

26 July 2022

ASX Announcement

Firebrick Presents at Healthcare Investor Conference

- **Firebrick presenting at Euroz Hartleys Healthcare Conference in Perth**
- **Conference to be attended by more than 20 institutional investors**

Firebrick Pharma Limited (ASX:FRE) (**Company** or **Firebrick**) is pleased to advise that the Executive Chairman, Dr Peter Molloy, will be presenting an investor update on the Company at the Euroz Hartleys Healthcare Conference, taking place on Wednesday, 27 July, in Perth.

The Conference is scheduled to include presentations from nine leading ASX-listed biotech firms and is expected to be attended by more than 20 institutional investors as well as individual biotech investors.

The Firebrick investor presentation has been attached and will also be available on the Company's website for review by all shareholders.

This announcement was authorised for release by Dr Peter Molloy, Executive Chairman, Firebrick Pharma Limited.

- ENDS -

About Firebrick Pharma

Firebrick is a pharmaceutical company founded in 2012 to develop and commercialise a nasal spray treatment for the common cold based around the potential of povidone-iodine as a broad-spectrum antimicrobial agent. The Company subsequently developed Nasodine® Nasal Spray ("Nasodine") and owns numerous granted and pending patents, including a core patent family that covers the use of Nasodine for the treatment and prevention of the common cold. The Company also owns a patent family that covers the use of Nasodine for the prevention of pandemic viral diseases, including COVID-19. Firebrick is currently undertaking two major clinical trials: A Phase 2 trial of Nasodine in COVID-19 and a Phase 3 trial for Nasodine, to confirm its efficacy as a treatment for the common cold and support international approvals.

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ASX: FRE

INVESTOR PRESENTATION

EUROZ HARTLEYS HEALTHCARE CONFERENCE 27 JULY 2022

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FIREBRICK PHARMA (ASX: FRE)

AUSTRALIAN PHARMACEUTICAL INNOVATOR WITH A BREAKTHROUGH TREATMENT FOR THE COMMON COLD

* Nasodine®: The nasal spray that kills viruses

- *Kills*¹ the viruses that cause the common cold
- First medicine that targets the viral cause of colds, where colds start – in the nose

* Same active as BETADINE® products²

- Povidone-iodine (PVP-I) widely/safely used as a throat gargle, for the first time in a nasal spray
- Patent protected by FRE as a treatment and preventative for common cold

* Potential for early approval and launch:

- Potential for early AU launch³
- Approvals in EU, US and other markets expected over the following 3-4 years
- Manufacturing ready, with local capacity to meet global demand



* Large addressable market

- Up to 20 billion colds p.a. worldwide
- Sales potential likely to be attractive to international distribution partners

* Potential for high market adoption

- Very high consumer stated intent to purchase as soon as it is available
- Australian doctors and pharmacists indicate they will recommend and support it

* Opportunities beyond the common cold

- Potential for expansion into hospital use, prevention and other indications
- Pandemic and biodefense potential
- Phase 2 COVID-19 clinical trial underway in South Africa

¹ “Kill” indicates permanent elimination of viral infectivity. In in vitro studies, Nasodine has been shown to eliminate the infectivity of representative strains of all viruses known to the common cold.

² Betadine® is a registered trademark of Mundipharma AG and is not associated with Firebrick Pharma. PVP-I is widely available and can be supplied and used without license from Mundipharma or other party

³ Subject to a successful outcome in planned appeal to Administrative Appeals Tribunal (AAT).

THE NASODINE® BREAKTHROUGH

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

EXISTING COLD TREATMENTS TARGET SYMPTOM RELIEF ONLY

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

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

NASODINE NASAL SPRAY TARGETS 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
- * 1st Phase 3 trial showed that Nasodine reduces overall cold severity (in key subsets) and impact of colds on daily activities in all subjects.



