



Strong Potential: Targeting mainstream markets with significant potential

Alpha Deal Group considers SUDA Limited (ASX: SUD) as a unique opportunity to benefit from the rapidly evolving drug delivery market. SUDA reformulates existing drugs into an oral spray for delivery of the drug through the oral mucosa. It is targeting mainstream markets which have significant potential such as migraine, malaria, chemotherapy-induced nausea, pulmonary arterial hypertension and pre-procedural anxiety, and erectile dysfunction. Licensing deals for ZolpiMist®, an oral spray for insomnia, could be secured in CY2016 and act as a catalyst for the share price. We maintain our BUY rating on SUDA Limited with a target price of \$0.22.

Licensing Deals for In-House Pipeline of Oral Sprays

The Company is in advanced negotiations with multiple pharmaceutical companies regarding licensing its first-in-class oral sprays in a variety of countries. In April 2016, SUDA's business development team attended the BIO-Europe Spring international partnering conference in Stockholm, Sweden. The team conducted one-to-one meetings with over 30 pharmaceutical companies. These included several prospective partners that have completed their due diligence and with whom SUDA is negotiating financial terms for a license in various territories. SUDA aims to finalize licensing agreements within the next few months.

ArTiMist™

SUDA has conducted productive meetings with global health philanthropic groups and the Medicines for Malaria Venture to discuss its ArTiMist™ sublingual anti-malarial spray. SUDA aims to secure non-dilutive funding for a 2nd Phase III trial of ArTiMist™ as an early interventional treatment of paediatric malaria in the pre-referral setting. The Company also met with the WHO to update the Global Malaria Program members and to discuss its plans regarding ArTiMist™.

Granted Canadian Patent for SUD-002

In April 2016, SUD-002 was granted Canadian patent from the Canadian Intellectual Property Office. The patent is entitled "Stable Anti-nausea Oral Spray Formulations and Methods" and has an expiry date of December 21, 2027. This is the second patent to be issued in Canada for SUDA's SUD-002 oral spray to treat nausea and vomiting induced by chemotherapy, radiotherapy and also in post-operative settings. Clinical studies have successfully demonstrated that the SUD-002 spray is statistically bioequivalent to the commercially available ondansetron tablet. It is well tolerated and can be conveniently administered in multiple doses.

Received \$0.7m R&D Tax Incentive Refund

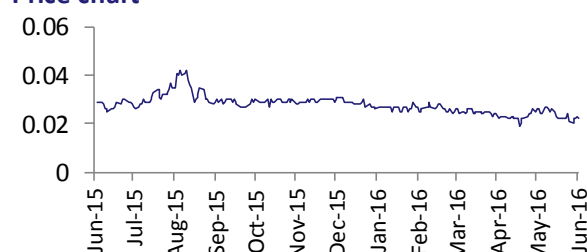
On February 5, 2016, the Company announced that it received a refund of \$0.7m from the Australian Taxation Office under the R&D Tax Incentive for eligible expenditure during the 2015 financial year. The refund strengthened the Company's cash position as it continues to negotiate with prospective partners and advance its pipeline.

SUDA Limited (ASX: SUD)

BUY-SIDE PORTFOLIO SELECTION

Share price	AUD 0.02		
BidBookIQ Value© (Target Price)	AUD 0.22		
Alpha Deal Sweet Spot© (Valuation Gap)	981%		
Market cap (AUDm)	25		
Net cash (AUDm)	1.7		
Enterprise value (AUDm)	23		
No. of shares (m)	1,141.3		
Average daily vol ('000, -3m)	730		
Price/book	1.50		
12 month high/low (AUD)	0.05/0.02		
(%)	1m	3m	12m
SUD	(15.4)	(8.3)	(21.4)
S&P 500 Index	0.6	3.7	(0.0)

Price chart



Source: Reuters

Share Price as at close: June 10, 2016

Next news

- Licensing deals for in-house pipeline of oral sprays
- Clinical results from SUD-003 PoC PK study
- Interim clinical results from SUD-001 pivotal PK study
- Pre- NDA meeting for SUD-002 with FDA

Key Financial

ASX'000	Jun-13	Jun-14	Jun-15
Revenue	4,066	8,753	5,728
Net Income/ (Loss)	(1,668)	(2,061)	(3,378)
Cash	753	3,990	6,252
Total Assets	10,729	20,347	22,821

