

15 October 2014

The Manager Companies  
ASX Limited  
20 Bridge Street  
SYDNEY NSW 2000

(17 pages by email)

Dear Madam

### **FULLY UNDERWRITTEN RIGHTS ISSUE**

- **Fully underwritten rights issue to raise \$4.1 million**
- **Strong support from institutional and sophisticated investors**
- **Book significantly oversubscribed**
- **Attractive pricing – 51% discount to 1 month VWAP of 16.4 cents**
- **Free attaching options (exercise price 12 cents, two years) to be listed**
- **Shareholders can renounce their rights or apply for additional shares**
- **Rights to start trading from 17 October 2014**

**Sydney, Australia, 9 October 2014** – Australian drug development company Biotron Limited (ASX:BIT) today announced a fully underwritten renounceable rights issue to raise \$4.1 million. Net proceeds, in conjunction with existing cash reserves, will be used:

- To complete the current Phase 2 trial that is in progress (BIT225-008 - HCV genotypes 1 and 3 trial for 3 months dosing with BIT225 in combination with IFN/RBV).
- For studies to complete IND filings with the USA FDA:
  - drug-drug interaction studies with new DAAs to be used with BIT225 in the IND trial;
  - modelling pharmacokinetic data from previous trials to determine optimal BIT225 dose and frequency in the IND trial; and
  - additional *in vitro* laboratory studies of BIT225's antiviral activity, including studies with other DAA drugs.
- For commercialisation negotiation legal fees, travel and personnel costs.
- For general working capital.

The offer will be made to shareholders on a two for nine basis at the issue price of \$0.08, which represents a 51% discount to the 1 month volume weighted average price (VWAP) of \$0.164 and a 48% discount to the 3 month VWAP of \$0.153.

Shareholders will be given the opportunity to apply for additional shares in excess of their entitlement, however, allocations are not guaranteed. The issue is renounceable and shareholders will be able to guarantee an increase to entitlements by the purchase of additional rights.

The Directors are pleased with the strong demand received from the institutional and sophisticated investors. The bookbuild closed significantly oversubscribed, indicating a level of demand in support of the potential of the Company's drug development program, positive clinical trial results to date and commercialisation potential.

Patersons Securities Limited acts as Lead Manager and the Underwriter.

#### **Enquiries**

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#### **About Biotron and BIT225**

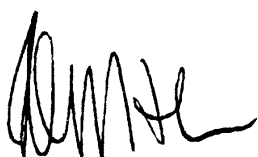
A presentation on the Company's activities is attached.

Biotron Limited is engaged in the research, development, and commercialisation of drugs targeting significant viral diseases with unmet medical need, with a major focus on HIV and HCV. The Company has BIT225 in clinical development for both HIV and HCV, and also has several earlier stage preclinical and research programs for several other viral infections including Dengue.

BIT225 has recorded encouraging data against HCV in clinical trials. A phase 2a trial in HCV demonstrated that 100% of HCV genotype 1 infected patients receiving BIT225 (400 mg) in combination with current standard of care therapies interferon and ribavirin had undetectable virus after 48 weeks. A phase 2 trial in HIV/HCV co-infected patients showed that all HCV genotype 3 patients completing 28 days of treatment with BIT225 in combination with interferon and ribavirin achieved SVR12, with undetectable HCV 12 weeks after completing all therapy.

BIT225 is also in development for treatment of HIV, and is the first in a new class of antiviral drugs that may provide a new approach to eradication of this virus. It has shown clinical efficacy against HIV in reservoir cells, and has the potential to be combined with new or existing anti-retroviral drugs to eradicate long-lived pools of virus that are not eliminated with current treatments.

