AUSTRALIAN
RESEARCH
INDEPENDENT INVESTMENT RESEARCH

SUDA Ltd (SUD)

Initiating Coverage

February 2014

INDEPENDENT
INVESTMENT RESEARCH

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INDEPENDENT INVESTMENT RESEARCH

SUDA Ltd (SUD)

Initiating Coverage

Investment Profile	
Share price ($) as at 11 February 2014	0.063
Valuation ($)	0.17
Issued capital:	
Ordinary shares (M)	921.7
Options (M)	50.9
Fully Diluted (M)	972.6
Market capitalisation ($M)	58.1
52-week low/high ($)	0.024/0.086

Board and Management

Michael Stewart: Non-Executive Chairman

Ken Robson: Non-Executive Director

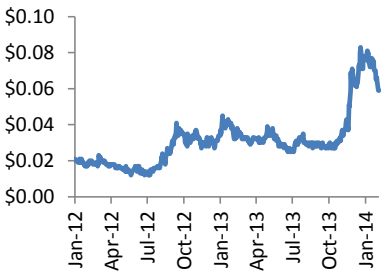
Stephen Carter: Chief Executive Officer

Joseph Ohayon: Chief Financial Officer/ Company Secretary/Executive Director

Nick Wolf: Chief Business Officer

Dr. Carol Worth: Technical Manager

Share price performance



DELIVERING DRUGS THROUGH ORAL SPRAYS

SUDA Ltd (SUD) is an ASX-listed drug delivery company that reformulates existing drugs into an oral spray for delivery of the drug through the oral mucosa. The company currently has a number of drugs under development with ArtiMist™ (anti-malarial spray) and one of the mainstream drug portfolio (SUD-001, SUD-002 and SUD-003) to be the transaction focus for 2014.

KEY POINTS

Drug Delivery: SUD is a drug delivery company focusing on reformulating existing drugs into an oral spray for delivery through the oral mucosa. The company currently has a number of drugs under development including an oral spray for the treatment of malaria in children and oral sprays for migraine, erectile dysfunction, chemotherapy-induced nausea, pulminary arterial hypertension and pre-procedural anxiety. Given the company is a drug delivery company as opposed to a drug development company, the approval process for use of the oral sprays is much less intensive than if the company was seeking approval to bring a new drug to market, with the company able to rely on the safety and efficacy information reported for the innovator drug.

Delivery of Drugs through the Oral Mucosa: The company has acquired technology to reformulate pharmaceuticals into oral sprays for delivery of the drug through the oral mucosa. The oral mucosa is the lining of the mouth. It has been shown that delivery through the oral mucosa provides more effective delivery of the drug with the drug being delivered faster, reduced dosage of active pharmaceutical ingredient required and it avoids the need to swallow or be taken with water, providing for a more convenient experience for the patient. The company is targeting pharmaceuticals that come in the form of a tablet, that have the ability to become soluble and made into an oral spray.

ArtiMist™: ArtiMist™ is an anti-malarial oral spray for children with severe malaria. The company has completed phase III clinical trials, which involved testing the drug on 150 children throughout Africa compared to an intravenous quinine treatment. The trial showed the use of ArtiMist™ to treat malaria in children was superior to the use of the intravenous quinine. SUD is seeking to undertake a trade sale or collaboration with a pharmaceutical company in 2014 with regulatory documentation for registration application expected to be completed in mid-2014.

Oral Sprays for Mainstream Markets: The company currently has five products in addition to ArtiMist™ that it is developing for mainstream markets. The oral sprays are developed using oro-mucosal technology. The technology and the portfolio was acquired from NovaDel Pharma Inc. in August 2013. The company will be seeking to secure license agreements with pharmaceutical companies to bring the treatments to market. The company is currently developing marketing packs for the three products that have completed proof-of-concept studies, however we expect the first product to secure an agreement for development will be SUD-001 (oral spray for migraines).

Westcoast Surgical and Medical Supplies Pty Ltd (Westcoast): Westcoast is a medical supplies company, which is a wholly owned subsidiary of SUD. Westcoast provides medical supplies to West Australian hospitals, aged care facilities, pharmacies, mining companies and other healthcare providers. During 2013, Westcoast was announced a preferred supplier for International Health and Medical Services (IMHS), a government funded organisation, which has significantly lifted cashflow for the business.

Capital Position: The company is currently in a strong capital position after the successful completion of a $5.6M capital raising in November 2013. The capital raising takes the company's cash position to in excess of $5M as December-end 2013. With the expectation of a signed agreement in CY'14 and the profits being delivered by Westcoast, we do not expect the company will have to raise any additional capital in the short-term.

Valuation: We have a risk-adjusted base case valuation of $0.17 for SUD. We expect the announcement of a licensing agreement being secured to be a share price catalyst. We currently expect ArtiMist™ and SUD-001 to be the first products to secure agreements which would result in the company potentially getting a cash injection of US$70M if compensation is in line with our expectations.

