# FirebrickPharma

ASX: FRE

EUROZ HARTLEYS HEALTHCARE FORUM
2 FEBRUARY 2023

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FirebrickPharma

Firebrick Pharma is an Australian pharmaceutical innovator that has developed a breakthrough treatment for the common cold:

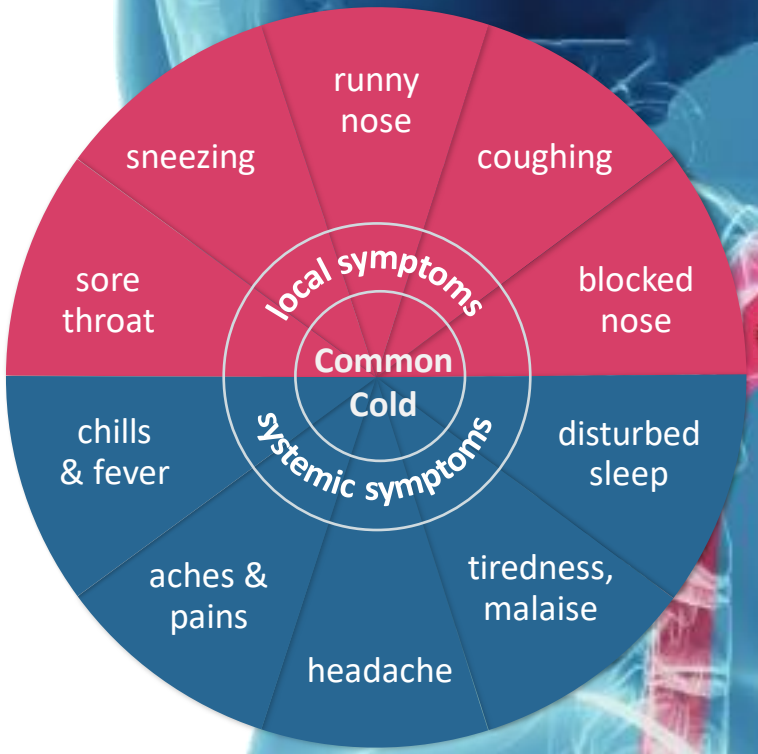
**Nasodine® Nasal Spray**

Nasodine is a first-in-class nasal spray medicine that actually targets the viral cause of the common cold[1,2]

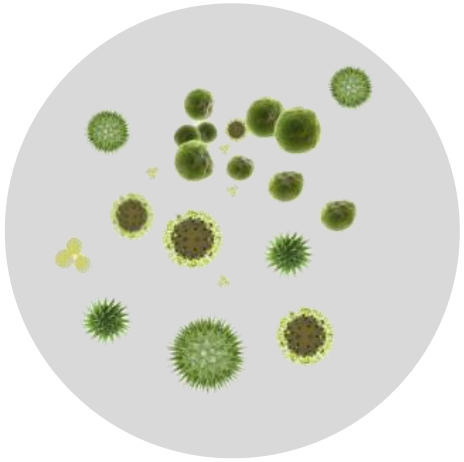

DRAFT LABELLING

[1] NASODINE is an internationally registered trademark of Firebrick Pharma
[2] Nasodine Nasal Spray is not approved for sale

The viruses enter the nose and readily infect nasal cells triggering the symptom complex we call the “common cold”

