

R H I N O M E D

RHINOMED'S NEW SNORING PRODUCT MUTE™ RECEIVES MAJOR REGULATORY APPROVALS

- **Mute successfully registered with US Food and Drug Administration (FDA) as medical device**
- **Receives clearance from Therapeutic Goods Administration (TGA) to begin selling in Australian market**
- **Receive CE Mark opening up opportunity to sell directly into European markets**

Melbourne, Australia. December 3, 2014.

Melbourne technology firm, Rhinomed (ASX:RNO) is pleased to announce that it has successfully completed the testing and technical documentation that has enabled its new novel snoring and sleep quality product - Mute™ to gain acceptance with the US Food and Drug Administration (FDA), European authority (CE Mark) and the Australian Therapeutic Goods Association (TGA).

The Mute™ is an internal nasal dilator that increases airflow, which allows people to breathe more and snore less.

In a recently independently conducted trial results announced 2nd December 2014, the Mute™ achieved the primary endpoints – significant reduction in snoring severity, volume, frequency and duration. The trial (n=236) exceeded in pre-specified criteria showing clear improvement in reported sleep quality in both snorer and partner.

Successfully registering the Mute™ with the US FDA as a Class 1, 510(k) exempt medical device product allows the Mute™ to be sold online and in store within the United States of America. A market where, according to the US National Institutes of Health (NIH), close to 70% of the adult population suffers from poor sleep quality.

Conforming to the regulatory and manufacturing requirements necessary to receive a CE Mark opens the way for the Mute™ to be marketed directly to European consumers, as well to consumers in the four member states of the European Free Trade Association and in Turkey.

Australian TGA registration ensures that the company can commence its test-marketing program immediately. This is a critical step in the planned roll out of the Mute™ technology.

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Rhinomed CEO Michael Johnson said, “The testing, process and steps we put in place for the our first product - the Turbine™ - ensured that our second technology - Mute™ was right from the start designed, tested and manufactured to fully comply with the most rigorous of regulatory requirements. Our internal team and regulatory advisors have done a great job of ensuring that we built the required testing and quality control processes that have enabled the Mute™ to comply with ISO Standard 13485 for the development of medical devices and to be successfully registered with the European, US and Australian Authorities.”

The Mute™ is available to pre-order online at www.mutesnoring.com

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About Rhinomed Limited (ASX:RNO)

Rhinomed Limited is a medical technology firm with a focus on nasal, respiratory and breathing management technologies. The company is seeking to monetise applications of its BreatheAssist technology portfolio in the Sport, Sleep, Wellbeing and Drug Delivery markets. For more information go to: <http://www.rhinomed.com.au>

About Mute

Snoring disrupts the sleep quality and the lives of millions of people worldwide.

Mute has been designed to give Snoring the silent treatment. Mute is a unique nasal respiratory technology that will help you to breath more and snore less.

Mute is easy to use and discreet. It has been designed to fit the anatomy of your nose and to gently expand each nostril giving you more air.

Made from ultra-soft medically approved polymer materials, Mute increases the volume of air travelling through the nose during sleep, preventing congestion and encouraging nasal breathing – factors critical to a reduction in snoring and a better quality of sleep. For more information visit www.mutesnoring.com