PROFIT & LOSS ($M)					
Y/E June	2012A	2013A	2014F	2015F	2016F
Revenue	4.1	4.1	10.0	42.2	31.9
Cost of Sales	-3.4	-3.3	-7.1	-15.1	-7.4
Employee Benefit Expense	-1.3	-1.3	-1.3	-1.4	-1.5
Depreciation	-0.1	-0.0	-0.0	-0.0	-0.0
Finance Costs	-0.1	-0.1	-0.6	-0.0	-0.0
Impairment of PPE	-2.8	-	-	-	-
Other	-1.2	-1.3	-0.5	-0.5	-0.5
Loss before tax	-4.7	-1.8	0.4	25.0	22.5
Tax	0.3	0.2	0.1	-	6.8
Profit/Loss after tax	-4.4	-1.7	0.5	25.0	29.3

BALANCE SHEET ($M)					
Y/E June	2012A	2013A	2014F	2015F	2016F
Cash & Equivalents	1.6	0.8	3.6	33.1	60.1
Trade and other receivables	0.7	0.6	0.6	0.6	0.6
Inventories	0.7	0.8	0.8	0.9	0.9
Other	0.1	0.2	-	-	-
Current Assets	3.1	2.4	5.1	34.6	61.6
Property, Plant & Equipment	0.1	0.1	0.1	0.1	0.1
Intangible Assets	6.6	8.2	10.3	2.8	3.3
Non-current Assets	6.7	8.3	10.4	2.9	3.4
Total Assets	9.8	10.7	15.5	37.5	65.0
Trade and other payables	2.0	2.9	2.5	15.1	7.4
Borrowings	0.7	0.6	-	-	-
Current Liabilities	2.7	3.4	2.5	15.1	7.4
Long-term Borrowings	-	0.6	1.9	2.5	2.5
Total Liabilities	2.7	4.0	4.4	17.6	9.9
Net Assets	7.0	6.7	11.1	19.9	55.2
Contributed Equity	38.9	40.1	48.0	-	-
Reserves	1.3	0.1	0.3	30.8	36.9
Accumulated Losses	-33.1	-33.5	-36.0	-11.0	18.3
Other	-	-	-1.2	-	-
Total Equity	7.0	6.7	11.1	19.9	55.2

CASHFLOW ($M)					
Y/E June	2012A	2013A	2014F	2015F	2016F
Receipts from customers	4.0	4.2	10.0	42.2	31.9
Net Interest	0.0	-0.0	-0.0	-0.0	-0.0
R&D Concession	-	0.3	-	-	-
Payments to suppliers & employees	-5.8	-6.1	-12.5	-15.1	-7.4
Operating Cash Flow	-1.8	-1.6	-2.5	27.0	24.5
Proceeds from sale of property, plant & equipment	-	0.0	-	-	-
Purchase of property, plant and equipment	-0.0	-0.1	-0.5	-	-
Other	-0.0	-0.8	-1.7	-	-
Loans to related parties	0.0	-	-	-	-
Investing Cash Flow	-0.0	-0.9	-2.2	-	-
Issue of Shares	0.2	1.0	6.1	-	-
Borrowings	0.1	1.0	2.5	2.5	2.5
Repayment of borrowings	-0.5	-0.4	-0.6	-	-
Other	-	0.1	-0.4	-	-
Financing Cash Flow	-0.2	1.7	7.6	2.5	2.5
Net Increase/Decrease in Cash	-2.0	-0.9	2.8	29.5	27.0
Cash at beginning of the year	3.6	1.6	0.8	3.6	33.1
FX adjustment	-	0.0	-	-	-
Cash	1.6	0.8	3.6	33.1	60.1

Key Assumptions	
Market Size:	
Malaria	~US$1B
Sumatriptan	US$3.4B
Ondansetron	US$2.5B
Sidenifil	US$4B
Market Penetration:	
ArtiMist™	30%
SUD-001	10%
SUD-002	10%
SUD-003	30%
Payment Schedule:	
Upfront	20%
Milestones	80%
Royalties	10%
WACC	15%
AUD/USD	0.85
Discount Factor	50%

OVERVIEW

- Suda Limited (SUD) is an ASX-listed biotech company, focused on reformulating US Food and Drug Administration (FDA) approved drugs into oral sprays, in particular drugs that come in the form of tablets and capsules.
- In August 2013, the company completed the acquisition of NovaDel Pharma Inc. assets, which included the NovaMist technology. NovaMist is the patented oro-mucosal technology which essentially covers the delivery of liquid formulations of pharmaceutical products to the oral cavity in the form of a mist that covers the oral mucosal membranes. The acquisition included a portfolio of products which the company is currently seeking to further develop.
- In 2013, the company completed Phase III trials for ArtiMist™, an oral spray treatment for severe malaria in children. The company will be focusing on approaching pharmaceutical companies in 2014 with the aim of achieving a trade sale of the product to enable the development and commercialisation. The results from the clinical trials suggest ArtiMist™ is a superior product to the current Qunine treatment, which is the most frequently used treatment for severe malaria. ArtiMist™ provides a pharmaceutical company with the opportunity to contribute to the reduction in deaths of children in malaria effected regions such as Sub-Sahara Africa. We expect the company will be able to reach an agreement in CY'14 for the sale of ArtiMist™.
- As a result of the NovaDel acquisition the company currently has a portfolio of products, with three of these products having completed proof-of-concept studies (SUD-001, SUD-002 and SUD-003). These three products provide a reformulation of the current innovator drug for each of the respective active pharmaceutical ingredients into an oral spray. All these markets are sizable and offer SUD the opportunity to participate in such markets until they are diluted by generic manufacturers.
- In FY'13, the company's only revenue producing asset was the wholly-owned subsidiary Westcoast., which distributes medical and surgical supplies to a range of institutions throughout Western Australia. In August 2013, Westcoast secured preferred supplier status with International Health and Medical Services (IMHS), a government-funded organisation for distribution of medical products to sites throughout Western Australia. The contract has had an instant impact on revenues, with first half FY'14 revenue up 195% on the previous corresponding period.

