



SUDA LTD

ANNUAL REPORT 2017

SUDA LTD

SUDA LTD AND CONTROLLED ENTITIES / ABN 35 090 987 250

ANNUAL FINANCIAL REPORT

30 JUNE 2017

CORPORATE DIRECTORY

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Company Secretary	Mr Joseph Ohayon	
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LETTER FROM THE CHAIRMAN

"...I have seen management put in place the foundations and building blocks for what has become a very specialised pharmaceutical company with a diversified asset base..."

My name is Mike Stewart and I am the Chairman of SUDA Limited and a major shareholder. I am writing to you, both because I am passionate about what SUDA is striving to achieve, but probably like you, sometimes frustrated.

It would be wrong of me not to suggest that at times SUDA has been a frustrating investment. Most people have short-term expectations and want immediate returns. SUDA has not delivered that.

Unlike you, I have the benefit of understanding the internal workings of SUDA and the challenges we have faced so I am hoping to provide you with a more balanced view of the way I see things developing for SUDA in the future.

Why has the share price stagnated despite excellent news flow?

There are a number of factors:

- Management has focussed more on building a business rather than promoting the business. The pharmaceutical industry is a very complex business with high entry barriers and risks on the one hand, but very large returns for those who get the formulae right. It takes time and resources to build a viable business and I strongly believe that building the business is the absolute bedrock for developing long term and sustainable value for shareholders.
- As you know the share market can be very fickle and shares are often over-bought or over-sold, something management has little day-to-day control over. However the Board recognise that we need to do a better job of communicating our successes to the market and potential new shareholders. You should expect to see and hear more from SUDA in the coming months.
- SUDA, like other pharmaceutical businesses, is a long-term strategic investment for investors with patience. There is a saying: "if you are not investing with a 5-10 year view you are not investing, you are speculating"

You may be interested to know that our Top 50 investors hold 40 per cent of SUDA shares and, in the main, they hold and accumulate on price weakness. These investors have a real interest in what we do and have a longer-term investment horizon. By contrast, of our 2,500 shareholders, around 1,700 shareholders hold less than 200,000 shares



(\$3,600) and account for much of the daily churn. They tend to sell into any small price rise and momentum trade.

So, why SUDA?

In the 1980s, I spent a decade working on aid projects in underdeveloped countries, so I have a real understanding of the impact of tropical diseases in small rural communities. I was attracted to SUDA because of my interest in malaria and the significant impact ArTiMist could have for young children in malaria endemic areas. As time moved on I have witnessed our malaria project advance, against all odds, and I have assisted SUDA untangle a range of legal issues inherited (unfortunately) by the current Board.

Over time, I have seen management put in place the foundations and building blocks for what has become a very specialised pharmaceutical company with a diversified asset base.

Today, SUDA has some 10 highly qualified and dedicated staff covering areas such as research and development, regulatory affairs and business development and compliance. We have a world class, accredited formulation / laboratory facility and have built an impressive, patent protected intellectual property portfolio. Our product pipeline is quite outstanding and, slowly but surely, we are gaining recognition worldwide.

We have signed two important Licensing Agreements; one with Teva Pharmaceutical Industries and another with Eddingpharm. These deals alone are independently valued at \$50 – \$160 million. However, for me what is far more impressive is the Feasibility and Option Agreement with the big global player Pfizer. This speaks volumes about the calibre of our staff and our science.

As I see it, SUDA is a small company focused on building a global reputation.

Guidance

Looking forward, it is always extremely difficult for management to provide guidance and timelines. There are too many variables and many are out of our control. Transactions in the pharmaceutical space are complex and involve extensive due diligence. It is not uncommon for the due diligence and negotiation process to take 12-18 months

with extensive market research, verification and documentation. Laboratory research and product formulation is also a time-consuming process and clinical trials are expensive.

Also putting together the right team and building a reputation for excellence takes time, particularly on the global stage. It can take years to build a reputation and minutes to destroy it.

We have a bold mission: **to revolutionise drug delivery**. This is the mission that underlies the work done by our people, their efforts and their commitment. We have strong leadership, a strong team and a clear direction of what we are looking to achieve.

I genuinely believe that we will continue to grow the value of SUDA with the right resources and dedication and attention to detail.



Michael Stewart
Chairman

MISSION STATEMENT

SUDA LTD is revolutionising drug delivery to improve the health and lifestyle of the global community by providing new, high-quality, innovative, oro-mucosal spray pharmaceutical products to assist in the treatment of various conditions whilst maintaining consistent growth and investment value for its shareholders

REVIEW OF OPERATIONS

KEY MILESTONES FOR THE 2017 FINANCIAL YEAR:

1. Signed a licence and supply deal for ZolpiMist™ (plus an additional licence and supply deal after the reporting date)

2. Feasibility and option agreement with major pharma company

3. ArTiMist® marketing application submitted to TGA

4. New provisional patent for permeation-enhancing technology

1. Signed licencing deals for ZolpiMist™

i. Eddingpharm (Asia) Macao Commercial Offshore Limited (Eddingpharm)

In November 2016, SUDA entered into an exclusive license agreement with Eddingpharm, a leading Chinese pharmaceutical company, for the development and commercialisation of SUDA's novel ZolpiMist™ oral spray of zolpidem tartrate to treat insomnia in China. Once approved by the Chinese Food and Drug Administration (CFDA), ZolpiMist would be the first fast-acting oral spray of zolpidem tartrate available in China.

Under the terms of the agreement, SUDA received an upfront cash payment of US\$300,000 (approx. A\$400,000) and is entitled to receive a further milestone payment of US\$200,000 (approx. A\$260,000) following registration of the product in China. In addition, once ZolpiMist is registered for sale in China, SUDA will receive escalating tiered royalties on net sales in the territory. The total value of the deal could exceed US\$26 million (approx. A\$34 million) based on Eddingpharm's forecast sales for the first 15 years from launch.

ii. Teva Pharmaceuticals International GmbH (post balance date)

Post the reporting date, on 4 July 2017, SUDA entered into an exclusive licence and supply agreement with Teva Pharmaceuticals International GmbH, an affiliate of Teva Pharmaceutical Industries Limited ("Teva"), a leading global pharmaceutical company and the world's largest generic medicines producer, for ZolpiMist™ in multiple countries. SUDA granted Teva a licence to distribute and market ZolpiMist in Brazil, Mexico and Chile, together with an 18-month option to license the product in Argentina, Israel and Australia.

Under the terms of the agreement, SUDA receives an upfront payment of US\$300,000 (approx. A\$400,000) and is entitled to receive further licence fees, registration milestone payments and commercial milestone payments of up to US\$1,750,000 (approx.

A\$2,300,000). In addition, once ZolpiMist is registered for sale in the territory, SUDA will supply the product to Teva and receive a double-digit royalty on net sales.

2. Feasibility and Option agreement with major pharma company

In March 2017, SUDA entered into a feasibility and option agreement with Pfizer Consumer Healthcare. Under the agreement, SUDA is applying its proprietary OroMist® oro-mucosal spray technology to two over-the-counter (OTC) molecules for evaluation by Pfizer.

To date, SUDA has provided Pfizer with preliminary formulations and the parties are discussing next steps.

3. ArTiMist marketing application submitted to TGA

In late 2016, SUDA made a pre-submission to the Australian Therapeutic Goods Administration (TGA) and subsequently submitted the Marketing Authorisation Application (MAA) for ArTiMist (artemether sublingual spray) for the treatment of children with severe malaria. In April 2017, the TGA was accepted the dossier for evaluation. The TGA is expected to complete its review and provide an opinion, including potential approval of ArTiMist, in the first half of 2018.

4. New provisional patent for permeation-enhancing technology

SUDA filed a provisional patent application with IP Australia for a novel mucosal permeation-enhancing drug delivery technology. The application was filed under the international Patent Cooperation Treaty (PCT), which enables SUDA to seek patent protection for its technology in more than 145 countries.

The technical field of the provisional patent application is entitled: 'A method for modifying the penetration of active agents through mucosal membranes using hydrotropes.' It is based on positive results from *in-vitro*, *ex-vivo* and *in-vivo* studies evaluating SUDA's new-generation formulation of SUD-003 sildenafil oral spray for erectile dysfunction, together with *in-vitro* and *ex-vivo* data investigating the technology with a broad range of other molecular drug classes.

This permeation-enhancing technology is intended to overcome some of the challenges associated with delivery of therapeutic drugs across the oro-mucosal membrane (further discussed under OroMist Technology on page 05).

SUDA'S OROMIST® TECHNOLOGY

Increasing the bioavailability (the amount of a drug that become biologically active upon use) of our drug targets, and decreasing the time for the drug to act, are the primary challenges for SUDA's OroMist® sprays. Our suite of technologies addresses bioavailability and onset of action by a combination of proven proprietary and known technologies to optimise solubility, stability, permeability and palatability. Formulations are developed in a logical fashion beginning with simple GRAS (Generally Regarded As Safe) approved excipients and only building to complex solubilisation and or permeability enhancers if required.

With the OroMist® technology, SUDA uses a range of proprietary co-solvents, unique combinations of hydrotropes (see below), plus pH and/or electrolyte addition via specific salts or mixes of excipients for ionisable compounds to solubilise sufficient drug in the correct stable form to provide efficient permeation through the oral mucosa. Lipids (Fats) and lipid/ aqueous mixtures may be used to provide solubility and aid permeation for more lipophilic compounds.

SUDA also has an extensive knowledge of proven techniques to improve solubility including particle size

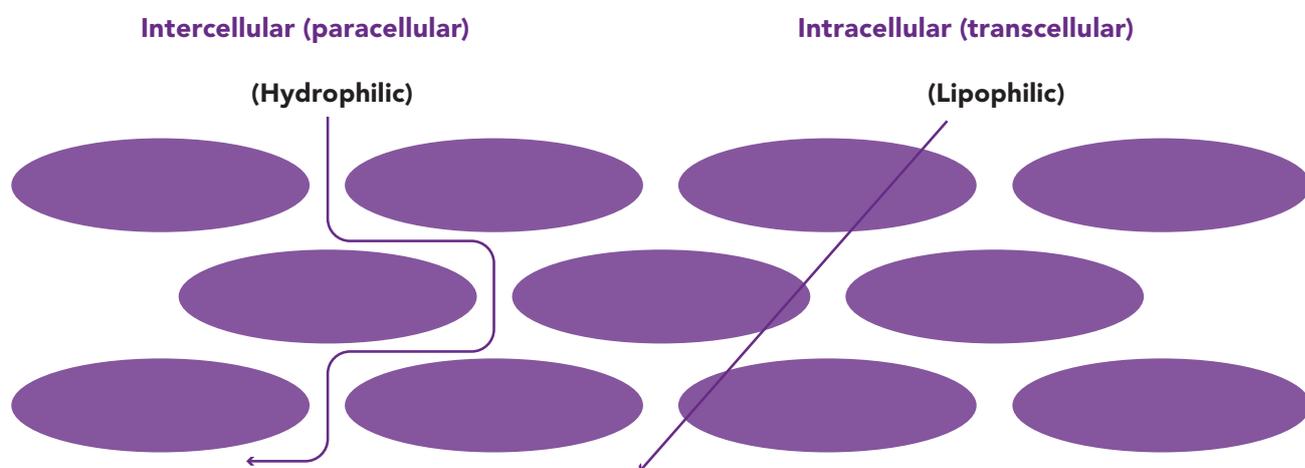
reduction and solid dispersions, complexation with materials such as cyclodextrins and micellar dispersion in emulsions, which may be utilised if required.

Many drugs are very bitter and must be taste masked and flavoured for patient compliance in such a way that solubility and permeation are enhanced or at least maintained. SUDA's use of specific flavour/sweetener/ taste-mask combinations ensure that the formulation is palatable to the user whilst maintaining bioavailability and onset of action requirements.

Permeability enhancers may be required to improve bioavailability and SUDA employs a logical succession of simple to complex systems to aid oro-mucosal permeation.

There are two key ways that a drug can travel across the mucosal tissue, through the cells (transcellular) this is used mostly by fat soluble (water hating) or around the cells (paracellular) for water soluble (fat hating) drugs.

The two mucosal permeation pathways are shown below:



Permeation-enhancing technology

Experiments have shown that most compounds traverse the oro-mucosa via the intercellular pathway.

SUDA's proprietary permeation-enhancing technology is based on novel combinations of hydrotropes. Hydrotropes are broadly defined as a class of compounds able to increase the aqueous solubility of sparingly soluble solutes. They are structurally defined as a molecule consisting of a polar and a non-polar end able to aggregate but unable to form micelles. SUDA has discovered that certain hydrotropes combinations form a complex with the certain active

drug types, thus providing lipophilicity and enhancing permeability.

It was this hydrotrope technology that led Pfizer Consumer Healthcare to sign a feasibility agreement with SUDA in April 2017. The financial benefit for SUDA from feasibility agreements include a fee for service and the potential for commercial licence fees, milestones and royalties. The IP remains the property of SUDA.

REVIEW OF OPERATIONS

Selection of an OroMist reformulation

SUDA has extensive know-how and has developed an internal step-wise approach for the selection of drug candidates to be reformulated. Whilst a key decision point is market size and position of the drug in the market we also look at the potential benefits that an oral spray can bring to the target patient population. Once we have identified a product candidate we then look at the formulation process. It is important to realise that each formulation is tailored-made to accommodate the requirements of the potential target patient population. Furthermore, we need to ensure that we look at a number of key parameters due to the different chemical structure and characteristics of the Active Pharmaceutical Ingredients (API) of interest, which include but it is not limited to:

- intrinsic solubility characteristics;
- hydrophilicity/hydrophobicity;
- molecular weight;
- dose and dosing requirements;
- medical indication;
- acute or chronic illness; and
- IP positions and challenges, if any.

Iterations of formulations are assessed for physical and chemical stability; relative permeability is assessed using our in-house in-vitro and ex-vivo permeation models and using our taste panel to determine palatability. This rigorous process further ensures that formulations that make it through to *in-vivo* pharmacokinetic (PK) and toxicological studies have been thoroughly characterised and have the highest chance of success.

Intellectual Property

SUDA's intellectual property includes granted and pending patents, trademarks and proprietary know-how. The patent estate covers liquid spray formulations of approximately 300 APIs from a wide range of drug classes such as anti-infectives, (i.e. antibiotics and antifungals), anti-asthmatics, barbiturates, and opioids as well as biologically active peptides hormones such as, insulin and cyclosporine. These formulations can be administered to the oral cavity in the form of a micro-mist covering the oral mucosal membranes. The management is currently working with the technical team to further strengthen the intellectual property portfolio as it progresses with its R&D efforts, including the provisional patent application for the hydrotrope permeation-enhancing technology that was filed in November 2016. A list of patents is shown on pages 18 and 19.



BACKGROUND TO ORO-MUCOSAL DRUG DELIVERY

Oral Route

Among the various routes of drug delivery, the oral route is perhaps one of the most studied and preferred by patients and clinicians. About 70% of drugs are administered orally, primarily in tablet or capsule form. However, there are a number of disadvantages associated with the solid-oral administration such as hepatic first-pass metabolism as well as acidic and enzymatic degradation within the gastrointestinal (GI) tract, which can cause a relatively lengthy onset time and/or can exacerbate erratic absorption patterns. Furthermore, patients must be conscious and able to swallow (40% of US adults and 54% of children (6-11 years) report swallowing difficulties) and, in most cases, need to have access to drinking water.

Oral Mucosa

The oral cavity is an attractive site for the delivery of drugs. Its attractiveness resides in the fact that the oro-mucosal membrane is readily accessible to patients and/or carers, the high vascularisation can promote a faster onset of action, and can reduce or avoid the hepatic and intestinal degradation mechanisms.

There are numerous pharmacologically active compounds that could benefit from improved delivery attributes as they present poor oral bioavailability due to poor aqueous solubility, degradation within the GI contents, poor membrane permeability or pre-systemic metabolism [1].

The oral mucosa is the mucous membrane of the oral cavity, which includes the tongue, cheeks, palate and gums. Drug delivery within the oral mucosal cavity is classified into five categories:

- i. local delivery, which is drug delivery into the oral cavity;
- ii. sublingual delivery, which is systemic delivery of drugs through the mucosal membranes lining the floor of the mouth;
- iii. buccal delivery, which is drug administration through the mucosal membranes lining the cheeks (buccal mucosa);
- iv. lingual delivery is drug administration over the tongue; and
- v. gingival delivery is drug administration through the gums.

1 Bruce J Aungst, *Absorption enhancers applications and advances*; 2011 American Association of Pharmaceutical Scientists; (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3291189/pdf/12248_2011_Article_9307.pdf)

The oral mucosa and skin bear many structural similarities, where both epithelial tissues play a crucial role as a barrier against exogenous substances, pathogens and mechanical stress. But their function in the body differs with the oral mucosa being hydrated by saliva while the skin provides a waterproof barrier and the most superficial layer is highly keratinised.

The oral mucosa is 4-4000x [2] more permeable compared to the skin depending on the substance considered. In general, the permeability of the oral mucosa decreases in the order of sublingual being greater than buccal, and buccal being greater than palatal. This rank order is based on the relative thickness and degree of keratinization of these tissues.

The sublingual mucosa is relatively thin, non-keratinised and highly permeable (in the case of water it has been calculated to be 20x [3] higher than human skin) with a rich blood supply consenting a rapid onset of action and absorption of lipophilic drugs. The absorption of a drug via the sublingual route is 3 to 10x greater than the oral route and is only surpassed by intravenous injection. The buccal mucosa is thicker, about 40-50 cell layers, and non-keratinized, and the palatal intermediate in thickness but keratinized.

Additionally, it is estimated that between 60 and 70% [4] of New Molecular Entities (NMEs) potentially exhibit sub-optimal drug delivery characteristics. The balance between 'perfection' and 'good enough' in clinical development is allowing for less than ideal bioavailability or delivery properties, which are tolerated to reduce clinical complexity and increase speed to market. Perhaps it is not a coincidence that two thirds of product launches under-perform expectations.



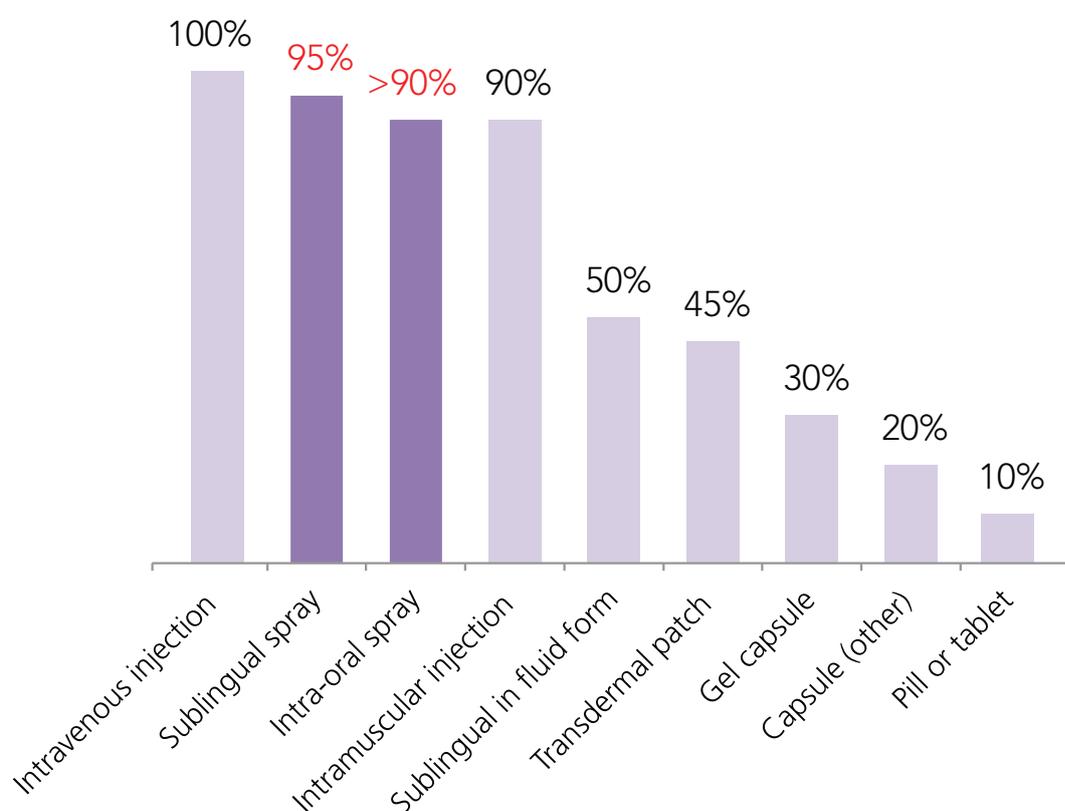
2 *Mathematical modelling of transmucosal drug delivery*
<http://www.maths-in-medicine.org/uk/2012/transmucosal-drug-delivery-report.pdf>

3 C.A. Lesch, C.A. Squier, A. Cruchley, D.M. Williams, P. Speight, *The permeability of human oral mucosa and skin to water*, *J. Dent. Res.* 68 (1989) 1345-1349

4 Catalent, Inc. and Quotient Bioresearch

REVIEW OF OPERATIONS

Bioavailability comparison of different drug administration routes



Source: Physician's Desk Reference, NPPDR, No. 18:676, 1997

Reformulations: a shortcut to market

Development timelines of reformulated drugs can be considerably shorter (3-7 years) when compared to the development of a New Chemical Entity (NCE) which can be over 13 years from discovery to approval, and the development risks are considerably lower than a NCE due to the extensive amount of pre-existing data.