Yours sincerely



Peter J. Nightingale  
Company Secretary

pjn7862

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

**Investor Presentation**  
**October 2014**

*Biotron*



# 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.

# BIT225 Snapshot

- First in class drug and new drug target for treatment of HIV and Hepatitis C virus (HCV)
- Seven clinical trials completed; one in progress
- Over 170 subjects dosed with BIT225 to date
  - HCV GT1 (BIT225-005) – 100% receiving 400mg (28 days in combination with 48 weeks IFN/RBV) were virus-free at 48 weeks
  - BIT225 increases the rate at which HCV is cleared (especially for GT3)
  - 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)
- Independently shown to have 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

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# Biotron - Advanced Pipeline Overview

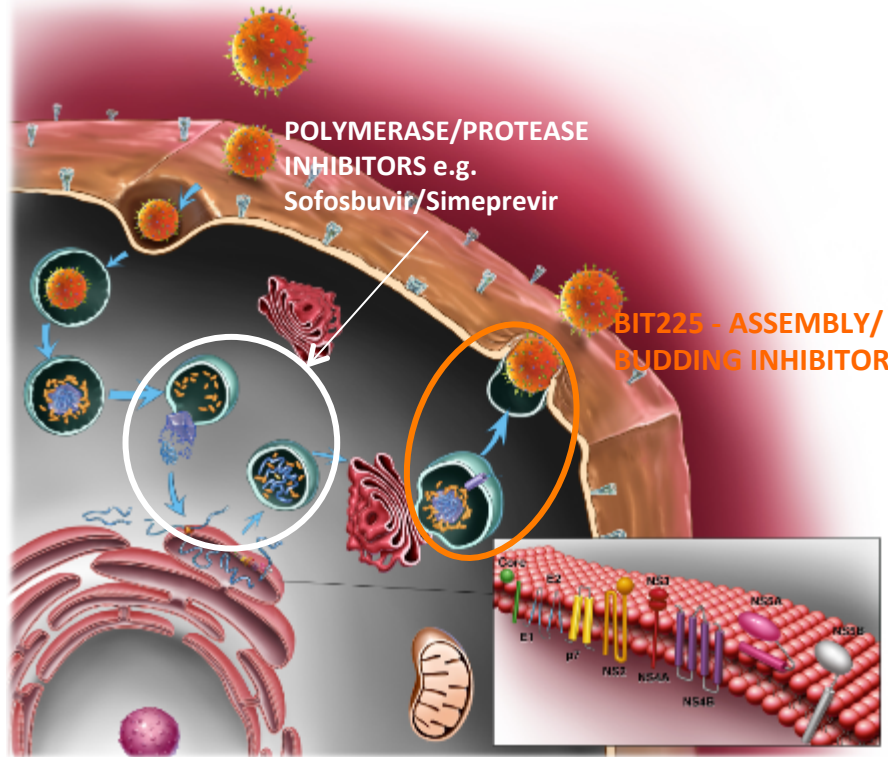
INDICATION	COMPOUND	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Hep C	BIT225					
HIV/Hep C	BIT225					
HIV	BIT225					
Next generation - HCV	BIT314					
Dengue	Leads					

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# Global Market for Hepatitis C

- Worldwide market for Hepatitis C forecast to grow from \$4.7bn in 2012 to over \$19bn by 2016
  - 180 million people infected worldwide (3% world population)
  - Estimated 3 to 5 million patients in US
  - Estimated 30 million patients in China
- New drugs have demonstrated significant pricing power
  - Gilead's Sovaldi (Sofosbuvir) at US\$84,000 for a 12 week course
  - Q1 2014 sales US\$2.3 bn; Q2 2014 sales US\$3.5 bn
- Need for optimal HCV drug combinations
  - Pan-genotypic
  - Much shorter treatment period (ideally 4 weeks) and oral therapy only
- Partnering still active
  - Merck bought Idenix for US\$3.8 bn in June 14

# BIT225 – First of a New Class of HCV Drugs



- ✓ Novel, oral, small molecule
- ✓ Only one of its class (p7 inhibitor) in clinical trials
- ✓ Inhibits viral assembly and infectivity
- ✓ Pan-genotype activity:
  - ✓ Active *in vitro* against all main genotypes
  - ✓ Clinically active against hard-to-treat HCV Gen 1 (1a and 1b) and Gen 3
- ✓ Potential to add to other new HCV drugs to:
  - ✓ Shorten treatment times
  - ✓ Improve outcome in specific patient groups

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# BIT225 Clinical Program – Trials to Date

