SUDA PHARMACEUTICALS LTD

Newsletter

MARCH 2021

AN EXCITING YEAR AHEAD

SUDA is set for an exciting 2021. We will continue to build out ZolpiMist, develop anagrelide for the treatment of metastatic disease and progress our development partnerships with Sanofi, Strides Pharma and Cann Pharma. In addition, we look forward to adding new technologies to strengthen our pipeline.

To stay up to date on the latest developments, please subscribe to Shareholder Email Alerts on our website.

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SUDA... FORGING AHEAD IN 2021

Hello again and welcome to our first update for 2021. As much as 2020 was a year best consigned to history we emerged leaner but stronger and our focus is still two-fold – to bring our science to market and at the same time honour your commitment and investment with us.

"Your loyalty and perseverance in sticking with us has given us the wherewithal to continue our current development as well as our search for synergistic opportunities for the company. We consider ourselves fortunate that you have chosen our register and the path we have taken to bring innovation to the delivery process for medication and our novel approach in the fight against cancer as we progress the development of anagrelide for the treatment of metastatic disease."

Throughout 2020 we, like many other businesses, encountered a few bumps in the road, but our core business and eye on emerging technologies in the fields of oncology and the central nervous system are on track and moving forward.

We are financially healthy thanks to a successful raising of $2.76m from new and sophisticated investors in December 2020, and thanks to the government's R&D Tax Incentive Program, we also received a refund of $662k. It would be remiss of me not to thank Adelaide's Baker Young for their support as lead manager to the issue.

We have noted the feedback from our shareholders, where more transparency and disclosure would be appreciated. My response is there is nothing I would like more but our particular business model, working with large pharmaceutical companies, has very defined levels of communication. The ensuing negotiations do not allow detailed disclosure of deal terms, including the identification of the drug in question or development timelines.

Please be assured that SUDA complies with all regulatory and fiduciary responsibilities to the letter in keeping the market informed but there are ongoing negotiations that by their nature need be kept confidential until contracts and agreements are in place.

In this bulletin we will introduce you to some of our key staff and give you up to date reviews on ZolpiMist, sumatriptan (migraine) and we will provide the latest updates on anagrelide, which include appointing MedPharm to assist with formulation optimisation and the appointment of **DR. ANIL SOOD** to our scientific advisory board.

We recently concluded a strategic review of the company's activities and one of the findings has resulted in our general manager, **TONY MACINTYRE** taking on the joint role and duties of Chief Technology Officer with me. This is designed to increase efficiency within SUDA and to leverage the expertise of both Tony and myself.

We are well underway with our projects in 2021 as we approach the Easter period. We hope you all have a well-deserved break and may I conclude by saying 2021 is still to be defined in light of the ongoing pandemic but here at Team Suda we have adapted to the changing environment and our core activities remain focussed. In the months to come we expect to bring you news that will reflect our development and strategy to bring our science to market and at the same time reward your faith in us.

Dr Michael Baker
Chief Executive Officer
and Managing Director

CATCH A FEW Z'S WITH ZOLPIMIST!

With the Therapeutic Goods Administration (TGA) giving approval for ZolpiMist to be marketed in Australia, SUDA continues to progress discussions to secure an Australian partner for the commercialisation throughout the Australian market.

Our sights however are also set on opening up the ASEAN region and with Mitsubishi Tanabe Pharma Singapore indicating their intention not to proceed with the license and supply agreement for ZolpiMist, a decision with no material effect to Suda, we have broadened our focus on acquiring international partners for the region.

Until such time as we are allowed to inform the market as to these negotiations, we thought it would be a good idea to give you a few facts and figures on the debilitating effects of insomnia and ZolpiMist's role in addressing the issue in markets where it is available for sale.

As a reminder, ZolpiMist is the spray version of Sanofi's blockbuster drug Ambien and we have, excluding North America, rest of world rights to market and sell the product. For the territories where we currently have licence and supply agreements, the populations total more than 400 million people.

It is FDA approved and available for purchase in The United States. In fact, it is the only oral spray approved for the short-term treatment of insomnia characterised by difficulties with sleep initiation.

In March of 2021, Phillips released the results of a survey of 13,000 adults across 13 countries (including Australia). This survey revealed that, since the beginning of the COVID-19 pandemic, 70% of respondents experienced one or more new sleep challenges, with 60% reporting that the pandemic had directly impacted their ability to sleep well.

