

**27 November 2024**

**ASX Announcement**

## **Chairman's Annual General Meeting Presentation**

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**Firebrick Pharma Limited (ASX:FRE) (Firebrick, Company)** is pleased to provide the attached presentation and transcript to be made by the Chairman at today's Annual General Meeting.

This presentation and transcript has been authorised for release by Peter Molloy, Executive Chairman and CEO of Firebrick Pharma Limited

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### **About Firebrick (ASX:FRE)**

Firebrick Pharma is a pharmaceutical innovator focused on developing and commercialising novel formulations and uses of povidone-iodine (PVP-I). The Company has successfully developed a PVP-I nasal spray (Nasodine® Nasal Spray) and filed international trademarks and multiple patents on the product. The Company has also completed multiple clinical trials that have affirmed the product's safety and generally supported its efficacy as an antimicrobial nasal spray with utility in a range of clinical settings. Firebrick is now commercialising Nasodine in international markets, with the product already launched in the United States and Singapore. The Company also expects to launch Nasodine in the Philippines in the near term.

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Presentation by  
Peter Molloy  
Executive Chairman

Annual General Meeting  
27 November 2024



Authorised for release by Peter Molloy, Executive Chairman of Firebrick Pharma Limited

The World Needs

**Nasodine®**  
Nasal Spray

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# Our primary asset: Nasodine® Nasal Spray

- Firebrick has developed the world's first clinically-supported povidone-iodine nasal spray, Nasodine® Nasal Spray (“Nasodine”).
- *In vitro*, Nasodine kills all known respiratory viruses and bacteria – including pandemic strains – with no potential for resistance development.
- *In vivo*, Nasodine has been proven safe, and in one common cold Phase 3 trial was clinically effective in reducing overall cold severity; in a COVID-19 Phase 2 trial, Nasodine completely cleared SARS-CoV-2 from the nasal passages.
- R&D development of Nasodine is complete, removing any significant forward R&D risk; our past R&D investment has created a strong IP foundation to support commercialisation of Nasodine.
- Nasodine now will be marketed as a nasal antiseptic, which meets multiple unmet medical needs for consumers, doctors, hospitals and governments; our patents and other IP continue to be relevant to this indication.



# One year ago...

## **What Firebrick faced:**

- Negative result in our second Phase 3 trial
- Withdrawal from AAT appeal, which stopped Nasodine approval in Australia, extinguishing our plan to build Australian sales as a springboard for global partnering

## **What we did about it:**

- We continued to believe in Nasodine and that the world needed this valuable product
- We decided to make Nasodine available in all international markets where regulations would allow it (despite absence of Australian approval)