FINANCIAL POSITION

- At 31 December 2013, the company had $5.5M cash, $0.4M in debt and 2.4M convertible notes on issue. The cash position was boosted during the December quarter from a $5.6M capital raising to institutional investors.
- Sales from the Wescoast subsidiary increased 105% over the December quarter to $4.1M after the subsidiary secured preferred supplier status for a government funded organisation for the supply of pharmaceuticals, consumables, equipment and vaccines. Westcoast revenues are up 195% in 1H'14 from the previous corresponding period.
- We expect the company will be able to secure license agreements for ArtiMist™ and SUD-001 in CY'14. If the agreements are in line with our expectations, the company will receive a cash injection of ~US$70M. This will significantly boost the company's balance sheet and assist with funding research and development of further products using the SudaMist technology.

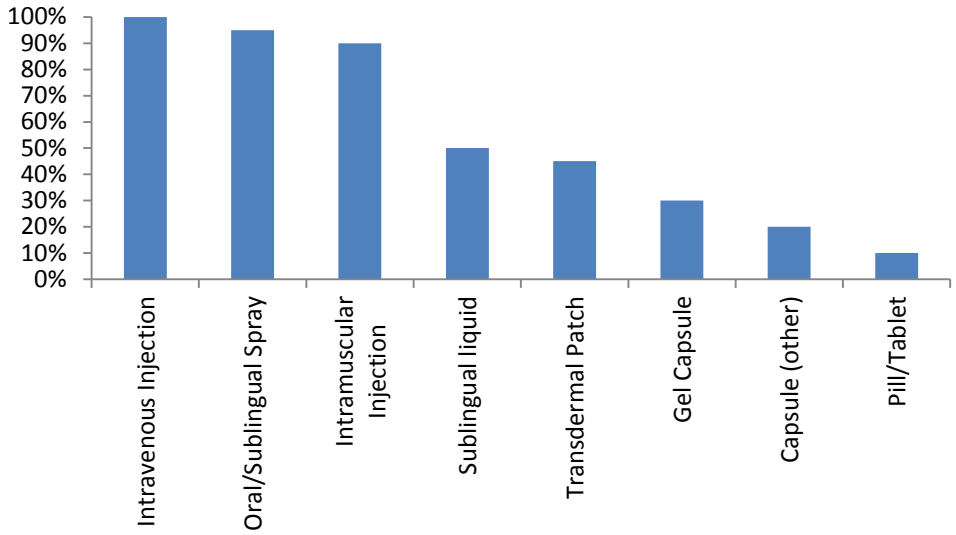
STRATEGY

- The company seeks to reformulate existing tablets and capsules into an oral spray using its oro-mucosal technology. To date, the company has only focused on off-patent drugs, however there is an opportunity for the company to work with pharmaceutical companies to manage the lifecycle of on-patent drugs.
- The short-term focus of the company is to secure license agreements for the more advanced products (ArtiMist™/SUD-001/SUD-002/SUD-003). Beyond this, the company will seek to continue to develop its pipeline of products as well as explore other opportunities for oral spray reformulation.

ORO-MUCOSAL TECHNOLOGY

- The acquisition of the NovaDel Pharma Inc assets has resulted in SUD having ownership of NovaDel's oro-mucosal technology. The technology essentially covers the delivery of liquid formulations of pharmaceutical products to the oral cavity in the form of a mist that covers the oral mucosal membranes.
- Delivery of a drug through an oral spray is a superior treatment to a tablet or capsule as it enters the bloodstream faster, bypassing the stomach and avoiding the metabolism associated with the first circulatory pass through the liver. This results in faster absorption and improved onset of treatment.
- Decreased degradation and higher absorption may permit the use of a lower dose of the active pharmaceutical ingredient than required in tablet or capsules for the same therapeutic effect. This can reduce the risk of adverse effects and reduce production costs. Furthermore, an oral spray makes treatment easier for those patients that have difficulty with swallowing tablets or capsules.
- The below graphic illustrates that delivery via an oral spray is second only to delivery intravenously for absorption efficiency.

Absorption Rate of Drug Delivery Methods



Source: SUDA Ltd

PRODUCTS

The company has a number of products in the pipeline, all of which are at different stages. We have detailed the products in which proof-of-concept studies have been completed and which are therefore first in line to be presented to pharmaceutical companies in the hope that a company will be interested in funding the development of the product. The acquisition of the NovaDel assets has placed the company in a position of strength for the development of a range of oral sprays for drugs in the mainstream market.