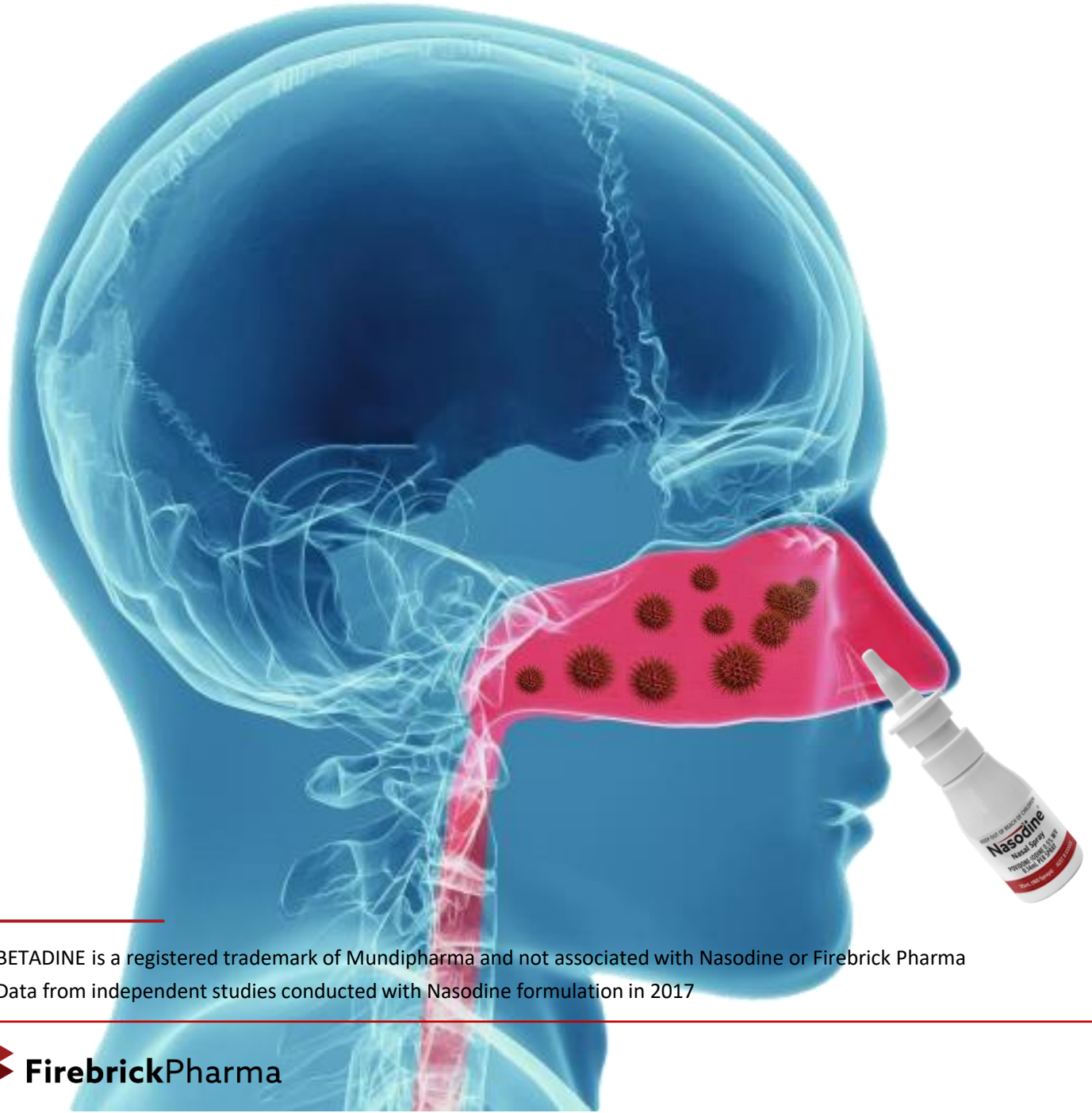



## Upper respiratory infections are spread through virus-laden microdroplets in the air and on surfaces



Hundreds of variants from six major virus families are the primary cause of URI

Cold & flu medications suppress some of the symptoms but do nothing to stop the virus




Nasodine contains povidone-iodine (PVP-I)

**Same active ingredient as in Betadine® Sore Throat Gargle[1]**

PVP-I in Nasodine attacks essential viral proteins and membranes, inactivating most URI (cold) viruses within 60 seconds (*in vitro*)[2]

The effect is virucidal (permanent), broad-spectrum (kills all viruses) and non-selective (non-resistance inducing)

By repeated application (4 times daily) Nasodine is expected to:

- suppress the viral load in the nasal passages
- interrupt the infection cycle (stop spread of the infection)
- reduce symptoms and severity of the cold