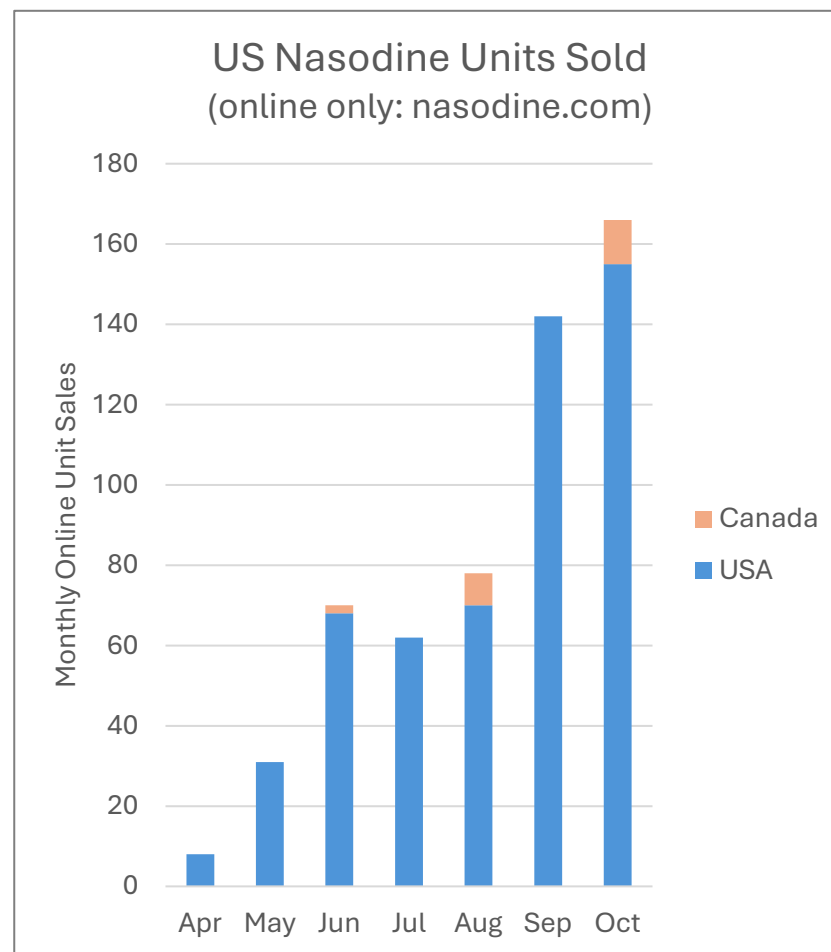
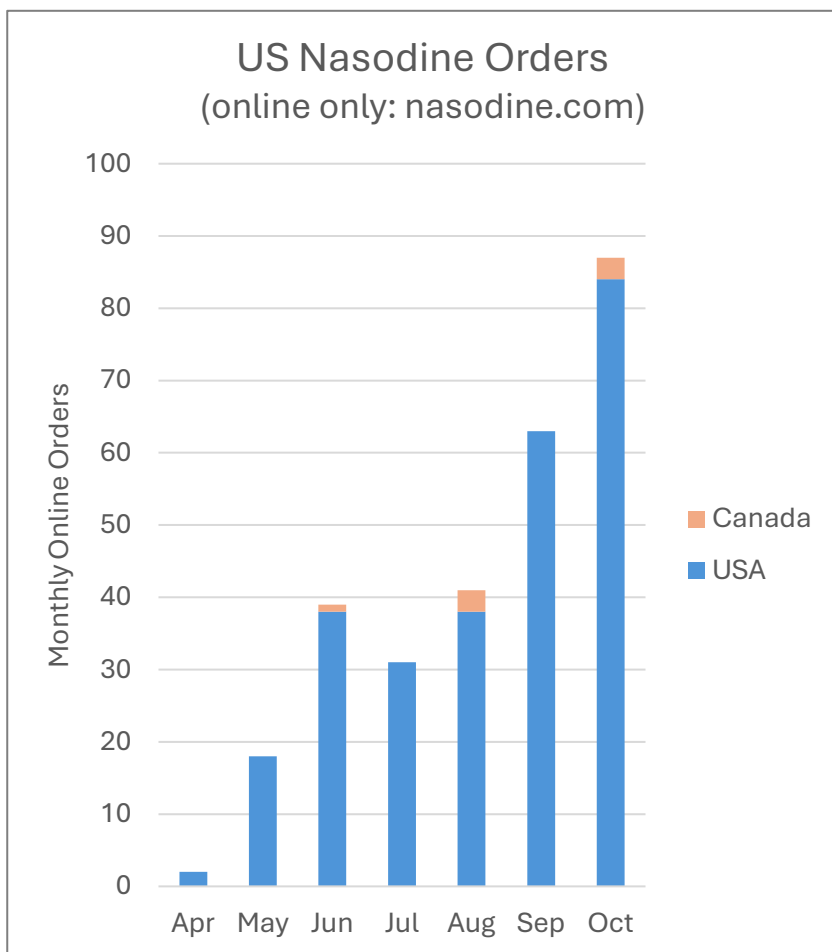
## **What we have achieved over the last year...**

# 1. The US launch

- Nasodine to be made available as ‘nasal cleanser’ under cosmetic provisions of FD&C Act.
- Created US corporation, Firebrick Pharma, Inc. with banking and credit card services.
- Agreement with US manufacturer to produce Nasodine; successfully completed first commercial batch in March 2024.
- Agreement with warehousing/fulfilment partner in US to supply US, Canada and Mexico
- Created high-quality e-commerce website ([nasodine.com](https://nasodine.com))
- Agreement with US digital marketing partner to run social media advertising program
- Announced the US launch in April 2024
- US sales have developed positively; gained 40 5-star reviews of Nasodine on the website
- Influencer program about to start