HOW NASODINE WORKS

The unique properties of povidone-iodine (PVP-I)

* PVP-I is a unique antimicrobial agent

- It kills all bacteria, fungi and viruses, most in <60 sec, yet is safe for human use
- Its is non-selective, so viral resistance is not a problem

* Safety

- Has been used safely as a throat gargle for >35 years
- In the right formulation, it is also safe to use in the nose

* Treatment of common cold is novel

- Prior to Nasodine, PVP-I had never been used as a treatment for the common cold
- The idea of turning it into a nasal spray treatment for the common cold was the rationale for the creation of Firebrick and the basis for the Company's core patent

A novel approach to treating the common cold

* The common cold is a local infection

- Despite the systemic symptoms, a cold is a superficial infection of the cells inside the nose
- Infected cells release thousands of virus particles into the nasal mucous to infect other cells & other people
- PVP-I rapidly kills all the viruses known to cause colds

* Nasodine attacks the viral load

- By frequently (4-times-daily) reducing the viral load in the nasal mucous, Nasodine can interrupt the infection cycle and reduce overall cold severity
- If used early in a cold, it could quickly bring a cold to heal
- It may also reduce the risk of transmission to others and the risk of secondary illnesses

CLINICAL PROOF OF CONCEPT

Nasodine Nasal Spray Phase 3 clinical trial

THE 2019 PHASE 3 CLINICAL TRIAL AND TGA FEEDBACK

What the 2019 Phase 3 trial showed us about Nasodine's efficacy

- * **Nasodine treats the whole cold**
 - Nasodine has its greatest impact on overall cold severity (GSS*) and 'quality of life' (how much a cold interferes with daily life, not just local symptoms (e.g. nasal symptoms))
- * **Nasodine works best if used early in a cold**
 - Best results were in those who started treatment in the first 24 hours after symptom onset
- * **Nasodine works better in those with stronger symptoms at start of treatment**
 - People with stronger symptoms experience a better reduction in overall severity
- * **Nasodine works better in those with genuine viral colds**

* GSS is the key outcome measure from the WURSS-21 common cold survey, a validated tool for measuring impact of an intervention in the common cold

TGA feedback on initial registration dossier (filed May 2020)

- * **Dosage**
 - Dosage is 3 sprays in each nostril (0.84mL), 4 times daily for 5 days to treat a cold
- * **Safety**
 - Nasodine is well-tolerated and meets TGA's requirements for safety in an OTC product
- * **Quality & Manufacturing**
 - Nasodine meets TGA's quality and manufacturing requirements; product is stable with a shelf life of 2 years
- * **Efficacy**
 - TGA is yet to be satisfied that Nasodine meets its efficacy requirements based on the 1st Phase 3 trial not meeting its primary endpoint; Firebrick is appealing TGA's decision while also conducting a second Phase 3 trial

2022 (2ND) PHASE 3 STUDY OF NASODINE AS A TREATMENT OF THE COMMON COLD

* Overview

- Repeat Phase 3 trial to confirm the efficacy of Nasodine Nasal Spray as a treatment for the common cold
- Trial commenced on 3 May 2022 with first patient recruited at the Adelaide site; four other sites now also recruiting
- Target: 196 subjects with confirmed viral colds
- Primary endpoint is GSS*

* Why is this trial required?

- 1st Phase 3 trial (2019) showed Nasodine has a positive impact on GSS, but GSS was not the pre-stated primary endpoint in that study, so TGA was unwilling to approve Nasodine based on that trial
- Firebrick is now appealing TGA's position in the AAT (Administrative Appeals Tribunal)
- In parallel, we are conducting this repeat Phase 3 study, this time with GSS as the pre-stated primary endpoint

* GSS is the key outcome measure from the WURSS-21 common cold survey, a validated tool for measuring impact of an intervention in the common cold

2022 PHASE 3 CLINICAL TRIAL	
KEY FEATURES	DESCRIPTION
TRIAL DESIGN	Randomised, controlled, Phase 3 study across five sites in Australia and South Africa
DOSAGE TESTED (same as previous studies)	3 sprays per nostril, 4 times daily for 5 days
TARGET POPULATION FOR PRIMARY ENDPOINT	196 adults with viral colds: Must have stronger symptoms; Must start trial within 36 hours of first symptoms; Any COVID-positive subjects excluded
PRIMARY ENDPOINT	Nasodine efficacy vs placebo on the Global Severity Score (GSS)*

