

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

**Annual General Meeting**  
**19 November 2020**



***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.



# Key Achievements 2019/2020 FY

- Reported positive results from the Phase 2 HIV-1 clinical trial of BIT225
  - Presented key data on BIT225 at two international meetings
  - Publication of data in peer-reviewed, prestigious international journal
  - Filed new patent applications based on Phase 2 data
- Set up world-class Advisory Board of international HIV-1 experts
- Appointed US-based Chief Medical Officer
- Completed 6-month toxicology studies of BIT225 to support long-term dosing in human trials



# Key Achievements 2019/2020 FY (cont)

- Expanded antiviral screening program to include SARS-CoV-2, the causative agent of COVID-19
  - Identified a series of Biotron compounds with *in vitro* activity against SARS-CoV-2
- Continued to make good progress with promising Hepatitis B Virus (HBV) program
- Raised \$5.8 million in Dec 2019 from exercise of BITOB options
- Focus on commercialisation activities and setting up technology for Phase 3 and beyond



# Coronavirus

- Biotron's core expertise is designing drugs to target key viral proteins called viroporins that are found on a range of different viruses
  - Biotron has had a long-standing interest in Coronaviruses (CoVs) since SARS-1 outbreak
  - Biotron researchers were first to identify and report on this protein (E protein) on coronaviruses (Refer Wilson et al, Virology 330 (2004):322-31)
  - Designed compounds targeting E protein of SARS-1 and other human and animal coronaviruses (Refer Wilson et al, Virology, 353 (2006):294-306)
  - Validated coronavirus E protein as a target for antiviral drugs (Refer Wilson et al, Adv Exp Med Biol. 581 (2006):573-8)



# SARS-CoV-2

- Reinstated and expanded Biotron's coronavirus program to cover SARS-CoV-2 in response to the COVID-19 pandemic
- Since the COVID-19 outbreak Biotron has been screening its compounds for activity against SARS-CoV-2
  - Identified several that inhibit growth of SARS-CoV-2 (Refer BIT ASX announcement 7/9/2020)
- Currently expanding its SARS-CoV-2 screening, with aim of identifying compound(s) that may be progressed to the clinic



# HIV-1 Eradication

## Why is HIV-1 eradication necessary?

- Current antiretroviral drugs (ART) do not eradicate the virus
- Long-term health implications eg. HAND, immune activation, increase in malignancies and chronic diseases, drug-drug interactions
  - Major burden on healthcare systems

**Significant increase in Comorbidities in ART-treated HIV-positive  
Compared to HIV-negative leading to:**

- Early onset CV disease
- Metabolic diseases
- Liver and kidney disease
- Cognitive impairment
- Increased frequency of cancer
- Frailty (incl. bone density)
- Excess healthcare burden / costs



# HIV Treatment Gaps

## What has been achieved

- Durable and potent antiretroviral therapy (ART)
- Viral suppression possible through continuous, lifelong ART
- Profound reductions in mortality, morbidity and transmission have occurred
- Global economic stability noted

## Where gaps remain

- **ART is not curative, latent viral reservoirs remain and reactivate**
- **Immune reconstitution is only partial and accompanied by a state of chronic inflammation**
- **A significant excess of chronic diseases, malignancy and neurocognitive deficits result in individual and societal burdens**
- **Global treatment costs are not remotely sustainable**





# BIT225 and HIV-1

- Untreated HIV is associated with extreme levels of inflammation and immune activation
  - ART helps, but does not return inflammation and activation levels to normal
- With modern ART, the next challenge is less about killing the virus, and more about the immune response
- **BIT225 combines direct antiviral activity with immune modulation**

*This is a unique mechanism of action*



# BIT225 and HIV-1 – Positioning Potential

- A safe and effective agent that in conjunction with ART reduces inflammation and leads to fewer HIV comorbidities, improved health and lessened healthcare costs
- A safe and effective agent that in conjunction with ART leads to increased immune system recognition and eradication of HIV



# Hepatitis B Virus

- ~300 million worldwide chronically infected with HBV
- Increased risk of significant liver disease, including liver failure and cancer
- HBV causes up to 80% of liver cancers
  - 5 year survival of 15%
- >780,000 die every year
- as a consequence of HBV infection
- ***Current treatments suppress virus replication but do not deliver a cure***
- Cure will likely require attacking multiple targets of the HBV lifecycle
  - Aggressive suppression of replication
  - Inhibition of formation as well as elimination of cccDNA
  - Boost host immune response to chronic infection



# Biotron HBV Program

- Biotron has a portfolio of novel small molecule compounds with good activity against HBV
- **Extensive package of preclinical *in vitro* data includes evidence of reduction in cccDNA, HBsAg, and other relevant HBV markers**
- **Biotron compounds have a unique mechanism of action with implications for HBV cure**
- A lead series of compounds has been identified and a lead for animal studies is expected to be selected in early 2020



# Outlook for 2020/2021 FY

- HIV-1 program is the prime focus
  - Conferring with KOLs/advisory group to map out details of BIT225-010 trial
  - Progressing discussions with potential partners
- Continuing screening to identify lead anti-SARS-CoV-2 compound(s) to progress to next stage of development
- Hepatitis B (HBV) remains a promising and important early stage program. Additional resources are being committed to progress this to partner-ready status
- **Multiple partnering opportunities across Biotron's portfolio**



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