

# ASX Release

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## SUDA LTD: AUSBIOTECH PRESENTATION

**PERTH, AUSTRALIA - 25 September 2014:** SUDA LTD (ASX: SUD) today announces that Mr. Stephen Carter, Managing Director and CEO, and Mr. Nick Woolf, Chief Business Officer, are presenting at the AusBiotech “Broker Meets Biotech” event held today at Flinders in the City in Adelaide at 4.00pm (GMT+9.30).

The event is designed to provide listed and IPO-ready companies opportunities to present to a captive audience of brokers and investors. Over 50 brokers and investors are scheduled to attend the event.

The presentation follows.



**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 low-risk oral sprays using novel formulations of existing off-patent 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 most advanced product is a novel sub-lingual treatment, ArTiMist™, for severe malaria in children. In a Phase III trial, ArTiMist™ was shown to be superior to intravenous quinine. Other development stage products include oral sprays for the treatment of migraine headache, erectile dysfunction and chemotherapy-induced nausea and vomiting.

# SUDA LTD

Drug delivery through the oral mucosa

**Nick Woolf – Chief Business Officer**

**BROKER MEETS BIOTECH, ADELAIDE  
25 September 2014**

**SUDA LTD**

## Disclaimer

The purpose of the presentation is to provide an update of the business of SUDA LTD (ASX:SUD) ['SUDA']. These slides have been prepared as a presentation aid only and the information they contain may require further explanation and/or clarification. Accordingly, these slides and the information they contain should be read in conjunction with past and future announcements made by SUDA and should not be relied upon as an independent source of information. Please contact SUDA and/or refer to the Company's website for further information.

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## Overview

- SUDA (ASX: SUD) is a drug delivery company commercialising low-risk pharmaceuticals
- World-leading technology for reformulating drugs into oral sprays with faster onset of action
- Multiple patent families covering approx. 300 widely-used off-patent drugs
- Breakthrough sub-lingual spray for treatment of children with severe malaria - completed Phase III trial
- Multiple oral sprays for large mainstream markets – migraine, erectile dysfunction, chemo-induced nausea
- Strategy for rapid commercialisation through trade sales or collaborations

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## Oro-mucosal delivery | Better patient experience

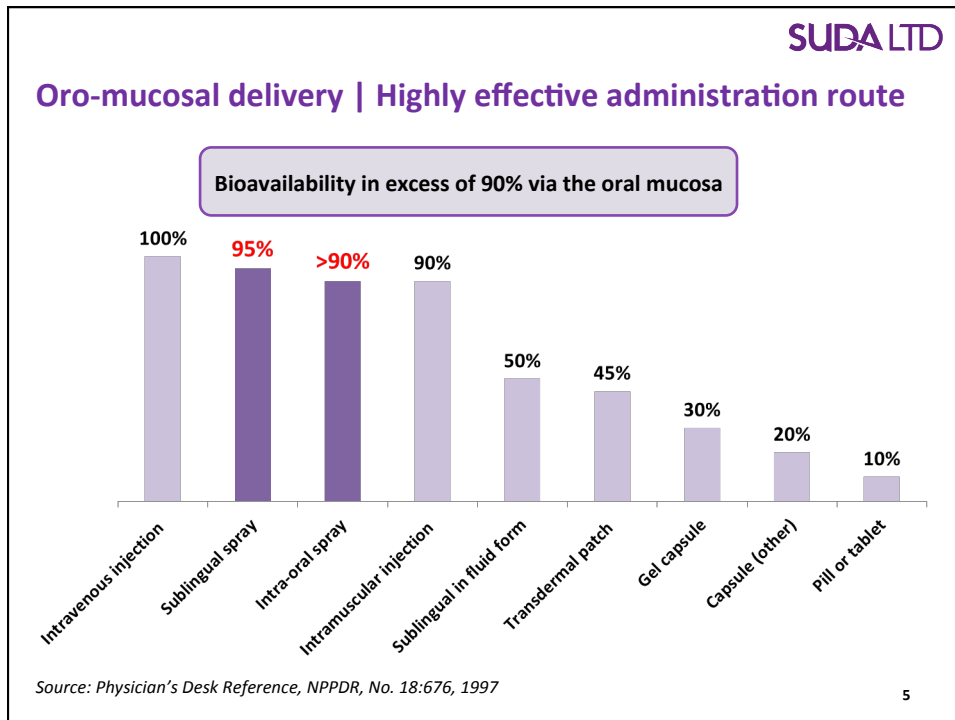
- Oral mucosa is the lining of the mouth, richly supplied by blood vessels
- Unique advantages of oral sprays compared to tablets
  - Faster onset of action
  - Reduction in dose level and dose variability
  - Enhanced patient convenience
  - Avoids the need to swallow or be taken with water <sup>1,2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

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### Oro-mucosal delivery | Platform technology

