

EXCITING NEW YEAR AHEAD

We truly have a **treasure chest of product lines** for you to contemplate and hopefully join our register. Our current share price does not reflect our potential.

Oral spray versus pill? No contest. The benefits of oral spray technology are here.



Newsletter

JANUARY 2020

SUDA...UNDER THE MICROSCOPE

One of the benefits of accepting the chair of a public company is the ability to cast aside undue formality and occasionally reach out to you, the shareholder and potential investor, in an armchair fashion such as this. Our political masters call it the “pub test.”

Whilst everything I want to bring to your attention is grounded in fact, I am writing to you in a less than formal manner. A brief G'Day as it were.

I want you to walk away from this reading feeling we've just had the opportunity to tell you a story, a good story. It's about the evolution of oral spray technology supplanting the traditional pill delivery route. We are not a one-technology company. We have many separate and distinct product lines.

I accepted the chair of SUDA Pharmaceuticals last May and in the months since have come to learn what a remarkable company it is, and can be, as our unique oral spray technology comes to the world's attention.

“Firstly, let me introduce myself. My name is Paul Hopper and the lifesciences, biotech and investment sectors are my stock-in-trade. For twenty-five years I have assisted and driven fund raisings in Australia, Asia, Europe and the United States. I have been privileged to have technology seeded four companies on the ASX here in Australia and can look back in pride to my tenure as chairman of Viralytics Ltd, who last year were the success story of the biotech sector prior to being acquired by Merck for half a billion dollars.”

That's a bit about me and I now have the pleasure to tell you how fortunate we are to have signed on our new chief executive officer, Dr Michael Baker, who officially joined the company on the 2nd of January 2020. As you read this, I will be working with him, to transition him into the business and I will be continuing as Executive Chairman during the CEO transition period.

We've announced his appointment to the market but I'd like to give you a more hands-on description as to the man and the position. Dr. Baker will lead the company at a tumultuous time in its history and he has exactly the right combination of scientific and business skills to position us as the leader in the field of oral spray technology. He has a PhD in Biochemistry from La Trobe University and a Master of Business Administration from Melbourne Business School. In his formative academic years, he spent three years abroad where he was a von Humboldt fellow at the University of Cologne in Germany.

He has individually and jointly authored 18 research papers, one in the acclaimed journal, “Science” and has accumulated over 1600 citations. Whilst at university, he also won the prestigious Nancy Mills award for the most outstanding thesis in the Faculty of Science, Technology and Engineering.

He comes to us from a management role at leading Australian life science fund, BioScience Managers.

His particular blend of scientific and business knowledge is exactly what SUDA needs. His practical experience quotient takes in the commercialisation of technologies from pre-clinical research through to clinical trials.

You will be hearing from him on a regular basis and in my role as your executive chairman I look forward to supporting him in his endeavours to reposition your company and be rewarded for your faith in us.



Mr Paul Hopper
Executive Chairman

NOW, BACK TO THE BUSINESS OF THE COMPANY

The drug development process, our core business, can be an expensive and long term process. In SUDA's case however it is not an issue.

We apply our own oral spray technology platform OroMist® to existing drugs already approved and acknowledged to be safe and effective. We reformulate these drugs and then administer them as a spray through the mouth direct to the cheeks, gums, palate or under the tongue, which ensures faster delivery to the bloodstream than traditional pill delivery methods. As we work with drugs already approved by regulatory authorities, we do not have to carry out extensive pre-clinical testing including some animal studies.

Accordingly, we are eligible to submit what is known as an abbreviated drug approval package, a 505(b)(2) NDA. In most cases we are only required to show that drug delivery via our OroMist technology provide the same amount of drug to the bloodstream that the manufacturers of the drug were able to achieve in pill form and we can also rely on the originator's regulatory, clinical and safety data, hence there is no need to redo this work.

That is not our benchmark however. Research to date has shown that OroMist delivery hits the bloodstream twice as fast as pill delivery. A terrific advantage. Equally as important, most cases can achieve patient advantage by this faster onset of delivery with subsequent lower dosage required, resulting in less side effects. We can also overcome problems aligned to pill delivery methodology such as gastro-intestinal irritation and difficulties in swallowing. Lastly, the ability of a drug to reach the blood stream using oro-mucosal delivery means that the drugs avoid the digestive tract and this can potentially limit them being broken down into toxic intermediates.