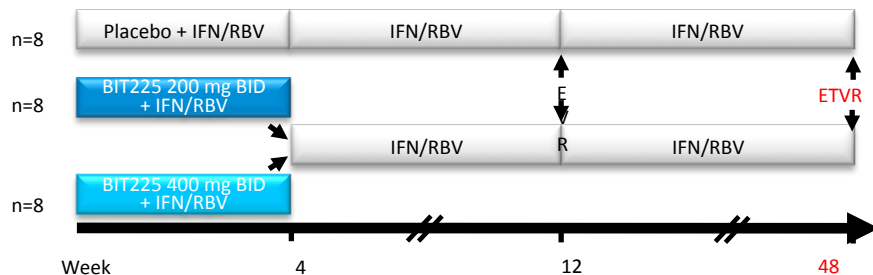
- **BIT225-001:** Phase 1a, single dose, dose escalating study in healthy volunteers (48 subjects; Aust)
- **BIT225-003:** Phase 1b, 7-day, repeat dose study in HCV+ patients (35 and 200 mg BID; 18 subjects; Aust)
- **BIT225-004:** Phase 2a, 10-day, repeat dose study in HIV+ patients (400 mg BID; 21 subjects; Thailand)
- **BIT225-005:** Phase 2a, 28-day, repeat dose study in HCV G1 patients in combination with PEG/RBV (200 and 400 mg BID; 24 patients; Thailand)
- **BIT225-006:** Phase 2, 28-day, repeat dose, open label study in HIV/HCV G1 and 3 co-infected patients in combination with PEG/RBV (300 mg BID; 12 patients; Thailand)
- **BIT225-007:** Phase 1, BE/PK study in healthy volunteers, cross-over, single dose comparing capsule formulation with existing powder (400 mg BID; 12 subjects; Aust)
- **BIT225-008:** Phase 2, 3 month, repeat dose study in HCV+ patients (G1 & 3) in combination with PEG/RBV (200 mg BID; 60 subjects; Thailand) IN PROGRESS

*NB BIT225-002 was an ex vivo study of BIT225 on HIV-infected cells isolated from HIV-positive patients*

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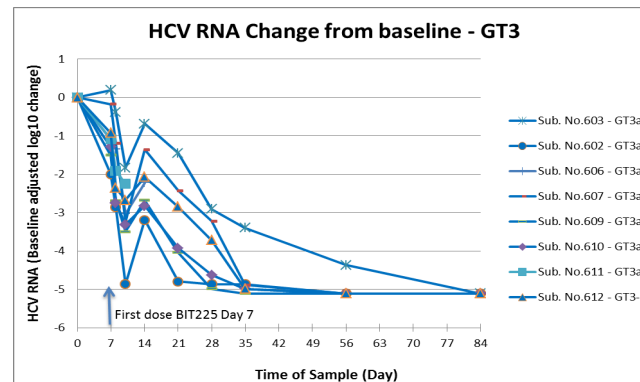
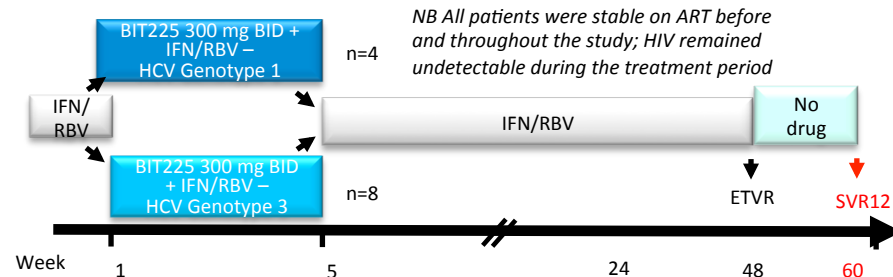
# BIT225 - Clinical Activity in HCV and HIV/HCV Patients

