SUDA LTD

ACN 090 987 250

ASX Release

SUDA LTD PUBLISHES SHAREHOLDER NEWSLETTER

PERTH, AUSTRALIA – 13 September 2016: SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, today published its sixth shareholder newsletter, which will be mailed to shareholders.

Mr Stephen Carter, Chief Executive Officer of SUDA said: "The newsletter is a valuable forum for us to put recent news in context; to highlight upcoming events; and to set out in more detail the progress and activities at SUDA.

"In this newsletter, we provide an update on business development activities as we advance towards our first commercial agreements. We describe the progress with ZolpiMist™, our oral insomnia spray, including the successful re-launch in the US and our plans to manufacture and register this unique product in Australia. In this edition, we also discuss our strategy to benefit from non-dilutive funding from grants and the R&D Tax Incentive. There is an update on ArTiMist®, including a new patent that has been allowed in Eurasia and our progress towards registration of our sublingual anti-malarial spray by the Australian TGA as requested by the World Health Organisation. In addition, we report on the feedback from an independent market research group who interviewed over 60 US physicians who manage migraine to assess their views on our novel anti-migraine spray, SUD-001."

Further information:
STEPHEN CARTER
CHIEF EXECUTIVE OFFICER / MANAGING DIRECTOR
SUDA LTD
Tel: +61 8 6142 5555
sjcarter@sudaltd.com.au

NOTES TO EDITORS:About SUDA LTD

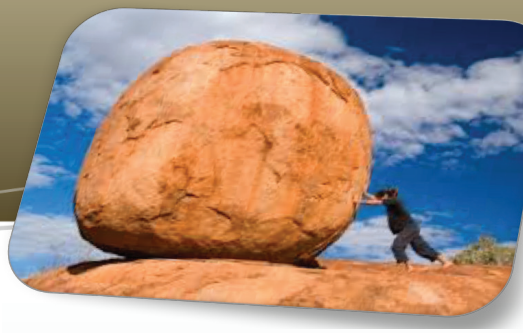
SUDA LTD (ASX: SUD) is a drug delivery company focused on oro-mucosal administration, headquartered in Perth, Western Australia. The Company is developing low-risk oral sprays using novel formulations of existing off-patent pharmaceuticals. The many potential benefits of administering drugs through the oral mucosa (ie: cheeks, tongue, gums and palate) include ease of use, lower dosage, reduced side effects and faster response time. SUDA's product pipeline includes ZolpiMist™, a first-in-class oral spray of zolpidem for insomnia. ZolpiMist is marketed in the USA and SUDA has rights to the product outside of North America. SUDA's most advanced development-stage product, ArTiMist®, is a novel sublingual malaria treatment for children. In a Phase III trial, ArTiMist was shown to be superior to intravenous quinine. Other products in development include oral sprays for the treatment of migraine headache, chemotherapy-induced nausea and vomiting, erectile dysfunction and pre-procedural anxiety. For more information, visit 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.



Building momentum towards a series of business development deals

Our negotiations with pharmaceutical companies to license SUDA's first-in-class oro-mucosal sprays continue to advance towards final agreements. These discussions span various products and territories with some being global, some multi-country and others being individual countries.

SUDA expanded its business development outreach in China and met with over 25 Chinese pharmaceutical companies at the ChinaBIO conference in Suzhou on 18-19 May 2016. Some of these meetings have rapidly advanced to full due diligence and discussion of terms.

The business development team also attended the annual BIO International Convention, which is the largest partnering event for the industry. The event was held in San Francisco on 6-9 June 2016. The Company met with over 40 prospective partners, including companies with which SUDA is in advanced term-sheet negotiations https://embed.ticketbooth.com.au/event/decadent-fromage-walking-tour.

The conversion rate from our outreach to the industry into active discussions has been higher than expected. We are actively engaged with over 60 companies who are at various stages of evaluation, due diligence or deal negotiation.

We have overcome several product-related challenges, which have slowed the pace of licensing discussions. With these matters addressed, we are well placed to finalise a series of commercial agreements.

Diary Events

7-9 November 2016 – Cologne, Germany
BIO-Europe 2016
This is a pre-eminent international partnering event in Europe that attracts over 3,000 attendees, including business leaders from large and mid-sized Pharma companies, investors and other industry experts.

16-19 November 2016 – Nanjing, China
Annual Symposium of Drug Delivery Systems
SUDA has been invited to present a paper on its recent breakthrough in oro-mucosal delivery at this scientific conference. The event brings together scientists, academia, as well as healthcare providers, policy makers and investors to provide insights into advances in drug delivery technologies. It will also have a focus on collaborations between China and the rest of the world.

