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INDEPENDENT INVESTMENT RESEARCH

Suda Pharmaceuticals Limited (ASX: SUD)

First Product Approved for Sale

August 2020

INDEPENDENT
INVESTMENT RESEARCH

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INDEPENDENT INVESTMENT RESEARCH

Suda Pharmaceuticals Limited (ASX: SUD)

Initiating Coverage

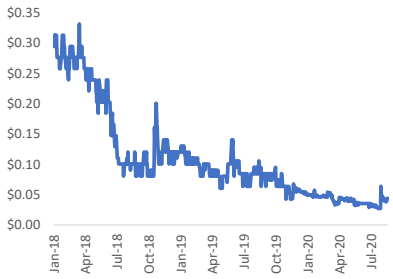
Investment Profile	
Share price ($) as at 18 August 2020	0.047
Issued capital:	
Ordinary shares (M)	305.8
Options (M)	73.2
Fully Diluted (M)	379.0
Market capitalisation ($M)	14.4
12-month Share Price Low/High ($)	0.025/0.106

Board and Management
Dr. Michael Baker: CEO & Managing Director
Paul Hopper: Chairman (Non-Executive)
David Phillips: Director (Executive)
David Simmonds: Director (Non-Executive)

Largest Shareholders	%
UBS Nominees Pty Ltd	2.8
Kamala Holdings Pty Ltd	2.2
Scintilla Strategic Investments Limited	2.0
Bamber Investments Pty Ltd	1.3
Sempai Investments Pty Ltd	1.1

Source: SUD

Share Price History



FIRST PRODUCT APPROVED FOR SALE

Suda Pharmaceuticals Limited (ASX: SUD) is an ASX-listed drug development company. Historically the company has focused on reformulating existing drugs into an oral spray for using their unique OroMist technology. Under the new management, the company will seek to expand it's drug development focus to incorporate other technologies and take advantage of opportunities that are outside of the oral spray scope. The company received it's first product marketing approval in July, with the TGA approving the distribution of ZolpiMist in Australia.

KEY POINTS

SUD Receives TGA Approval for ZolpiMist: The Therapeutics Goods Administration (TGA) has approved the registration of ZolpiMist allowing for distribution in Australia. The approval has come before the expected date in 4Q'CY20. This is a significant milestone for the company and one of its lead products, as was highlighted by the positive market reaction on the release of the announcement. SUD has the rest-of-world rights for ZolpiMist, which includes the rights to supply and distribute ZolpiMist in all countries outside of North America. SUD is currently looking for a distribution partner in Australia. Given the recent announcement we would expect a partner to be secured quickly. Once a partner has been secured the company can commence production and sales at which point the company will begin to generate revenue, the extent of which will depend on the agreement reached. The approval from the TGA is expected to assist with the progression of regulatory approvals currently under review by regulatory authorities in other countries with the companies current partners, TEVA and Mitsubishi Tanabe Pharma.

Converting Anagrelide to an Oral Spray: In January 2018, SUD acquired the global intellectual property rights to anagrelide from UK based Aluztra Bio Ltd. Anagrelide is an anti-thrombotic agent that is used to reduce elevated levels of platelets. SUD believes anagrelide could be an effective anti-cancer agent as it is recognised that platelets play an important role in the growth and spread of tumours. In its current form anagrelide's use is limited due to the cardiovascular side effects observed post administration. The drug is metabolised in the liver the first time it passes through into the blood stream (first pass metabolism) resulting in the generation of cardiotoxic intermediate that can cause heart palpitations, increased heart rate and/or a severe headache. SUD believes that these side effects can be reduced or avoided through the use of an oral spray to be used as an adjuvant in the treatment of solid tumours.

Rejuvenated Board and Management: After nine years as CEO, Stephen Carter resigned from the position in late 2019. Dr. Michael Baker was appointed as CEO and commenced his position in January 2020. Dr. Baker has a wealth of experience in the biotech and life sciences industry and will seek to progress what Mr. Carter has built over the last decade with the OroMist technology and introduce additional technologies to the business. In 2019, there was also a board restructure with two new appointments - Paul Hopper (Non-Executive Chairman) and David Simmonds (Non-Executive Director). David Phillips moved from a non-executive to an executive director. The new board appointments are well credentialed and will provide valuable input and oversight to the business.