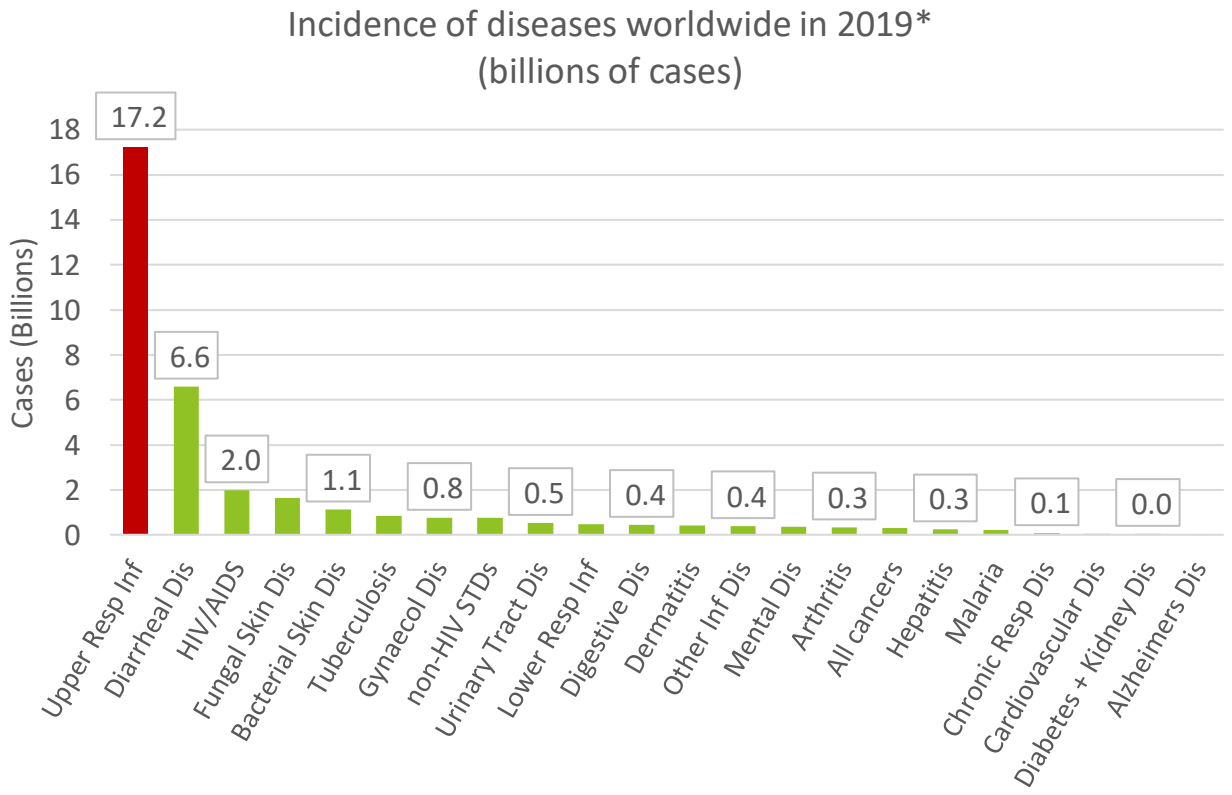
[1] BETADINE is a registered trademark of Mundipharma and not associated with Nasodine or Firebrick Pharma

[2] Data from independent studies conducted with Nasodine formulation in 2017

# Upper Respiratory Infection (URI)

Excludes all lower respiratory infections and otitis media (ear infections), i.e., equivalent to what we call the "common cold"

## Is by far the most common ailment afflicting humanity




- URI dwarfs all other diseases
  - » 65 million cases annually in Australia alone
  - » 99 times more common than all lower respiratory infections combined (e.g., influenza)
- Although generally mild, the total impact of URI is high for both the individual and society
  - » Morbidity, impaired quality of life, medication costs
  - » Days off work, doctor visits, antibiotic prescriptions
- Even a modest benefit from a new treatment could have an enormous overall impact
  - » And a small share of this market could be extremely attractive

How much benefit could Nasodine produce?

*Jin, X. et al. (2021) "Global burden of upper respiratory infections in 204 countries and territories, from 1990 to 2019" eClinicalMedicine, Volume 37, 100986

# The Nasodine benefit

## Clinical evidence in support of efficacy

2019 Phase 3 clinical trial compared Nasodine with saline nasal spray (*which is marketed for relief of cold symptoms*)

**Results:**

- All **symptom endpoints pointed in favour of Nasodine** over saline nasal spray
- Nasodine improved **overall cold severity*** and reduced the interference of the cold on daily activities **(quality-of-life)**, especially the ability to **sleep, think clearly, exercise and work**
- The clinical benefits of **Nasodine were magnified in:**
  - Those with a **confirmed viral infection**
  - Those starting **treatment on the 1st day of symptoms**

- TGA approval process
  - Based on these results, Firebrick submitted an application to TGA for marketing approval of Nasodine in Australia
  - Nasodine met all TGA **quality** and **safety** hurdles but TGA declined approval, based on insufficient evidence of **efficacy**
- Firebrick appealed TGA's decision through the Administrative Appeals Tribunal (AAT)
  - Expert evidence now being prepared and a **conciliation meeting** (FRE, TGA & AAT) is currently scheduled for end May 2023
  - If successful, Nasodine could be **approved in 2023**
- In addition (and as a backup), Firebrick is conducting a second Phase 3 trial, to be completed in 2023

* Overall cold severity = global severity score (GSS) = the sum of 10 symptom measures and 9 quality-of-life (QoL) measures.
GSS is a validated measure of cold severity using the Wisconsin Upper Respiratory Symptom Survey (WURSS-21).