25 November 2016 – Floreat, Perth WA
Annual General Meeting
The AGM will be at the Boulevard Centre in Floreat, Perth 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

Plan to manufacture and register ZolpiMist™ in Australia

We are working with a multi-national contract manufacturer regarding the manufacture of ZolpiMist™ in their Australian facility. With the prospect of licensing deals that lead to registration of ZolpiMist™ in Asia, Europe, South America and Oceania, we could be supplying millions of units from this manufacturing site.

We have also embarked on the initial steps towards registration of ZolpiMist™ by the Australian Therapeutic Goods Administration (TGA). Our regulatory team is evaluating what additional information may, if any, be required for registration beyond the dossier that was used for US FDA approval.

Successful US re-launch of ZolpiMist™ with new branding and marketing

Magna Pharmaceuticals Inc re-launched ZolpiMist™ in the US market in late March 2016. The product has been rolled out in over 20 states so far with an expanding sales force of more than 50 reps.

The new ZolpiMist™ website www.myzolpimist.com and marketing material highlight that the spray initiates sleep quickly. Significantly more patients achieved therapeutic blood levels of the active drug in 15 minutes with ZolpiMist™ than with the branded tablets.

Magna's marketing campaign includes a TV commercial, which is currently being aired in the US. Shareholders can view the advert via the link https://vimeo.com/157661202.

"The best night's sleep I've had in years! This is a great product and super excited to share for other patients to finally be able to get the rest they need!!"

A 30-day supply of ZolpiMist™ in the US market is US$38.88 for the 5mg dose and US$69.88 for the 10mg dose of the oral spray.

Health insurance companies are adopting the product onto their formularies and patients are requesting re-fills of their prescriptions.

Broader rights to ZolpiMist™ include South America

We amended our agreement with Amherst Pharmaceuticals, expanding our rights to ZolpiMist™ to include South and Central America and South Africa. As a result, SUDA now has a global license, excluding North America.

In the countries newly added to the licensing agreement with Amherst, the companies will share equally the proceeds from commercialisation of ZolpiMist™.

As part of the amended agreement, SUDA has also regained global rights to SUD-002, our oral spray of ondansetron for treating nausea and vomiting induced by chemotherapy, radiotherapy or surgery.

We have accelerated our efforts to finalise the formulation of SUD-002 prior to scheduling a meeting with the FDA. We are targeting early CY2017 for the FDA meeting.

These broader rights open new opportunities for SUDA to execute licensing deals. Our business development activities for ZolpiMist™ are well advanced in many parts of the world, including the newly added territories.

The outcome of this meeting will be an important catalyst for out-licensing SUD-002 in the USA and elsewhere in the world. We already have prospective licensees awaiting the FDA's feedback.

Non-dilutive funding from grants and R&D Tax Incentive

We were recently awarded an Innovation Connections matched grant of $50,000 to support the development of our new-generation SUD-003 sildenafil oral spray using our permeation enhancing technology in collaboration with the University of Western Australia.

This initiative is part of the Australian government's National Innovation and Science Agenda and is intended to connect more small and medium businesses with researchers and to foster the development of new ideas with commercial potential.

We are constantly seeking opportunities to benefit from non-dilutive funding in order to support the development of our OroMist® technology and novel oral sprays, as well as our commercialisation activities.

We received a refund of $0.7 million from the Australian Taxation Office under the R&D Tax Incentive for eligible expenditure during the 2015 financial year. We anticipate claiming a similar refund this year, based on our R&D expenditure for the 2016 financial year.

The R&D tax incentive provides a tax offset for eligible R&D activities, and targets R&D benefiting Australia. The incentive, which came into effect in 2011 and replaces the R&D tax concession, encourages companies to engage in R&D. It is a valuable benefit for companies such as SUDA, which are investing to develop innovative new therapies.

SUDA also benefits from Australia's Export Market Development Grants (EMDG) scheme, designed to support the country's aspiring and current exporters. Administered by Austrade, the scheme covers a wide range of industry sectors and products, including business development activities such as ours to export intellectual property and know-how outside Australia.

In the 2015 financial year, we received an EMDG grant of approximately $80,000. We envisage claiming for a similar grant for the 2016 financial year, based on our ongoing commercial activities.

Brexit impacts our strategy to secure European grants

With the decision made and steps underway to constitutionally separate Britain from the EU, researchers have begun to experience the effects that Brexit will have on science and research. There is already evidence that EU bodies awarding funding are reluctant to commit short term and long term funding to British science.

> An email from a EU funding group to a UK university: "Unfortunately, the general consensus was that it is preferable to exclude the UK members. The main argument is a sort of 'precaution principle': provided the confusion, incertitude and lack of information."

SUDA Europe Ltd, based in the UK, applied for a European & Developing Countries Clinical Trials Partnership (EDCTP) to accelerate the development of ArTiMist® for use as a pre-referral treatment of paediatric malaria.

