

# ASX Release

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## SUDA LTD PUBLISHES QUARTERLY NEWSLETTER

**PERTH, AUSTRALIA - 17 February 2014:** SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, today published its quarterly newsletter, which has been mailed to shareholders.

Stephen Carter, SUDA's Chief Executive Officer, commented: "The newsletter provides a valuable forum for us to put recent news in context; to highlight upcoming events; and to set out in more detail some of the significant assets and activities at SUDA. The theme for this edition of our newsletter is 'Business Development'. There is also a fireside chat with our recently appointed Chairman, Mr. Michael Stewart, in which he articulates the reasons that he joined the Board in 2009 and where he sees the opportunities for the Company today. We hope you find it insightful and interesting."



**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 (ie: 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, chemotherapy-induced nausea and vomiting and erectile dysfunction. For more information, visit [www.sudaltd.com.au](http://www.sudaltd.com.au)

# SUDA LTD

## Drug delivery through the oral mucosa

### Fast tracking pharmaceutical development

Our business model is to develop low-risk pharmaceuticals using novel formulations of existing drugs that are off patent. We re-formulate these drugs to provide patentable products or line extensions for existing franchises.



## Pushing forward to achieve our business development goals in 2014

In our inaugural newsletter dated November 2013, we described our strong foundations for growth following the successful ArTiMist™ Phase III trial in severe malaria; and the integration of the oro-mucosal technology and pipeline acquired from NovaDel. The next step in our growth strategy is to monetize these assets.

Our objective is to complete the divestment of ArTiMist™ and also to secure a collaboration on at least one of our mainstream oro-mucosal products by the end of CY2014. We are currently preparing Asset Packs ready for an initial outreach to prospective pharmaceutical partners in the first half of CY2014.

The typical licensing transaction in the life sciences sector involves multiple steps, some of which are complex. Experience is critical. We have put in place a first-rate team and we are working with leading international consultants. Our team has relevant experience from past partnering transactions; has strong personal relationships within the industry; and understands the factors that drive relative negotiating leverage.

We are now well positioned to manage the partnering process and to execute transactions that realize the value of our Assets and maximize returns for our shareholders. It should be an exciting 2014.

### Diary Events

**10-12 March 2014 - Turin, Italy**  
*BIO-Europe Spring 2014*

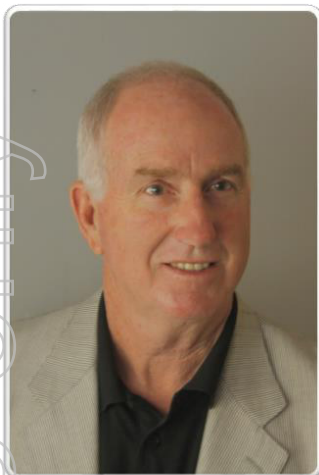
Pre-eminent international partnering event, attracts a wide range of business leaders, including senior executives and business development teams from large and midsize Pharma companies, investors and other industry experts.

**23-26 June 2014 - San Diego, USA**  
*BIO International Convention*

Largest global industry event, attracts the biggest names in biotech, offers key networking and partnering opportunities, and provides insights and inspiration on the major trends affecting the industry



Our proprietary and patented drug delivery platform has broad potential to enhance many classes of existing drugs and we have established a rich pipeline of product candidates



**Michael Stewart**  
appointed Chairman

Mr. Stewart joined the Board of SUDA LTD in June 2009. He has extensive experience with small and mid-cap companies with a background in corporate finance and management. He was previously a Director of DJ Carmichael, one of Western Australia's leading brokerage houses. Mr. Stewart has also been involved in bilateral donor funded and World Bank co-financed aid projects in under-developed countries, which is particularly relevant to SUDA's anti-malarial treatment, ArTiMist™.

## Preparing SUD-001 'Asset Pack' for partnering with Pharma

Our **SUD-001** product is the world's first lingual spray formulation of sumatriptan (marketed in tablet form and in a nasal spray by GlaxoSmithKline under the brand name Imitrex®). Sumatriptan is one of the most widely used drugs for the treatment of acute migraine in adults.

Clinical trials of SUD-001 have shown that it is significantly more effective than the equivalent Imitrex® tablet and offers a quicker onset of action. With SUD-001, patients can anticipate rapid and reliable relief of symptoms regardless of nausea.

According to a 2011 WHO report, migraine affects about 11% of the global adult population and the market value for the same year was estimated to be around US\$3.2bn. It is forecast to reach US\$4.4bn by 2020.