We currently are in commercial negotiations with a number of companies with regard to new, co-development projects as well as working full steam ahead with our existing partners.

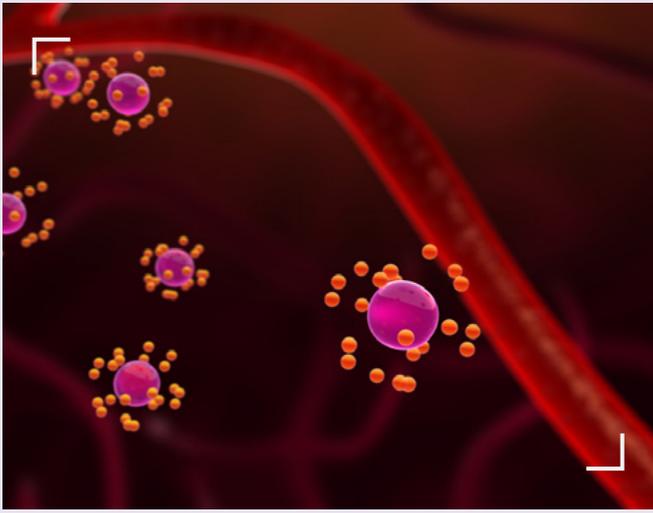
As well as our oral spray technology for delivery alone, we have also joined the fight against cancer via our platelet reducing technology, Anagrelide. More on that later in this report.

Signing off for the moment may I say many thanks to our loyal shareholders who took up and over-subscribed to our recent rights issue and in the same breath thank our new investors who saw merit in our offer.

I am proud to be your chairman and you may expect regular communication from Dr. Baker as we accelerate our main projects, Anagrelide in the cancer fighting corner and our core spray delivery projects, our USA approved and in-market ZolpiMist (insomnia), Sumatriptan (migraine), Midazolam (sedatives and epilepsy) as well as other projects currently under investigation in the field of oral spray delivery.

These brief words are not meant to give you a complete picture of what the company is or what it is doing. It is more a gentle stir-you-in-the-right-direction and to update you on our potential.

Mr Paul Hopper
Executive Chairman



GET TO KNOW US!

The biotech and health sciences sector can be confronting for the lay person to evaluate or understand the scientific complexities of language used within.

There certainly is a degree of Latin inspired or chemically derived descriptions in our word basket and we'll do our best to give you a straightforward description of our varied products and protocols.

The first of which is ... hydrotropes! They are our proprietary permeating-enhancing technology based on novel combinations. What are they? Broadly defined they are a class of compounds able to increase the aqueous solubility of other compounds.

We have discovered that certain hydrotrope combinations form a complex with certain active drug types, thus providing lipophilicity (the affinity of a drug for a lipid environment) and subsequently enhancing the permeability factor. Once the drug has passed through the mouth's mucosa, the hydrotrope releases the drug directly into the bloodstream whereupon it is rapidly absorbed. Utilising our core technology, we had a busy and productive 2019 with numerous positive achievements.

Please go to our website where chapter and verse are laid out for your clinical evaluation.
sudapharma.com

INTERNATIONAL TEAM NEWS

IN THIS ISSUE OF OUR NEWSLETTER, WE'LL TELL YOU ABOUT OUR BUSINESS DEVELOPMENT TEAM AS WE STRATEGICALLY EXPAND OUR OPERATIONS INTO THE USA, EUROPE, RUSSIA AND CHINA.



Heading up our international and national marketing efforts is our new **EXECUTIVE DIRECTOR, DAVID PHILLIPS**. Based in Melbourne, he has approximately thirty years' experience in the sales and marketing of new drugs. He spent 22 years with GSK including time with GSK's corporate venture fund, SR One. He recently was with BioScience Managers, a leading life sciences investment firm based in Melbourne.

As well as his broad reaching oversight of the company's development he will also search out opportunities in the Asia Pacific region.

