

# ASX Release

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## SUDA LTD: 2014 ANNUAL GENERAL MEETING PRESENTATION

**PERTH, AUSTRALIA - 27 November 2014:** SUDA LTD (ASX: SUD) announces that the Company's 2014 Annual General Meeting will be held today at 10.30am (GMT+8) in Perth, Western Australia.

The following presentation will be given at the Meeting.



**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

**Stephen Carter - Chief Executive Officer**

**Nick Woolf - Chief Business Officer**

**ANNUAL GENERAL MEETING  
27 November 2014**

SUDA LTD

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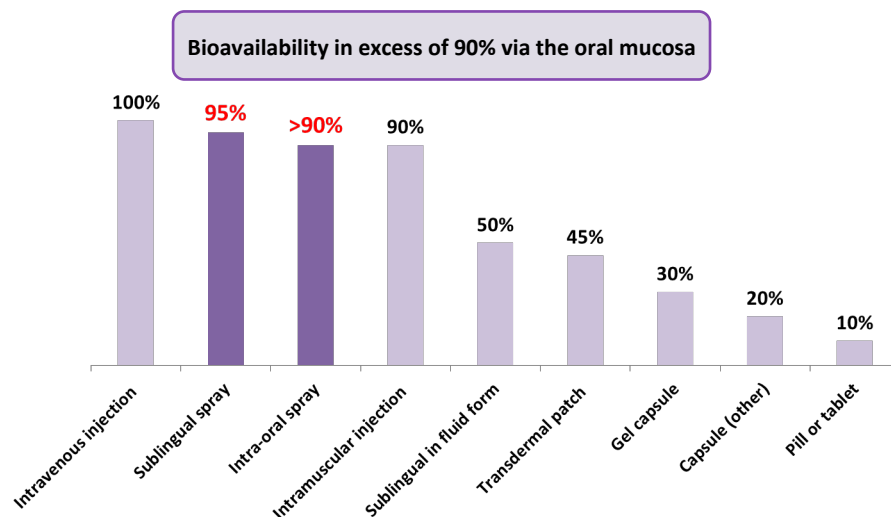
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**Introduction**

- Oral mucosa is ideal for drug delivery, avoiding first-pass metabolism effects
- Oro-mucosal sprays have unique advantages vs. other routes of administration
- SUDA's OroMist sprays facilitate new indications and can breathe new life into existing therapies with poor bioavailability or requiring a rapid therapeutic effect
- SUDA has multiple patent families granted and pending in both North America and Europe, covering 300 high-usage existing drugs
- SUDA has extensive proprietary technology, expertise and knowhow in formulating and manufacturing oral sprays
- SUDA's first-in-class oral sprays have demonstrated meaningful advantages vs. standard-of-care tablets in multiple clinical studies

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**Oro-mucosal spray delivery | Highly effective drug delivery method**



Source: Physician's Desk Reference, NPPDR, No. 18:676, 1997

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### Oro-mucosal spray delivery | Efficient & effective

- Oral mucosa is the lining of the mouth, richly supplied by blood vessels
- Oral mucosa comprises various surfaces with differing levels of keratinization
- Key areas within the oral mucosa, in decreasing order of absorption are:

- Sublingual
- Lingual
- Buccal
- Gingival
- Palatal



**Drugs absorbed via the oral mucosa are delivered directly into the blood, avoiding first-pass metabolism effects of the liver and gut wall**

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### Oro-mucosal spray delivery | Unique advantages

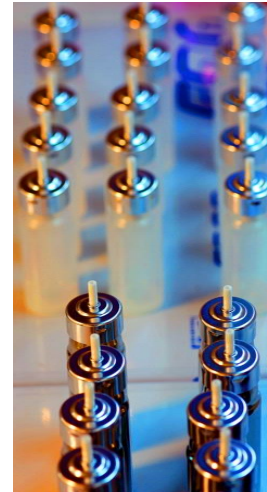
- Bypasses gastrointestinal tract and hepatic portal system, increasing bioavailability
- Less API required to achieve therapeutic effect, potentially reducing off-target side-effects
- Rapid onset of action can be achieved relative to oral tablet formulations
- Greater tolerability vs. tablets in patients with nausea and vomiting
- Can be used in cases of unconscious and uncooperative patients
- High patient compliance due to elimination of injection pain or the need to swallow<sup>1,2</sup> or inhale

