

Level 2, 66 Hunter Street  
Sydney NSW 2000  
Tel: (61-2) 9300 3344  
Fax: (61-2) 9221 6333  
E-mail: [pnightingale@biotron.com.au](mailto:pnightingale@biotron.com.au)  
Website: [www.biotron.com.au](http://www.biotron.com.au)

24 October 2023

The Manager Companies  
ASX Limited  
20 Bridge Street  
Sydney NSW 2000

(14 pages by email)

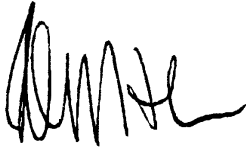
Dear Madam

**PRESENTATION TO INVESTORS**

I attach a PowerPoint presentation, which is being presented by Biotron Limited's Managing Director, Dr Michelle Miller, to investors.

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

Yours sincerely



Peter J. Nightingale  
Company Secretary

pjn11911

**Enquiries**

Dr Michelle Miller  
Managing Director  
Biotron Limited  
+61-(0)412313329

Rudi Michelson  
Monsoon Communications  
+61-3 9620 3333

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

October 2023



# 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.



# Industry-leading experts focused on transformative treatments for viral diseases

- Experienced Board and management team with pharma, financial and VC backgrounds
- Clinical stage company with portfolio of small molecule drugs targeting viral diseases with major health problems and large international markets

## **SARS-CoV-2/COVID-19**

Global market for COVID-19 therapeutics was valued at US\$14.6 billion in 2022

## **HIV-1**

The HIV-1 global drug market was estimated as US\$30 billion in 2022

## **Hepatitis B Virus (HBV)**

Global market for HBV therapeutics was valued at US\$4.6 billion in 2022



# Near-term value creation milestones anticipated in late 2023

- **The headline results from three human Phase 2 clinical trials are expected in coming weeks**
  - Two HIV-1 Phase 2 trials and a SARS-CoV-2/COVID-19 Phase 2 trial
  - All three trials have been completed i.e. all patients have been recruited and completed dosing with drug
- Clinical trials are the key currency of the biotech/pharma industry
  - Successful results significantly de-risk the asset
    - Demonstrate to potential partners and regulatory agencies that the drug is safe and effective
- Phase 2 is the ideal stage for partnering to multinational pharmaceutical companies



# Financial Information

## Key Financial Metrics

Ticker Code	ASX: BIT
Share Price (19/10/2023)	A \$0.088
Market Cap	A \$77 million
12 Month Trading Range	A \$0.024 – 0.115
BITOC 25/11/24 \$0.06 listed options	A \$0.055 (19 Oct)
Cash Position (06/2023)	A \$3.98 million
Top 20 shareholders	18.87%

## 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



# Portfolio of Clinical and Preclinical Assets

INDICATION	COMPOUND	RESEARCH		DEVELOPMENT		
		DISCOVERY/LEAD OPTIMISATION	IND ENABLING/ PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
HIV-1	BIT225					
HIV-1	Next generation					
COVID-19	BIT225					
COVID-19	Next generation					
HBV	Lead Optimisation					
Dengue, Influenza, and others	Leads					

*\* Headline results expected late 2023*

# Recent Milestones & Achievements

- Completed enrolment of two Phase 2 HIV-1 clinical trials that build on positive results in previous clinical studies
- Completed enrolment of Phase 2 COVID-19 clinical trial
  - Based on demonstration that BIT225 prevents development of COVID-19 disease in an industry-recognised animal model of COVID disease
- Headline results for all three trials expected late 2023
  - These studies are key to positioning of BIT225 for partnering
- Raised \$6 million in via rights issue and top-up placement in October 2022





