SUDA LTD

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# ASX Release

## SUDA LTD SHAREHOLDER UPDATE

- Progressing business development activities across the portfolio
- Meetings scheduled with lead prospects at BIO Convention in June 2015
- ArTiMist™ pre-referral clinical trial protocol to be presented to WHO
- ZolpiMist® attracting interest from multiple prospective licensees
- Amherst Pharmaceuticals progressing SUD-002 New Drug Application in the USA
- Finalising briefing package for FDA meeting regarding SUD-001 development plan
- Developed second-generation formulation of SUD-003 with enhanced properties

**PERTH, AUSTRALIA – 9 June 2015**: SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, has observed the weakness in the Company's share price since the placement on 27 March 2015 to raise gross proceeds of $5.3 million. The Company has also noted a lower volume of trading activity over this period. This reduction in liquidity may have contributed to the decline in the share price. Whilst this is disappointing, it is not in any way reflective of the operating position of SUDA. The Company today provides an update to shareholders on its core OroMist® oro-mucosal drug delivery business.

SUDA continues to advance its business development activities with prospective partners and licensees for the Company's pipeline of first-in-class oral sprays and its proprietary OroMist® technology.

SUDA will be part of the Australian biotech delegation that is attending and exhibiting at the BIO International Convention, being held at Philadelphia, PA on 15-18 June 2015. The convention is the largest, most influential global industry conference, which attracts the biggest names in the pharmaceutical and biotech sector, offering key networking and partnering opportunities. During the BIO Convention, SUDA is meeting with many of its lead prospective partners within the industry.

Interest from the industry spans the Company's clinical-stage oral sprays, as well as the application of SUDA's OroMist® drug delivery technology to other pharmaceuticals:

**ArTiMist™: treatment for malaria**

SUDA is finalising the design of a pivotal clinical trial of the Company's antimalarial sublingual spray, ArTiMist™, as an early interventional treatment in the pre-referral

setting of paediatric malaria. The trial protocol will be presented to the World Health Organisation as a first step towards securing funding for the trial from global philanthropic groups.

Negotiations with a number of pharmaceutical companies regarding ArTiMist™ are progressing, although are unlikely to complete before 30 June 2015. However, the Board remains confident in securing a deal that provides a significant return on the Company's investment in the programme.

**ZolpiMist®: treatment for insomnia**

Since entering the cross-license and collaboration agreement with Amherst Pharmaceuticals in January 2015, SUDA has added ZolpiMist® to its business development activities. Discussions are advancing rapidly with specialty pharmaceutical companies in Asia and Europe who are interested in licensing this novel US-approved oral spray for the treatment of insomnia.

**SUD-002: treatment for nausea and vomiting**

Amherst Pharmaceuticals, SUDA's licensee of SUD-002 in North and South America, has reviewed SUDA's draft New Drug Application (NDA) for the product in the USA. Amherst has been advised by its Regulatory Consultant that the clinical data are sufficient for registration and the company is scheduling a pre-NDA meeting with the FDA in the second half of CY2015. The completion of the regulatory dossier by Amherst will support SUDA's efforts to secure partners for SUD-002 in territories outside of the Americas.

**SUD-001: treatment for migraine**

The FDA has accepted SUDA's request for a Type C meeting to discuss the pivotal development plan for SUD-001. The Company's project management, clinical and regulatory teams, together with the experts on SUDA's Clinical Advisory Board for SUD-001, are completing the briefing package to be submitted to the FDA. A formal response from the FDA is expected in the third quarter of CY2015. Agreement with the US regulatory agency on the final stage of development for SUD-001 will strengthen SUDA's negotiating position with partners by quantifying the cost and time to register the product for commercialisation in the USA, which is the world's largest pharmaceutical market.

**SUD-003: treatment for erectile dysfunction.**

SUDA's laboratory team has been optimising the formulation of SUD-003 to enhance the taste and the permeation characteristics of the drug across the oro-mucosal membrane.

The second-generation formulation, developed by the Company's scientists, is flavoured with peppermint and spearmint, thus providing a pleasant taste for the patient. In addition, the data from *in vitro* studies, using a synthetic membrane model, show that the second-generation oral spray is absorbed more rapidly and efficiently than the original formulation of SUD-003. This suggests that the new formulation has the potential for

quicker onset of action, which is a valuable attribute for patients with erectile dysfunction. The Company plans to report the full results from the preclinical studies comparing the new formulation with the original SUD-003 in the next few weeks.

At the request of SUDA's prospective pharmaceutical partners, the Company is designing a development plan for the second-generation formulation, which will be presented to the FDA in the second half of CY2015 at a Type C meeting. This, again, will add value to the product and assist SUDA's partnering discussions.

SUDA's CEO, Mr Stephen Carter, commented: "I am pleased by the progress that we are making across our oro-mucosal drug delivery business. Next month we will be attending BIO 2015, which provides another valuable opportunity for us to highlight our assets and capabilities as part of our ongoing marketing and commercialisation efforts."

"SUDA is better positioned today than at any point in the four and a half years that I have been involved with the Company. We have established a pipeline and platform technology that has the potential to deliver significant returns for our shareholders."

"The global pharmaceutical industry is driven by the highest standards of compliance and due diligence, with the commercial reality being that deals in this space have long lead times, but the returns in completed transactions are commensurate. The absolute timing of licensing deals is not always in our control, but we are working hard to achieve our stated goals at the earliest opportunity, whilst ensuring that we secure optimal value for our assets."

**Further information:**
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**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 novel oral spray formulations of existing off-patent pharmaceuticals using its proprietary OroMist® drug delivery technology platform. The many potential benefits of administering drugs through the oral mucosa (ie: 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® has been approved in the USA and SUDA has rights to the product outside of the Americas and South Africa. 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