



# FirebrickPharma

INVESTOR PRESENTATION  
11 MARCH 2022

EUROZ HARTLEYS ROTTNEST ISLAND INSTITUTIONAL CONFERENCE

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# FIREBRICK IPO STORY

## Australian Pharmaceutical Innovator Focused on Infectious Disease

### Breakthrough Product: Nasodine

- \* Kills<sup>1</sup> the viruses that cause colds
- \* First-in-class nasal spray medicine that targets the viral cause of the common cold
- \* Acts in the nose, where colds start

### Same active as BETADINE® products<sup>2</sup>

- \* Povidone-iodine (PVP-I) widely used as a gargle, now in a nasal spray, **Nasodine® Nasal Spray**
- \* Patent protected to 2034/2035 as a treatment or preventative for common cold

### Pandemic Potential

- \* Kills SARS-CoV-2 *in vitro*
- \* Phase 2 COVID-19 clinical trial in 2022
- \* US Patent granted for use in COVID-19



### Late-stage Biopharma story

- \* Nasodine completed Phase 1-3 trials
- \* Second Phase 3 trial in 2022
- \* Manufacturing ready
- \* Potential near-term regulatory approval

### Large Addressable Market

- \* Global potential
- \* Billions of colds each year worldwide
- \* Potential for broad market adoption

### Proven Successful Team

- \* Firebrick founder launched Betadine® Gargle<sup>2</sup>
- \* Track record of success on ASX
- \* Experienced management and board

<sup>1</sup> For viruses, the term “kill” indicates elimination of viral infectivity. In *in vitro* studies, Nasodine has been shown to eliminate the infectivity of representative strains of all viruses known to cause respiratory infections, such as the common cold.

<sup>2</sup> Betadine® is a registered trademark of Mundipharma AG and in Australia is now licensed to Sanofi Aventis. There is no association between Firebrick, Mundipharma, Sanofi Aventis or the Betadine brand. Povidone-iodine is widely available and can be supplied and used without license from Mundipharma or any other party.

# IPO PERFORMANCE

## Listed on ASX as 'FRE' on 28 January 2022

### Extensive media coverage



28 Jan 2022

**Firebrick launch on ASX receives national media attention**

### High performance in bear market

- \* IPO: \$0.20 x 169m shares = \$34m m/cap
- \* 52 million shares traded in first 5 days
- \* 5-day VWAP to 8 March = \$0.43  
still up >100% on IPO price; m/cap ~ \$70m
- \* Shareholders increased from 400 -> 4,600



### The Firebrick appeal

- \* Many early investors were Australian doctors who believe in the product concept
- \* Technology story is easy to comprehend: *kills viruses in the nose to treat colds*
- \* Unprecedented public awareness of the role of viruses in respiratory illness
- \* The common cold is a huge global market – first nasal spray medicine targeting viral cause
- \* Perceived low risk Phase 3 trial with potential for near-term approval
- \* Upside of potential COVID-19 use and role in future pandemics
- \* Management calibre & track record on ASX
- \* Support of Euroz Hartleys – sole Lead Manager



# NASODINE® NASAL SPRAY

- \* **Australian breakthrough** that could be the world's first approved nasal medicine that actually **targets the viral cause** of colds
- \* **Contains povidone-iodine (PVP-I) 0.5%**
  - In a proprietary formulation, safe for use on nasal tissue<sup>1</sup>
- \* **Kills<sup>2</sup> all respiratory viruses**
  - PVP-I releases free iodine that kills all respiratory viruses
  - Virucidal – leads to permanent loss of viral infectivity
  - Non-selective – viral resistance has not been reported to PVP-I
- \* **Strong patent position; granted patents in the U.S, EU, AU + others**
  - Protect use of intranasal PVP-I as treatment/preventative for common cold (2034/35) and use in pandemic viral diseases (2040)
- \* **Nasodine® Nasal Spray (“Nasodine”) is not yet approved for sale**
  - 2<sup>nd</sup> Phase 3 trial planned for 2022 prior to re-submission to TGA
  - Potential for approval in 2022 if Section 60 appeal succeeds

<sup>1</sup> At low concentrations (e.g., 0.5%) and in an appropriate formulation

<sup>2</sup> For viruses, the term “kill” indicates elimination of viral infectivity. In *in vitro* studies, Nasodine has been shown to eliminate the infectivity of representative strains of all viruses known to cause respiratory infections, such as the common cold.

