EDISON

SUDA Pharmaceuticals

Initiation of coverage

Improving delivery of existing drug products

Pharma & biotech

SUDA Pharmaceuticals has focused on reformulating established drugs into oro-mucosal spray formulations for better bioavailability. Its lead commercial product is ZolpiMist, an oro-mucosal spray version of Ambien for the treatment of insomnia that is partnered in certain regions with Teva and Mitsubishi Tanabe. SUDA is also working on formulating an oro-mucosal version of anagrelide for the treatment of solid tumours in patients who have high platelet counts. Anagrelide is currently used as an anti-thrombotic agent to reduce elevated levels of platelets in essential thrombocythemia.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/18	0.4	(6.2)	(0.11)	0.0	N/A	N/A
06/19	1.2	(2.4)	(0.02)	0.0	N/A	N/A
06/20e	0.7	(4.5)	(0.03)	0.0	N/A	N/A
06/21e	0.6	(5.4)	(0.04)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Commercialising ZolpiMist globally

ZolpiMist is an oro-mucosal spray version of Ambien that has a faster onset than the pill form. SUDA has the rights outside of North America and has out-licensed rights in Mexico, Brazil and Chile to Teva, and in Singapore, Malaysia, the Philippines and Korea to Mitsubishi Tanabe. Royalties are typically double digit and include a handling fee.

Reducing anagrelide cardiotoxicity

Anagrelide is an effective agent used to reduce elevated levels of platelets in essential thrombocythemia but use has been limited by cardiotoxicity. SUDA believes that an oro-mucosal spray version could minimise these issues by reducing first-pass generation of a highly potent cardio-excitatory metabolite of the drug in the liver, 3-hydroxy anagrelide.

Additional shots on goal

Besides ZolpiMist and anagrelide, SUDA is also using its technology to reformulate sumatriptan for migraine (partnered with Strides) and has programmes with Zelira Therapeutics and Cann Pharma Australia on cannabinoid formulations. Additionally, there are projects on undisclosed targets being funded by Sanofi and Ordesa.

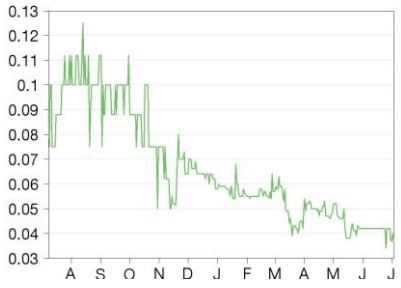
Valuation: A$18m or A$0.13 per basic share

We value SUDA at A$18m or A$0.13 per basic share (A$0.09 per diluted share) using a risk-adjusted net present value (NPV) model. We currently only attribute value to the ZolpiMist programme as it is the most advanced and the rest are still in formulation stages. Once these programmes advance, we would add them to our valuation. The company had A$1.5m in cash on hand at 31 March 2020 and we estimate a need to raise A$10m in FY21 (A$22.5m total over the next three years) to fund operations based on the current business plan.

6 July 2020

Price	**A$0.04**
Market cap	**A$5m**
	A$1.67/US$
Net cash (A$m) at 31 March 2020	1.5
Shares in issue	142.3m
Free float	79.1%
Code	SUD
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(14.3)	(30.8)	(64.0)
Rel (local)	(15.7)	(42.6)	(60.5)
52-week high/low	A$0.13		A$0.04

Business description

SUDA Pharmaceuticals has historically been a drug delivery company focusing on developing oro-mucosal spray versions of established medicines. It has the rights to ZolpiMist, the spray version of Ambien for insomnia, outside of North America. SUDA is also working on formulating an oro-mucosal version of anagrelide for the treatment of solid tumours, sumatriptan for migraine, cannabinoids for various conditions, as well as other projects.

Next events

TGA approval ZolpiMist	Q4 CY20
Additional licensing deals	FY21

Analysts

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Edison profile page

Investment summary

Company description: A focus on oncology and CNS

SUDA Pharmaceuticals is an Australia-headquartered healthcare company formed in 1999 that has historically focused on its innovative drug delivery platform (OroMist). Its lead commercial product on the drug delivery side is ZolpiMist, an oro-mucosal spray version of Ambien for the treatment of insomnia that is partnered in certain regions with Teva and Mitsubishi Tanabe. It is also developing formulations of anagrelide for the treatment of solid tumours in patients who have elevated platelet levels, sumatriptan for the treatment of migraine (partnered with Strides Pharma Global for the US market) and cannabinoids for various indications. Additionally, there are projects on undisclosed targets being funded by Sanofi and Ordesa.