In addition, in Hong Kong we've appointed **ZONA YIM**, the CEO of Jezans, a company servicing the life sciences industry in China, Russia and Europe. Zona has a long and successful track record in business development transactions throughout these territories.

Our scientific potential is now backed by an aggressive and talented bank of individuals capable of taking our products to the world, be it in Shanghai, Zurich, Chicago or downtown Australia.

2019 HIGHLIGHTS

REFRESHED TEAM - 2019 SAW A PRONOUNCED BOARD RESTRUCTURE



PAUL HOPPER was appointed as Chairman of SUDA Pharmaceuticals in May and given his longstanding background in the life sciences and biotechnology arena, this a very exciting addition for SUDA.

In addition, **DAVID SIMMONDS**, a former Senior Audit Partner with Ernst and Young from 1989-2017, was appointed to the board in March. David brings a wealth of experience and continues to serve as a Director, and chairs the Audit and Risk Committee of, MS Research Australia.

Lastly, **DAVID PHILLIPS**, who was appointed as a non-executive director in April 2018, became an Executive Director in May 2019. David's strong background across business development and venture investing adds an additional dimension to the board.

With the appointment of **DR. MICHAEL BAKER** as CEO, Paul will continue as Executive Chairman of SUDA throughout the CEO integration period.

SUDA also appointed **DR RICHARD FRANKLIN** as a Project Director for the anagrelide program. Dr Franklin was involved in the development and European registration of anagrelide as Xagrid® for the treatment of the orphan condition, Essential Thrombocythemia. Dr Franklin brings a wealth of scientific and regulatory experience to the program.

We have a strong and experienced group of people equally knowledgeable with the science of oral spray delivery and the business of the science necessary to take the company to the world as well as making our mark here in Australia.

PROGRAM ACHIEVEMENTS



ZOLPIMIST™

For ZolpiMist, a post hoc analysis from a pivotal Phase 3 study was published in the journal *Pharmacy and Pharmacology*. Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, “We are pleased with the reported results of this new analysis that demonstrate a more rapid onset of sleep and increased bioavailability of ZolpiMist when compared to zolpidem tablets. The novel oral spray form embodied in ZolpiMist may present patients with a more convenient form and a simple way to achieve rapid sleep onset. For the first time this study has established the clinical proof demonstrating fast sleep onset and the distinct pharmacokinetics of ZolpiMist that support its use in the short-term treatment of insomnia.”



ORDESA & SANOFI

SUDA saw additional support for its platform technology, signing a co-development deal with the Spanish pharmaceutical company, Laboratorios Ordesa, S.L. for a major consumer product in the paediatric market. Upon successful completion of the initial feasibility study that is fully funded by Ordesa, they may elect to expand the scope of the work or to exercise their option for full development of the product. SUDA received an upfront option fee of US\$100,000 and all IP from the feasibility study and full development is to be jointly owned. SUDA also entered into a fully funded feasibility agreement with Sanofi. Based on the outcomes of the study, Sanofi and SUDA may enter into further collaboration.



PATENT EXPANSION

SUDA continued to expand its patent estate across its key programs. The European and Chinese Intellectual Property Offices accepted SUDA's patent applications for its sildenafil-based products: SUD-004 (Pulmonary Arterial Hypertension and Selective Serotonin Receptor Induced Erectile Dysfunction). Furthermore, the European Patent Office also accepted SUDA's patent application for SUD-003 (sildenafil-based products for erectile dysfunction) and the patent has been validated in the United Kingdom, France and Germany. SUDA has had similar patents have been granted in the USA, Japan, Russia, Australia, Canada, South Africa and Singapore. The patent families for Pulmonary Arterial Hypertension and for Erectile Dysfunction provide protection until 2032.



ANAGRELIDE

For the anagrelide program, SUDA received confirmation that the European Patent Office will grant its anagrelide patent, which is a significant value creation point for the program.

The patent covers a broad range of routes of administration beyond SUDA's proprietary oro-mucosal and hydrotrope technologies, including transdermal patches, cream lotions, gels and injectable formulations. The patent has an expiry date of December 2035.