Financial Position: The company has recently raised $4.1 million (before costs) through an Entitlement Offer and placement to Sophisticated investors. In total 163.6 million new shares were issued at $0.025 per share. For the Entitlement Offer, one option was attached for every three shares issued. The capital raising provides the company with a much needed capital boost to fund the development of key projects and the distribution of ZolpiMist. Based on the FY20 cash burn rate, the capital injection will fund one year of operations without any revenue injection.

Actively Searching for New Assets: The company has stated that it is actively searching for new assets to expand the existing product portfolio. The company will continue to develop its existing key projects using the OroMist technology, however will be expanding its focus in its search for new assets to diversify the portfolio and improve the value proposition for shareholders.

Investment View: Given the binary nature of the company's operations an investment in SUD is speculative. The recent marketing approval from the TGA for ZolpiMist is a key milestone for the company and once a partner is secured will allow for sales to commence in Australia providing a revenue stream. We expect the first sales of ZolpiMist to be a catalyst for the share price along with the achievement of marketing approval from other regulatory authorities for the distribution and sale of ZolpiMist in other countries.

SWOT ANALYSIS

STRENGTHS

- The company has received marketing approval for ZolpiMist in Australia from the TGA. Once the company has secured a distribution partner sales can commence and the company will begin generating revenue.
- The business model of securing partners before further developing products in the OroMist portfolio reduces the capital risk associated with development of these products as the partners fully fund the development.
- The company is looking to acquire new assets to broaden the existing portfolio. We view this as a positive as the company is actively seeking to enhance shareholder value.
- The OroMist technology is unique technology and is valued in the marketplace. This is highlighted by a number large pharmaceutical companies seeking to gain access to the technology. The reformulation of existing drugs into an oral spray using SUD's oral spray technology can provide for new patents or extensions to existing patents.
- The company recently completed a canine pharmacokinetic study to test their hypothesis that an oral spray version of anagrelide could be more safely administered to cancer patients, potentially resulting in fewer cardiovascular side effects. Three formulations were tested against the capsule form of the drug and preliminary data suggested that one of the formulations was able to increase bioavailability of the drug while reducing exposure to a cardio stimulatory metabolite. The company is expecting the final report to be completed shortly.
- The company recently raised $4.1 million (before costs) in an oversubscribed Entitlement Offer and placement to Sophisticated investors providing a much needed capital boost to the company.

WEAKNESSES

- The company is yet to generate a regular income stream and therefore remains largely dependent on capital raisings to continue research and development activities.
- The reformulation of anagrelide provides a significant opportunity for the company, however, there are a number of hurdles that need to be overcome such as achieving a formulation that is satisfactory for consumption by humans. The development of this product will take several years.

OPPORTUNITIES

- The company has the rest of world rights for the supply and distribution of ZolpiMist. Studies have shown that ZolpiMist achieves sleep onset more quickly than the oral tablet of zolpidem (Ambien). If the company can secure distribution partners and regulatory approvals in multiple jurisdictions there is an opportunity for the company to participate in the growing insomnia market.
- In the event the company can get a satisfactory reformulation of anagrelide and the pre clinical trials suggest the cardiovascular side effects can be avoided as an oral spray, the market potential for this product as a adjuvant for treatment of solid tumours is significant.

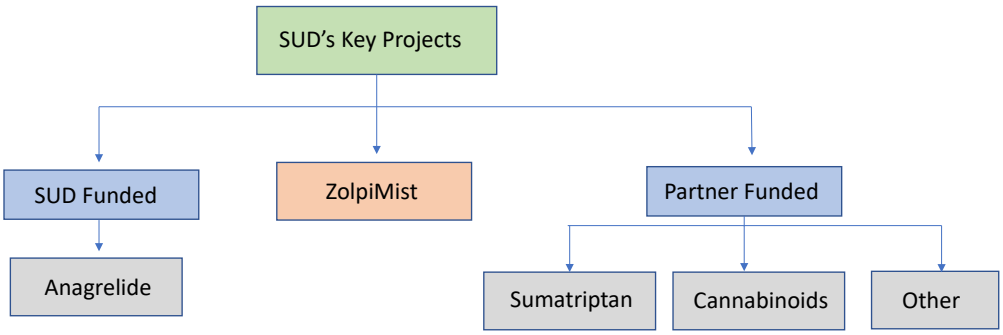
THREATS

- The reformulation of anagrelide is complicated given the drug is almost insoluble. Whilst the company is making progress on this front an alternative delivery mechanism may be required to be licenced if an acceptable level of solubility can't be reached. Further to this, the product may not be successful in its intended use in cancer treatment.
- The company has a number of fully funded co-development projects for the reformulation of drugs currently in progress, however, is yet to commercialise a product using its OroMist technology. There is little visibility as to if and when one of the co-development products will be commercialised.

