225, in a user friendly format suitable for larger scale trials
Patent position strengthened	Key patents for BIT225 and other compounds issued in the USA and other jurisdictions
\$8 million raised	July 15 – Placement plus SPP raised \$4 million; Nov 14 - fully underwritten rights issue closed over-subscribed with no shortfall raising \$4 million

# Biotron's Core Technology & Pipeline

Designed library of compounds to target **viroporins**:  
**>250 compounds designed and synthesised**

**VIROPORINS**

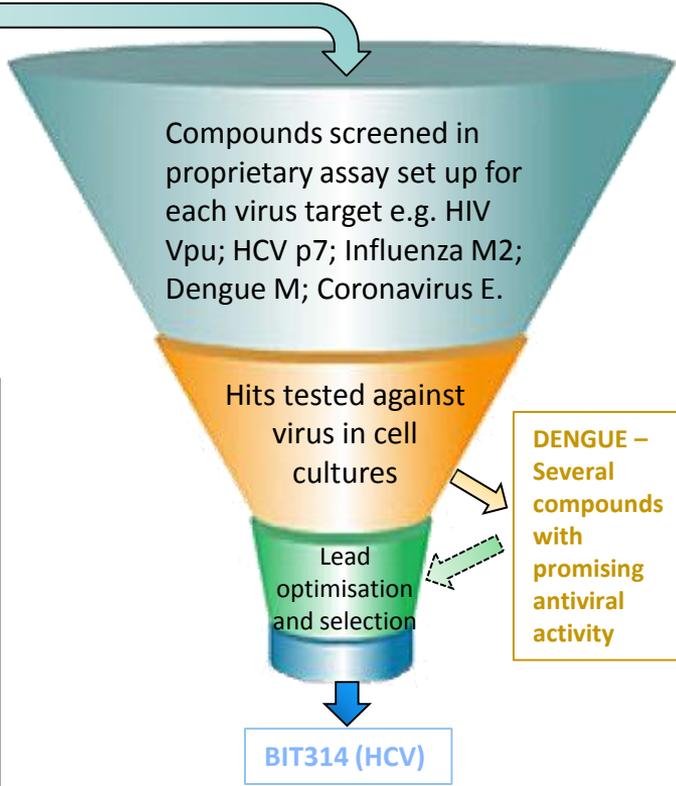
- New class of viral proteins
- Key roles in production and release of infectious virus

**a Class I**  
 Subclass A: IAV: M2, HIV-1: Vpu, CoV: E  
 Subclass B: HRSV: SH, PV: P3A

**b Class II**  
 Subclass A: HCV: p7, SV: Gk  
 Subclass B: PV: P2B

ER lumen, N-terminal domain, C-terminal domain, Cytosol

Nature Reviews | Microbiology 10, 563-574 (2012)



**DENGUE – Several compounds with promising antiviral activity**

## PIPELINE

	Leads	PRE-CLIN	PH 1	PH 2	PH 3
HCV BIT225	→				
HIV/HCV BIT225	→				
HIV BIT225	→				
Next gen – HCV BIT314	→				
Dengue	→				



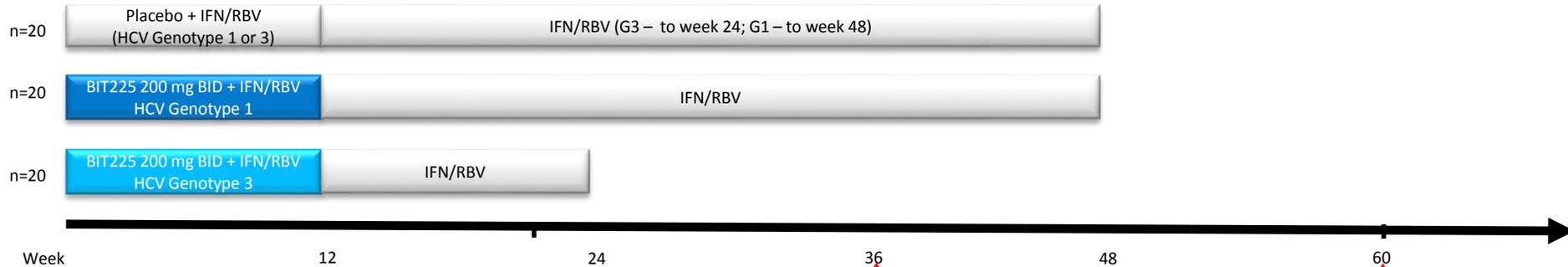
# BIT225 - Proven Clinical Track Record

- Over 200 patients and healthy volunteers dosed with BIT225 to date
- Positive data recorded in all trials
- HCV G1 (BIT225-005) – 100% receiving 400mg (28 days in combination with 48 weeks IFN/RBV) were **virus-free** at 48 weeks
- Co-infected HIV/HCV GT3 (BIT225-006) – 100% completing course of 300mg (28 days in combination with 48 weeks IFN/RBV) were HCV-free 12 weeks post-treatment (SVR12) i.e. **cured of HCV infection**
- BIT225 increases the rate at which HCV is cleared