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Table of Contents

Investment Summary	3
Investment Thesis	5
Valuation	9
Financials	11
Share Price	13
Disclaimer and Notes	14

Investment Summary

SUDA is a drug delivery company focusing on reformulating existing drugs into an oral spray for delivery through the oral mucosa. The Company utilizes its proprietary OroMist® oro-mucosal drug delivery technology to develop low-risk, innovative pharmaceuticals that improve the health and lifestyle of patients. The potential benefits of administering drugs through the oral mucosa, which is the moist lining of the oral cavity (i.e.: cheeks, tongue, gums and palate), include ease of use, lower dosage, reduced side effects and faster response time.

SUDA's product pipeline includes ZolpiMist®, a first-in-class oral spray of zolpidem (Ambien®) for insomnia. ZolpiMist® is marketed in the USA and the Company has recently amended its agreement with Amherst to expand territorial rights to the product to include South America, Central America, and South Africa, as a result, SUDA now has a global license, excluding North America. Given that ZolpiMist® is approved for use in the US market, no further clinical development may be required for registration in most other countries.

The Company's most advanced development-stage product is a first-in-class sub-lingual spray, ArTiMist™, for treatment of malaria in children. The active anti-malarial in ArTiMist™ is artemether, which is widely used in other formulations. ArTiMist™ has been shown to provide a more consistent dose response and avoids the first pass effect associated with oral Artemisia in-based monotherapies. The Company has successfully completed a Phase III trial of ArTiMist™ in severe paediatric malaria across multiple African countries. The Company is preparing a regulatory submission and aims to commercialise the programme through a partnership or divestment. Discussions with philanthropic groups and other providers of non-dilutive funding for a second Phase III study of ArTiMist™ in paediatric malaria are also progressing.

SUDA has IP covering over 300 widely-used APIs formulated into oro-mucosal sprays. The Company's development pipeline includes oral sprays of sumatriptan for migraine (SUD-001); ondansetron for chemotherapy-induced nausea and vomiting (SUD-002); sildenafil for erectile dysfunction (SUD-003) and PAH (SUD-004); and midazolam for pre-procedural anxiety (SUD-005).

SUDA has a fully owned subsidiary, Westcoast Surgical and Medical Supplies Pty Ltd (Westcoast), which provides medical supplies to Australian leading hospitals, aged care facilities, pharmacies, mining companies and other healthcare providers. Westcoast generated revenue of \$5.7 million in FY2015.

On October 8, 2015, the US Patent and Trademark Office allowed SUDA's first US patent application for its sildenafil based products, SUD-

003 and SUD-004. The allowed claims cover the administration of sildenafil, being the active pharmaceutical ingredient in SUD-003 and SUD-004, via oral spray formulations at a pH of between 1.5 and 2.4 for the treatment of sexual dysfunction induced by Selective Serotonin Reuptake Inhibitor (SSRI) anti-depressants and for the treatment of pulmonary arterial hypertension (PAH). The PAH market is forecast to grow at a CAGR of 5% and to reach \$3.6bn in 2015 (source: Global Data Analysis).

We believe that this is an exciting period for SUDA. The Company's investment in the development of novel oral sprays where there is a real need for improved treatments has been recognized by the pharmaceutical industry. It is in advanced negotiations with multiple pharmaceutical companies regarding licensing its first-in-class oral sprays in a variety of countries. We believe that the Company will achieve some value-adding milestones and licensing deals over the next few months that will add value to share price and a return for shareholders. In addition, the interest in ArTiMist™ from pharmaceutical companies and philanthropic groups continues to grow as the management seeks to expand the use of the product to include treatment of paediatric malaria in the pre-referral setting.

Investment Thesis

Strategy

SUDA has established a world leading oro-mucosal drug delivery platform with its OroMist® technology and a broad pipeline of novel first-in-class oral sprays. SUDA has adopted a classic business model for its OroMist® technology, in which the Company is focused on its core competencies of formulating and developing its oral sprays. SUDA does not intend, at this stage of its evolution, to establish its own sales and marketing operations. The Company aims to partner or out-licence its pipeline of oral sprays in all territories.

The Company is also working towards a partnership or divestiture of its anti-malarial spray, ArTiMist™, to a major pharmaceutical company. ArTiMist™ is primarily positioned for public markets, where it will be available for large-scale procurement of anti-malarial drugs by groups such as the World Health Organisation.