COMPANY OVERVIEW

- SUD is a an ASX-listed drug development company seeking to develop and commercialise products using novel methods of delivery. The company is focused on the reformulation of ex-blockbuster drugs using its unique OroMist technology. While the company will continue to work with its numerous partners and develop projects using OroMist, the company will be seeking to broaden its portfolio to assess all drug development opportunities and not just OroMist technology opportunities.
- The pivot in direction comes with a rejuvenated board and the appointment of a new CEO, Dr. Michael Baker. We view the rejuvenation of the board and management as a positive step for the company.
- In late 2019, marketing approval for the companies leading drug candidate, ArTiMist, was denied by the Therapeutics Goods Administration (TGA). Despite the setback, the company is moving forwards and has a number of products under development as shown in the below graphic. The products can be broken down into those being funded by SUD and co-development projects which are fully funded by partners. SUD is funding the development of anagrelide. Outside of anagrelide, the company will be carrying out work on fully funded co-development reformulation projects, of which there are a number across a range of markets.
- The company recently announced the expansion of ZolipiMist distribution licences to South Korea after signing an additional licence agreement with Mitsubishi Tanabe Pharma Korea. The company has now signed licence agreements for ZolpiMist with two large pharmaceutical companies, TEVA Pharmaceuticals and Mitsubishi Tanabe for the distribution of ZolpiMist in seven countries. In July 2020, the company received marketing approval from the TGA for the distribution of ZolpiMist in Australia. This is the first product approval received by the company and marks a significant milestone for the company. We expect the approval to assist with the approval processes being undertaken in other jurisdictions.
- Outside of the key projects, all other OroMist reformulation projects will remain dormant until a partner is secured to fund development. This is to ensure the best use of the company's resources.
- A key event for the company in recent months was the share consolidation on a 1:25 basis. This saw the number of shares reduce from 3.56 billion to 142.2 million. This was a significant event for the company and puts it in a much better position moving forward with respect to capital raising prospects.

SUD's Key Projects



FINANCIAL POSITION

- The company reported a loss of $7.8m for FY19, an increase on the FY18 loss of $5.5m. The $6.3m writedown of ArTiMist was a significant contributor to the loss. Revenues increased from $0.4m in FY18 to $1.2m in FY19 as the upfront payments from some of the co-development programs flowed through. We note that revenue recognition will be lumpy through the development phase of the products being co-developed.
- The company recently raised $4.1 million (before costs) through an Entitlement Offer and a placement to Sophisticated investors. In total,163.6 million new shares were issued at $0.025 per share. For the Entitlement Offer, one option was attached for every three shares issued. The capital raising boosts the cash reserves of the company to over $4

million providing the company with sufficient cash to continue operations for one year based on the FY20 cash burn.

- The company will be seeking to improve its financial position over the long-term through the commercialisation of products that will generate supply agreements and royalty payments. The current roll out of ZolpiMist provides a model which the company will be seeking to replicate with other products.

CAPITAL STRUCTURE

- In November 2019, SUD completed a share consolidation on a 25-for-1 basis. As a result of the consolidation, the number of shares on issue was reduced from 3.56 billion to 142.25 million and the number of options on issue (both listed and unlisted) was reduced from 1.24 billion to 49.74 million. The share consolidation was a positive for shareholders putting the company in an improved position for future capital raisings.
- In June 2020, SUD completed an Entitlement Offer, raising $3.56 million through the issue of 142.25 million ordinary fully paid shares at $0.025 per share, a 34.3% discount to the 15 day trading VWAP. One option for every three new shares issued under the offer was attached with an exercise price of $0.05 and a two year maturity date from the issue.
- A further $0.53 million was raised through a placement to Sophisticated investors in August 2020. Shares were issued at the same price as the Entitlement Offer of $0.025 per share.

