

17 April 2024

ASX Announcement

Nasodine Nasal Spray Launch in the USA

Firebrick Pharma Limited (ASX:FRE) (**Firebrick, Company**) is proud to announce that its product, **Nasodine® Nasal Spray** (“Nasodine”) is being launched in the United States today. Nasodine is now available to purchase from the Company’s US website (nasodine.com) and online promotion is commencing this week across the US.

In the US, Nasodine will be promoted for ‘nasal hygiene’ without any therapeutic claims. Based on legal advice obtained by the Company, this allows Nasodine to be marketed without FDA approval. Since 2020, multiple PVP-I nasal sprays have been introduced in the US and continue to be marketed this way.

“Nasodine will be the only PVP-I nasal spray in the US that is supported by demonstrated safety in clinical trials and a growing list of peer-reviewed publications,” said Firebrick Executive Chairman, Dr Peter Molloy.

“Our position has always been that if we can make Nasodine available, people will use it,” said Dr Molloy. “In a post-COVID world, where everyone is concerned about nasal hygiene, we believe Nasodine is the answer.”

In the US, Nasodine is manufactured for Firebrick by a contract manufacturer who recently completed their first US commercial batch of finished product. Warehousing and order fulfilment is provided by a third party logistics partner in the US. For marketing, Firebrick has engaged a US-based online marketing agency to develop and execute a social media advertising campaign.

Initially, Nasodine will be marketed online only, although in the future it is expected to be available in US pharmacies as well.

The Company has several other products in development and expects some of these to become available in the future for the US market.

“We plan to build a portfolio of products under the Nasodine brand and launch them in the US and other markets,” said Dr Molloy.

“Launching Nasodine into the world’s premier pharmaceutical market is a momentous event for our company, culminating more than 10 years of R&D and heralding our transition to a commercial pharmaceutical business,” said Dr Molloy.

This announcement was authorised by the Board of Firebrick Pharma Ltd.

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More information about the launch of Nasodine in the USA: Q&A

Packaging and presentation of Nasodine Nasal Spray in the United States

<p>Use</p> <p>For nasal hygiene, apply 3-4 sprays per nostril, up to 4 times daily.</p> <p>Nasodine Nasal Spray is a Povidone-iodine nasal cleanser to promote nasal hygiene.</p> <p>Directions for use</p> <ol style="list-style-type: none"> 1. Blow your nose before use. 2. Holding your head upright, gently insert the nozzle into one nostril, closing the other nostril with a finger. 3. Depress pump firmly while inhaling. 4. Replace the protective cap after use. <p>No need to shake the bottle before use.</p>	<p>Caution</p> <p>For adults and children 12 and older. Use only as directed. Do not use if you are allergic to any of the ingredients. Stop using and consult a doctor if you experience swelling, rash, difficulty breathing or other signs of allergic reaction. Consult a doctor before use if you have thyroid disease.</p> <p>Ingredients</p> <p>Water, PVP-iodine (0.5%), glycerin, menthol, alcohol, potassium iodate, potassium iodide, sodium phosphate, sodium hydroxide.</p> <p>25 mL (0.85 oz) Store below 86°F</p> <p>MADE IN THE USA BY Nasodine LLC Henderson, NV, 89052 For more information, visit Nasodine.com</p>	<div style="display: flex; justify-content: space-between;"> <div style="text-align: left;"> <p>Nasodine[®] Nasal Spray</p> </div> <div style="text-align: right; color: red;"> <p>Promotes optimal nasal hygiene</p> </div> </div>  <p style="text-align: center; color: red;">POVIDONE-IODINE Nasal Cleanser 25 mL (0.85 oz)</p> <p style="text-align: right; color: red;">Nasodine Nasal Spray eliminates nasal contaminants to promote nasal hygiene.</p>
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POVIDONE-IODINE
Nasal Cleanser
25 mL (0.85 oz)

Q. Is the product the same as the Nasodine formulation that was tested in clinical trials and shown to be safe?

A. Yes, the product formulation and packaging (bottle and pump) are identical.

Q. Under what corporate structure is Firebrick operating in the US?

A. The Company recently established a wholly owned US entity, **Firebrick Pharma, Inc.**, that provides it a legal corporate base in the US, and a daughter entity, **Nasodine LLC**, that is dedicated to the marketing of Nasodine brand products in the US. Nasodine LLC is based in Henderson, Nevada. This structure was recommended by the Company's US legal advisers and provides benefits and protections for the Australian entity, while also allowing it to open US bank accounts and compliantly engage in all the normal commercial arrangements needed to operate in the US. Dr Peter Molloy and Dr Stephen Goodall are directors and form the current board of Firebrick Pharma, Inc.

Q. What is the retail price of Nasodine in the US?

A. The online retail price for Nasodine is US\$ 24.99, although discounts may apply. For more information visit: www.nasodine.com

Q. How much stock of Nasodine do you have and how quickly can you top up if sales are above your expectations?

A. We currently have around 30,000 units available for sale and have already scheduled follow-on production orders in the event that demand exceeds current supply.

Q. If no therapeutic claims can be made, what can you say to promote Nasodine?

A. In the US, we describe Nasodine as a nasal cleanser with the power of povidone-iodine. It can help maintain nasal hygiene by eliminating germs, allergens and other airborne threats that disrupt nasal hygiene. See the nasodine website for more information.

Q. How is it used, who can use it and are there any restrictions on its use?

A. As per our clinical trials, Nasodine Nasal Spray is recommended to be applied as 3-4 sprays per nostril, up to 4 times daily whenever people feel concern about threats to nasal hygiene, such as when commuting, when people around them are sick and while travelling; it can be used by adults and children older than 12. See the nasodine website for more information.

Q. Why isn't Nasodine available in Australia?

A. Nasodine has not been approved for marketing in Australia as a treatment for the common cold. Firebrick intends to continue its discussions with the Therapeutic Goods Administration (TGA) about potential pathways to Nasodine's approval in Australia. In the meantime, Australians can buy Nasodine from the US website and import it for personal use under the TGA's Personal Importation Scheme: <https://www.tga.gov.au/products/unapproved-therapeutic-goods/personal-importation-scheme>. Under the scheme, the maximum number of bottles that an individual can order at one time for personal use is a 3-month supply at the maximum recommended dose (16 bottles).

Q. What do you expect the level of sales to be in the US?

A. We are not providing sales forecasts, but we are optimistic, given that the US is a large market, that there is an established opportunity for PVP-I nasal sprays, and that Nasodine has important benefits over the existing products.

About Firebrick (ASX:FRE)

Firebrick Pharma is a pharmaceutical innovator focused on developing and commercialising novel formulations and uses of povidone-iodine. The Company has successfully developed a povidone-iodine nasal spray (Nasodine®) and filed international trademarks and multiple patents on the product. The Company has also completed six clinical trials for the nasal spray, which 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.

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