In the USA, the regulatory pathway for approval of reformulations falls under the abbreviated FDA 505(b)(2) legislation. In Europe, there is an analogous legislation, which is based on a hybrid application under Article 10(3) of Directive 2001/83/EC and successive amendments. Applications through either the FDA 505(b)(2) pathway or the EMA hybrid process can leverage the safety and efficacy data generated for the formulations already approved and can rely solely on data showing comparable bioavailability to the reference drug.

PHARMACEUTICAL INDUSTRY: OUTLOOK IN A COST-CONSCIOUS WORLD

Small and large pharmaceutical companies are increasingly outsourcing significant portions of their R&D, manufacturing and corporate processes and rely extensively on partnerships and alliances. In addition, an increasing number of generics firms are expected to enter the top 50 global pharmaceutical companies.

Part of this changing landscape has been also the surge of interest in novel drug delivery technologies and systems. Until not long ago drug delivery was considered of lesser importance in the development process of a pharmaceutical, despite the fact that without an adequate delivery technology a drug is next to useless. In recent years, the market has evolved with the development of drugs and delivery systems being integrated at each step of the way from the preclinical to clinical stage, and in so doing optimising both the commercial and therapeutic drivers. The global drug delivery technologies market is poised to reach \$198.4 billion in 2017 [5].

The pharmaceutical industry continues to take advantage of drug delivery technologies in its efforts to add years to product revenue streams. Although there are several approaches available to companies to manage the lifecycle of products, those who have pursued drug delivery approaches have proven to be more effective than most, particularly when patient/clinical benefits are apparent. New formulation strategies have been shown to deliver the best return on investment, proving significantly more effective than an OTC/branded generic route, repositioning, or a new indication.

Over the last couple of years, the global pharmaceutical industry has been characterized by a major debate on drug pricing pressures, tightening regulatory environment and stagnating economies. These challenges remain for the industry.

The healthcare industry is not immune from cyclical economic ups-and-downs and there is a strong correlation between income and healthcare expenditure. A rise in living standards and ageing society, in both high and low-to-medium income countries, are contributing to an increase in lifestyle-related diseases, ensuring that the industry continue to grow at a faster rate than the global economy. Growth rates in advanced economies are projected to be ranging between low to mid-single digits, whereas in emerging countries pharmaceutical sales are forecast to reach double digits.

Healthcare spending varies with income for two reasons: a) demand rises more than proportionally with income; and b) as countries become richer, households are prepared to forego more discretionary consumption in favour of medical treatments. The level of income influences also the rate of epidemiological change, transitioning from primarily communicable diseases (CDs) to non-communicable diseases (NCDs). Countries in the midst of an epidemiological transition experience much more rapid

increases in health spending than economies that have already made the transition.

Policymakers are unlikely to consent to significant increases in spending, and tight limits will continue to be imposed on public and private healthcare providers. This is particularly true when the demand grows faster than the capacity of the industry itself, which causes prices to rise faster than the economy-wide rate of inflation.

Across the developed world, increasingly stringent medical procurement policies require pharmaceuticals companies to use real-world evidence on health outcomes to convince payers and providers to use their drugs. New procurement policies are likely to slow the pace of 'technological adoption', or the rate at which newly introduced drugs and/or devices, are adopted. In turn this is having an effect on the licensing processes and drug approval timelines.

Cross-border licensing agreements are becoming increasingly complex, lengthening completion timelines and requiring the parties to overcome a wide range of cultural, regulatory and legal hurdles that can greatly differ from country to country and type of drug. Very importantly, the ability and willingness of the interested party to pay for innovative medicinal products, given the ongoing global economic uncertainties, are likely to slow down healthcare spending at least in the medium term.

Among large economies, the biggest increase in health spending is likely to occur in China, which is expected to age like an advanced economy at the same time as per capita income continues to grow at among the fastest rates in the world. The US dollar exchange rate, which has been volatile in many countries is also playing a role in the determination of a suitable transfer price. Nevertheless, the rise in healthcare spending is real enough, and the Chinese healthcare sector will see steady improvement over the next few years, with life expectancy rising along with the number of doctors and healthcare structures.

Stronger US dollar and weak economic outlook is impacting the healthcare expenditure in Latin America. Spending continues to slow as economies remain under pressure, particularly in Brazil and Colombia. Even so, several governments are trying to improve public healthcare systems as much as their budgets allow.

In Europe, economic pressures and a decline in the Euro continue to limit healthcare spending, despite the health needs of an ageing population. The EMEA region is projected to see the world's slowest growth in healthcare spending up to 2019. Spending in Germany, the United Kingdom and Sweden is expected to fare better than in Greece, Italy, Ireland, Portugal and Spain, the countries most impacted by the Eurozone crisis.

REVIEW OF OPERATIONS

PRODUCT PIPELINE: KEY PROJECTS

The table below shows the promising projects that have been prioritised for further development and commercialisation. A number of additional attractive product candidates, in a varied development stage, are being evaluated for inclusion.

Product	Active Ingredient	Pre-clinical	Clinical	Approval	Mkt Size	Partnerships (Incl. territories)
*ZolpiMist™	Zolpidem	Insomnia			\$2.1bn	Eddingpharm (China) TEVA (Brazil, Mexico, Chile)
ArtiMist®	Artemether	Malaria			>\$500m	
SUD-002	Ondansetron	Chemotherapy induced nausea & vomiting			\$2.5bn	Kwang Dong (Korea)
SUD-001	Sumatriptan	Migraine headache			\$3.2bn	
SUD-003 DuroMist™	Sildenafil	Erectile dysfunction			\$4.1bn	
SUD-004	Sildenafil	Pulmonary arterial hypertension			\$2.7bn	
SUD-005	Midazolam	Pre-procedural anxiety & epileptic seizures			>\$170m	

Suda's pipeline of key projects

* SUDA has an exclusive license to ZolpiMist in all countries excluding US and Canada

ZolpiMist™: treatment for insomnia

Background

ZolpiMist™ is a US approved, patented, cherry-flavoured, oro-mucosal spray formulation of zolpidem tartrate (marketed under the brand name of Ambien® or Stilnox®), a non-benzodiazepine prescribed for the short-term treatment of insomnia characterised by difficulties with sleep initiation, as per Ambien's approved indication. The spray offers quicker sleep onset latency, patient convenience, and ease of use compared to conventional tablets. Zolpidem tartrate is the most widely prescribed sleep aid on the market with a market share in excess of 70%. The global insomnia therapeutic market is forecast to reach US\$2.1bn in 2017.

The pivotal studies demonstrated bioequivalence of ZolpiMist 5mg and 10mg doses with the respective Ambien tablets. The time to detectable levels of both ZolpiMist doses were significantly shorter than the corresponding Ambien tablets. Also, there was a significantly greater decrease in Digit Symbol Substitution Test (DSST) scores (a measure of attention, perceptual speed, motor speed, visual scanning and memory) for both ZolpiMist doses when compared to Ambien at 13 minutes post dose. Hence, ZolpiMist induced sleepiness significantly faster than Ambien.

Developments in 2017 financial year

SUDA's out-licencing activities for ZolpiMist gained real momentum in 2016/2017. The Company signed a licence and supply agreement with Eddingpharm in November 2016 and with Teva Pharmaceuticals after the year end in July 2017. These deals cover seven countries, including three of the top-10 most populous countries in the world, and have the potential to generate downstream value of \$50 million to \$160 million through milestone payments, double-digit royalty rates on sales and supply of the finished product.

SUDA is targeting registration of ZolpiMist by the Australian Therapeutic Goods Administration (TGA) and, in 2017, engaged regulatory consultants to prepare the Marketing Authorisation Application, which will be based on the US regulatory dossier.

Intentions for future years

In June 2017, SUDA had a constructive and successful meeting with the UK's Medicines & Healthcare products Regulatory Agency (MHRA) to discuss the development plan and registration strategy in Europe.

SUDA's Australian registration strategy is in parallel to the progress that its partners are making to achieve approval of ZolpiMist in Latin America and China. The first regulatory dossier could be submitted as early as the end of 2017.

ArTiMist®: malaria

Background

ArTiMist® is the world's first sublingual 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 was designed with a child in mind: a child living in a challenging environment where healthcare resources can be very scarce and time is of the essence. The simple sublingual spray could be particularly valuable as a pre-referral treatment when children first show signs of a malaria-like fever, before being referred to hospital. ArTiMist is owned and managed by SUDA's subsidiary company, Malaria Research Company Pty Ltd (MRC).

ArTiMist has been successfully evaluated in four clinical studies, including a Phase III study in children with severe, complicated or uncomplicated malaria, but who were unable to tolerate oral medication. Patients were randomised to receive either ArTiMist or intravenous quinine. The primary endpoint was parasitological success, defined as a reduction in parasite count of $\geq 90\%$ of baseline at 24 hours after the first dose. In the Phase III study, 94% of ArTiMist-treated patients compared to 39% of patients treated with quinine had parasitological success ($p < 0.0001$). Indicators of parasite clearance were also significantly superior for children treated with ArTiMist than those treated with quinine.

Developments in the 2017 financial year

SUDA submitted a Marketing Authorisation Application to the TGA, which was accepted for review in April 2017.

Intentions for the short-medium term

SUDA anticipates the TGA review to be completed in the first half of CY2018. The Company continues its discussions with pharmaceutical companies in relation to the sale or licence of ArTiMist, as well as with potential distributors that have a strong franchise in anti-malarials in Sub-Saharan Africa and SE Asia. These two options are not mutually exclusive.



REVIEW OF OPERATIONS

SUD-001: migraine headache

Background

SUD-001 is a first-in-class mint-flavoured oral 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.

Two pilot trials have been conducted to evaluate SUDA's first-generation formulation. The pilot pharmacokinetic (PK) study in 10 healthy male volunteers demonstrated a statistically significant faster rate of absorption with SUD-001 than tablets and up to a 50% increase in relative bioavailability of sumatriptan. The rate of drug absorption is believed to be predictive of the degree and speed of migraine relief.

The second pilot trial evaluated efficacy and safety in migraineurs. This was a multi-centre, active control, open-label, dose-ranging study. In the primary analysis of efficacy, being the percentage of patients responding to treatment at or before 60 minutes post-dosing, the 30mg and 40mg dosages of SUD-001 provided a statistically significant greater reduction in headache pain compared to the 50mg tablet and were comparable to the higher (100mg) dose of the tablet formulation.

Overall, these results indicate that SUD-001 at doses of 30mg and 40mg may be significantly more effective than the 50mg sumatriptan tablet in reducing pain and other symptoms associated with migraine headaches and produce a degree of relief that is qualitatively similar to the 100mg sumatriptan tablet.

Migraine is a painful and debilitating condition that disrupts lives, impacts careers and costs employers in lost work and diminished productivity. According to the WHO, migraine affects at least one adult in every seven in the world (14.3%). The migraine market value is expected to reach US\$5.8 billion in 2021 in the seven major markets where 75 million adults are affected [6].

Developments in 2017 financial year

SUDA has developed a second-generation formulation of SUD-001 using its novel permeation-enhancing technology. This new formulation has potential patent protection until 2036 and could provide even faster onset of action and better bioavailability than the original SUD-001. Both the first and second-generation formulations are the subject of licensing discussions with prospective partners.

Intentions for the short-medium term

SUDA anticipates further studies, including a pivotal PK study, for either the US and/or European market, pending a licensing deal in one or both territories.

SUD-002: chemotherapy-induced nausea and vomiting (CINV) and post-operative nausea and vomiting (PONV)

Background

SUD-002 is a first-in-class, mint-flavoured 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 in post-operative settings.

SUD-002 achieves therapeutic drug levels by delivering a micro-mist of concentrated ondansetron over the oral mucosa and may offer a desirable alternative to patients requiring anti-emetic therapy who have difficulty in swallowing.

The product has been evaluated in over 300 patients in multiple clinical trials. These included four randomized studies in which the PK profile of SUD-002 was compared with ondansetron tablet in about 100 subjects, including both men and women. The studies successfully demonstrated that SUD-002 at an 8mg dose was statistically bioequivalent to the current commercially available 8mg ondansetron tablet. It was well tolerated and could be conveniently administered in multiple doses. In addition, SUD-002 delivered statistically faster absorption as defined by median time to detectable drug levels of ondansetron at 15 minutes versus 30 minutes for the tablet.

The global anti-emetics market estimated to reach US\$4.6 billion in 2018 [7].

Developments in 2017 financial year

SUDA completed its enhancements to the manufacturing process, which have improved the stability of SUD-002 and, hence, its commercial potential.

Intentions for the short-medium term

SUDA anticipates meeting with a European regulatory agency and/or the US FDA to discuss the requirements for registration and whether any further clinical data are required, pending discussions with prospective partners in both territories.



SUD-003: erectile dysfunction

Background

SUD-003 (DuroMist®) is a first-in-class 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.

Sildenafil is the largest selling drug globally for ED and is also approved to treat pulmonary arterial hypertension (see SUD-004).

SUDA has broad patent protection of its first-generation sildenafil spray until 2031.

The Company's first-generation formulation of SUD-003 has been evaluated in a pilot PK clinical trial comparing the oral spray to the Viagra tablet. The results from the trial successfully demonstrated that SUD-003 had superior bioavailability compared to the tablet with respect to systemic exposure.

The global erectile dysfunction market is estimated to reach US\$3.4 billion in 2019 [8]. In the USA alone, more than 18 million individuals suffer from ED. The risk of developing ED increases with age. Primary market research conducted in the USA suggests that over two thirds of physicians would prescribe SUD-003 to their patients if the oral spray achieved a quicker onset of action or reduced the side-effects associated with Viagra.

SUDA has appointed three leading erectile dysfunction specialists to its Clinical Advisory Board (CAB). These experts are providing advice and guidance on the pivotal development plan, which will be submitted to the FDA for review. This, again, will add value to the product and assist SUDA's partnering objectives.

Developments in 2017 financial year

SUDA is continuing the marketing of the first-generation SUD-003 and, in parallel, continuing the optimisation of a new-generation formulation of SUD-003, which includes flavouring, taste masking and the Company's novel permeation-enhancing technology that is designed to enhance further the bioavailability of the drug. The data from *in-vitro*, *ex-vivo* and *in-vivo* studies with the new-generation formulation of SUD-003 have been encouraging.

The Japan Patent Office issued SUDA's first Japanese patent for our sildenafil-based products, SUD-003 and SUD-004, in 2017. A patent application directed to similar subject matter was approved in Russia. Similar patents have been granted in the USA, Australia, New Zealand and Singapore; and patent applications are pending in other jurisdictions. These patents provide protection until 2031.

The claims of these patents cover the administration of sildenafil in an oral spray for the treatment of sexual dysfunction induced by Selective Serotonin Reuptake Inhibitor (SSRI) anti-depressants and for the treatment of pulmonary arterial hypertension.

SSRI-induced sexual dysfunction is a common condition, affecting up to 75% of patients taking SSRIs such as Prozac®, Zoloft® and Paxil®.

Intentions for the short-medium term

SUDA plans to advance its optimised new formulation of SUD-003 into a pilot PK study versus Viagra with the objective of demonstrating the enhanced bioavailability and onset of action of the spray compared to the tablet. The Company also plans to publish the data from the new-generation formulation in a peer-reviewed journal.

SUDA will continue its discussions with prospective partners on the first generation product and will continue discussions on the new formulation after completing its optimisation work.



REVIEW OF OPERATIONS

SUD-004: pulmonary arterial hypertension

Background

SUD-004 is based on the first-generation SUD-003 oral spray formulation of sildenafil. It is designed to treat pulmonary arterial hypertension (PAH) in adults. With PAH, the blood pressure in the lungs is too high and the heart has to work hard to pump blood into the lungs. Sildenafil improves the ability to exercise and slows down worsening changes in the patient's physical condition. Sildenafil is marketed in tablet form as Revatio® by Pfizer.

SUD-004 is formulated such that each actuation delivers 10mg of sildenafil, which is sprayed directly in the mouth over the tongue. The recommended dose of Revatio for treatment of PAH is 20mg (one tablet) taken three times a day. Unlike SUD-003, the optimal target product profile for SUD-004 is to be bio-equivalent to the Revatio tablet.

The PK data generated with DuroMist successfully demonstrated that the 20mg dose (two sprays) of sildenafil was effectively absorbed through the oral mucosa. Also, DuroMist, and thus also SUD-004, demonstrated an excellent safety profile and was well tolerated in the PK study at all dose levels.

The PAH market is growing at a CAGR of 5% and is expected to reach US\$5.19 billion by 2020. [9].

Developments in 2017 financial year

As described on page 13, a new patent was issued in Japan and Russia for SUD-004. Similar patents have been granted in the USA, Australia, New Zealand and Singapore; and patent applications are pending in other jurisdictions. These patents provide protection until 2031.

Intentions for the short-medium term

SUDA is refining its development plan for a pivotal PK study of SUD-004 whilst continuing discussions with prospective partners.

SUD-005: pre-procedural anxiety and epileptic seizures

Background

SUD-005 is a first-in-class strawberry/mint-flavoured oral spray formulation of midazolam (available as an injection and as a syrup under the brand name Versed®) for the treatment of pre-procedure anxiety in imaging and dental procedures and also for the treatment of epileptic seizures. Initial formulation work of SUD-005 has been completed and stability studies have been successful.

One major advantage of the SUD-005 oral spray compared to an oral syrup or a tablet is the possible avoidance of first-pass metabolism. This offers advantages such as an increase in the bioavailability of the drug; a reduction in dose variability; and more predictable pharmacological effects. Additionally, its pleasant taste and easy administration would make it particularly useful for young, anxious patients.

Midazolam is one of the most frequently used agents for sedation in paediatric dentistry, imaging and pre-medication in adults due to its potent anxiolytic, amnesic, and sedative properties. The market size for treatments of pre-procedure anxiety is estimated to be US\$150-170 million. The epilepsy therapeutics market value in the top eight countries is expected to increase from US\$3.4 billion in 2012 to US\$4.5 billion by 2019 [10].

Developments in 2017 financial year

Following significant interest from perspective partners, SUDA has raised the priority of SUD-005 within its pipeline. The Company has prepared a development plan with the initial target indication being for the treatment of epileptic seizures.

Intentions for the short-medium term

SUDA plans to optimise further the formulation(s) of SUD-005 using its proprietary permeation-enhancing technology prior to commencing a pilot PK study.



Formulation services

Background

SUDA has optimised its laboratory formulation activities to offer value-added development services to companies seeking to formulate APIs into proprietary oro-mucosal sprays with unique advantages. The services include: (i) full feasibility assessment of the API to be formulated into a spray; (ii) detailed work plan of the formulation project with go/no-go decision points; (iii) rigorous supervision and execution of the entire project; and (iv) potential to generate new IP and/or use SUDA's background IP.

The Company's formulation services can be used for prescription, OTC, veterinary, vitamin and nutraceutical oral sprays. SUDA has established a first-class Quality Control system with ISO 9001:2015 accreditation and has been certified by AusIndustry as a Registered Service Provider.

ISO 9001 is the international standard that specifies requirements for a quality management system. Organisations, such as SUDA, use the ISO 9001 standard to demonstrate our ability to provide products and services consistently that meet customer and regulatory requirements.

The Company provides formulation services on a contract fee-for-service basis (plus licence fees, milestone payments and royalties for commercial rights) or as part of a co-development agreement with shared costs and rewards. The ISO 9001 certification helps to attract pharmaceutical partners to work with SUDA in the knowledge that SUDA has a quality management system that meets the highest international standards.