In addition, the Mayo Clinic, in a review of insomnia published in late 2020, identified ZolpiMist as one of four treatments available to deal with the issue.

We thought we would bring you their advice in part:

- Stay active
- Check your medications
- Avoid or limit naps
- Avoid or limit caffeine and alcohol and don't use nicotine
- Don't put up with pain
- Avoid large meals before bed, light snacks OK.
- Make your bedroom comfortable
- Create relaxing bedtime rituals
- Get out of bed when not sleeping.

As we move closer to the day that ZolpiMist will be available for sale here in Australia it is heartening to know that in markets where it is available, it is being reviewed in positive fashion and playing a proactive role in dealing with the effects of short-term sleep deprivation.

SUMATRIPTAN UPDATE!

Migraine can be a debilitating affliction. Anyone suffering from it knows full well the incapacitating effects involve an almost complete shutdown of normal bodily functions. The advantages of an oral spray version of sumatriptan are two-fold. Firstly, the drug can enter the blood stream faster as it avoids the passage of the digestive tract before being absorbed and secondly, some individuals suffering from a migraine also experience nausea and vomiting. Following oral spray delivery, and once the drug has crossed the lining of the cheek and entered the blood stream, it is no longer possible for the drug to be lost through vomiting.

We currently have a partnership with Strides Pharma to develop an oral spray version of sumatriptan for The United States market, initially.

Migraine is a condition that affects between 13-15% of the adult population. According to the Migraine Research Foundation, migraine is the 3rd most prevalent illness worldwide, there are 39 million sufferers in the US and the vast majority of migraine suffers do not seek medical attention for their pain. According to IndustryARC, triptans will continue to have the highest market share for the period of 2020-2025, with the anti-migraine market estimated to reach US$10.5 billion by 2025.

With those figures and the strength and resolve of our relationship with Strides, we are excited to continue working to develop the oral spray formulation in our efforts to bring this product to market.

ANAGRELIDE UPDATE!

WORK CONTINUES STEADILY ON THE FORMULATION FOR ANAGRELIDE TO DEVELOP A PHARMACEUTICAL GRADE PRODUCT.

With the final analysis results in from highly regarded British contract research organization, Covance, we are working to optimise the formulation to take the product into preclinical toxicology studies before advancing into clinical trials. We have contracted the services of the world-leading Contract Development and Manufacturing Organisation (CDMO), MedPharm. They provide topical and transdermal product design and development services and expertise to companies around the world. MedPharm have deep experience in working with numerous formulations having played a role in the approval of 55 approved drug products. We are looking forward to advancing our formulation with their support.

We are also delighted that **DR ANIL SOOD** has agreed to join the scientific advisory board of SUDA. Dr. Sood was the lead investigator in a seminal body of research that was published in the New England Journal of Medicine in 2012, describing the role that platelets play in ovarian cancer in relation to reducing patient survival.

Dr. Sood is a Professor and Vice Chair for Translational Research in the Departments of Gynecologic Oncology and Cancer Biology and co-director of the Center for RNA Interference and Non-Coding RNA at The University of Texas MD Anderson Cancer Center. He is also Director of the multi-disciplinary Blanton-Davis Ovarian Cancer Research Program. Dr. Sood co-leads the Ovarian Cancer Moon Shot Program.

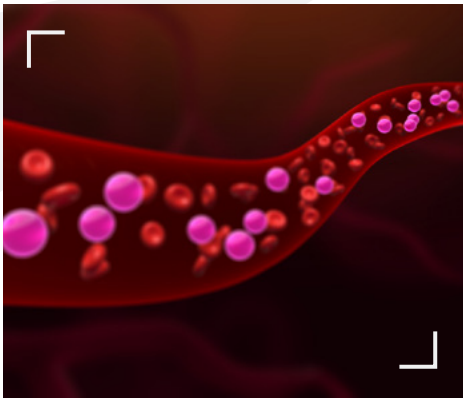
We are delighted that Dr. Sood has agreed to join our scientific advisory board as we mount our attack against cancer by using anagrelide to reduce platelets in patients with specific solid tumours.

A refresher for you on the novel and unique attributes Anagrelide brings to the fight against cancer.