# US sales development

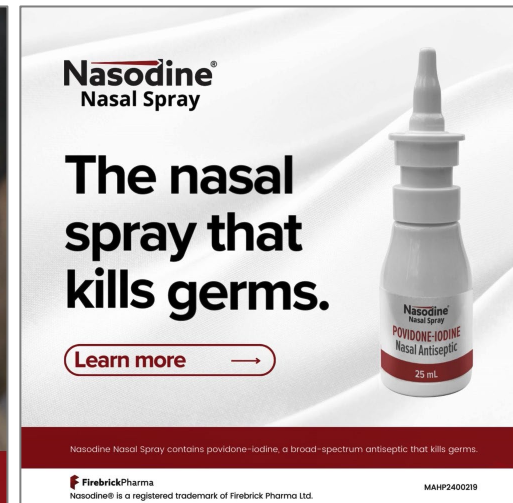




## 2. The Singapore launch – Phase 1

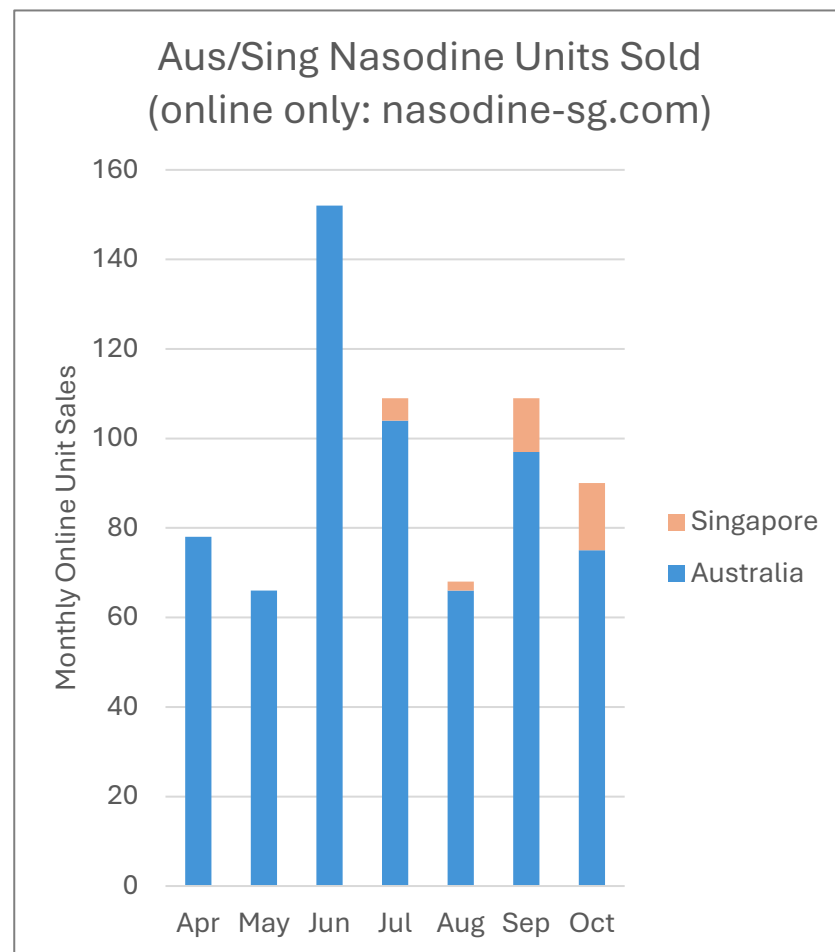
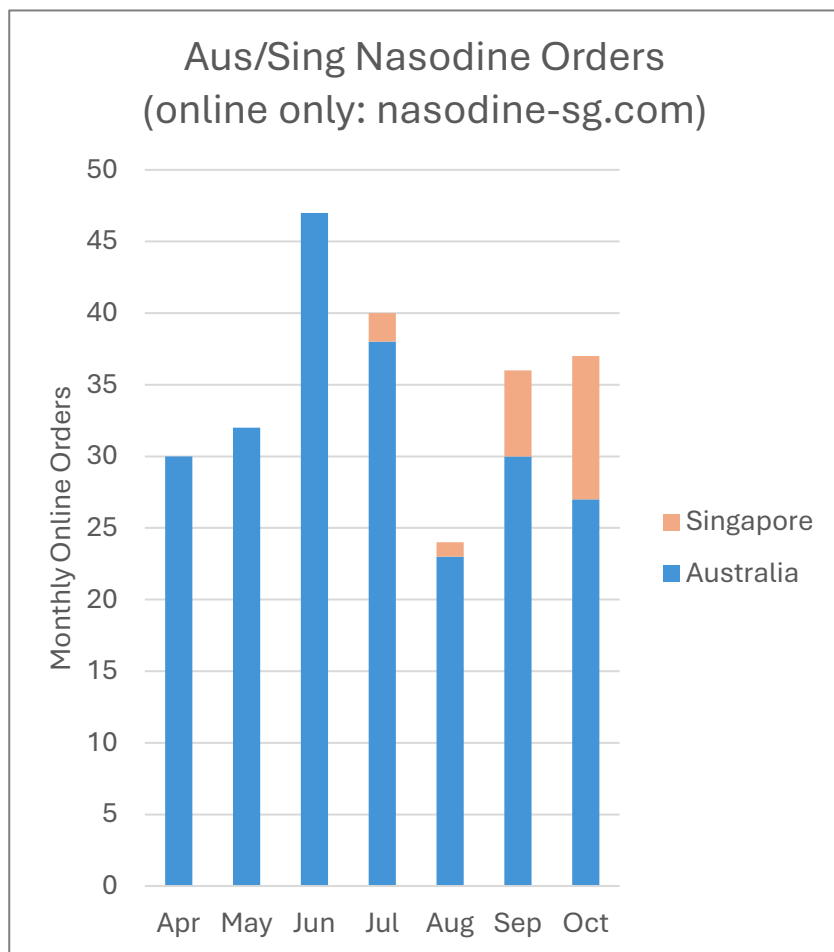
### Social media launch