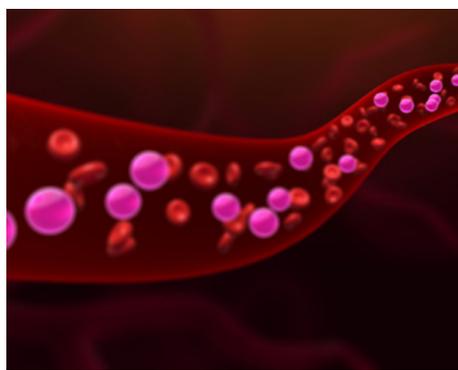
Lastly, SUDA completed a successful rights issue and we recognize that all of the achievements in 2019 were not possible without the support of our shareholders and the further interest of those looking to join the register.

We are delighted with the ongoing support from our current shareholders and we look forward to 2020 as we work to create value for our shareholder base.

“THE SUDA TREASURE CHEST”

The company currently has numerous projects underway and full details are listed on the company’s website.

ASSET	INDICATION	STAGE	PARTNERS
ZOLPIMIST	Insomnia	Commercially available in the USA and regulatory submissions for other territories	TEVA, Mitsubishi Tannabe Pharma Singapore
SUMATRIPTAN	Migraine	Formulation development (late stage)	Strides
MEDICAL GRADE CANNABIS PRODUCTS	Drug Resistant Epilepsy, Melanoma, Motion Sickness, Insomnia and opioid reduction.	Formulation development	Cann Pharmaceutical Australia, Zelira Therapeutics
ANAGRELIDE	Platelet reduction in cancer patients	Formulation development	Internal development
SILDENAFIL	Erectile Dysfunction, Pulmonary Arterial Hypertension	Active IND; Manufacturing in place; Demonstrated bioequivalence	Discussions ongoing
MIDAZOLAM	Pre-procedural anxiety and epileptic seizures	Formulation development (late stage)	Discussions ongoing



ANAGRELIDE

An adjunctive oro-mucosal drug delivery that current research (many peer reviews) shows could improve survival as well as the performance of immunotherapeutic treatments currently making their way to market.

On a standalone consideration, Anagrelide reduces an elevated platelet count. This a beneficial step as a high platelet count plays a key role in the growth and metastatic spread of cancerous tumours.

Like the role of immunotherapy, current data indicates that Anagrelide, once absorbed into the blood stream, can “un-hide” invading cancerous cells so that the immune system can wake up and fight them.