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

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**OroMist technology | Drug & device capabilities**

- Technology for producing OroMist formulations utilising polar and non-polar solvents, GRAS excipients and propellants
- Expertise with a range of flavoring and taste modifying agents, - synthetic or natural peppermint, spearmint, citrus oils, fruit flavours, honey and sweeteners
- Expertise with penetration enhancers to increase permeability via mucosa
- Experience with different pump systems - air-activated pumps and propellant-driven aerosol sprays
- Experience with different containers - multi-dose and single-unit

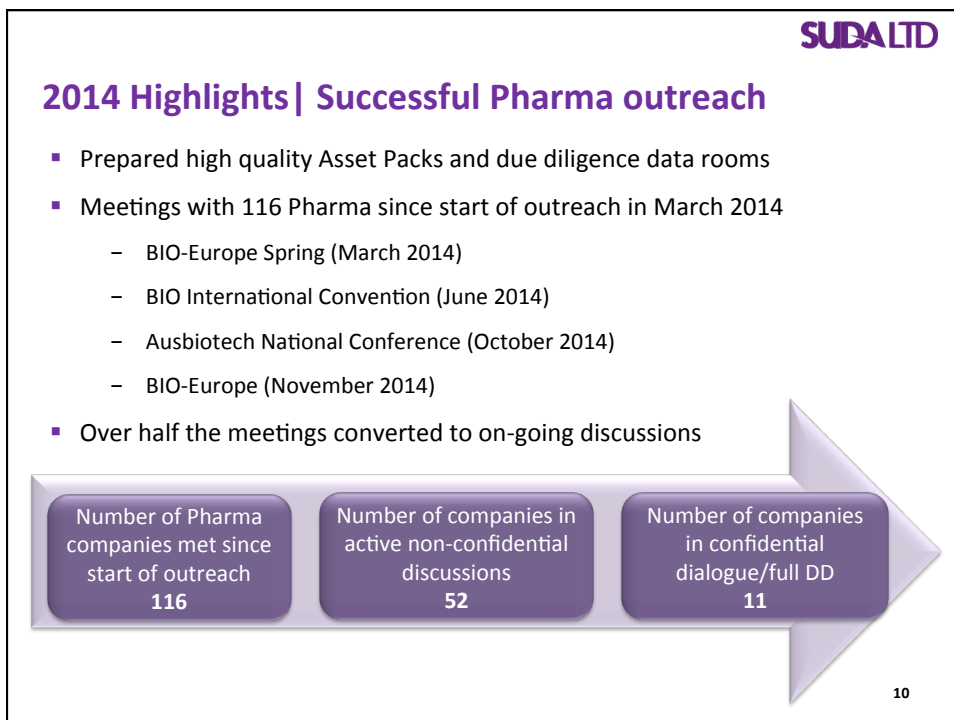
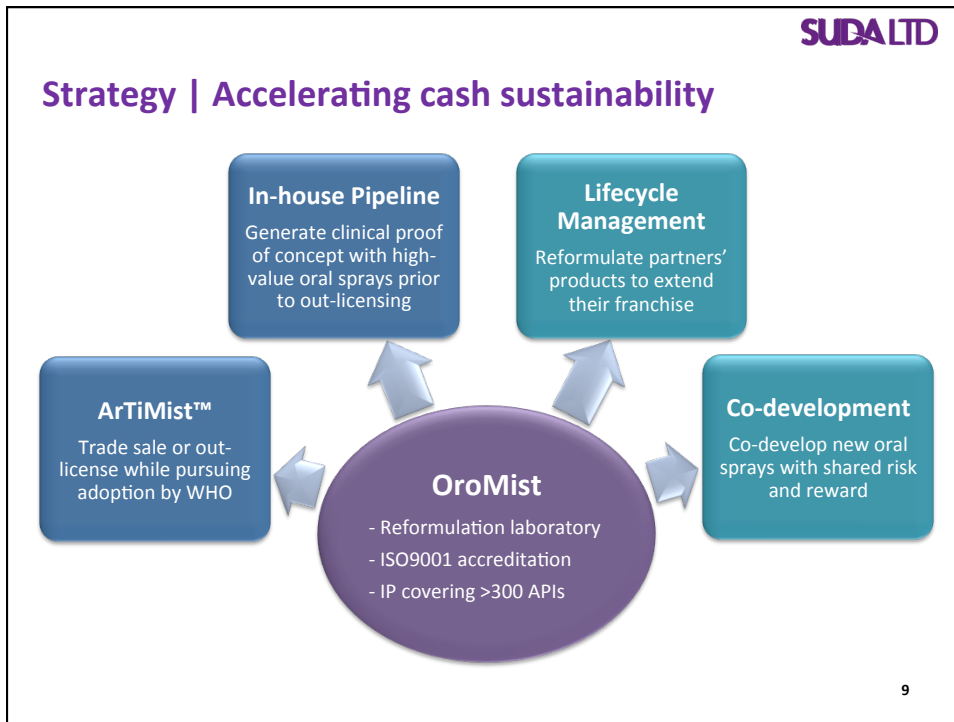