More and more emerging research indicates that a high platelet count in certain cancer types leads to poor outcomes. High platelet count indicates a poor prognosis and reduces the duration of patient survival. It is now well established that platelets proactively support cancer by helping cancerous cells grow, move around the body and at the same time shielding the cells from our own immune system.

This works on a feedback loop; as the platelets assist the cancerous cells and also send out a signal to produce more platelets. A vicious cycle. Any treatment that can safely reduce the platelet count is a sought-after result. Anagrelide has been in clinical use for more than 20 years, to treat Essential Thrombocythemia. There has been one roadblock to its wide-spread adoption however in that delivery of the drug as a capsule results in the generation of a cardiostimulatory intermediate that is responsible for a number of unwanted side effects and safety issues. The tactical strategy and road ahead for SUDA is that delivery of anagrelide via an oral spray will result in the drug being absorbed across the lining of the cheek, bypassing the normal route of drug absorption, thereby reducing the generation of the cardiostimulatory intermediate and limiting the unwanted side effects.

We anticipate this for an oral spray of anagrelide as we expect that it will be absorbed directly into the bloodstream via the lining of the cheek and it will avoid what is known as first pass metabolism, which occurs in the liver.

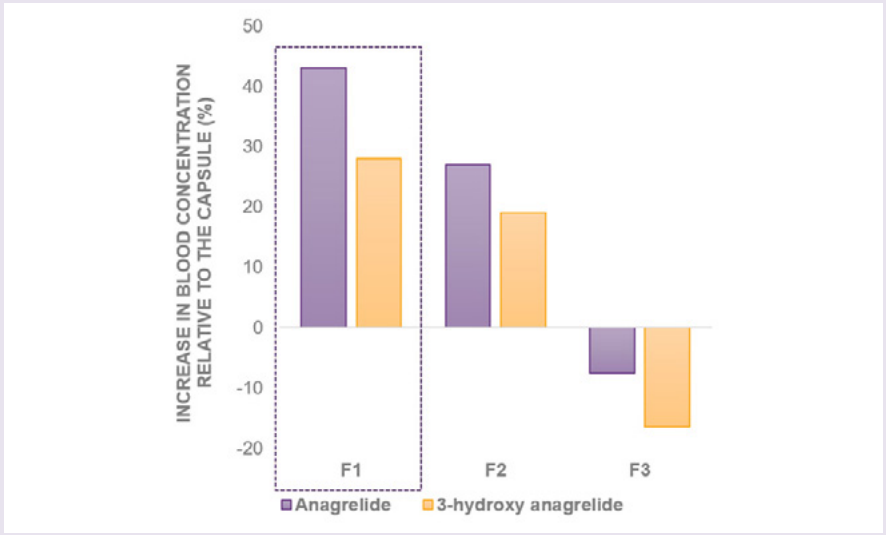


ANAGRELIDE UPDATE CONTINUED

The Covance study demonstrated that for one of the oral sprays developed by SUDA, it displayed a statistically significant increase in bioavailability of the drug compared with analysis of the capsule form, Xagrid. Following a single application, the oral spray formulations tested did not result in increased heart rate in the animals or any signs of irritation. There was a lesser increase in the generation of the cardiostimulatory intermediate, which suggests that a lower dose is possible and it would provide a lower exposure to the intermediate that is potentially detrimental to the heart.

On the business front we have strong IP and as anagrelide is currently an FDA and EMA approved drug, we can leverage much of the work that has been performed previously, thereby reducing the time and cost relative to a drug that has not been tested before. We have patents that cover use of the drug for the treatment of metastatic disease in Japan, Europe and Australia and we are continuing to investigate opportunities in additional territories such as China and the US. From the studies that we have completed, we are also looking to file new IP to fortify our level of protection.

We firmly believe that this program presents a promising addition to the many complex areas of cancer research and treatment.



Bioavailability of three anagrelide formulations delivered as an oral spray versus the approved capsule form of the drug. Oral spray F1 results in an increased bioavailability with a lesser increase of the cardiostimulatory metabolite, 3-hydroxy anagrelide

THE QUALITY ASPECT

In this edition we also acknowledge and bring to your attention the efforts of our Quality Assurance Associate, **PETER O'BYRNE**. Peter devotes much of his time making sure that all aspects at SUDA are in accordance with our high-quality expectations.