# Large and Growing Global Market for Hepatitis C

- Forecast to grow to over \$19bn by 2016
  - 180 million infected worldwide (3% world population)
  - ~3 to 5 million in US & 30 million in China
- New drugs have demonstrated significant pricing power
  - Gilead's Sovaldi (Sofosbuvir) at US\$84,000 for a 12 week course
  - Best performing 'first year' sales: ~US\$10 billion
- Recent new HCV drug combinations not optimal
  - Lengthy treatment – 12 weeks or more
  - Not pan-genotypic – **BIT225 is pan-genotypic *in vitro***
  - Not as effective against HCV G3 – **BIT225 has good activity against HCV G3**
  - More treatment failures than anticipated – **need for new classes of drugs like BIT225**
- Partnering still active
  - J&J partnered Achillion in US\$1.1 bn deal in May '15; Merck bought Idenix for US\$3.8 bn in June '14

# BIT225-008: Phase 2 HCV Three-Month Dosing Trial



## Design:

- Randomised, placebo-controlled, double-blind trial (n=60)
- Treatment naïve, HCV gen 1 and 3
- 3 months dosing with BIT225 in combination with IFN/RBV
- Using new capsule formulation
  - 1.6 fold higher blood levels than previous formulation
- Fully recruited
  - **SVR12 for G3 due 3Q15; SVR12 for G1 due 1Q16**

**\*SVR12 FOR G3**

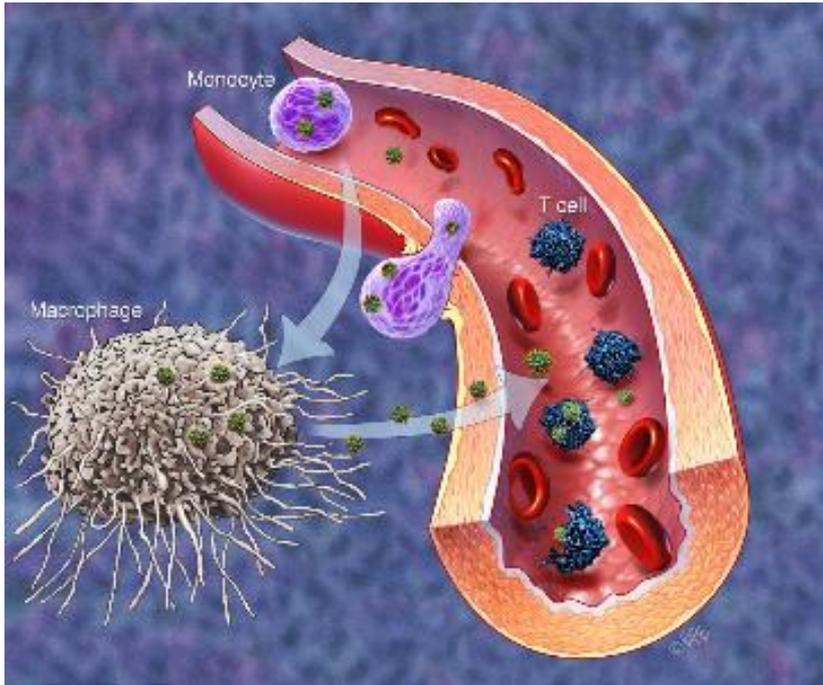
**\*SVR12 FOR G1**

## Aims:

- Demonstrate safety of BIT225 with 3 months dosing
- Extend HCV gen 3 efficacy data
- Provide key data to assist with determining future dosing with BIT225 capsules
- Generate safety data to support US FDA IND filing for combination trial with other HCV direct-acting antivirals (DAAs)

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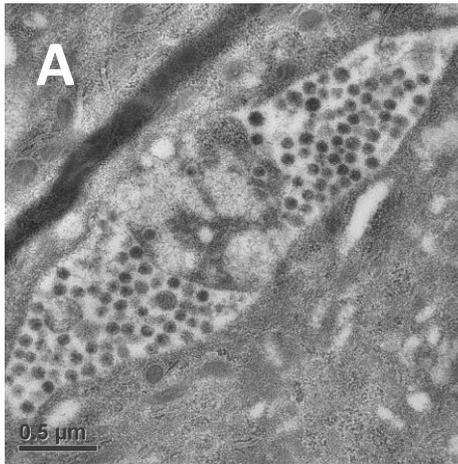
# HIV – Towards a Cure