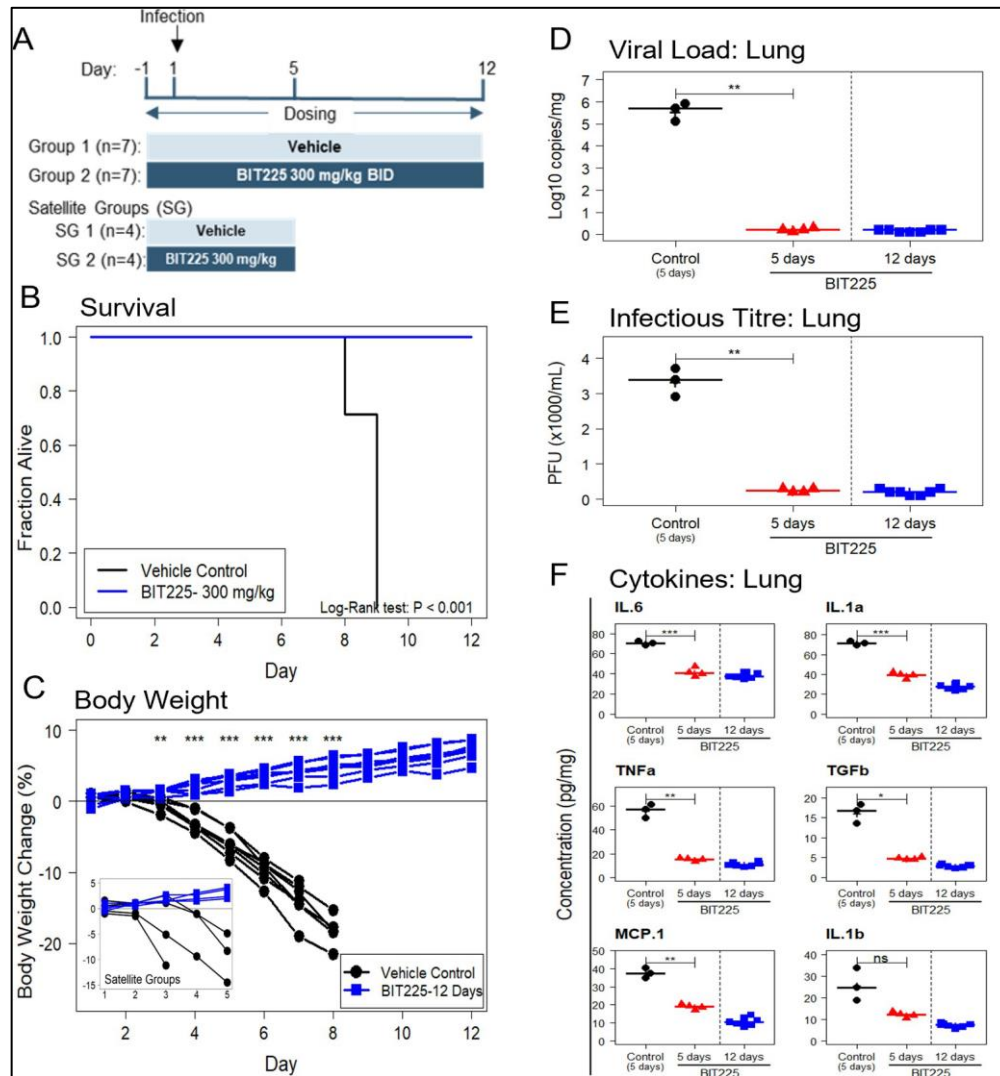
# COVID-19 Clinical Program

## WHY COVID?

- **Some vulnerable populations remain at risk**
- **Current drugs have limitations due to dosing, interactions with other meds, etc**
- **Long COVID is a growing issue. At least 65 million people are estimated to have long COVID**
- **Need to remain ahead of any emerging new variants**
- **Strong international focus on ensuring preparedness for future pandemics**

- In 2022 Biotron's lead antiviral drug BIT225 was shown to:
  - Prevent COVID-19,
  - Reduce virus levels, and
  - Stop the cytokine storm in a relevant, robust, industry-recognised animal model of disease\*
- As BIT225 had been tested in humans for other viral diseases it could move quickly into clinical testing
- Following receipt of guidance from the USA Food and Drug Administration (FDA) a Phase 2 trial was designed and initiated
- Trial started in May 2023 and finished recruitment in August 2023
- Post-trial laboratory and other analyses currently in progress
- Headline results expected in late 2023

# BIT225 Prevents COVID-19 in Animal Model of Disease



## Twelve-day treatment of SARS-CoV-2 infected K18-hACE2 mice with BIT225.

(A) Dosing Scheme.