# Second Phase 3 trial (2022/23) is underway:

Started in 2022, already 50% recruited, expected to be completed by mid-2023

The trial is intended to provide additional clinical evidence to support:

- **Australian approval** if AAT appeal is unsuccessful
- **International regulatory approvals**
- **Licensing deals** especially in US and Europe

| Comparison of the two Phase 3 trials | | |
|---|---|---|
| | 2019 Phase 3 trial | 2022/23 Phase 3 trial |
| Number of subjects | 255 | Up to 500 |
| Sites | 2 sites, Australia only | 5 sites, multinational: 2x Australia, 3x South Africa |
| Time since symptom onset for all subjects | ≤ 60 hours | ≤ 36 hours |
| Primary endpoint | Impact on nasal symptoms (GSS was secondary endpoint) | Overall cold severity (GSS) |
| Primary endpoint population | All subjects | Subjects with confirmed viral infection |

More subjects reduces risk

Multinational & multisite makes trial more robust for regulatory purposes

Nasodine works better if used early and most people expected to use it early

GSS is a well-validated endpoint and was positive for Nasodine in 2019 trial

In 2019 trial, Nasodine performed better in subjects who had confirmed infection

# The importance of the 2022/23 Phase 3 Trial

**SUCCESSFUL PIVOTAL TRIAL**

Definitive clinical proof that Nasodine is a breakthrough treatment for common cold – a disease with 17 billion cases worldwide

**TGA APPROVAL**

Increases certainty of approval in Australia (regardless of AAT appeal outcome)

**APPROVAL IN EUROPE**

Allows filing of EU MAA (Marketing Authorisation Application)[1] opening the way to approval in up to 30 countries

**EXISTING LICENSEES**

Allows filing for marketing approval in current licensed markets:

- New Zealand
- South Africa
- Philippines

**GLOBAL LICENSING DEAL**

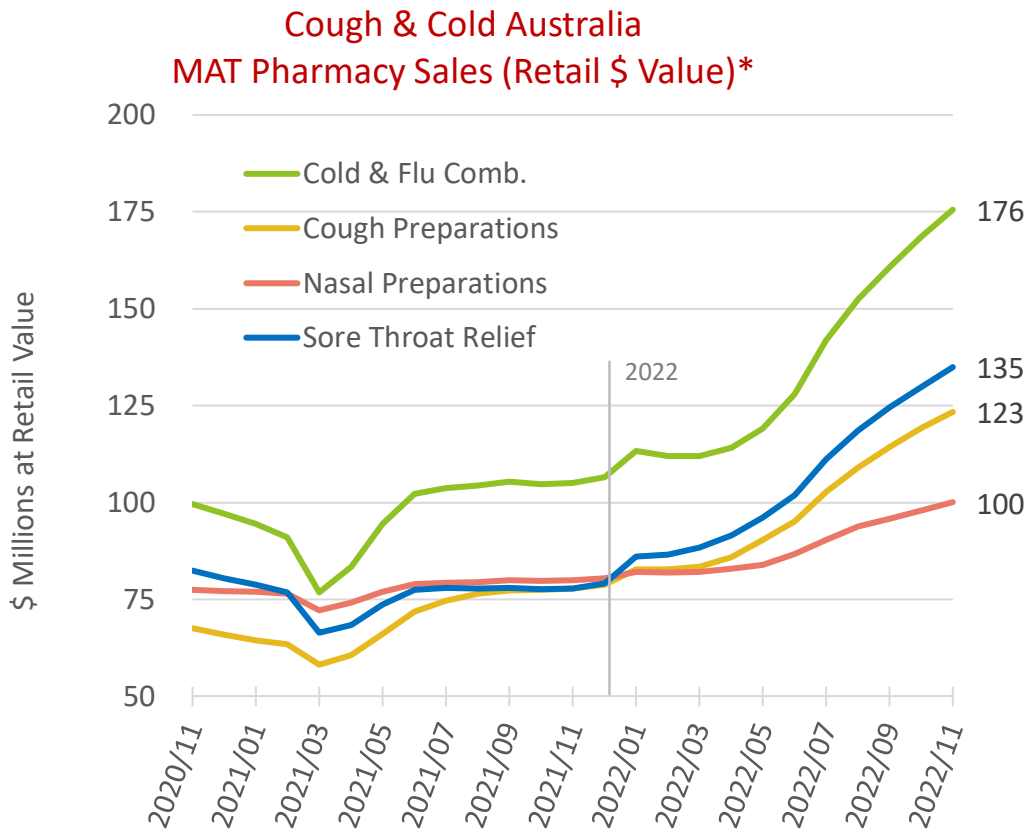
Provides the data needed to close a major licensing deal in US or EU (or both)