SUDA aims to strengthen its capital resources from the divestiture of projects and/or partnering activities and non-dilutive financing by applying for grants. In addition, SUDA is pursuing collaborations to reformulate partner companies' current or developmental drugs, or to extend their life cycle by developing novel OroMist® formulations with new intellectual property.

OroMist® Technology

SUDA's OroMist® technology can deliver a broad range of drug classes in the form of a liquid micro-mist through either the cheeks, gums, tongue or floor of the mouth. The technology is compatible with, and patented for, use in either pump (air-activated) or aerosol (propellant-driven) spray systems, and can be provided in either multi-dose or unit containers based on the medical need and marketing requirements for each product. The technology and delivery route can provide meaningful benefits compared to other modes of drug administration, including: provide faster onset of action; reduce the dose level; increase bioavailability of the drug by avoiding first pass metabolism in the liver; and others.

Delivery of Drugs through the Oral Mucosa

SUDA reformulates pharmaceuticals into oral sprays for delivery of the drug through the oral mucosa. About 70% of drugs are administered orally, primarily in tablet or capsule form. However, there are a number of disadvantages associated with the solid-oral administration such as hepatic first-pass metabolism and enzymatic degradation within the gastrointestinal (GI) tract, which cause a relatively lengthy onset time and/or erratic absorption patterns. Furthermore, patients must be conscious and able to swallow (40% of US adults and 54% of children (6-

11 years) report swallowing difficulties). 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 API required and it avoids the need to swallow or be taken with water. The oral spray formula provides pharmaceutical companies with a treatment that avoids the need for patients to swallow tablets.

Oral Sprays for Mainstream Markets

The Company currently has five products in addition to ArtiMist™ and ZolpiMist® that it is developing for the US and RoW markets. The oral sprays are developed using oro-mucosal technology. SUDA is targeting markets with significant potential including: migraine which is expected to grow to US\$5.8bn in 2021 from US\$3.2bn currently; chemotherapy, radiotherapy and post-operative induced nausea and vomiting market is estimated to be in excess of US\$2B; erectile dysfunction market which is estimated to be approx. US\$4.1bn; pulmonary arterial hypertension (PAH) market which is forecasted to reach \$3.6bn by the end of 2015; as well as pre-procedure anxiety market which is estimated to be US\$150-170mn.

Licensing and collaboration agreement with Amherst

In December 2015, SUDA amended its previously existing cross-licence agreement with Amherst to commercialise ZolpiMist® and SUDA's oral spray of ondansetron (SUD-002). Under the terms of the agreement, SUDA received an exclusive licence to manufacture, develop and commercialise ZolpiMist® in all territories excluding North America. Expanded rights to the product are expected to open more opportunities for sub-licensing deals. Business development discussions with prospective partners are progressing in several countries, including in the expanded territory.

We believe ZolpiMist® is a significant value proposition because no further development work is required for approval in most countries. Market applications may be filed within 12 months. In a comparable deal - Orexo AB received USD20m upfront for a sublingual tablet of zolpidem and an anti-histamine nasal spray. This global deal indicates the potential value of the Company's oral spray of ZolpiMist®.

SUDA takes full control of Malaria Research Company

SUDA acquired the remaining 20% stake in Malaria Research Company (MRC) from the UK based ProtoPharma Ltd (PPL) and its parent London Pharma Ltd (LPL) for A\$1.2m. The payment is in full and final settlement of all outstanding liabilities between the two companies. Also PPL and LPL have agreed not to compete with MRC's ArtiMist™ spray. MRC owns the rights to SUDA's novel sublingual anti-malarial spray, ArtiMist™. This acquisition is an important step towards SUDA's objective to commercialize ArtiMist™ through a collaboration or trade sale. SUDA

now owns 100% stake in ArtiMist™ with no further payment or royalty obligations to PPL.

Received Positive Response from FDA Regarding SUD-001 Development Plan

The Company has received a written response from the US FDA regarding the development plan for the Company's SUD-001 sumatriptan oral spray the treatment of migraine. The FDA's constructive responses will keep the Company on track to secure a US partner to support the ongoing development and registration of SUD-001 in the US.

