SUDA PHARMACEUTICALS LTD

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Special update from the CEO

OCTOBER 2020

SUDA NEWS

Positive Steps Forward

Hello and welcome to our latest update on your company. I thought it appropriate to open my comments to you by reflecting upon the current reality dealing with the social and economic effects of COVID-19.

I would like to extend my hope that you are finding the energy and heart to adjust to these new and trying conditions.

Here at SUDA, in our engine room in Perth and in the eastern states it is all systems go and we are pleased that we have a busy, positive and stable base to operate from.

Since I last wrote to you, we have received early TGA approval for the registration of our lead product, ZolpiMist, used for the treatment of short-term insomnia in adults. We were particularly pleased with this notification as it represents SUDA's first TGA approved product and it was not expected until the last quarter of the year. More on this notable achievement later in this letter.

As I write this to you, we're also proud to announce that the results are in from our pre-clinical animal trials on anagrelide and they are positive indeed. Please look further in this bulletin to find more detail on this significant progression. And, we recently received notification from the Australian Patent Office. They have accepted our anagrelide patent application and it will now proceed to grant, adding to the granted patents already in place in Europe and Japan.

Our current focus areas are oncology and the central nervous system, with our lead product in each area being anagrelide and ZolpiMist. We are committed to building our presence in these areas in addition to executing on the programs that we have underway.

> *"We're also proud to announce that results are in from our pre-clinical animal trials on anagrelide and they are positive indeed."*

Financially we're more than comfortable for the next year's operation thanks to your vote of confidence in filling the entitlement offer that was heavily over-subscribed and resulting in a further placement, in all totalling $4.09 million. Adelaide's Baker Young were lead manager to the issue and our hat is tipped in their direction. To you, our shareholder, a sincere thank-you from all of us in the SUDA team.

As we are all faced with the issue of travel bans, we have taken a forward position with all aspects of digital media and communication. We regularly participate in investment seminars staged via Zoom and other mediums and I have participated in interviews with channels such as Boardroom Media, Proactive Investor, Ticker, AusBiz, Stockhead and Stockpal Asia, all of which are available on our website. Edison Research and Independent Investment Research also initiated coverage on the company and copies of their research can be found on our website.

Special update continued on the following page

On the welcome and farewell front, we greet our new company secretary, Phillip Hains and say goodbye to our long-serving CFO and company secretary, Joseph Ohayon. Phillip is a chartered accountant running a specialist public practice, The CFO Solution. Joseph served the company faithfully since 2010 and his invaluable contribution to both the company and myself will be missed. He left at the end of September and we wish him well in his new endeavours.

We also welcome aboard our new General Manager, Tony Macintyre, and later in the piece you can find more about Tony and our Quality Manager, Clare Newby. Our team is the heartbeat of the company and very much deserve acknowledgment for their important contribution.

We have a strong balance sheet, TGA approval for our lead product and positive progress for our cancer program. I am happy to bring good news to your desk and I hope you find the rest of this newsletter a reinforcement of your acuity in the decision to invest in us and a confirmation that we are treating your investment seriously.

With Kind Regards,
Dr Michael Baker, CEO & MD

WELCOME ABOARD TONY

We have a new General Manager! Tony Macintyre has joined the team and brings with him a diverse and valuable bundle of talents. He started his career as a medical scientist in the field of diagnostic pathology and subsequently moved on to B2B sales before again adjusting his experience bank and proceeding into operations management in the field of medical device manufacture.

He is excited by our technology platforms and the challenges in the field of pharmaceutical development that are synergistic with his experience in the operational and commercial fields.

"I love the big picture and working with people to help realise their potential and achievement of shared goals."

Tony Macintyre
General Manager

THE QUALITY ASPECT

In this edition we also acknowledge and bring to your attention the efforts of our Quality Manager, Clare Newby. Every company has an engine room and within there needs to be someone who ensures that it runs to expectation and efficiency.

That person is Clare Newby.

Her background includes managerial roles in analytical chemistry, laboratory management and she has been active in key areas of creating analytical development methods.

Outside the office she is active in the Scouting movement (having received her own Queen Scout award from Her Majesty at Windsor Castle in 2002) and as well as her science driven abilities she is a qualified high school teacher in maths and science.

Her abilities and commitment are an integral ingredient in the smooth running of Team SUDA.

