

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

**Investor Briefing**  
**October 2013**

*Biotron*

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# Forward Looking Statements

This presentation may contain forward-looking statements with respect to the financial condition, results and business achievements/performance of Biotron Limited 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 Limited Overview

- Clinical stage antiviral drug development company
  - Clinical programs for Hepatitis C virus (HCV) and HIV
  - Earlier stage programs include Dengue and others
  - Spun out from Australian National University, Canberra, Australia
  - Headquartered in Sydney, Australia
  - IPO Jan 2001 (ASX:BIT)
- **Key recent highlights**
  - **July 2013 – HIV/HCV: Completed Phase 2 trial recruitment**
  - **Mar 2013 – HIV: Announced positive preliminary headline results from Phase 2a trial**
  - **Nov 2012 – HCV: Announced positive 48-week follow-up data from Phase 2a trial**

# Key Financials and Facts

## KEY FINANCIALS

ASX Code	BIT
Recent Share Price (21 October 2013)	A\$0.10
52 Week High	A\$0.15
52 Week Low	A\$0.08
Shares on Issue	228 million
Market Capitalization	A\$23 m
Net Cash (30 Sept '13)	A\$3.5 m






## BOARD AND MANAGEMENT

Mr Michael Hoy	Chairman
Dr Michelle Miller	CEO & Managing Director
Dr Denis Wade	Non-Executive Director
Dr Susan Pond	Non-Executive Director
Mr Robert Thomas	Non-Executive Director
Mr Bruce Hundertmark	Non-Executive Director
Mr Peter Nightingale	CFO & Company Secretary



**Biotron**

# Biotron - Advanced Pipeline of Clinical Programs

INDICATION	VIRAL TARGET	DISCOVERY	PRECLINICAL	PHASE 1a	PHASE 1b	PHASE 2a	PHASE 2b	STATUS
Hep C	p7							<ul style="list-style-type: none"> <li>Ph 2a complete;</li> <li>Ph 2b (3 mth dosing) scheduled for 4Q13</li> </ul>
HIV	Vpu							<ul style="list-style-type: none"> <li>Ph 2a complete</li> </ul>
HIV/Hep C	Vpu/p7							<ul style="list-style-type: none"> <li>Ph 2 completed clinical phase</li> </ul>
Next generation - HCV	p7							<ul style="list-style-type: none"> <li>Ready for IND-enabling (formal preclinical) studies</li> </ul>
Dengue	M							



# Hepatitis C Virus – The Silent Killer

- 180 m people infected worldwide (3% world population); 130 m are chronically infected; 4 m patients in US (2.7 m chronically infected)
- Majority of infected patients remain untreated or untreatable
  - Up to 50% patients don't respond to current treatment
  - Standard of care is interferon and ribavirin
  - Significant side effect profile – high drop out rate
  - Documented need for new, safer, direct-acting antiviral (DAA) drugs

# Direct-Acting Antiviral Drugs

- Industry focus is on developing direct-acting antiviral drugs (DAAs)
- Future treatments expected to be combination of different classes of DAAs
  - Genotype differences in treatment response
  - Potential for virus resistance with some classes of DAAs
  - Main focus is on polymerase and protease inhibitor classes
- Likely to be more than one DAA combination to cover the wide spectrum of HCV disease