Valuation: A$18m or A$0.13 per basic share

We are initiating coverage of SUDA Pharmaceuticals at A$18m or A$0.13 per basic share (A$0.09 per diluted share) using a risk-adjusted NPV model focusing strictly on the ZolpiMist programme. We attribute a 70% chance of success to ZolpiMist as it has already been approved in the United States (though not yet in the SUDA territories) by the FDA, one of the most stringent regulators in the world. Additionally, we are modelling peak sales across all currently licensed territories conservatively at US$11.7m (A$19.5m). We are not yet including SUDA's other programmes as they are still being formulated, but will include them once they advance.

Financials: Funding needed to advance programmes

SUDA reported A$1.5m in net cash on its balance sheet at the end of March 2020. Historically the company has had a relatively low burn rate in terms of operating cash flow of about A$2.5m in both FY18 and FY19. However, as programmes such as anagrelide advance we expect the burn rate to increase. We estimate a need to raise A$10m in FY21 (A$22.5m total over the next three years) to fund operations based on the current business plan. The company is currently conducting a A$3.6m entitlement offer and is expecting to announce the results of the offer on 27 July 2020.

Sensitivities: Dilution, commercial and development risk

Given the current market capitalisation, share issuance over the next few years may be multiples of the current shares outstanding in order to fund SUDA's programmes (shares outstanding will double if the current entitlement offer is fully subscribed). However, some of this could be mitigated by future business development deals. Additionally, ZolpiMist will be launched into a very competitive and genericised insomnia market with little pricing power, hence we only project ZolpiMist peak sales of A$19.5m in the regions with existing partnership arrangements. Also a number of pipeline programmes are still in the formulation stages, including anagrelide and sumatriptan (though none of these are included in our valuation) and there is no guarantee that a formulation will be developed that has an attractive profile in competitive genericised markets. For anagrelide, the company has stated that early animal results indicated that it had a formulation that increased bioavailability and decreased exposure to the cardio stimulatory metabolite. We await full results and it is currently unclear how clinically meaningful that reduced exposure would be. Sumatriptan has a variety of oral, injectable, needle-free, patch and intranasal formulations for patients to choose from and it may be difficult to achieve the target profile of a fast onset of action (as observed with the injectables) but with the convenience of an oro-mucosal spray.

Company description: Drug delivery and innovation

SUDA Pharmaceuticals has historically been a drug delivery company focusing on reformulating established drugs into oro-mucosal spray (via its OroMist platform) formulations for better bioavailability. Its lead commercial-stage product is ZolpiMist, an oro-mucosal spray version of Ambien for the treatment of insomnia that it has partnered in certain regions with Teva and Mitsubishi Tanabe (SUDA obtained the rights outside of North America). It is also working on a number of other projects using OroMist including anagrelide (for the treatment of high platelet counts in cancer patients), sumatriptan (migraine), cannabinoids and others.

Exhibit 1: SUDA Pharmaceuticals pipeline

Programme	Indication	Status	Partners	Comments
ZolpiMist	Insomnia	Registration	Teva (Mexico, Chile, Brazil), Mitsubishi Tanabe (Korea, Philippines, Singapore, Malaysia)	Faster onset than standard version. Approved in one country, the US, where rights sit with Aytu. Exact timelines for registration in partner areas unclear due to confidentiality
Anagrelide	High platelet counts in cancer	Formulation	None	Possibly fewer cardiac side effects than standard version. Possible use in a variety of different cancers where high platelet counts are correlated with poor outcomes such as ovarian, lung and pancreatic
Sumatriptan	Migraine	Formulation	Strides (United States)	Faster onset than oral version but without needing to resort to injection
Cannabinoids	Various	Feasibility	Zelira and Cann Pharma Australia	Early stage deals to convert cannabinoid products into oro-mucosal sprays
Undisclosed	Undisclosed	Feasibility	Sanofi	Using OroMist technology on undisclosed active ingredient for Sanofi
Undisclosed	Undisclosed	Feasibility	Ordesa	Using OroMist technology on undisclosed active ingredient for Ordesa

Source: SUDA Pharmaceuticals

The ZolpiMist franchise

ZolpiMist is the oro-mucosal spray version of the blockbuster insomnia drug Ambien (zolpidem tartrate), which has 30m prescriptions written for it in the United States annually. Approximately 2.5m prescriptions are written for novel formulations, such as controlled release and sublingual tablets. SUDA has the rights to ZolpiMist in all regions outside of the United States and Canada, while Aytu BioScience has the rights to both countries and receives a portion of the royalties/milestones received by SUDA (SUDA originally obtained the rights outside of the Americas and South Africa from Amherst Pharmaceuticals in January 2015 and signed a new agreement with Aytu in March 2019, obtaining full rights outside of North America).

