

Company Announcements Office Australian Securities Exchange Limited Level 4, Exchange Centre 20 Bridge Street SYDNEY NSW 2000

#### **By: e-lodgement**

Dear Sir

#### **RESULTS OF GENERAL MEETING**

In accordance with Listing Rule 3.13.2 and section 251AA of the Corporations Act, set out below are the details of the resolutions passed and the proxies received in respect of each resolution in the Notice of Meeting:.

#### $Resolution \ 1- {\sf Ratification} \ of \ {\sf Allotment} \ of \ the \ {\sf Bergen} \ {\sf Convertible} \ {\sf Security} \ with \ face \ value \ of \ {\sf $600,000} \ issued \ 7 \ {\sf December} \ 2012$

The instructions given to validly appointed proxies in respect of the resolution were:

For	Against	Abstain	Proxy's Discretion
43,874,335	1,682,090	12,650	11,543,750

The resolution was carried as an ordinary resolution on a show of hands.

# Resolution 2 – Ratification of allotments of prior issue of 36,980,307 Ordinary Shares and 7,500,000 Unlisted Options to Bergen and HSBC Custody Nominees for the Account of Bergen pursuant to the Bergen Agreement

The instructions given to validly appointed proxies in respect of the resolution were:

For	Against	Abstain	Proxy's Discretion
43,774,335	1,782,090	12,650	11,543,750

The resolution was carried as an ordinary resolution on a show of hands.

ASX Announcement No.: 632

#### $\label{eq:Resolution 3-Approval to issue shares and options to NovaDel pursuant to the NovaDel Agreement$

The instructions given to validly appointed proxies in respect of the resolution were:

For	Against	Abstain	Proxy's Discretion
66,978,168	1,457,090	12,650	11,543,750

The resolution was carried as an ordinary resolution on a show of hands.

#### Resolution 4 – Approval to issue 4,000,000 options to John Billingham

The instructions given to validly appointed proxies in respect of the resolution were:

For	Against	Abstain	Proxy's Discretion
63,113,168	5,302,090	12,650	11,543,750

The resolution was carried as an ordinary resolution on a show of hands.

A copy of the Executive Chairman's presentation is attached.

Yours faithfully

**Stephen Carter** Director Chief Executive Officer

# SUBAL

# **Focussed on Oro-Mucosal** Delivery

## **Stephen Carter Executive Chairman / CEO**

## **About US**

Operationally, Suda comprises two distinct business units.

- oro-mucosal spray drug delivery platform
  - SUDAMist<sup>™</sup>, an Oro-mucosal drug delivery platform. (subject to Novadel shareholder approval)
  - ArTiMist<sup>™</sup> sublingual treatment for malaria

#### med tech and consumables distribution

 Westcoast Surgical & Medical Supplies Pty Ltd

#### Key data

ASX Code	SUDA
Current share price	\$0.027
52wk range	\$0.011-\$0.049
Shares on Issue	Approx. 630M
Average Trading Volume	1.7M /day
Market Cap	\$18m
Cash at 1 <sup>st</sup> April 2013	\$1.3M

## Westcoast Surgical & Medical Supplies Pty Ltd

- Westcoast Surgical & Medical Supplies Pty Ltd (Westcoast) is a sales and logistics operation for medical devices and consumables. Westcoast focuses on 5 key areas:
  - Hospitals
  - Aged Care
  - Allied Health
  - Mining
  - Detention Centres
- Westcoast's key selling proposition is: Flexible Solutions, Innovative Service. This reflects its service levels which differentiates it from other players in a highly competitive industry.
- Significant growth and a turnaround business.

# SUDALTD Our People

#### Stephen Carter. Chairman and Chief Executive Officer

 Has extensive pharmaceutical industry experience with multi-national pharmaceutical and listed public companies.

#### Michael Stewart. Non-Executive Director

 Broad corporate and management background and involvement in bilateral donor funded and World Bank co-financed Aid Projects

#### Ken Robson Non-Executive Director

 His background includes extensive experience as a Corporate Lawyer and Advisor, specialising in fundraising, market compliance and Mergers & Acquisitions.

#### Joseph Ohayon CFO and Director

 Has over 20 years' experience in financial roles including 12 years within health-related industries.

# NovaDel

# **A Transformational Acquisition.**

- SUDA has signed a Sale and Purchase Agreement to purchase the NovaDel IP and inventory.
- The agreement is subject to NVD shareholder approval and should be finalised early Q3 2013.
- The benefit of this technology is that it not only compliments SUDA's current ArTiMist<sup>™</sup> Project but it also provides a strong foundation for the development of other drug candidates which may open the doors to lucrative licensing agreements.
  - The NovaMist<sup>™</sup> platform also provides a valuable life cycle extension strategy for innovators whose products are facing patent expiration and new product development opportunities for companies wishing to develop their own brand of a competitor's drug that is approaching patent expiration.