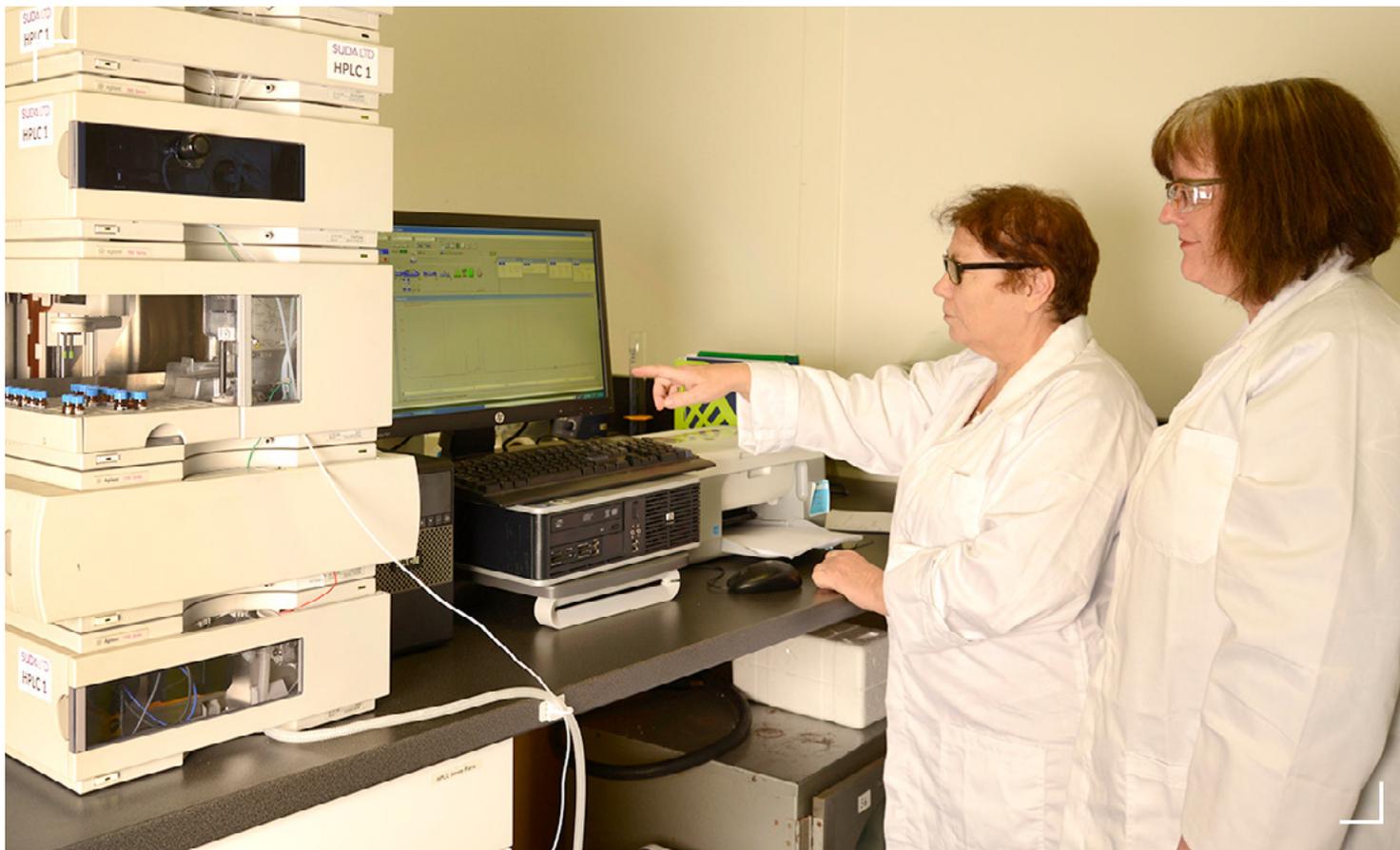
The company has added weight to the project by the appointment of **DR RICHARD FRANKLIN** as Project Director. Richard was involved in the early development of anagrelide during his time at Shire.

Go to our website for more information: sudapharma.com

SUDA PARTNERS



THE YEAR AHEAD



WE HAVE A NUMBER OF NEW AGREEMENTS IN PLACE: CANN PHARMACEUTICAL AUSTRALIA; ZELIRA THERAPEUTICS; LABORATORIOS ORDESA AND SANOFI.

The securing of these partnerships is testament to the strength of our core technology, highlighted by our partners' willingness to engage.

For the current portfolio of products outlined earlier, SUDA will continue to place a large emphasis on partnering with pharmaceutical companies to facilitate development on the technological and regulatory fronts.

In addition to the current programs, SUDA will continue to review the landscape for additional assets in an opportunistic fashion looking to bring novel technologies into the company.

The team at SUDA will continue to build out the ZolpiMist opportunity. With Teva and Mitsubishi Tannabe Pharma Singapore Pte Ltd already on board with license and supply agreements, SUDA is continuing discussions with a number of pharmaceutical companies.

The aim will be to cover additional geographies and build out commercialisation of ZolpiMist worldwide. SUDA will also continue to work closely with the TGA to gain approval for the marketing authorisation application submitted in 2019.

Managing costs will be a core focus for 2020. We will continue to optimise the team to ensure that we are deploying our resources in the most cost-effective manner. We will ensure that we are dedicating resources to projects with the highest potential for value creation.

In 2020, we aim to be far more proactive in managing communication with you, our loyal shareholders. We are committed to ensuring that the business model and strategic direction of SUDA is clearly articulated. We are excited to be moving into 2020 and we certainly look forward to the challenges and rewards that the year is set to bring.



Dr Michael Baker
Chief Executive Officer

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Absorption Rate

95%

<25%



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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