The main benefit of ZolpiMist is the fast onset of action. Therapeutic levels were reached within 15 minutes following administration of the 10mg dose of ZolpiMist in 79% of patients compared to only 26% with the tablet version.[1]

ZolpiMist has been approved in the United States since 2008 (by the original developer, NovaDel) though sales have been limited (Aytu does not disclose ZolpiMist sales but it had four products on the market in 2019 and product sales for all of them totalled US$7.3m) partially due to the high price (US$798 retail for a 30-day supply package, or US$26.60 per day vs under US$20 for a 30-day supply of the generic oral tablet) and focus of marketing on high-end business travellers.

SUDA has licensed ZolpiMist to Teva for Mexico, Chile and Brazil, and to two separate divisions of Mitsubishi Tanabe for Singapore, Malaysia, the Philippines and Korea. While the upfront payments have been small, the royalty rates are all double digits and SUDA will also receive a handling fee. Additionally, SUDA submitted a marketing authorisation application (MAA) to the Therapeutic Goods Administration (TGA) for ZolpiMist in Australia. The review is currently expected to be completed in the fourth quarter of calendar 2020. The company has stated that it is in discussion for

1 Neubauer et al., ZolpiMist: a new formulation of zolpidem tartrate for the short-term treatment of insomnia in the US. *Nature and Science of Sleep* 2010:2 79–84

licensing deals for additional territories, in line with the strategy of commercialising the product globally. European deals are possible, but no licensing deals have been announced yet for any European countries.

Exhibit 2: ZolpiMist licensing deals

Partner	Countries	Populations	Terms	Comments
Teva	Mexico, Chile and Brazil	Mexico: 123m, Chile: 17m, Brazil: 213m	US$300,000 upfront, commercial milestones of US$1.75m and double-digit royalties	Agreement signed in 2017. Teva is currently working on approval in the three countries, launch timing undisclosed
Mitsubishi Tanabe Korea	South Korea	South Korea: 51m	US$100,000 upfront, US$100,000 on approval, up to US$300,000 in commercial milestones, a 12% royalty and a handling fee	Signed in 2020. Timing of approval and launch TBD
Mitsubishi Tanabe Singapore	Singapore, Malaysia, Philippines	Singapore: 6m, Malaysia: 32m, Philippines: 109m	US$100,000 upfront, up to US$880,000 in milestone and option payments, a double-digit royalty and a handling fee	Signed in 2018. Timing of approval and launch TBD

Source: SUDA Pharmaceuticals

According to the American Academy of Sleep Medicine, 30% of adults experience symptoms of insomnia and about 10% have insomnia that is severe enough to cause daytime consequences. There is no reliable international incidence data for insomnia, but based on the fact that SUDA has licensed ZolpiMist in countries with total populations of around 550 million people, the addressable market is likely quite large. And while expected pricing has not been disclosed, we believe average pricing will likely be closer to US$30 per month, making it more competitive and reasonably priced than in the US.