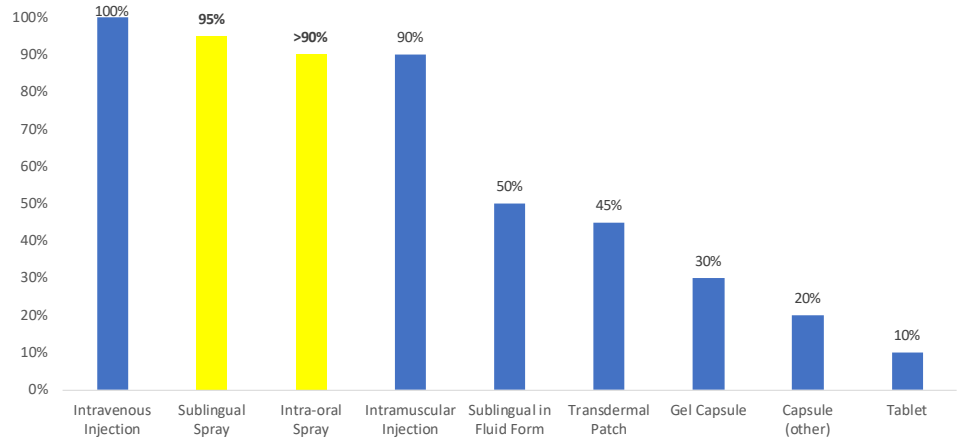
Capital Issued as at 18 August 2020			
Fully Paid Ordinary Shares	305,846,953		
Options:	**Number**	**Exercise Price**	**Expiry Date**
Listed	20,688,051	$0.37	30 June 2021
Listed	47,418,378	$0.05	31 July 2022
Unlisted	460,000	$0.57	10 December 2020
Unlisted	240,000	$0.1825	30 January 2022
Unlisted	520,000	$0.1475	14 May 2022
Unlisted	520,000	$0.1575	14 May 2022
Unlisted	560,000	$0.1675	14 May 2022
Unlisted	1,200,000	$0.0858	1 January 2024
Unlisted	800,000	0.0917	1 January 2024
Unlisted	800,000	0.0976	1 January 2024
Fully Diluted	**379,905,338**		

Source: IRESS/SUD/IIR

OROMIST TECHNOLOGY

- While the company will be seeking to broaden the portfolio of assets, the company will continue to develop the historical core business of the company, the reformulation of existing drugs using its OroMist technology.
- The OroMist technology provides for the reformulation of pharmaceutical products into an oral spray formulation for delivery of the drug through the to the oral mucosa. 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.

Drug Absorption Efficiency



Source: SUD

- The OroMist technology is unique and has been validated by the number of partners the company is currently working with to develop oral spray formulations of existing drugs. These partners include a number of large pharmaceutical companies. In 2019, the company signed a number of fully funded proof of concept and feasibility agreements with pharmaceutical companies to determine the feasibility of reformulating their drug assets.

505(B)(2) FDA REGULATORY PATHWAY

- The OroMist technology is used to reformulate existing drugs that have been approved by the relevant regulatory authorities and are shown to be safe and effective. As such, the company is able to use the 505(b)(2) pathway for the submission of approval. This is an abbreviated pathway, which allows the company to use existing safety and efficacy data for the active ingredient. This pathway significantly reduces the time to gain approvals as the company is not required to repeat pre-clinical safety studies. There is a similar pathway in the EU. We note that while the time to gain approvals is substantially reduced, clinical trials are still required to be completed which can still take a number of years.
- In most cases the company is only required to show that the drug delivery via the oral spray provides the same amount of drug to the blood stream as the existing drug provides.