## BIT225-005 (HCV)



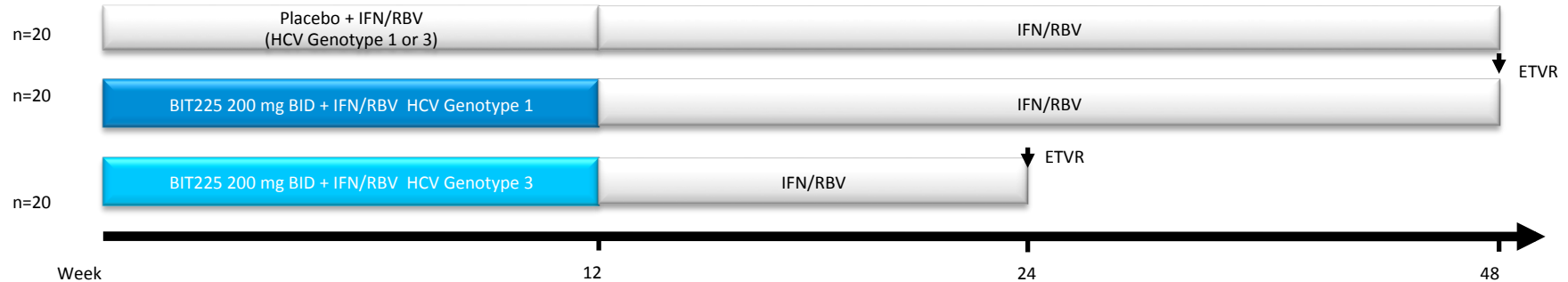
Treatment	Median log reduction at 35 days	% Complete EVR (<50 IU/ml at 12 weeks)	% ETVR (<50 IU/ml at 48 weeks)
400 mg BIT225 + SOC	-4.957	86	100
200 mg BIT225 + SOC	-4.351	88	88
Placebo + SOC	-3.649	63	75

## BIT225-006 (HIV/HCV)



**Week 60**  
All GT3 patient who completed treatment are HCV-free (SVR12)

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



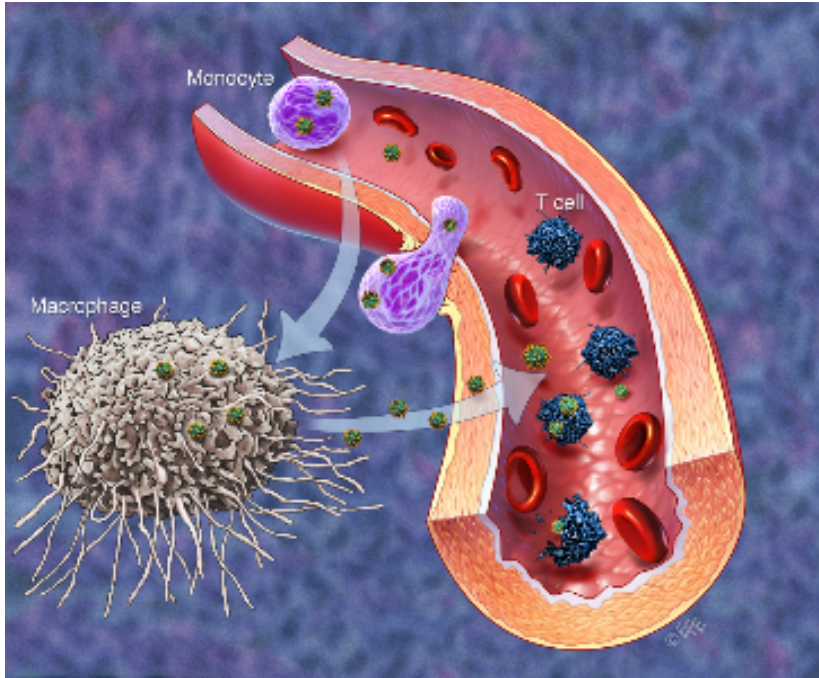
## Design:

- Randomized, 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
- IN PROGRESS (Thailand); Preliminary data expected late 2014

## Aims:

- Demonstrate safety of BIT225 with 3 months dosing
- Extend HCV gen 3 efficacy data