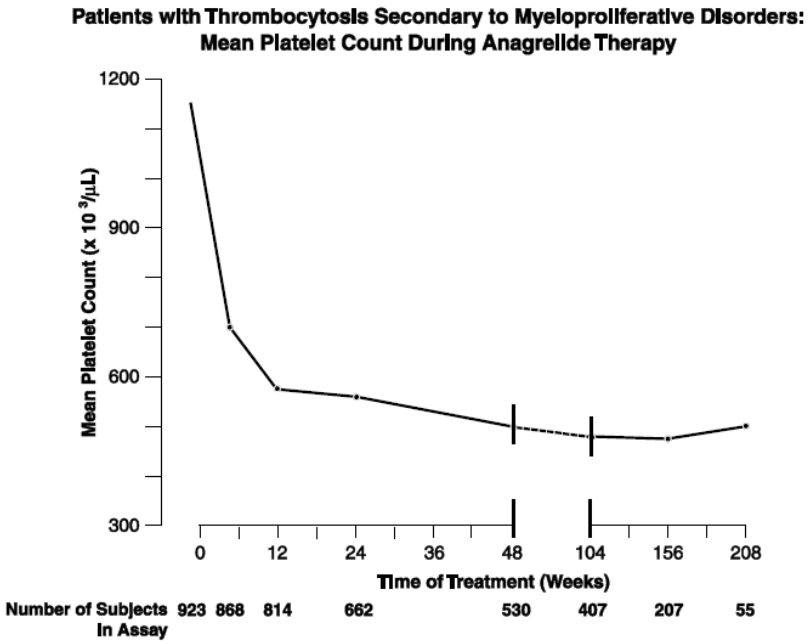
We are modelling peak sales across all currently licensed territories conservatively at US$11.7m (A$19.5m) but with a high probability of success (70%) as ZolpiMist has already been approved by the US FDA, which is one of the most stringent regulators in the world. Please note that we are not modelling any milestone payments or additional countries, so there is upside to our valuation as milestones are collected and additional partners are signed.

Anagrelide

SUDA is also developing an oro-mucosal spray formulation of anagrelide for the treatment of solid tumours in patients who have elevated platelet levels. Anagrelide is currently used as an anti-thrombotic agent to reduce elevated levels of platelets in essential thrombocythemia (a rare chronic blood cancer where the bone marrow produces too many platelets). The oral version of the drug was developed by Shire and received FDA approval in essential thrombocythemia in 1997 under the brand name Agrylin. While Anagrelide is effective (see Exhibit 3) it is known to have cardiotoxicity, which has limited its uptake. In clinical trials, 26% of patients reported heart palpitations, 8% reported tachycardia and 8% reported chest pain (though in the real-world setting post approval, palpitations were as high as 70% in some studies[2]).

2 Birgegard et al., Adverse effects and benefits of two years of anagrelide treatment for thrombocythemia in chronic myeloproliferative disorders. *Haematologica*. 2004 May;89(5):520–7

Exhibit 3: Anagrelide efficacy in reducing platelet counts



Source: FDA label

Due to these cardiotoxicity issues, Agrylin only had sales of US$153m in 2004, the year before the drug went generic. SUDA believes that an oro-mucosal spray version could minimise these issues by reducing first-pass generation of a highly potent cardio-excitatory metabolite of the drug in the liver, 3-hydroxy anagrelide. The effect of anagrelide in reducing platelet counts has been clearly demonstrated. Given the active role that platelets play in the proliferation and protection of cancer cells, anagrelide could play a key role in the treatment of a number of different solid tumours. Furthermore, with an improved pharmacokinetic profile, an oral spray version of anagrelide may also improve its use for the treatment of essential thrombocythemia, for which it was originally approved. Platelets can assist in the spread of cancer by supporting cancer stem cells, sustaining proliferative signals, resisting cell death, metastasis, evading immune detection and inducing angiogenesis.[3]

A large portion of cancer patients suffer from high platelet counts, which data indicate is a negative prognostic factor (see Exhibit 4). In a study in ovarian cancer patients, the 31% with high platelet counts were significantly more likely to have advanced disease, and vascular thromboembolic complications, than patients with normal platelets. Hence, their median overall survival was two years shorter (2.62 years vs 5.65 years) than those with normal platelets.[4] In another study of patients with pancreatic cancer, the 18% with high platelet counts had significantly shorter median overall survival (10.2 months vs 19 months) and shorter progression-free survival (7.8 months vs 11.1 months).[5] Correlation does not mean causation, but in this case there does seem to be a mechanistic reason for the differences.

3 Franco et al., Platelets at the interface of thrombosis, inflammation, and cancer. *Blood*. 2015 Jul 30; 126(5): 582–588

4 Stone et al., Paraneoplastic Thrombocytosis in Ovarian Cancer. *New England Journal of Medicine*. 2012;366:610–8.

5 Chadha et al., Paraneoplastic thrombocytosis independently predicts poor prognosis in patients with locally advanced pancreatic cancer. *Acta Oncologica*, 2015; 54: 971–978