Draft packaging only, not approved by TGA

# Nasodine Marketing

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

# Australian OTC cold & flu market has rebounded in 2022




* IQVIA pharmacy scan data; excludes all supermarket sales

- Cough & cold is one of the largest OTC categories in Australia
  - $534 million MAT Nov 2022
  - Sales grew dramatically (57%) in 2022 finishing up 10% on 2019 (pre-COVID)
- Dominated by oral combination treatments, most approved decades ago
  - Antihistamines, analgesics, cough suppressants and other pills/capsules that target symptoms
- Good time to be entering this market with a novel treatment like Nasodine
  - A share of the Australian market alone could be valuable

What are Nasodine's prospects for a share of this market?

IQVIA

# Common Cold Market Report

October 2021

Conclusions:

"The current in-market products are used primarily to treat the symptoms of colds as opposed to the underlying cause, which is viral infection. Consequently, a product that can effectively eliminate the viral causative agent and thereby reduce the level of discomfort experienced by individuals, can **expect broad market adoption**."

"Nasodine, a first-in-class nasal spray with clinical evidence to prove its efficacy in eliminating respiratory viruses and reducing cold severity, is **the only product that fits this profile**."

Consumer and HCP market research supports this…

# Australian consumers say they are excited about Nasodine

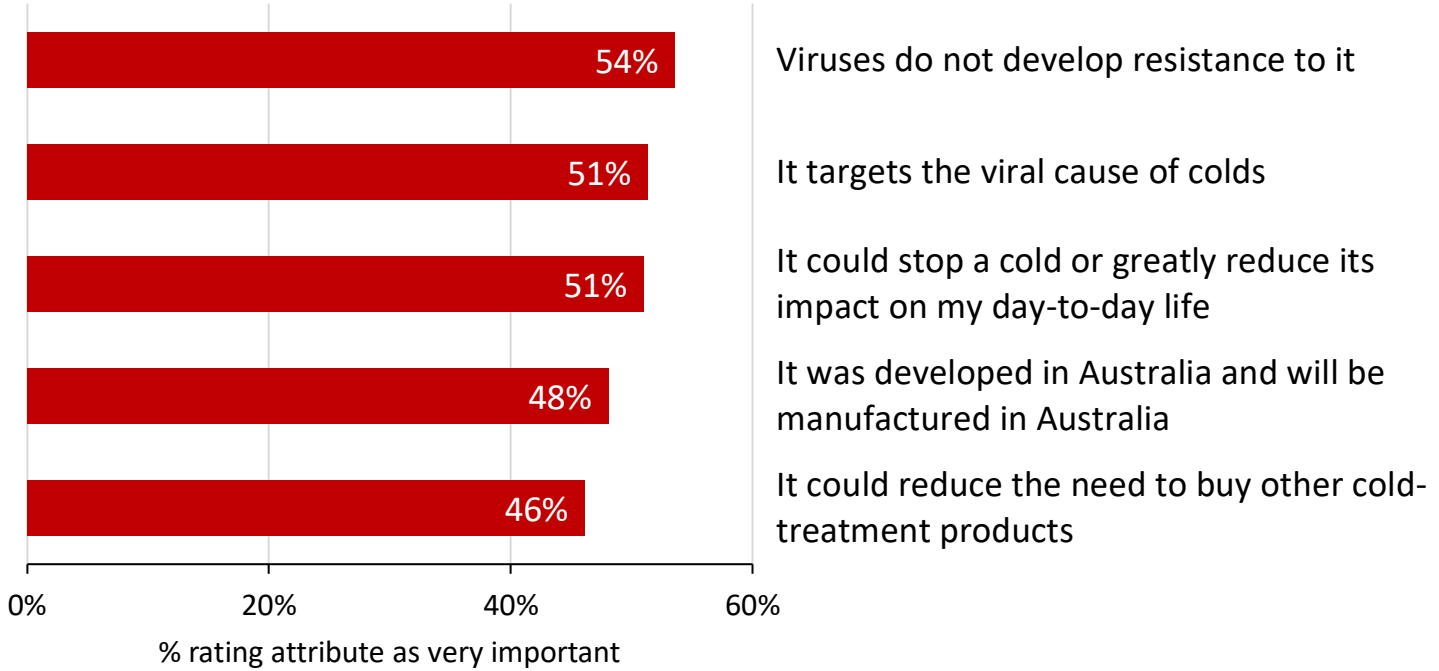
Survey of 308 Australian adults who typically suffered from colds*

