Acrux

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09 December 2024

FDA approves 6th topical ANDA

NEED TO KNOW

- Nitroglycerin Ointment, 0.4% approved by US FDA
- Annual addressable market sales now over US$23m for this product
- Substantial capital raise targets $4.65m

Nitroglycerin Ointment, 0.4% go-ahead represents Acrux's 6th topical ANDA approval: Acrux has announced that the US Food and Drug Administration (FDA) has approved the company's Nitroglycerin Ointment, 0.4%, a generic version of Rectiv(R) (a treatment for moderate to severe anal fissure pain). The market for this product is growing in the United States, with annual sales of the branded product plus the current generic exceeding US$23m.

Capital raise targeting $4.65m to advance key products in development: Acrux has also announced a share placement (with commitments already obtained for $2.65m) and a planned share purchase plan (SPP) (targeting $2m), equating to a total capital raise target of $4.65m. The company intends to use the funds to advance 4 specific products which are in the later development stages at contract manufacturers, preparing them for dossier submission to the FDA. Each share in the placement and SPP will be accompanied by an attaching option, with an exercise price of 5.25 cents and expiry in 2 years. Shares on issue will grow to 422.8m (from 290m currently), including 132.9m options (from zero currently).

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 transdermal/ topical generic market is generally less competitive than the much larger oral generic market.

Acrux's portfolio of approved products reaches critical mass: It has 15 products, 6 of which have been approved by the FDA and 4 of which have been commercialised.

Solid track record: Since incorporation in 1998, Acrux has successfully developed formulations and brought 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

Our revised fully diluted valuation Acrux stands at $0.11 per share (previously $0.19 per share undiluted) based on increase in shares on issue and issue of attached options post capital raise (see valuation section for details).

Risks

Our valuation is most sensitive to approval timing and commercial launch, as well as the ultimate pricing achieved given the number of competitors in specific product markets.

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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$0.11** *(from A$0.19)*
Current price	**A$0.04**
Market cap	**A$12m**
Cash on hand	**A$1.1m** *(30 Sep 2024)*

Upcoming Catalysts / Next News

Period	
2HCY24	Nitroglycerine 0.4% Ointment launch
1QCY25	Dapsone 7.5% Gel for acne launch
1HCY25	Acyclovir 5% Cream approval

Share Price (A$)

Source: FactSet, MST Access

Acrux Ltd — ACR-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA			
Price	**$**	**0.04**	
52 week high / low	$	0.04-0.08	
Valuation	**$**	**0.13**	
Market capitalisation	$m	12.0	
Shares on issue (basic)	**m**	422.8	*post capital raise*
Options / rights	m	146.9	*includes 14m directors rights*
Other equity	m	0.0	
Shares on issue (diluted)	**m**	**569.7**	

12-MONTH SHARE PRICE PERFORMANCE (A$)

INVESTMENT FUNDAMENTALS		FY23A	FY24A	FY25E	FY26E	FY27E
Reported NPAT	$m	(0.8)	(5.8)	(3.3)	2.6	5.0
Underlying NPAT	**$m**	**(0.8)**	**(5.8)**	**(3.3)**	**2.6**	**5.0**
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**	**6.6**	**3.5**
Operating cash flow per share	¢	0.2	(1.5)	(1.0)	0.7	1.2
Free cash flow per share	¢	0.2	(1.6)	(1.1)	0.6	1.2
Price to free cash flow per share	**x**	**20.1**	**nm**	**nm**	**6.5**	**3.5**
FCF Yield	%	5.0%	nm	nm	15.5%	28.9%
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**	**5.8**	**5.8**	**10.5**	**9.5**	**7.0**
EV/EBITDA	x	22.1	nm	nm	3.3	1.4
EV/EBIT	x	nm	nm	nm	3.8	1.5
Price to book (NAV)	x	1.3	3.6	(67.4)	7.0	2.3
Price to NTA	x	1.8	8.1	5.0	3.5	1.7

KEY RATIOS		FY23A	FY24A	FY25E	FY26E	FY27E
ROE	%	nm	nm	nm	107.2	67.0
ROA	%	nm	nm	nm	19.2	26.9
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)	(5.0)

DUPONT ANALYSIS		FY23A	FY24A	FY25E	FY26E	FY27E
Return on Assets	%	nm	nm	nm	19.2	26.9
Leverage	x	1.5	2.7	(64.0)	5.6	2.5
Return on Equity	%	nm	nm	nm	107.2	67.0