Peter has worked in Quality Control and Quality Assurance for a number of high-profile pharmaceutical companies over the last 2 decades. These include Norton Waterford, Ivax Pharmaceuticals, Teva Pharmaceuticals Ireland and Pfizer Perth Pty Ltd. During this time, he has had experience dealing with multiple pharmaceutical presentations and dozens of formulations. Peter has worked on inhalers, solid dose and sterile injectables as well as the associated API, excipients, components and packaging. His specialist skills consist of QC testing, QA processes, sampling, clean room particle monitoring, inventory management and instrumentation management.

Peter obtained his Bachelor of Science from the Waterford Institute of Technology in Ireland and has been living in Australia since 2011 where he lives with his wife and daughter. Peter joined Suda in August 2020 as the QA Officer and is a valuable addition to the SUDA team.

MEET DR CHIRAG DESAI – SENIOR FORMULATION CHEMIST

DR CHIRAG DESAI began his career as an Industrial Pharmacist in India, responsible for manufacturing of tablets, capsules, ointments and injectables. After relocating to Australia in 2002, Chirag completed his Master of Philosophy in Pharmaceutical Science. Subsequently, Chirag completed his PhD and PGDip in research commercialisation and worked in pharmaceutical, cosmetic and veterinary product development, quality and manufacturing. These formative years laid the foundation of his journey towards becoming a formulation scientist.

Chirag has also worked in pharmaceutical and veterinary product development, manufacturing and commercialisation, where he gained experience working with fast dissolving dosage forms, emulsions, suspensions and sustained release implants.

Chirag is passionate about translating scientific research projects from bench top to bedside, improving patient's health outcomes.

Go to our website for more information:
sudapharma.com

"BUILDING OUT THE PIPELINE"

The team at SUDA is continuing to identify new technologies that we believe align with our existing areas of interest, oncology and the central nervous system.

The board and senior management have a large amount of experience in drug development, from research through to commercialisation and we are leveraging that skill set to source, identify and acquire new technologies, in line with our strategic goals.

Currently in our portfolio, ZolpiMist is the most advanced product having approval from the FDA and the TGA. SUDA also has a number of technologies in the reformulation stages but we intend to search out technologies centred on oncology or the central nervous system that are in the late preclinical stages of development, ensuring that we have a full pipeline of technologies that reflect our knowledge and capability to bringing therapeutics to commercialisation.

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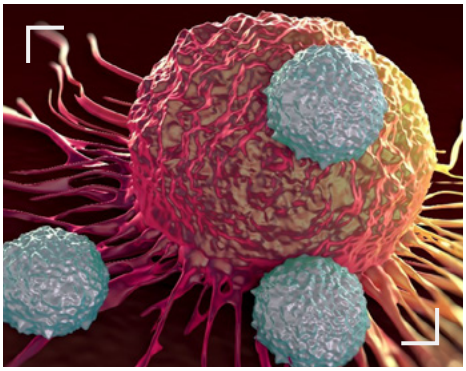
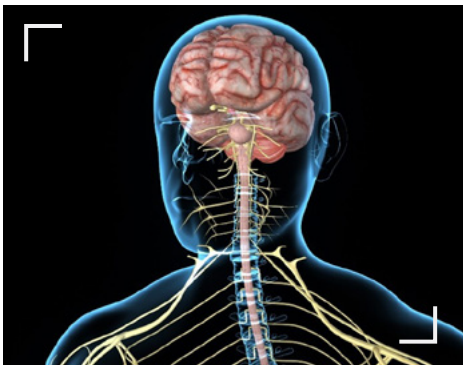




SUDA PIPELINE

DRUG	INTERNAL DEVELOPMENT	LICENSE					SALES (ROYALTIES)
		Feasibility	Preclinical	Clinical trials	Regulatory Submissions	Approved	
ZOLPIMIST* (INSOMNIA)					TEVA, Mitsubishi Tanabe Pharma	Australian Government Department of Health Therapeutic Goods Administration	
SUMATRIPTAN (MIGRAINE)		Strides					
MEDICAL GRADE CANNABIS		CANN PHARMACEUTICAL					
UNDISCLOSED		SANOFI					
ANAGRELIDE (SOLID TUMOURS)	Agrylin, Shire						