NASODINE – BEYOND THE COMMON COLD

Beyond treatment and prevention of the common cold

* Potential other respiratory indications

- Elimination of MRSA and other PPB (potentially pathogenic bacteria) from the noses of hospital staff and patients to reduce hospital acquired infections
- Prevention of secondary respiratory illnesses in 'at-risk' populations, such as asthmatics
- Treatment of the common cold in children (current approval is sought for adults only)

* Potential pandemic and biodefense applications

- In 2020, Firebrick filed a patent on the use of Nasodine to prevent infection by highly-pathogenic (pandemic) viruses, including pandemic flu, Ebola, MERS and SARS
- In 2021, a Firebrick patent covering the use of Nasodine for SARS-CoV-2 (COVID-19) was granted in the US

Nasodine and COVID-19

* Nasodine and COVID-19

- Many agents inactivate SARS-CoV-2 *in vitro*; Nasodine is particularly active against the virus, eliminating infectivity *in vitro* in under 60 seconds*
- In 2020/21 Firebrick sponsored a pilot study in South Africa, in which a single dose of Nasodine reduced the nasal viral load of SARS-CoV-2 for up to one hour*

* COVID-19 Phase 2 clinical trial

- In April 2022, Firebrick started a Phase 2 trial in South Africa to recruit 144 COVID-positive subjects
- Goal is to show that frequent use of Nasodine over 2-3 days reduces SARS-CoV-2 viral load, accelerates viral clearance and reduces days to negative RAT (versus placebo)

* Friedland *et al.* *In vivo* (human) and *in vitro* inactivation of SARS-CoV-2 with 0.5% povidone-iodine nasal spray. Aust J Otolaryngol 2022;5:2.



Draft packaging only,
not approved by TGA

NASODINE MARKETING

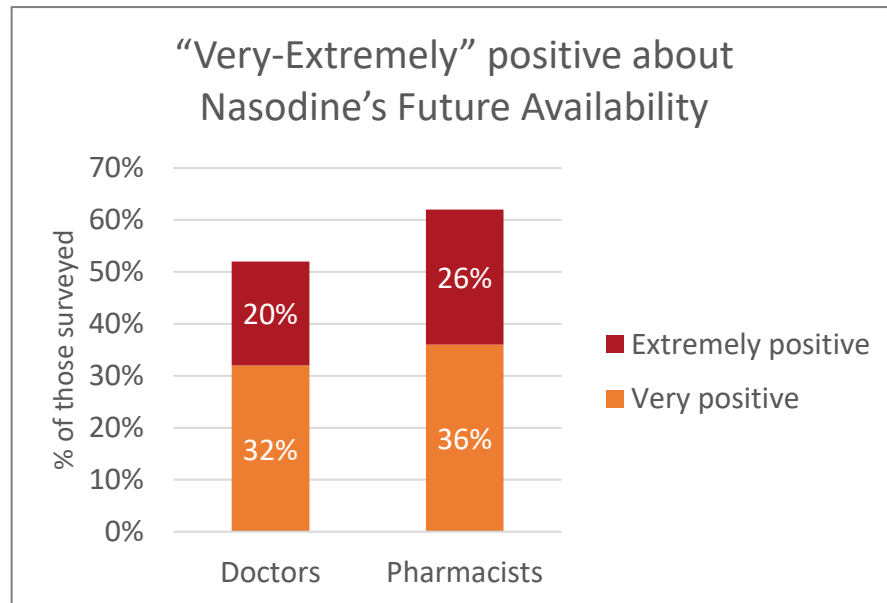
Once approved as an OTC for the common cold,
what are Nasodine's prospects?