(B) Kaplan-Meier plot: vehicle control (black line, n = 7, 0% survival); BIT225 12-day treatment group (blue line, n = 7, 100% survival).

(C) Body weight changes in individual animals. Inset: Satellite groups dosed for 5 days for viral load and inflammation analyses.

(D) Day 5 and Day 12 analysis of lung viral load by qRT-PCR.

(E) Day 5 and Day 12 analysis of lung virus titre by plaque assay. Vehicle control (black circles) and 5-day BIT225 (red triangles) treatment data are from the satellite group. 12-day data (blue squares) are from the surviving animals in the 12-day treatment group.

(F) Day 5 and Day 12 analysis of cytokines or chemokines in the lung. Symbols represent data for individual mice. Horizontal lines and “+” indicate the group median and mean, respectively. Welch’s T-tests were used to compare the group means and P-values are indicated as: ns— $P > 0.05$ ; \* $P < 0.05$ ; \*\*  $P < 0.01$ ; \*\*\*  $P < 0.001$ .

**Citation:** Ewart G, Bobardt M, Bentzen BH, Yan Y, Thomson A, Klumpp K, et al. (2023) Post-infection treatment with the E protein inhibitor BIT225 reduces disease severity and increases survival of K18-hACE2 transgenic mice infected with a lethal dose of SARS-CoV-2. *PLoS Pathog* 19(8): e1011328.

<https://doi.org/10.1371/journal.ppat.1011328>

# HIV-1 Clinical Program

## Why HIV-1?

- **Despite antiretroviral drugs (ART) over 38.4 million people globally are living with HIV**
- **1.5 million new infections each year**
- **~650,000 people die each year from AIDS-related illnesses**
- **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 demonstrated its ability to generate beneficial immunomodulatory changes on top of ART in previous clinical trial**

- Two Phase 2 HIV-1 clinical trials recently completed at sites in Sydney, Australia (Holdsworth House, East Sydney Doctors and St Vincent's Hospital, Darlinghurst) and in Thailand (Bangkok and Chiang Mai)
- Results expected late 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.
- These trials are designed to 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
- These two Phase 2 clinical trials have potential to provide significant near-term shareholder value
- These studies are key to positioning of BIT225 for partnering



# Unlocking value for other viral targets

- Post pandemic there is an international focus on preparedness for future viral outbreaks
- Small molecule drugs are essential to beating the next pandemic
- The threat of emerging pandemics is real, especially for coronavirus and other high-risk respiratory viral families
- Biotron has been developing a broad range of small molecule therapeutics to treat a range of viral diseases
  - Platform to design drugs that work against a key part of viruses that are involved in controlling how they avoid the body's immune defenses
- **BIT225 has demonstrated the robustness of Biotron's approach**
- The Company has compounds with activity against other key viruses; secondary screening is in progress; aim to identifying candidates to progress into IND-enabling studies and clinical trials



# 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
  - SARS-CoV-2/COVID-19 program provides further value for BIT225 with results from the completed Phase 2 COVID-10 clinical trial expected shortly
  - Results from three Phase 2 trials will be significant near-term milestones
  - 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 2024
- Pipeline of earlier stage, high value programs provide a solid base and potential future value for the Company



# BIOTRON LIMITED (ASX:BIT)

Michelle Miller  
Managing Director  
[mmiller@biotron.com.au](mailto:mmiller@biotron.com.au)  
[www.biotron.com.au](http://www.biotron.com.au)  
[+61 412313329](tel:+61412313329)



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