ARTIMIST™

- ArtiMist™ is a sub-lingual spray for the treatment of severe malaria in children under the age of five. The formula seeks to offer an alternative or even replace the current malaria treatments which are administered intravenously or by a tablet.
- The World Health Organisation (WHO) currently recommends severe malaria in children be treated with artemether or quinine either intravenously or via an injection. Further to this the WHO recommends that confirmation of the diagnosis is obtained before the treatment is started. The WHO recommends the use of artemether be used in preference to quinine given the improved effectiveness of the artemether. Although this recommendation was based on trials conducted in South East Asia. ~80% of malaria deaths in Sub-Sahara Africa occur in children under 5 and it has been shown that the use of artemether in children has no benefit over quinine.

- ArtiMist™ is able to be stored for up to four years in tropical climates with no refrigeration required. As such, ArtiMist™ may be able to be administered in the local village by individuals who are not required to be medically trained to curb the symptoms while the child is making their way to the hospital and does not require the disease to be diagnosed before administering the treatment.
- The company completed Phase III trials in mid-2013. The Phase III trial consisted of testing ArtiMist™ on 150 children across Africa against the use of Quinine, which is administered intravenously in the cases of severe malaria.
- The trial concluded that ArtiMist™ was superior to the use of intravenous quinine with 95.6% of patients treated with ArtiMist™ experiencing a parasite reduction of 90%+ within 24 hours compared to 40.6% reduction in parasites for those treated with quinine. Further to this there was no early treatment failure with the use of ArtiMist™ while there was ten cases of early treatment failure with the use of quinine.
- The trial results suggest that ArtiMist™ has the potential to be an effective treatment for severe malaria as well as a pre-referral treatment for children who are suspected to have malaria, in particular for those children who live in rural areas where medical facilities are a number of hours away.
- The company is seeking a trade sale of the drug to be able to bring the drug to market and subsequently distribute to those areas of Africa and other regions which are severely affected by malaria.

Key Benefits of ArtiMist™ over Quinine for Treatment of Severe Malaria in Children
• Can be stored for up to four years in tropical climates without the need for refrigeration
• In the form of an easy to administer oral spray, avoiding the need for children to swallow tablets
• Lower dosage required
• Superior reduction in parasite count
• Safe to administer even if child turns out not to have malaria therefore can be administered to start to reduce the effects of the disease while the child makes their way to a medical facility
• Does not require medically trained personnel to administer treatment
• No risk of infection from needle use

SUD-001: MIGRAINE

- SUD-001 is an oral spray formulation of **sumatriptan**, the active pharmaceutical ingredient in the product Imitrex, which comes in the form of a tablet and a nasal spray for the treatment of migraines. We note the patents for the Imitrex products has since expired and there are now a number of generic products available.
- Two clinical trials have been completed. Both trials thus far have compared only the Imitrex tablet and not the Imitrex nasal spray.
- **Trial 1:** the first trial seeked to demonstrate the absorption rate of SUD-001 compared to the Imitrex tablet. The trial was performed on 10 healthy males and compared the absorption of 20mg and 30mg of SUD-001 versus the 50mg tablet. The trial showed that SUD-001 was absorbed much faster than the tablet and showed a 50% increase in the bioavailability of sumatriptan.
- **Trial 2:** the second trial was conducted on migraine patients. All dosing was done on an outpatient basis with patients returning to the clinic between migraine attacks. Subjects received up to five treatments comprising single doses of the sumatriptan tablets (50mg & 100mg) and SUD-001 oral spray (20mg, 30mg and 40mg). Within 60 minutes after the treatment was administered, subjects showed a greater reduction in headache pain through the use of the 30mg and 40mg SUD-001 compared to the 50mg tablet, with 42% and 46%, respectively, of SUD-001 subjects reporting a reduction in pain compared to 12% for the tablet. The SUD-001 results were in line with the 100mg tablet at 42%. The results from the trial suggest that SUD-001 may be a more effective treatment than the 50mg tablet and provide a lower dosage alternative with the same therapeutic benefits as the 100mg tablet.

- The two trials suggest that SUD-001 is superior to the Imitrex tablet. Whilst no trials have been conducted to compare the oral spray to the Imitrex nasal spray, comparing the studies produced on the nasal spray suggest the oral spray is more efficient with the oral spray being absorbed ~70% faster for a 20mg dose of sumatriptan than the nasal spray.
- The evidence suggests that the oral spray is superior to the current market alternatives and as such has the potential for a pharmaceutical company to be interested in funding development and bringing the treatment to market.