STRONG SUPPORT FROM HEALTHCARE PROFESSIONALS

SURVEY OF AUSTRALIAN GPs AND RETAIL PHARMACISTS¹

Overall reaction (to future availability of Nasodine)

- 78% of GPs positive about Nasodine becoming available in Australia, with 52% “very/extremely positive”
- 87% of pharmacists were positive, with 62% “very/extremely positive”



Ranking of reasons for overall reaction

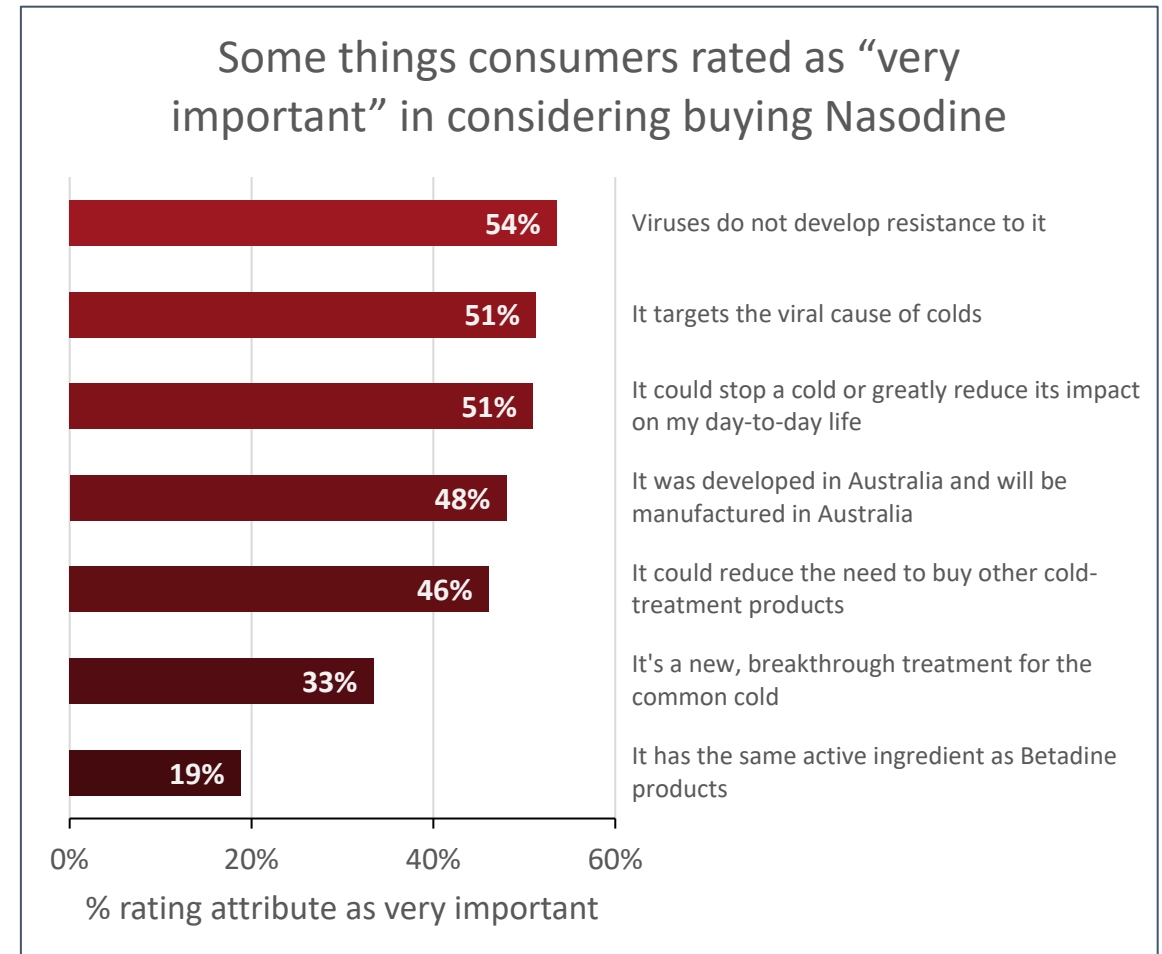
Rank	Doctors	Pharmacists
1	It could help people by reducing cold severity	Targets/kills the viruses that cause colds
2	Targets/kills the viruses that cause colds	It's pharmacy-only (won't be in supermarkets)
3	May reduce pressure to prescribe antibiotics	It could help people by reducing cold severity
4	It's an Australian innovation	It's an Australian innovation
5	Other	May reduce antibiotic prescribing by GPs