- **89% of consumers** surveyed were positive about Nasodine; most popular comment was:

  "*I am excited to hear about this product and keen to try it*"

- 76% indicated they were **likely to purchase**, once available
- Positive buying intent was across all ages and categories of current cough & cold product usage
  - » Nasodine expected to take share from all cold & flu medicines, not just nasal preparations

What consumers rated as "**very important**"




* Survey conducted by Firebrick in July 2022; participants were presented with a de-identified (unbranded) profile of Nasodine Nasal Spray

# Healthcare professionals are also very supportive of Nasodine

Survey of 200 Australian GPs and 200 retail pharmacists*

- 78% of GPs surveyed were positive about Nasodine becoming available in Australia, with 52% "*very/extremely positive*"
  - » Despite the product being available OTC (i.e., not a prescription medicine)
- 87% of pharmacists were positive, with 62% "*very/extremely positive*"
  - » Nasodine should expect strong support from Australian pharmacists

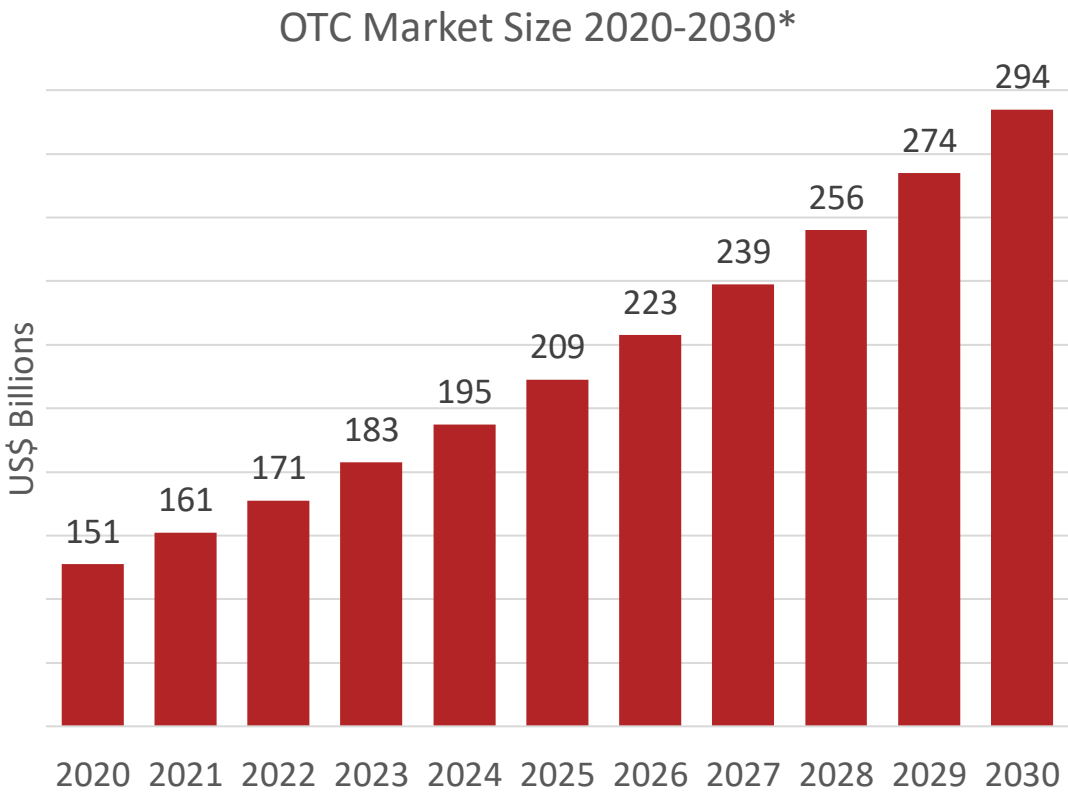
| Reasons HCPs are positive about Nasodine | | |
|---|---|---|
| Rank | Doctors | Pharmacists |
| 1 | It could help people by reducing cold severity | Targets/kills the viruses that cause colds |
| 2 | Targets/kills the viruses that cause colds | It's pharmacy-only (not in supermarkets) |
| 3 | May reduce pressure to prescribe antibiotics | It could help people by reducing cold severity |
| 4 | It's an Australian innovation | It's an Australian innovation |

