

ASX Release

SUDA LTD: INVESTOR ROAD SHOW PRESENTATION

PERTH, AUSTRALIA - **23 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 to institutional investors, brokers and analysts in Sydney, Melbourne and Adelaide during this week. The investor presentation follows.

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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 orals sprays for the treatment of migraine headache, erectile dysfunction and chemotherapy-induced nausea and vomiting.





Stephen Carter - Chief Executive Officer Nick Woolf - Chief Business Officer

September 2014

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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

3

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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 1,2



"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



Oro-mucosal delivery | Highly effective administration route Bioavailability in excess of 90% via the oral mucosa 100% 95% >90% 90% 50% 45% 30% 20% 10% 10% 10% Source: Physician's Desk Reference, NPPDR, No. 18:676, 1997

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Oro-mucosal delivery | Low-risk regulatory path



- Strategy to take advantage of faster and less expensive regulatory pathways
- FDA's 505(b)(2) legislation for reformulations of US-approved drugs
 - Leverage FDA's existing data on safety and efficacy of original drug
 - Simply demonstrate bioequivalence of reformulation vs. original drug
- FDA incentivises reformulations with 3 years market exclusivity in USA
- Most countries have adopted similar regulatory pathways to the FDA





Oro-mucosal delivery | Platform technology

- Technology for producing proprietary OroMist oral spray formulations
- Experience with different pump systems airactivated 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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Strategy | Accelerating cash sustainability

- Expand pipeline of first-in-class patentable oral sprays
 - Reformulate high-value drugs for which oro-mucosal delivery has advantages
 - Demonstrate superiority or bioequivalence to the original formulation
 - Out-license to Pharma companies for commercialisation
- Collaborate on oral spray formulations of interest to partners
 - Co-develop high-value off-patent drugs in oro-mucosal formulations
 - Collaborate with innovators of new chemical entities to enhance product profiles or extend lifecycles with oro-mucosal sprays



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 royalties¹ on sales
- Objective to achieve two collaborations/trade sales in H2 CY2014

COMPARABLE COLLABO	OMPARABLE COLLABORATION/TRADE SALE DEALS							
Generic drug	Sumatriptan	Midazolam	Midazolam Ondansetron					
Delivery Technology	Nasal spray	Oral buccal spray	Oral soluble film	Sublingual tablet				
Disease	Migraine	Seizures	Nausea/vomiting	Insomnia				
Licensor/Licensee	Optinose/Avanir	Auralis/ViroPharma	MonoSol/Strativa	Orexo/MEDA				
Territory	North America	Global	USA	Global				
Upfront Payment	US\$20M	US\$15M	US\$3M	US\$13M				
Milestones	US\$90M	US10M	US\$24M	US\$90M				
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

9

SUDALTD Low-risk pipeline targeting large markets Pre-Marketing Market Product Ingredient Approval ArTiMist™ Artemether Malaria >\$500m SUD-001 Sumatriptan Migraine headache \$3.2bn Chemotherapy induced SUD-002 Ondansetron \$2.5bn nausea & vomiting SUD-003 **Erectile dysfunction** Sildenafil \$3.4bn Pulmonary arterial SUD-004 Sildenafil \$4.5bn hypertension Pre-procedural SUD-005 Midazolam \$3.6bn



ArTiMist™ | Anti-malarial sublingual spray

- ArTiMist™ sublingual artemether for treatment of children with malaria
- Completed Phase III trial vs. intravenous guinine for severe paediatric malaria
 - 150 children from multiple sites in Africa
 - Conducted to highest standards for use in worldwide regulatory submissions
- 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

11

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ArTiMist™ | Progressing to registration

- Expanding the use of ArTiMist™ as an early interventional 'pre-referral' therapy
 - Appointed a Clinical Advisory Board comprising key opinion leaders in treatment of malaria
 - 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"



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
 - Significantly more effective than Imitrex® 50mg relief paralleling Imitrex® 100mg
 - Rapid onset of action and less drug needed to achieve desired therapeutic effect
- Primary Market Research suggests prescribers & payers see important role for SUD-002 in patients with nausea, GI problems or sudden onset headaches



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

13

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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.
 8mg Zofran® tablet
 - SUD-002 was bioequivalent, but quicker onset vs. tablets
- Clinical data potentially sufficient for registration
- Tablets are not ideal when patients are vomiting



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
- SUD-003 trial in 24 males showed safety and bioequivalence vs. Viagra®
 - 20mg SUD-003 was bioequivalent to 25mg Viagra® tablet
- 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

15

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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: preferred supplier to a 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"



Westcoast Surgical | New revenue drivers



- Strengthened aged care activities with launch of premium range of Lille incontinence products
- Launched HemoStyp® wound healing gauze, targeting defence forces, police and ambulance services
- Expanded to East coast with new Brisbane-based operations
- East coast business is expected to add \$3 -4 million in annual revenue

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

17

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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-forma¹ net cash (30 June2014) \$5.4 million

Shares in issue¹ 981.05 million

Convertible notes \$1.9 million convertible to 62.5 million shares

Options 21.5 mill @ \$0.05; and 5.0 mill @\$0.072 subject to performance

Performance rights 6.8 million shares subject to performance

 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	1	March 2014
Initiate outreach to Pharma industry	H1 CY2014	1	March 2014
Appoint Clinical Advisory Board for ArTiMist™	H1 CY2014	1	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

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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
- 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

21

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