## Novel wound healing gauze: HemoStyp®

We were excited to announce in January that Westcoast, our medical supplies subsidiary, has exclusive distribution rights to a novel wound healing gauze, HemoStyp®. The product has been approved by the TGA and is now on the market. Westcoast is offering a range of HemoStyp® gauzes through its established channels, including public and private hospitals, aged care, police and emergency services, government agencies including jails and detention centres, chemist and dental outlets and veterinary; and will also be targeting the Australian Defence Forces as a potential major customer.

HemoStyp® has the potential to make a materially positive impact on the net profit of our subsidiary Westcoast.



HemoStyp® is an all-natural product comprised of regenerated oxidized cellulose gauze, formulated to aid in the process of haemostasis (clotting) when positioned on a cut or wound. HemoStyp® stops bleeding faster than ordinary gauze and contains no potentially harmful chemicals or animal by-products and is hypoallergenic.



## Standing out from the crowd

Standing out from the crowd is fundamental to successful partnering. There are competing reformulation technologies, such as nasal sprays, lozenges and soluble films. We want to ensure that prospective pharmaceutical partners choose our products to in-license over the competitors.

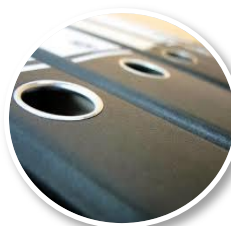
Naturally the science and the data have to be of the highest quality. However, there are other elements that need to be in place such as manufacturing and IP. As we prepare for our outreach to the pharmaceutical industry, we are compiling comprehensive Asset Packs for each of our products.

Our Asset Packs contain seven sections, as follows:

1. **Market analysis & current treatments:** this section sets out the scale of the disease (eg: prevalence) and analyses existing treatments by sales and prescription volumes.
2. **Clinical & preclinical data:** this section describes the studies conducted and the data generated to show that the product is safe and bioequivalent to the reference drug. It illustrates the advantages such as rapid onset of action and efficient absorption of the active.
3. **Regulatory path:** this section provides prospective partners with an understanding of our interactions with healthcare regulatory agencies (eg: the FDA and TGA). We also set out the development path, if further trials are required, to gain marketing approval for the product.
4. **Manufacturing:** this section describes the formulation itself and the manufacturing requirements for the product, such as the scalability of the process and the results of stability tests undertaken on existing batches. It also includes information on the container and pump (air-activated) or aerosol (propellant-device).



*Our mission is to improve the health and lifestyle of the global community by providing new, high-quality, innovative, pharmaceutical products to assist in the treatment of various conditions whilst maintaining consistent growth and investment value for shareholders.*



5. **Intellectual property:** this section comprises details of the patents that cover the product, including key claims, territories, expiry dates and any other relevant information attaining to market exclusivity and freedom to operate.

6. **Primary Market Research:** this section demonstrates the demand in the market for our oral spray. We use external market research companies to conduct surveys with doctors, specialists and healthcare payers. They are presented with a profile of our product and asked questions such as: What are the current limitations of the gold standard tablet? To how many of your patients would you prescribe this treatment? What pricing and reimbursement level would you support?

*“Our high quality Asset Packs, together with our strong industry relationships and deal-making experience, will ensure our oro-mucosal sprays attract the right partners and that we secure the optimal deals.”*

7. **Target Product Profile (TPP):** this section highlights the unique advantages of the product versus the reference drug (eg: quicker onset of action, lower dosage, enhanced patient convenience). It represents the elevator sales pitch as to what differentiates our product from the current standard of care.



## New subsidiary established with global rights to ArTiMist™ asset

- New alliance with our partner, ProtoPharma, expands SUDA's rights to ArTiMist™
- SUDA controls new subsidiary (MRC), which owns global rights to ArTiMist™ for the entire field of malaria
- No ongoing royalty obligation to ProtoPharma
- Structure of MRC enhances the value of the asset and sets the foundation for securing a global partnership
- SUDA and ProtoPharma are pooling expertise to fast track commercialisation

Over the past 2 years we have been working with our UK-based partner on the ArTiMist™ anti-malarial sublingual spray to restructure the alliance in readiness for an asset sale or a global partnership. We were delighted to finalise the new ownership structure in November 2013.

Formed in 2006, the original agreement provided SUDA with a license to ArTiMist™ in Africa, India, Asia and the Pacific region for the treatment of malaria primarily in children, subject to SUDA funding the clinical development. There was also a royalty obligation on product sales payable to ProtoPharma.

Under the new agreement, the intellectual property and global rights to ArTiMist™ are owned by an Australian company, Malaria Research Company Pty Ltd (MRC). SUDA has 80% ownership of MRC, with ProtoPharma owning the balance. There will be no royalty obligations to ProtoPharma, and the worldwide territorial rights to ArTiMist™ for the entire field of malaria will be consolidated into MRC.