Developments in 2017 financial year

In 2017, SUDA became one of the first Australian pharmaceutical companies to be certified under the more rigorous provisions of the latest version of the quality standard, ISO 9001:2015. This version includes greater emphasis on risk management, leadership involvement and interactions with stakeholders such as shareholders, pharmaceutical partners and regulatory agencies.

Pfizer Consumer Healthcare approached SUDA in early 2017 to learn about the new hydrotrope permeation-enhancing technology. The dialogue resulted in SUDA and Pfizer signing a feasibility of option agreement to formulate two specific Over The Counter (OTC) medicines that are of interest to Pfizer and would benefit from a rapid onset of action.

SUDA's formulations performed well in Pfizer's in-house models. Pfizer is evaluating next steps for the project. It can expand the scope of work with SUDA or exercise its option to negotiate a global commercial license to one or both OTC oral sprays that are formulated with SUDA's hydrotrope technology.

Intentions for the short-medium term

SUDA aims to sign more joint research feasibility and option agreements, and other collaborative partnerships to develop and formulate third party's molecules into oro-mucosal sprays.



REVIEW OF OPERATIONS

WESTCOAST SURGICAL & MEDICAL SUPPLIES

Background

Westcoast Surgical and Medical Supplies Pty Ltd (Westcoast) is a fully owned subsidiary of SUDA. It is a sales and logistics operation for medical devices, pharmaceuticals, vaccines and consumables with a key selling proposition of "Flexible Solutions, Innovative Service", reflecting its high level of service to customers. Westcoast has four core business units as follows:

- Hospitals
- Aged care
- Allied health
- Resource sector

Developments in 2017 financial year

Westcoast reported revenue of \$6.7 million for the 2017 financial year, an increase of 16 per cent compared to the previous year. During the period, Westcoast was awarded several new contracts. These included the supply of medical products to oil rigs, ships, custom vessels and floatels. These new supply contracts for the offshore resource sector are a higher margin business than Westcoast's traditional activities.

Intention for future years

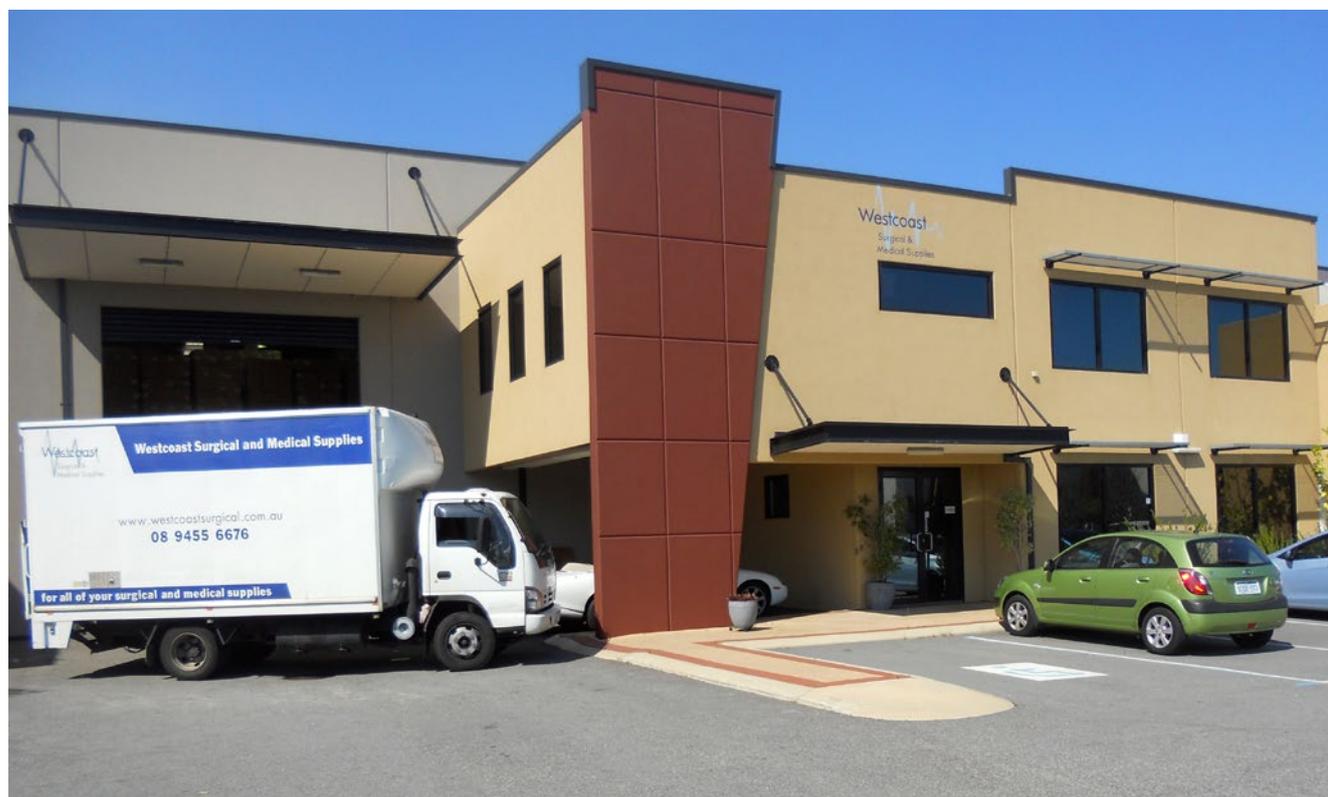
The anticipated expansion of the offshore contracts should continue to drive growth at Westcoast. In addition, Westcoast has submitted several large tenders to supply companies in the resources sector as well as infrastructure projects and decompression vessels.

Westcoast also plans to introduce some new product ranges over the next 12 months in its pharmacy business for treatment of adult incontinence. Furthermore, Westcoast intends to launch its own branded medical procedure packs for hospitals. With low-cost manufacturing overseas, the company anticipates higher margins with its branded packs.

With these additional opportunities, Westcoast is expected to maintain its double-digit revenue growth in FY2018.

Summary of results

	2017	2016
	\$	\$
Sales	6,753,333	5,785,802
EBITDA	146,070	(378,900)



STRATEGY

SUDA has established a world-leading oro-mucosal drug delivery platform with its OroMist technology and a broad pipeline of novel first-in-class oral sprays.

“Revolutionising drug delivery”

The aim is to develop products that can promptly answer the questions of potential partners ‘what is the added value of this product?’ and ‘what does this product do better when compared to what we already have or is available on the market?’ The scientific rationale behind the answers will highlight the notion of value, which is multi-dimensional and certainly goes beyond the demonstration of bioequivalence in the case of reformulated products, but will also show, for example, improved safety and efficacy profiles, quicker onset of action, ease of use leading to self-medication rather than reliance on medical personnel, and improvements that will contribute to increase the rate of therapeutic adherence and facilitate reimbursement.

SUDA has adopted a classic business model for its OroMist technology, in which the Company is focused on its core competencies of formulating and developing its oral sprays. SUDA does not intend, at this stage of its evolution, to establish its own sales and marketing operations. The Company aims to partner or out-license its pipeline of oral sprays in all territories.

A typical licensing deal comprises an upfront fee upon signature of the agreement, payments upon the achievement of development and regulatory milestones, royalties and supply of finished product. The terms of any

licensing agreements can differ markedly depending on the stage of the product development, therapeutic indication and addressed patient population. The management believes that out-licensing will take place once the Company has generated sufficient data to show that the formulation can provide a meaningful therapeutic/clinical value to patients, physicians and healthcare systems.

The Company also offers formulation services on a contract fee-for-service basis (plus licence fees, milestone payments and royalties for commercial rights) or as part of a co-development agreement with shared costs and rewards. In these service-based collaborations, SUDA formulates partner companies’ current or developmental drugs to create new product opportunities or to extend the life cycle of an existing franchise by developing novel OroMist formulations with patent protection.

The Company intends to adopt steps to achieve financial, clinical, technical and regulatory risk management by partnering certain assets at an early-mid stage of development, while advancing other product opportunities through late-stage development. The number of active projects will vary over time and will depend primarily on the available resources. SUDA aims to strengthen its capital resources through its partnering activities and non-dilutive financing.

SUDA aims to establish multiple, sustainable and royalty streams through the commercialisation of its oral spray formulations by the Company’s partners.

The Board of Directors is of the opinion that the Company’s current strategy and activities will form the basis on which to realise the Company’s maximum potential value.



LIST OF PATENTS

Country	Title	Earliest Priority	Status	Appln No.
USA	Buccal Polar Spray or Capsule	12-Apr-1996	Registered	09/199,380
USA	Buccal, Polar and Non-Polar Spray Containing Ondansetron	08-Jan-2009	Registered	13/445,331
USA	Buccal, polar and Non-Polar Spray or Capsule	24-Dec-2002	Registered	10/327,195
USA	Buccal, Polar and Non-Polar Spray or Capsule	18-Mar-2002	Registered	10/100,156
Australia	Oral spray formulations and Methods for Administration of Sildenafil	07-Jun-2010	Registered	2011264941
Brazil	Oral Spray Formulations and Methods for Administration of Sildenafil	07-Jun-2010	Pending	BR1120120312979
Canada	Oral Spray Formulations and Methods for Administration of Sildenafil	07-Jun-2010	Under exam	2,802,047
Europe	Oral Spray Formulations and Methods for Administration of Sildenafil	07-Jun-2010	Under exam	11793044.6
Hong Kong	Oral Spray Formulations and Methods for Administration of Sildenafil	07-Jun-2010	Pending	13111354.2
Australia	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Allowed	2012347997
Brazil	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Pending	BR112014013650-5
Canada	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Request for exam due	2858364
China	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Pending	201280068898.5
Europe	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Under exam	12806256.9
Hong Kong	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Pending	15100438.3
India	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Pending	5306/DELNP/2014
Israel	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Under exam	232970
Japan	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Registered	2014-545981
New Zealand	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Registered	625922
Republic of Korea	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Request for exam due	10-2014-7016435
Russian Federation	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Allowed	2014123435
Hong Kong	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Pending	15100438.3
India	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Pending	5306/DELNP/2014
Israel	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Pending	232970
Japan	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Under examination	2014-545981
New Zealand	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Registered	625922
Republic of Korea	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Request for exam due	10-2014-7016435

Country	Title	Earliest Priority	Status	Appln No.
Russian Federation	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Allowed	2014123435
Singapore	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Registered	11201402938R
South Africa	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Pending	2014/4091
USA	Oral Spray Formulations and Methods for Administration of Sildenafil	05-Dec-2011	Registered	14/363,245
Canada	Stable Anti-nausea Oral Spray Formulations and Methods	22-Dec-2006	Registered	2,673,049
Canada	Stable Hydroalcoholic Oral Spray Formulations and Methods	19-Apr-2007	Registered	2,649,895
Australia	Mucosal Active Agent Delivery	31-Oct-2016	Pending	2016904449
ARIPO	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Registered	AP/P/2013/006997
Australia	Anti-Malarial Pharmaceutical Composition	25-Oct-2007	Registered	2013201643
Bangladesh	Anti-Malarial Pharmaceutical Composition	29-Mar-2009	Pending	167/2013
Brazil	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Pending	BR122013005952-0
Burundi	Anti-Malarial Pharmaceutical Composition	09-Mar-2009	Registered	279/BUR
Cambodia	Anti-Malarial Pharmaceutical Composition	16-Jul-2013	Pending	KH/P/2013/00030
China	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Registered	200880113338.0
Democratic Republic of the Congo	Anti-Malarial Pharmaceutical Composition	04-Apr-2009	Pending	NP/013/EXT/2013
Ethiopia	Anti-Malarial Pharmaceutical Composition	26-Feb-2009	Registered	ET/P/2009/116
Eurasia	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Registered – not validated	201300151
Belgium	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Registered	13176933.3
France	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Registered	13176933.3
Ireland	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Registered	13176933.3
Italy	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Registered	13176933.3
Spain	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Registered	13176933.3
Switzerland	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Registered	13176933.3
United Kingdom	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Registered	13176933.3
Haiti	Anti-Malarial Pharmaceutical Composition	27-Mar-2009	Registered	007-HAI-DAJ-RE-6
Indonesia	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Pending	W-00201303488
Malaysia	Anti-Malarial Pharmaceutical Composition	07-Oct-2008	Application allowed	PI 2013002816
Mexico	Anti-Malarial Pharmaceutical Composition	25-Oct-2008	Registered	MX/a/2013/008621
OAPI	Anti-Malarial Pharmaceutical Composition	25-Oct-2007	Registered	1201000141
Philippines	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Registered	1-2013-501567
Rwanda	Anti-Malarial Pharmaceutical Composition	10-Mar-2009	Registered	123/ARK
Singapore	Anti-Malarial Pharmaceutical Composition	25-Oct-2007	Registered	201002621-9
South Africa	Anti-Malarial Pharmaceutical Composition	25-Oct-2007	Registered	2010/02607
United Kingdom	Anti-Malarial Pharmaceutical Composition	25-Oct-2007	Registered	GB0819559.6
Vietnam	Anti-Malarial Pharmaceutical Composition	27-Oct-2008	Under examination	1-2013-00873
Yemen	Anti-Malarial Pharmaceutical Composition	16-Dec-2008	Registered	424/2008

DIRECTORS' REPORT

Your Directors present their report together with the financial statements of the Group consisting of SUDA Limited and the entities it controlled during the period for the financial year ended 30 June 2016. In order to comply with the provisions of the Corporations Act 2001, the Directors' Report is as follows:

Directors

The names of directors who held office during or since the end of the year and until the date of this report are as follows. Directors were in office for this entire period unless otherwise stated.

Names, qualifications, experience and special responsibilities:



Mr Michael Stewart
Chairman

Qualifications:
Bachelor of Applied Science
(GeoPhysics), Associateship
(Geology)

Description of experience:

Michael Stewart joined the Board of SUDA Ltd on 11 June 2009. He has a broad corporate and management background and has been extensively involved in both the securities industry and in bilateral donor funded and World Bank co-financed Aid Projects in under-developed countries.

Michael Stewart is a member of the Group's Risk & Audit Committee, Nomination Committee and HR & Remuneration Committee.

In the 3 years immediately before the end of the financial year, Michael Stewart did not serve as a director of any other ASX-listed company.



Mr Stephen Carter
Managing Director,
Chief Executive Officer

Qualifications:
Bachelor of Science

Description of experience:

Stephen Carter joined the Board of SUDA Ltd on 26 October 2010. He has extensive pharmaceutical industry experience and has held a variety of senior positions with listed public companies including roles as both Chairman and Director. He has extensive contacts and experience in the financial markets and the pharmaceutical industry and is well equipped to lead executive management through the Company's product commercialisation phase.

Stephen Carter is a member of the Risk & Audit Committee, Nomination Committee and HR & Remuneration Committee.

In the 3 years immediately before the end of the financial year, Stephen Carter did not serve as a director of any other ASX-listed company.



Mr Joseph Ohayon
Director, Chief Financial Officer,
Company Secretary

Qualifications:
Chartered Accountant, Masters
of Business Administration:
International Business

Description of experience:

Joseph Ohayon joined the company on 4 July 2010 as the Chief Financial Officer and in March 2011 he took over the role of Company Secretary and then became an Executive Director and member of the Board on 1 December 2012. He has over 20 years' experience in financial roles.

Joseph Ohayon is a member of the Group's Risk & Audit Committee, Nomination Committee and HR & Remuneration Committee.

In the 3 years immediately before the end of the financial year, Joseph Ohayon did not serve as a director of any other ASX-listed company.

Company Secretary

Joseph Ohayon held the position as Company Secretary at the financial year end.

Principal Activities

The principal activities of the entities within the Group during the year were:

- Pharmaceutical development of drug delivery technology; and
- Medical devices and consumables distribution.

Review of operations

Group overview

The significant events during the 2016-17 financial year were:

i. Licence Agreement

SUDA and Eddingpharm (Asia) Macao Commercial Offshore Limited (Eddingpharm), a leading Chinese pharmaceutical company entered into an exclusive license and supply agreement for the development and commercialisation of SUDA's novel ZolpiMist™ oral spray of zolpidem tartrate to treat insomnia in China. Once approved by the Chinese Food and Drug Administration, ZolpiMist will be the first-imported, fast-acting, oral spray of zolpidem tartrate available in China.

Under the terms of the agreement, SUDA received an upfront cash payment of US\$300,000 (approx. A\$400,000) and is entitled to receive a further milestone payment of US\$200,000 (approx. A\$260,000) following registration of the product in China. In addition, once ZolpiMist is registered for sale in China, SUDA will receive escalating tiered royalties on net sales in the territory. The total value of the deal could exceed US\$26 million (approx. A\$34 million) based on Eddingpharm's forecast sales for the first 15 years from launch.

ii. New patent

SUDA has filed a provisional patent application with IP Australia for a novel mucosal penetration drug delivery technology. The application was filed under the international Patent Cooperation Treaty (PCT), which enables SUDA to seek patent protection for its technology in more than 145 countries.

The technical field of the provisional patent application is entitled: 'A method for modifying the penetration of active agents through mucosal membranes using hydrotopes.' It is based on positive results from ex-vivo and in-vivo studies evaluating SUDA's new-generation formulation of SUD-003 sildenafil oral spray for erectile dysfunction, together with in-vitro data investigating the technology with a broad range of other molecular drug classes.

The patent application is entering the national phase in November 2017.

iii. Feasibility study with Pfizer

SUDA entered into a feasibility and option agreement with Pfizer Consumer Healthcare. Under the agreed work plan, SUDA is applying its proprietary OroMist® oro-mucosal spray technology to two over-the-counter (OTC) molecules for evaluation by Pfizer.

iv. ArTiMist® oral spray for the treatment of paediatric malaria

SUDA submitted, and the Australian Therapeutic Goods Administration (TGA) accepted for review, the Marketing Authorisation Application (MAA) for ArTiMist® (artemether sublingual spray) for the treatment of children with severe malaria.

SUDA has commenced pre-planning for a product launch. This has included negotiations around manufacture and supply chain logistics, pricing models and distribution channels. A number of parties with a distribution footprint and extensive experience in Africa have expressed interest in entering into partnership with SUDA.

v. Westcoast Surgical & Medical Supplies (Westcoast)

Westcoast's revenue increased by \$967,826 to \$6,753,628 and generated a profit of \$119,332 (2016: loss \$416,961). Westcoast operates in the hospitals, aged care, allied and mining sectors. In 2016/2017, Westcoast was awarded several new contracts, including the supply of medical products to oil rigs, ships, custom vessels and floatels.

vi. Capital raising

SUDA successfully raised \$1.5 million via an over-subscribed placement of 75 million fully paid ordinary shares at a price of \$0.02 per share ("Placement"). The Placement was fully underwritten.

vii. Convertible Notes

SUDA amended the terms of its Convertible Notes, including extending the maturity date, and has raised a net amount of \$0.27m in new Convertible Notes in an over-subscribed offering.

SUDA previously issued \$1.73m Convertible Notes that matured on 31 March 2017. Of these, \$0.47m were redeemed and the balance of \$1.26m Convertible Notes was rolled over for a further two years with a maturity date of 31 March 2019. In addition, the Company issued \$0.74m new Convertible Notes including \$0.45m to Related Parties which are subject to shareholder approval. Pending approval, the total of new convertible notes will be \$2.00m.

DIRECTORS' REPORT

viii. Statement of claim received from HC Berlin Pharma AG

As reported on 3 June 2016, the Receiver issued a Statement of Claim on SUDA for €4 million plus 5% interest and costs from August 2008. This relates to an alleged failed in-kind capital contribution in 2008 when SUDA licensed manufacturing rights for SUDA's anti-malarial spray ArTiMist to HC Berlin Pharma, allegedly for 8 million one euro shares. SUDA took legal advice and believed that the claim was without merit. The matter was discussed in the 2016 Annual Accounts. In a closed hearing on Friday 20 January 2017 in the German courts, the judge ruled that the original 2008 in-kind contribution had failed and was thus invalid.

SUDA is entitled to, and initiated, an Appeal against the court judgement. Based on legal advice, the Board of SUDA believes the judgment contains both errors in fact and in law. Upon lodgement of the Notice to Appeal by SUDA the judgement against SUDA is automatically stayed in Germany and cannot be enforced unless the Receiver places a security equal to the judgement plus 10% (€4.4 million) with the courts.

SUDA lodged its appeal in August 2017.

Operating results for the year

The Group reported revenue of \$7,197,362 (2016: \$5,785,802) in the reporting period, an increase of \$1,411,560 or 24.4%.

