SUDA LTD

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ASX Release

SUDA LTD PUBLISHES INAUGURAL NEWSLETTER

PERTH, AUSTRALIA - 22 October 2013: Suda Ltd (ASX: SUD) today published its inaugural Company newsletter, which has been mailed to shareholders. The Company intends to issue these on a quarterly basis going forward. The newsletter provides a valuable informal forum for the management to put recent news and events in context for shareholders.

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

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.

Strong foundations for future growth and driving the business forward

With the successful completion of the NovaDel acquisition in August 2013, we now own a world leading technology for delivering drugs to the oral mucosa, together with a broad pipeline of new programmes. The most advanced programmes are for the treatment of migraine, erectile dysfunction, and chemotherapy-induced nausea and vomiting.

We moved into new premises in Osborne Park, WA, a few months ago, which ensures we have the space to expand the team and potentially add an in-house reformulation laboratory. Just last month, we announced the appointment of Mr Nick Woolf to the new position of Chief Business Officer and we are advertising for a head of Regulatory Affairs.

We strengthened the balance sheet with a Convertible Note issue to raise $1.9 million in September 2013. This new capital ensures that we are well positioned to deliver on our key objectives over the coming months.

We look forward to seeing as many of you as possible at our AGM on 12 November 2013.

Diary Events

28-29 October 2013
Australia Biotech Invest 2013
Melbourne Convention & Exhibition Centre, Victoria

30 October – 1 November 2013
Investor road show
Melbourne, Sydney and Brisbane

10.30am, 12 November 2013
Annual General Meeting
The Boulevard Centre
99 The Boulevard, Floreat, WA

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

Re-launched website with new content on ora-mucosal technology

This month we re-launched our website to reflect the breadth of our activities. We encourage you to read the new content on our ora-mucosal drug delivery platform. There are web pages on all of our new product candidates. Each is a low-risk reformulation of a widely used drug and, in each case, the market opportunity is substantial. Like ArTiMist™, our new products potentially offer important advantages such as quicker onset of action; lower doses; and enhanced patient convenience, particularly for those with difficulty swallowing.

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			$4.1bn
SUD-004	Sildenafil	Pulmonary arterial hypertension			$2.7bn
SUD-005	Midazolam	Pre-procedural anxiety			$170m

Nick Woolf appointed Chief Business Officer

Nick is an accomplished business executive, bringing two decades of biotechnology and pharmaceutical industry experience to Suda. He has a strong track record in structuring, negotiating and executing successful alliances, licensing agreements and M&A transactions as well as providing business development, management and strategic leadership to organisations. He was most recently a Director of Perth-based biotech company, Phylogica. He began his career as a healthcare investment banker and was formerly head of European biotech equity research at ABN Amro.

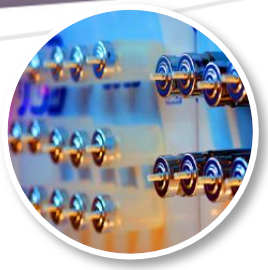
ArTiMist™ is the world's first sub-lingual spray for the treatment of *p. falciparum* severe paediatric malaria. The active pharmaceutical ingredient in ArTiMist™ is artemether, which is a widely used anti-malarial and is currently administered by infusion or orally in a tablet form.

ArTiMist™ progress continues

In April 2013, Suda Ltd released results from its ART004 Phase III trial in 150 patients across multiple sites in Africa. The results confirmed that ArTiMist™ was convincingly superior to the current gold standard intravenous Quinine treatment.

We are now making good progress towards the completion of the Common Technical Document (CTD). This comprehensive report will form the basis of applications for marketing approval and will be an important partnering tool as we seek to monetize ArTiMist™ through alliances or a trade sale.

In September 2013, we had an encouraging dialogue with the global partnership, Medicines for Malaria Venture. They have offered to assist us in getting ArTiMist™ more widely known and accepted by other global groups in the malaria community.