Clare Newby
Quality Manager

TGA APPROVAL

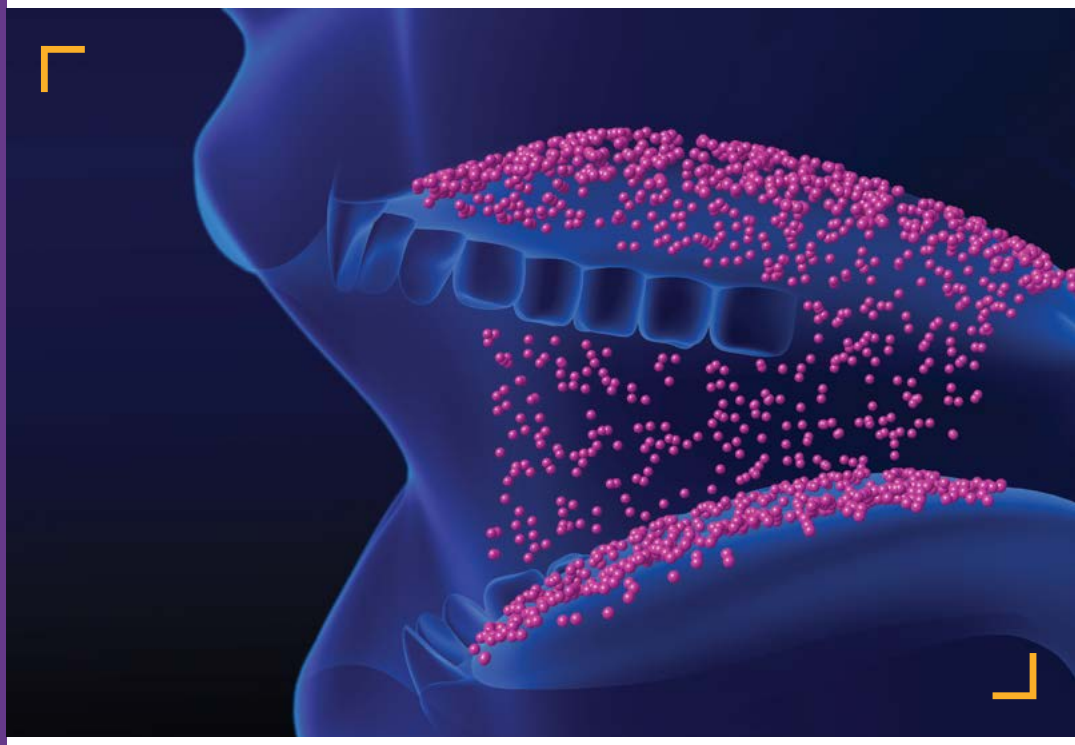
A significant event in the history of the company has occurred. In July, The Therapeutic Goods Administration granted us approval to proceed with the registration of ZolpiMist, our treatment for short-term insomnia in adults.

We are pleased indeed as we had not expected an outcome until later in the year. The approval also includes the supplemental API supplier and final product manufacturer. This allows us to supply the product at a more competitive price and potentially allows us to target additional territories. The benefits are many. (1) Zolpimist can be commercialised and sold within Australia. (2) It demonstrates our good manufacturing practice and ability to achieve regulatory approval for our products. (3) It will establish and cement further our credibility with our partners and assist them in their submissions in their respective territories with the amended API supplier and manufacturer.

We cannot over emphasise the importance of this approval to the company. It is the first step to bringing a product to market and we are excited to have reached this milestone. We are in discussions, looking to select our Australian commercialisation partner.

Another important aspect of the TGA approval is that the data will feed into the regulatory submissions of our partners. The partners that we have in place include TEVA covering Brazil, Chile and Mexico; Mitsubishi Tanabe Pharma Singapore covering Singapore, Malaysia and the Philippines; and we are very pleased to have recently added Mitsubishi Tanabe Pharma Korea to our partnerships for the territory of South Korea. We share the frustrations of our shareholders in that we are not in a position to provide updates on the progress of our partners. Rest assured that we continue to work closely with each of our partners and where possible, we will continue to keep the market updated and we look forward to doing so in due course.

Importantly, we are continuing to pursue partnerships to cover additional territories in line with commercialising the product across the globe.



POSITIVE RESULTS FOR ANAGRELIDE

As you know, we are repurposing anagrelide for the treatment of metastatic disease in patients that have particular solid tumour cancers. Continuing the good news flow, we are pleased to tell you that we have the results from the pharmacokinetic study performed at Covance Inc., analysing several oral spray formulations of anagrelide. One of the formulations that was included in the study demonstrated a statistically significant increase in bioavailability, with 43% higher levels in the blood compared to the capsule form of the drug, Xagrid™. The unwanted cardiostimulatory metabolite also showed an increase but this was much smaller (28%) and was not statistically significant. This supports the concept that we could provide patients with lower doses of the drug, while at the same time reducing their exposure to the cardiostimulatory intermediate. This reinforces our belief that an oral spray formulation of anagrelide could provide a safer means by which the drug could be more safely administered to patients for the treatment of metastatic disease.