- Technology for producing proprietary OroMist oral spray formulations
- Experience with different pump systems - air-activated pumps and propellant-driven aerosol sprays
- Experience with different containers - multi-dose and single-unit
- Expertise with a range of flavoring and taste modifying agents, - peppermint, spearmint, citrus oils, fruit flavours, honey and sweeteners
- Expertise with penetration enhancers to increase permeability via mucosa

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### Low-risk pipeline targeting large markets

Product	Active Ingredient	Pre-clinical	Clinical	Marketing Approval	Market Size
ArTiMist™	Artemether	Malaria			>\$500m
SUD-001	Sumatriptan	Migraine headache			\$3.2bn
SUD-002	Ondansetron	Chemotherapy induced nausea & vomiting			\$2.5bn
SUD-003 DuroMist™	Sildenafil	Erectile dysfunction			\$3.4bn
SUD-004	Sildenafil	Pulmonary arterial hypertension			\$4.5bn
SUD-005	Midazolam	Pre-procedural anxiety & epilepsy			\$3.6bn

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### 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
  - >90% parasite reduction at 24hrs: 96% of ArTiMist™ patients vs. 41% of quinine patients
  - 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*

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## ArTiMist™ | Progressing to registration

- Expanding the use of ArTiMist™ as an early interventional 'pre-referral' therapy
  - Clinical Advisory Board is designing a clinical protocol for 'pre-referral' use of ArTiMist™
  - Support and interest in the study from Medicines for Malaria Venture
  - Objective to secure clinical funding from WHO and philanthropic funds
- World Health Organisation reports 640,000 deaths annually from malaria



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

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## SUD-001 | Oral spray for migraine headache

- 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
- Evaluated in >40 patients showing safety and superiority to Imitrex® tablet
- Primary Market Research suggests prescribers & payers see important role for SUD-001 in patients with nausea, GI problems or sudden onset headaches



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

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**SUD-002 | Oral spray for chemo-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 vs. Zofran® tablet
- Clinical data potentially sufficient for registration
- Tablets are not ideal when patients are vomiting



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

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**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
- SUD-003 trial in 24 males showed safety and bioequivalence vs. Viagra®
- Developing second generation formulation with mint/vanilla and absorption enhancers
- Potential for faster onset as direct absorption avoids metabolism in gut

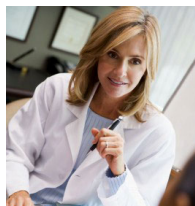


*DuroMist™ offers ease of administration and potentially faster onset of action than Viagra® tablet*

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### Westcoast Surgical | Rapid growth

- Wholly-owned subsidiary is a sales and logistics operation for medical devices and consumables based in Western Australia
- Five business units: Federal Government funded organisation, Aged Care, Hospitals, Allied Health and Mining
- Experiencing strong growth in revenue and profitability
- FY2014 revenue increased 115% to \$8.8 million vs. previous year



*“Westcoast has entered a new era in its operations”*

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### Westcoast Surgical | New revenue drivers



HEMOSTYP®

- Launched premium range of Lille incontinence products for Aged Care
- Launched HemoStyp® wound healing gauze, targeting defence forces, police and ambulance services
- Expanded to East coast, expected to add \$3-4 million in annual revenue

Westcoast's positive cash flow contributing to SUDA's financial sustainability

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## Key data & financial snapshot

### Corporate key data

ASX Code	SUD: AU
Current share price (Australian \$)	\$0.055
52 week range	\$0.026-\$0.086
Average volume (30-day)	1.1 million
Market cap	\$50 million

### Financials (Year-end: June)

Revenue (FY2014)	\$8.8 million
Net loss (FY2014)	(\$2.1 million)
Pro-forma <sup>1</sup> net cash (30 June 2014)	\$5.4 million
Shares in issue <sup>1</sup>	981.05 million

1. Shares in issue and pro-forma net cash include 28.2m options exercised at \$0.05 on 30 June 2014 and final tranche (\$100,000) of funding from Bergen Global Opportunity Fund

## Commercialisation goals | Key value-inflection points

Building competitive interest in our key clinical assets

ANTICIPATED EVENT	ANTICIPATED TIMING		ACHIEVED
Conduct primary market research on lead products	H1 CY2014	✓	March 2014
Initiate outreach to Pharma industry	H1 CY2014	✓	March 2014
Appoint Clinical Advisory Board for ArTiMist™	H1 CY2014	✓	April 2014
ArTiMist™ trade sale or out-licensing deal	H2 CY2014		
First oro-mucosal out-licensing deal	H2 CY2014		

**“The team is working hard to achieve our business development goals”**

1. Calendar year

## Summary

- World-leading proprietary technology for reformulating drugs into high-value oral sprays
- Breakthrough anti-malarial spray progressing towards commercialisation
- 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

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