ANAGRELIDE

- In January 2018, SUD acquired the global rights for the use of anagrelide as an adjuvant treatment for cancer.
- Anagrelide currently comes in the form of a capsule and is currently used to reduce elevated platelets and lower the thrombotic (blood clot) risk in myeloproliferative diseases associated with high platelet counts, primarily blood cancer. Anagrelide became off-patent in 2005 and since this time there have been a number of generics entering the market.
- Anagrelide acts by inhibiting the expansion of megakaryocytes thereby modulating platelet production. There is a growing amount of research that shows that platelets play a key role in the growth and spread of tumours. Given the role of platelets in tumour proliferation, platelet reduction could potentially help minimise tumour growth and metastasis and improve overall survival rates for those with elevated platelets.
- In its current form, anagrelide's use is limited due to the cardiovascular side effects observed post administration. The drug is metabolised in the liver during first pass metabolism, resulting in the production of a cardiotoxic intermediate that can cause heart palpitations, increased heart rate and/or a severe headache. SUD believes that these side effects can be reduced or avoided through the use of an oral spray which would mean the drug would not have to be metabolised by the liver before being absorbed, instead being absorbed through the oral mucosa.

- The company has been working to develop an oral spray formulation. The drug has been very difficult to reformulate with the drug almost insoluble. SUD has been able to improve the solubility substantially using its technology, however is still working to develop a product that meets the criteria for a pharmaceutical product. In the event the company cannot get the solubility to an appropriate level, the company may look to other delivery technologies to progress the product development.
- The company intends to conduct the early development work internally but will seek FDA and large pharma input to maximise the chance of regulatory success and securing a down stream licensing partner. Given the early stage of development there remains significant risk with this product.
- Once the company has developed a suitable oral spray formulation, the pre-clinical testing will commence to determine the ability of the formulation to reduce the cardiovascular side effects. The results from the pre-clinical testing will determine if the product progresses to human clinical trials.
- The company recently completed a canine pharmacokinetic study to test their hypothesis that an oral spray version of anagrelide could be more safely administered to cancer patients, potentially resulting in fewer cardiovascular side effects. Three formulations were tested against the capsule form of the drug and preliminary data suggested that one of the formulations was able to increase bioavailability of the drug anagrelide while reducing exposure to a cardio stimulatory metabolite. The study was performed by Covance Inc., in Harrogate, UK. The oral formulations were provided by SUD and has provided some insight into what formula the company will progress with. A final report is expected to be completed shortly providing further detail on the outcomes.

MARKET POTENTIAL

- The anagrelide reformulation will seek to be used as an adjuvant to existing treatments for solid cancers. According to the World Health Organisation (WHO), cancer is the second leading cause of death globally and was responsible for an estimated 9.6 million deaths in 2018.
- Thrombocytosis (excessive number of platelets in the blood which can lead to blood clots) affects 10%-57% of patients with solid tumours. As shown in the below table, the prevalence of thrombocytosis in solid cancers varies and is dependent on the stage and type of the cancer.
- The market size for the treatment of solid cancers is significant, as detailed in the below chart, and is constantly growing due to advancements in treatments alongside the growth in the number of cases. This provides a significant market opportunity for anagrelide with anagrelide potentially being able to be used in conjunction with chemotherapy drugs and immunotherapy treatments.
- While the market potential is significant, SUD is still in the process of reformulating the drug and is therefore in the early stages of development. Once the drug is sufficiently reformulated, clinical trials will need to be undertaken. Therefore there remains significant risk associated with the development of anagrelide for use in solid tumours.

Prevalence of Thrombocytosis in Solid Tumours

Cancer	Percentage of Thrombocytosis (Median across all stages)	Size of Market (US$)
Mesothelioma	28.10%	$338 million (2017)
Ovarian	24.00%	$1.8 billion (2018)
Vulvar	19.50%	$682 million (2018)
Cervical	17.70%	$6.3 billion (2017)
Renal cell	14.40%	$4.4 billion ()2016
Lung	13.10%	$15.2 billon (2016)
Glioblastoma	12.80%	$662 million (2016)
Pancreatic	12.60%	$1.9 billion (2018)
Colorectal	12.10%	$8.2 billion (2015)
Bladder	8.30%	$733 million (2018)
Gastric	6.90%	$1.4 billion (2018)
Head & neck	7.20%	$1.3 billion (2017)
Hepatocellular	5.50%	$680 million (2019)

Esophagus	3.40%	$765 million (2018)
Breast	2.60%	$17 billion (2017)
Melanoma	69.40%	$3.3 billion (2016)

Source: OncoFocus/Global Data/Market Research Future/Grand View Research/The Business Research Company