While this work was conducted in animals, the data generated has nevertheless given us confidence in the strategy of creating an oral spray technology for anagrelide. It is a significant step and it demonstrates that our approach of delivering drugs as an oral spray may be a better way to dose patients than the traditional delivery path of the tablet, pill or capsule. In this instance, the capsule form of anagrelide, Xagrid.

Our Project Director, Dr. Richard Franklin, who specialises in drug metabolism and pharmacokinetic studies and who has been involved in the development of anagrelide, said

"This is a very exciting development for the project. We are delighted that one of the formulations tested leads to increased bioavailability and could reduce exposure to the cardiostimulatory immediate."

Dr Richard Franklin
Project Director

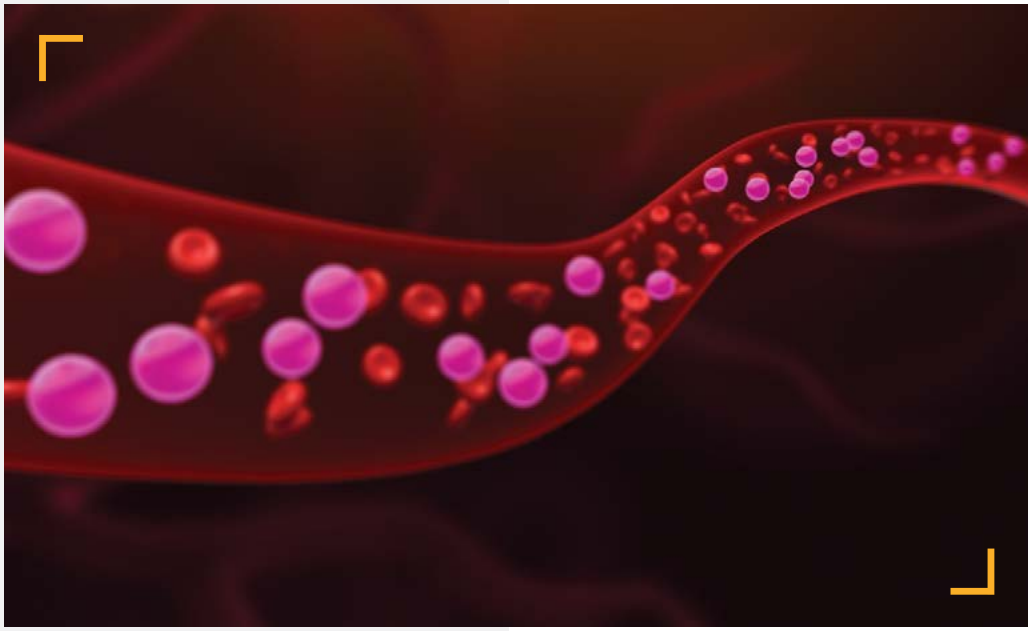
Dr Franklin gained his PhD from Surrey University in the UK in Drug Metabolism and Pharmacokinetics. He has worked for several major drug companies including Glaxo, Wyeth, Sterling Winthrop and AstraZeneca. He was head of New Product Innovation at Shire Pharmaceuticals and involved in the development and registration of anagrelide for the treatment of essential thrombocythemia in Europe.

Richard joined SUDA in August 2019 as a Project Director.

NEXT STEPS

We are continuing to optimise and enhance the formulation for anagrelide with the aim of producing a pharmaceutical grade product. Once the formulation has been refined, we will complete pre-clinical toxicology studies, prior to initiating clinical trials.

As anagrelide has previously been approved by both the FDA and the EMA, it is anticipated that a much-reduced package of pre-clinical testing will be required for the future development of this unique formulation.



ANAGRELIDE AND CANCER

In recent years, a number of reports have been published showing that in several solid tumour cancers, increased platelet levels result in lower rates of survival compared to patients who have normal platelet numbers. A recent study that looked at the role of platelets in cancer development expressed the view that platelet inhibition promotes antitumor activity via an immunologically based mechanism. This suggests that new immuno-oncology therapies, such as checkpoint inhibitors or even Chimeric Antigen Receptor (CAR) T cell therapies could work well in combination with anagrelide. The authors of this work also expressed the hope that their studies would catalyse efforts to optimise cancer therapy by simultaneously blocking platelets and immune check point molecules in upcoming clinical trials.