**“Hepatitis C market is forecast to grow by 230%, peaking at \$15.5bn in 2022”**

**Source: Datamonitor Healthcare**

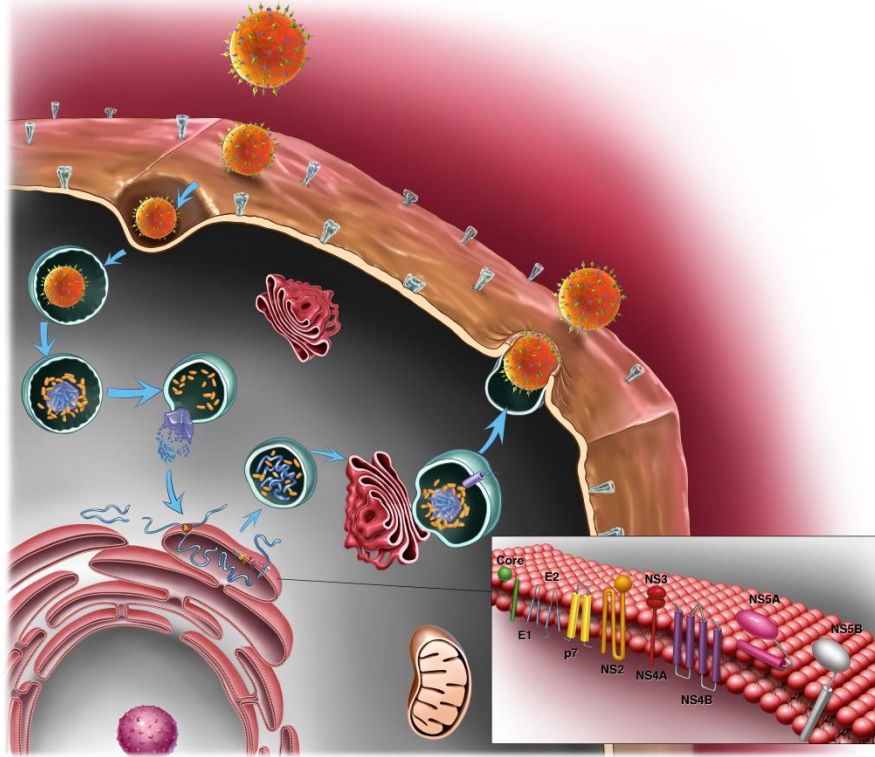
# HCV – Scene of Billion Dollar Deals

**Nov 2011 – Gilead (GILD) acquired Pharmasset (VRUS) for US\$11 billion**  
- PSI-7977 was in early Phase 3 trials

**Jan 2012 – BMS acquired Inhibitex (INHX) for US\$2.5 billion**  
- INX-189 was in Phase 2 trials

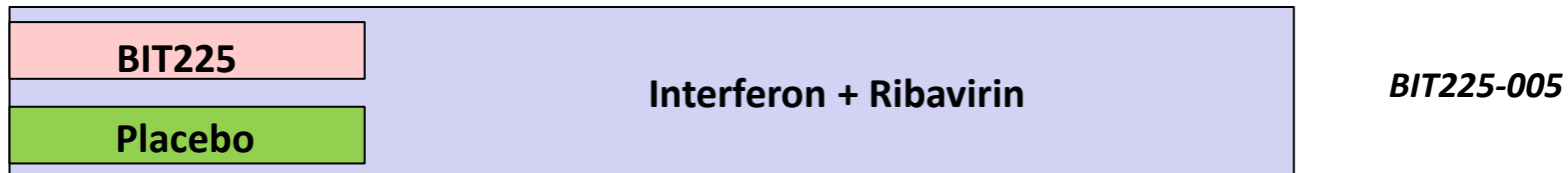


# BIT225 – New Class of HCV DAA Drug



- ✓ Novel, oral, small molecule compound
- ✓ Only one of its class (p7 inhibitor) in clinical trials
- ✓ Inhibits viral assembly; active at later stage of virus life cycle to polymerase and protease inhibitors
- ✓ Doesn't readily generate resistance
- ✓ Synergistic *in vitro* with HCV polymerase inhibitors
- ✓ Clinically active against hard-to-treat HCV genotype 1 (1a and 1b)
- ✓ Also active against HIV - potential for use in HCV/HIV co-infected patients

# BIT225 – Proven Clinical Activity Against HCV



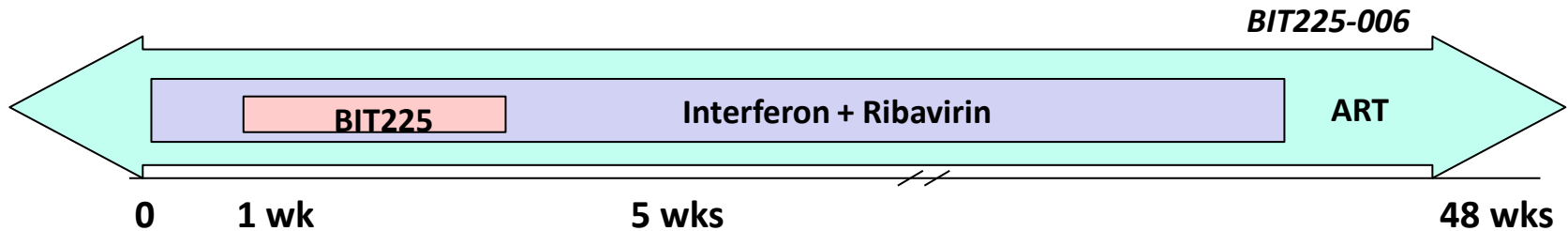
Treatment	12 WEEKS	48 WEEKS
	Early Virological Response*	Sustained Virological Response*
400 mg BIT225 + IFN/RBV	86%	100%
200 mg BIT225 + IFN/RBV	88%	88%
Placebo + IFN/RBV	63%	75%

*\*virus levels below limit of detection i.e. 50 IU/ml*

**Clear demonstration that BIT225 has good antiviral activity in hard-to-treat, treatment-naïve HCV genotype 1 patients**

# BIT225 – HIV / HCV Co-Infected Trial

- **Phase 2 HIV/HCV trial - completed clinical phase in July 2013**
  - ~30% of HIV-infected people in the USA are also HCV-infected
  - Significantly worse prognosis than mono-infected patients



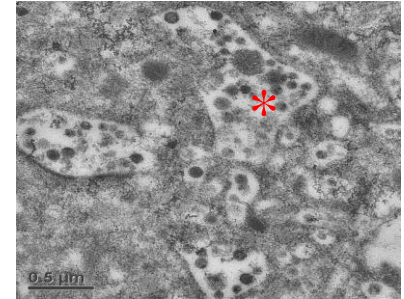
- 28 days dosing in combination with IFN/RBV
- Treatment-naïve to HCV treatment with RBV and/or IFN; virologically suppressed on HIV drugs (ART)
- Genotypes 1 and 3
- ***Preliminary, interim data expected 2H13***

