Acrux Limited

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5 March 2024

Dapsone 5% gel launch imminent; expecting strong 2HFY24

NEED TO KNOW

- Dapsone 5% gel launch imminent
- 1HFY24 result: 19% decrease in operating expenses
- API cost of goods pass-through bodes well for 2HFY24 sales of Prilocaine/Lidocaine

Dapsone 5% launch to add in 2HFY24: The imminent launch of Dapsone 5% gel and potential approval of the 3 dossiers currently under FDA review bode well for revenue growth in FY24. Moreover, Acrux has another 6 undisclosed products in development.

1HFY24 result: Operating expenses in 1HFY24 amounted to $4.71m, a decrease of $1.13m (down 19%) compared to the previous corresponding period. This company primarily attributed this reduction to the timing of external research and development project costs resulting from the stage of project development within the product development cycle. The net loss after tax for the period was $3.2m, slightly lower than the net loss of $3.3m in 1HFY23. As of 31 December 2023, Acrux had cash on hand of $4.6m, compared to $6.2m at the end of June 2023.

API sales bode well for scale-up of Prilocaine/Lidocaine: Under the commercialisation agreement with Padagis, Acrux presently manages the acquisition of the active pharmaceutical ingredients (APIs) essential for the manufacture of Prilocaine 2.5% and Lidocaine 2.5% cream. While the revenues in 1HFY24 from the APIs are simply a pass-through from COGS, this first reporting of this item is a good sign of sales for Prilocaine/Lidocaine in 2H.

Investment Thesis

Topical generic pharmaceuticals 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 16 products in its portfolio, of which 6 have been approved by the FDA and 4 commercialised.

Consistent record of commercialisation: Since incorporating 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 out-licensing of products to strategic partners, reducing commercialisation risk.

Valuation

We value Acrux at $0.25 per share (unchanged) using a DCF methodology, assuming a 12.3% discount rate and shares on issue of 288.7m.

Risks

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

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Pharmaceuticals, Biotechnology & Life Sciences

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Acrux is a specialty pharmaceutical company focused on developing and commercialising generic versions of topically applied prescription pharmaceuticals 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.

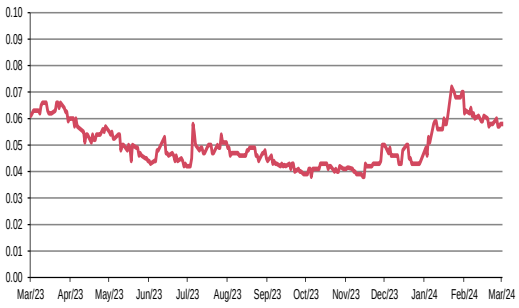
https://www.acrux.com.au/

Valuation	**A$0.25** *(unchanged)*
Current price	**A$0.06**
Market cap	**A$17m**
Cash on hand	**A$4.6m** *(31 December 2023)*

Upcoming Catalysts and Newsflow

Period	
1QFY24	Launch of Dapsone gel, 5%
2HFY24	Sales update of Prilocaine/Lidocaine
2HFY24	Pipeline progress, FDA approvals and ANDA filings

Share Price (A$)



Source: FactSet, MST Access.

Financial Summary

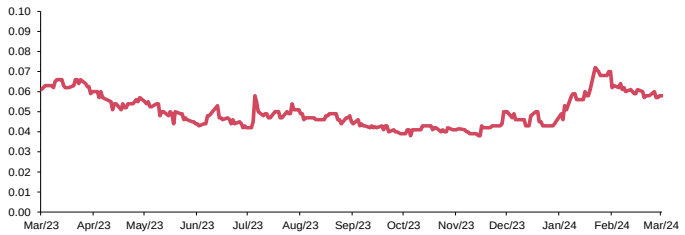
Acrux Ltd — ACR-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	**$**	**0.06**
52 week high / low	$	0.04-0.07
Valuation	**$**	**0.25**
Market capitalisation	$m	16.7
Shares on issue (basic)	**m**	288.7
Options / rights	m	0.0
Other equity	m	0.0
Shares on issue (diluted)	**m**	**288.7**

12-MONTH SHARE PRICE PERFORMANCE (A$)



INVESTMENT FUNDAMENTALS		FY22A	FY23A	FY24E	FY25E	FY26E
Reported NPAT	$m	(9.8)	(0.8)	(3.8)	2.4	10.4
Underlying NPAT	**$m**	**(9.8)**	**(0.8)**	**(3.8)**	**2.4**	**10.4**
Reported EPS (diluted)	¢	(3.5)	(0.3)	(1.3)	0.8	3.6
Underlying EPS (diluted)	**¢**	**(3.5)**	**(0.3)**	**(1.3)**	**0.8**	**3.6**
Growth	%					
Underlying PER	x	**nm**	**nm**	**nm**	**6.9**	**1.6**
Operating cash flow per share	¢	(3.1)	0.2	(1.2)	0.9	3.7
Free cash flow per share	¢	(3.3)	0.2	(1.2)	0.9	3.7
Price to free cash flow per share	**x**	**nm**	**28.4**	**nm**	**6.2**	**1.6**
FCF Yield	%	nm	3.5%	nm	16.1%	63.6%
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**	**10.9**	**10.5**	**14.1**	**11.6**	**1.1**
EV/EBITDA	x	nm	nm	nm	5.6	0.1
EV/EBIT	x	nm	nm	nm	4.9	0.1
Price to book (NAV)	x	1.8	1.9	3.4	2.3	0.9
Price to NTA	x	2.3	2.5	5.8	3.2	1.1

