

16 November 2022

The Manager Companies  
ASX Limited  
20 Bridge Street  
SYDNEY NSW 2000

(13 pages by email)

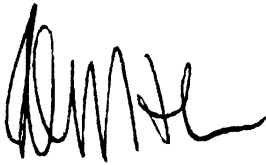
Dear Madam,

**PRESENTATION TO ANNUAL GENERAL MEETING**

I attach a Chairman's Address and a PowerPoint presentation to be delivered at today's Annual General Meeting which is convened to be held at 11.00 am.

This announcement has been approved by the Company's Managing Director.

Yours faithfully



Peter J. Nightingale  
Company Secretary

pjn11456

16 November 2022

## CHAIRMAN'S ADDRESS TO THE AGM

My Fellow Shareholders

After an enforced three year absence it is a pleasure to return to a face to face meeting with shareholders.

It is more than ironic that a company focused on antiviral solutions finds itself so severely buffeted by a pandemic for which we have the temerity to suggest we may have a future medical solution.

To understate the case considerably, conducting clinical trials during COVID has been enormously challenging. Only the extraordinary effort by Biotron management, staff, consultants and trial associates has ensured that the Company not only survived but emerged in a hearteningly strong position.

We did not escape entirely unscathed. Our programs suffered a six month delay which, considering the forces amassed against us, was a remarkably good outcome. That delay is the reason we have again turned to you, our shareholders, for assistance in the current capital raising round.

Before the end of the current financial year, the Company expects to deliver results from three Phase 2 clinical trials. Two trials target HIV and, subject to funding availability, one trial will target COVID. Additionally, the Company hopes to produce results from a further COVID clinical sub-study.

In any normal year, one such trial is an onerous undertaking.

While we have high hopes for successful COVID trial outcomes, HIV remains the Company's primary objective. The current HIV trials are pivotal to Biotron's near term commercialisation aspirations.

These trials were specifically designed and undertaken to address questions from potential partners on how our lead compound, BIT 225, could fit into the HIV landscape. The anticipated data is key to providing necessary answers.

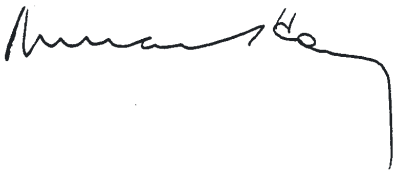
Full details of these undertakings will be discussed during the Managing Director's presentation.

We also remain unwavering in our belief that the Company's Hepatitis B program has the potential to achieve longer term success in an arena which has substantial unmet need.

Biotron is a small Australian biotechnology company with international ambitions. The markets we expect to enter are huge. This drives our conservative, step-wise strategy. The science at the core of the Company's endeavours is unquestionably sound. Our results to date speak for themselves. Nine successful clinical trials soothe natural anxieties about anticipated outcomes during the next immediate period.

The data to be generated in the next six months is the result of many years of hard work and substantial investment. We approach it with confidence and more than a little sense of excitement.

Sincerely

A handwritten signature in black ink, appearing to read "Michael J. Hoy". The signature is fluid and cursive, with a long horizontal stroke that ends in a vertical line extending downwards.

Michael J. Hoy  
Chairman

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

**Annual General Meeting**  
16 November 2022



*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 in 2021/2022 FY

- 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)



# BIOTRON LIMITED (ASX:BIT)

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