

# ASX Release

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## SUDA LTD: INVESTOR PRESENTATION

**PERTH, AUSTRALIA – 25 February 2016:** SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, today announces that Mr. Stephen Carter, Chief Executive Officer and Managing Director, is presenting today at the Wholesale Investor – Life Science and Healthcare Showcase 2016 in Sydney.

The presentation follows.



**Further information:**

**STEPHEN CARTER**

**CHIEF EXECUTIVE OFFICER / MANAGING DIRECTOR**

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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 low-risk oral sprays using novel formulations of existing off-patent pharmaceuticals. 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® 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)



Drug delivery through the oral mucosa

**Stephen Carter – Managing Director/Chief Executive Officer**

**February 2016**

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# Overview

- SUDA (ASX: SUD) is a drug delivery company commercialising low-risk pharmaceuticals
- Extensive proprietary technology, expertise and knowhow in formulating and manufacturing oral sprays
- Multiple patent families covering approx. 300 widely-used drugs formulated into oral sprays
- SUDA's first-in-class oral sprays have demonstrated meaningful advantages vs. standard-of-care tablets in multiple clinical studies
- Multiple oral sprays for large markets – insomnia, malaria, migraine, erectile dysfunction, chemo-induced nausea

## Oro-mucosal delivery | Better patient experience

- Oral mucosa is the lining of the mouth, richly supplied by blood vessels
- Oral cavity is ideal for systemic therapy, avoids metabolism in the gut
- Unique advantages of oral sprays compared to tablets
  - Faster onset of action
  - Reduction in dose level and dose variability
  - Enhanced patient convenience
  - Avoids the need to swallow or be taken with water <sup>1,2</sup>



*“Our oral sprays potentially offer improved efficacy and a better outcome for patients”*

1. >40% of adults experience difficulties swallowing
2. >50% of children (6 to 11 years) have problems swallowing tablets

# Pipeline | Targeting large markets

Product	Active Ingredient	Pre-clinical	Clinical	Marketing Approval	Mkt Size	Partnerships (Incl. territories)
*ZolpiMist®	Zolpidem	Insomnia			\$2.1bn	
ArtiMist™	Artemether	Malaria			>\$500m	
SUD-002	Ondansetron	Chemotherapy induced nausea & vomiting			\$2.5bn	Kwang Dong (Korea)
SUD-001	Sumatriptan	Migraine headache			\$3.2bn	
SUD-003 DuroMist™	Sildenafil	Erectile dysfunction			\$4.1bn	
SUD-004	Sildenafil	Pulmonary arterial hypertension			\$2.7bn	
SUD-005	Midazolam	Pre-procedural anxiety			\$170m	

\* SUDA has an exclusive license to ZolpiMist® in all countries excluding North America

# ArTiMist™ | Anti-malarial sublingual spray



- ArTiMist™ sublingual artemether for treatment of children with malaria
- Completed Phase III trial vs. intravenous quinine for severe paediatric malaria
- Primary endpoints were achieved showing superiority to quinine
  - Patients with >90% parasite reduction at 24hrs: 94% with ArTiMist™ vs. 39% with quinine
  - Total parasite clearance: 30 hours with ArTiMist™ vs. 68 hours with quinine
- Thompson Reuters identified ArTiMist™ as one of the world's Top-5 most promising Phase III drugs in 2011
- Expanding the use of ArTiMist™ as an early interventional 'pre-referral' therapy
- Pursuing adoption by WHO in Treatment Guidelines for severe paediatric malaria
- Three peer-reviewed papers published in prestigious US medical journal in 2015