The Consolidated loss for the Consolidated Group was \$1,238,309 (2016 loss: \$2,286,813) after providing for an income tax benefit. The decrease in the loss was primarily due to the increase in revenues.

The income tax benefit relates to the R&D Tax Incentive claim for the 2016-17 year of \$792,000 (2016: \$765,785).

SUDA ended the financial year with net cash of \$1,769,812 compared to \$2,448,771 at 30 June 2016.

Risk Management

Business risks and mitigations

SUDA has adopted a risk management framework which sets out the processes for the identification and management of risk across the Group. The risk management framework aligns with ISO 9001:2015.

The Risk & Audit committee assists the Board, and reports to, the Board in relation to risk management. The Committee's responsibilities include oversight of the Company's risk management system and to assist the Board to review the adequacy and effectiveness of that system.

The Chief Executive Officer, with the assistance of the Chief Financial Officer and other management, is responsible for establishing and implementing the system for adequately managing risks. Management is also responsible for developing and enhancing specific risk policies, processes and procedures.

The Company was awarded ISO 9001:2015 certification for its quality management system and its laboratory works within the guidelines of Good Manufacturing Practice.

Through its risk management framework, SUDA seeks to:

- i. Protect its people, communities and the environment and its assets and reputation;
- ii. Ensure good governance and legal compliance; and
- iii. Enable it to realise opportunities and create long term shareholder value.

Set out below are the key risk areas that could have a material impact on the Company and its ability to achieve its objectives. The nature and potential impact of risks changes over time. The risks described below are not the only risks that SUDA faces, and whilst every effort is made to identify and manage material risks, additional risks not currently known or detailed below may also adversely affect the future performance.

Regulatory and licensing risk

If the Company does not obtain the necessary regulatory approvals it may be unable to commercialize its pharmaceutical products. Even if it receives regulatory approval for any product candidates, profitability will depend on its ability to generate revenues from the sale of its products or the licensing of its technology.

The clinical development, manufacturing, sales and marketing of the Company's products are subject to extensive regulation by regulatory authorities in the United States, the United Kingdom, the European Union, Australia and elsewhere. These regulations vary in important, meaningful ways from country to country.

Despite the substantial time and expense invested in preparation and submission of a Marketing License Application or equivalents in other jurisdictions, regulatory approval is never guaranteed.

Success of future trials

Ongoing and future clinical trials of the Company's product candidates may not show sufficient safety or efficacy to obtain requisite regulatory approvals for commercial sale.

Phase I and phase II clinical trials are not primarily designed to test the efficacy of a product candidate but rather to test safety and to understand the product candidate's side effects at various doses and schedules. Furthermore, success in preclinical and early clinical trials does not ensure that later large scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. Further, phase III clinical trials may not show sufficient safety or efficacy to obtain regulatory approval for marketing.

The Company may conduct lengthy and expensive clinical trials of its product candidates, only to learn that the product candidate is not an effective treatment or not sufficiently safe. A number of companies in the biotechnology industry have suffered significant setbacks in clinical trials, even after promising results in earlier trials. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could require that the clinical trial be redone or terminated. In addition, failure to construct appropriate clinical trial protocols could result in the test or control group experiencing a disproportionate number of adverse events and could require that a clinical trial be redone or terminated.

Key personnel and contractor reliance risk

The responsibility of overseeing the day-to-day operations and the strategic management of the Company depends substantially on its senior management and its key personnel. There can be no assurance given that there will be no detrimental impact on the Company if one or more of these employees cease their employment.

To the extent the Company relies significantly on contractors, it will be exposed to risks related to the business conditions of its contractors.

Future funding requirements

The Company may require substantial additional financing in the future to sufficiently fund its operations, research and development. It has been incurring losses and will continue to do so as it expands its drug development programs. The Company's actual cash requirements may vary from those now planned and will depend upon many factors, including:

- the continued progress of its research and development programs;
- the timing, costs and results of clinical trials;
- the cost, timing and outcome of submissions for regulatory approval;
- the commercial potential of its product candidates; and
- the status and timing of competitive developments.

Significant changes in the state of affairs

Other than signing a licence agreement, completing a placement, rolling over and issuing new convertible notes, there have been no significant changes in the state of affairs of the Group to the date of this report.

Significant events after balance date

- i. Licence Agreement with Teva Pharmaceuticals International GmbH (Teva)

SUDA entered into an exclusive licence and supply agreement with Teva for ZolpiMist™ oral spray

of zolpidem tartrate to treat insomnia in multiple countries. Teva is a leading global pharmaceutical company and the world's largest generic medicines producer. SUDA has granted Teva a licence to ZolpiMist in Brazil, Mexico and Chile, together with an 18-month option to license the product in Argentina, Israel and Australia.

ZolpiMist is registered for sale in the territory, SUDA will supply the product to Teva and receive a double-digit royalty on net sales less the supply price.

- ii. HC Berlin Pharma

SUDA lodged its appeal in August 2017 as outlined on page 22.

Likely developments and expected results

The Company's drug delivery business is in various stages of development and is adopting a staged business and marketing strategy as the Company moves along the growth path and remains abreast with developments in the pharmaceutical industry.

The Company intends to adopt steps to achieve financial, clinical, technical and regulatory risk reduction by combining the sale of certain assets and, in parallel, run in-house development of some projects and collaborate with partners on others.

Future license agreements and research collaborations represent key strategic assets both from a financial and knowledge point of view, helping to finance other in-house projects.

The initial focus is on a partnership or divestiture of ArTiMist and of at least one of the other lead development products.

The Company's project pipeline intends to adopt a multi-pronged commercial strategy providing income streams in the short to medium-term and the potential for a big upside in the future. The Board of Directors is of the opinion that the Company's current strategy and activities will form the basis on which to realise the Company's maximum potential value.

Environmental legislation

The Group is currently not subject to any significant environmental legislation.

Dividends

No dividends have been paid or declared since the start of the financial year and the Directors do not recommend the payment of a dividend in respect of the financial year.

DIRECTORS' REPORT

Interests in the shares, options, performance rights and convertible notes of the Company and related bodies corporate

The following relevant interests in shares and options of the Company or a related body corporate were held by the directors as at the date of this report.

Directors	Number of fully paid ordinary shares	Number of performance rights	Number of convertible notes
Michael Stewart	24,411,890	-	50,000
Stephen Carter	-	-	50,000
Joseph Ohayon	-	2,750,000	20,000

There were no unissued ordinary shares of the Company under option.

There were no shares issued during or since the end of the year as a result of exercise of options.

REMUNERATION REPORT (AUDITED)

This report, which forms part of the Directors' report, outlines the remuneration arrangements in place for the key management personnel ("KMP") of SUDA Limited (the "Company") for the financial year ended 30 June 2017. The information provided in this remuneration report has been audited as required by Section 308(3C) of the Corporations Act 2001.

The Remuneration Report details the remuneration arrangements for KMP who are defined as those persons having authority and responsibility for planning, directing and controlling the major activities of the Company and the Group, directly or indirectly, including any director (whether executive or otherwise) of the parent Company.

Key Management Personnel

Directors

Michael Stewart	Chairman (non-executive)
Stephen Carter	Managing Director / Chief Executive Officer
Joseph Ohayon	Chief Financial Officer / Company Secretary

Executives

Nick Woolf	Chief Business Officer
John Billingham	General Manager – Westcoast

Remuneration philosophy

The performance of the Company depends upon the quality of the directors and executives. The philosophy of the Company in determining remuneration levels is to:

- set competitive remuneration packages to attract and retain high calibre employees;
- link executive rewards to shareholder value creation; and
- establish appropriate, demanding performance hurdles for variable executive remuneration.

HR & Remuneration Committee

The HR & Remuneration Committee of the Board of Directors of the Company is responsible for determining and reviewing compensation arrangements for the directors, the CEO and the executive team.

The HR & Remuneration Committee assesses the appropriateness of the nature and amount of remuneration of directors and executives on a periodic basis by reference to relevant employment market conditions with an overall objective of ensuring maximum stakeholder benefit from the retention of a high quality Board and executive team.

Remuneration structure

In accordance with best practice corporate governance, the structure of non-executive director and executive remuneration is separate and distinct.

Relationship between remuneration policy and company performance

The remuneration policy has been tailored to increase goal congruence between shareholders, Directors and executives. The methods implemented are discussed below.

The following lists the performance of the company since the 2013 financial year:

	2013	2014	2015	2016	2017
	\$	\$	\$	\$	\$
Revenue	4,065,665	8,753,164	5,727,589	5,871,615	7,197,362
Net Loss	(1,667,519)	(2,060,850)	(3,378,331)	(2,286,813)	(1,238,309)
Share Price at year-end	0.025	0.05	0.028	0.020	0.019
Dividends Paid	0.00	0.00	0.00	0.00	0.00
Market capitalisation	16.34m	51.31m	31.81m	22.83m	23.17m

Non-executive director remuneration

The Board seeks to set aggregate remuneration at a level that provides the Company with the ability to attract and retain directors of the highest calibre, whilst incurring a cost that is acceptable to shareholders.

The ASX Listing Rules specify that the aggregate remuneration of non-executive directors shall be determined from time to time by a general meeting. The latest determination was at the Annual General Meeting held on 25 November 2010 when shareholders approved an aggregate remuneration of \$200,000 per year.

The amount of aggregate remuneration sought to be approved by shareholders and the manner in which it is apportioned amongst directors is reviewed annually. The Board considers advice from external shareholders as well as the fees paid to non-executive directors of comparable companies when undertaking the annual review process.

Each director receives a fee for being a director of the Company.

Senior manager and executive director remuneration

Remuneration consists of fixed remuneration and variable remuneration (comprising short-term and long-term incentive schemes).

Fixed remuneration

Fixed remuneration is reviewed annually by the Remuneration Committee. The process consists of a review of relevant comparative remuneration in the market and internally and, where appropriate, external advice on policies and practices. The Committee has access to external, independent advice where necessary.

The fixed remuneration component of the key management personnel is detailed in the table on page 29.

DIRECTORS' REPORT

Variable remuneration

The Directors considered that it was desirable to establish various employee incentive plans, in order to:

- a. reward employees of the Company;
- b. assist in the retention and motivation of employees of the Company; and
- c. provide an incentive to employees of the Company to grow shareholder value by providing them with an opportunity to receive an ownership interest in the Company.

Accordingly, on 6 March 2014, the Directors adopted the:

- a. Employee Share Option Plan (Option Plan) under which Directors and executives and other employees may be offered the opportunity to be granted Options;
- b. Employee Performance Rights Plan (Performance Rights Plan) under which Directors, executives, contractors and consultants and other employees may be offered the opportunity to be granted Performance Rights;
- c. Tax Exempt Plan under which eligible employees may be issued up to \$1,000 of Shares; and
- d. Short Term Incentive Plan (STIP) under which executives and other eligible employees may be offered an award upon satisfaction of performance conditions. Currently, executive Directors have not received approval to participate in the STIP.

The plans are designed to provide incentives to the employees and Directors of the Company and to recognise their contribution to the Company's success. Under the current circumstances the Directors consider that the incentive plans are a cost effective and efficient incentive for the Company as opposed to alternative forms of incentives such as increased cash based remuneration. To enable the Company to secure employees and Directors who can assist the Company in achieving its objectives, it is necessary to provide remuneration and incentives to such personnel. The plans are designed to achieve this objective, by encouraging continued improvement in performance over time and by encouraging personnel to acquire and retain shareholdings in the Company.

As Directors of the Company may receive securities in the Company under the Option Plan or Performance Rights Plan, prior shareholder approval will therefore be required before a Director or related party of the Company can participate in an issue of Options under the Option Plan or an issue of Performance Rights under the Performance Rights Plan. Directors will not participate in the Tax Exempt Plan.

Short-Term Incentive Plan

The objective of the STIP is to link the achievement of the Group's operational targets with the remuneration received by the executives charged with meeting those targets. The total potential short term incentive available is set at a level so as to provide sufficient incentive to the senior manager to achieve the operational targets and such that the cost to the Group is reasonable in the circumstances.

Actual payments granted to each senior manager depend on the extent to which specific operating targets set at the beginning of the financial year are met.

Aspect	Plan Rules, Offers and Comments
Measurement period	The Company's financial year, i.e. from 1 July to the following 30 June, with a review after 6 months.
Eligible participants	Senior management and consultants that have worked with the Company for at least 2 years.
Performance conditions	The profit before income tax of the Group must exceed \$2m.
Incentive pool	The incentive pool will be 4% of the profit before income tax.
Award opportunities	KMP's have been allocated a percentage of the pool, of which 75% of the award is directly linked to the financial performance of the Group and the remaining 25% is linked to KPIs and are at the CEO/Board discretion.

The CBO has the opportunity to earn 1% of total sales value of a project.

Executive Long-Term Incentive Plan (LTIP)

Aspect	Plan Rules and Offers
Measurement Period	The LTIP is for the period to November 2017.
LTI Offer	Options and Performance Rights were offered under the Plan during the financial year with the relevant policies and Plan rules.
Eligible participants	Executive directors, non-executive directors and senior management are eligible for the LTIP.
Performance conditions	<p>The Directors are of the opinion that the performance conditions of Options and Performance Rights should be linked to shareholder return and consider that the most appropriate measure is the market capitalisation of the Company.</p> <p>The market capitalisation on the date of approval of the Option Plan and Performance Rights Plan by the Board on 6 March 2014, was \$60,089,390 (MC). The intention of the Directors is that the market capitalisation of the Company increase by 100% during the life of the Option Plan and Performance Rights Plan in order for the Directors to receive the full benefit of the Options or Performance Rights.</p> <p>The performance conditions are also linked to continuous employment so that the Directors have to be employed by the company for a minimum of 12 months before any Options or Performance Rights vest.</p>
Terms of Options	<p>Each Option will be granted to eligible employees under the Option Plan for nil consideration.</p> <p>The exercise price of an Option shall be 145% of the VWAP of Shares sold on ASX during the five trading days up to and including the grant date, or such other period as determined by the Board in its discretion.</p>
Vesting	The Options will vest following satisfaction of the performance conditions or such other date as determined by the Board in its discretion.
Cashless Exercise Facility	Participants may, at their election, elect to pay the exercise price for an Option by setting off the exercise price against the number of Shares which they are entitled to receive upon exercise (Cashless Exercise Facility). By using the Cashless Exercise Facility, the participant will receive Shares to the value of the surplus after the exercise price has been set off.
Disposal restrictions	A participant may not transfer an Option granted under the Option Plan without the prior consent of the Board.
Terms of Performance Rights	Each Performance Right will be granted to eligible employees under the Performance Rights Plan for nil consideration.
Vesting	The Performance Rights will vest following satisfaction of the performance conditions or such other date as determined by the Board in its discretion.
Disposal restrictions	<p>A participant may not transfer a Performance Right granted under the Performance Rights Plan without the prior consent of the Board.</p> <p>A participant may not transfer a Share issued under the Performance Rights Plan for a period of two years after the date of issue without the prior consent of the Board or such other period as determined by the Board in its discretion.</p>

DIRECTORS' REPORT

Lapse	A Performance Right will immediately lapse upon the first to occur of: <ul style="list-style-type: none">i. its expiry date;ii. the performance condition(s) (if any) not being satisfied prior to the end of the performance period(s);iii. the transfer or purported transfer of the Performance Right in breach of the Performance Rights Plan rules;iv. if the Performance Right has not vested, the day that is 30 days following the date the participant voluntarily or for a bona fide reason ceases to be employed or engaged by the Company or an associated body corporate;v. termination of the participant's employment or engagement with the Company or an associated body corporate for cause; orvi. 6 months after an event which gives rise to a vesting under the Performance Rights Plan rules.
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The aggregate of annual payments available for executives across the Group is subject to the approval of the Remuneration Committee.

The Company also makes long term incentive payments to reward senior executives in a manner that aligns this element of remuneration with the creation of shareholder wealth.

Employment Contracts

The details of the executives' employment contracts are:

Executive	Period of notice
Stephen Carter	3 months
Joseph Ohayon	3 months
Nicholas Woolf	3 months
John Billingham	3 months

REMUNERATION OF KEY MANAGEMENT PERSONNEL

Key Management Personnel remuneration for the years ended 30 June 2017 and 30 June 2016

	Short-term employee benefits			Post-employment benefits	Share-based payments	Total	Performance Related
	Salary & fees	Bonus	Other	Super-annuation	Performance Rights		
30 June 2017	\$	\$	\$	\$	\$	\$	%
Directors							
Michael Stewart	70,000	-	3,600	6,650	-	80,250	0.0%
Stephen Carter	255,000	-	-	24,225	-	279,225	0.0%
Joseph Ohayon	215,000	-	-	20,425	3,532	238,957	1.5%
Executives							
Nick Woolf	163,000	4,021	-	15,867	2,569	185,457	3.6%
John Billingham	120,000	-	-	11,400	-	131,400	0.0%

	Short-term employee benefits			Post-employment benefits	Share-based payments	Total	Performance Related
	Salary & fees	Bonus	Other	Super-annuation	Performance Rights		
30 June 2016	\$	\$	\$	\$	\$	\$	%
Directors							
Michael Stewart	70,000	-	2,000	6,650	-	78,650	0.0%
Stephen Carter	255,000	-	-	24,225	-	279,225	0.0%
Joseph Ohayon	212,916	-	-	20,227	43,983	277,126	15.9%
Executives							
Nick Woolf	158,924	-	-	15,098	31,988	206,010	15.5%
John Billingham	120,000	-	-	11,400	-	131,400	0.0%

Option plans in existence during the financial year

	Option grant date	Expiry date	Grant date fair value	Vesting date
ESOP	12 May 2014	11 May 2017	75,838	Note (i)

Note (i): For details on the valuation of the options, including models and assumptions used, please refer to Note 15. There were no alterations to the terms and conditions of options granted as remuneration since their grant date.

Bonuses

Nick Woolf was paid a bonus based on 1% of the upfront fee on the signing of the licence agreement with Eddingpharm.

Share-based payments granted as compensation to key management personnel during the current financial year

There were no share-based payments granted as compensation to key management personnel.

DIRECTORS' REPORT

Options granted, exercised or lapsed during the year.

	Value of options granted at the grant date	Value of options exercised at the exercised date	Value of options lapsed at the date of lapse
	\$	\$	\$
Directors			
Michael Stewart	-	-	75,838
Stephen Carter	-	-	-
Joseph Ohayon	-	-	-
Executives			
Nick Woolf	-	-	-
John Billingham	-	-	-

Performance Rights granted, exercised or lapsed during the year.

	Value of PRs granted at the grant date	Value of PRs exercised at the exercised date	Value of PRs lapsed at the date of lapse
	\$	\$	\$
Directors			
Michael Stewart	-	-	74,060
Stephen Carter	-	-	111,090
Joseph Ohayon	-	-	-
Executives			
Nick Woolf	-	-	-
John Billingham	-	-	-

Shareholdings of Key Management Personnel

	Balance at beginning of period	Granted as remuneration	On Exercise of Options or conversion of convertible note	Net Change Other	Balance at end of period	Balance held nominally
30 June 2017	Number	Number	Number	Number	Number	Number
Directors						
Michael Stewart	24,411,890	-	-	-	24,411,890	24,411,890
Stephen Carter	-	-	-	-	-	-
Joseph Ohayon	-	-	-	-	-	-
Executives						
Nick Woolf	-	-	-	-	-	-
John Billingham	1,156,673	-	-	-	1,156,673	1,156,673

	Balance at beginning of period	Granted as remuneration	On Exercise of Options or conversion of convertible note	Net Change Other	Balance at end of period	Balance held nominally
30 June 2016	Number	Number	Number	Number	Number	Number
Directors						
Michael Stewart	23,483,334	-	-	928,556	24,411,890	24,411,890
Stephen Carter	-	-	-	-	-	-
Joseph Ohayon	-	-	-	-	-	-
Executives						
Nick Woolf	-	-	-	-	-	-
John Billingham	1,156,673	-	-	-	1,156,673	1,156,673

All equity transactions with key management personnel other than those arising from the exercise of remuneration options have been entered into under terms and conditions no more favourable than those the Group would have adopted if dealing at arm's length.