Migraine Market

- Decision Resources forecasts the migraine market to grow to US$5.8B in 2021, from US$3.3B in 2011, across the major markets of the US, France, Germany, Italy, Spain, the UK and Japan.
- Migraines are prevalent throughout the global population with the Migraine Research Foundation suggesting 10% of the global population suffer from migraines. In the US, it's estimated that 36 million people suffer from migraine attacks which typically occur once to twice a month.
- In addition to the sumatriptan tablet and nasal spray, the FDA approved Zecuity in 2013, a sumatriptan patch applied to the arm and absorbed through the skin and there is the potential for the approval of Levadex in 2014, which is delivered by inhalation from aerosol. Allergan Inc, the producers of Levadex are currently working on the manufacturing issues that were highlighted by the FDA and are currently delaying approval for the drug.
- Imitrex was the innovator drug and is marketed by GlaxoSmithKline PLC, however the patent has expired and there are a number of generic products available on the market, which have resulted in a decline in the sales of Imitrex. The table below details what GlaxSmithKline considers there greatest competition for sumatriptan tablets and nasal sprays and the revenue from the products in 2012 to highlight the level of sales for current products on the market.

Sumatriptan Prescription Drugs		
Product	**Marketer**	**Revenue 2012**
Imitrex	GlaxoSmithKline PLC	£190M
Zomig	Impax Laboratories Inc	na
Maxalt	Merck & Co Inc	US$638M
Relpax	Pfizer	US$368M

Recent Deals

1) In 2012, Impax Laboratories Inc paid AstraZeneca a total of US$83.76M for the rights related to both the Zomig tablet and nasal spray formula.

2) In 2013, OptiNose partnered with Avanir Pharmaceuticals for the development and commercialisation of OptiNose's Breath Powered intranasal delivery system, which if approved by the FDA will be the first dry-powder nasal spray for the delivery of sumatriptan. Avanir Pharmaceuticals will pay OptiNose up to US$110M, with a $20M upfront payment and up to an additional US$90M in the event stipulated milestones are achieved. OptiNose will also be eligible for royalty payments on net sales of the product in North America.

SUD-002: CHEMOTHERAPY/RADIOTHERAPY/POST OPERATIVE INDUCED NAUSEA AND VOMITING

- SUD-002 is an oral spray formulation of **ondansetron**, the most commonly prescribed anti nausea and vomiting treatment induced by chemotherapy, radiotherapy and post surgery. Ondansetron is the active pharmaceutical ingredient in Zofran, the innovator drug marketed by GlaxoSmithKline.
- Zofran is currently available by injection, a tablet or as a disintegrating tablet. The tablet comes in strengths of 4mg, 8mg and 24mg of ondansetron. Zofran disintegrating tablets gained FDA approval in January 1999. As it currently stands there are a number of generic forms of ondansetron that have gained FDA approval. The oral spray formula may provide the original manufacturer, GlaxoSmithKline, with a new patented product to market.

- Four clinical trials have been undertaken for SUD-002. The four studies involved the comparison of the 8mg ondansetron tablet compared to 8mg of SUD-002.
- The studies showed that SUD-002 was absorbed faster than the ondansetron tablet with the median time for therapeutic effect being 15 minutes for SUD-002 compared to 30 minutes for the tablet. The studies also showed that the SUD-002 had the same therapeutic effect that was provided by the tablet.
- With respect to adverse effects of treatment, subjects reported headaches of 14% in women and men with the use of SUD-002, while 27% of women and 10% of men reported headaches from the use of the tablet. Dizziness was reported in 5% of cases for both women and men with the use of SUD-002, while no women and 10% of men reported dizziness with the use of the tablet. Overall, SUD-002 faired better with respect to adverse effects compared to the tablet.
- Unlike other ingredients in the pipeline, SUD-002 requires the same amount of ondansetron as was in the tablet, however did provide the benefit of faster onset and less adverse effects after use.
- Research produced by GlaxoSmithKline suggests regular Zofran tablet and disintegrating tablet are interchangeable with the bioavailability the same, however there was no mention of whether or not the disintegrating tablet was absorbed more quickly. While there was no data published on the absorption rate, it is believed that the delivery through the oral mucosa from the oral spray will have a more effective absorption rate than the disintegrating tablet.

Ondansetron Market

- In addition to the Zofran tablet and disintegrating tablet, Vestiq Pharmaceuticals have issued Zuplenz, a soluble film taken orally. There are also a number of generic drugs which have diluted the market in the US. In Europe, APR Applied Pharma Research S.A market the drug Setofilm, which is a soluble film in which ondansetron is the active pharmaceutical ingredient.
- Research produced by GlaxoSmithKline suggests regular Zofran tablet and disintegrating tablet are interchangeable with the bioavailability the same, however there was no mention of whether or not the disintegrating tablet was absorbed more quickly. While there was no data published on the absorption rate, it is believed that the delivery through the oral mucosa from the oral spray will have a more effective absorption rate than the disintegrating tablet.
- In 2012, the FDA issued a safety warning advising the market that they were undertaking a safety review of Zofran after it has been determined that it may increase the risk of developing abnormal changes in the electrical activity of the heart. Depending on the outcome of this review this may result in delays in the approval process.
- The chemotherapy, radiotherapy and post operative induced nausea and vomiting market is estimated to be in excess of US$2B, with 6.6 million chemotherapy induced nausea and vomiting treatments in 2011.
- In 2012, GlaxoSmithKline reported revenues of £83M, a significant reduction from 2006 in which it generated revenues of £682M from sales of Zofran. The market for GlaxoSmithKline has been adversely affected by the entrance of generic manufacturers.

