Acrux

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MST Access
A research platform of MST Financial

04 September 2024

Building Critical Mass

NEED TO KNOW

- **Growing portfolio with product launches ahead**
- **Diversification across niche markets underpins sustainability**
- **Cash on hand of $2.9m; net loss improving when non-recurring item stripped out**

Portfolio healthy, approvals progressing: Acrux's continued focus on flow through its pipeline is bearing fruit. The company continues to rack up achievements in its portfolio, covering 15 products from the development phase to marketed products. Acrux has received 2 approvals in CY24, and the FDA is assessing another 2 products.

Diversification on track: Acrux's strategy is to develop a diversified range of topical products that deliver sustainable revenue. Its product pipeline covers a wide range of indications and formulations.

FY24 result and cash on hand: When adjusted for a non-recurring item from FY23, revenue from client contracts increased to $5.1m in FY24 (including $3.9m in pass-through revenues related to raw materials). The net loss adjusted to exclude the one-time item and associated asset impairment improved by $1.9m yoy. Research and development expenses were lower than in FY23. At the end of FY24, Acrux held $2.9m in cash and cash equivalents.

Investment Thesis

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

Portfolio of approved products reaches critical mass: Acrux has 15 products in its portfolio, with 6 approved by the FDA and 4 commercialised.

Consistent record of commercialisation: Since incorporation in 1998, Acrux has been successful in developing formulations and bringing them to market via licensee partners in Europe and the US. A key aspect of its business model is the out-licensing of products to strategic partners, reducing commercialisation risk.

Valuation

Based on new IQVIA data, we have adjusted our valuation of Acrux, after taking into account changes in our estimates of the addressable markets for Dapsone 7.5% Gel, Dapsone 5% Gel, and Nitroglycerin 0.4% Ointment. As such, we value Acrux at $0.19 per share (previously $0.25 per share), using a DCF methodology, a discount rate of 12.3% and shares on issue of 290.7m.

Risks

Our valuation is most sensitive to approval timing, as well as 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$0.19** *(from A$0.25)*
Current price	**A$0.06**
Market cap	**A$18m**
Cash on hand	**A$2.9m** *(30 June 2024)*

Upcoming Catalysts / Next News

Period	
2HCY24	Dapsone 7.5% Gel for acne launch
2HCY24	Nitroglycerine 0.4% Ointment launch
2HCY24	Acyclovir 5% Cream launch

Share Price (A$)

Source: FactSet, MST Access.

Report prepared by MST Access, a registered business name of MST Financial services ABN 617 475 180 AFSL 500 557.
This report has been prepared and issued by the named analyst of MST Access in consideration of a fee payable by: Acrux (ACR.AX)

Acrux Ltd — ACR-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	**$**	**0.06**
52 week high / low	$	0.04-0.08
Valuation	**$**	**0.19**
Market capitalisation	$m	17.7
Shares on issue (basic)	**m**	290.7
Options / rights	m	14.0
Other equity	m	0.0
Shares on issue (diluted)	**m**	**304.8**

12-MONTH SHARE PRICE PERFORMANCE (A$)

INVESTMENT FUNDAMENTALS		FY23A	FY24A	FY25E	FY26E	FY27E
Reported NPAT	$m	(0.8)	(5.8)	(3.4)	2.5	4.9
Underlying NPAT	**$m**	**(0.8)**	**(5.8)**	**(3.4)**	**2.5**	**4.9**
Reported EPS (diluted)	¢	(0.3)	(2.0)	(1.2)	0.9	1.7
Underlying EPS (diluted)	**¢**	**(0.3)**	**(2.0)**	**(1.2)**	**0.9**	**1.7**
Growth	%					
Underlying PER	**x**	**nm**	**nm**	**nm**	**7.0**	**3.6**
Operating cash flow per share	¢	0.2	(1.5)	(1.0)	1.0	1.8
Free cash flow per share	¢	0.2	(1.6)	(1.1)	0.9	1.7
Price to free cash flow per share	**x**	**29.9**	**nm**	**nm**	**6.8**	**3.6**
FCF Yield	%	3.3%	nm	nm	14.6%	27.7%
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**	**11.5**	**11.5**	**16.3**	**19.7**	**17.3**
EV/EBITDA	x	44.1	nm	nm	6.9	3.4
EV/EBIT	x	nm	nm	nm	7.8	3.6
Price to book (NAV)	x	2.0	5.4	(80.5)	7.6	2.5
Price to NTA	x	2.6	12.0	(8.7)	34.5	3.3