- Nasodine is a ‘topical antiseptic’ under HSA regulations.
- Manufacturing by Probiotec of the first commercial batch of Nasodine in Australia for sale in Singapore, and successful export of finished product to Singapore for sale.
- Created dedicated Singapore website ([nasodine-sg.com](https://nasodine-sg.com)) with full e-commerce functionality, supported by Singapore-based digital marketing, warehousing and fulfilment services
- Gained HSA (Health Sciences Authority) approval to market Nasodine as a ‘topical antiseptic’ for nasal use supported by consumer advertising (example below)





# Australia/Singapore sales development



## 2. Singapore launch – Phase 2

### Doctor and retail pharmacy launch

- Successfully exhibited at two key Singapore HCP conferences: WONCA (World Congress of Family Doctors) and the Singapore Pharmacy Congress, introducing Nasodine to HCPs.
- Executed a marketing representation agreement with Innorini Life Sciences and started active promotion and sampling to Singapore doctors.
- The largest pharmacy chain in Singapore (Guardian) has agreed to stock and promote Nasodine in all 121 of their stores, including 6 at Changi Airport – a major endorsement of the value of Nasodine.
- Distribution agreement with DKSH to support the Guardian agreement.
- New Nasodine packaging for the retail pharmacy launch.

HCP brochure used  
at WONCA, SPC  
and by Innorini



New retail  
packaging for  
Guardian launch

# 3. The Philippines – the next launch

- Philippines FDA (PFDA) confirmed that subject to local manufacturing, Nasodine could be launched in the Philippines as a nasal disinfectant and without further clinical studies
- Existing partnership with SV More amended to include right to local manufacturing (ASX ann. 15 August 2024)
- Tech transfer to Philippines manufacturer (Hizon Laboratories Inc) in progress with initial manufacturing expected in Q1 calendar 2025
- SV More statement:
  - “Since the onset of the pandemic, we have been committed to making this innovative product available, and we are thrilled to be one step closer to seeing it on drugstore shelves across the country. Our extensive discussions with leading ENTs have revealed strong anticipation for Nasodine, and we are confident that doctors nationwide will be key advocates for this groundbreaking solution.”
- Why the Philippines is important to Firebrick:
  - Large pharmaceutical market in Southeast Asia (approx. 20x population of Singapore)
  - Committed pharmaceutical partner in place to handle doctor and pharmacy marketing
  - No manufacturing or marketing investment needed by Firebrick

## 4. Beyond existing markets

- Europe
  - Firebrick filed an application for approval of Nasodine in Europe as a nasal antiseptic (ASX ann. 9 Sept 2024).
  - Sweden's Medical Products Agency (MPA) is leading the review, with the Icelandic Medicines Agency conducting a parallel assessment.
  - Following approval in these countries (if granted) approvals in other EU countries (total of 27 countries) could proceed under the mutual recognition procedure.
  - Initial evaluation phase expected to be completed by 19 December 2024, after which Firebrick will have 90 days (extendable) to address any questions raised by the initial evaluation.
- Asia beyond Singapore and Philippines
  - We are exploring other Asian markets, including China, Indonesia, Korea and Thailand as possible early opportunities for Nasodine.
  - We will continue to explore all possible pathways to make Nasodine available in Australia.

# 5. Resourcing and funding

- Operating cost base greatly reduced in calendar 2024
  - Overall operating costs expected to be down by more than 50%
  - Reflects focus transition from R&D to commercialization, but also significant infrastructure cost reductions
- Funding
  - In CY2024, we received \$920K in R&D tax incentive income and raised a total of \$1,594k in placement or SPP funds from existing shareholders
- New skills to drive commercialization
  - Firebrick hired former head of J&J Consumer Health in Asia-Pacific (Keith Shortall) to drive pharmacy distribution of Nasodine in Singapore and partnering in Asia
  - Primary goal was to achieve pharmacy chain distribution in Singapore by 30 June 2025; this goal has now been achieved well ahead of schedule

# Firebrick's future is bright

- Nasodine is on the market in two countries, with a third soon to be added; the market response has been positive, endorsing the breakthrough potential of Nasodine and our new commercialisation strategy.
- In Singapore, the exclusive distribution through Guardian pharmacies is a major milestone, which along with active promotion to HCPs, could be transformative for Firebrick in 2025; we can also expect a second important Nasodine product to be launched into the retail and HCP channels in Singapore by the end of calendar 2025.
- In the US, our current initiatives should accelerate sales growth in 2025 and as the consumer awareness and adoption of Nasodine grows, we can pursue distribution through pharmacies and clinics.
- In the Philippines, our new agreement with SV More promises positive newsflow in 2025 and a potential launch in 2026 that could dwarf the successes in Singapore.
- Europe and other markets could add new opportunities in 2025.

## **Transcript of AGM presentation by Executive Chairman, 27 November 2024**

The following are verbal comments to be made by the Executive Chairman, Dr Peter Molloy, in relation to each slide:

### **Slides 1-3:**

No comments.

### **Slide 4:**

One year ago, we were all reeling from the negative results of our second common cold Phase 3 trial; the results were inexplicable and completely at odds with the results of the first Phase 3 trial, which based on our expert evidence showed that Nasodine was clinically effective in reducing overall cold severity, with up to a 40% benefit in people who started treatment in the first 24 hours after symptom onset.

At the time, we were entrenched in an AAT appeal against TGA's refusal to approve Nasodine based on the first trial's results. The results of the second trial left us with no realistic prospect of succeeding with the appeal, so we formally withdrew from the appeal process last December and resigned ourselves to the fact that Nasodine would not be approved in Australia, anytime soon.

This also meant that our plans to (a) build a profitable business based on Australian sales and (b) use the Australian success to drive royalty-generating partnerships worldwide, were extinguished.