## **Business Strategy**

The pharmaceutical business is semi-virtual

#### Drug Life-cycle Management (DLM)

DLM strategies are complex and require an integrated, multidisciplinary and cross functional team approach to manage the various activities and processes

- Lower development risk: Profile of the drugs are well known
- The aim is to provide: therapeutic, scientific or technical innovation
- Possibly shorter development time lines: 3-5 years
- IP: strengthened
- Regulatory pathway : 505(b)(2) in US and Article 3(3) of Regulation 726/2004 in EU



## **Business Strategy** cont'd

Out-licensing - SUDAMist<sup>™</sup> technology Longer-term - the development (in parallel with DLM) of novel oro-mucosal spray compounds



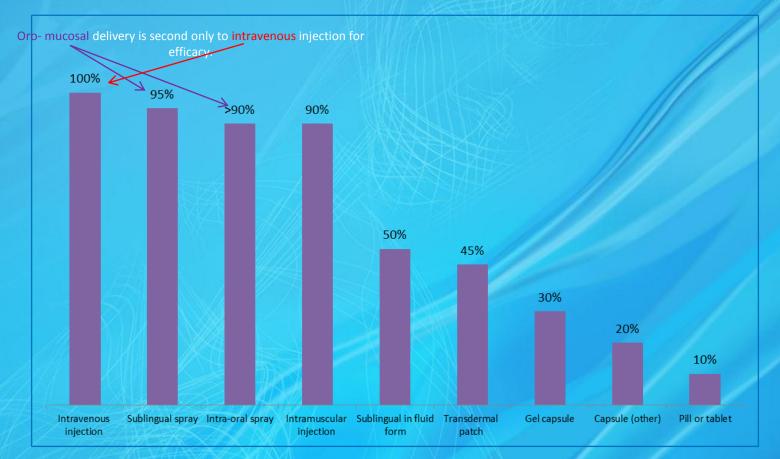
- Continue to expand IP through research and collaboration
- Continue to look for complementary acquisitions

## **R&D Funding Strategy**

- Trade sales and licensing of selected projects
- Partnering, co-development and pharma research collaborations to progress the R&D programs.
- Identify and apply for grants and other non-dilutive funding.
- Selective investment in Proof of Concept work and early PK studies.
- Identification of potential VC/Pharma spin out projects.
  - Manage the use of our US\$7m facility.
- Selective use of capital markets.

# **Why Oro-Mucosal drugs?**

# Efficacy comparison of different drug delivery methods

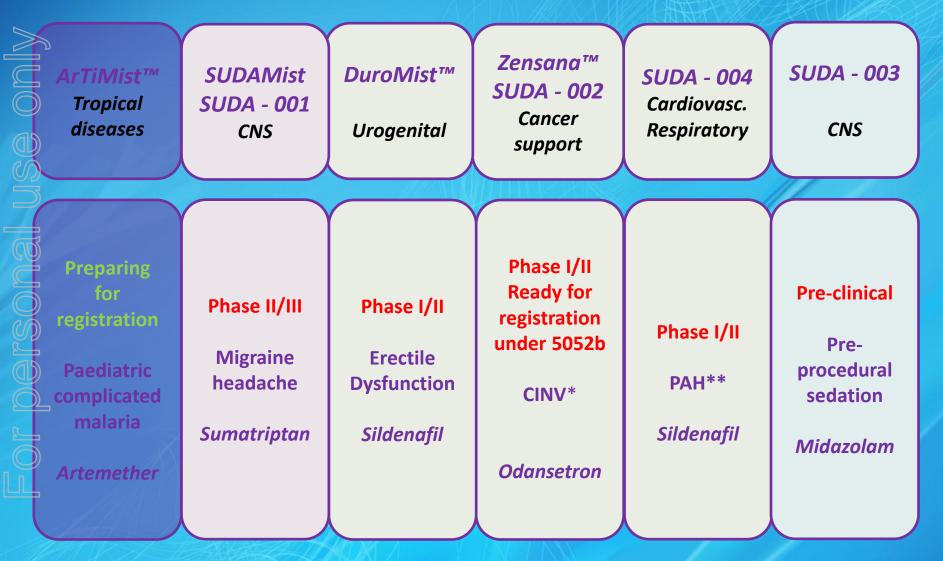


Source: Physician's Desk Reference, NPPDR, No. 18:676, 1997 and from SUDAMist' S clinical trials

# **SUDAMist**<sup>™</sup>

- SUDAMist<sup>™</sup> is an oro-mucosal drug delivery platform that may provide substantial potential benefits compared to other modes of drug administration including:
  - Faster onset of action
  - Possibility to use a lower quantity of drug resulting in a Lower dose
  - The reduction of side effects in most cases
  - Allows for accurate metered dosing
  - Increased bioavailability by avoiding first pass metabolism
  - Enhanced patient compliance and convenience
  - Particularly suitable or dysphasia patients and young children due to;
    - Avoiding the need to swallow
    - Allowing medication to be taken without water

# SUBALTD 'Low hanging fruits'



\*Chemo-induced nausea and vomiting \*\* Pulmonary Arterial Hypertension

# ArTiMist™

- Our lead product ArTiMist<sup>™</sup>, a sub-<mark>lingual artemether based malaria treatment, has been developed specifically for children with complicated malaria.</mark>
- In 2011 Thompson Reuters identified ArTiMist™ as one of the 5 worlds most promising drugs in Phase III clinical development.
  - Successfully completed ArTiMist<sup>™</sup> Phase III clinical trial in Children in Severe or complicated Malaria.