This structure gives SUDA greater control and broader commercial rights to our lead development product. We are now working closely with ProtoPharma to complete the regulatory dossier for the first marketing application and also to realise the full value of this phenomenal asset.



*Extract from MMV's  
December 2013 report*

## Malaria R&D Funding Needs into the Next Decade

Malaria remains one of the world's great public health challenges, claiming the life of a child in Africa each minute and the life of a pregnant woman worldwide each hour. Notwithstanding impressive progress in the development of and access to new tools, backed by significant increases in funding over the last decade, there were still 219 million cases of malaria worldwide and at least 660,000 deaths in 2010.

There has always been a paradox at the heart of drug treatment for acute *P falciparum* malaria: more than 85% of those who die are children younger than five years old, yet available drugs have always been developed as tablets for adults and therefore need to be broken up or crushed for children, making it difficult to give the exact dose. Additionally, many of the most widely available antimalarials are bitter to taste, causing children to gag or spit out the very medicine that could save their lives.

The total funding need for malaria R&D in the next decade is projected at between \$5.5 billion and \$8.3 billion, with the midpoint averaging around \$700 million on an annual basis—a relatively modest funding increase to deliver the new tools necessary to effectively combat malaria.

## Fireside chat with new Chairman, Michael Stewart



### **Q: What initially attracted you to join the Board in 2009?**

A: "The Company looked very different in 2009 than it does today. I was attracted by the potential of our ArTiMist™ anti-malarial spray to make a meaningful difference to the treatment of children with severe malaria. Just look at the successful results from the Phase III trial reported in 2013!"

### **Q: In addition to ArTiMist™, SUDA had some underperforming businesses back in 2009. What was your game plan?**

A: "I realised from the outset that we needed to completely restructure certain aspects of our operations. I also believe that good people build good businesses and that a team has to have a clear vision. That starts with clearly articulating what we stand for and Our Values. That was essentially the starting point. Of course the challenge is always how to build a company using a limited capital base."

### **Q: It's been a fantastic turnaround in 4 years. What's the secret of this success?**

A: "Success is a choice not a chance. I knew that with the right management and resources in place, we could reshape the Company with the aim of delivering exceptional shareholder returns. We brought in Stephen Carter in 2010 to orchestrate the turn around and he has shown excellent judgement in all respects."

### **Q: Please elaborate on Stephen's judgement?**

A: "Stephen has recruited a first-rate team to support him. He was instrumental in finalising the acquisition of the NovaDel oro-mucosal assets and in restructuring the ArTiMist™ ProtoPharma alliance."

### **Q: What triggered the split of Chairman and CEO roles?**

A: "Having an independent Chairman brings us into line with corporate governance best practise. The timing was essentially Stephen's decision.

Having restructured SUDA into an oro-mucosal drug delivery company, Stephen, in the CEO role, can now focus on our operational goals."

### **Q: What do you consider to be the key operational goals?**

A: "The focus for 2014 is on business development. We now have a portfolio of oral sprays, each of which offers advantages over current standard treatments. Our goal this year is to divest ArTiMist™ to a major pharmaceutical company and to partner at least one of our mainstream therapies. We are already ahead of where we wanted to be at this stage of the year."

### **Q: Which of the products acquired from NovaDel excites you most?**

A: "You probably expect me to say SUD-003, our oral spray of Viagra®. In fact, SUD-001 for migraine is the one that I think has the potential to really change prescribing habits. The clinical data suggests that SUD-001 has a much quicker onset of action and requires less active drug to have the same therapeutic effect as the gold standard Imitrex® tablet. These attributes are important for migraine patients."

### **Q: Do you have a closing message for our shareholders?**

A: "It is an honour to take on the role of Chairman at this exciting time in the Company's evolution. I am very confident that our management team can achieve the goals we have set. I would like to thank our shareholders for their support and I look forward to our journey ahead."



## World-leading advisory firm assisting our business development activities

We engaged Torreya Insights in November 2013 to assist with our strategic partnering and asset sale of ArTiMist™. Torreya Insights is the consulting arm of Torreya Partners, a leading boutique advisory firm focused on M&A and partnering in the life science sector. Torreya has offices in New York and London; and, in total, has carried out over 500 M&A and financing transactions with a notional value in excess of \$250 billion.

The benefits of working with Torreya have become evident even in the few months since we engaged them. Torreya has excellent reach and contacts within the pharmaceutical industry and has already managed to open doors for our products to be evaluated. Their advice will greatly assist our efforts to secure the optimal transactions.



*"We have hit the ground running in CY2014. Our outreach to prospective pharmaceutical partners is underway and we have multiple meetings planned for March 2014 around a partnering conference in Europe called BIO-Europe. I am delighted by the level of interest in our assets."*

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