KEY RATIOS		FY23A	FY24A	FY25E	FY26E	FY27E
ROE	%	nm	nm	nm	109.5	67.8
ROA	%	nm	nm	nm	27.5	35.1
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)	1.9	(0.5)

DUPONT ANALYSIS		FY23A	FY24A	FY25E	FY26E	FY27E
Return on Assets	%	nm	nm	nm	27.5	35.1
Leverage	x	1.5	2.7	(31.3)	4.0	1.9
Return on Equity	%	nm	nm	nm	109.5	67.8

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**	**2.2**	**3.0**	**3.0**
Operating expenses	$m	12.1	17.1	12.1	12.1	12.1
EBITDA	**$m**	**0.3**	**(5.2)**	**(3.0)**	**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	$m	0.1	0.1	0.1	0.0	0.1
Pretax Profit	**$m**	**(0.2)**	**(5.6)**	**(3.4)**	**2.5**	**4.9**
Tax expense	$m	(0.6)	(0.2)	0.0	0.0	0.0
Reported NPAT	**$m**	**(0.8)**	**(5.8)**	**(3.4)**	**2.5**	**4.9**
Underlying NPAT	$m	(0.8)	(5.8)	(3.4)	2.5	4.9
Weighted average diluted shares	m	286.5	289.5	290.7	290.7	290.7

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	1.1	3.4	8.2
Receivables	$m	0.4	0.1	0.1	0.1	0.1
Current assets	**$m**	**9.9**	**6.0**	**4.1**	**6.5**	**11.2**
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**	**6.9**	**9.3**	**14.0**
Trade and other payables	$m	0.8	0.9	0.8	0.8	0.8
Other	$m	1.6	2.9	4.4	4.4	4.4
Current liabilities	**$m**	**2.4**	**3.7**	**5.2**	**5.2**	**5.2**
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	**$m**	**4.6**	**5.7**	**7.1**	**6.9**	**6.7**
Net assets	**$m**	**8.7**	**3.3**	**(0.2)**	**2.3**	**7.2**
Share capital	$m	114.9	115.0	114.9	114.9	114.9
Retained earnings	$m	(114.5)	(120.3)	(123.7)	(121.1)	(116.2)
Other	$m	8.3	8.6	8.6	8.6	8.6
Total equity	**$m**	**8.7**	**3.3**	**(0.2)**	**2.3**	**7.2**

CASH FLOW		FY23A	FY24A	FY25E	FY26E	FY27E
Net profit (loss) for period	**$m**	**(0.8)**	**(5.8)**	**(3.4)**	**2.5**	**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	0.0	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**	**1.3**	**(0.2)**	**(0.2)**
Cash year end	**$m**	**6.2**	**2.9**	**1.1**	**3.4**	**8.2**
Free cash flow	**$m**	**0.6**	**(4.6)**	**(3.2)**	**2.6**	**4.9**