Granting of more patents in the US and African Markets

In October 2015, the US Patent and Trademark Office allowed SUDA's first patent application for its sildenafil based products, SUD-003 and SUD-004, in the US. The allowed claims cover the administration of sildenafil, being the API in SUD-003 and SUD-004, via oral spray formulations at a pH of between 1.5 and 2.4 for the treatment of sexual dysfunction induced by SSRI anti-depressants and for the treatment of pulmonary arterial hypertension (PAH). The PAH market is forecast to grow at a CAGR of 5% and to reach \$3.6bn in 2015 (source: Global Data).

In July 2015, the MRC's intellectual property estate for ArtiMist™ was strengthened by the grant of a key patent in Africa. The patent was issued by the African Regional Intellectual Property Organisation (ARIPO), which is an intergovernmental organisation, comprising 19 African states, including the major countries in malaria-endemic Sub-Saharan Africa. The patent covers the pharmaceutical composition of ArtiMist™, the route of delivery, the device and methods for the treatment of uncomplicated and complicated malaria. It expires in 2026.

We expect FY 2016 to be much stronger period for SUDA due to its recent acquisitions made in the US and UK and also granting of more patent rights in the US and African countries and FDA approvals. Westcoast continues to be a strong player in the supply of medical consumables within the Aged Care, Allied Health, Mining and Hospital sectors in Western Australia. Further, we believe that the Company will achieve some value-adding milestones over the next few months that will act as a catalyst to share price and a return for shareholders.

Peer Comparison

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 is one company which is directly comparable to SUDA -Phosphagenics Limited (ASX: POH). POH has delivery technologies with which it is seeking to reformulate existing drugs. POH has developed a technology for the delivery of drugs through the skin.

There are a number of international companies that have oral mucosal drug delivery technologies that compete with SUDA's oro-mucosal technology. We believe that SUDA is extremely under-valued at its current market cap of \$25 million relative to other companies given that the Company's leading oro-mucosal drug delivery platform with its OroMist® technology and a broad pipeline of first-in-class oral sprays.

Company	Headquarter	Technology	Delivery Method	Market Cap (AUDm)
Tesa Labtech	Germany	Rapidfilm	Oral dissolvable film	Private
CIMA Labs	US	OraVescent	Oral disintegrating tablet	Private
Monosol Rx	US	PharmFilm	Oral soluble film	Private
Corden	Germany	Sterile emulsion	Oral film coated tablets, capsules	Private
Catalent	US	Zydis	Oral dissolvable tablet	2,857
BioDelivery Sciences International	US	BioErodible MucoAdhesive	Oral soluble film	143
Durect Corporation	US	Oradur	Oral gel-cap	177
IX Biopharma Ltd.	Singapore	Waferix	Oral dissolvable wafer	200
Oxford Pharmascience Group Plc	UK	OXF chew, OXF zero	Oral dissolvable tablet	80
IntelliPharmaCeutics International Inc.	Canada	Hypermatrix	Oral capsules	55
Alexza Pharmaceuticals Inc	US	Staccato	Oral inhalation powder	21
Phosphagenics Limited	Australia	Targeted Penetration Matrix	Oral Spray	18

Source: Capital IQ, Alpha Deal Group

Valuation

We at Alpha Deal Group consider an investment in SUDA Limited (ASX: SUD) as a long-term wealth creation opportunity. We valued SUDA using revenue multiple analysis. We also compared SUDA with publicly traded peers operating in the Company's core markets and found that the Company is extremely undervalued. We considered Australian competitors such as Phosphagenics as well as international peers such as Catalent, Durect, BioDelivery Sciences International, IX Biopharma Ltd and others.

Our sales model for SUDA is primarily driven by assumptions regarding: 1) market size and penetration of the products, 2) royalty payment for each of the products in the event they are launched to market 3) actual compensation for the products if a licensing agreement is secured.