# Nasodine's Initial Indication: The COMMON COLD in adults

## \* Large addressable market

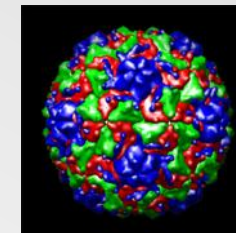
- 2.5 billion colds annually in US and Europe<sup>1</sup> (60 million in AU)
- High economic cost in lost productivity, doctor visits and medications<sup>1</sup>
- COVID has elevated viral infectious disease as a therapeutic priority

## \* Colds are caused by viruses

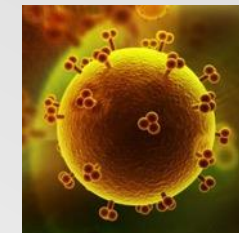
- The viral infection starts in the nose
- It's a superficial infection of the nasal cells, despite the systemic symptoms

## \* Colds are very difficult to treat

- Antibiotics don't work against viruses
- Colds can be caused by up to 200 different viruses<sup>1</sup>
- Needs a broad-spectrum solution – like Nasodine® Nasal Spray



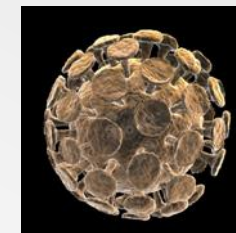
Rhinovirus



Respiratory Syncytial



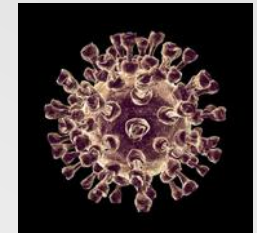
Metapneumovirus



Coronavirus



Influenza virus



Parainfluenza virus

MAJOR VIRUS FAMILIES THAT CAUSE COLDS

<sup>1</sup> IQVIA Industry and Market Overview report 2021

# THE NASODINE® BREAKTHROUGH

A cold begins when a virus infects the cells lining the nasal passages



Nasodine® Nasal Spray disperses through the nasal passages to target the viruses that cause the infection



EXISTING COLD TREATMENTS TARGET SYMPTOM RELIEF ONLY

NASODINE NASAL SPRAY TARGETS THE VIRAL CAUSE OF COLDS

- \* Temporary relief of symptoms
  - Sore throat
  - Runny nose
  - Cough
  - Allow the sufferer to “soldier on”
- \* No impact on the viral cause of colds

- \* Nasodine (if approved) will be the world’s first approved nasal spray medicine that kills the viruses that cause colds
- \* 1<sup>st</sup> Phase 3 trial showed that Nasodine reduces overall cold severity (in key subsets) and impact of colds on daily activities in all subjects.



# COMMON COLD MARKET OPPORTUNITY

## THE PRODUCT

- \* Dosage for common cold treatment is:  
3 sprays per nostril, 4 times daily for 5 days
- \* Each 25ml bottle contains 30 doses  
(20 doses needed for each cold)
- \* Expected retail price is **AU\$24**<sup>1</sup>  
(once approved) sold in **pharmacies only**
- \* **Market research** suggests strong support  
for Nasodine from GPs and pharmacists<sup>2</sup>
- \* **Nasodine is a consumer product** that may  
be used regularly by everyday Australians  
(potential shareholders in FRE)



## THE OPPORTUNITY

**US\$40 billion economic  
cost of colds in U.S. alone**

**60 million adult colds  
in Australia per year**

**2.5 billion colds in U.S.  
& Europe per year<sup>3</sup>**



<sup>1</sup> Estimated retail pricing, subject to change

<sup>2</sup> IQVIA 2021 survey of 200 Australian GPs and 200 Australian pharmacists

<sup>3</sup> IQVIA Industry and Market Overview report 2021

# MANUFACTURING READY, PARTNERSHIP AGREEMENTS IN PLACE

## AUSTRALIA

- \* Firebrick to market all its products **directly in Australia**
- \* Management has experience in building sales and marketing organisations, and in launching and marketing OTC products in Australia
- \* **Manufacturing ready:** All packaging, formulation and process development completed. Exclusive manufacturing and supply agreement with Probiotec (ASX: PBP) in Laverton North VIC

## GLOBAL

- \* Outside Australia, licensed distributors to be used. **Agreements already in place** in Philippines, New Zealand and Sub-Saharan Africa, where Firebrick is to receive a royalty on sales
- \* Partnerships in Europe and US likely to be pursued once Phase 3 trial completed
- \* Management has experience in international licensing and distribution, and board with US/global reach

# PATHWAY TO APPROVAL

- \* Initial registration dossier submitted to TGA in 2020:
  - Nasodine met all manufacturing, quality and safety hurdles
  - But TGA decided that clinical efficacy was not satisfactorily established by the first Phase 3 trial, because the positive result on the selected primary endpoint (nasal symptoms) was not statistically significant
- \* However, Nasodine did have a significant positive impact on quality-of-life (impact of the cold on daily life) in all subjects, and overall cold severity in key subsets:
  - Those with stronger cold symptoms
  - Those with confirmed viral infections
  - Those who started treatment early (<24 hours after 1<sup>st</sup> symptoms)
- \* Firebrick believes the trial results do support approval and is currently appealing the initial decision by TGA; if successful (result by end July 2022), Nasodine could be approved in 2022
- \* In parallel, Firebrick will conduct a second Phase 3 trial during 2022 to support approval in Australia (if the appeal is unsuccessful)
- \* Trial results also expected to be needed for registration filings in Europe and U.S. (input to trial design received from EMA and FDA)
- \* Trial expected to begin **before May 2022**; **headline results expected in Q4 CY2022**