SUD-003: ERECTILE DYSFUNCTION

- SUD-003 is an oral spray formula for **sidenafil citrate**, which is the active ingredient in Viagra, which is currently exclusively marketed by Pfizer. Pzifer's patent on Viagra does not expire until 2020 in the US.
- An initial trial was completed in 2010 to assess the therapeutic effectiveness of single and multiple doses of 10mg of SUD-003 compared to a 25mg Viagra tablet.
- 24 males took part in the study, with data from 23 of the subjects included in the results. The study lasted for approximately nine weeks over which time the subjects took four doses of each of the treatments and were required to remain at the clinical site for at least 24 hours after each treatment.

- The study demonstrated that a 20mg dose of SUD-003 (2 sprays) was bioequivalent to the 25mg viagra tablet, suggesting that the product can be manufactured in a more cost effective manner given the lower dosage requirement. Peak plasma concentrations were comparable to the tablet with the overall systemic exposure of SUD-003 consistently higher than the tablet. The time to reach the maximum concentration was similar to the tablet.
- An investigational New Drug Application (IND) has been opened with the FDA and a plan for the Abbreviated New Drug Application (ANDA) has been determined. The company now requires a partner to complete the required regulatory requirements.

Sidenafil Market

- Currently Pfizer has exclusive marketing rights to Viagra (oral tablet in which sidenafil is the active pharmaceutical ingredient) in the US until 2020. Pfizer has had to lodge a number of infringement notices against generic manufacturers who have filed for ANDAs with the FDA. To date the company has successfully defended its patent rights however there are a number of generic manufacturers that have gained tentative approval for a generic version of Viagra. The company's patent has expired in markets outside of the US, which has resulted in a decline in Pfizer's revenue from Viagra outside the US.
- In 2012, Pfizer reported revenues from the sale of Viagra of ~US$2B, a 4% increase on the previous year. The total erectile dysfunction market was estimated at US$4.2B in 2012, with a number of other products on the market using other active pharmaceutical ingredients, including Cialis, Levitra, Stendra, Zydena and Mvix. All these products are competition for Viagra, however we note that the sidenfil market currently makes up almost 50% of the market with Viagra the most commonly prescribed treatment.

WESTCOAST SURGICAL & MEDICAL SUPPLIES

- Westcoast Surgical and Medical Supplies (Westcoast) as the name suggests, supplies medical and surgical devices and consumables to hospitals, aged care facilities, pharmacies, mining companies and other healthcare providers in Western Australia.
- In FY'13, Westcoast generated revenue of $4M, a 3.5% increase on FY'12 sales. Further to this, gross margins increased from 17% in FY'12 to 20.6% in FY'13.
- In August 2013, Westcoast secured preferred supplier status with International Health and Medical Services (IHMS). Under the contract, Westcoast will supply a full range of medical products to various remote sites. The contract is set for renewal in 2015.
- The contract with IHMS has resulted in a significant increase in Westcoast's revenues. In the 1H of FY'14, Westcoast has realised sales of $6.2M, a ~195% increase on the previous corresponding period, and posted a 1H'14 profit of $1.2M. We note that the nature of the business can result in lumpy revenues throughout the year. The company has provided revenue guidance for FY'14 of $10M for Westcoast, resulting in profits before tax of $2M at a net margin of 20%.
- In January 2014, Westcoast became the sole distributor of HemoStyp, a healing gauze, in Australia, New Zealand, New Guinea and the Pacific Islands, and expanded its activities in the aged care market through a distribution agreement with Ontex Healthcare to supply their range of Lille branded continence management products throughout Western Australia. Both of these new distribution agreements will have a positive impact on revenues.

VALUATION

- We have derived our base case valuation for SUD based on a sum of parts principal for each of the products that have completed proof-of-concept studies as well as an NPV for the Westcoast subsidiary. We note there a number of revenue stream prospects for the business on both the off-patent and on-patent oral drug market, however at this stage it is difficult to put a monetary value on all aspects of the business and as such we have just focused on the visible short-to-medium term revenue potential.

- We have used a combination of benchmarking and assumptions regarding market size and penetration to value the oral spray products. Heavy discount values have been applied to the valuation for each of the products given agreements are yet to be secured.
- We have incorporated a royalty payment for each of the products in the event they are launched to market. We have made conservative assumptions across the products regarding market penetration. We note, that market penetration will depend on the pharmaceutical company that acquires the license as each company is able to reach different markets in different capacities.
- The actual compensation for the products if a licensing agreement is secured may differ from our assumptions given the compensation will largely be dependent on the agreed market value determined by both parties.
- Given the malaria market is not a mainstream market we have relied upon a market value calculation by a UK consultant. The estimated value is based on WHO reports to determine the number of treatments malaria cases and expected number of treatments as well as a detailed cost schedule.