Exhibit 4: High platelet counts in select cancers

	US annual incidence	% high platelet	Median overall survival (months), high platelet vs normal patients*
All cancer	1,762,450	10–57%	
Ovarian	22,530	31%	31.4 vs 67.8
Pancreatic	56,770	18%	10.2 vs 19.0
Breast	268,600	18%	12.5 vs 26.0
Lung	228,150	22%	38.0 vs 63.1

Source: National Cancer Institute, Sierko et al., Platelets and Angiogenesis in Malignancy. *Seminars in Thrombosis and Hemostasis,* volume 30, number 1, 2004., Stone et al., Paraneoplastic Thrombocytosis in Ovarian Cancer. *New England Journal of Medicine*. 2012;366:610–8., Chadha et al., Paraneoplastic thrombocytosis independently predicts poor prognosis in patients with locally advanced pancreatic cancer. *Acta Oncologica*, 2015; 54: 971–978. Maraz et al., Thrombocytosis Has a Negative Prognostic Value in Lung Cancer. *Anticancer Research* April 2013 vol. 33 no. 4 1725–1729.
Note: *The median overall survival figures are the results of specific studies, which may not be entirely representative of the cancer as a whole.

We have not included anagrelide in our valuation as it is still in the formulation stage and the exact timing of entry to the clinic is uncertain. However, once the programme enters the clinic, we will include it in our model and it may have a meaningful valuation associated with it given its potential applicability across cancers (though the initial focus may be ovarian, lung and pancreatic). If we assume a 20% market share in ovarian and pancreatic patients with high platelets and 10% market share in lung cancer patients with high platelets as well as a US$50,000 per patient price, peak sales in the US alone could reach US$470m (A$785m).

This will all depend however on SUDA being able to formulate a version with significantly less cardiotoxicity while providing efficacy. The company has stated that early animal results indicated that it had a formulation that increased bioavailability and decreased exposure to the cardio stimulatory metabolite. We await full results and it is currently unclear how clinically meaningful that reduced exposure would be.

Achieving these potential peak sales estimates will also depend on funding as SUDA will be seeking a different label from anagrelide (both with regards to safety as well as additional indications specifically including cancer) and therefore will likely have to run a traditional clinical trial programme rather than a shorter 505(b)2 version (this had been the pathway for ZolpiMist, which did not require a full clinical trial programme as it was simply a reformulation that was going after the same indication as zolpidem).

Sumatriptan

SUDA is also developing an oro-mucosal spray version of sumatriptan for the treatment of migraines. Migraines are a very common and debilitating ailment often lasting between four and 72 hours, with prevalence of around 13% in the US[6] and around 15%[7] in the EU, totalling over 100 million sufferers across the two regions. Sumatriptan was the first drug within the triptan class available for the treatment of migraines and has been the standard of care since. There are a number of different dosage forms available, including traditional injectable, needle-free, nasal, patch, oral tablet and oral melt (see Exhibit 5). The oral forms together dominate the market, accounting for over 95% of all doses according to Symphony Health. Injectable forms (both traditional and needle-free) are less than 3% of the market despite having a much faster onset of action, with migraine relief coming in a matter of minutes instead of a matter of hours.

6 Victor T et al., *Cephalalgia* 2010 Sep;30(9):1065–72

7 Stovner L et al., *Journal of Headache Pain* (2010) 11:289–299

Exhibit 5: Triptan competitive landscape for migraine

Drug	Brand	Route of administration	Time to peak concentration (Tmax)	Relief at 1 hour	Relief at 2 hours
Sumatriptan	Sumavel DosePro	Needle-free	12 minutes	70%	81–82%
Sumatriptan	Imitrex	Autoinjector pen	12 minutes	70%	81–82%
Sumatriptan	Imitrex	Nasal	N/A	38–46%	43–64%
Zolmitriptan	Zomig	Nasal	3 hours	60%	69–70%
Sumatriptan	Zecuity	Patch	1.1 hours	N/A	53%
Zolmitriptan	Zomig-ZMT	Oral melting tablet	3 hours	33–43%	63%
Rizatriptan	Maxalt-ZMT	Oral melting tablet	1.6–2.5 hours	38–43%	59–74%
Sumatriptan	Imitrex	Oral	2–2.5 hours	28–36%	50–62%
Sumatriptan + naproxen sodium	Treximet	Oral	1 hour	28%	57–65%
Zolmitriptan	Zomig	Oral	1.5 hours	35–45%	59–67%
Rizatriptan	Maxalt-ZMT	Oral	1–1.5 hours	38–43%	60–77%
Naratriptan	Amerge	Oral	2–3 hours	19–21%	50–66%
Almotriptan	Axert	Oral	1–3 hours	32–36%	55–65%
Frovatriptan	Frova	Oral	2–4 hours	12%	37–46%
Eletriptan	Relpax	Oral	1.5 hours	20–30%	47–77%