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

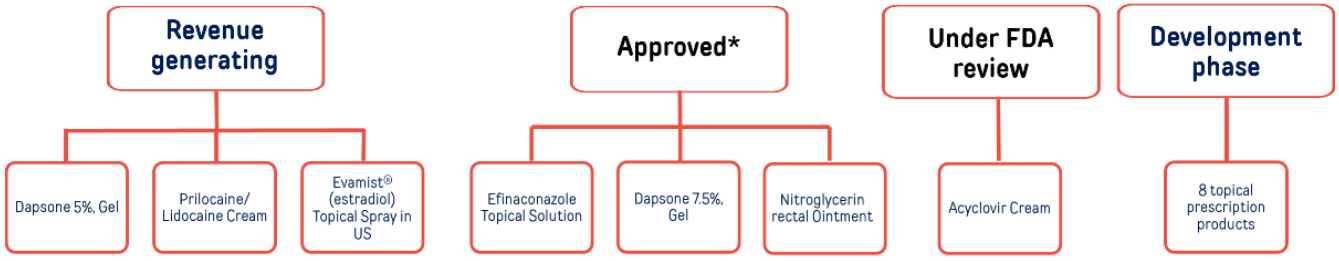
PROFIT AND LOSS		FY23A	FY24A	FY25E	FY26E	FY27E
Revenue	**$m**	**8.4**	**5.1**	**6.9**	**11.9**	**14.2**
Other income	**$m**	**3.4**	**2.9**	**2.3**	**3.0**	**3.0**
Operating expenses	$m	12.1	17.1	12.1	12.1	12.1
EBITDA	**$m**	**0.3**	**(5.2)**	**(2.9)**	**2.8**	**5.1**
Depreciation & Amortisation	$m	0.6	0.5	0.4	0.3	0.3
EBIT	**$m**	**(0.3)**	**(5.7)**	**(3.4)**	**2.5**	**4.8**
Net interest	$m	0.1	0.1	0.1	0.1	0.2
Pretax Profit	**$m**	**(0.2)**	**(5.6)**	**(3.3)**	**2.6**	**5.0**
Tax expense	$m	(0.6)	(0.2)	0.0	0.0	0.0
Reported NPAT	**$m**	**(0.8)**	**(5.8)**	**(3.3)**	**2.6**	**5.0**
Underlying NPAT	$m	(0.8)	(5.8)	(3.3)	2.6	5.0
Weighted average diluted shares	m	286.5	289.5	290.7	422.8	422.8

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	5.5	8.0	12.8
Receivables	$m	0.4	0.1	0.1	0.1	0.1
Current assets	**$m**	**9.9**	**6.0**	**8.5**	**11.0**	**15.8**
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**	**11.3**	**13.8**	**18.6**
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**	**4.2**	**6.8**	**11.8**
Share capital	$m	114.9	115.0	114.9	114.9	114.9
Retained earnings	$m	(114.5)	(120.3)	(123.6)	(121.0)	(116.0)
Other	$m	8.3	8.6	8.6	8.6	8.6
Total equity	**$m**	**8.7**	**3.3**	**(0.2)**	**2.5**	**7.5**

CASH FLOW		FY23A	FY24A	FY25E	FY26E	FY27E
Net profit (loss) for period	**$m**	**(0.8)**	**(5.8)**	**(3.3)**	**2.6**	**5.0**
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)**	**3.0**	**5.3**
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**	**5.7**	**(0.2)**	**(0.2)**
Cash year end	**$m**	**6.2**	**2.9**	**5.5**	**8.0**	**12.8**
Free cash flow	**$m**	**0.6**	**(4.6)**	**(3.2)**	**2.7**	**5.0**

Figure 1: Acrux topical product portfolio



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

* Lenzetto® is marketed in ex-US and the Acrux royalty stream was monetised in FY23

Source: Acrux

Strategy on track

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

Key achievements

- Nitroglycerin 0.4% Ointment product will be indicated for the treatment of moderate to severe pain associated with anal fissure. Its approval markthe company's seventh regulatory dossier submission since 2017. The Acyclovir 5% Cream product is currently undergoing FDA review, 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 – Nitroglycerin 0.4% Ointment for pain from anal fissure
- 1QCY25 – Dapsone 7.5% Gel for acne
- 1HCY25 – Acyclovir 5% Cream for cold sores (pending approval)

Capital raising

Acrux aims to raise a total of $4.65m (pre-costs) through the Placement and SPP to fund the advancement of four key pharmaceutical products in its pipeline. The offer price for the capital raising is 3.5 cents per new share, representing a 19.35% discount to the 5-day VWAP of 4.34 cents per share to 3 December 2024. Placement and SPP participants will be offered one free attaching option for every share subscribed for.

Figure 2: Use of funds (indicative)

Use of Proceeds	Amount (A$m)
Analytical Method development, validation and verification	2.45
Demonstration of bioequivalence	0.80
Validation of manufacturing processes and process optimisation	0.50
Manufacture of engineering and registration batches	0.60
Capital raising expenses	0.30
Aggregate use of proceeds raised from the Placement and SPP	4.65

Source: Acrux

Valuation

We have revised our valuation given the capital raising and revised our shares on issue and options assumptions to reflect the following:

- **Increase in Share Capital**: Acrux will issue 132.9m new shares to raise $4.65m through a combined Placement and Share Purchase Plan (SPP), increasing the total number of shares on issue from 290m to 422.8m.
- **Option Issuance**: Concurrently, Acrux will issue 132.9m options on a 1:1 basis with the new shares. These options will have an exercise price of 5.25 cents and expire 2 years after issuance.
- Cost of capital raising of 6%
- **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.
- Our revenue forecasts include the Nitroglycerin product and therefore remain unchanged.

As such, we value Acrux at $0.13 per share based on shares on issue of 422.8m (previously $0.19 per share based on 290m shares on issue), using a DCF methodology on free cash flow.

On a fully diluted basis, we value Acrux at $0.11 per share based on shares on issue of 422.8m and options outstanding of 132.9m (previously zero options). This assumes options are all exercised and contribute approximately $7m to cash on hand.

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 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$m	**(5.0)**	**(2.9)**	**2.8**	**5.1**	**7.2**	**7.9**	**8.4**	**8.6**	**8.8**	**8.9**	**8.9**
Less capex	A$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$m	70.3										
NPV of terminal value	A$m	22.0										
PV of cash flows	A$m	50.1										
PLUS: Value of investments	A$m	-										
LESS: Net debt	A$m	(5.8)										
Equity value	**A$m**	**55.8**										
Ordinary shares	m	422.8										
Value per share	**A$**	**0.13**										

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.

Company disclosures

The companies and securities mentioned in this report, include:

Acrux (ACR.AX) | Price A$0.04 | Valuation A$0.11;

Price and valuation as at 09 December 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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