Acrux

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Portfolio Continues to Grow with New Approvals in 1H, Healthy Cash

NEED TO KNOW

- Cash of $3.3m at end of period post successful capital raise
- One product approval and one product launch in 1HFY25, more announcements coming in 2HFY25

Cash position means Acrux is ready to keep growing: Acrux has reported its 1HFY25 results, with cash at the end of the period of $3.3m. A December capital raising brought in $4.0m before costs (through a combination of a placement and a share purchase plan). The company received an R&D Tax Incentive Rebate of $2.73m which it used to repay short-term borrowings in full. The healthy cash position provides a runway for Acrux to continue the development and approval process for its pipeline of products – currently 4 products are marketed in the US, with another planned for launch soon – as revenues ramp up and first Nitroglycerin revenues are received in 4QFY25.

Products keep moving through the pipeline: In December, Acrux launched Nitroglycerin 0.4% Ointment, with launch activities currently underway. This drug for the treatment of moderate to severe pain associated with anal fissure has an addressable market of US$23.2m according to Acrux. Dapsone 7.5% Gel, for the treatment of acne (addressable market of US$37.4m as per Acrux), was also approved during the period, with a launch planned for FY25. Next to watch will be Efinaconazole Solution (recently approved) and Acyclovir Cream (currently with FDA for review).

Investment Thesis

Topical generic pharmaceuticals are more complex and less competitive: Acrux's proprietary drug delivery technology comprises known skin penetration enhancers, excipients, and solvents comprising volatile/non-volatile liquids. Acrux patents cover technology for delivering drugs through the skin using proprietary delivery methods. The topical generic market is generally less competitive than the much larger oral generic market.

Acrux's portfolio of approved products reaches critical mass: The company has 15 products, 6 of which have been approved by the FDA and 4 of which have been commercialised. Acrux has seen a steady stream of approvals and launches in recent years, which we expect to continue over our forecast period, leading to revenue growth of ~ 40% CAGR to FY27E.

Solid track record: A key aspect of Acrux's business model is the out-licensing of products to strategic partners. We believe this model reduces commercialisation risk and makes the business more scalable.

Valuation/Risks

Our valuation for Acrux moves to $0.09/share (previously $0.11/ share), on a fully diluted basis, using shares on issue of 407.3m and options (& performance rights) of 169.5m following the capital raise. We expect continued product launches and FDA approvals to represent catalysts for the stock, with the Nitroglycerin 0.4% Ointment launch currently underway and Dapsone 7.5% Gel up next after its recent FDA approval. Our valuation is most sensitive to approval timing, commercial launch, and the ultimate pricing achieved given the number of competitors in specific product markets.

Equity Research Australia

Health Care Equipment & Services

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Acrux is a specialty pharmaceutical company focused on developing and commercialising generic versions of topically applied prescription pharmaceuticals primarily for the US market. Acrux leverages on-site laboratories, a GMP manufacturing suite, and its clinical and commercial experience and has been successful over 25 years in bringing products to market through licensee partners in the US and Europe. The company's 16-product portfolio includes 6 approved products (4 commercialised, 2 pending) and 10 other products at various stages of development. www.acrux.com.au

Valuation	**A$0.09** *(from A$0.11)*
Current price	**A$0.03**
Market cap	**A$11m**
Cash on hand	**A$3.3m** *(31 December 2024)*

Upcoming Catalysts / Next News

Period	
2HFY25	Dapsone 7.5% Gel launch

Share Price (A$)

Source: FactSet, MST Access.

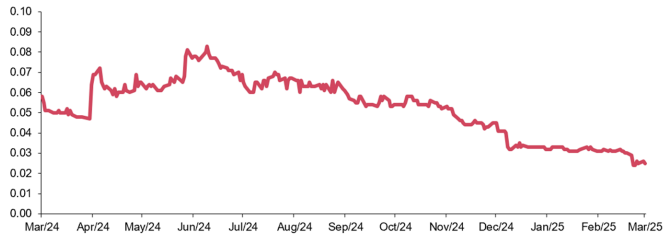
Acrux Ltd — ACR-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	**$**	**0.03**	
52 week high / low	$	0.02-0.08	
Valuation	**$**	**0.09**	*(fully diluted)*
Market capitalisation	$m	11.0	
Shares on issue (basic)	**m**	407.3	
Options / rights	m	169.5	*includes ~17.9m directors rights*
Other equity	m	0.0	
Shares on issue (diluted)	**m**	**576.8**	