In earlier work, the incidence of certain cancers observed amongst 5,845 patients included in various anagrelide clinical trials was compared to that seen in the Surveillance, Epidemiology, and End Results (SEER) Program, which provides information on cancer statistics in the general population. For certain cancer types such as colon, lung, breast, uterine, prostate and bladder cancer, there were between 25%-54% fewer cases in the anagrelide treated group, suggesting a potential protective effect of the drug. This external evaluation is insightful and bodes well for our future research and development of the product.

In other work we have looked at a number of different cancer types that could be candidates for clinical trials given the incidence of increased platelet levels (thrombocytosis), the use of combination immunotherapies and the targetable pool of patients suffering from the particular cancer. We are now performing additional work to further define the most suitable cancer target.

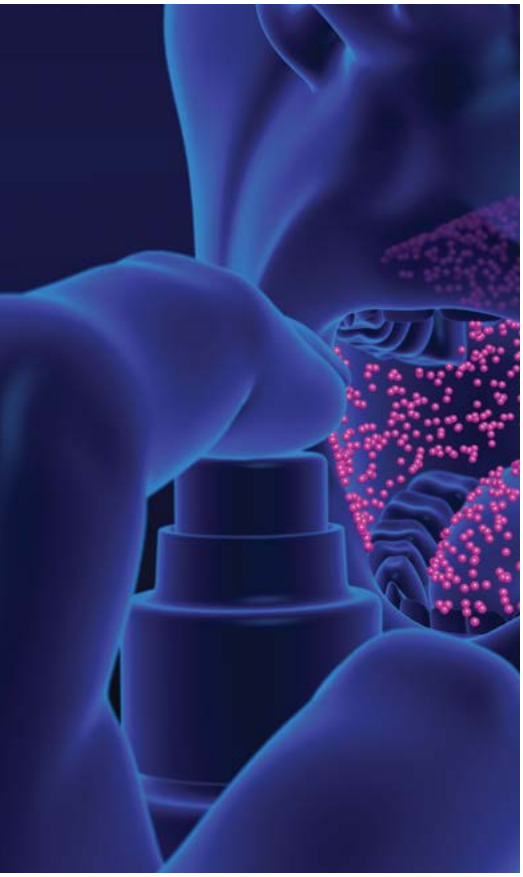
	Median % of Thrombocytosis[#]	Potential Combination Therapy	Targetable Pool of Patients in the US[*]
Non-small cell lung	25.2%	Keytruda	44,100
Ovarian	29.0%	Avastin + Chemo	13,000
Renal	23.7%	Yervoy + Opdivo	7,200
Colorectal	11.6%	Avastin + Chemo	34,100

[#]stage 3/4 cancer
[*]new cases per year, estimate from Oncofocus Solutions

ANAGRELIDE PATENT

As we go to press, we've recently announced that the Australian Patent Office has accepted our patent application and the patent will now proceed to grant status.

It has an expiry date of December 2035 and joins our patent approval family in Europe and Japan. We are pleased indeed as in the drug development space, patents are key to unlocking value creation. We are continuing our efforts to secure grants for the patent in additional markets, including North America.



STRATEGY FOR 2020 AND BEYOND

SUDA currently has a number of products under development using our OroMist platform.

We have partnerships with Sanofi, Ordesa, Strides, Zelira Therapeutics and Cann Pharma. In addition, we have anagrelide under development, which we are deliberately developing internally, as we believe there is a large amount of value to be created by taking this program further along the development pathway.

In order to maintain focus, SUDA has put a number of its legacy programs on hold. ArTiMist has been put on hold and the company will not be committing any further resources toward Midazolam, Ondansetron and Sildenafil.

Nevertheless, we will still look to opportunistically enter into co-development partnerships for these products.