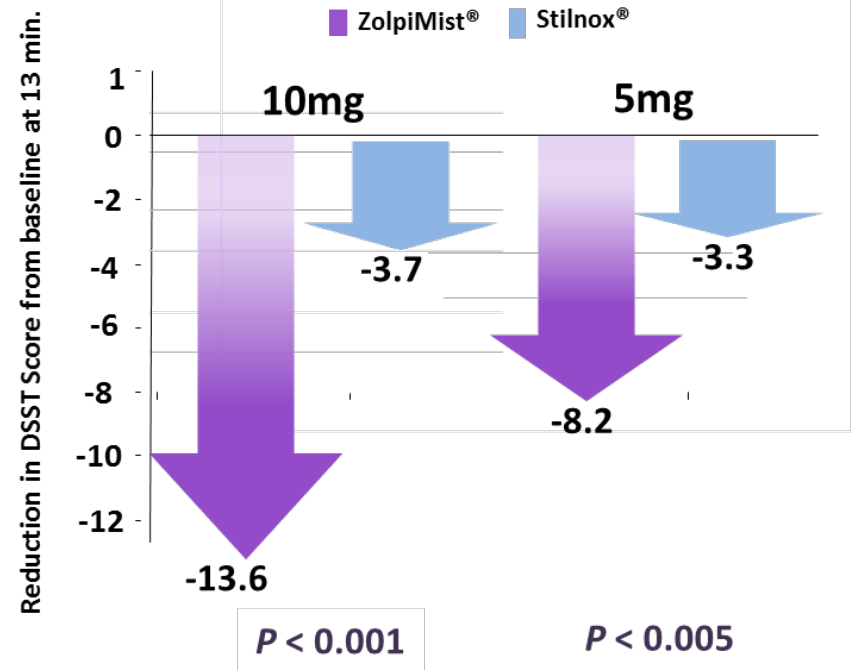


*ArTiMist™ has huge potential as an early interventional treatment for children with malaria*

# ZolpiMist® | Sleep response

- ZolpiMist® is a first-in-class oral spray of zolpidem for treatment of insomnia
- Has been approved by the FDA and licensed to SUDA for the world excluding North America
- Global sleeping tablet market is approx. \$2.1bn. Zolpidem has 70% market share
- Rapidly absorbed with detectable plasma levels immediately following administration
- Requires no further development work for approval in most countries
- Progressing licensing discussions in several territories with competitive interest

## Head-to-head drowsiness study of ZolpiMist® against market leading Stilnox® tablets



**ZolpiMist® demonstrated significant faster onset of sedation compared to Stilnox® tablets**



## SUD-001 | Oral spray for migraine

- SUD-001 is first oral spray of sumatriptan (GSK's Imitrex® tablet) for rapid relief of migraine headache
- Migraine market is approx \$3.2 billion. Sumatriptan has 50% market share
- Phase II study showed quicker onset of action and less drug needed to achieve pain relief vs. Imitrex® tablet
- Primary Market Research suggests prescribers & payers see important role for SUD-001 in patients with nausea, GI problems or sudden onset headaches
- Successful meeting with FDA in July 2015 regarding pivotal development plan
  - FDA accepted novel pharmacokinetic trial design, thus avoiding the need for costly efficacy studies prior to approval



*SUD-001 has superior profile to market leading Imitrex® tablet*

## SUD-002 | Oral spray for cancer-induced nausea & vomiting

- SUD-002 is first oral spray of ondansetron (GSK's Zofran® tablet) to treat nausea & vomiting induced by chemotherapy or radiotherapy
- Global anti-emetics market is approx. \$2.5 billion
- SUD-002 evaluated in >300 patients in multiple trials
  - SUD-002 was bioequivalent with quicker onset vs. Zofran® tablet
- Clinical data potentially sufficient for registration
- SUDA is planning pre-NDA meeting with the FDA in 2016



*SUD-002 has superior profile to market leading Zofran® tablet*

## SUD-003 | Oral spray for erectile dysfunction

- SUD-003 (DuroMist™) is first oral spray of sildenafil (Pfizer's Viagra® tablet) for erectile dysfunction
- ED market is >\$3 billion. Viagra® is world's top selling ED drug
- First-generation SUD-003 showed superior bioavailability vs. Viagra®
- Optimised second-generation formulation with mint flavour and enhanced absorption characteristics
  - Anticipate quicker onset of action and enhanced bioavailability
- Plan to lodge new IP and publish *ex-vivo* and *in-vivo* study results in 2016



*DuroMist™ offers ease of administration and potentially faster onset of action than Viagra® tablet*