12-MONTH SHARE PRICE PERFORMANCE (A$)



INVESTMENT FUNDAMENTALS		FY23A	FY24A	FY25E	FY26E	FY27E
Reported NPAT	$m	(0.8)	(5.8)	(3.3)	2.6	4.9
Underlying NPAT	**$m**	**(0.8)**	**(5.8)**	**(3.3)**	**2.6**	**4.9**
Reported EPS (diluted)	¢	(0.3)	(2.0)	(1.1)	0.6	1.2
Underlying EPS (diluted)	**¢**	**(0.3)**	**(2.0)**	**(1.1)**	**0.6**	**1.2**
Growth	%					
Underlying PER	**x**	**nm**	**nm**	**nm**	**4.0**	**2.1**
Operating cash flow per share	¢	0.2	(1.5)	(1.0)	0.7	1.3
Free cash flow per share	¢	0.2	(1.6)	(1.1)	0.6	1.2
Price to free cash flow per share	**x**	**12.3**	**nm**	**nm**	**3.9**	**2.1**
FCF Yield	%	8.2%	nm	nm	25.7%	48.5%
Dividend	**¢**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Payout	%	0.0%	0.0%	0.0%	0.0%	0.0%
Yield	**%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**
Franking	%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterprise value	**$m**	**4.8**	**4.8**	**9.5**	**8.5**	**6.1**
EV/EBITDA	x	18.3	nm	nm	3.0	1.2
EV/EBIT	x	nm	nm	nm	3.4	1.3
Price to book (NAV)	x	0.8	2.2	1.7	1.5	0.9
Price to NTA	x	1.1	4.9	3.1	2.1	1.0

KEY RATIOS		FY23A	FY24A	FY25E	FY26E	FY27E
ROE	%	nm	nm	nm	38.1	42.1
ROA	%	nm	nm	nm	24.1	31.9
Net tangible assets per share	$	0.0	0.0	0.0	0.0	0.0
Book value per share	$	0.0	0.0	0.0	0.0	0.0
Net debt/(cash)	$m	(6.2)	(6.2)	(1.5)	(2.5)	(4.9)

DUPONT ANALYSIS		FY23A	FY24A	FY25E	FY26E	FY27E
Return on Assets	%	nm	nm	nm	24.1	31.9
Leverage	x	1.5	2.7	2.0	1.6	1.3
Return on Equity	%	nm	nm	nm	38.1	42.1

KEY PERFORMANCE INDICATORS	FY23A	FY24A	FY25E	FY26E	FY27E
Commercialised	4	4			
Approved	6	6			
Under review by FDA	3	2			
Under development	7	7			

HALF YEARLY DATA		2H22	1H23	2H23	1H24	2H24
Revenue	$m	1.0	1.4	7.0	4.4	0.7
Other income	$m	2.0	1.8	1.5	1.4	1.5
Operating expenses	$m	7.0	6.0	5.5	8.4	4.8
EBITDA	$m	(4.3)	(3.1)	2.7	(2.9)	(2.8)
EBIT	$m	(4.0)	(2.8)	3.0	(2.6)	(2.6)
PBT	$m	(4.3)	(3.1)	2.9	(2.9)	(2.7)
Reported NPAT	$m	(4.4)	(3.3)	2.5	(3.2)	(2.6)