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**Low-risk pipeline | Targeting large markets**

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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## 2014 Highlights | Expanding ArTiMist™ market potential

- 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 and philanthropic funds
- Dialogue with World Health Organisation to accelerate adoption into Guidelines
  - Targeting FDA, EMA or other stringent regulatory authority for ArTiMist™ review
  - Presented Phase III data at major medical conference, ASTMH, in November
  - Submitting peer-reviewed papers for publication in medical journals

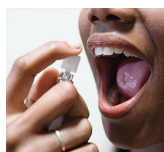


*ArTiMist™ has huge potential as an early interventional treatment for children with malaria*

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## 2014 Highlights | Advancing in-house pipeline of sprays

- Multiple oral sprays for large mainstream markets – migraine, erectile dysfunction, chemo-induced nausea, hypertension and anxiety
- Re-activated the US regulatory process for development of in-house sprays
- Configured development plans for sharing with prospective partners
- Optimising lead products for pivotal registration studies
  - SUD-001 migraine spray enhanced with new Extra-Mint taste
  - SUD-003 erectile dysfunction spray enhanced with Mint-Vanilla flavour and permeation enhancers to boost onset of action
- Planning multiple FDA meetings in 2015 to confirm registration requirements



*Our oral spray formulations offer lower dosages with improved onset of action, safety and patient convenience*

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### 2014 Highlights | Upgraded formulation laboratory

- Upgraded laboratories provide:
  - Reformulation chemistry
  - Analytical capabilities
- Primary purpose to enhance and expand in-house pipeline
- Resources to support anticipated co-development and lifecycle management deals
- ISO9001 quality system accreditation



*Our laboratory features an array of modern equipment and advanced scientific instruments; a dynamic team of experienced scientists and an outstanding quality system meeting the standards required by the pharmaceutical industry*

### Revised guidance | Key value-inflection events

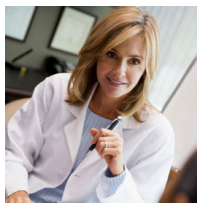
- Building competitive interest in our key clinical assets with over 60 discussions
- Interest spans in-house products, co-development and lifecycle management opportunities
- Prospective partners range from top-10 to regional specialty pharmaceutical companies
- Multiple parties reviewing ArTiMist™, but process slowed by near-term focus on Ebola crisis
- Deal flow expected to accelerate in CY2015

ANTICIPATED EVENT	PREVIOUS GUIDANCE		NEW GUIDANCE
First in-house spray out-licensing deal	H2 CY2014	✓	December 2014
ArTiMist™ trade sale or out-licensing deal	H2 CY2014	✗	H1 CY2015
Co-development/lifecycle management deal	-	new	CY2015
In-house sprays out-licensing deals	-	new	CY2015



### 2014 Highlights | 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
- Experienced strong growth in revenue and profitability
- FY2014 revenue increased 115% to \$8.8 million vs. previous year
- FY2015 focus is on new opportunities and reinvestment



*Westcoast has entered a new era in its operations*

### Key data & financial snapshot

#### Corporate key data

ASX Code	SUD: AU
Current share price (Australian \$)	\$0.066
52 week range	\$0.044-\$0.086
Average volume (30-day)	1.0 million
Market cap	\$65 million

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

Revenue (FY2014)	\$8.8 million
Net loss (FY2014)	(\$2.1 million)
Net cash (30 September 2014)	\$3.9 million
Shares in issue	984.0 million
Convertible notes	\$1.9 million convertible to 62.5 million shares
Options	19.0 mill @ \$0.05; and 5.0 mill @\$0.072 subject to performance
Performance rights	6.8 million shares subject to performance

## 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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