ZOLPIMIST

- SUD secured the rest-of-world rights for ZolpiMist in 2015. This includes the rights to supply and distribute ZolpiMist in all countries outside of North America. Aytu Bioscience, a NASDAQ listed pharmaceutical company, has the rights to distribution in North America.
- ZolpiMist is an oral spray formulation of zolpidem tartrate, which is used to treat insomnia and is commonly marketed under the brand Ambien or Stilnox. Ambien was a blockbuster drug for Sanofi. ZolpiMist was approved by the FDA in 2008 for the short-term treatment of insomnia.
- In August 2019, SUD announced that clinical study results demonstrated that ZolpiMist achieves sleep onset more quickly than the oral tablet of zolpidem (Ambien). This is an important selling point for ZolpiMist over the current tablet formulas.
- Aytu Bioscience began marketing the product in North America in 2019. Unfortunately the company does not provide a breakdown of the source of revenues by product and therefore we do not know the market penetration rate of ZolpiMist over it's short time in the market to date.
- The company currently has licence and supply agreements for ZolpiMist with three companies and a number of agreements currently under negotiation. The current agreements include:

  1) TEVA Pharmaceuticals for distribution in Brazil, Chile and Mexico.

  2) Mitsubishi Tanabe Pharma Singapore (MTPS) covering Philippines, Malaysia, Singapore.

  3) Mitsubishi Tanabe Pharma Korea for distribution in South Korea.
- The company had an agreement with a pharmaceutical company in China, however, this agreement has since been terminated and the company is actively seeking another partner in the region.
- TEVA Pharmaceuticals lodged an application for marketing approval in December 2017 in its licensed territory. The approval was expected to take 12 months however is yet to be received. There has been no comment from TEVA regarding the cause of the delay for approval providing uncertainty with respect to if and when approval will be received.
- In July 2020, the TGA approved the distribution and sale of ZolpiMist in Australia. The company is now looking for a partner to distribute the product. A response to the submission was expected to be received in 4Q'CY20, so the approval was received early. The "Asleep on the Job Report" published by Deloitte Access Economics in August 2017, outlining the costs of poor sleep on the Australia economy detailed that in 2016-2017, AUD$310.1 million was spent on therapeutic pharmaceuticals for sleep disorders.
- For each of the licence and supply agreements with partners, SUD receives an upfront payment, milestone payments and royalties on sales. The below details the licence agreements to date for ZolpiMist.

ZolpiMist Licence Agreements					
Partner	**Date of Agreement**	**Territories**	**Upfront Payment**	**Milestone Payment**	**Royalties on Sales**
TEVA Pharmaceuticals	June 2017	Brazil, Mexico & Chile	US$300,000	• US$700,000 registration and commercial milestone payments	Undisclosed
Mitsubishi Tanabe Singapore	December 2018	Singapore, Malaysia & Philippines	US$100,000	• US$120,000 on receipt of marketing authorisation; • Up to US$650,000 on exceeding sales targets.	Undisclosed
Mitsubishi Tanabe Korea	December 2019	South Korea	US$100,000	• US$100,000 on receipt of marketing authorisation; • Up to US$300,000 for commercial milestones.	12% royalty on net sales + handling fee.

Source: SUD

REVENUE POTENTIAL

- According to the Global Insomnia Market Research Report published by Market Research Future in March 2020, North America accounts for 45% of the global insomnia market. The global insomnia therapeutics market was estimated to be US$4.093 billion in 2016 and is expected to grow to in excess of US$5 billion by 2023. This means there is an addressable market of US$2.2-$2.75 billion for ZolpiMist for SUD. If distribution partners were able to capture 1% of this market, that would equate to US$22.2-$27.5 million sales per year. Assuming a 10% royalty for SUD, this would equate to US$2.22-$2.75 million in royalties per annum. Given that zolpidem tartrate is the most prescribed therapeutic drug to treat insomnia globally, we believe a 1% market share is more than achievable.
- TEVA Pharmaceuticals currently sells a generic form of Ambien (zolpidem tartrate) tablets. It launched the product in the US in 2007 and has also commenced sales outside of the US. Unfortunately, TEVA do not provide a breakdown of sales of their generic drugs and therefore we do not know the extent of sales by the company which may be partially addressed by the oral formulation, ZolpiMist. However, it provides confidence that TEVA has existing sales channels for the product.
- There have been some setbacks with some partnerships and delays with marketing approval application decisions. However, we expect the TGA approval for distribution of ZolpiMist in Australia will assist with progressing the approvals currently underway with the company's international partners.