DIRECTORS' REPORT

Option holdings of Key Management Personnel

	Opening balance	Granted as remuneration	Options exercised	Net change Other	Closing balance	Vested but not exercisable	Vested and exercisable	Options vested during year
30 June 2017	Number	Number	Number	Number	Number	Number	Number	Number
Directors								
Michael Stewart	5,000,000	-	-	(5,000,000)	-	-	-	-
Stephen Carter	-	-	-	-	-	-	-	-
Joseph Ohayon	-	-	-	-	-	-	-	-
Executives								
Nick Woolf	-	-	-	-	-	-	-	-
John Billingham	-	-	-	-	-	-	-	-
30 June 2016								
	Opening balance	Granted as remuneration	Options exercised	Net change Other	Closing balance	Vested but not exercisable	Vested and exercisable	Options vested during year
30 June 2016	Number	Number	Number	Number	Number	Number	Number	Number
Directors								
Michael Stewart	5,000,000	-	-	-	5,000,000	-	-	-
Stephen Carter	-	-	-	-	-	-	-	-
Joseph Ohayon	-	-	-	-	-	-	-	-
Executives								
Nick Woolf	-	-	-	-	-	-	-	-
John Billingham	4,000,000	-	-	(4,000,000)	-	-	-	-

Performance Rights of Key Management Personnel

	Opening balance	Granted as remuneration	PRs exercised	Net change Other	Closing balance	Vested but not exercisable	Vested and exercisable	PRs vested during year
30 June 2017	Number	Number	Number	Number	Number	Number	Number	Number
Directors								
Michael Stewart	2,712,820	-	-	(2,712,820)	-	-	-	-
Stephen Carter	4,069,231	-	-	(4,069,231)	-	-	-	-
Joseph Ohayon	2,750,000	-	-	-	2,750,000	-	-	-
Executives								
Nick Woolf	2,000,000	-	-	-	2,000,000	-	-	-
John Billingham	-	-	-	-	-	-	-	-
30 June 2016								
	Opening balance	Granted as remuneration	PRs exercised	Net change Other	Closing balance	Vested but not exercisable	Vested and exercisable	PRs vested during year
30 June 2016	Number	Number	Number	Number	Number	Number	Number	Number
Directors								
Michael Stewart	2,712,820	-	-	-	2,712,820	-	-	-
Stephen Carter	4,069,231	-	-	-	4,069,231	-	-	-
Joseph Ohayon	2,750,000	-	-	-	2,750,000	-	-	-
Executives								
Nick Woolf	2,000,000	-	-	-	2,000,000	-	-	-
John Billingham	-	-	-	-	-	-	-	-

DIRECTORS' REPORT

Convertible Note holdings of Key Management Personnel

	Opening balance	Granted as remuneration	Received on exercise of options	Net change Other	Closing balance	Balance held nominally
30 June 2017	Number	Number	Number	Number	Number	Number
Directors						
Michael Stewart	50,000	-	-	-	50,000	50,000
Stephen Carter	50,000	-	-	-	50,000	50,000
Joseph Ohayon	20,000	-	-	-	20,000	20,000
Executives						
Nick Woolf	-	-	-	20,000	20,000	20,000
John Billingham	-	-	-	-	-	-

30 June 2016	Number	Number	Number	Number	Number	Number
Directors						
Michael Stewart	350,000	-	-	(300,000)	50,000	50,000
Stephen Carter	50,000	-	-	-	50,000	50,000
Joseph Ohayon	20,000	-	-	-	20,000	20,000
Executives						
Nick Woolf	-	-	-	-	-	-
John Billingham	-	-	-	-	-	-

Transactions and balances with Key Management Personnel

	Consolidated	
	2017	2016
Key Management Personnel	\$	\$
Mr Michael Stewart – consulting services	3,600	2,000
Mr Michael Stewart – interest on convertible notes	6,500	29,172
Mr Stephen Carter – interest on convertible notes	6,500	5,140
Mr Joseph Ohayon – interest on convertible notes	2,600	2,165
Mr Nicholas Woolf – bonus	4,021	-
Balance on Convertible Notes		
Mr Michael Stewart	50,000	50,000
Mr Stephen Carter	50,000	50,000
Mr Joseph Ohayon	20,000	20,000
Mr Nicholas Woolf	20,000	-

END OF REMUNERATION REPORT

Directors' Meetings

The number of meetings of directors (including meetings of committees of directors) held during the year and the number of meetings attended by each director was as follows:

	Directors' meetings	Risk and Audit Committee	HR and Remuneration Committee	Nomination Committee
Number of meetings held:	7	2	1	1
Number of meetings attended:				
Michael Stewart	7	2	1	1
Stephen Carter	7	2	1	1
Joseph Ohayon	7	2	1	1

Indemnification and insurance of Directors and Officers

The Company has agreed to indemnify all the directors of the Company for any liabilities to another person (other than the Company or related body corporate) that may arise from their position as directors of the Company and its controlled entities, except where the liability arises out of conduct involving a lack of good faith.

During the financial year the Company paid a premium in respect of a contract insuring the directors and officers of the Company and its controlled entities against any liability incurred in the course of their duties to the extent permitted by the Corporations Act 2001. The contract of insurance prohibits disclosure of the nature of the liability and the amount of the premium.

Proceedings on behalf of the Company

No person has applied for leave of court to bring proceedings on behalf of the Company or intervene in any proceedings to which the Company is a party for the purpose of taking responsibility on behalf of the Company for all or any part of those proceedings.

Auditor Independence and Non-Audit Services

Section 307C of the Corporations Act 2001 requires our auditors, HLB Mann Judd, to provide the directors of the Company with an Independence Declaration in relation to the audit of the annual report. This Independence Declaration is set out on page 36 and forms part of this directors' report for the year ended 30 June 2017.

Non-Audit Services

Details of amounts paid or payable to the auditor for non-audit services provided during the year by the auditor are outlined in Note 21 to the financial statements. The directors are satisfied that the provision of non-audit services is compatible with the general standard of independence for auditors imposed by the Corporations Act 2001.

The directors are of the opinion that the services do not compromise the auditor's independence as all non-audit services have been reviewed to ensure that they do not impact the impartiality and objectivity of the auditor and none of the services undermine the general principles relating to auditor independence as set out in Code of Conduct APES 110: Code of Ethics for Professional Accountants issued by the Accounting Professional & Ethical Standards Board.

Corporate Governance

The Corporate Governance Statement can be found on the Company's website, www.sudaltd.com.au under the Corporate section.

Signed in accordance with a resolution of the Directors.

Stephen Carter
Director
Perth 22 September 2017





Accountants | Business and Financial Advisers

AUDITOR'S INDEPENDENCE DECLARATION

As lead auditor for the audit of the consolidated financial report of Suda Limited for the year ended 30 June 2017, I declare that to the best of my knowledge and belief, there have been no contraventions of:

- a) the auditor independence requirements of the *Corporations Act 2001* in relation to the audit; and
- b) any applicable code of professional conduct in relation to the audit.

HLB Mann Judd
Chartered Accountants

A handwritten signature in blue ink, appearing to read 'Norman G. Neill'.

N G Neill
Partner

Perth, Western Australia
22 September 2017

HLB Mann Judd (WA Partnership) ABN 22 193 232 714

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HLB Mann Judd (WA Partnership) is a member of  HLB International, a world-wide organisation of accounting firms and business advisers

STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED 30 JUNE 2017

	Notes	Consolidated	
		2017	2016
		\$	\$
Revenue	2	7,197,362	5,785,802
Interest income		24,023	85,813
Other income	2	110,903	74,681
Raw materials and consumables used		(5,541,205)	(5,044,696)
Employee benefits expense		(2,180,829)	(2,301,495)
Depreciation expense	9	(124,247)	(122,363)
Finance costs		(223,450)	(209,556)
Other expenses	2	(1,292,866)	(1,320,784)
Loss before income tax expense		(2,030,309)	(3,052,598)
Income tax benefit	3	792,000	745,785
Net Loss for the year		(1,238,309)	(2,286,813)
Total comprehensive loss for the year		(1,238,309)	(2,286,813)
Loss and total comprehensive loss attributable to:			
Owners of the parent		(1,238,309)	(2,286,813)
Basic earnings per share (cents per share)	5	(0.11)	(0.20)
Diluted earnings per share (cents per share)	5	(0.11)	(0.20)

The accompanying notes form part of these financial statements

STATEMENT OF FINANCIAL POSITION

AS AT 30 JUNE 2017

	Notes	Consolidated	
		2017	2016
		\$	\$
Assets			
Current assets			
Cash and cash equivalents	6	1,769,812	2,448,771
Trade and other receivables	7	1,607,802	1,517,120
Inventories	8	1,110,718	1,132,177
Other assets		121,736	194,930
Total current assets		4,610,068	5,292,998
Non-current assets			
Property, plant and equipment	9	232,079	271,763
Intangible assets	10	15,173,396	13,950,723
Total non-current assets		15,405,475	14,222,486
Total assets		20,015,543	19,515,484
Liabilities			
Current liabilities			
Trade and other payables	11	1,360,689	1,179,271
Borrowings	12	-	1,730,000
Total current liabilities		1,360,689	2,909,271
Non-current liabilities			
Borrowings	12	1,802,500	-
Total non-current liabilities		1,802,500	-
Total liabilities		3,163,189	2,909,271
Net assets		16,852,354	16,606,213
Equity			
Issued capital	13	57,138,713	55,716,942
Reserves	14	2,171,201	2,108,522
Accumulated losses		(42,457,560)	(41,219,251)
Total equity		16,852,354	16,606,213

The accompanying notes form part of these financial statements

STATEMENT OF CHANGES IN EQUITY

FOR THE YEAR ENDED 30 JUNE 2017

	Consolidated					
	Issued capital \$	Accumulated losses \$	Share-based payment reserve \$	Minority Interest Acquisition Reserve \$	Non-controlling interests \$	Total equity \$
Balance as at 1 July 2015	55,573,622	(38,932,438)	628,255	-	2,031,148	19,300,587
Shares issued during the year	143,320	-	-	-	-	143,320
Recognition of share based payments expenses	-	-	76,000	-	-	76,000
Project development reserve on acquisition of minority shareholding	-	-	-	1,404,267	-	1,404,267
Acquisition of minority shareholding	-	-	-	-	(2,031,148)	(2,031,148)
Loss for the year attributable to members of the parent entity	-	(2,286,813)	-	-	-	(2,286,813)
Balance as at 30 June 2016	55,716,942	(41,219,251)	704,255	1,404,267	-	16,606,213
Balance as at 1 July 2016	55,716,942	(41,219,251)	704,255	1,404,267	-	16,606,213
Shares issued during the year	1,574,450	-	-	-	-	1,574,450
Share issue costs	(152,679)	-	-	-	-	(152,679)
Recognition of share based payments expenses	-	-	62,679	-	-	62,679
Loss for the year attributable to members of the parent entity	-	(1,238,309)	-	-	-	(1,238,309)
Balance as at 30 June 2017	57,138,713	(42,457,560)	766,934	1,404,267	-	16,852,354

The accompanying notes form part of these financial statements

STATEMENT OF CASH FLOWS

FOR THE YEAR ENDED 30 JUNE 2017

	Notes	Consolidated	
		2017	2016
		\$	\$
Cash flows from operating activities			
Receipts from customers		7,082,136	5,889,989
Receipts for R&D tax incentive		856,656	687,626
Payments to suppliers and employees		(8,667,742)	(8,338,004)
Interest received		23,727	109,651
Finance costs		(149,000)	(151,365)
Net cash outflows from operating activities	6	(854,223)	(1,802,103)
Cash flows from investing activities			
Payments for property, plant and equipment	9	(84,563)	(65,328)
Payments for intangible assets	10	(1,222,673)	(1,396,273)
Payments for equity investments		-	(647,077)
Proceeds from sale or property, plant and equipment		-	38,605
Net cash outflows from investing activities		(1,307,236)	(2,070,073)
Cash flows from financing activities			
Proceeds from issue of shares	13	1,500,000	-
Proceeds from borrowings		542,500	1,025,000
Repayment of borrowings		(470,000)	(920,000)
Payments for capital raising costs		(90,000)	(36,000)
Net cash inflows from financing activities		1,482,500	69,000
Net decrease in cash and cash equivalents			
		(678,959)	(3,803,176)
Cash and cash equivalents at the beginning of the year		2,448,771	6,251,947
Cash and cash equivalents at the end of the year	6	1,769,812	2,448,771

The accompanying notes form part of these financial statements

NOTE 1: STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES

a. Basis of preparation

These financial statements are general purpose financial statements, which have been prepared in accordance with the requirements of the Corporations Act 2001, Accounting Standards and Interpretations and comply with other requirements of the law.

The financial statements comprise the consolidated financial statements for the Group. For the purposes of preparing the consolidated financial statements, the Company is a for-profit entity.

The accounting policies detailed below have been consistently applied to all of the years presented unless otherwise stated. The financial statements are for the Group consisting of SUDA Limited and its subsidiaries.

The financial statements have been prepared on a historical cost basis. Historical cost is based on the fair values of the consideration given in exchange for goods and services.

The financial statements are presented in Australian dollars.

The Company is a listed public Company, incorporated in Australia. The entity's principal activities are:

- Pharmaceutical development of drug delivery technology
- Medical devices and consumables distribution

b. Adoption of new and revised standards

Standards and Interpretations applicable to 30 June 2017

In the year ended 30 June 2017, the Directors have reviewed all of the new and revised Standards and Interpretations issued by the AASB that are relevant to the Company and effective for the current annual reporting period. As a result of this review, the Directors have determined that there is no material impact of the new and revised Standards and Interpretations on the Group and, therefore, no material change is necessary to Group accounting policies.

Standards and Interpretations in issue not yet adopted

The Directors have also reviewed all new Standards and Interpretations that have been issued but are not yet effective for the year ended 30 June 2017. As a result of this review the Directors have determined that the following Standards and Interpretations may have a material effect on the Group in future reporting periods.

- AASB 15 Revenue from contracts with Customers
- AASB 16 Leases
- AASB 9 Financial Instruments

The Group have elected to not early adopt these Standards and Interpretations and have not quantified the material effect of application on future periods.

Other than the above, there are no other material impact of the new and revised Standards and Interpretations on the Group and therefore no change is necessary to Group accounting policies.

c. Statement of compliance

The financial report was authorised for issue on 22 September 2017

The financial report complies with Australian Accounting Standards, which include Australian equivalents to International Financial Reporting Standards (AIFRS). Compliance with AIFRS ensures that the financial report, comprising the financial statements and notes thereto, complies with International Financial Reporting Standards (IFRS).

d. Basis of consolidation

The consolidated financial statements incorporate the financial statements of SUDA Limited and entities controlled by the Group and its subsidiaries. Control is achieved when the Company:

- Has power of the investee;
- Is exposed, or has rights, to variable returns from its involvement in with the investee; and
- Has the ability to its power to affect its returns.

The Company reassess whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements listed above.

When the Company has less than a majority of the voting rights if an investee, it has the power over the investee when the voting rights are sufficient to give it the practical ability to direct the relevant activities of the investee unilaterally. The Company considers all relevant facts and circumstances in assessing whether or not the Company's voting rights are sufficient to give it power, including,

- the size of the Company's holding of voting rights relative to the size and dispersion of holdings of the other vote holders;
- potential voting rights held by the Company, other vote holders or other parties; rights arising from other contractual arrangements; and
- relevant activities at the time that decisions need to be made, including voting patterns at previous shareholder meetings

NOTE 1: STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Consolidation of a subsidiary begins when the Company obtains control over the subsidiary and ceases when the Company loses control of the subsidiary. Specifically, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated statement of comprehensive income from the date the Company gains control until the date when the Company ceases to control the subsidiary.

e. Significant accounting estimates and judgements

The application of accounting policies requires the use of judgements, estimates and assumptions about carrying values of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions are recognised in the period in which the estimate is revised if it affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

Inventories

Management estimates the net realisable values of inventories, taking into account the most reliable evidence available at each reporting date. The future realisation of these inventories may be affected by future technology or other market-driven changes that may reduce future selling prices.

Useful lives of depreciable assets

Management reviews its estimate of the useful lives of depreciable assets at each reporting date, based on the expected utility of the assets. Uncertainties in these estimates relate to technical obsolescence that may change the utility of certain software and IT equipment.

Impairment

In assessing impairment, management estimates the recoverable amount of each asset or cash-generating unit based on expected future cash flows and uses an interest rate to discount them. Estimation uncertainty relates to assumptions about future operating results and the determination of a suitable discount rate.

Capitalisation of internally developed project development

Distinguishing the research and development phases of a new project development and determining whether the recognition requirements for the capitalisation of development costs are met requires judgement. After capitalisation, management monitors whether the recognition requirements continue to be met and whether there are any indicators that capitalised costs may be impaired.

Impairment of intangibles and goodwill:

The Group determines whether intangibles with indefinite useful lives, intangible assets not yet available for use and goodwill are impaired at least on an annual basis. This requires an estimation of the recoverable amount of the cash generating units to which the goodwill and intangibles are allocated. The assumptions used in this estimation of recoverable amount and the carrying amount of goodwill and intangibles are discussed in Note 10.

Share-based payment transactions:

The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is either determined by an external valuer using a Binomial model, or internally using a Black-Scholes model, using the assumptions detailed in Notes 13 and 15.

The Group measures the cost of cash-settled share-based payments at fair value at the grant date using the Black-Scholes model taking into account the terms and conditions upon which the instruments were granted.

Fair value of financial instruments

Management uses valuation techniques to determine the fair value of financial instruments (where active market quotes are not available) and non-financial assets. This involves developing estimates and assumptions consistent with how market participants would price the instrument. Management bases its assumptions on observable data as far as possible but this is not always available. In that case management uses the best information available. Estimated fair values may vary from the actual prices that would be achieved in an arm's length transaction at the reporting date.

Recognition of service and construction contract revenue

Determining when to recognise revenues from after-sales services requires an understanding of the customer's use of the related products, historical experience and knowledge of the market.

Share-based payment transactions:

The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by an external valuer using a Black and Scholes model or a Binomial model, using the assumptions detailed in Note 15.

f. Going concern

The financial statements have been prepared on the going concern basis, which contemplates continuity of normal business activities and the realisation of assets and settlement of liabilities in the ordinary course of business. This includes the continued development and commercialisation of the Group's current projects.

The consolidated entity has reported a net loss from operations for the period of \$1,238,309 (2016: \$2,286,813) and a net cash outflow from operations and investing activities for the year of \$2,161,459 (2016: \$3,872,176).

The Directors are of the opinion that the Group is a going concern as the cash balance at 30 June 2017 was \$1,769,812 (2016: \$2,448,771), and management's internal cash flow projections indicate that the Company has sufficient capital to continue to operate as planned and, based on prior experience, the directors are confident that they can raise additional capital if required.

g. Foreign currency translation

Both the functional and presentation currency of SUDA Limited and its subsidiaries is Australian dollars.

Transactions in foreign currencies are initially recorded in the functional currency by applying the exchange rates ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are retranslated at the rate of exchange ruling at the balance date.

All exchange differences in the consolidated financial report are taken to profit or loss with the exception of differences on foreign currency borrowings that provide a hedge against a net investment in a foreign entity. These are taken directly to equity until the disposal of the net investment, at which time they are recognised in profit or loss.

Tax charges and credits attributable to exchange differences on those borrowings are also recognised in equity.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rate as at the date of the initial transaction.

Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined. Translation differences on assets and liabilities carried at fair value are reported as part of the fair value gain or loss.

NOTE 2: REVENUE AND EXPENSES

Accounting policies

Revenue recognition

Revenue is measured at fair value of the consideration received or receivable. Amounts disclosed as revenue are net of returns, trade allowances, and volume rebates.

Sale of goods

Revenue is recognised when the goods are delivered and titles have passed, at which time all the following conditions are satisfied:

- the Group has transferred to the buyer the significant risks and rewards of ownership of the goods;
- the Group retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold;
- the amount of revenue can be measured reliably;
- it is probable that the economic benefits associated with the transaction will flow to the Group; and
- the costs incurred or to be incurred in respect of the transaction can be measured reliably.

Rendering of services

Revenue from the rendering of services is recognised by reference to the stage of completion of the contract. The stage of completion of the contract is determined as follows:

- Contract income is recognised by reference to the total actual costs incurred at the end of the reporting period relative to the proportion of the total costs expected to be incurred over the life of the contract;
- Servicing fees are recognised by reference to the proportion of the total cost of providing the service for the product sold; and
- Revenue from time and material contracts are recognised at the contractual rates as labour hours are delivered and direct expenses are incurred.

Interest income

Interest income from a financial asset is recognised when it is probable that the economic benefits will flow to the Group and the amount of revenue can be reliably measured. Interest income is accrued on a time basis, by reference to the principal outstanding and at the effective interest rate applicable, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to that assets' net carrying amount on initial recognition.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

NOTE 2: REVENUE AND EXPENSES (CONTINUED)

Government grants

Grants, such as Export Market Development Grants (excluding Research and Development Tax Incentives – refer to Note 3), from the government are recognised at their fair value where there is a reasonable assurance that the grant will be received and the Group will comply with all attached conditions.