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FY24 result

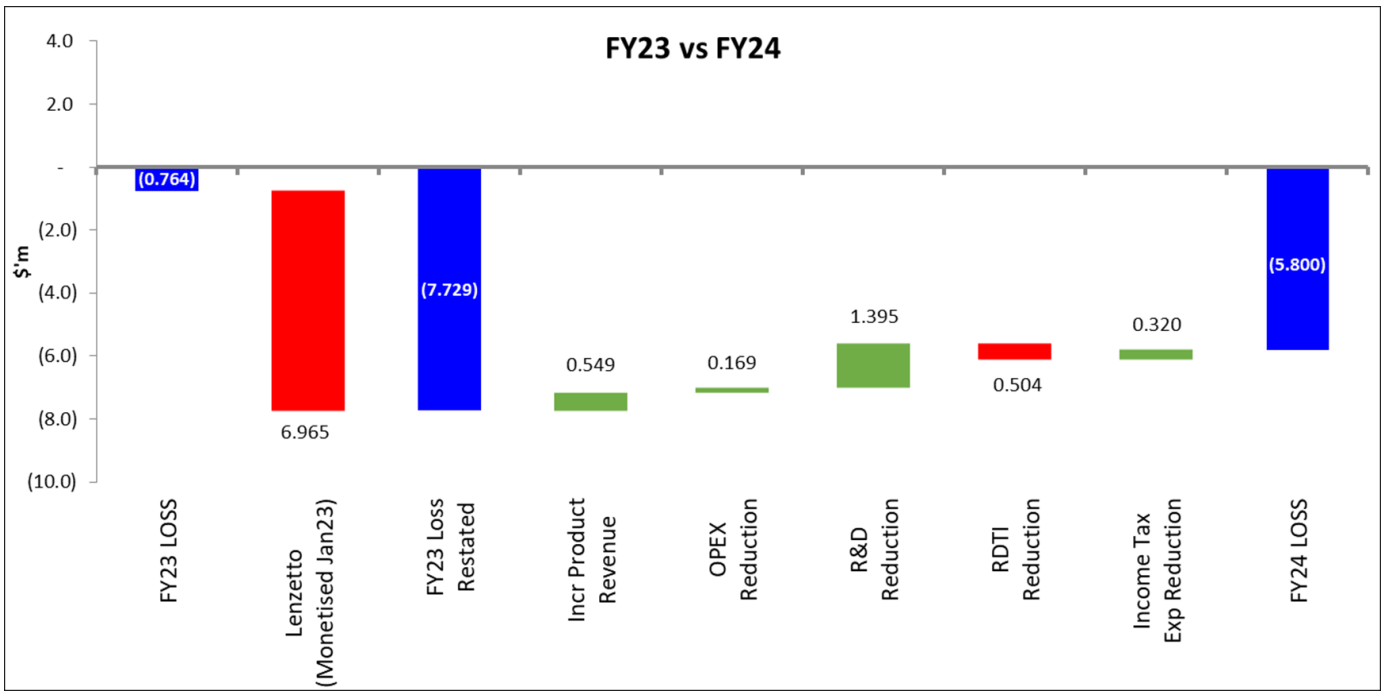
Acrux reported total revenue of $8.1m in FY24, a decrease of $3.8m from the previous year. However, we note that this decline was primarily due to the absence of the one-time $6.3m gain realised in FY23 from the monetisation of the future Lenzetto® royalty stream.

When adjusted for this non-recurring item, and 6 months of Lenzetto® royalty income in FY23, revenue from client contracts increased to $5.1m in FY24, including $3.9m in pass-through revenues related to raw materials. Excluding the impact of Lenzetto® in FY23, underlying client-based profit share and royalty revenue grew from $0.585m to $1.134m.

Research and development expenses were lower yoy due to Acrux being more focused on supporting the FDA's ongoing evaluation of 2 products and early-stage development of 7 others during the period, activities which incur fewer expenses.

The net loss before tax for FY24 was $5.8m, a deterioration of $5.0m compared to the prior year. However, excluding the impact of the one-time Lenzetto® monetisation and associated asset impairment, the underlying net loss before tax improved by $1.9m. At the end of FY24, Acrux held $2.9m in cash and cash equivalents.