Source: FDA, Zogenix, Edison Investment Research

SUDA is developing a version of sumatriptan under the 505(b)2 pathway that would have a faster onset of action compared to the oral formulations (ideally one similar to that of injectables) while using a non-invasive method. The company has licensed the US market rights to Indian specialty pharmaceutical company Strides. Under the terms of the agreement, SUDA received US$400,000 upfront and is eligible for US$600,000 in milestones, a double-digit royalty and a handling fee. As with anagrelide, we are not currently including sumatriptan in our model as it is still in development. Additionally, as this is an especially competitive market with so many formulations, it may be challenging to develop a product with a commercially successful profile. For example, Sumavel DosePro, the needle-free injection version of sumatriptan, was only able to achieve US$36m in peak sales in 2012 despite a fast onset (mainly due to a high rate of injection site reactions as it would propel the drug through the skin).

Other programmes

SUDA also has deals to develop oro-mucosal spray version of cannabinoids. There is a feasibility and option agreement with Zelira (formerly Zelda) Therapeutics to develop an oral spray of pharmaceutical-grade cannabinoid derivatives. Zelira paid an A$100,000 upfront fee (with an additional A$100,000 in development milestone payments) and is covering the cost of formulation work. Also, in October, SUDA signed an agreement with Cann Pharma Australia to develop oral spray versions of pharmaceutical-grade cannabinoid derivatives to treat drug-resistant epilepsy (note that Epidiolex, a cannabinoid approved for drug-resistant epilepsy, had sales of around US$300m in 2019, its first year of launch, and is expected to have US$1.6bn in peak sales according to EvaluatePharma), melanoma and motion sickness. Terms of the agreement include a A$200,000 upfront fee, A$650,000 in potential development milestones, an additional A$650,000 in commercial milestones, a 10% royalty rate and a 10% handling fee for arranging the manufacture and supply of the product.

Additionally, SUDA has two partnerships regarding undisclosed molecules. In December, SUDA signed a deal with Spanish pharmaceutical company Ordesa to develop a spray version of a ‘major consumer product for the paediatric market’. Ordesa paid an upfront fee of US$100,000 and will fund the feasibility study, after which a definitive agreement will be negotiated. That same month, SUDA announced a deal in which Sanofi will fund a feasibility study regarding an undisclosed active ingredient. A new agreement may be negotiated if the feasibility study is positive.

We do not include the cannabinoid or undisclosed molecule programmes in our model as the timing for further development or commercial launch is unclear.

Sensitivities

With such a low market capitalisation, the primary risk is dilution. Share issuance over the next few years may be multiples of the current shares outstanding in order to fund its programmes (shares outstanding will double if the current entitlement offer is fully subscribed). However, some of this could be mitigated by future business development deals. Also a number of pipeline programmes are still in the formulation stages, including anagrelide and sumatriptan (though none of these are included in our valuation) and there is no assurance that a formulation will be developed that has an attractive profile in competitive genericised markets. For anagrelide, the company has stated that early animal results indicated that it had a formulation that increased bioavailability and decreased exposure to the cardio stimulatory metabolite. We await full results and it is currently unclear how clinically meaningful that reduced exposure would be. Sumatriptan has a variety of oral, injectable, needle-free, patch and intranasal formulations for patients to choose from and it may be difficult to achieve the target profile of a fast onset of action (as observed with the injectables) but with the convenience of an oro-mucosal spray. With regards to commercial risk, the markets being entered are very competitive and genericised though our projections for these are very conservative. We only project ZolpiMist peak sales of A$19.5m in the SUDA Pharmaceuticals regions and do not include any revenue for ZolpiMist from areas it has not yet currently licensed (although negotiations for additional licensing deals are ongoing). Additionally, while there should be little regulatory risk with the reformulated compounds, it is still present. SUDA had previously attempted to gain approval for its artemisinin spray, ArTiMist, for malaria, but it was denied in 2019 for various reasons though they seem to be mostly related to the use of artemisinin monotherapy as well as risks from patient non-compliance to treatment guidelines, rather than an issue with the formulation itself. However, in our view similar issues are unlikely with the current set of pipeline products.