KEY FEATURES	2022 PHASE 3 TRIAL
Primary endpoint	Overall cold severity ( <u>GSS</u> ) (validated endpoint of WURSS-21)
Population for primary endpoint assessment	People with confirmed <u>viral colds</u> (based on nasal swabs and PCR)
Inclusion criteria (differences)	Early symptoms only (< <u>36 hours</u> after onset)
	People with <u>stronger symptoms</u>
Trial design	Randomised, controlled, confirmatory Phase 3 trial in 196 adults with viral colds

# FUTURE OPPORTUNITIES



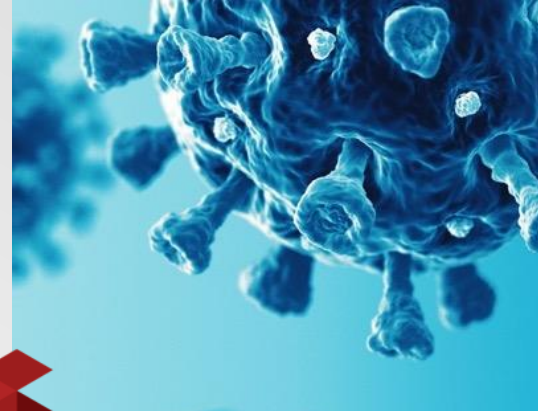
## COMMON COLD PREVENTION

- \* Subject to further clinical trials Nasodine could be approved for prevention of colds



## REDUCING HOSPITAL INFECTION RISK BY PPB

- \* Nasodine could be used in hospitals to decolonize the nasal passages of staff and patients
- \* Goal: eliminate MRSA and other bacteria to reduce surgical site infection risk



## COVID-19 & FUTURE PANDEMICS

- \* Nasodine is effective *in vitro* against SARS-CoV-2 and reduced viral shedding in pilot human study for up to one hour post-dose
- \* COVID-19 Phase 2 trial to start in 2022



## PRODUCT DEVELOPMENT

- \* Several new products in development beyond Nasodine Nasal Spray

# COVID-19 PHASE 2 CLINICAL TRIAL

- \* Randomised controlled Phase 2 trial in South Africa of Nasodine in COVID-19 patients
- \* Subjects: 144 adults who will be confirmed to be actively shedding SARS-CoV-2
- \* Goal: Demonstrate that frequent doses of Nasodine significantly reduces nasal shedding
- \* SAHPRA and HREC approvals in place; patient recruitment to start soon with results expected in Q3 CY22
- \* If Nasodine reduces or eliminates viral shedding, it could potentially reduce the risk of transmission and/or reduce isolation period for those with COVID-19
- \* Results may point to role of Nasodine in future pandemics, with potential for pandemic stockpiling as first line of defence



## STUDY ENDPOINT

Nasodine application 8 times daily (every 2 hours) for 2.5 days significantly reduces nasal shedding of SARS-CoV-2 [compared with placebo nasal spray]



## OTHER OBJECTIVES

- Reduces the number of days to a negative RAT
- Accelerates clearance of SARS-CoV-2 from nose and throat
- Beneficial impact on symptoms of COVID-19

# OUTSTANDING BOARD WITH GLOBAL REACH AND EXPERIENCE



Microbiologist & biochemist who built the Betadine OTC franchise, launched Betadine® Sore Throat Gargle.

General Manager Faulding Medical Products; President Faulding (USA) Inc.; Managing Director Pharmacia Australia; Vice President Strategic Marketing Pharmacia (USA).

Launched 23 products, executed 40 international licensing/distribution deals.

CEO of two leading ASX biotechs:

- Biota (BTA) 2002-05; m/cap grew from \$30m to \$300m;
- Race Oncology (RAC) 2016-20; listed at \$11m, currently ~\$400m

PhD in business: Investor performance in the Australian biotech sector



PhD chemist, co-founder and co-inventor on Firebrick patents. Developer of Nasodine formula.

Previously, was Chief Operating Officer of Viralytics (later acquired in 2018 for \$500 million by Merck), Director of Pharmaceutical Development at Vapotronics, Director of Development at AGEN Biomedical.

Hands-on experience in all phases of development and manufacturing of pharmaceuticals.



Phyllis Gardner MD is Professor of Medicine at Stanford University and on the Board of Fellows of Harvard Medical School.

Obtained her MD from Harvard Medical School, trained in internal medicine at Mass. General Hospital and post-doc fellowships in Pharmacology at Columbia University and University College, London.

Former Head of Research at ALZA Corporation and Partner at leading US VC firm, Essex Woodlands.

Director on boards of multiple US public biotech firms.