# ArTiMist™

#### Phase III Results

- 151 patients in 3 sites in Africa
- Sub-lingual ArTiMist<sup>™</sup> superior to i.v. quinine
- 95.6% of ArTiMist<sup>™</sup> patients had reduced parasite counts by >90% in the first 24 hours compared with only 40.6% using intravenous (IV) quinine
- Parasite clearance time 30 hours with ArTiMist<sup>™</sup> vs. 68 hours with Quinine
- No Early treatment failures in Artimist<sup>™</sup> arm 10 in quinine.
- Results support that ArTiMist<sup>™</sup> is an effective treatment for children with malaria
- results provide a compelling argument for the potential use of ArTiMist<sup>™</sup> as an early interventional treatment for children

# ArTiMist™

- Advantages of ArTiMist<sup>™</sup> over other treatments are:
  - It does not require medically trained personnel for administration;
  - Not affected by GI complications;
  - By-passes the Liver and the significant metabolism seen from the first pass effect;
  - Does not require fatty diet for maximum effect;
  - Rapidly absorbed;
  - Can be administered to comatose patients;
  - Negates risk of infection from needle use;
  - Has a long shelf life; and
  - Critically, in hot climates, does not require cold chain storage

## **ArTiMist<sup>™</sup> - Value proposition**

- Confirmed superiority of ArTiMist<sup>™</sup> vs. gold standard IV quinine
- Massive un-met medical need
- Completed commercial scale manufacture program
- Currently drafting regulatory documentation
- Turn key trade sale

## **Product Pipeline**

#### NovaMist R&D PIPELINE

PROJECT	ACTIVE PHARMACEUTICAL INGREDIENT	DEVELOPMENT STATUS	INDICATION	GLOBAL MARKET SIZE	CURRENT AVAILABLE DOSE FORMS
DuroMist™	Sildenafil citrate	Completed a non-IND pilot clinical trial (Demonstrated bioequivalence). IND opened for further work	Erectile Dysfunction (ED)	US\$4.1bn	Oral tablet
SUDA - 001	Sumatriptan	2 pivotal clinical trial	Migraine headache	US\$200m in USA alone	Tablet, injection and nasal spray
SUDA - 002	Ondansetron	Completed clinical trials for registration under the FDA section 505(b)(2)	Chemotherapy induced nausea and vomit (CINV)	US\$3.6bn in 2015	Liquid and solution for IV, IM, syrup, oral tablet, oral disintegrating tablet, oral film and suppositories.
SUDA - 003	Midazolam	Completed formulation	Pre-procedural anxiety	US\$150-170m	IV, IM, continuous infusion and buccal liquid
SUDA – 004	Sildenafil citrate	Completed Formulation	Pulmonary Arterial Hypertension	US \$3.59B in 2015	Tablet ,injection

# **SUBALTD** Unlocking the value in the pipeline

PROJECT		INDICATION	Actions to Unlock value
DuroMist™	INGREDIENT Sildenafil citrate	Erectile Dysfunction (ED)	<ul> <li>License to major player in ED field</li> <li>Licence out to various companies for territorial exclusivity</li> <li>Develop further under co-development agreement</li> </ul>
SUDA - 001	Sumatriptan	Migraine headache	<ul><li>Correlate Data</li><li>License out</li></ul>
SUDA - 002	Odansetron	Chemotherapy induced nausea and vomit (CINV)	<ul> <li>Correlate data</li> <li>Start Regulatory process and license out</li> </ul>
SUDA - 003	Midazolam	Pre-procedural anxiety	<ul><li>Phase 1 PK study</li><li>License out</li></ul>
SUDA – 004	Sildenafil citrate	Pulmonary Arterial Hypertension	<ul> <li>Complete Pre Clinical development</li> <li>Phase 1 study</li> <li>License out</li> </ul>
ArTiMist	Artemether	Severe malaria	<ul><li>Finalise CTD documentation</li><li>Trade Sale</li></ul>

Note: Partnership strategy to reduce reliance on internal resources and mitigate risk

## **Future milestones**

Milestone	Expected time frame
ArTiMist™ Final Clinical trial Report	Q3 2013
Completion of NovaMist™ Acquisition	Q3 2013
Lodging of ArTiMist™ Regulatory File in first jurisdiction	Q1 2014
First NovaMist™ deal	Q2 2014
ArTiMist™ Trade Sale	H2 2014

