# RHINOMED

# RHINOMED'S MUTE™ SUCCESSFUL IN DEMONSTRATING EFFICACY AND BENEFIT IN SNORING TRIAL

#### **HIGHLIGHTS:**

- Achieved primary endpoint significant reduction in snoring severity, volume, frequency and duration.
- Independently conducted trial (n=236) exceeded pre-specified criteria showing clear improvement in reported sleep quality in both snorer and partner.
- Results validate Mute<sup>™</sup> as a compelling solution to unmet needs in the billion dollar global OTC snoring and nighttime nasal congestion market.
- Applications to register the Mute<sup>™</sup> with the FDA, TGA and European Authority have been submitted.
- Commercial launch of Mute<sup>™</sup> is now imminent.
- Submission made for mild moderate Sleep Apnoea ethics approved trial to be carried out at Monash University in early 2015.

### Melbourne, Australia. December 2, 2014.

Melbourne technology firm, Rhinomed (ASX:RNO) today announced the topline results from its independent trial in snoring, sleep quality and night time nasal congestion which successfully demonstrated significant benefit of its new Mute nasal technology. The Company has submitted applications to the European, US and Australian regulatory authorities that will allow sale of the Mute technology to commence.

The OTC snoring, sleep quality and night time nasal congestion market is a multi-billion dollar global market in which there are limited effective solutions. According to the National Sleep Health Foundation 40% of Australian males and 30% of Australian women snore. This has a significant impact on sleep quality of both the snorer and their partner.

The Mute<sup>™</sup> technology is a nasal breathing aid that has been designed to increase airflow in and out of the nose and upper airway and is designed to alleviate the incidence and severity of snoring and improve sleep quality. 79% of the subjects in the trial reported that their partners snoring affected their ability to get an uninterrupted nights sleep with 54% reporting that it had a high or extreme impact on their physical wellbeing and energy levels.

The independently conducted in- home trial was carried out in November 2014 and was the first trial that assessed the impact of the Mute technology on the snoring and sleep quality of the snorer and the impact of this on their bed partner. Importantly, inclusion criteria included an opt-out of the trial if participants

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had an objection to placing something in their nose. Only 6% of eligible subjects elected to discontinue for this reason.

#### **Trial Methodology**

The independently conducted in-home trial involved 118 subjects aged 35-65 and their partners (n= 236). Diagnosed sleep apnoea patients were screened out of selection, as were those whose snoring emanates from their throat or lower airways and those whose BMI placed them in a morbidly obese category. Snoring subjects were asked to assess their sleep quality before the use of the technology and then again during five days of continual use of the Mute technology. The trial was also enriched with their partners (118) completing an assessment of their sleep quality before and during the trial.

End points included in the study captured measures across sleep quality, general wellbeing and sleep hygiene and also captured responses to specific questions regarding competitive products. Rhinomed will publish and present a full analysis of the results at the consumer launch.

## Topline impact of Mute™

The primary endpoint was to evaluate the impact of the Mute technology on both snoring and sleep quality. Evidence of benefit in the Snorer group was clear with 75% of respondents reporting a reduction in their snoring and 78% reporting an improvement in their ability to breathe at night. The Partner group reported a significant reduction in snoring severity (73%), volume (67%), frequency (63%) and duration (65%). By day three of the trial 72% of all subjects reported being comfortable with the product.

Additionally, sleep quality scores improved within both the Snorer group and the Partner group. The Snorer group who reported good and or excellent sleep quality increased from 21% pre-trial to 57% during the trial. The Partner group reporting good or excellent sleep quality increased from 14% pre-trial to 60% during the trial.

Rhinomed CEO Michael Johnson commented. "Snoring is a problem that afflicts millions of people world wide. It has a clear and undeniable impact on the sleep quality of snorers and their partners. The trial clearly and unequivocally shows that the Mute technology can improve the breathing of the snorer and that it may alleviate snoring. This is genuinely exciting news for millions of couples who are awoken each night by snoring. The trial results have exceeded our expectations and we look forward to receiving the appropriate approvals and registration advice from the relevant regulatory authorities that will allow Mute to be available to the millions of couples who are currently impacted by snoring."

Upon receiving the relevant regulatory approvals and registrations the Mute will be available initially online before a broader roll out through the pharmacy and grocery retail sector. Mute is available to preorder online today from <a href="https://www.mutesnoring.com">www.mutesnoring.com</a>

The imminent launch of Mute meets the Company's milestone to deliver a new product into the OTC sleep market before the end of the year. Rhinomed is currently awaiting ethics approval for the clinical trial of its all new sleep apnoea technology. This trial is due to commence in March 2015 with results due in the later half of the year.

"We have a compelling technology pipeline and are building a portfolio of increasingly accepted technologies and brands that provide a comprehensive range of solutions to significant unmet needs right across the sleep and respiratory markets." Mr Johnson said. "The Turbine has opened the door for nasal technology and Mute will ensure that our unique technology and approach will gain an even greater foothold in the lives of our customers."

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## The Mute<sup>™</sup> 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, all natural 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

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