* Survey conducted by IQVIA in 2021; participants were presented with a de-identified (unbranded) profile of Nasodine Nasal Spray

# Nasodine's global opportunity

- The global OTC (over-the-counter) pharmaceutical market is currently valued at more than US$170 billion and expected to grow 72% by 2030*
- **Cough, cold & flu** remedies segment is expected to dominate the market*
- For OTC companies, a product with $1 billion global sales potential could be viewed as very attractive

Major OTC Pharmaceutical Companies

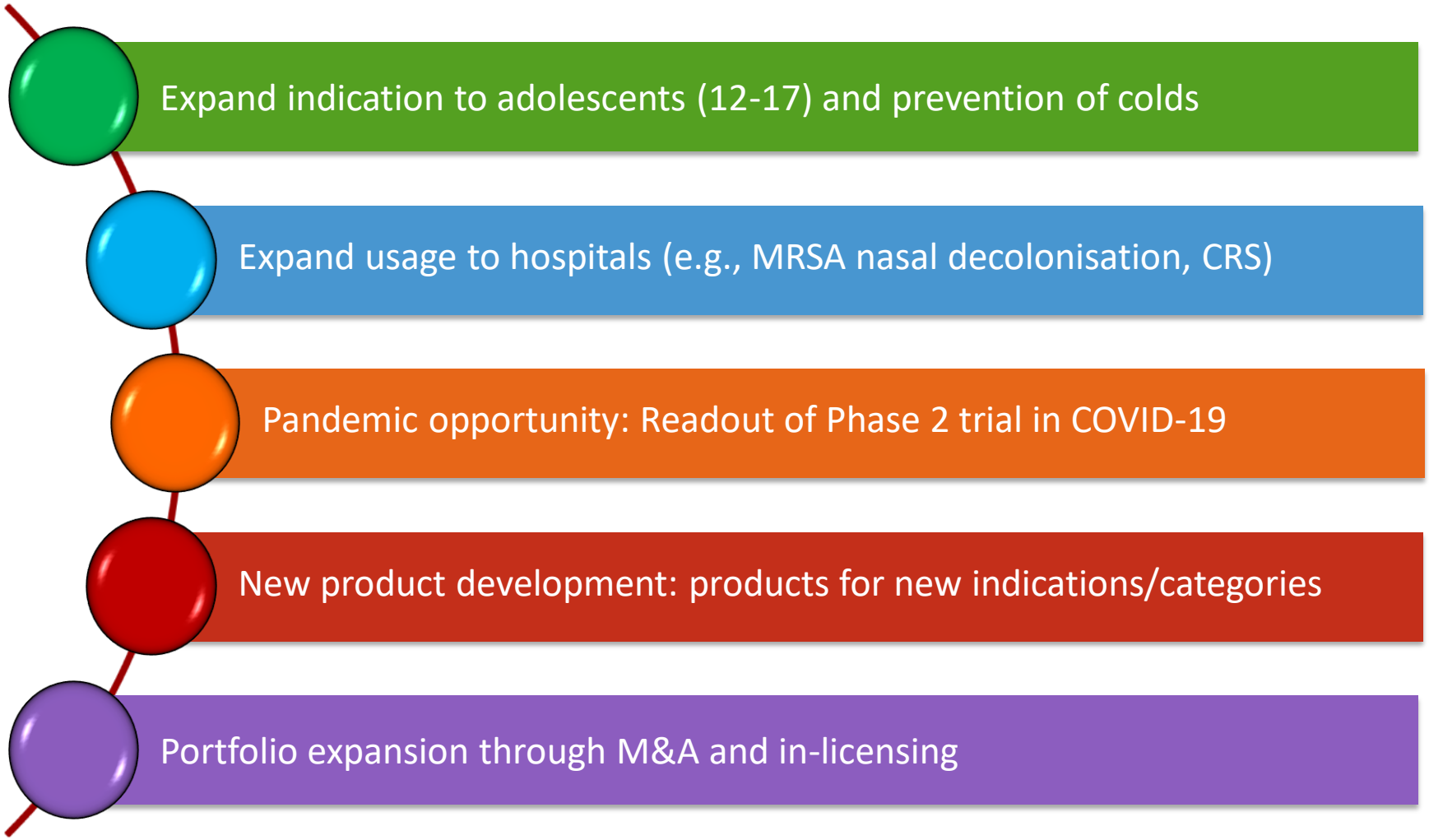

* https://www.precedenceresearch.com/over-the-counter-drugs-market

# Licensing strategy for 2023

- US and EU account for an estimated 60% of Nasodine's global sales potential
- FRE has retained US-based Pullan Consulting[1] to act as its licensing consultant and intermediary in this project
  - Pullan Consulting is a globally recognised expert in licensing, listing approx. 40 client biotech firms and 65 licensing deals [1,2]
- 2023 Plan
  - Introduce Nasodine to prospective global OTC companies and initiate negotiations towards a deal for US, EU or both
  - Prepare and file an EU marketing authorisation application (MAA)
  - Commence US IND preparation to support a US Phase 3 trial (required for FDA approval)

[1] pullanconsulting.com
[2] www.nature.com/articles/d43747-020-00602-6

# Firebrick growth opportunities after the launch of Nasodine



# 2023 potential catalysts for FRE

| | Outcomes | Earliest potential date | Comments and caveats |
|---|---|---|---|
| AAT appeal and Australian approval | • Conciliation meeting outcome<br>• Nasodine approval in Australia | • Jun<br>• Sep-Dec | Conciliation meeting date is 30 May but could move or have no substantive outcome; AAT Hearing may be required causing delays; if appeal process is unsuccessful, FRE may have to refile for TGA approval based on new Phase 3 data |
| Phase 3 common cold trial | • Recruitment restarts<br>• Recruitment closes<br>• Trial results reported | • Mar-Apr<br>• Jun-Jul<br>• Aug-Sep | If recruitment is slower than expected, trial closure could be delayed, delaying reporting of results and related outcomes, potentially including international registrations |