**BIT225 is uniquely placed due to dual anti-HIV and anti-HCV activity**

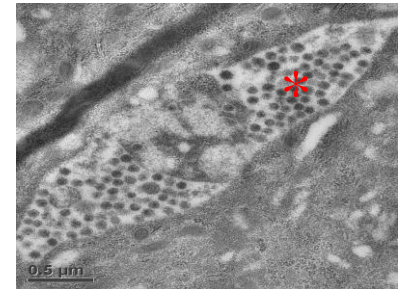
# HIV – Towards a Cure

- 34 million people worldwide living with HIV
- Anti-HIV drugs (ART) have improved the quality of life for HIV+ patients
- BUT – ART does not eradicate HIV infection
- Sustained, low-level HIV replication occurs in ART-treated patients
- Reservoirs of infection hide virus from the immune system and ART
- Industry is now focused on developing drugs to eradicate or cure HIV infection
- **BIT225 is active against HIV in the monocyte-derived macrophage reservoirs**

**Reservoirs are last of the holy grail in HIV treatment**



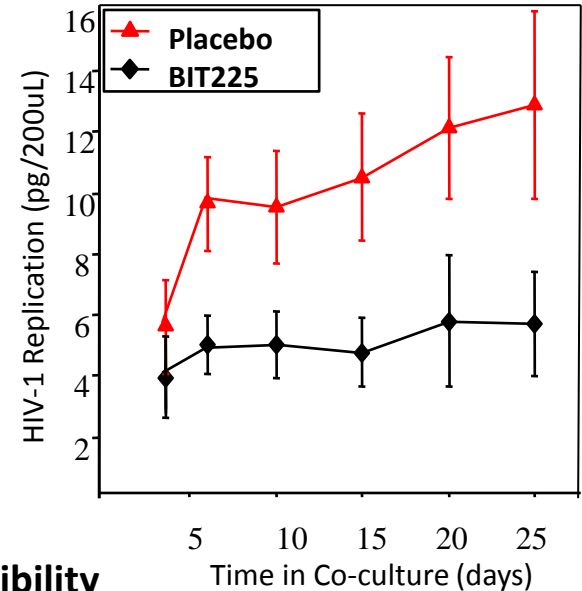
**+BIT225**



**Control**

# BIT225 – Proven Clinical Activity Against HIV

- **Phase 2a trial of BIT225 in HIV+ve's completed in late 2012**
  - Randomised, placebo controlled, double-blind trial
  - 24 patients, HIV+, treatment-naïve
  - 10 days dosing with BIT225 (monotherapy)
- **Results demonstrated that:**
  1. **BIT225 significantly reduces HIV levels in the macrophage (reservoir) cells in HIV-infected subjects**
  1. **BIT225 can cross the blood-brain barrier, opening up the possibility of treatment of AIDS-related dementia**



**Results support a potential role for BIT225 in cure/eradication strategies**

# BIT225 – Multiple Market Opportunities

- **Hepatitis C**

- Potential for future combination cocktails with polymerase and protease inhibitors
  - Unique mode of action
  - Good drug-drug interaction profile
  - Limited alternative classes for combinations (prevention of resistance)
  - Potential to fill gaps left by other DAA classes
- Add-on to IFN/RBV treatment ex-USA

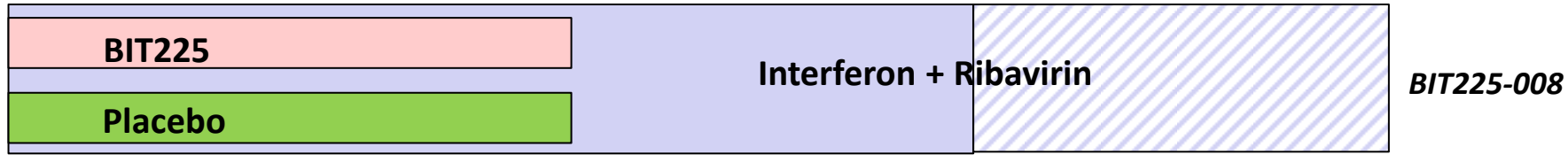
- **HIV/HCV**

- Part of combination cocktail with either IFN/RBV and/or other new DAAs

- **HIV**

- Add-on to anti-retroviral treatment to clean out underlying reservoirs
- Part of future eradication or cure strategies

# BIT225 - HCV Phase 2 Three-Month Dosing Trial



- Randomised, placebo-controlled, double-blind trial
  - Treatment naïve, HCV gen 1 and 3
  - 3 months dosing with BIT225 in combination with IFN/RBV
  - Using new capsule formulation
  - Scheduled to commence Oct '13
- (end for Gen 3)      (end for Gen 1)

## AIMS:

- Demonstrate safety of BIT225 with 3 months dosing
- Extend efficacy data to HCV gen 3
- Set BIT225 up for partnering with other DAA classes





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