Revenue Forecast					
	12 months	12 months	12 months	12 months	12 months
AUDm	Jun-30-2014A	Jun-30-2015A	Jun-30-2016F	Jun-30-2017F	Jun-30-2018F
Revenue	8.8	5.9	6.6	49.0	64.3
Growth Over Prior Year	115.3%	(33.1%)	12.6%	642.4%	31.2%

Source: Alpha Deal Group

Valuation Multiples based on Current Capitalization				
	12 months	12 months	12 months	12 months
	Jun-30-2012A	Jun-30-2013A	Jun-30-2014A	Jun-30-2015A
TEV/Total Revenue	7.1x	7.0x	3.2x	4.8x
TEV/EBITDA	NM	NM	NM	NM
TEV/EBIT	NM	NM	NM	NM
P/Sales	7.7x	7.6x	3.5x	5.3x
P/Diluted EPS	NM	NM	NM	NM
P/BV	2.3x	2.6x	1.8x	1.8x
Price/Tang BV	2.3x	2.6x	1.8x	1.8x

Source: Capital IQ, Alpha Deal Group

We have used revenue multiple analysis due to the fact that SUDA has not yet reached profitability. Therefore, based on the average historical valuation multiples for the past four years, we applied 5.5x multiple to our 2017F revenues for EV/ Revenue multiple and 6.0x multiple to our 2017F revenues for P/ Sales multiple, we arrived at a fair value range of \$0.238 to \$0.258 per share. We then applied a 10% discount rate to lower end of the fair value to arrive at a price target of \$0.22.

Forecasted Revenue Analysis	
Estimated 2017 Revenues (AUD million)	49.0
Year	2017
Fair Value Range (AUD)	0.238-0.258
Discount Rate	10%
Price Target (AUD)	0.22
Valuation Gap	
Current market price (AUD)	0.02
Target price (AUD)	0.22
Potential Upside (Downside)	981%

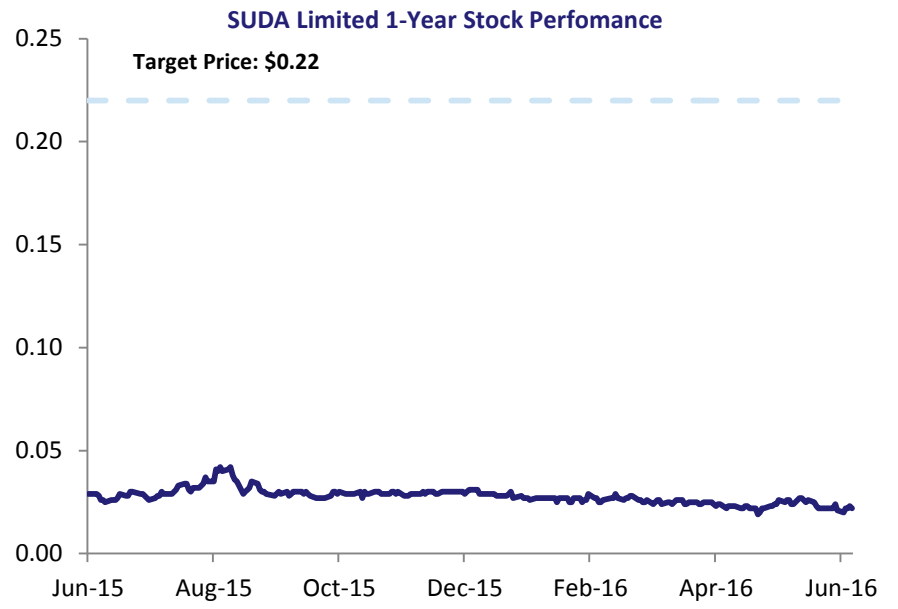
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SUDA Limited (ASX: SUD) Financials