CO-DEVELOPMENT PROJECTS

- The company has a number of co-development projects underway. These projects involve the reformulation of current drugs of the company's pharmaceutical partners. These projects are fully funded by the development partners.
- The company currently has five agreements for the reformulation of existing drugs. These agreements are detailed below. For the majority of the agreements, SUD has received an upfront payment to be followed by milestone payments and potential royalties in the event the product is commercialised. With respect to the two latest agreements with Sanofi and Ordesa, these two agreements are Feasibility Studies whereby the partners will pay the costs for the study. Depending on the results of the studies, further agreements may be reached.
- Given the fully funded nature of these projects there is no capital risk for SUD for the development of these projects.
- The partnership from pharmaceutical companies for the development of new delivery mechanisms for their products continues to provide confidence for the OroMist technology and its potential in the market place.

Co-Development Licence Agreements						
Partner	**Project**	**Date of Agreement**	**Upfront Payment**		**Milestone Payment**	**Royalties on Sales**
Strides Pharma Global Pte Limited	Sumatriptan	November 2018	US$400,000	•	US$600,000 in reaching certain milestones including the pilot first-in-man clinical study, submission and approval for the product in the U.S.	TBD
Zelira Therapeutics	Cannabinoid	December 2018	AUD$100,000	•	AUD$100,000 upon certain milestones being reached.	TBD
Cann Pharmaceuticals	Cannabinoid	October 2019	US$200,000	•	US$650,000 on development milestones; • US$650,000 commercial milestone payments.	10% on net sales + 10% handling fee.
Ordesa	Not disclosed	December 2019	US$100,000	•	TBD	TBD
Sanofi	Not disclosed	December 2019	Nil	•	Development costs	TBD

Source: SUD

INVESTMENT VIEW

- SUD is a drug development company and therefore is speculative in nature. As such investors should have a high level of risk tolerance.
- SUD provides investors with a opportunity to gain exposure to a drug development company that has a unique technology platform in OroMist to reformulate existing drugs into an oral spray formulation.
- The denial of marketing approval of ArTiMist was a setback for the company, however the company is moving forwards with a focus on the development of its two key products - Anagrelide and ZolpiMist. In addition to the development and distribution of these assets, the company will continue with the development of the co-development projects.
- While in the early stages of development, the reformulation of anagrelide for use in cancer treatment in conjunction with other treatments provides a significant value opportunity for the company in the event the assets can be progressed through trials with positive results.
- The company received Marketing Approval for ZolpiMist from the TGA for distribution in Australia. This is the first product approval for SUD and is therefore a significant milestone for the company. The company will now be focused on securing a distribution partner for ZolpiMist as well as advance the regulatory approval process in other regions. The first sales as well as further regulatory approvals in other parts of the world will be significant milestones and catalysts for the share price.
- The company has a rejuvenated board and management team that we believe are in a strong position to generate shareholder value from the portfolio of assets.
- The share price has been in a state of decline over the past 12 months on the back of delays, raising capital at a discount to the share price and ultimately the denial of marketing approval for ArTiMist. We believe the company has reached a turning point with the approval of ZolpiMist by the TGA.
- While we view there to be upside potential for SUD we note that there remains significant risk. In addition to the development risks, capital risk is also apparent with companies that do not currently generate a recurring revenue stream. Commencement of ZolpiMist sales and further regulatory approvals and sales in other jurisdictions will alleviate this risk to some degree.