Figure 1: Key financials

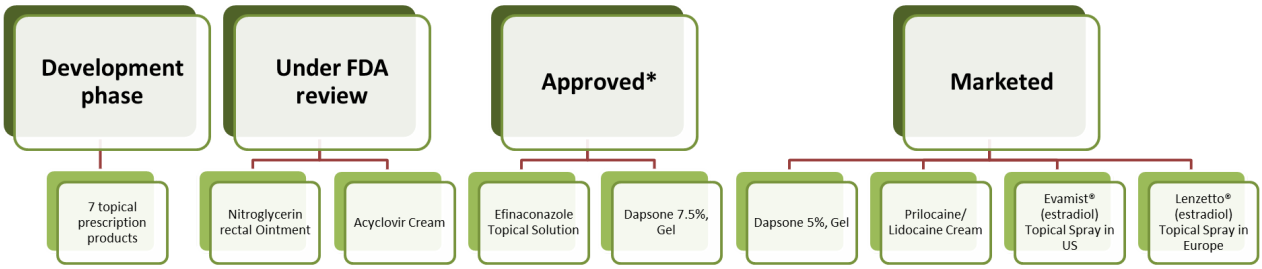


Source: Acrux, MST Access.

Pipeline progress

Acrux now has a diversified portfolio of 15 products, with 9 actively under development, including 2 in the late stages of FDA review. Additionally, 4 products are currently marketed, while 2 others have been approved but have not yet been launched.

Figure 2: Acrux topical product portfolio



*Source: Acrux (*Efinaconazole Topical Solution US launch date is based on Paragraph IV IP settlement).*

Strategy on track

The company's strategy is centred on developing a diversified range of topical products that deliver sustainable revenue within the market. Additionally, the company is committed to maintaining a robust product development pipeline to ensure a continuous flow of regulatory submissions, approvals, and subsequent product launches.

Key achievements

- Acrux successfully submitted Nitroglycerin 0.4% Ointment to the FDA for review at the beginning of the fiscal year. Upon approval, the Nitroglycerin 0.4% Ointment product will be indicated for the treatment of moderate to severe pain associated with anal fissure. This marked the company's seventh regulatory dossier submission since 2017. The Nitroglycerin 0.4% Ointment product is currently undergoing FDA review, along with one other Acrux product, Acyclovir 5% Cream. Acyclovir 5% Cream is a treatment for cold sores.
- In April 2024, Dapsone 5% Gel was launched into the United States market following FDA approval. This product is indicated for the treatment of acne vulgaris.
- In August 2024, Acrux received FDA approval for Dapsone 7.5% Gel, also intended for the treatment of acne vulgaris.

Upcoming launches

- 2HCY24 – Dapsone 7.5% Gel for acne
- 2HCY24 – Nitroglycerin 0.4% Ointment for pain from anal fissure
- 2HCY24 – Acyclovir 5% Cream for cold sores

Valuation

Based on new IQVIA data, we have adjusted our valuation of Acrux, taking into account changes in our estimates of the addressable markets and therefore market potential for Dapsone 7.5% Gel, Dapsone 5% Gel, and Nitroglycerin 0.4% Ointment. (IQVIA Inc. is a US-based multinational company and a leading global provider of market sales value and volume data to the pharmaceutical industry.)

As such, we value Acrux at $0.19 per share (previously $0.25 per share), using a DCF methodology on free cash flow. Key DCF inputs are a 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.

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 7 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 3: 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$m	**(5.0)**	**(3.0)**	**2.8**	**5.1**	**7.2**	**7.9**	**8.4**	**8.6**	**8.8**	**8.9**	**8.9**
Less capex	A$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)**	**(3.3)**	**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$m	70.3										
NPV of terminal value	A$m	22.0										
PV of cash flows	A$m	50.1										
PLUS: Value of investments	A$m	-										
LESS: Net debt	A$m	(6.2)										
Equity value	**A$m**	**56.3**										
Ordinary shares	m	290.7										
Value per share	**A$**	**0.19**										

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.

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$2.9m as of 30 June 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.

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The companies and securities mentioned in this report, include:

Acrux (ACR.AX) | Price A$0.06 | Valuation A$0.19;

Price and valuation as at 04 September 2024 (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

Methodology & Disclosures

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