EDISON

SUDA Pharmaceuticals

Financial update

A TGA approval and a capital raise

Pharma & biotech

SUDA has had a busy couple of months, announcing approval for ZolpiMist in Australia by the Therapeutics Goods Administration (TGA) in July, as well as raising A$4.1m in additional capital. The TGA approval demonstrates SUDA's compliance with Good Manufacturing Practice (GMP) as well as an ability to obtain regulatory approvals. This approval will assist SUDA's current partners in their submissions in the territories for which they are responsible.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/19	1.2	(2.4)	(0.02)	0.0	N/A	N/A
06/20	0.5	(4.7)	(0.03)	0.0	N/A	N/A
06/21e	0.6	(5.5)	(0.02)	0.0	N/A	N/A
06/22e	1.1	(5.6)	(0.02)	0.0	N/A	N/A

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

TGA approval for ZolpiMist

ZolpiMist is an oro-mucosal spray version of Ambien, which has a faster onset than the pill form. SUDA had submitted a marketing authorisation application (MAA) to the TGA in April 2019 for ZolpiMist in Australia. It had most recently expected completion of the TGA review in Q4 CY20, so approval in July comes a few months ahead of schedule.

Commercialising ZolpiMist globally

SUDA has the rights outside 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. The TGA approval will assist SUDA's current partners in their submissions in the territories for which they are responsible.

A$4.1m in additional capital

SUDA conducted an entitlement offer in which eligible shareholders were able to subscribe for one new share at A$0.025 for each share currently held, and one option for each three shares subscribed for. Through this, A$3.6m in gross proceeds was raised. Due to the high demand for shares in the entitlement offer, the company subsequently raised an additional A$0.5m via a private placement.

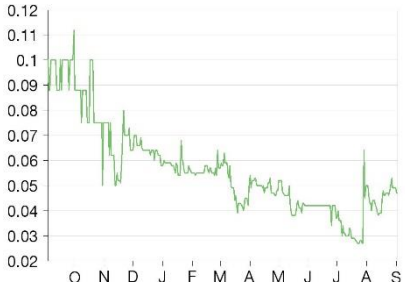
Valuation: A$24m or A$0.08 per basic share

We have adjusted our valuation for SUDA to A$24m or A$0.08 per basic share (A$0.06 per diluted share) from A$18m or A$0.13 per basic share (A$0.09 per diluted share). The total valuation has increased due to higher net cash and rolling forward our NPV, while the per-share value has decreased due to a greater number of shares outstanding. The company had A$1.0m in cash on hand at 30 June 2020 and raised an additional A$4.1m. After taking into account the recent raise, we estimate the need to raise an additional A$6m in FY21 (A$18.5m total over the next three years) to fund operations based on the current business plan.

3 September 2020

Price	**A$0.05**
Market cap	**A$15m**
	A$1.35/US$
Net cash (A$m) at 30 June 2020 + offering	5.1
Shares in issue	305.8m
Free float	97.2%
Code	SUD
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	2.2	32.1	(26.0)
Rel (local)	(1.1)	25.9	(21.0)
52-week high/low	A$0.10		A$0.03

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

Additional licensing deals	FY21

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Edison profile page

FY20 results

ZolpiMist is the oro-mucosal spray version of zolpidem tartrate (the branded form is the blockbuster insomnia drug Ambien), which has 30m prescriptions written for it in the US annually. Approximately 2.5m prescriptions are written for novel formulations, such as controlled release and sublingual tablets. 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 US since 2008 (where Aytu BioScience has the rights) and this approval in Australia is the first outside the US and the first by SUDA. SUDA has out-licensed ZolpiMist to Teva for Mexico, Chile and Brazil, and to two separate divisions of Mitsubishi Tanabe for Singapore, Malaysia, the Philippines and South Korea. While upfront payments have been small, the royalty rates are all double digit and SUDA will also receive a handling fee. The company has stated that it is in discussions for licensing deals for additional territories (SUDA has rights outside the US and Canada), in line with the strategy of commercialising the product globally.

Exhibit 1: 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$700,000 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, US$770,000 in regulatory and commercial milestones, a double-digit royalty and a handling fee	Signed in 2018. Timing of approval and launch tbd

Source: SUDA Pharmaceuticals

Valuation

We have adjusted our valuation for SUDA to A$24m or A$0.08 per basic share (A$0.06 per diluted share) from A$18m or A$0.13 per basic share (A$0.09 per diluted share). The total valuation has increased due to higher net cash and rolling forward our NPV, while the per-share value has decreased due to a greater number of shares outstanding.

