

# ASX Release

---

## **SUDA EXPANDS PATENT COVERAGE FOR SUD-003 AND SUD-004**

**SUDA has been granted its first patent in Japan and has had a patent granted in Russia for “Oral Spray Formulations and Methods for Administration of Sildenafil”**

**PERTH, AUSTRALIA – 3 March 2017:** SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, today announces that the Japan Patent Office has issued SUDA’s first Japanese patent for its sildenafil-based products, SUD-003 and SUD-004. The patent (Japanese Patent 6047174) is titled: *Oral Spray Formulations and Methods for Administration of Sildenafil*.

A patent application directed to similar subject matter has also been approved in Russia (Russian Patent Application 2014123435).

Similar patents have been granted in the USA, Australia, New Zealand and Singapore; and patent applications are pending in other jurisdictions. These patents provide protection until 2032. The claims of these patents cover the administration of sildenafil, being the active pharmaceutical ingredient in SUD-003 and SUD-004, via an oral spray for the treatment of sexual dysfunction induced by Selective Serotonin Reuptake Inhibitor (SSRI) anti-depressants and for the treatment of pulmonary arterial hypertension (PAH).

The global Erectile Dysfunction (ED) drugs market was valued at over US\$ 4.4 billion in 2014. It affects about 150 million men worldwide and about 50% of men aged 40-88 suffer from the disorder with the prevalence increasing with age.

SSRI-induced sexual dysfunction is a common condition, affecting up to 75% of patients taking SSRIs such as Prozac®, Zoloft® and Paxil®.

PAH is a disease that affects blood pressure between the heart and the lungs. PAH occurs at all ages; however, the incidence of it increases with age. It is more common among women and people aged over 75, and is often linked to heart failure. The PAH market is estimated to be growing at a CAGR of 5% and reached US\$ 3.6 billion in 2015.

Japan has the largest elderly population in the world and ED is a major and growing health problem. The age-adjusted prevalence of ED prevalence in Japan has been estimated by several published scientific papers to be around 34%.

In six regions of the Russian Federation, a recent survey of men aged 20-77 years (N = 1,225) in community and healthcare settings (without established urological disease) found that ED was present in 49% of men.

Mr Stephen J Carter, SUDA's CEO and Managing Director, commented: "We are delighted to have been issued this patent in Japan and to have had it approved in Russia. It reinforces our proprietary position covering the oral spray delivery of sildenafil for erectile dysfunction and pulmonary arterial hypertension. If we consider all countries where this patent or similar patents have been granted, then we have patent protection for SUD-003 and SUD-004 covering approximately 60% of the world's healthcare market. We are finalising our new-generation formulation of SUD-003 with enhanced bioavailability and onset of action in preclinical models. In 2017, we anticipate continuing and furthering our discussions with prospective pharmaceutical partners globally who have shown interest in licensing our novel oral spray treatment for erectile dysfunction."



**Further information:**

**STEPHEN CARTER**

**CHIEF EXECUTIVE OFFICER / MANAGING DIRECTOR**

**SUDA LTD**

Tel: +61 8 6142 5555

[sjcarter@sudaltd.com.au](mailto:sjcarter@sudaltd.com.au)

**NOTES TO EDITORS:**

**About SUDA LTD**

SUDA LTD (ASX: SUD) is a drug delivery company focused on oro-mucosal administration, headquartered in Perth, Western Australia. The Company is developing low-risk oral sprays using its OroMist® technology to reformulate existing pharmaceuticals. The many potential benefits of administering drugs through the oral mucosa (i.e.: cheeks, tongue, gums and palate) include ease of use, lower dosage, reduced side effects and faster response time. SUDA's product pipeline includes Zolpimist™, a first-in-class oral spray of zolpidem for insomnia. Zolpimist™ is marketed in the USA and SUDA has rights to the product outside of North America. SUDA's most advanced development-stage product, ArTiMist®, is a novel sublingual malaria treatment for children. In a Phase III trial, ArTiMist® was shown to be superior to intravenous quinine. Other products in development include oral sprays for the treatment of migraine headache, chemotherapy-induced nausea and vomiting, erectile dysfunction and pre-procedural anxiety. For more information, visit [www.sudaltd.com.au](http://www.sudaltd.com.au)