Government grants relating to costs are deferred and recognised in the profit or loss over the period necessary to match them with the costs that they are intended to compensate.

Borrowing costs

All other borrowing costs are recognised in profit or loss in the period in which they are incurred.

Leases

Leases are classified as finance leases whenever the terms of the lease transfer substantially all the risks and rewards of ownership to the lessee. All other leases are classified as operating leases.

Operating lease payments are recognised as an expense on a straight-line basis over the lease term, except where another systematic basis is more representative of the time pattern in which economic benefits from the leased asset are consumed.

Revenue	Consolidated	
	2017	2016
	\$	\$
<i>Sales revenue</i>		
Sale of goods	7,197,362	5,785,802
<i>Other income</i>		
Gain on disposal of property, plant and equipment	-	78
Other income	110,903	74,603
	110,903	74,681
<i>Other expenses</i>		
Interest expense	223,450	209,556
Write down of inventory to net realisable value	63,276	27,794
Write-off of obsolete stock	-	397,475
Depreciation of non-current assets	124,247	122,363
Impairment of receivables	78,947	-
Operating lease rental expense	204,804	213,434
Share-based payment expense	6,101	76,000
Legal fees (net of recoveries)	470,272	152,663
Professional fees	111,700	135,248

NOTE 3: INCOME TAX

Accounting policy

Income tax

The income tax expense or benefit for the period is the tax payable on the current period's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary difference and to unused tax losses.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where the Company's subsidiaries and associates operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Current tax assets and liabilities for the current and prior periods are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted by the balance date.

Deferred income tax is provided on all temporary differences at the balance date between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred income tax liabilities are recognised for all taxable temporary differences except:

- when the deferred income tax liability arises from the initial recognition of an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- when the taxable temporary difference is associated with investments in subsidiaries, associates or interests in joint ventures, and the timing of the reversal of the temporary difference can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred income tax assets are recognised for all deductible temporary differences, carry-forward of unused tax assets and unused tax losses, to the extent that it is probable that taxable profit will be available against which the deductible temporary differences and the carry-forward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred income tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- when the deductible temporary difference is associated with investments in subsidiaries, associates or interests in joint ventures, in which case a deferred tax asset is only recognised to the extent that it is probable that the temporary difference will reverse in the foreseeable future and taxable profit will be available against which the temporary difference can be utilised.

The carrying amount of deferred income tax assets is reviewed at each balance date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred income tax asset to be utilised.

Unrecognised deferred income tax assets are reassessed at each balance date and are recognised to the extent that it has become probable that future taxable profit will allow the deferred tax asset to be recovered.

Deferred income tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the balance date.

Income taxes relating to items recognised directly in equity are recognised in equity and not in profit or loss.

Deferred tax assets and deferred tax liabilities are offset only if a legally enforceable right exists to set off current tax assets against current tax liabilities and the deferred tax assets and liabilities relate to the same taxable entity and the same taxation authority.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

NOTE 3: INCOME TAX (CONTINUED)

Tax consolidation legislation

SUDA Limited and its 100% owned Australian resident subsidiaries have implemented the tax consolidation legislation. Current and deferred tax amounts are accounted for in each individual entity as if each entity continued to act as a taxpayer on its own.

SUDA Limited recognises its own current and deferred tax amounts and those current tax liabilities, current tax assets and deferred tax assets arising from unused tax credits and unused tax losses which it has assumed from its controlled entities within the tax consolidated Group.

Assets or liabilities arising under tax funding agreements with the tax consolidated entities are recognised as amounts payable or receivable from or payable to other entities in the Group. Any difference between the amounts receivable or payable under the tax funding agreement are recognised as a contribution to (or distribution from) controlled entities in the tax consolidated Group.

Other taxes

Revenues, expenses and assets are recognised net of the amount of GST except:

- when the GST incurred on a purchase of goods and services is not recoverable from the taxation authority, in which case the GST is recognised as part of the cost of acquisition of the asset or as part of the expense item as applicable; and
- receivables and payables, which are stated with the amount of GST included.

The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the statement of financial position.

Cash flows are included in the statement of cash flows on a gross basis and the GST component of cash flows arising from investing and financing activities, which is recoverable from, or payable to, the taxation authority are classified as operating cash flows.

Commitments and contingencies are disclosed net of the amount of GST recoverable from, or payable to, the taxation authority.

Research and Development Tax

The Research and Development Tax Incentive is recognised at its fair value where there is a reasonable assurance that the tax incentive will be received and the Group will comply with all attached conditions.

Income tax recognised in profit or loss. The major components of tax expense are:

	Consolidated	
	2017	2016
	\$	\$
Current tax	(680,000)	(744,064)
Under provision in respect of prior years	(112,000)	(21,721)
Total tax benefit	(792,000)	(765,785)

The prima facie income tax benefit on pre-tax accounting profit from operations reconciles to the income tax benefit in the financial statements as follows:

	Consolidated	
	2017	2016
	\$	\$
Net loss for the period	(2,030,309)	(3,052,597)
Prima Facie tax (benefit) on loss from ordinary activities before income tax at 27.5%	(558,335)	(915,779)
Add Tax effect of:		
Non-deductible expense		
Options Expense	-	22,800
R&D Expenditure	429,885	496,043
Expenditure not allowed for income tax purposes	64,198	27,986
Research and development tax offset	(680,000)	(744,064)
Tax effect of temporary differences and tax losses not brought to account	64,252	368,950
Unders/(overs) – R&D tax offset	(112,000)	(21,721)
Income tax benefit	(792,000)	(765,785)

The tax rate used in the above reconciliation is the corporate tax rate of 27.5% payable by Australian corporate entities on taxable profits under Australian tax law. There has been no change in this tax rate since the previous reporting period.

Amounts recognised directly in equity

Unrecognised deferred tax balances of Australian income tax consolidated group:		
• Unrecognised deferred tax asset – revenue losses	8,211,609	8,731,189
• Unrecognised deferred tax asset – capital losses	1,537,854	1,677,659
• Unrecognised deferred tax asset – other	247,159	94,770
• Unrecognised deferred tax equity	71,367	95,527
• Unrecognised deferred tax liabilities	(674,286)	(335,539)
Net unrecognised deferred tax asset	9,393,703	10,263,606

NOTE 4: SEGMENT REPORTING

Accounting policy

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. The chief operating decision maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Board of Directors of SUDA Limited.

Description of segments

The Group has identified its operating segments based on the internal reports that are reviewed and used by the Board of Directors (chief operating decision makers) in assessing performance and in determining the allocation of resources.

The Group is managed primarily on the basis of product category and service offerings as the diversification of the Group's operations inherently have notably different risk profiles and performance assessment criteria. Operating segments are therefore determined on the same basis.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

NOTE 4: SEGMENT REPORTING (CONTINUED)

The Group has 3 main types of products and services by segment:

- i. Suda: the pharmaceutical development segments and performs research and development to create new human pharmaceutical products by combining proven drugs with innovated, patented, delivery technologies.
- ii. Westcoast Surgical & Medical Supplies (Westcoast): sales and logistics operation for medical devices and consumables.
- iii. Malaria Research Company (MRC): pharmaceutical development segment for the treatment of malaria, i.e. ArTiMist™ project.

Segment information

The following tables present revenue and profit information and certain asset and liability information regarding business segments for the years ended 30 June 2017 and 30 June 2016.

	Suda	Westcoast	MRC	Other	Consolidated
30 June 2017	\$	\$	\$	\$	\$
Revenue					
Sales to external customers	444,029	6,753,333	-	-	7,197,362
Inter-segment sales (i)	871,856	-	-	-	871,856
	<u>1,315,885</u>	<u>6,753,333</u>	<u>-</u>	<u>-</u>	<u>8,069,218</u>
Inter-segment sales eliminated					(871,856)
Total segment revenue					<u>7,197,362</u>
Segment net operating profit (loss) after tax					
	(1,141,533)	119,332	(2,525)	(213,583)	(1,238,309)
Interest revenue	23,728	295	-	-	24,023
Interest expense	(223,382)	(68)	-	-	(223,450)
Depreciation and amortisation	(97,577)	(26,670)	-	-	(124,247)
Segment assets	<u>11,521,050</u>	<u>2,034,070</u>	<u>11,540,877</u>	<u>(575,701)</u>	<u>23,876,944</u>
Inter-segment eliminations					(4,504,753)
Total assets					<u>20,015,543</u>
Capital expenditure	70,426	14,136	-	-	84,563
Other assets	542,104	-	680,569	-	1,222,673
Segment liabilities	<u>2,198,907</u>	<u>3,315,716</u>	<u>1,509,967</u>	<u>-</u>	<u>7,024,590</u>
Inter-segment eliminations					(3,861,401)
Total liabilities					<u>3,163,189</u>
Cash flow information					
Net cash flow from operating activities	(1,296,239)	334,998	107,018	-	(854,223)
Net cash flow from investing activities	(826,114)	(14,135)	(466,986)	-	(1,307,235)
Net cash flow from financing activities	1,482,500	-	-	-	1,482,500

(i) Intersegment revenue is recorded at amounts equal to competitive market prices charged to external customers for similar goods and is eliminated on consolidation.

	Suda	Westcoast	MRC	Other	Consolidated
30 June 2016	\$	\$	\$	\$	\$
Revenue					
Sales to external customers	-	5,785,802	-	-	5,785,802
Inter-segment sales (i)	425,454	-	-	-	425,454
	425,454	5,785,802	-	-	6,211,256
Inter-segment sales eliminated					(349,523)
Total segment revenue					5,624,815
Segment net operating profit (loss) after tax					
	(1,733,548)	(416,961)	12,017	(148,321)	(2,286,813)
Interest revenue	85,813	-	-	-	85,813
Interest expense	(205,302)	(4,254)	-	-	(209,556)
Depreciation and amortisation	(88,556)	(33,807)	-	-	(122,363)
Segment assets					
	11,197,493	1,771,344	10,974,311	(362,177)	23,580,971
Inter-segment eliminations					(4,065,487)
Total assets					19,515,484
Capital expenditure					
	49,801	2,500	-	-	52,301
Other assets	668,603	-	336,859	(142,485)	862,977
Segment liabilities					
	2,218,267	3,168,537	940,877	-	6,327,681
Inter-segment eliminations					(3,418,410)
Total liabilities					2,909,271
Cash flow information					
Net cash flow from operating activities	(1,745,131)	(146,728)	89,756	-	(1,802,103)
Net cash flow from investing activities	(1,112,218)	11,256	(969,111)	-	(2,070,073)
Net cash flow from financing activities	69,000	-	-	-	69,000

Intersegment revenue is recorded at amounts equal to competitive market prices charged to external customers for similar goods and is eliminated on consolidation.

Other segment information

Revenue from external customers by geographical locations is detailed below. Revenue is attributed to geographical location based on the location of customers. The Company does not have external revenues from external customers that are attributable to any foreign country other than shown.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

NOTE 4: SEGMENT REPORTING (CONTINUED)

	Consolidated	
	2017	2016
	\$	\$
Australia	6,753,333	5,785,802
China	417,713	-
USA	26,316	-
Total revenue	7,197,362	5,785,802

Segment net operating profit

The executive management committee meets on a monthly basis to assess the performance of each segment by analysing the segment's net operating profit after tax. A segment's net operating profit after tax excludes non-operating income and expense such as dividends received, fair value gains and losses, gains and losses on disposal of assets and impairment charges. Income tax expenses are calculated as 27.5% (2016: 28.5%) of the segment's net operating profit.

Segment assets

In assessing the segment performance on a monthly basis, the executive management committee analyses the segment result as described above and its relation to segment assets. Segment assets are those operating assets of the entity that the management committee views as directly attributable to the performance of the segment. These assets include plant and equipment, receivables, inventory and intangibles and exclude available-for-sale assets, derivative assets, deferred tax assets, and pension assets.

Segment liabilities

Segment liabilities include trade and other payables and debt. The Group has a centralised finance function that is responsible for raising debt and capital for the entire operations. Each entity or business uses this central function to invest excess cash or obtain funding for its operations. The executive management committee reviews the level of debt for each segment in the monthly meetings.

The Group has a number of customers to whom it provides both products and services. The Group supplies a single external customer in the medical devices and consumables segment who accounts 18% of external revenue (2016: 19%). The next most significant client accounts for 9% (2016: 10%) of external revenue.

NOTE 5: EARNINGS PER SHARE

Accounting policy

Basic earnings per share is calculated as net profit attributable to members of the parent, adjusted to exclude any costs of servicing equity (other than dividends) and preference share dividends, divided by the weighted average number of ordinary shares, adjusted for any bonus element.

Diluted earnings per share is calculated as net profit attributable to members of the parent, adjusted for:

- costs of servicing equity (other than dividends) and preference share dividends;
- the after tax effect of dividends and interest associated with dilutive potential ordinary shares that have been recognised as expenses; and
- other non-discretionary changes in revenues or expenses during the period that would result from the dilution of potential ordinary shares; divided by the weighted average number of ordinary shares and dilutive potential ordinary shares, adjusted for any bonus element.

Basic earnings per share

	Consolidated	
	2017	2016
	Cents per share	Cents per share
Total basic earnings per share	(0.11)	(0.20)
Diluted earnings per share	(0.11)	(0.20)

Basic earnings per share and Diluted earnings per share

The earnings and weighted average number of ordinary shares used in the calculation of basic earnings per share and diluted earnings per share is as follows:

	Consolidated	
	2017	2016
	\$	\$
Earnings	(1,238,309)	(2,286,813)

	Number	Number
	Weighted average number of ordinary shares for the purpose of basic earnings per share	1,155,909,911
Weighted average number of ordinary shares for the purpose of diluted earnings per share	1,155,909,911	1,139,508,407

NOTE 6: CASH AND CASH EQUIVALENTS

Accounting policy

Cash comprises cash at bank and in hand. Cash equivalents are short term, highly liquid investments that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

For the purposes of the statement of cash flows, cash and cash equivalents consist of cash and cash equivalents as defined above, net of outstanding bank overdrafts.

	Consolidated	
	2017	2016
	\$	\$
Cash at bank and on hand	1,769,812	498,771
Short-term deposits	-	1,950,000
	1,769,812	2,448,771

Cash at bank earns interest at floating rates based on daily bank deposit rates.

Short-term deposits are made for varying periods of between one and seven months, depending on the immediate cash requirements of the Group, and earn interest at the respective short-term deposit rates.

Reconciliation to the Statement of Cash Flows:

For the purposes of the statement of cash flows, cash and cash equivalents comprise cash on hand and at bank and investments in money market instruments, net of outstanding bank overdrafts.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

Cash and cash equivalents as shown in the statement of cash flows is reconciled to the related items in the statement of financial position as follows:

	Consolidated	
	2017	2016
	\$	\$
Cash and cash equivalents	1,769,812	2,448,771

Reconciliation of profit for the year to net cash flows from operating activities

Loss for the year	(1,238,309)	(2,286,813)
Share-based payment expense	74,450	119,320
Depreciation	124,247	122,363
Impairment	78,947	-
Write-off of obsolete stock / inventory write down	63,276	425,269
Net (gain)/loss on disposal of property, plant and equipment	-	30,761
Change in net assets and liabilities		
(Increase)/decrease in assets:		
Trade and other receivables	(97,890)	(211,374)
Prepayments	73,195	38,328
Inventories	(41,816)	(34,622)
Increase/(decrease) in liabilities:		
Trade and other payables	123,719	(31,159)
Provisions	(14,042)	25,824
Net cash from operating activities	(854,223)	(1,802,103)

NOTE 7: TRADE AND OTHER RECEIVABLES

Accounting policy

Trade receivables are measured on initial recognition at fair value and are subsequently measured at amortised cost using the effective interest rate method, less any allowance for impairment. Trade receivables are generally due for settlement within periods ranging from 30 days to 60 days.

Impairment of trade receivables is continually reviewed and those that are considered to be uncollectible are written off by reducing the carrying amount directly. An allowance account is used when there is objective evidence that the Group will not be able to collect all amounts due according to the original contractual terms. Factors considered by the Group in making this determination include known significant financial difficulties of the debtor, review of financial information and significant delinquency in making contractual payments to the Group.

The impairment allowance is set equal to the difference between the carrying amount of the receivable and the present value of estimated future cash flows, discounted at the original effective interest rate. Where receivables are short-term discounting is not applied in determining the allowance.

The amount of the impairment loss is recognised in the statement of comprehensive income within other expenses. When a trade receivable for which an impairment allowance had been recognised becomes uncollectible in a subsequent period, it is written off against the allowance account. Subsequent recoveries of amounts previously written off are credited against other expenses in the statement of comprehensive income.

	Consolidated	
	2017	2016
	\$	\$
Trade receivables (i)	1,026,170	791,882
Allowance for impairment	(97,773)	(18,826)
	928,397	773,056
R&D tax incentive receivable	679,405	744,064
	1,607,802	1,517,120

- i. the average credit period on sales of goods and rendering of services is 45 days. An allowance has been made for estimated irrecoverable trade receivable amounts.

	Consolidated	
	2017	2016
	\$	\$
Ageing of past due but not impaired		
30 – 60 days	35,556	41,913
60 – 90 days	23,928	1,304
90 – 120 days	-	27,908
120 days +	106,501	-
Total	165,985	71,125

Movement in the allowance for doubtful debts

	Consolidated	
	2017	2016
	\$	\$
Balance at the beginning of the year	18,826	18,826
Impairment losses recognised on receivables	78,947	-
Balance at the beginning and end of the year	97,773	18,826

In determining the recoverability of a trade receivable, the Group considers any changes in the credit quality of the trade receivable from the date credit was initially granted up to the balance date. The concentration of credit risk is limited due to the customer base being large and unrelated. Accordingly, the directors believe that there is no further credit provision required in excess of the allowance for impairment.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

NOTE 8: INVENTORIES

Accounting policy

Inventories are valued at the lower of cost and net realisable value.

Costs incurred in bringing each product to its present location and condition is accounted for as follows:

- Finished goods and work-in-progress – cost of direct materials and labour and a proportion of manufacturing overheads based on normal operating capacity but excluding borrowing costs.

Net realisable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

	Consolidated	
	2017	2016
	\$	\$
Finished goods – at cost/net realisable value	982,918	1,004,377
Raw materials – at cost/net realisable value	127,800	127,800
	<u>1,110,718</u>	<u>1,132,177</u>

Inventory write-downs and obsolete stock charged to cost of sales totalled \$63,276 (2016: \$425,269).

NOTE 9: PROPERTY, PLANT AND EQUIPMENT

Accounting policy

Plant and equipment is stated at cost less accumulated depreciation and any accumulated impairment losses. Such cost includes the cost of replacing parts that are eligible for capitalisation when the cost of replacing the parts is incurred. Similarly, when each major inspection is performed, its cost is recognised in the carrying amount of the plant and equipment as a replacement only if it is eligible for capitalisation.

Land and buildings are measured at fair value less accumulated depreciation on buildings and less any impairment losses recognised after the date of the revaluation.

Depreciation is calculated on a straight-line basis over the estimated useful life of the assets as follows:

Leasehold improvements	3 - 5 years
Plant and equipment	2 - 5 years

The assets' residual values, useful lives and amortisation methods are reviewed, and adjusted if appropriate, at each financial year end

Impairment

The carrying values of plant and equipment are reviewed for impairment at each balance date, with recoverable amount being estimated when events or changes in circumstances indicate that the carrying value may be impaired.

The recoverable amount of plant and equipment is the higher of fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

For an asset that does not generate largely independent cash inflows, recoverable amount is determined for the cash-generating unit to which the asset belongs, unless the asset's value in use can be estimated to approximate fair value.

An impairment exists when the carrying value of an asset or cash-generating units exceeds its estimated recoverable amount. The asset or cash-generating unit is then written down to its recoverable amount.

For plant and equipment, impairment losses are recognised in the statement of comprehensive income in the cost of sales line item. However, because land and buildings are measured at revalued amounts, impairment losses on land and buildings are treated as a revaluation decrement.

Derecognition and disposal

An item of property, plant and equipment is derecognised upon disposal or when no further future economic benefits are expected from its use or disposal.

Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in profit or loss in the year the asset is derecognised.

