

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

**Investor Update**  
November 2022



# 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 Overview

- Clinical stage company with portfolio of small molecule drugs targeting viral diseases with major health problems:
  - HIV-1 , COVID-19, Hepatitis B virus and others
- **Unique approach to tackling virus infections**
  - **New class of anti-viral drugs that work in two ways:**
    - **Stop replication of the virus**
    - **Inhibit the damaging inflammatory response that the virus initiates**
- Experienced Board and management team with pharma, financial and VC backgrounds
- Headquartered in Sydney, Australia



# Key Achievements in 2022

- Completed enrolment of two Phase 2 HIV-1 clinical trials that build on positive results in previous clinical studies
  - Results expected mid-2023
  - These studies are key to positioning of BIT225 for partnering
- Demonstrated that BIT225 stops replication of SARS-CoV-2 and prevents development of COVID-19 disease in an industry-recognised animal model
- Commenced a human COVID-19 trial as a sub-study in one of the current HIV-1 Phase 2 clinical trials
- Extended Biotron's patent portfolio to cover this new therapeutic indication
- Announced a renounceable rights issue to raise up to \$4.2 million before costs in October 2022



# HIV-1 Clinical Program Update

- Two Phase 2 HIV-1 clinical trials currently in progress at sites in Sydney, Australia (Holdsworth House, East Sydney Doctors and St Vincent's Hospital, Darlinghurst) and in Thailand (Bangkok and Chiang Mai)
  - Both trials are fully recruited
  - Results expected mid-2023
    - These trials build on nine previous clinical trials of BIT225 that established its safety and potential benefits in patients with HIV-1 and Hepatitis C virus infections.
    - Generating data on specific health-related outcomes that will be key to future regulatory filings
      - Assessing key biomarkers (immunological and virological) consistent with accepted clinical and commercial applications
    - Completion of these Phase 2 clinical trials in mid-2023 will be significant near-term milestones
    - These studies are key to positioning of BIT225 for partnering



# HIV-1 Market Opportunity

- In 2021, despite availability of antiretroviral drugs (ART) -
  - Over 38.4 million people globally were living with HIV
  - 1.5 million newly infected with the virus
  - An estimated 650,000 people died from AIDS-related illnesses.
  - The global HIV drug market in 2021 was estimated to be US\$30 billion.
  - The increased prevalence of HIV-1 infections, percentage of patients on treatment due to improved disease awareness and the need for treatments to improve quality of life are expected to drive market growth to over US\$50 billion by 2030.
- An estimated one third of the ART-treated HIV-infected population achieves only partial immune reconstitution
  - This population is at increased risk of clinical progression to AIDS and other morbidities and mortality
  - BIT225 has particular potential benefit in this group.



# SARS-CoV-2/COVID-19 Program Update

- BIT225 has demonstrated ability to prevent COVID-19, reduce virus and stop the cytokine storm in a relevant, robust, industry-recognised animal model of disease\*
- A human COVID-19 study is in progress as a sub-study in Thailand in one of the current HIV-1 Phase 2 clinical trials
- Sites have been identified and documentation is in progress for a new Phase 2 COVID-19 clinical trial
  - Trial design is based on guidance received from the USA Food and Drug Administration (FDA) earlier in 2022
  - Subject to funding as well as regulatory and ethics approval the trial is anticipated to commence in late 2022, with results available in mid-2023

*\*See BIT announcements of 25 Nov 21, 17 Mar 22, 2 May 22*



# Ongoing Need for SARS-CoV-2/COVID-19 Anti-Viral Drugs

- Vaccines remain central to control of the pandemic but there is an unmet need for effective drugs to treat COVID
  - Uncertain global pandemic outlook
  - On-going risk of emergence of new SARS-CoV-2 variants
  - At risk populations e.g. immunodeficient patients, transplant recipients, oncology patients, elderly (defined at >65 years), chronic health conditions e.g. diabetes, cardiovascular disease, obesity, chronic lung disease, etc remain vulnerable
- Biotron has had an interest in coronaviruses since SARS-1
  - First to demonstrate that the coronavirus E protein is a druggable target
- Similar to HIV, BIT225 works by both inhibiting virus replication AND stopping the inflammatory response leading to severe COVID



# BIT225 Opportunity Summary

- BIT225 is a very important clinical asset for Biotron
  - Previous positive clinical trial data have significantly de-risked the program
  - Clear clinical development program designed to demonstrate to regulators and pharma how the drug may be used to improve health outcomes in combination with ART
  - Results from two Phase 2 trials, due in mid-2023, will be significant near-term milestones
  - SARS-CoV-2/COVID-19 program provides further value for BIT225
  - A proposed Phase 2 COVID-19 clinical trial is expected to be completed in mid-2023 (Subject to funding)
  - Positive data from these trials across two different disease indications will put the Company in a strong position as it moves to partner the programs in the second half of 2023

# Outlook for 2023

- 2023 will be an important year for this Company
  - Results of three Phase 2 clinical trials expected in mid-2023
    - Two Phase 2 HIV-1 clinical trials
      - Includes the COVID-19 sub-study that is in progress
    - New Phase 2 COVID clinical trial (subject to funding)
  - These will be key value-adding milestones
  - Focus will be on partnering with the results in hand
- Hepatitis B virus (HBV) remains an important early-stage program for the Company, and activities to progress a lead compound to be clinic-ready will be accelerated in the first half of 2023 (subject to funding)
- Portfolio will be further de-risked by bringing through next-generation drugs for HIV-1 and COVID through to clinic-ready status (subject to funding)



# Financial Information

## Key Financial Metrics

Ticker Code	ASX: BIT
Share Price (10/11/2022)	A \$0.035
Market Cap	A \$25 million
12 Month Trading Range	A \$0.033 – 0.111
Cash Position (09/2022)	A \$0.68 million + Anticipate receipt of R&D Tax refund of ~\$1.4 m before end 2022

## Board

Michael Hoy	Non-executive Chairman
Michelle Miller	Managing Director
Stephen Locarnini	Non-executive Director
Susan Pond	Non-executive Director
Robert Thomas	Non-executive Director



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