What we did about it was to continue to believe in Nasodine and that it could have saved many lives in the COVID pandemic, if TGA had allowed this safe and sensible nasal sanitiser to be available for consumers and healthcare workers. Our job now was to make this valuable product available before the next pandemic and no longer rely on Australia as the springboard.

### **Slide 5:**

We found two immediate opportunities for marketing Nasodine internationally. The first target was the US where several PVP-I nasal sprays were already on the market as nasal cleansers; by avoiding therapeutic claims and focusing on nasal hygiene, these products were able to be marketed as cosmetics in the US. We joined the fray with the intention of leading the growth of the market as the only PVP-I nasal spray that was clinically proven to be safe and supported by real R&D and peer-reviewed publications.

By December 2023, we had set up a wholly-owned US company, Firebrick Pharma, Inc. to manage US sales and expenses. We succeeded in setting up banking and credit card services to manage transactions. In March, we successfully manufactured our first US commercial-scale batch of Nasodine (approx. 30,000 units), through a California contract pharmaceutical manufacturer.

In parallel, we executed an agreement with a warehousing and fulfilment partner to ship Nasodine to customers across the US and Canada. Initially, our US site also supplied Nasodine to fulfil orders from Australian customers.

Also in parallel, we created a high-quality US website ([nasodine.com](https://nasodine.com)) with fully functioning e-commerce, allowing consumers to buy Nasodine online.



Considering all the potential pitfalls and challenges of US commercialisation, our launch in April went smoothly, and since then, US sales have developed in a positive pattern and we have received 40 5-star reviews.

We are now starting an influencer social media campaign to boost sales and accordingly expect to see accelerated sales growth in calendar 2025.

**Slide 6:**

No comments.

**Slide 7:**

Singapore was the other immediate marketing opportunity for Nasodine, where unlike the US, the product could be sold as a ‘topical antiseptic’ for nasal use – effectively a nasal sanitiser – and we could make direct antimicrobial claims, such as “kills the germs that cause nasal infections”.

In March, through our Australian manufacturing partner, Probiotec Ltd, we successfully completed the first commercial-scale production of Nasodine in Australia and shipped finished product to Singapore ready for sale in April.

Like in the US, we created a high-quality e-commerce website to process online sales of Nasodine, we hired a local digital marketing firm to run social media advertising, and executed agreements with local warehousing and fulfilment partners to manage orders.

To promote to consumers, we needed HSA (Health Sciences Authority) approval on all our advertising; this took us until mid-June, but it was a useful exercise because it left us with HSA-approved messaging that was quite strong, namely: “If people around you have symptoms and you are concerned about airborne germs, consider using Nasodine Nasal Spray, the nasal spray that kills germs”.

The Singapore initiative also gave Australians access to Nasodine at a much lower cost than the US platform; accordingly, we geo-directed all Australian IP addresses away from the US site and towards the Singapore site, which is still the best site for Australians to buy the product.

**Slide 8:**

No comments.

**Slide 9:**

In August, we introduced Nasodine to HCPs at the World Congress of Family Doctors (“WONCA”) in Singapore; the response was universally positive; doctors were genuinely excited about Nasodine’s availability. We repeated the exercise at the Singapore Pharmacy Congress in Singapore in October, with a similarly positive response from hospital and retail pharmacists. These conferences, above all, confirmed what we believed – that the world needs Nasodine!

In October we announced our deal with Innorini Life Sciences to detail and sample Nasodine to doctors in Singapore. In the three weeks ending 21 November, they had reached 115 doctors or hospitals HCPs and provided a total 236 samples of Nasodine. Doctors dispense and sell medicines in Singapore, and we are now starting to see sales from this segment.

This week, we announced the big news, which is that Guardian Health & Beauty, the largest pharmacy chain in Singapore, has agreed to exclusively distribute Nasodine through all 121 of their retail pharmacies, including their six premier pharmacies at Changi Airport. When we met with the senior executives at Guardian in October, both of whom were pharmacists, they were

genuinely excited about the prospects for Nasodine in retail pharmacy, as are we. The launch is scheduled for January, and we are looking forward to seeing the sales offtake in calendar 2025.