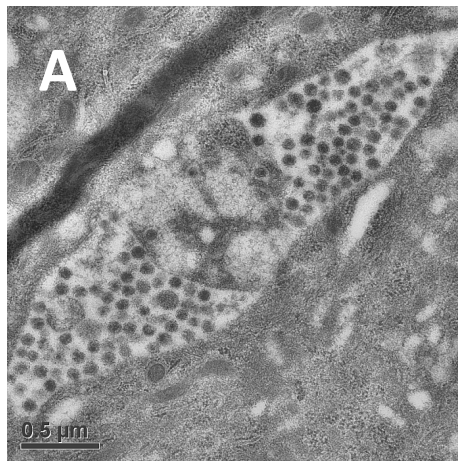
# HIV – Towards a Cure



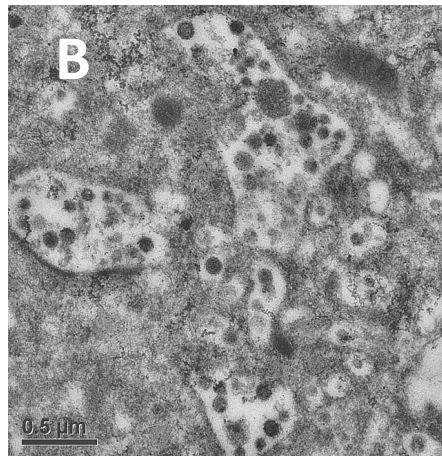
- Infection rates in Australia are at 20 year high
- Over 1.1 million people living with HIV in the USA, with 1 in 6 unaware of diagnosis
- US\$11.9 bn sales in US, Europe and Japan in 2013; expected to grow to US\$16.8 bn by 2020
- HIV patients need to stay on antiretroviral drugs (ART) to keep virus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

# BIT225 Targets HIV in Reservoir Cells

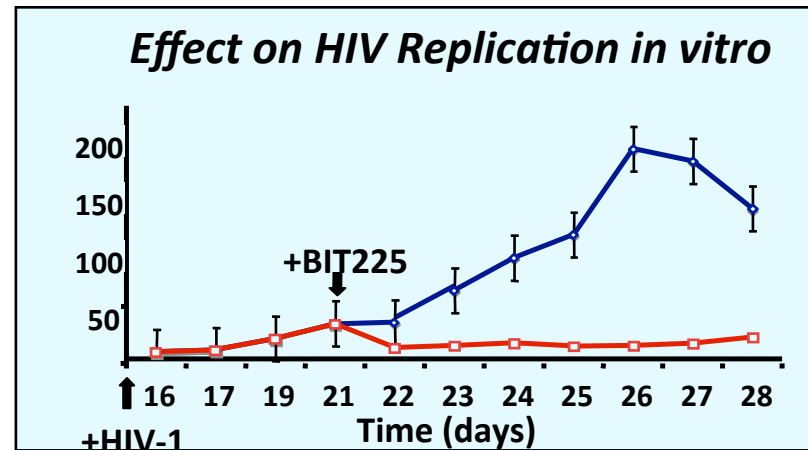
- BIT225 inhibits assembly and budding of new virions
- Phase 2a trial (004) showed that BIT225 can reduce HIV levels in macrophage cells *in vivo*, paralleling *in vitro* studies
- Potential benefits on immune aging and HIV-associated dementia
- Potential for use in future virus eradication treatment



(A) Untreated Controls



(B) BIT225 treated cells



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# 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
    - HCV Genotype 3
    - HIV/HCV co-infected patients
    - Cirrhotic patients
  - 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

# Next Steps

- Complete HCV trial currently in progress
  - Preliminary data expected late 2014
- Engage with US FDA - Investigational New Drug application(s) (INDs)
  - Complete IND-related activities
  - File IND application(s)
- Continue commercialisation activities aimed at attracting partners
- Expand earlier stage drug programs e.g. Dengue virus when funding becomes available through commercialisation of later stage programs

# The Offer

- Entitlement issue
  - 2:9 @ 8 cents with 1:1 30/9/16 options @ 12 cents
  - Raise \$4.1 million before costs, to fund:
    - Completion of the BIT225-008 trial currently in progress in Thailand
    - Completion of activities leading to filing INDs, including
      - Drug-drug interaction studies
      - Modeling of pharmacokinetic data from previous trials to determine optimal BIT225 dose and frequency in IND trials
      - Additional IND-supporting *in vitro* laboratory studies with BIT225
  - Expansion of the Company's executive team as it moves towards commercialisation
  - Working capital for day to day activities

# Financial Information

## Key Financial Metrics

Ticker Code	ASX: BIT
Share Price (10 Oct 2014)	A \$0.15
Market cap	A \$34.2 million
12 Month Trading Range	A \$0.075 – 0.315
Shares Outstanding	228 million
Cash Position (06/14)	A \$1.76mn

## Board

Michael Hoy	Non-exec Chairman
Michelle Miller	CEO and MD
Susan Pond	Non-exec Director
Rob Thomas	Non-exec Director
Denis Wade	Non-exec Director

## 12 Month Share Price Performance

BIT - Daily Line Chart [Close]



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