	Consolidated	
	Plant and equipment	Total
<i>Gross carrying amount</i>	\$	\$
Balance at 1 July 2015	664,676	664,676
Additions	52,301	52,301
Disposals	(100,374)	(100,374)
Balance at 1 July 2016	616,603	616,603
Additions	84,563	84,563
Balance at 30 June 2017	701,166	701,166

	Consolidated	
	Plant and equipment	Total
	\$	\$
<i>Accumulated depreciation and impairment</i>		
Balance at 1 July 2015	276,059	276,059
Depreciation expense	122,363	122,363
Disposals	(53,582)	(53,582)
Balance at 1 July 2016	344,840	344,840
Depreciation expense	124,247	124,247
Balance at 30 June 2017	469,087	469,087
Carrying value: 30 June 2017	232,079	232,079
Carrying value: 30 June 2016	271,763	271,763

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

NOTE 9: PROPERTY, PLANT AND EQUIPMENT (CONTINUED)

	Consolidated	
	2017	2016
	\$	\$
Cost	701,166	616,603
Accumulated depreciation and impairment	(469,087)	(344,840)
Net carrying amount	232,079	271,763

Plant and equipment with a carrying amount of \$232,079 (2016: \$271,763) for the Group and \$194,962 (2016: \$219,040) for the parent are pledged as securities for current and non-current liabilities as disclosed in Note 12.

NOTE 10: INTANGIBLE ASSETS

Accounting policy

Intangible assets acquired separately are recorded at cost less accumulated amortisation and impairment. Amortisation is charged on a straight-line basis over their estimated useful lives when available for use. The estimated useful life and amortisation method is reviewed at the end of each annual reporting period, with any changes in these accounting estimates being accounted for on a prospective basis.

Internally generated intangible assets – research and development expenditure

Expenditure on research activities is recognised as an expense in the period in which it is incurred. Where no internally-generated intangible asset can be recognised, development expenditure is recognised as an expense in the period as incurred.

An intangible asset arising from development (or from the development phase of an internal project) is recognised if, and only if, all of the following have been demonstrated:

- The technical feasibility of completing the intangible asset so that it will be available for use or sale;
- The intention to complete the intangible asset and use or sell it;
- The ability to use or sell the intangible asset;
- How the intangible asset will generate probable future economic benefits;
- The availability of adequate technical, financial and other resources to complete development and to use or sell the intangible asset; and
- The ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognised for internally-generated intangible assets is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above.

Subsequent to initial recognition, internally-generated intangible assets are reported at cost less accumulated amortisation and accumulated impairment losses, on the same basis as intangible assets acquired separately.

Impairment of tangible and intangible assets other than goodwill

The Group assesses at each balance date whether there is an indication that an asset may be impaired. If any such indication exists, or when annual impairment testing for an asset is required, the Group makes an estimate of the asset's recoverable amount. An asset's recoverable amount is the higher of its fair value less costs to sell and its value in use and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or Groups of assets and the asset's value in use cannot be estimated to be close to its fair value. In such cases the asset is tested for impairment as part of the cash-generating unit to which it belongs. When the carrying amount of an asset or cash-generating unit exceeds its recoverable amount, the asset or cash-generating unit is considered impaired and is written down to its recoverable amount.

In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. Impairment losses relating to continuing operations are recognised in those expense categories consistent with the function of the impaired asset unless the asset is carried at revalued amount (in which case the impairment loss is treated as a revaluation decrease).

An assessment is also made at each balance date as to whether there is any indication that previously recognised impairment losses may no longer exist or may have decreased. If such indication exists, the recoverable amount is estimated. A previously recognised impairment loss is reversed only if there has been a change in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognised. If that is the case the carrying amount of the asset is increased to its recoverable amount. That increased amount cannot exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognised for the asset in prior years. Such reversal is recognised in profit or loss unless the asset is carried at revalued amount, in which case the reversal is treated as a revaluation increase. After such a reversal, the depreciation charge is adjusted in future periods to allocate the asset's revised carrying amount, less any residual value, on a systematic basis over its remaining useful life.

	Development Costs	Total
	\$	\$
<i>Gross carrying amount</i>		
Balance at 1 July 2015	13,087,746	13,087,746
Additions	862,977	862,977
Balance at 30 June 2016	13,950,723	13,950,723
<hr/>		
Balance at 1 July 2016	13,950,723	13,950,723
Additions	1,222,673	1,222,673
Balance at 30 June 2017	15,173,396	15,173,396

The Board assesses each project at balance date:

i. ArTiMist

The Company had commissioned an independent valuation of the ArTiMist project in May 2012. This initial valuation forms the underlying basis for the impairment review and is updated on an annual basis to reflect any changes in assumptions used in the initial valuation.

Management prepare an internal model yearly on balance date for review and assessment by the Board.

ii. Other projects (including SUD001, SUD002, SUD003, SUD004 and Zolpimist)

Management prepare an internal model yearly on balance date for review and assessment by the Board.

No impairment loss was recognised for continuing operations in the 2017 financial year.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

NOTE 11: TRADE AND OTHER PAYABLES (CURRENT)

Accounting policy

Trade payables and other payables are carried at amortised cost and represent liabilities for goods and services provided to the Group prior to the end of the financial year that are unpaid and arise when the Group becomes obliged to make future payments in respect of the purchase of these goods and services. Trade and other payables are presented as current liabilities unless payment is not due within 12 months.

	Consolidated	
	2017	2016
	\$	\$
Trade payables (i)	1,100,055	993,694
Sundry payables and accrued expenses	220,884	144,332
Interest payable (ii)	40,050	41,245
	<u>1,360,989</u>	<u>1,179,271</u>

- i. Trade payables are non-interest bearing and are normally settled on 30-45 day terms.
- ii. Interest payable is normally settled six-monthly throughout the financial year and relates to convertible notes (refer to Note 12).

Information regarding the interest rate, foreign exchange and liquidity risk exposure is set out in Note 16.

NOTE 12: BORROWINGS

Accounting policy

Borrowings are initially recognised at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortised cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognised in profit or loss over the period of the borrowings using the effective interest method. Fees paid on the establishment of loan facilities are recognised as transaction costs of the loan to the extent that it is probable that some or all of the facility will be drawn down. In this case, the fee is deferred until the draw down occurs. To the extent there is no evidence that it is probable that some or all of the facility will be drawn down, the fee is capitalised as a prepayment for liquidity services and amortised over the period of the facility to which it relates.

The fair value of the liability portion of a convertible note is determined using a market interest rate for an equivalent non-convertible note. This amount is recorded as a liability on an amortised cost basis until extinguished on conversion or maturity of the note. The remainder of the proceeds is allocated to the conversion option. This is recognised and included in shareholders' equity, net of income tax effects.

Borrowings are removed from the statement of financial position when the obligation specified in the contract is discharged, cancelled or expired. The difference between the carrying amount of a financial liability that has been extinguished or transferred to another party and the consideration paid, including any non-cash assets transferred or liabilities assumed, is recognised in profit or loss as other income or finance costs.

Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the reporting period.

	Consolidated	
	2017	2016
Current	\$	\$
Secured		
Convertible Notes	-	1,730,000
Total secured borrowings	-	1,730,000

	Consolidated	
	2017	2016
Non Current	\$	\$
Secured		
Convertible Notes	1,802,500	-
Total secured borrowings	1,802,500	-

Fair value disclosures

Details of the fair value of the Group's borrowings are set out in Note 16.

Summary of borrowing arrangements

The key terms of the Convertible Notes are:

- i. Convertible at \$0.0238 per share
- ii. Issue price at \$1.00 each
- iii. Interest rate at 8% paid semi-annually
- iv. Maturity date is 31 March 2019
- v. Security is a general security interest
- vi. Redemption, if not converted at expiry, the Convertible Notes will be redeemed at 105% of the face value

The company's 2015 convertible note matured on 31 March 2017. At that date, the number of convertible notes on issue were 1,730,000. A total of 470,000 convertible notes were redeemed on 31 March 2017, with 1,260,000 rolled over under the terms outlined above and new subscribers to the 2017 convertible note totalled 742,500, of which 450,000 were related parties.

Conversion may occur at any time between 1 April 2017 and 31 March 2019. If the notes have not been converted, they will be redeemed on 31 March 2019 at \$1.05. Interest of 8% is paid 6-monthly in arrears up until settlement date.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

NOTE 12: BORROWINGS (CONTINUED)

Assets pledged as security

The carrying amounts of assets pledged as security for current and non-current interest bearing liabilities are:

	Consolidated	
	2017	2016
	\$	\$
Current		
Floating charge		
Receivables	928,397	773,056
Inventories	1,110,717	1,132,177
Total current assets pledged as security	2,039,114	1,905,233
Non-Current		
Property, plant and equipment	232,079	271,763
Intangible assets	15,173,396	13,950,723
Total non-current assets pledged as security	15,405,475	14,222,486
Total assets pledged as security	17,444,589	16,127,719

Financing facilities available

At balance date, the following finance facilities had been negotiated and were available:

	Consolidated	
	2017	2016
	\$	\$
Total facilities		
Convertible notes	2,002,500	1,730,000
Facilities used at balance date		
Convertible notes	1,802,500	1,730,000
Facilities unused at balance date		
Convertible notes	200,000	-

The unused facility is due to the amount due from related parties and subject to shareholder approval.

NOTE 13: ISSUED CAPITAL

Accounting policy

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds. Incremental costs directly attributable to the issue of new shares or options for the acquisition of a new business are not included in the cost of acquisition as part of the purchase consideration.

	Consolidated	
	2017	2016
	\$	\$
1,219,858,520 (2016: 1,141,272,286) fully paid ordinary shares	57,138,713	55,716,942

Ordinary shares entitle the holder to participate in dividends and the proceeds on winding up of the Company in proportion to the number of and amounts paid on the shares held.

On a show of hands every holder of ordinary shares present at a meeting in person or by proxy, is entitled to one vote, and upon a poll each share is entitled to one vote.

Ordinary shares have no par value and the Company does not have a limited amount of authorised capital.

Movement in ordinary shares on issue

	2017		2016	
	Number	\$	Number	\$
Balance at beginning of year	1,141,272,286	55,716,942	1,136,010,587	55,573,622
Shares issued during the year:			5,261,699	143,320
Settlement of premium on redemption of convertible notes	2,657,411	56,850		
Placement	75,000,000	1,500,000		
Settlement of interest on convertible notes	885,345	17,600		
Employee Share Scheme	43,478	-		
Share issue costs	-	(152,679)		
Balance at end of year	1,219,858,520	57,138,713	1,141,272,286	55,716,942

Share options

The Company has two share based payment option schemes under which options to subscribe for the Company's shares have been granted to certain Directors, other Key Management and other employees, refer Note 15.

Movement in shares on issue

	2017		2016	
	Number	\$	Number	\$
Balance at beginning of year	5,000,000	0.072	19,000,000	0.056
Share options issued during the year (Note i)	10,000,000	0.040	-	-
Share options expired during the year (refer to Note 15)	(5,000,000)	0.072	(14,000,000)	0.05
Balance at end of year	10,000,000	0.04	5,000,000	0.072

Note i: Share options were issued in relation to share issue costs.

There were 10,000,000 (2016: 5,000,000) share options outstanding at the end of the year with an exercise price of \$0.04 (2016: \$0.072) and a weighted average remaining contractual life was 1,030 days (2016: 315 days).

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

NOTE 13: ISSUED CAPITAL (CONTINUED)

The fair value of the equity-settled share options granted during the year related to the capital raising (Placement) and is estimated as at the date of grant using the Black and Scholes model taking into account the terms and conditions upon which the options were granted.

	Capital raising
30 June 2017	\$
Dividend yield (%)	0.00%
Expected volatility (%)	78.32%
Risk-free interest rate (%)	2.5%
Expected life of option (years)	3 years
Exercise price (cents)	4.0
Grant date share price (cents)	2.3

NOTE 14: RESERVES

Nature and purpose of reserves

Share based payments reserve

This reserve is used to record the value of equity benefits provided to employees and directors as part of their remuneration. Refer to note 15 for further details of these plans.

Transactions with non-controlling interests

This reserve is used to record the differences described in note 1(d) which may arise as a result of transactions with non-controlling interests that do not result in a loss of control.

NOTE 15: SHARE-BASED PAYMENT PLANS

Accounting policy

Equity settled transactions

The Group provides benefits to employees (including senior executives) of the Group in the form of share-based payments, whereby employees render services in exchange for shares or rights over shares (equity-settled transactions).

There are currently three plans in place to provide these benefits:

- i. the Employee Share Option Plan (ESOP), which provides benefits to directors and senior executives;
- ii. the Employee Performance Rights Plan (EPRP); and
- iii. the Tax Exempt Plan under which eligible employees may be issued up to \$1,000 of shares, excluding senior executives and directors.

The cost of these equity-settled transactions with employees is measured by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by using a Black-Scholes model or an external valuer using the Binomial model, further details of which are given in Note 15.

In valuing equity-settled transactions, no account is taken of any performance conditions, other than conditions linked to the price of the shares of SUDA Limited (market conditions) if applicable.

The cost of equity-settled transactions is recognised, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled, ending on the date on which the relevant employees become fully entitled to the award (the vesting period).

The cumulative expense recognised for equity-settled transactions at each balance date until vesting date reflects (i) the extent to which the vesting period has expired and (ii) the Group's best estimate of the number of equity instruments that will ultimately vest.

No adjustment is made for the likelihood of market performance conditions being met as the effect of these conditions is included in the determination of fair value at grant date. The statement of comprehensive income charge or credit for a period represents the movement in cumulative expense recognised as at the beginning and end of that period.

No expense is recognised for awards that do not ultimately vest, except for awards where vesting is only conditional upon a market condition.

If the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payment arrangement, or is otherwise beneficial to the employee, as measured at the date of modification.

If an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. However, if a new award is substituted for the cancelled award and designated as a replacement award on the date that it is granted, the cancelled and new award are treated as if they were a modification of the original award, as described in the previous paragraph.

The dilutive effect, if any, of outstanding options is reflected as additional share dilution in the computation of earnings per share, refer Note 5.

Employee Share Option Plan (ESOP)

On 6 March 2014, the Directors adopted the following plans:

- i. Employee Share Option Plan (Option Plan) under which Directors and executives and other employees may be offered the opportunity to be granted Options;
- ii. Employee Performance Rights Plan (Performance Rights Plan) under which Directors, executives, contractors and consultants and other employees may be offered the opportunity to be granted Performance Rights;
- iii. Tax Exempt Plan under which eligible employees may be issued up to \$1,000 of Shares

The vesting of Options and Performance Rights under the terms of the Plans is dependent on both of the following performance conditions being satisfied:

- i. Market capitalisation, and
- ii. Continuous employment

The contractual life of each option granted is 3 years. Options can be settled by payment at the exercise price or a cashless exercise facility is available.

The expense recognised in the statement of comprehensive income in relation to share-based payments is disclosed in Note 2.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

NOTE 15: SHARE-BASED PAYMENT PLANS (CONTINUED)

The following share-based payment arrangements were in place during the current and prior periods:

	Number	Grant date	Expiry date	Exercise price	Fair value at grant date	Vesting date
				\$	\$	
Options	5,000,000	12 May 2014	11 May 2017	7.2 cents	75,838	Subject to performance conditions
Performance Rights	6,782,051	12 May 2014	11 May 2017	n/a	185,150	Subject to performance conditions
Performance Rights	4,750,000	28 Nov 2014	27 Nov 2017	n/a	58,297	Subject to performance conditions
Options under employment agreement	4,000,000	21 July 2013	20 July 2015	5.0 cents	140,367	21 July 2013

There has been no alteration of the terms and conditions of the above share-based payment arrangement since grant date.

The following table illustrates the number and weighted average exercise prices of and movements in share options, under the ESOP, issued during the year:

	2017		2016	
	Number	Weighted average exercise price	Number	Weighted average exercise price
		\$		\$
Outstanding at the beginning of year	5,000,000	0.072	19,000,000	0.056
Exercised during the year	-	-	-	-
Expired during the year	(5,000,000)	0.072	(14,000,000)	0.050
Outstanding at the end of year	-	-	5,000,000	0.072
Exercisable at the end of year	-	-	-	-

The share options outstanding at the end of the year had an exercise price of \$0.072 (2015: \$0.056) and a weighted average remaining contractual life of 315 days (2015: 280 days).

The fair value of the equity-settled share options granted under both the option and the performance rights plans is estimated as at the date of grant using the Black and Scholes model or the Binomial model taking into account the terms and conditions upon which the options were granted.

There were no share options outstanding at the end of the year.

The expected life of the options is based on historical data and is not necessarily indicative of exercise patterns that may occur. The expected volatility reflects the assumption that the historical volatility is indicative of future trends, which may also not necessarily be the actual outcome. No other features of options granted were incorporated into the measurement of fair value.

Movement in Performance Rights

	2017	2016
	Number	Number
Balance at beginning of year	11,532,051	11,532,051
Performance Rights expired during the year (11 May 2017)	(6,782,051)	-
Balance at end of year	4,750,000	11,532,051

The performance rights outstanding at the end of the year have an expiry date of 27 November 2017.

The carrying amount of the liability relating to the cash-settled share-based payment at 30 June 2017 is \$140,367 (2016: \$675,727).

NOTE 16: FINANCIAL INSTRUMENTS

Capital risk management

The Group manages its capital to ensure that entities in the Group will be able to continue as a going concern while maximising the return to stakeholders through the optimisation of the debt and equity balance.

The Group's overall strategy remains unchanged from 2016.

The capital structure of the Group consists of debt, cash and cash equivalents and equity attributable to equity holders of the parent, comprising issued capital, reserves and retained earnings.

None of the Group's entities are subject to externally imposed capital requirements.

Operating cash flows are used to maintain and expand operations, as well as to make routine expenditures such as tax and general administrative outgoings.

Gearing levels are reviewed by the Board on a regular basis in line with its target gearing ratio, the cost of capital and the risks associated with each class of capital.

Categories of financial instruments

		Consolidated	
		2017	2016
	Note	\$	\$
<u>Financial assets</u>			
Cash and cash equivalents	6	1,769,812	2,448,771
Trade and other receivables	7	928,397	773,364
		2,698,209	3,222,141
<u>Financial liabilities</u>			
Trade and other payables	11	1,360,989	1,179,271
Borrowings	12	1,802,500	1,730,000
		3,163,489	2,909,271

Financial risk management objectives

The Group is exposed to market risk (including currency risk, fair value interest rate risk and price risk), credit risk, liquidity risk and cash flow interest rate risk.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

NOTE 16: FINANCIAL INSTRUMENTS (CONTINUED)

The Group seeks to minimise the effect of these risks, by using derivative financial instruments to hedge these risk exposures. The use of financial derivatives is governed by the Group's policies approved by the board of directors, which provide written principles on foreign exchange risk, interest rate risk, credit risk, the use of financial derivatives and non-derivative financial instruments, and the investment of excess liquidity. Compliance with policies and exposure limits is reviewed by management on a continuous basis. The Group does not enter into or trade financial instruments, including derivative financial instruments, for speculative purposes.

Market risk

The Group's activities expose it primarily to the financial risks of changes in foreign currency exchange rates, commodity prices and exchange rates. The Group enters into a variety of derivative financial instruments to manage its exposure to foreign currency and commodity price risk including foreign exchange forward contracts to hedge the exchange rate and commodity price risk arising on its production.

There has been no change to the Group's exposure to market risks or the manner in which it manages and measures the risk from the previous period.

Foreign currency risk management

The Group undertakes certain transactions denominated in foreign currencies, hence exposures to exchange rate fluctuations arise. Exchange rate exposures are managed within approved policy parameters utilising forward foreign exchange contracts.

The carrying amounts of the Group's foreign currency denominated monetary assets and monetary liabilities at the balance date expressed in Australian dollars are as follows:

	Liabilities		Assets	
	2017	2016	2017	2016
	\$	\$	\$	\$
GBP	-	34,924	2,110	3,205
EUR	24,505	12,718	1,291	528
USD	-	36,922	354,000	46,968
	24,505	84,564	357,401	50,701

Foreign currency sensitivity analysis

The Group is exposed to GB Pounds (GBP) Euros (EUR) and US Dollar (USD) currency fluctuations.

The following table details the Group's sensitivity to a 5% increase and decrease in the Australian dollar against the relevant foreign currencies. 5% is the sensitivity rate used when reporting foreign currency risk internally to key management personnel and represents management's assessment of the possible change in foreign exchange rates. The sensitivity analysis includes only outstanding foreign currency denominated monetary items and adjusts their translation at the period end for a 5% change in foreign currency rates. A positive number indicates an increase in profit or loss and other equity where the Australian Dollar strengthens against the respective currency. For a weakening of the Australian Dollar against the respective currency there would be an equal and opposite impact on the profit and other equity and the balances below would be negative.