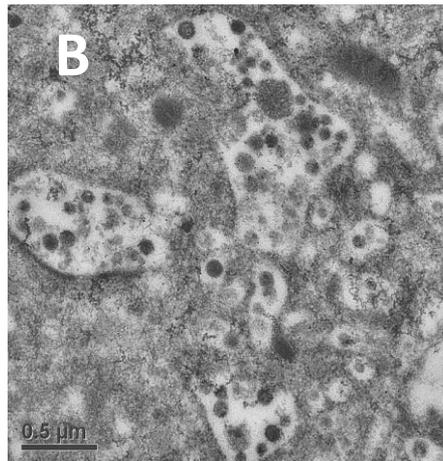
- Infection rates in Australia are at 20 year high
- Over 1.1 million people living with HIV in the USA, with 1 in 6 unaware of diagnosis
- US\$11.9 bn sales in US, Europe and Japan in 2013; expected to grow to US\$16.8 bn by 2020
- HIV patients need to stay on antiretroviral drugs (ART) to keep virus levels under control
- New mode of actions drugs are needed to eradicate or cure HIV infection

# BIT225 Targets HIV in Reservoir Cells

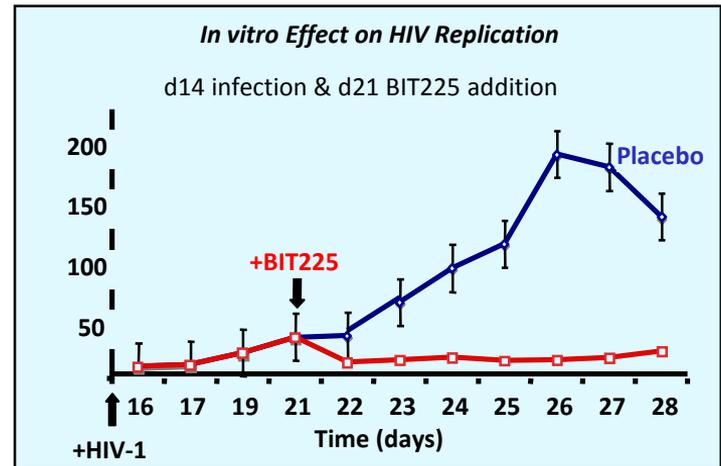
- BIT225 inhibits assembly and budding of new virus
- Phase 2a trial (004) showed that BIT225 can reduce HIV levels in macrophage cells *in vivo*, paralleling *in vitro* studies
- Potential benefits on immune aging and HIV-associated dementia
- **Potential for use in future virus eradication treatment**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



(A) Untreated Controls



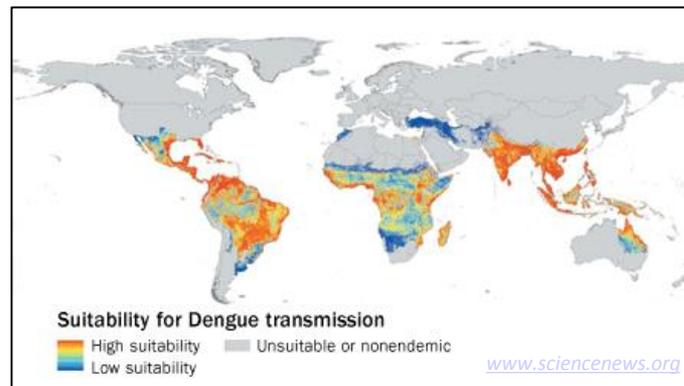
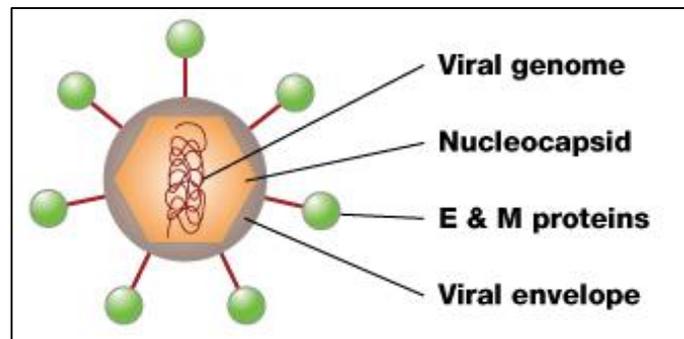
(B) BIT225 treated cells



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# 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 at early stage of development



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# Investment Proposition

- HCV and HIV are high growth, multi-billion dollar markets
  - Significant 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
    - HCV Genotype 3
    - HIV/HCV co-infected patients
    - Cirrhotic patients & treatment failures
  - Potential to eradicate important HIV reservoirs, plus may impact on HIV-associated dementia
- Flexibility to combine with any other HCV and HIV drug combinations
- Significantly undervalued in comparison with other HCV companies

# Outlook for 2015/16

- Complete BIT225-008 HCV trial currently in progress
  - SVR12 for G3 due **3Q15**; SVR12 for G1 due **1Q16**
- Investigational New Drug application (IND)
  - Engaged with FDA - pre-IND consultation HCV combination trial with DAA
  - File HCV IND application late 2015
    - Currently completing studies required by FDA
- Progress protocol and regulatory documentation for key Phase 2 HIV trial
- 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