Valuation

We are initiating coverage of SUDA Pharmaceuticals with a valuation of A$18m or A$0.13 per basic share (A$0.09 per diluted share) using a risk-adjusted NPV model focusing strictly on the ZolpiMist programme (see Exhibit 6). We do not include the six other programmes as they are still being formulated. We will likely include them in our valuation once the formulations have been finalised and they have entered human clinical trials. For anagrelide, if we assume a 20% market share in ovarian and pancreatic patients with high platelets and 10% market share in lung cancer patients with high platelets as well as a US$50,000 per patient price, peak sales in the US alone could reach US$470m (A$785m). Using a 10% probability of success once the programme achieves human clinical trial status and a 2029 launch year, our illustrative NPV value for anagrelide would be around US$28m (A$47m).

Exhibit 6: SUDA valuation table

Product	Main indication	Status	Probability of successful commercialisation	Launch year	Peak sales (A$m)	Economics	rNPV (A$m)
ZolpiMist	Insomnia	Pre-registration	70%	2020	19.50	Double-digit royalties	16.7
Total							16.7
Net cash (as of 31 March 2020)							1.5
Total firm value (A$)							18.12
Total basic shares (m)							142.3
Value per basic share (A$)							0.13
Options (m)							54.1
Total number of shares (m)							196.4
Diluted value per share (A$)							0.09

Source: Edison Investment Research

Note that we list 54.1m options for the company. Of those, approximately 28.0m will expire on 31 July 2020 and 20.7m will expire on 30 June 2021. Both of these are well out of the money (with exercise prices at over A$0.36).

SUDA is currently conducting an entitlement offer in which eligible shareholders can subscribe for one new share for each share currently held and one option for each three shares subscribed for. If fully subscribed, the company would raise A$3.6m, total shares outstanding would increase to 284.5m and there would be 101.6m options. Under this scenario, our valuation for the company would be A$22m or A$0.08 per basic share (A$0.06 per diluted share), taking into account both the increase in cash and dilution.

Financials

SUDA reported A$1.5m in net cash on its balance sheet at the end of March 2020. Historically, the company has had a relatively low burn rate in terms of operating cash flow, of about A$2.5m in both FY18 and FY19 as development has typically been partner-funded. The firm also reported a A$2.8m cash burn rate in the nine months ending 31 March 2020 (9M20) in its most recent Appendix 4C financial statement. However, as programmes such as anagrelide advance we expect the burn rate to increase. We estimate a need to raise A$10m in FY21 (A$22.5m total over the next three years) to fund operations based on the current business plan. As mentioned, the company is conducting an entitlement offer which, if fully subscribed, would raise $3.6m through the issuance of an additional 142.3m shares at A$0.025 per share. Subscribing shareholders would also receive one option for every three shares subscribed for, and those options would have an exercise price of A$0.05 and expire in two years. If all options are exercised, it could potentially provide A$2.4m in additional funding. The company expects to announce the results of the entitlement offer on 27 July 2020.