All numbers are in (AUD 000's)	Annual		
	Jun-13	Jun-14	Jun-15
Income Statement			
Revenues	4,066	8,753	5,728
Other income	4	-	136
Raw materials and consumables used	(3,260)	(6,113)	(5,023)
Employee benefits expense	(1,259)	(2,111)	(2,470)
Depreciation and amortisation expense	(34)	(67)	(181)
Finance costs	(68)	(159)	(156)
Other expenses	(1,291)	(2,545)	(2,070)
Loss before income tax expense	(1,842)	(2,241)	(4,036)
Benefit from income taxes	174	180	658
Net Loss	(1,668)	(2,061)	(3,378)
Balance Sheet			
Current assets			
Cash and cash equivalents	753	3,990	6,252
Other current assets	1,679	3,495	3,092
Total Current Assets	2,432	7,485	9,344
Property and Equipment, Net	117	312	389
Intangible assets, net	8,180	12,549	13,088
Total Assets	10,729	20,347	22,821
Liabilities			
Trade and other payables	2,877	2,480	1,795
Borrowings (Current)	562	-	1,725
Borrowings (Non Current)	600	1,875	-
Total Liabilities	4,039	4,355	3,520
Equity			
Issued capital	40,129	48,945	55,574
Reserves	75	570	628
Accumulated losses	(33,513)	(35,565)	(38,932)
Shareholders equity	6,690	13,949	17,269
Non-controlling interests	-	2,042	2,031
Liabilities and Shareholders equity	10,729	20,347	22,821
Cash flow statement			
Operating activities			
Receipts from customers	4,242	8,849	6,298
Receipts for R&D tax incentive	304	174	188
Payments to suppliers and employees	(6,114)	(11,555)	(9,630)
Interest received	21	49	103
Finance costs	(62)	(132)	(114)
Cash flow from operating activities	(1,609)	(2,615)	(3,154)
Investing activities			
Payments for property, plant and equipment	(78)	(288)	(282)
Payments for intangible assets	(833)	(1,716)	(996)
Proceeds from sale or PPE	4	-	5
Cash flow from investing activities	(907)	(2,004)	(1,273)
Financing activities			
Proceeds from issue of shares	1,001	6,394	6,986
Payments for share issue costs	(13)	(449)	(296)
Proceeds from borrowings	968	1,900	-
Receipt of funds for future issue of shares	100	-	-
Repayments of borrowings	(392)	-	-
Cash flow from financing activities	1,664	7,845	6,690
Cash flow for the period	(853)	3,226	2,263
Cash at the beginning of the period	1,590	753	3,990
Effect of exchange rate fluctuations	16	12	(1)
Cash and cash equivalents at end of period	753	3,990	6,252

All numbers are in (AUD 000's)	Semi- Annual		
	Dec-13	Dec-14	Dec-15
Income Statement			
Revenues	6,242	2,934	2,834
Other income	-	177	53
Raw materials and consumables used	(4,207)	(2,482)	(2,250)
Employee benefits expense	(887)	(1,255)	(1,004)
Depreciation and amortisation expense	(21)	(55)	(69)
Finance costs	(62)	(83)	(135)
Other expenses	(1,397)	(1,193)	(1,239)
Loss before income tax expense	(332)	(1,957)	(1,811)
Benefit from income taxes	-	-	-
Net Loss	(332)	(1,957)	(1,811)
Balance Sheet			
Current assets			
Cash and cash equivalents	5,527	3,050	3,396
Other current assets	3,311	2,942	2,908
Total Current Assets	8,838	5,992	6,304
Property and Equipment, Net	162	354	318
Intangible assets, net	12,329	12,917	13,506
Total Assets	21,329	19,264	20,127
Liabilities			
Trade and other payables	1,936	1,844	1,366
Borrowings (Current)	883	1,875	-
Borrowings (Non Current)	1,900	-	1,730
Total Liabilities	4,718	3,719	3,096
Equity			
Issued capital	48,136	50,397	55,705
Reserves	269	628	2,071
Accumulated losses	(33,845)	(37,510)	(40,744)
Shareholders equity	14,560	13,515	17,031
Non-controlling interests	2,051	2,030	-
Liabilities and Shareholders equity	21,329	19,264	20,127
Cash flow statement			
Operating activities			
Receipts from customers	6,019	3,055	2,861
Receipts for R&D tax incentive	-	188	-
Payments to suppliers and employees	(7,385)	(5,137)	(4,108)
Interest received	21	93	32
Finance costs	(29)	(47)	(101)
Cash flow from operating activities	(1,374)	(1,848)	(1,316)
Investing activities			
Payments for property, plant and equipment	(94)	(85)	(42)
Payments for intangible assets	(1,471)	(688)	(1,598)
Proceeds from sale or PPE	-	-	32
Cash flow from investing activities	(1,565)	(774)	(1,609)
Financing activities			
Proceeds from issue of shares	6,159	1,713	-
Payments for share issue costs	-344	(33)	(36)
Proceeds from borrowings	-	-	(920)
Receipt of funds for future issue of shares	1,900	-	-
Repayments of borrowings	-	-	1,025
Cash flow from financing activities	7,714	1,681	69
Cash flow for the period	4,775	(941)	(2,856)
Cash at the beginning of the period	753	3,990	6,252
Cash and cash equivalents at end of period	5,527	3,050	3,396

Share Price History



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