Source: Company reports, MST Access estimates

PROFIT AND LOSS		FY23A	FY24A	FY25E	FY26E	FY27E
Revenue	**$m**	**8.4**	**5.1**	**6.9**	**11.9**	**14.2**
Other income	**$m**	**3.4**	**2.9**	**2.3**	**3.0**	**3.0**
Operating expenses	$m	12.1	17.1	12.1	12.1	12.1
EBITDA	**$m**	**0.3**	**(5.2)**	**(2.9)**	**2.8**	**5.1**
Depreciation & Amortisation	$m	0.6	0.5	0.4	0.3	0.3
EBIT	**$m**	**(0.3)**	**(5.7)**	**(3.4)**	**2.5**	**4.8**
Net interest	$m	0.1	0.1	0.1	0.1	0.1
Pretax Profit	**$m**	**(0.2)**	**(5.6)**	**(3.3)**	**2.6**	**4.9**
Tax expense	$m	(0.6)	(0.2)	0.0	0.0	0.0
Reported NPAT	**$m**	**(0.8)**	**(5.8)**	**(3.3)**	**2.6**	**4.9**
Underlying NPAT	$m	(0.8)	(5.8)	(3.3)	2.6	4.9
Weighted average diluted shares	m	286.5	289.5	290.7	407.3	407.3

GROWTH PROFILE		FY23A	FY24A	FY25E	FY26E	FY27E
Revenue	%	390.3	(39.6)	34.7	74.0	19.0
Other income	%	nm	nm	nm	nm	nm
EBITDA	%	nm	nm	nm	nm	nm
EBIT	%	nm	nm	nm	nm	nm
Reported NPAT	%	nm	nm	nm	nm	nm

BALANCE SHEET		FY23A	FY24A	FY25E	FY26E	FY27E
Cash	$m	6.2	2.9	2.5	4.9	9.7
Receivables	$m	0.4	0.1	0.1	0.1	0.1
Current assets	**$m**	**9.9**	**6.0**	**5.5**	**7.9**	**12.7**
Deferred tax asset	$m	0.8	0.6	0.6	0.6	0.6
Leased assets	$m	2.0	1.8	1.8	1.8	1.8
Non current assets	**$m**	**3.4**	**3.0**	**2.8**	**2.8**	**2.8**
Total assets	**$m**	**13.3**	**9.0**	**8.3**	**10.7**	**15.4**
Trade and other payables	$m	0.8	0.9	0.8	0.8	0.8
Other	$m	1.6	2.9	1.4	1.4	1.4
Current liabilities	**$m**	**2.4**	**3.7**	**2.2**	**2.2**	**2.2**
Lease liabilities	$m	2.2	1.9	1.9	1.7	1.5
Non current liabilities	**$m**	**2.2**	**2.0**	**1.9**	**1.7**	**1.6**
Total liabilities	**$m**	**4.6**	**5.7**	**4.1**	**3.9**	**3.7**
Net assets	**$m**	**8.7**	**3.3**	**4.2**	**6.8**	**11.7**
Share capital	$m	114.9	115.0	119.3	119.3	119.3
Retained earnings	$m	(114.5)	(120.3)	(123.6)	(121.0)	(116.1)
Other	$m	8.3	8.6	8.6	8.6	8.6
Total equity	**$m**	**8.7**	**3.3**	**4.2**	**6.8**	**11.7**

CASH FLOW		FY23A	FY24A	FY25E	FY26E	FY27E
Net profit (loss) for period	**$m**	**(0.8)**	**(5.8)**	**(3.3)**	**2.6**	**4.9**
Depreciation & Amortisation	$m	0.6	0.5	0.4	0.3	0.3
Changes in working capital	$m	(0.3)	0.3	0.0	0.0	0.0
Other	$m	1.2	0.7	0.0	0.0	0.0
Operating cash flow	**$m**	**0.7**	**(4.3)**	**(2.9)**	**2.9**	**5.2**
Payments for PPE	$m	(0.1)	(0.3)	(0.3)	(0.3)	(0.3)
Investing cash flow	**$m**	**(0.1)**	**(0.3)**	**(0.3)**	**(0.3)**	**(0.3)**
Capital raising costs	$m	0.0	0.0	(0.3)	0.0	0.0
Lease liability prinicipal repayments	$m	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)
Other	$m	0.0	1.5	(1.5)	0.0	0.0
Financing cash flow	**$m**	**(0.2)**	**1.3**	**2.7**	**(0.2)**	**(0.2)**
Cash year end	**$m**	**6.2**	**2.9**	**2.5**	**4.9**	**9.7**
Free cash flow	**$m**	**0.6**	**(4.6)**	**(3.2)**	**2.6**	**4.9**

1HFY25 result – strong portfolio, approvals keep coming

Acrux reported its 1HFY25 result. The cash position is healthy post a capital raise and R&D tax incentive payment, which we expect will see the company through its planned continued drug development and approvals while revenues ramp up. The pipeline although undisclosed continues to produce new drug candidates for FDA submissions and approvals continue, which we view as a positive indicator of the company's momentum.