Assumptions	
Market Size:	
Malaria	~US$1B
Sumatriptan	US$3.4B
Ondansetron	US$2.5B
Sidenifil	US$4B
Market Penetration:	
ArtiMist™	30%
SUD-001	10%
SUD-002	10%
SUD-003	30%
Payment Schedule:	
Upfront	20%
Miletones	80%
Royalties	10%
WACC	15%
AUD/USD	0.85
Discount Factor	50%

- We have provided a breakdown of the valuation below. We note that the values have been determined based on broad based assumptions regarding market size, market penetration and payment schedules.

Valuation Breakdown	
Product	**Value Per Share ($)**
ArtiMist™	0.02
SUD-001	0.05
SUD-002	0.02
SUD-003	0.06
Westcoast	0.02
Total	**0.17**

Valuation Upside

- There is plenty of upside potential for the valuation of SUD as key milestones are achieved, reducing commercialisation risk.
- There a number of other drugs which the company is assessing as to whether they are suitable for reformulation into an oral spray, which would open up new revenue streams.

- The company with the acquisition of the NovaMist technology has been developing formulations for off-patent pharmaceutical ingredients. There is also an opportunity for the company to work with companies whose formulas are still on-patent to extend the life of the patent through the reformulation of the drug delivery and reduce the resultant dilution from the entrance of generic options, as well as an opportunity to improve the profile of development-stage drugs with oro-mucosal delivery.

PEER COMPARISON

ASX-LISTED PEERS

- There are a number of biotech companies listed on the ASX, all undertaking research and development of drugs with the aim of commercialising the product, however there are two companies which are directly comparable to SUD - Imugene Limited (ASX: IMU) and Phosphagenics Limited (ASX: POH).
- Both IMU and POH have delivery technologies with which they are seeking to reformulate existing drugs. IMU's drug delivery platform "Linguet", reformulates drugs into a tight pressed powder for delivery through the oral mucosa, while POH has developed a technology for the delivery of drugs through the skin.
- IMU and SUD are both reformulating drugs for delivery through the oral musoca, however the method of delivery is quite different. IMU's Linguet platform delivers the drug through a melt-in-mouth tablet, compared to the oral spray delivery of SUD. We believe that SUD's technology is superior given IMU's tablet takes 45 seconds to dissolve compared to the instant spray, however we note that IMU will be able to service a larger market than SUD given not all drugs can be reformulated into a spray.
- IMU's Linguet technology is still in the early phases of development with clinical data yet to be released on its products, however we do note that in July 2013, the company entered into an agreement with IDT Australia Ltd to develop the formulation and manufacture Linguet melt-in-mouth iburprofen tablets.

Peer Comparison (as at 5 February 2014)			
Company	**Share Price ($)**	**Market Cap ($M)**	**Cash ($M)**
IMU	0.017	14.9	2.5
POH	0.115	117.4	14.1*
SUD	0.059	54.4	5.5

* As at 30 June 2013

INTERNATIONAL PEERS

- There are a number of international companies that have oral mucosal drug delivery technologies that compete with SUD's oro-mucosal technology. We provide a list of companies and their products below. In addition to the below listed technologies, SUD will be competing with other forms of delivery such as inhalation, nasal and transdermal.
- Monosol RX's PharmFilm technology is currently being used by Vestiq Holdings for the product Zuplenz, a soluble film in which ondansetron is the active pharmaceutical ingredient. Zuplenz is a direct competitor to SUD-002.
- Generex Biotechnology also has a oral spray technology, RapidMist. In May 2011, the company signed an agreement with Amarantus BioSciences for use of the RapidMist technology with its MANF proteins. Amarantus paid Generex Biotechnology a $10M licence fee. This was the first time the company had out-licensed its technology. Prior to this the technology was used exclusively in its Generex Oral-lyn insulin spray.

International Peers			
Company	**Headquarter Location**	**Technology**	**Delivery Method**
Tesa Labtech GmbH	Germany	Rapidfilm	Oral dissolvable film
CIMA Labs	US	OraVescent	Oral disintegrating tablet
Generex Biotechnology	Canada	RapidMist	Oral Spray
Catalent	US	Zydis	Oral dissolvable tablet
Monosol Rx	US	PharmFilm	Oral soluble film