Exhibit 2: SUDA valuation table

Product	Main indication	Status	Probability of successful commercialisation	Approval year	Peak sales (A$m)	Economics	rNPV (A$m)
ZolpiMist	Insomnia	Registered (Australia), pre-registration (other regions)	70%	2020	19.50	Double digit royalties	18.7
Total							18.7
Net cash (at 30 June 2020 + offering)							5.1
Total firm value (A$)							23.79
Total basic shares (m)							305.8
Value per basic share (A$)							0.08
Options (m)							68.1
Total number of shares (m)							374.0
Diluted value per share (A$)							0.06

Source: Edison Investment Research

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.

Financials

For FY20, the company reported A$0.5m in revenue (down 56% compared to FY19, mainly due to the timing of licensing, upfront and milestone payments) and a loss of A$9.9m, although A$5.9m was due to intangible asset impairment related to ArTiMist. Operating cash burn for the year was A$2.9m. We have not made substantial changes to our FY21 estimates and introduce our FY22 estimates, which feature A$1.1m in revenues and include some ZolpiMist royalties flowing through.

SUDA had A$1.0m in cash on hand at 30 June 2020 and raised an additional A$4.1m after the end of the fiscal year. It raised A$3.6m in an entitlement offer through the issue of 142.3m shares and 47.4m listed options at a cost of A$0.025 per unit. The options expire on 31 July 2022 and have an exercise price of A$0.05. Due to the high demand seen in the entitlement offering, the company placed an additional 21.3m shares at A$0.025 per share with no additional options in a private placement, raising A$0.5m.

After taking into account the recent raise, we estimate the need to raise an additional A$6m in FY21 (A$18.5m total over the next three years) to fund operations based on the current business plan.

Exhibit 3: Financial summary

A$'000s	2019	2020	2021e	2022e
Year end 30 June	AIFRS	AIFRS	AIFRS	AIFRS
PROFIT & LOSS				
Revenue	1,219	533	566	1,138
Cost of Sales	0	0	0	0
Gross Profit	1,219	533	566	1,138
Sales, General and Administrative Expenses	(3,129)	(4,788)	(4,979)	(5,178)
Research and Development Expense	0	0	(500)	(1,020)
EBITDA	(1,878)	(4,112)	(4,913)	(5,061)
Operating Profit (before amort. and except.)	(2,349)	(4,684)	(5,485)	(5,633)
Intangible Amortisation	0	0	0	0
Other	32	143	0	0
Exceptionals	(6,277)	(5,938)	0	0
Operating Profit	(8,626)	(10,622)	(5,485)	(5,633)
Net Interest	(94)	22	23	24
Other	0	0	0	0
Profit Before Tax (norm)	(2,443)	(4,662)	(5,462)	(5,609)
Profit Before Tax (FRS 3)	(8,720)	(10,600)	(5,462)	(5,609)
Tax	925	656	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(1,518)	(4,006)	(5,462)	(5,609)
Profit After Tax (FRS 3)	(7,795)	(9,944)	(5,462)	(5,609)
Average Number of Shares Outstanding (m)	98.6	142.3	306.0	309.1
EPS - normalised ($)	(0.02)	(0.03)	(0.02)	(0.02)
EPS - Reported ($)	(0.08)	(0.07)	(0.02)	(0.02)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	10,658	4,673	4,941	5,215
Intangible Assets	10,291	4,251	4,384	4,517
Tangible Assets	367	365	500	641
Other	0	57	57	57
Current Assets	5,595	2,035	6,618	8,792
Stocks	45	22	22	22
Debtors	1,121	869	913	114
Cash	4,314	977	5,517	8,490
Other	115	166	166	166
Current Liabilities	(1,349)	(2,022)	(1,677)	(1,677)
Creditors	(1,312)	(2,010)	(1,677)	(1,677)
Short term borrowings	(36)	(12)	0	0
Long Term Liabilities	(927)	(550)	(6,724)	(14,225)
Long term borrowings	(17)	(4)	(6,178)	(13,678)
Other long-term liabilities	(910)	(545)	(546)	(546)
Net Assets	13,978	4,135	3,157	(1,895)
CASH FLOW				
Operating Cash Flow	(2,495)	(2,884)	(5,160)	(4,127)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(1,384)	(388)	(394)	(400)
Acquisitions/disposals	0	0	0	0
Financing	8,095	0	4,093	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	4,215	(3,272)	(1,460)	(4,527)
Opening net debt/(cash)	1,951	(4,260)	(961)	661
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	1,996	(27)	(162)	(162)
Closing net debt/(cash)	(4,260)	(961)	661	5,350

Source: Edison Investment Research, company reports

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