Financial highlights

Revenue: Revenues decreased significantly by 70% to $1.7m compared to $5.8m in the pcp. However, we note that revenues from prior periods are not directly comparable to those from the current period because previous years' revenues contained a large proportion of 'pass-through' revenues. This was because, in previous periods, Acrux was responsible for procuring and selling active pharmaceutical ingredients (API) used in the commercial manufacture of Prilocaine 2.5% Cream and Lidocaine 2.5% Cream to its commercial partner. Acrux is no longer responsible for this procurement, as it is now being undertaken by the company's commercial partner directly.

Net loss: The net loss after tax attributable to members increased by 6% to $3.4m, compared to a loss of $3.2m in the prior corresponding period.

Product licensing income decrease: Income decreased to $0.1m from $0.5m, reflecting partner sales of marketed products. This income reflects partner sales of Evamist®, Dapsone 5% Gel, Nitroglycerine 0.4% Ointment, and Prilocaine and Lidocaine 2.5% Cream. Acrux expects this to increase in 2H with the launch of Dapsone 7.5% Gel and the range extension of Dapsone 5% Gel.

R&D tax incentive: Acrux received $2.7m from the RDTI for FY24, with $1.6m recognised in 1HFY25. This includes $1.3m estimated receivable for the period and $0.2m relating to FY24 received in December.

Operating expenses: Total operating expenses increased to $5.3m, primarily due to increased R&D project expenses, interest accrued on short-term RDTI funding, CPI-based salary increases, and increased provisions for long service leave. The increase in operating expenses is attributable to increased investment in R&D activities, the cost of short-term RDTI funding, and increased employee-related costs (salaries and provisions for leave). The increase in R&D spend suggests continued investment in future product development, while the RDTI funding interest highlights the company's reliance on this rebate to fund its operations.

Cash and capital raising: Acrux raised $4.0m before costs through a placement to investors and a Share Purchase Plan (SPP). The cash balance at the end of the period was $3.3m.

Options offer: Subscribers to the Placement and SPP were offered Attaching Options, which, if fully exercised, could raise a further $8.9m. Following receipt of valid acceptances, 151.6m options were issued on 19 February 2025. The due date for outstanding acceptances has been extended to 31 March 2025, with remaining options to be issued at that time.

Corporate highlights

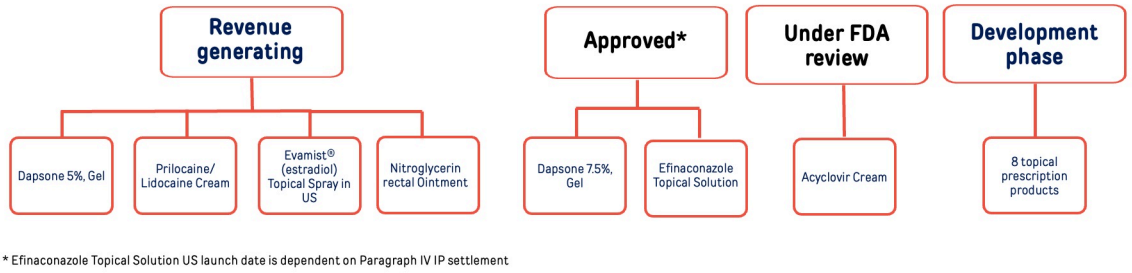
FDA approvals: The FDA approved 2 ANDA submissions for generic versions of existing medications: Dapsone 7.5% Gel and Nitroglycerin 0.4% Ointment.

Product launches: Commercial launch activities commenced for Nitroglycerin 0.4% Ointment in December, with Dapsone 7.5% Gel launch planned for FY25. Dapsone 5% Gel was launched in a 60mg pack and a 90mg presentation was introduced in December.

Marketed products: Acrux has 4 marketed products in the US: Prilocaine 2.5% and Lidocaine 2.5% Cream; Evamist®; Dapsone 5% Gel; and Nitroglycerin 0.4% Ointment.