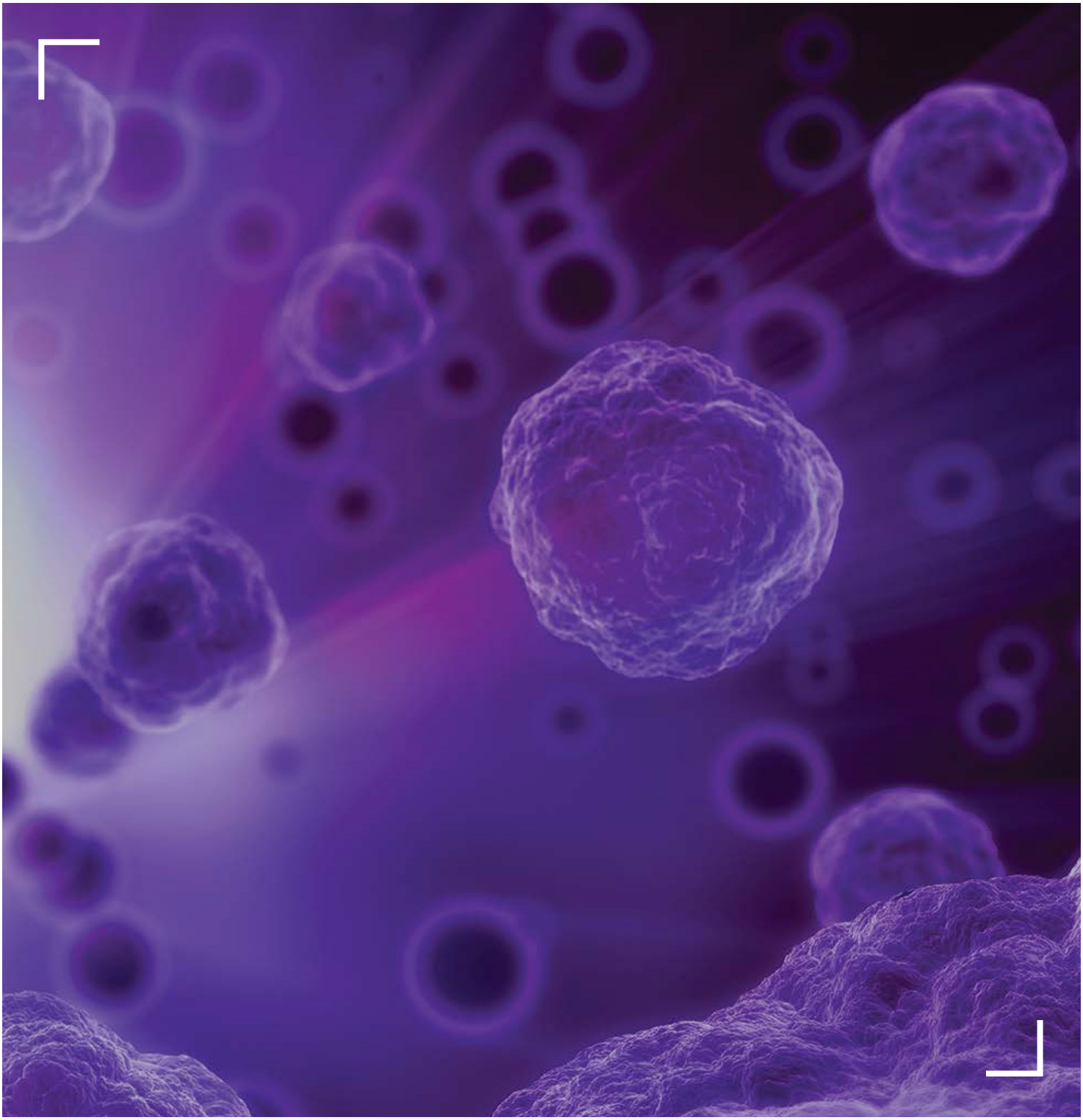
TARGET ASSETS

VALUE

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

SUDA PARTNERS

TEVA
SANOFI
Mitsubishi Tanabe Pharma
CANN PHARMACEUTICAL
AYTU BioScience
Strides



SUDA Pharmaceuticals Ltd (SUDA) is a world leading pharmaceutical company focussing 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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