Strategy for success

We are building a pharmaceutical business based on reformulated products that demonstrate major cost, functional and effectual advantages over competitors, thereby securing patient demand. Each new drug formulation developed must address an unmet market need and use well-characterised molecules that have been approved and accepted by healthcare regulatory authorities in the world's major territories.

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.

Our commercial strategy is to add value to each programme through to a stage where we can secure licensing or collaborative development agreements or alternatively an outright sale of the respective asset.

We aim to achieve financial, clinical, technical and regulatory risk reduction through the sale of certain assets and, in parallel, in-house development of some projects and collaborative development of others.

The number of active projects will increase over time and will depend primarily on our resources. Naturally, our objective is to drive cash flow and profitability, which, initially, will come from the divestiture or partnering of our most advanced assets - ArTiMist™ and the newly added clinically mature products in our pipeline.

Development timelines of reformulated drugs are considerably shorter (3-7 years) when compared to the development of a New Chemical Entity (NCE), which can be up to 13.5 years from discovery to approval, and development risks are considerably lower than a NCE due to the extensive amount of pre-existing data.

The regulatory strategy is to seek marketing approval in the USA by filing Applications under the abbreviated FDA 505(b)(2) legislation and the equivalent strategy in Europe and other jurisdictions.

See Regulatory Strategy on page 6

There are many ways a licensing agreement can be structured. We anticipate that the licensing agreements entered into will be typically on product-by-product and territory-by-territory bases, as there are many different licensing strategies that can be applied depending on the countries and therapeutic indication.

The terms of such agreements can differ markedly depending on the stage of the product development, patient population and potential sales. We expect licensing or outright disposals will only be achievable once the programmes have reached certain key inflection points that demonstrate meaningful therapeutic and clinical value to patients, physicians and healthcare systems.

Our Drug Lifecycle Management (DLM) strategy is complex and will require an integrated, multi-disciplinary and cross-functional team to manage the various activities and processes (science, formulation changes, clinical trials, regulatory and legals, finances, M&A, public relations, reputation, etc.). Many aspects of this structure are not in place yet, but we have planned for them and will make new hires or outsource certain functions as and when it is necessary.

Oral mucosa offers significant advantages for administering drugs

The oral mucosa is the highly absorptive lining of the mouth. There are real advantages compared to other modes of drug administration from using this route to reach the systemic blood circulation:

- Provide faster onset of action;
- Reduce the dose level;
- Increase bioavailability of the drug by avoiding first pass metabolism in the liver
- Minimise dose variation related to gastrointestinal tract motility;
- Enhance patient compliance and convenience;
- Avoid the need to swallow, which is a problem for many people;
- Allow for the medication to be taken without water;
- Facilitate self-medication; and
- Decrease the need of medical personnel.

Drug delivery via the oral mucosa can minimise dose variation related to gastrointestinal tract motility, stomach emptying time, food effects, tablet/capsule disintegration and dissolution and enzymatic or chemical degradation in the gut.

Due to decreased degradation and higher absorption, oral sprays often permit the use of a lower dose of the active ingredient compared with tablet formulations of the same drug, potentially reducing the risk of adverse drug reactions.

In many cases, including treatments for patients with difficulty swallowing or nausea, oral spray administration provides enhanced convenience resulting in greater compliance. In fact, swallowing problems (known as dysphagia) are extremely common with an estimated prevalence as high as 22% in those over 50 years of age.

Approximately, 10 million Americans are evaluated each year with swallowing difficulties. Furthermore, many children have difficultly swallowing tablets without water.

Extensive patent estate protects our technology

Suda's patented technology essentially covers the delivery of liquid formulations of pharmaceutical products to the oral cavity in the form of a mist that covers the oral mucosal membranes. The oral mucosa is richly supplied with blood vessels and the mucosal membrane is relatively permeable. As a result, contact with these surfaces enables rapid drug absorption into the systemic circulation. The formulations reach the systemic circulation through different sites within the oral mucosal cavity.

The technology is compatible with, and patented for, use in either pump (air-activated) or aerosol (propellant-driven) spray systems, and can be provided in either multi-dose or unit containers based on the medical need and marketing requirements for each product.