CEO retirement: Michael Kotsanis is planning to retire from his role as CEO and Managing Director. Mr Kosanis has indicated that he will continue to carry out his responsibilities until a successor is appointed.

Figure 1: Acrux topical product portfolio



* Efinaconazole Topical Solution US launch date is dependent on Paragraph IV IP settlement

Source: Acrux.

Valuation

Our valuation for Acrux moves to $0.09/share (vs $0.11/share previously), on a fully diluted basis, after incorporating actual shares on issue of 407.3m (vs 422.8m previously) and actual options (& rights) of 169.5m (vs 132.9m previously) and net cash of A$3.3m.

Our valuation reflects the following:

- **Key DCF inputs** are beta of 1.22, WACC of 12.3% and a conservative terminal growth rate of 0%. We think DCF methodology allows for granular modelling of accumulated tax losses and best captures the cash flow generation potential of the business over time.
- **Revenue forecasts:** These include the Nitroglycerin product and therefore remain unchanged.

Our revenue forecasts reflect the growing contribution of existing products on the market and anticipated approvals and launches of new generic products that are in the public domain.

We assume each product partner will absorb the cost of goods, resulting in a 60% gross margin for all products commercialised. Further, we assume each product will be partnered, with net profits shared equally with Acrux. We do not include the now 8 products currently in development given they remain undisclosed at this point, which limits our ability to assess the end target market, potential market share and relative pricing dynamics. Nonetheless, based on an average revenue contribution of around $3m per product per annum and development timelines of around 5 years, we note that the contribution to the total revenue of these currently undisclosed products could be material and could represent further upside over the medium term.

Figure 2: DCF valuation and key assumptions

		Jun-24	Jun-25	Jun-26	Jun-27	Jun-28	Jun-29	Jun-30	Jun-31	Jun-32	Jun-33	Jun-34
EBIT	A$m	(5.7)	(3.4)	2.5	4.8	7.0	7.7	8.1	8.4	8.5	8.6	8.7
Tax at standard rate	A$m	**(0.2)**	-	-	-	-	-	-	-	-	-	-
Post-tax EBIT	A$m	**(5.5)**	**(3.4)**	**2.5**	**4.8**	**7.0**	**7.7**	**8.1**	**8.4**	**8.5**	**8.6**	**8.7**
Depreciation & Amortization	A$m	0.5	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Post-tax cash flow	A$m	**(5.0)**	**(2.9)**	**2.8**	**5.1**	**7.2**	**7.9**	**8.4**	**8.6**	**8.8**	**8.9**	**8.9**
Less capex	A$m	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)
Less change in working capital	A$m	0.3	-	-	-	-	-	-	-	-	-	-
Free cash flow	A$m	**(4.9)**	**(3.2)**	**2.6**	**4.8**	**7.0**	**7.7**	**8.1**	**8.4**	**8.5**	**8.6**	**8.7**
Discount coefficient	years	0.0	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0
Discounted cash flow	A$m		**(2.9)**	**2.0**	**3.4**	**4.4**	**4.3**	**4.0**	**3.7**	**3.4**	**3.0**	**2.7**
Sum of discount streams	A$m	28.1										
Terminal growth	%	0.0%										
Future value into perpetuity	A$m	70.5										
NPV of terminal value	A$m	22.1										
PV of cash flows	A$m	50.1										
PLUS: Value of investments	A$m	-										
LESS: Net debt	A$m	(3.3)										
Equity value	**A$m**	**53.5**										
Ordinary shares	m	407.3										
Value per share	**A$**	**0.13**										
Value per share ***(fully diluted)***	**A$**	**0.09**	***- includes options/rights of 169.5m***									

Source: MST Access.

Sensitivities and risks to our view

New product development: A key commercial objective in generics development is the early introduction of products to the market to gain commercial advantages over competitors, and ideally secure 180-day market exclusivity for those situations where it is first to file with the FDA. As such, Acrux has demonstrated an ability to identify niche product targets for the development of its generic versions and built a diversified portfolio of products, including those approved and others pending FDA review, where this potential for first-mover advantage is within reach. The challenge therefore is to maintain momentum in this evaluation process, given the opaque nature of competitor development pipelines and changes to the FDA's specific product guidelines. As such, the submission for review by the FDA of any of the 8 product candidates currently in development could provide upside to our view.