INVESTMENT CASE

- The company is well placed to collaborate with pharmaceutical companies to develop existing drugs into an oral spray. The oro-mucosal technology provides the company with a unique formula that provides administrative benefits for the use of the drug.
- Given the company is seeking to reformulate existing drugs into an oral spray, the company is able to apply under section 505(b)(2) of the FDA new drug application legislation, meaning they are able to rely on published safety and effectiveness evidence published by the innovator of the drug. This significantly reduces the cost and time required to gain approval from the FDA given the company only has to demonstrate the bioequivalence of the new formulation. While there still may be delays as the FDA requests additional studies and information, the extent of the clinical trial process is significantly reduced than that for a new drug application.
- The oral spray formula provides pharmaceutical companies with a treatment that avoids the need for patients to swallow tablets, with 40% of adults in the US reportedly having difficulties in swallowing tablets.
- The company has completed proof of concept studies for SUD-001, SUD-002 and SUD-003, with all trials producing successful results when compared to the tablets available in the market. This will allow the company to approach pharmaceuticals for sale of the licensing rights to bring the treatment to market. There is a risk that the company will not be able to attract a partner for the development of the treatment, however we believe that reformulating drugs into oral sprays provides a commercially attractive option for pharmaceutical companies, given the quicker absorption of oral sprays and the lower dosage requirements to produce the same therapeutic effects, reducing production costs.
- As with all biotech companies that are seeking to commercialise their drugs, there are risks. The company is yet to finalise any agreements with pharmaceutical companies and upon an agreement the company will likely be compensated upon the achievement of milestones. There is the risk that these milestones will not be met and therefore the drug may not make it to market.
- In the event license agreements can be secured, the company expects the partner to pay for all additional development and regulatory costs. Therefore, the products will be purely a cashflow positive for the company.
- In addition to the current product pipeline which focuses on reformulating drugs that are off-patent, the company has the ability to work with companies on reformulating drugs that are on-patent. Pharmaceutical companies may seek to do this to extend their current market advantage as the innovator of the drug and reduce the impact of generic drug makers entering the market once the patent for the original drug has expired. It is difficult to quantify at this stage the monetary value of this market, however this certainly provides some revenue upside for the company over the medium-to-long term.

CAPITAL STRUCTURE

- As at 5 February 2014, the company had 921.7M ordinary shares, 50.9M unlisted options and 2.4M convertible notes on issue.
- 522,000 of the convertibles notes mature on 30 June 2014 with the company paying 8%p.a. interest. The remaining 1.9M of convertible notes mature on 30 September 2015 and have an interest rate of 6%p.a.
- The top shareholders at the date of this report are:
  - HSBC Custody Nominees (Australia) Limited: 6.2%
  - Citicorp Nominees Pty Limited: 5.1%
  - UBS Nominees Pty Ltd: 4.3%
  - National Nominees Limited: 4.3%
  - Bergen Global Opportunity Fund LP: 2.7%

RISKS

- **Licensing Risk:** SUD has yet to secure a licensing deal for any of their products, however is believed to be in talks with some pharmaceutical companies and is finalising the completion of the marketing packs to approach pharmaceutical companies. Whilst we believe there is a high chance that the company will secure an agreement there is the chance that an agreement may not be secured for one or all of the products, which will likely result in the product not making it to market.
- **Compensation Risk:** Given the company is yet to secure a license agreement we have made some assumptions based on comparable deals and the market size. The actual compensation received by the company may differ from our assumptions and may either positively or adversely effect the fundamental value of the company. Further to this, royalties may be subject to either global sales or only regional sales which may impact the revenue generating potential of the products for the SUD.
- **FDA Approval:** Given the company is reformulating existing drugs into an oral spray the risk of not getting approval from the FDA is low, however, there is still a chance that the application will not gain FDA approval or issues with the application of the formula may result in delays for approval. An example of this exists for Novadel before SUD acquired their assets, whereby Novadel's approval for the ondansetron oral spray was delayed due to some issues with stability of the formula. Whilst in this circumstance the issue was easy to rectify, this resulted in the partner at the time moving in a different direction and has resulted in the formula yet to gain approval for development.
- **Pipeline Risk:** While there are a number of drugs that can be reformulated into an oral spray, not all drugs can be, which may in the long-term limit the products available for the company to develop.

BOARD OF DIRECTORS & MANAGEMENT

- **Michael Stewart: Non-Executive Chairman -** Mr. Stewart was appointed as Chairman in January 2014 after joining the Board in June 2009. Mr. Stewart has a broad corporate and management background and has been extensively involved in bilateral donor funded and World Bank co-financed Aid Projects in under-developed countries.
- **Ken Robson: Non-Executive Director -** Mr. Robson's background includes extensive experience as a Corporate Lawyer and Advisor, specialising in fundraising, market compliance and Mergers & Acquisitions. Mr. Robson has also been a barrister in the High Court and Courts of Appeal.
- **Stephen Carter: Chief Executive Officer -** Mr. Carter joined the company in 2010 as CEO. Mr. Carter has over 25 years pharmaceutical industry experience and has held a variety of senior positions with publicly listed companies including roles as both Chairman and Managing Director. Amongst his previous roles, Mr. Carter was Chairman of Hollista Colltech Ltd and DelMedica Ltd; and he was Managing Director of ASX-listed Solbec Pharmaceuticals Ltd. 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.
- **Joseph Ohayon: Chief Financial Officer/Company Secretary/Executive Director -** Mr. Ohayon joined the company in July 2010 as the Chief Financial Officer and in March 2011 he took over the role of Company Secretary before becoming a member of the Board in December 2012. Mr. Ohayon has over 20 years experience in financial roles including 12 years within health-related industries.
- **Nick Woolf: Chief Business Officer -** Mr. Woolf is an accomplished business executive, bringing two decades of biotechnology and pharmaceutical industry experience to the company. Mr. Woolf has a strong track record in structuring, negotiating and executing successful alliances, licensing agreements and M&A transactions as well as providing business development, management and strategic leadership to organisations. Mr. Woolf was most recently Chief Financial Officer and Vice President of Corporate Development of Phylogica Limited based in Western Australia. Prior to Phylogica, Nick was Chief

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