Despite positive feedback from the reviewers, our UK subsidiary was not successful in its application. Only 5 projects were accepted by EDCTP from 150 proposals.

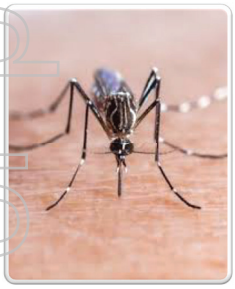
Our mission is to improve the health and lifestyle of the global community by providing new, high-quality, innovative, pharmaceutical products to assist in the treatment of various conditions whilst maintaining consistent growth and investment value for shareholders.

Progressing towards registration submission of ArtiMist® with the TGA

SUDA is progressing towards a submission to the Australian Therapeutic Goods Administration (TGA) to register ArTiMist® as a treatment for severe paediatric malaria. The regulatory dossier, submitted in the form of a Common Technical Document, is a huge undertaking that involves preparing and submitting more than 1,000 individual files.

The challenges that we have faced to complete the dossier relate to the insufficiency of some of the work undertaken by our former collaborators in the UK. We gained full control of ArTiMist® in 2015 through the acquisition of minority shareholding in Malaria Research Company Pty Ltd owned by UK-based ProtoPharma Ltd and its parent London Pharma Ltd.

The TGA usually takes about 12 months to complete their review of a regulatory dossier.



"We are progressing towards the submission of our regulatory dossier for ArTiMist® with the TGA in CY2016. This will be a significant milestone for SUDA and an important step towards large-scale access to our novel sublingual spray for children suffering with the disease in malaria-endemic countries."

In our discussions with the World Health Organisation regarding Pre-Qualification of ArTiMist®, one of their key requirements was for the product to be reviewed by one of the five major regulatory agencies across the world, which includes the TGA. Pre-Qualification by the WHO will ensure that ArTiMist® is available for the procurement of anti-malarial treatments by national and international agencies.

New ArTiMist® patent granted in Eurasia

We have been granted a new patent for ArTiMist® in Eurasia.

The Eurasian patent system provides a uniform application procedure in the territory of nine States party to the Eurasian Patent Convention (EAPC): Turkmenistan, Republic of Belarus, Republic of Tajikistan, Russian Federation, Republic of Kazakhstan, Republic of Azerbaijan, Kyrgyz Republic, Republic of Moldova, Republic of Armenia.

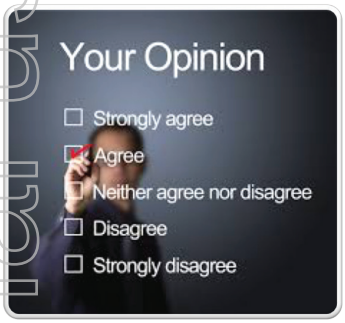
The patent covers the pharmaceutical composition of ArTiMist®, the route of delivery, the device and methods for the treatment of uncomplicated and complicated malaria. The patent provides protection for ArTiMist® until 2026.

Approximately 270 million people are at risk of malaria in the Middle East and Eurasia, which represents 8% of the world population at risk. Since the early 1990s, malaria transmission in the region has increased due to political and socioeconomic problems, mass population migration and weakened malaria prevention and control programs.

"This new patent further strengthens our intellectual property in key territories. The broad claims in this patent ensure proprietary ownership of our unique sub-lingual spray for paediatric malaria."

Ask the medical experts: *SUD-001 market research*

An independent market research group interviewed over 60 US physicians who manage acute migraines to assess their views on SUDA's novel sumatriptan anti-migraine spray, SUD-001, and whether they would prescribe it. The group also spoke to several payers regarding pricing in the US market. This is an extract from the interviews:



Q: What do you prescribe as 1st line abortive therapy for migraine?

A: Oral triptans dominate the market with 7 triptan molecules approved. The market leader is sumatriptan.

Q: What about patients with severe or sudden onset migraines who want faster pain relief?

A: Good options for these patients are triptans delivered by injection, nasal spray or transdermal patch.

Q: What are the other drivers for prescribing triptans with an alternative route of administration to a tablet?

A: Patients who experience vomiting may not be able to swallow tablets and thus need an alternate route of administration.

Q: Why is sumatriptan the most widely prescribed triptan?

A: Sumatriptan was the first triptan on market, launched by GSK as Imitrex®/Imigran®, and still holds a majority share with 63% of script volumes.

Q: What is the key unmet need for migraineurs?

A: Better routes of administration to obtain faster onset of action is an unmet need, because most patients do not like injections.

Q: What is your reaction to the profile of SUD-001 oral spray?

A: SUD-001 seems like a viable treatment option. I don't think many things will work better than this. There is better bioavailability with this product.

Q: What will drive the use of SUD-001 in the market?

A: Ease of administration – current injection and nasal sprays have shortcomings. Patients will prefer an oral spray versus an injection or nasal spray.