| Phase 2 COVID-19 trial | • Recruitment closes<br>• Trial results reported | • Apr-May<br>• Aug-Sep | Primary endpoint is based on culture assays that are time-intensive; any delays in the assay procedure could delay reporting of results |
| International approvals[1] | • MAA[2] filing in EU<br>• Registration filings in NZ, SA, PH | • Nov-Dec<br>• Nov-Dec | Registration filings require extensive documentation, especially in Europe; delays can easily occur, potentially pushing out filing dates into 2024 |
| Licensing deal for US/EU | • Binding term sheet or other agreement executed | • Nov-Dec | Any EU/US licensing deal would be subject to successful Phase 3 results and other factors; a US licensing deal execution could push out until IND filing in 2024 |

[1] US approval requires filing and IND and completing a new Phase 3 trial in the US; earliest date for filing IND is mid-2024 due to the additional nonclinical and other studies required by the FDA.

[2] MAA = Marketing Authorisation Application; prior to acceptance for evaluation, an MAA requires submission and approval of a Paediatric Investigation Plan (PIP); any delay in submission or approval of the PIP could delay the MAA filing date.

# Firebrick is different to most biotech firms

| | Firebrick Pharma | Drug development biotech (DDB) |
|---|---|---|
| Value creation strategy | Australian launch, then launch globally through distribution partnerships<br><br>Goal is to become a profitable pharmaceutical business | Achieve clinical milestones towards a Big Pharma licensing deal or trade sale<br><br>Goal is to monetise the technology via a valuable deal |
| Risk profile | Lower risk<br>Already on the cusp of Australian approval and has met quality and safety hurdles | High risk<br>Binary risks at each stage of clinical development, then stiff competition for Big Pharma deals |
| Market Opportunity | High volume, affordable OTC drug; market opportunity is global | Low volume, expensive Rx drug; market opportunity is focused on US |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