¹ Survey of 200 GPs and 200 pharmacists conducted by IQVIA in 2021; ; all participants presented with a de-identified (unbranded) profile of Nasodine

AUSTRALIAN CONSUMERS ARE ALSO EXCITED ABOUT NASODINE

- * Consumer survey of 308 Australian adults¹ who typically suffered from colds. All were presented with a de-identified (unbranded) profile of Nasodine
- * Like HCPs, consumers were very positive about Nasodine
- * 89% were positive, most popular comment was: *"I am excited to hear about this product and keen to try it"*
- * 76% indicated they were 'somewhat likely' or 'very likely' to purchase, once available
- * 58% said that they can see themselves buying Nasodine to keep on hand in case they catch a cold
- * Positive buying intent was across all age groups and all categories of current cough & cold product usage

¹ Firebrick Pharma commissioned survey, July 2022; all participants presented with a de-identified (unbranded) profile of Nasodine



GLOBAL MARKETING PLAN



Draft packaging only,
not yet approved



* Firebrick to market Nasodine in Australia, as soon as approved

- To be marketed as a 25 mL bottle with metered dose pump
- Each bottle contains enough for approx. 1.5 colds (when used as directed)
- Projected Australian retail price: \$24.99
- OTC product available in pharmacies, contract pharmacy sales force
- Sampling and promotion to GPs
- Extensive PR and advertising to support Australian launch

* International marketing through distribution partners

- Partners already in place in South Africa, New Zealand, Philippines; other distribution partners being sought in US, Europe and other markets
 - Firebrick entitled to a royalty on sales (or profit share margin from sales)
- Product to be exported from Australia
 - Nasodine to be supplied from Australia to the world market

FIREBRICK GOALS OVER NEXT 12 MONTHS

* Common Cold Phase 3 clinical trial

- Complete recruitment and report trial results

* TGA approval and launch

- Continue to seek immediate approval of Nasodine via the appeal process
- If unsuccessful, re-submit to TGA once results obtained from the second Phase 3 trial

* International registrations

- Once Phase 3 trial completed, commence filing in EU and other markets
- File an IND in the US for a further Phase 3 study (required by FDA)

* Partnering

- Continue discussions with US/EU distribution partners and aim to secure an agreement for regional distribution rights to Nasodine

* Phase 2 COVID-19 study

- Complete the Phase 2 study in 2022 and report results
- Review the results to determine if further studies are warranted

* New Product Development

- Complete development work and file for TGA approval on all new products under development

FRE SHOULD APPEAL TO ALL AUSTRALIAN INVESTORS

* A timely Australian breakthrough

- Unprecedented public awareness of the role of viruses in respiratory illness
- The first broad-spectrum medicine targeting viral cause
- Simple story: “kills viruses in the nose to treat colds”

* Large global market potential

- Global market of up to 20 billion colds pa
- Product expected to sell for \$25/bottle in Australia
- Potential for strong market share performance
- Patent protection from competitors until 2034/35
- Upside of future pandemic and other indications

* Late stage and lower risk

- Manufacturing ready, capacity of 1 million units/week
- Topical treatment with excellent safety profile
- Proof-of-concept established in first Phase 3 trial; second Phase 3 trial underway to confirm efficacy
- Potential for near-term approval in Australia

* Australian innovation and manufacturing

- Opportunity to support a breakthrough Australian innovation
- Manufacturing is in Australia for export worldwide

* Portfolio development

- Other products under development and likely to be launched within 2 years

* Proven board and management team

- Executive Chairman launched Betadine® Sore Throat Gargle in Australia
- Outstanding board with successful ASX track record and international reach

* Current investment considerations

- Low valuation (~\$50m)
- Australian approval & launch expected to be major value inflexion point



FirebrickPharma

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