Exhibit 7: Financial summary

A$'000s	2018	2019	2020e	2021e
Year end 30 June	AIFRS	AIFRS	AIFRS	AIFRS
PROFIT & LOSS				
Revenue	426	1,219	740	566
Cost of Sales	0	0	0	0
Gross Profit	426	1,219	740	566
Sales, General and Administrative Expenses	(6,375)	(3,129)	(4,711)	(4,899)
Research and Development Expense	0	0	0	(500)
EBITDA	(5,886)	(1,878)	(3,957)	(4,833)
Operating Profit (before amort. and except.)	(6,044)	(2,349)	(4,531)	(5,407)
Intangible Amortisation	0	0	0	0
Other	63	32	13	0
Exceptionals	(560)	(6,277)	(5,490)	0
Operating Profit	(6,604)	(8,626)	(10,022)	(5,407)
Net Interest	(175)	(94)	4	4
Other	0	0	0	0
Profit Before Tax (norm)	(6,218)	(2,443)	(4,527)	(5,403)
Profit Before Tax (FRS 3)	(6,778)	(8,720)	(10,018)	(5,403)
Tax	745	925	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(5,473)	(1,518)	(4,527)	(5,403)
Profit After Tax (FRS 3)	(5,459)	(7,795)	(10,018)	(5,403)
Average Number of Shares Outstanding (m)	48.9	98.6	145.1	146.6
EPS - normalised (A$)	(0.11)	(0.02)	(0.03)	(0.04)
EPS - reported (A$)	(0.11)	(0.08)	(0.07)	(0.04)
Dividend per share (A$)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	15,571	10,658	5,470	6,853
Intangible Assets	15,399	10,291	4,765	5,812
Tangible Assets	173	367	609	945
Other	0	0	95	95
Current Assets	1,071	5,595	1,230	4,604
Stocks	98	45	22	22
Debtors	791	1,121	340	358
Cash	98	4,314	802	4,159
Other	84	115	66	66
Current Liabilities	(3,835)	(1,349)	(1,271)	(1,245)
Creditors	(1,812)	(1,312)	(1,245)	(1,245)
Short term borrowings	(2,023)	(36)	(26)	0
Long Term Liabilities	(1,342)	(927)	(551)	(10,729)
Long term borrowings	(26)	(17)	(8)	(10,182)
Other long term liabilities	(1,316)	(910)	(544)	(547)
Net Assets	11,465	13,978	4,878	(517)
CASH FLOW				
Operating Cash Flow	(2,548)	(2,495)	(2,114)	(5,234)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(908)	(1,384)	(1,397)	(1,410)
Acquisitions/disposals	1,584	0	0	0
Financing	0	8,095	0	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(1,872)	4,215	(3,511)	(6,643)
Opening net debt/(cash)	(836)	1,951	(4,260)	(768)
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	(916)	1,996	19	(148)
Closing net debt/(cash)	1,951	(4,260)	(768)	6,023

Source: company reports, Edison Investment Research

Contact details	Revenue by geography	Re

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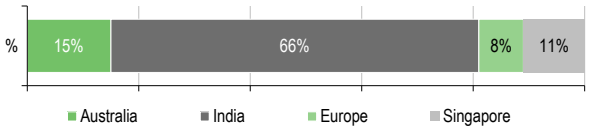

Management and board

CEO and Managing Director: Michael Baker

Dr Baker was an investment manager with a leading Australian life science fund, BioScience Managers, where he was responsible for deal sourcing from networks, conferences, universities and research institutes. He also conducted due diligence to shortlist investment opportunities and played an active role in managing portfolio companies. Michael was a senior manager at Hexima Limited, which specialises in developing agricultural and pharmaceutical products. Dr Baker has a PhD in biochemistry and was also awarded the prestigious Nancy Millis award for the most outstanding thesis for the Faculty of Science, Technology and Engineering, 2010. Dr Baker also holds an MBA from Melbourne Business School.

Executive chairman: Paul Hopper

Mr Hopper has international and ASX biotech capital markets experience and over 25 years' experience in the medical, healthcare and life sciences sectors, particularly in immunoncology and vaccines. Mr Hopper was also recently appointed co-chairman of Scopus BioPharma. He 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. He is the former chairman of Viralytics (acquired by Merck for A$500m in 2018), founder and former director of Prescient Therapeutics, founder of Imugene and Polynoma, and former director of pSivida, SomnoMed and Fibrocell Science.

Executive director: David Phillips

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 GSK Mr Phillips spent 12 years at board level as chief business officer of Argenta Discovery, The Automation Partnership and BioFocus (Galapagos NV). Mr Phillips re-joined GSK in the corporate venture arm as managing partner of 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. During this period, he was a member of the investment committee reviewing more than 30 deals. Mr Phillips has been responsible for over 50 pharma/biotech deals and 10 M&A transactions. He leads the business development activities.

Director (non-executive): David Simmonds

Mr Simmonds was a senior audit partner with Ernst & Young from 1989 to 2017. From 2008 to 2013, he led the Capital Markets desk in Australia with responsibility for overseeing or reviewing all Australian cross-border fund-raisings. As an audit partner, he was involved in several high-profile businesses including Ramsay Health Care, John Fairfax Holdings and Commonwealth Bank of Australia, and was also 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 served on the board and chaired 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.

Principal shareholders	(%)
Kamala Holdings	3.1
Tom McGellin	1.6
Scintilla Strategic Investments	1.4
Bamber Investments	1.4

Companies named in this report

Teva (TEVA), Mitsubishi Tanabe (4188:JP), Strides (STR:IN), Zelira (ZLD:AU), Sanofi (SNY), Aytu (AYTU), Cann Pharma Australia (private), Ordesa (private)

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