	Consolidated	
	Profit	Equity
Year ended 30 June 2017	\$	\$
+/- 2% interest rates	(36,050)	36,050
+/- 5% in AUD / GBP	(106)	106
+/- 5% in AUD / EUR	(65)	65
+/- 5% in AUD / USD	(17,700)	17,700
Year ended 30 June 2016		
+/- 2% interest rates	(34,600)	34,600
+/- 5% in AUD / GBP	(1,746)	1,746
+/- 5% in AUD / EUR	(636)	636
+/- 5% in AUD / USD	(1,846)	1,846

This is mainly attributable to the exposure outstanding on USD, GBP and EUR currencies held at year end in the Group.

Interest rate risk management

The Company and the Group have minimised their exposure to interest rate risk as entities in the Group borrow funds at fixed interest rates.

The Company and Group's exposures to interest rate on financial assets and financial liabilities are detailed in the liquidity risk management section of this note.

Credit risk management

Credit risk refers to the risk that a counter-party will default on its contractual obligations resulting in financial loss to the Group. The Group has adopted a policy of only dealing with creditworthy counterparties and obtaining sufficient collateral where appropriate, as a means of mitigating the risk of financial loss from defaults. The Group only transacts with entities that are rated the equivalent of investment grade and above. This information is supplied by independent rating agencies where available and, if not available, the Group uses publicly available financial information and its own trading record to rate its major customers.

The Group's exposure and the credit ratings of its counterparties are continuously monitored and the aggregate value of transactions concluded is spread amongst approved counterparties. Credit exposure is controlled by counterparty limits that are reviewed and approved by the risk management committee annually.

The Group does not have any significant credit risk exposure to any single counterparty or any Group of counterparties having similar characteristics. The credit risk on liquid funds and derivative financial instruments is limited because the counterparties are banks with high credit ratings assigned by international credit rating agencies.

The carrying amount of financial assets recorded in the financial statements, net of any allowance for losses, represents the Group's maximum exposure to credit risk without taking account of the value of any collateral obtained.

Liquidity risk management

Ultimate responsibility for liquidity risk management rests with the board of directors, who have built an appropriate liquidity risk management framework for the management of the Group's short, medium and long-term funding and liquidity management requirements. The Group manages liquidity risk by maintaining adequate reserves, banking facilities and reserve borrowing facilities by continuously monitoring forecast and actual cash flows and matching the maturity profiles of financial assets and liabilities. Included in note 12 is a listing of additional undrawn facilities that the Group has at its disposal to further reduce liquidity risk.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

NOTE 17: COMMITMENTS AND CONTINGENCIES

Property leases

The property leases are non-cancellable leases with either on a one-year term or a five-year term, with rent payable monthly in advance. Contingent rental provisions within the lease agreement require that minimum lease payments shall be increased by the change in the consumer price index (CPI). An option exists to renew the leases at the end of the term for an additional term of one or three years. The leases allow for subletting of all lease areas.

Future minimum rentals payable under non-cancellable operating leases as at 30 June are as follows:

	2017	2016
	\$	\$
Within one year	173,110	167,680
After one year but not more than five years	309,975	524,140
	<u>483,085</u>	<u>691,820</u>

Legal claim

HC Berlin Pharma

The Company was notified of a court judgement in relation to an alleged failed in-kind contribution with HC Berlin Pharma (in liquidation) which was in favour of the Receiver. The Receiver had initiated a Statement of Claim against Suda for Euro 4 million plus 5% interest from August 2008 as outlined in the announcement of 3 June 2016.

Based on the judgement all the rights to ArTiMist are unencumbered and owned by SUDA.

SUDA lodged an appeal in August 2017 against the judgement and has taken legal advice and believes the judgment contains both errors in fact and in law and accordingly there are reasonable prospects of success upon appeal. Upon lodgement of the appeal the judgement is automatically stayed in Germany and cannot be enforced unless the Receiver places a security equal to the judgement plus 10% (€4.4M) with the courts.

Any registration and subsequent enforcement of the judgment in Australia under the applicable Australian legislation is not possible whilst the judgment is stayed in Germany. It is expected that the matter may not be resolved for a further 3 years.

The Directors are of the opinion, based on legal advice, that the likelihood of enforcement by the Receiver in Australia and subsequent payment by the Company can only be confirmed by the occurrence, or non-occurrence, of one or more uncertain future events not wholly within the control of the entity, and hence, has disclosed the matter with HC Berlin Pharma AG as a contingent liability.

Critical Health Products Pty Ltd

The Company received a statement of claim from Critical Health in respect of a breach of contract with the Company's subsidiary company, Westcoast. The Company has made a counter-claim against Critical Health. The Directors of SUDA are confident that there will be a satisfactory resolution to this matter and there will be no detrimental impact for shareholders.

Guarantees

SUDA Ltd has the following guarantee at 30 June 2017:

The parent entity and its subsidiary company, Westcoast Surgical and Medical Supplies Pty Ltd, have provided security to third parties in relation to the convertible notes. The security is for the term of the facility. The period covered by the security is until maturity of the convertible notes on 31 March 2019.

At the end of the reporting period, the balance on the convertible notes was \$1,802,500 (refer to Note 12).

NOTE 18: RELATED PARTY DISCLOSURE

The consolidated financial statements include the financial statements of SUDA Limited and the subsidiaries listed in the following table.

	Country of incorporation	% Equity interest	
		2016	2015
Westcoast Surgical and Medical Supplies Pty Ltd	Australia	100%	100%
Malaria Research Company Pty Ltd	Australia	100%	100%
Eastland CN Nominees Pty Ltd	Australia	100%	100%
Suda Europe Ltd	United Kingdom	100%	100%

SUDA Limited is the ultimate Australian parent entity and ultimate parent of the Group.

Transactions with Key Management Personnel

Refer to Note 22 for details of transactions with key management personnel.

Terms and conditions of transactions with related parties

Sales to and purchases from related parties are made in arm's length transactions both at normal market prices and on normal commercial terms. Outstanding balances at year-end are unsecured, interest free and settlement occurs in cash.

NOTE 19: PARENT ENTITY DISCLOSURES

Accounting policy

The financial information for the parent entity, SUDA Limited, disclosed below has been prepared on the same basis as the consolidated financial statements, except as set out below.

Investments in subsidiaries, associates and joint venture entities

Investments in subsidiaries, associates and joint venture entities are accounted for at cost in the parent entity's financial statements. Dividends received from associates are recognised in the parent entity's profit or loss, rather than being deducted from the carrying amount of these investments.

Share-based payments

The grant by the Company of options over its equity instruments to the employees of subsidiary undertakings in the Group is treated as a capital contribution to that subsidiary undertaking. The fair value of employee services received, measured by reference to the grant date fair value, is recognised over the vesting period as an increase to investment in subsidiary undertakings, with a corresponding credit to equity.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

Financial position

	2017	2016
	\$	\$
Assets		
Current assets	2,612,889	3,457,075
Non-current assets	8,908,161	7,740,418
Total assets	11,521,050	11,197,493
Liabilities	396,407	2,218,267
Current liabilities	1,802,500	-
Total liabilities	2,198,907	2,218,267
Equity		
Issued capital	57,138,713	55,716,942
Reserves: Share-based payments	766,934	704,255
Retained earnings	(48,583,504)	(47,441,971)
Total equity	9,322,143	8,979,226

Financial performance

Total loss and total comprehensive loss	(1,141,533)	(1,733,548)
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Guarantees

Suda Ltd has not entered into any guarantees, in the current or previous financial year, in relation to the debts of its subsidiaries.

Contingent liabilities of the parent entity

For details on commitments, see note 17.

NOTE 20: EVENTS AFTER THE REPORTING PERIOD

Licence Agreement

In July 2017, SUDA Ltd entered into an exclusive licence and supply agreement with Teva Pharmaceuticals International GmbH, an affiliate of Teva Pharmaceutical Industries Limited ("Teva"), for SUDA's ZolpiMist™ oral spray for insomnia in multiple countries. Teva is a leading global pharmaceutical company and the world's largest generic medicines producer. SUDA Ltd granted Teva a licence to ZolpiMist in Brazil, Mexico and Chile, together with an 18-month option to license the product in Argentina, Israel and Australia.

Once ZolpiMist is registered for sale in the territory, SUDA will supply the product to Teva and receive a double-digit royalty on net sales less the supply price.

NOTE 21: AUDITOR'S REMUNERATION

The auditor of SUDA is HLB Mann Judd.

	Consolidated	
	2017	2016
	\$	\$
Auditor of the parent entity		
Audit or review of the financial statements	56,000	54,000

NOTE 22: DIRECTORS AND EXECUTIVES DISCLOSURES

Details of Key Management Personnel

Directors

Michael Stewart	Chairman (Non-Executive)
Stephen Carter	Chief Executive Officer
Joseph Ohayon	Chief Financial Officer / Company Secretary

Executives

Nick Woolf	Chief Business Officer
John Billingham	General Manager - Westcoast Surgical & Medical Supplies

Key management personnel remuneration has been included in the Remuneration Report section of the Directors' Report.

Other transactions and balances with Key Management Personnel

	Consolidated	
	2017	2016
	\$	\$
Key Management Personnel		
Mr Michael Stewart – consulting services	3,600	2,000
Mr Michael Stewart – interest on convertible notes	6,500	29,172
Mr Stephen Carter – interest on convertible notes	6,500	5,140
Mr Joseph Ohayon – interest on convertible notes	2,600	2,165
Mr Nicholas Woolf	-	-
Balance on Convertible Notes		
Mr Michael Stewart (Note i)	50,000	50,000
Mr Stephen Carter	50,000	50,000
Mr Joseph Ohayon	20,000	20,000
Mr Nicholas Woolf	20,000	-

Note i: A total of \$250,000 convertible notes (of which \$50,000 has been received) are related parties of Mr Michael Stewart and are subject to shareholder approval.

The aggregate compensation made to Directors and other key management personnel of the Group is set out below:

Short-term employee benefits	830,621	818,840
Other long-term benefits	6,101	75,971
Post-employment benefits	78,567	77,600
	<u>915,289</u>	<u>972,411</u>

DIRECTORS DECLARATION

1. In the opinion of the directors of SUDA Limited (the 'Company'):
 - b. the accompanying financial statements and notes are in accordance with the Corporations Act 2001 including:
 - i. giving a true and fair view of the Group's financial position as at 30 June 2017 and of its performance for the year then ended; and
 - ii. complying with Australian Accounting Standards, the Corporations Regulations 2001, professional reporting requirements and other mandatory requirements.
 - b. there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.
 - c. the financial statements and notes thereto are in accordance with International Financial Reporting Standards issued by the International Accounting Standards Board.
2. This declaration has been made after receiving the declarations required to be made to the directors in accordance with Section 295A of the Corporations Act 2001 for the financial year ended 30 June 2017.

This declaration is signed in accordance with a resolution of the Board of Directors.



Stephen Carter
Director

Dated this 22 day of September 2017

INDEPENDENT AUDITOR'S REPORT

To the members of Suda Limited

Report on the Audit of the Financial Report

Opinion

We have audited the financial report of Suda Limited ("the Company") and its controlled entities ("the Group"), which comprises the consolidated statement of financial position as at 30 June 2017, the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, and the directors' declaration.

In our opinion, the accompanying financial report of the Group is in accordance with the *Corporations Act 2001*, including:

- a) giving a true and fair view of the Group's financial position as at 30 June 2017 and of its financial performance for the year then ended; and
- b) complying with Australian Accounting Standards and the *Corporations Regulations 2001*.

Basis for opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Financial Report* section of our report. We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants* ("the Code") that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial report of the current period. These matters were addressed in the context of our audit of the financial report as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

HLB Mann Judd (WA Partnership) ABN 22 193 232 714

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Key Audit Matter	How our audit addressed the key audit matter
<p>Carrying amount of Intangible assets Refer to Note 10, Intangible assets</p> <p>Included within non-current assets as at 30 June 2017 is intangible assets balance of \$15,173,396. The intangible asset is comprised of intellectual property acquired separately and internally generated intangible ArTimist project.</p> <p>In accordance with AASB 138 Intangible assets, the Group capitalises acquisition costs of intellectual property acquired separately and accounts for costs incurred after recognition as either research phase expense or capitalises development phase costs when recognition criteria in paragraph 57 are satisfied.</p> <p>The evaluation of the recoverable amount of these assets is considered a key audit matter as it was based upon a value-in-use calculation which required significant judgement in verifying the key assumptions supporting the expected discounted future cash flows of the intangible assets. Additionally as the most significant balance in the statement of financial position, this asset is key to readers understanding of the financial report.</p>	<p>Our procedures included but were not limited to:</p> <ul style="list-style-type: none"> • Obtaining an understanding of the key controls associated with the preparation of the model used to assess the recoverable amount of the intangibles; • Critically evaluating management's methodology in the value-in-use model and the basis for key assumptions such as discount rate; • Performing sensitivity analyses around the key inputs used in the cash flow forecasts that either individually or collectively would be required for assets to be impaired and considered the likelihood of such a movement in those key assumptions arising; • Reviewing the mathematical accuracy of the value-in-use model; • Comparing value-in-use to the carrying value of the assets comprising the CGU; • Considering the results of independent technical reports obtained; • Comparing key assumptions in forecast cash flows to historical results and, where this were materially different, critically reviewing the basis for differing future expectations; • Assessing the appropriateness of the disclosures included in the relevant notes to the financial report; and • Consideration of impairment indicators under AASB 136 Impairment of Assets.
<p>Contingency liability relating to court ruling Refer to Note 17, Commitments and Contingencies</p> <p>As disclosed in Note 17, On 20 January 2017 a German Court ruled in favour of a client by the Receiver of HC Berlin Pharma, that 2008 in-kind contribution failed, which gives rise to a possible 4.4M Euro claim against Suda. Notice to Appeal has been initiated by Suda Limited.</p> <p>The Court ruling is considered to be a key audit matters given the complexity surrounding it's appeal and any subsequent enforcement action. Due to its size it is also key to readers understanding of the financial report.</p>	<p>Our procedures included but were not limited to:</p> <ul style="list-style-type: none"> • We enquired with management, reviewed ASX announcements and minutes of Directors' meetings to ensure that the German Court ruling was accounted for appropriately. • We examined the disclosures made in the financial report. • We examined memorandum prepared by management. • We examined correspondence with the Receiver. <p>We evaluated relevant external legal advice received by the Group in connection with the matter and obtained formal confirmation from the Group's external solicitors on the status of these matters</p>

Information other than the financial report and auditor's report thereon

The directors are responsible for the other information. The other information comprises the information included in the Group's annual report for the year ended 30 June 2017, but does not include the financial report and our auditor's report thereon.

Our opinion on the financial report does not cover the other information and accordingly we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the directors for the financial report

The directors of the Company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

In preparing the financial report, the directors are responsible for assessing the ability of the Group to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

As part of an audit in accordance with the Australian Auditing Standards, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial report, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial report or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial report, including the disclosures, and whether the financial report represents the underlying transactions and events in a manner that achieves fair presentation.

We communicate with the directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the directors, we determine those matters that were of most significance in the audit of the financial report of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Report on the Remuneration Report

Opinion on the remuneration report

We have audited the remuneration report included in the directors' report for the year ended 30 June 2017.

In our opinion, the remuneration report of Suda Limited for the year ended 30 June 2017 complies with section 300A of the *Corporations Act 2001*.

Responsibilities

The directors of the Company are responsible for the preparation and presentation of the remuneration report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the remuneration report, based on our audit conducted in accordance with Australian Auditing Standards.

A stylized blue ink signature of the firm HLB Mann Judd.

HLB Mann Judd
Chartered Accountants

A blue ink signature of Norman G. Neill.

N G Neill
Partner

Perth, Western Australia
22 September 2017

ADDITIONAL SECURITIES EXCHANGE INFORMATION

The following information is current as at 4 September 2017:

1. Shareholding

a. Distribution of Shareholders

	Number
Category (size of holding)	Ordinary
1 – 1,000	77
1,001 – 5,000	150
5,001 – 10,000	270
10,001 – 100,000	1,175
100,001 – and over	1,066
	2,758

b. The number of shareholdings held in less than marketable parcels is 788.

c. There were no substantial shareholders as at the reporting date.

d. Voting Rights

The voting rights attached to each class of equity security are as follows:

Ordinary shares: Each ordinary share is entitled to one vote when a poll is called, otherwise each member present at a meeting or by proxy has one vote on a show of hands.

e. 20 Largest Shareholders — Ordinary Shares

Rank	Name	Number of Ordinary Fully Paid Shares Held	% Held Of Issued Ordinary Capital
1	Citicorp Nominees Pty Ltd	42,849,938	3.51
2	Kamala Holdings Pty Ltd	24,411,890	2.00
3	UBS Nominees Pty Ltd	23,899,960	1.96
4	Bamber Investments Pty Ltd	23,577,364	1.93
5	J P Morgan Nominees Australia Limited	23,277,639	1.91
6	Brispot Niminess Pty Ltd	18,798,228	1.54
7	CS Fourth Nominees Pty Ltd	15,956,397	1.31
8	Ms Giovanna Lina Gan	14,000,000	1.15
9	Mr Peter Norman Dunn	14,000,000	1.15
10	Miss Jessica Lien	13,202,650	1.08
11	Mr Steve John Wicks	12,479,682	1.02
12	HSBC Custody Nominees	12,025,666	0.99
13	Onicas Investments Pty Ltd	12,000,000	0.98
14	CS Third Nominees Pty Ltd	11,598,479	0.95
15	Peto Pty Ltd	10,440,000	0.86
16	Mr Thomas Paul McGellin _ Ms Tanya Margaret Karal	10,020,536	0.82
17	Kamala Holdings Pty Ltd	10,000,000	0.82
18	Dr Michael Wunsch	10,000,000	0.82
19	Mr James Bradley Richardson	9,000,000	0.74
20	Mrs Linda Lien	8,294,750	0.68

ADDITIONAL SECURITIES EXCHANGE INFORMATION (CONTINUED)

- The name of the company secretary is Joseph Ohayon.
- The address of the principal registered office in Australia is Level 1, Unit 12, 55 Howe Street, Osborne Park, Western Australia 6017. Telephone (08) 6142 5555.
- Registers of securities are held at the following addresses

Advanced Share Registry: 110 Stirling Hwy, Nedlands, WA 6009

- Stock Exchange Listing

Quotation has been granted for all the ordinary shares of the Company on all Member Exchanges of the Australian Securities Exchange Limited. The stock code is SUD.

- Unquoted Securities

Convertible Notes

1,802,500 convertible notes are on issue and are held by: Foskin Pty Ltd, J&L Stevenson, Termco Pty Ltd, T McGellin, Pivic Pty Ltd, Greanseas Investments Pty Ltd, M Quinsee, Chelsea Investments (WA) Pty Ltd, Zerrin Investments Pty Ltd, Weringa Nominees Pty Ltd, Continental Global Investments Ltd, R Parry, Banlan Pty Ltd, Bamber Investments Pty Ltd, Fano Pty Ltd, Arrisan Pty Ltd, J Richardson, Bill Brooks Pty Ltd, B Alimonti, M Duncan-Smith, N Stewart, Kamala Holdings Pty Ltd, Pearlcove Consulting Group Pty Ltd, J Ohayon and N Woolf

Options over Unissued Shares

10,000,000 options with an exercise price of \$0.04 at the reporting date.

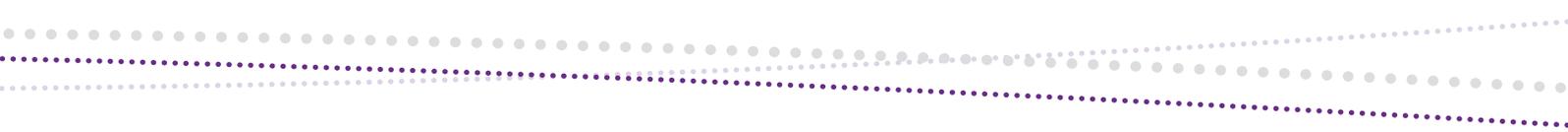
Performance Rights

4,750,000 performance rights are on issue to Joseph Ohayon and Nicholas Woolf under the Executive Long-Term Incentive Plan

- Annual General Meeting

The Annual General Meeting of the Company will be held at 10:30am (WST) on 28 November 2017 at The Boulevard Centre, 99 The Boulevard, Floreat, WA.





SUDA LTD

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