Suda has several granted patent families with patent life on some extending to 2031. The patents cover the drug delivery technologies and the active pharmaceutical ingredients. In addition, Suda has a number of filed patents, granted trademarks and know-how.

The management intends to strengthen the intellectual property portfolio as it progresses with its R&D efforts.

Our oral spray products are targeting large markets

ArTiMist™ is the world's first sub-lingual spray for the treatment of *p. falciparum* severe paediatric malaria. The active pharmaceutical ingredient is artemether, which is a widely used anti-malarial and is currently administered by infusion or orally in a tablet form.

WHO estimates that 3.3 billion people or about half of the world's population is at risk of malaria with one million children dying each year as a direct result of malaria, although a more recent article suggests this figure is likely to be substantially higher. Extensive marketing studies indicate a potential market size in excess of 300 million doses per year.

SUD-001 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 and works by narrowing the blood vessels in the brain.

Migraine is a painful and debilitating condition that disrupts lives, impacts careers and costs employers in lost work and diminished productivity. 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 and is forecast to reach US$4.4bn by 2020.

SUD-002 is the world's first oral spray formulation of ondansetron (marketed in tablet form by GlaxoSmithKline under the brand name Zofran®), the most commonly prescribed antiemetic to treat nausea and vomiting induced by chemotherapy or radiotherapy and also other post-operative settings.

The global anti-emetics market is estimated to reach US$3.6bn in 2015 from US$2.5bn in 2010.

DuroMist™ is an oral spray formulation of sildenafil (marketed in tablet form by Pfizer under the brand name Viagra®), sprayed directly in the mouth over the tongue for the treatment of erectile dysfunction (ED). The Duromist™ dosage form is a metered spray that offers the potential for increased patient convenience, reduced food effect and lower dose.

Treatment of erectile dysfunction was a multi-billion dollar global market in 2012. In the USA alone, more than 18 million individuals suffer from ED. The risk of developing ED increases with age.

SUD-004 is based on the DuroMist™ oral spray formulation of sildenafil and is designed to treat pulmonary arterial hypertension (PAH) in adults. With PAH, the blood pressure in your lungs is too high and your heart has to work hard to pump blood into your lungs. Sildenfail improves the ability to exercise and slows down worsening changes in your physical condition. Sildenafil is marketed in tablet form as Revatio® for PAH by Pfizer.

Sales of therapies to treat PAH, a rare but life-threatening disorder, are estimated to reach $3.5 billion over the next 10 years. Sales of Pfizer's Revatio® tablets for PAH in the USA totalled US$340 million in the 12 months to 30 September 2012, which was the month that Pfizer lost marketing exclusivity, hence opening the market to generic competition.

SUD-005 is an innovative oral spray formulation of midazolam (marketed in the USA as an injection or an oral syrup under the brand name Versed® by Roche) for the treatment of pre-procedure anxiety in imaging and ambulatory/dental procedures.

The market size for treatments of pre-procedure anxiety is estimated to be US$150-170 million.

Following a low-risk regulatory strategy

The strategy of reformulating marketed drugs allows Suda to take advantage of development and regulatory pathways, which are faster and less expensive than for new chemical entities. Our products can potentially be approved in the USA by the US Food and Drug Administration (FDA) under the 505(b)(2) regulation; and in other major territories under similar legislation.

The 505(b)(2) regulatory path is designed for products that are reformulations of existing drugs approved by the FDA. A major advantage of this pathway is that it allows a sponsor to rely, at least in part, on the FDA's findings of safety and effectiveness for the previously approved drug (known as the reference drug), thereby reducing the number of clinical trials required for approval.

Another incentive is three to five years of market exclusivity for 505(b)(2) products, depending upon the extent of changes to the reference product and the type of clinical data included in the approved New Drug Application (NDA).

Our oral spray formulations potentially offer improved efficacy, safety, patient compliance, and patient convenience, compared to the existing marketed products.

ASX ticker symbol: SUD

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