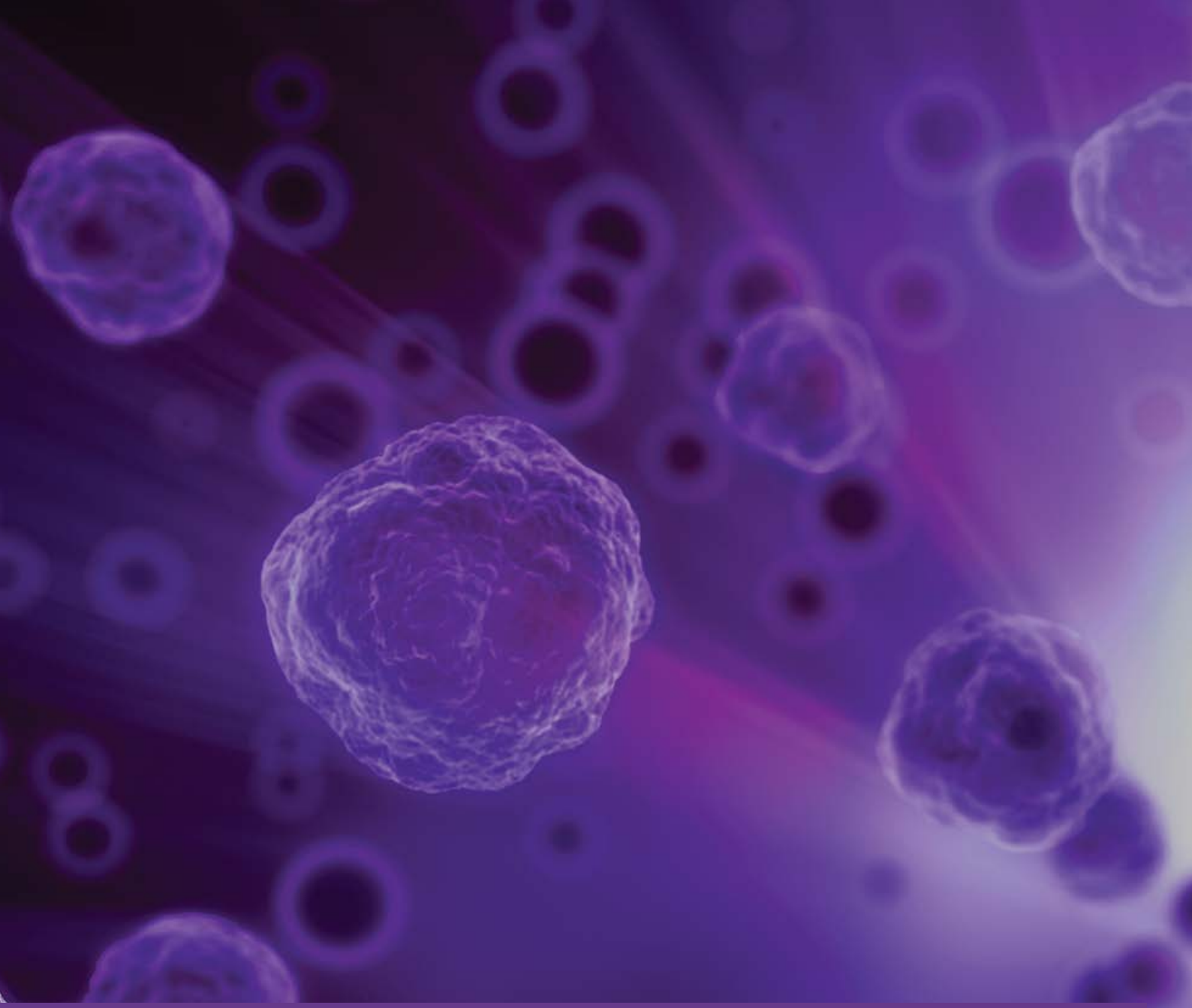
SUDA continues its efforts to secure additional technologies that we will look to develop internally. We are continuing our search unabated to secure new technologies to add to our portfolio with a focus on securing technologies that fit within our current focus areas, namely oncology and the central nervous system.

Preliminary searches have identified a number of interesting technologies that we believe could enhance our current portfolio of products and we look forward to keeping our shareholders and the market updated on this front.

PRODUCT PORTFOLIO

		Licence					
Drug	Internal Development	Feasibility	Pre-clinical	Clinical trials	Regulatory Submission	Approved	Royalties
ZolpiMist* (insomnia)					TEVA, Mitsubishi Tanabe Pharma	Australian Government Department of Health Therapeutic Goods Administration	
Sumatriptan (migraine)		Strides					
Medical Grade Cannabis		zelira THERAPEUTICS, Cann Pharmaceutical					
Undisclosed		ORDESA, SANOFI					
Anagrelide (solid tumors)							

*ZolpiMist has been approved by the TGA and the FDA. SUDA holds the license to ZolpiMist outside of North America



SUDA PHARMACEUTICALS LTD

SUDA Pharmaceuticals Ltd (SUDA) is a world leading pharmaceutical company focusing on delivery of drugs across the oral mucosa using its proprietary OroMist® technology. The Company is publicly listed on the Australian Stock Exchange (ASX: SUD) and headquartered in Perth, Western Australia.

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OUR PARTNERS

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