To support the Guardian sales, we also executed an agreement with a local logistics partner, DKSH, which works closely with Guardian and is essential to managing the relationship with them.

Based on suggestions from Guardian, we have created new dedicated packaging for the Singapore retail market, which will be shipped to Singapore in the next week or so for the scheduled January launch.

**Slide 10:**

Like Singapore, the Philippines provided an opportunity to launch Nasodine as a nasal disinfectant – again effectively, a nasal sanitiser – without additional clinical studies. To achieve this, we were advised that we needed to manufacture the product in the Philippines. In August, we reached agreement with our existing Philippines pharmaceutical marketing partner, SV More, to accommodate local manufacturing. We have been working hard to make that happen since including completing a tech transfer to SV More's manufacturer, Hizon. We now expect local manufacturing by Hizon to start in the New Year; they need 6 months of stability data to submit to the PFDA for local approval, after which SV More could launch, potentially in early 2026, at this stage. Our experiences in the HCP and retail sectors in Singapore will provide important input to the Philippines launch.

The Philippines is crucially important to Firebrick because (a) it is a large pharmaceutical market, (b) we have a committed, experienced marketing partner in place that will manage all HCP and retail pharmacy marketing, and (c) importantly, we won't have to fund any of the manufacturing or upfront marketing investment the way we have had to in Singapore.

Given the size of the market opportunity and the drive and commitment of SV More, we believe that the Philippines launch will be an important value inflection point for Firebrick and along with Singapore, provide a valuable success story to foster partnering of Nasodine in other markets.

**Slide 11:**

In September this year, and through our European regulatory consultants, we filed a marketing application for approval of Nasodine in Europe as a 'topical antiseptic for nasal use'. The initial evaluation phase is scheduled for completion on 19 December, after which we will have 90 days to respond to any objections and/or questions raised.

We also expect that active marketing in Singapore and approval in Philippines may allow us to attract partners and sell Nasodine in other Asian markets, including Indonesia, and potentially Korea, China and Thailand, which are all major pharmaceutical markets.

**Slide 12:**

While achieving all these market entries and market development goals, we knew we had to keep a tight rein on spending, because at the end of 2023 our cash reserves were limited and the market appetite for more investment in Firebrick at the time was understandably subdued. We recognised that we needed to first convince our shareholders and the market that our audacious pivot was realistic and as exciting as we believed it to be.

So in the last 12 months we have cut total operating expenses by more than 50% with the main savings in R&D and administrative overhead. This in part reflected our rapid transition from R&D

to commercialisation. However, it also involved significant cost-cutting that included reducing staff and consulting roles, while freezing executive salaries. This happened in a period where management bandwidth was severely stretched with everything that needed to occur around the launches in the US and Singapore.

Suffice to say, 2024 was a very challenging year, but also one that has made us leaner and stronger, and now we are extremely optimistic about Firebrick's future.

As one sign of that optimism, we brought on board Keith Shortall, the former head of J&J Consumer Health in Asia-Pacific to drive pharmacy distribution in Singapore; he has now achieved this goal, effectively 5 months ahead of schedule. We hope to continue his services in 2025 to drive distribution throughout Asia-Pacific.

**Slide 13:**

In 2025, we can expect significant sales growth out of Singapore driven by the Guardian pharmacy sales but also HCP sales; 2026 should see a further step up in sales as the other pharmacy chains and all the independent pharmacies are able to take and promote Nasodine as well. We also planning an important new Nasodine product to be launched towards the end of calendar 2025, which we believe will further excite the HCP and consumer market in Singapore.

Meanwhile in the US, where we are much more limited as to claims, we are already seeing good sales growth and expect that to continue in 2025 with various initiatives we have planned.

In the Philippines, there should be a stream of newsflow from our activities there, as we prepare to gain PFDA approval and launch into this important market.

Apart from sales in these markets, there is the potential for approval and partnering in Europe in 2025 and approvals or partnering in many other markets.

Overall and given where we were 12 months ago, your Board is now confident about the future of Firebrick and excited about its prospects in the coming year.