Q: How would you compare SUD-001 with first-line Imitrex®/Imigran® tablets?

A: If I'm in that subset of patients that benefit from SUD-001 over the high-dose 100mg Imitrex® tablet, that means something to me. And if I'm in the vomiting group, it's very useful to me.

Q: Any other benefits of SUD-001 versus tablets?

A: There are also patients who experience poor gastrointestinal tract absorption of the tablets who would benefit from the SUD-001 oral spray.

Q: To how many patients would you prescribe SUD-001?

A: Physicians interviewed would prescribe SUD-001 in up to 35% of their patients who experience nausea and/or vomiting; additionally, 50% of physicians would prescribe SUD-001 before nasal sprays and injectable triptans.

Q: What price would be acceptable for SUD-001 in the US market?

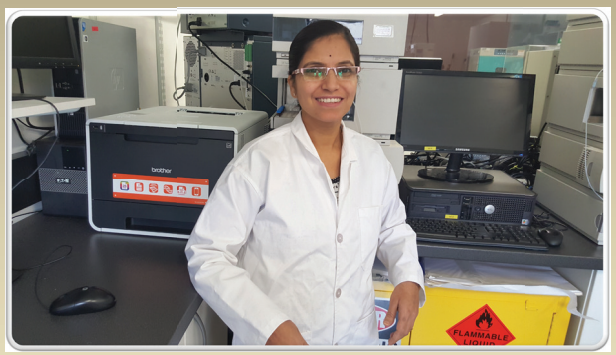
A: Payers in the US would tolerate up to a premium of 20% for SUD-001 from current branded triptans before facing additional market access restrictions. The leading nasal spray in the US, Zomig®, is priced at approximately US$395 per prescription.

Staff profile: Kalpana Baride – Development Chemist

I am a research & development professional with over 16 years experience. My expertise includes formulation development, pilot-scale manufacturing, process validation, stability analysis and optimisation, and patent searches.

My educational background is broad, covering several specialisations. I have Masters in Life Sciences and in Chemistry from Osmania University, India, as well as a MBA and Post-Graduation Diploma in Intellectual Property from Indira Gandhi National Open University.

I joined SUDA in November 2014 and I am working in our formulation laboratory on several of our key pipeline projects. These include the taste improvements to our SUD-001 sumatriptan oral spray for migraine and also the development of our novel permeation-enhancing technology that we have utilised in our new-generation SUD-003 sildenafil oral spray for erectile dysfunction.



Kalpana Baride in SUDA's formulation laboratory in Osborne Park, Western Australia

Top-20 Shareholders - as at 29 August 2016

	Name	Number of Ordinary Fully Paid Shares Held	% Held of Issued Ordinary Capital
1	CITICORP NOMINEES PTY LIMITED	67,810,173	5.94
2	CS FOURTH NOMINEES PTY LIMITED	49,171,293	4.31
3	UBS NOMINEES PTY LTD	35,799,960	3.14
4	HSBC CUSTODY NOMINEES	22,134,145	1.94
5	J P MORGAN NOMINEES AUSTRALIA LIMITED	18,251,526	1.60
6	KAMALA HOLDINGS PTY LTD <KAMALA 1994 SUPER FUND A/C>	14,411,890	1.26
7	MR PETER NORMAN DUNN	14,000,000	1.23
8	MISS JESSICA LIEN	13,288,700	1.16
9	MS GIOVANNA LINA GAN	12,100,000	1.06
10	BAMBER INVESTMENTS PTY LTD	11,827,364	1.04
11	ONICAS INVESTMENTS PTY LTD	11,089,187	0.97
12	KAMALA HOLDINGS PTY LTD <THE KAMALA (1994) S/F A/C>	10,000,000	0.88
13	MR THOMAS PAUL MCGELLIN + MS TANYA MARGARET KARAL	9,903,675	0.87
14	DR MICHAEL WUNSH <SUPER PLAN A/C>	9,000,000	0.79
15	BAMBER INVESTMENTS PTY LTD	8,350,000	0.73
16	MRS LINDA LIEN	8,294,750	0.73
17	MR REGINALD CRAIG FREIER + MR MARK DAMIAN FREIER	7,936,092	0.70
18	W PAUL SUPER PTY LTD <W PAUL SUPER FUND A/C>	7,645,000	0.67
19	PETO PTY LTD <1953 SUPER FUND A/C>	7,440,000	0.65
20	M & S BROOKE PTY LTD	7,176,000	0.63
Total: Top-20 Shareholders of SUD Ordinary Fully Paid Shares		**345,629,755**	**30.30**

SUDA LTD

Level 1, Unit 12, 55 Howe Street, Osborne Park, Western Australia 6017
Phone: +61 8 6142 5555 Fax: +61 8 9443 8858 Email: info@sudaltd.com.au Website: www.sudaltd.com.au