RISKS

- **Drug Development Risk:** There are significant risks associated with the development of drugs with the development process having a binary outcome - either the drug works or it doesn't. The company is currently developing and reformulating a number of drugs which diversifies the risk to some extent, but as was the experience with ArTiMist there is no guarantee that drugs will successfully make it to the approval process and if they do they may not be successful in being granted approval. In addition to the binary outcome, there is also timing risk. While the company will seek to complete trials within a specified timeframe, there may delays with patient recruitment that may result in delays to the completion of trials.
- **Capital Risk:** The company does not generate a regular income stream at this point in time and is therefore largely dependent on capital raisings to continue research and development activities for its portfolio of products. The company recently raised $4.1 million (before costs) through an Entitlement Offer and a placement to institutional investors. Based on the FY20 cash burn, the company has sufficient cash reserves to fund operations for one year.
- **Dilution Risk:** Capital raisings may be dilutive to shareholders. We saw this with the recent issue of shares to Sophisticated investors with shares issued at a significant discount to the share price.
- **Foreign Exchange Risk:** The company is exposed to foreign currency risk and in the event further products are approved will continue to be exposed to foreign currency risks. Therefore, movements in currencies will impact the Australian dollar revenues and costs.
- **Regulatory Risk:** There is always regulatory risk associated with drug development. Developers are highly dependent on regulatory authorities to determine whether or not a drug can progress through clinical trials and ultimately progress to market.

BOARD AND MANAGEMENT

Dr. Michael Barker - Chief Executive Officer & Managing Director: Dr. Baker took on the role as CEO of SUD in January 2020 and was appointed to the board on 1 July. Dr. Baker was previously an Investment Manager with the leading Australian life science fund, BioScience Managers, where he was responsible for deal sourcing from networks, conferences, universities and research institutes. Dr. Baker also conducted due diligence to shortlist investment opportunities and played an active role in managing portfolio companies. Prior to BioScience Managers, Dr. Baker was a project manager and a member of the senior leadership group at Hexima Limited, which specialises in developing agricultural and pharmaceutical products. He led a team of research scientists and drove project development, including helping guide a drug candidate from discovery to clinical trials..

Dr. Baker has a PhD in Biochemistry and was awarded the prestigious Nancy Millis award for the most outstanding thesis for the Faculty of Science, Technology and Engineering, 2010. Dr. Baker holds an MBA from Melbourne Business School.

Paul Hopper - Chairman (Non-Executive): Mr. Hopper has international and ASX biotech capital markets experience and over 25 years' experience in the medical, healthcare & life sciences sectors, particularly in immune-oncology and vaccines. Mr. Hopper is the former Chairman of Viralytics Ltd (acquired by Merck for $500m in 2018), Founder and former Director of Prescient Therapeutics Ltd, Founder of Imugene Ltd and Polynoma LLC, former Director of pSivida Corp, Somnomed Ltd and Fibrocell Science, Inc. Mr. Hopper has founded or technology seeded four companies on the ASX with technologies he has licensed from Yale, the University of Vienna Medical School, City of Hope National Medical Center, Genentech, the University of South Florida and Moffitt Cancer Center. Mr. Hopper has significant experience in corporate governance, risk and strategy.

David Phillips - Director (Executive): Mr. Phillips joined the Board in April 2018 as a Non-Executive Director before moving to an Executive Director in 2019. Mr Phillips has 35 years experience in the healthcare industry 23 of which were with Glaxo Wellcome and then GSK. After Glaxo Wellcome Mr. Phillips spent 12 years at Board level as Chief Business Officer of Argenta Discovery, The Automation Partnership and BioFocus PLC (Galapagos NV).Mr Phillips rejoined GSK in the Corporate Venture arm SR One in 2008 to pioneer a new function to incubate and spin-out technologies from GSK and in parallel investing in early stage life

science companies. Mr. Phillips has been responsible for over 50 Pharma/Biotech deals and 10 M&A transactions. Mr. Phillips leads the Business Development activities.

David Simmonds - Director (Non-Executive): Mr. Simmonds was a senior audit partner with Ernst & Young from 1989 to 2017. From 2008 to 2013, Mr. Simmonds led the Capital Markets desk in Australia with responsibility for overseeing or reviewing all Australian cross border fundraisings. As an audit partner, Mr. Simmonds was involved in several high-profile businesses including Ramsay Health Care Ltd, John Fairfax Holdings and Commonwealth Bank of Australia and also was audit partner for the Australian operations of the leading US technology companies Hewlett Packard, Sun Microsystems and Oracle. Until recently, for five years, Mr. Simmonds was a member of the Board and chairs the Audit, Risk and Finance Committee of MS Research Australia, the largest national not-for-profit body dedicated to funding and coordinating multiple sclerosis research in Australia.

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