## Oro-mucosal delivery | Comparable deals

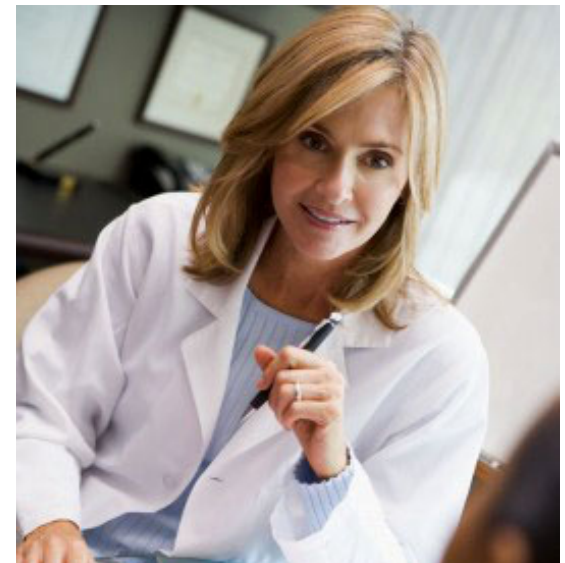
- Collaboration/trade sale deals usually structured with multiple payments:
  - Upfront payment on signature
  - Milestone payments on clinical and regulatory events
  - Milestone payments on achieving sales targets and royalties<sup>1</sup> on sales

COMPARABLE COLLABORATION/TRADE SALE DEALS				
Generic drug	Sumatriptan	Midazolam	Ondansetron	Zolpidem
Delivery Technology	Nasal spray	Oral buccal solution	Oral soluble film	Sublingual tablet
Disease	Migraine	Seizures	Nausea/vomiting	Insomnia
Licensors/Licensee	Optinose/Avanir	Auralis/ViroPharma	MonoSol/Strativa	Orexo/MEDA
Territory	North America	Global	USA	Global
Upfront Payment	US\$20M	US\$15M	US\$3M	US\$20M
Milestones	US\$90M	US\$10M	US\$24M	Undisclosed
Royalties on Sales	Yes, tiered	No	Yes, tiered	Yes, double digit
Date Signed	July 2013	May 2010	Sept 2008	April 2008

1. Trade sale deals do not include royalties

## 2015 Highlights | Westcoast growth & investment

- Wholly-owned subsidiary, surgical and medical supplies, based in Western Australia
- Four core business units servicing:
  - Aged care
  - Hospitals
  - Allied health
  - Mining
- FY2015 revenue (excluding detention centres) increased 23% to \$5.7 million vs. previous year
- Investing in new higher-margin revenue streams



# Key data & financial snapshot

## Corporate key data

ASX Code	SUD:AU
Current share price (Australian \$)	\$0.027
52 week range	\$0.023-\$0.047
Average volume (30-day)	>1 million
Market cap	\$30 million

## Financials *(Year-end: June)*

Revenue FY2015	\$5.7 million
Net operating cash loss FY2015	(\$3.2 million)
Net cash 31 December 2015	\$3.4 million
Shares in issue	1,141 million
Convertible notes	\$1.6 million convertible to 54 million shares

# Management & Directors

## **Stephen Carter - Chief Executive Officer and Managing Director**

>25 years' pharmaceutical industry experience with multi-national pharmaceutical and listed public companies

## **Joseph Ohayon – Chief Financial Officer and Director**

>20 years' experience in financial roles including 12 years within health-related industries

## **Nick Woolf – Chief Business Officer**

>20 years' experience in pharma/biotech investment banking and industry with extensive BD knowledge

## **Carol Worth – Technical Manager**

>25 years' experience in formulating/developing drugs and managing accredited laboratories

## **Non-Executive Directors**

### **Michael Stewart - Non-Executive Chairman**

Broad corporate and management background and involvement in bilateral donor funded and World Bank co-financed aid projects

## Summary

- World-leading proprietary technology for reformulating drugs into high-value oral sprays
- Pipeline of oral sprays offering superior profiles (eg: faster onset) than standard of care
- Targeting large markets with short timelines for development
- Strategy for rapid value creation through collaborations or trade sales
  - Anticipate first cash inflow from licensing deals in FY2015/16
  - Anticipate first royalty streams from product sales in FY2016/17



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