Drug pricing relative to branded product and level of competition: The entry and ultimate number of generics have a direct impact on pricing for all market participants, and the branded drug in particular. Branded drugs have been known to lose more than 80% of their price in the first six months after going off-patent. As such, the discount to brand pricing is highly correlated with how many competitors are targeting the same branded product market.

Competition can come from both the innovator (branded product originator) through an authorised generic or from other generic manufacturers.

A lack of patent protection inherent in generic drug development and the commercial advantage of being first to market makes it difficult to assess competitor pipelines before submission of dossiers to the FDA for review.

In addition to these sources of competition, challenges to existing patents of branded drugs under Paragraph IV can allow entry of generic manufacturers and also disrupt pricing dynamics of product target markets.

Lastly, Indian and Chinese generic manufacturers often compete based on price given their access to cheaper labour, further eroding prices for product markets that they enter.

Purchasing power of integrated buyer groups, evolving drug channels, and impact to generics pricing: The bargaining power of large buyer groups can also impact pricing given their strategic position in the US pharmaceutical supply chain.

Buyers of generic drugs include both wholesale distributors and large intermediary customer groups such as pharmacy benefit managers (PBMs) and group purchasing organisations (GPOs). A number of these have consolidated in recent years in the US, either through acquisition or joint ventures, to form wholesale buying consortia. The three largest wholesale buying consortia together represent about 90% of all generics purchases by volume, equating to significant purchasing power.

Commercial partnering/licensing: A key aspect of the Acrux business model is the out-licensing of products developed to strategic development partners with distribution capabilities. However, appropriate licensee partners for product candidates might not be found, or commercially attractive licensing agreements established, despite progress on the R&D pipeline.

Technological issues: Other drug delivery technologies are under development, one or more of which could displace Acrux's products. In addition, Acrux relies on third-party contract manufacturing organisations (CMOs) to scale production. This involves a technical transfer of the Acrux-developed formulations of generic products and the associated methods of manufacture to a CMO that will scale up manufacturing to commercial batch sizes for both regulatory submission and commercial purposes. As such, there is a risk of failing to replicate formulations or maintain batch quality at scale.

Pooled development fund structure and shareholder risk considerations: Acrux is structured as a Pooled Development Fund. Under the Pooled Development Fund Act 1992, shareholders are entitled to concessionary tax treatment in Australia for income and capital gains derived in connection with their shareholding. Gains realised on the disposal of shares will not be included in an investor's assessable income in Australia. An investor will not be entitled to any deduction or capital loss on the sale of shares. Unfranked dividends received by an Australian resident will be exempt from tax. Franked dividends will also be exempt from tax unless the shareholder elects to be taxed. While this structure benefits shareholders by not taxing capital gains if the share price increases, it conversely prevents any capital losses incurred through a decline in the share price from being used as a tax offset for the shareholder.

Funding: Notwithstanding cash of A$3.3m as of 31 December 2024, growing revenues from the launch of new products and the R&D tax incentive rebate, Acrux remains exposed to funding risk should near-term commercialisation of new products fall short of expectations and not cover operating expenses. However, this is also contingent on the terms of commercialisation agreements with partners and the sharing of costs.

Personal disclosures

Chris Kallos, CFA received assistance from the subject company or companies in preparing this research report. The company provided them with communication with senior management and information on the company and industry. As part of due diligence, they have independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in this report. They have taken care to maintain honest and fair objectivity in writing this report and making the recommendation. Where MST Financial Services or its affiliates has been commissioned to prepare content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid has, or will, directly or indirectly impact the content provided in this report.

Company disclosures

The companies and securities mentioned in this report, include:

Acrux (ACR.AX) | Price A$0.03 | Valuation A$0.09;

Price and valuation as at 05 March 2025 (not covered)*

Additional disclosures

This report has been prepared and issued by the named analyst of MST Access in consideration of a fee payable by: Acrux (ACR.AX)

Other disclosures, disclaimers and certificates

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