KEY RATIOS		FY22A	FY23A	FY24E	FY25E	FY26E
ROE	%	nm	nm	nm	33.0	58.7
ROA	%	nm	nm	nm	20.0	46.2
Net tangible assets per share	$	0.0	0.0	0.0	0.0	0.1
Book value per share	$	0.0	0.0	0.0	0.0	0.0
Net debt/(cash)	$m	(5.8)	(6.2)	(2.7)	(5.2)	(15.7)

DUPONT ANALYSIS		FY22A	FY23A	FY24E	FY25E	FY26E
Return on Assets	%	nm	nm	nm	20.0	46.2
Leverage	x	1.6	1.5	2.0	1.6	1.3
Return on Equity	%	nm	nm	nm	33.0	58.7

KEY PERFORMANCE INDICATORS	FY22A	FY23A	FY24E	FY25E	FY26E
Commercialised	3	4			
Approved	5	6			
Under review by FDA	3	3			
Under development	8	7			

HALF YEARLY DATA		2H21	1H22	2H22	1H23	2H23
Revenue	$m	0.5	0.7	1.0	1.4	7.0
Other income	$m	3.4	1.4	2.0	1.8	1.5
Operating expenses	$m	9.2	7.1	7.6	6.0	6.1
EBITDA	$m	(5.6)	(5.3)	(4.9)	(3.1)	2.2
EBIT	$m	(5.2)	(5.0)	(4.6)	(2.8)	2.4
PBT	$m	(4.9)	(5.3)	(4.9)	(3.1)	2.9
Reported NPAT	$m	(4.8)	(5.5)	(5.0)	(3.3)	2.5

Source: Company reports, MST Access estimates

PROFIT AND LOSS		FY22A	FY23A	FY24E	FY25E	FY26E
Revenue	**$m**	**1.7**	**8.4**	**6.5**	**12.3**	**20.2**
Other income	**$m**	**3.4**	**3.4**	**2.9**	**3.2**	**3.2**
Operating expenses	$m	14.7	12.7	13.3	13.1	13.1
EBITDA	**$m**	**(10.3)**	**(0.9)**	**(4.3)**	**2.1**	**10.0**
Depreciation & Amortisation	$m	0.7	0.6	0.4	0.3	0.3
EBIT	**$m**	**(9.6)**	**(0.3)**	**(3.9)**	**2.4**	**10.3**
Net interest	$m	0.0	0.1	0.1	0.1	0.1
Pretax Profit	**$m**	**(9.6)**	**(0.2)**	**(3.8)**	**2.4**	**10.4**
Tax expense	$m	(0.3)	(0.6)	0.0	0.0	0.0
Reported NPAT	**$m**	**(9.8)**	**(0.8)**	**(3.8)**	**2.4**	**10.4**
Weighted average diluted shares	m	283.9	286.5	288.7	288.7	288.7

GROWTH PROFILE		FY22A	FY23A	FY24E	FY25E	FY26E
Other income	%	(11.1)	0.3	(15.3)	12.4	0.0
EBITDA	%	(23.0)	(96.5)	1,076.0	(159.9)	337.0
EBIT	%	(21.9)	(90.9)	367.9	(147.4)	386.3
Reported NPAT	%	(22.1)	(92.2)	397.1	(163.5)	331.4

BALANCE SHEET		FY22A	FY23A	FY24E	FY25E	FY26E
Cash	$m	5.8	6.2	2.7	5.2	15.7
Receivables	$m	0.4	0.4	0.4	0.4	0.4
Current assets	**$m**	**10.0**	**9.9**	**6.3**	**8.8**	**19.3**
Leased assets	$m	1.9	2.0	2.0	2.0	2.0
Non current assets	**$m**	**4.3**	**3.4**	**3.2**	**3.2**	**3.2**
Total assets	**$m**	**14.3**	**13.3**	**9.6**	**12.0**	**22.5**
Trade and other payables	$m	0.9	0.8	0.8	0.8	0.8
Other	$m	2.4	1.6	1.6	1.6	1.6
Current liabilities	**$m**	**3.3**	**2.4**	**2.4**	**2.4**	**2.4**
Total liabilities	**$m**	**5.2**	**4.6**	**4.7**	**4.7**	**4.8**
Net assets	**$m**	**9.1**	**8.7**	**4.9**	**7.3**	**17.7**
Share capital	$m	114.6	114.9	114.9	114.9	114.9
Retained earnings	$m	(113.7)	(114.5)	(118.3)	(115.9)	(105.5)
Other	$m	8.3	8.3	8.3	8.3	8.3
Total equity	**$m**	**9.1**	**8.7**	**4.9**	**7.3**	**17.7**

CASH FLOW		FY22A	FY23A	FY24E	FY25E	FY26E
Net loss for period	**$m**	**(9.8)**	**(0.8)**	**(3.8)**	**2.4**	**10.4**
Depreciation & Amortisation	$m	0.7	0.6	0.4	0.3	0.3
Changes in working capital	$m	(0.4)	(0.3)	0.0	0.0	0.0
Other	$m	0.8	1.2	0.0	0.0	(0.0)
Operating cash flow	**$m**	**(8.8)**	**0.7**	**(3.4)**	**2.7**	**10.7**
Payments for PPE	$m	0.0	0.0	0.0	0.0	0.0
Investing cash flow	**$m**	**(0.5)**	**(0.1)**	**0.0**	**0.0**	**0.0**
Capital raising costs	$m	0.0	0.0	0.0	0.0	0.0
Lease liability prinicipal repayments	$m	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)
Financing cash flow	**$m**	**(0.2)**	**(0.2)**	**(0.2)**	**(0.2)**	**(0.2)**
Cash year end	**$m**	**5.8**	**6.2**	**2.7**	**5.2**	**15.7**
Free cash flow	**$m**	**(9.3)**	**0.6**	**(3.4)**	**2.7**	**10.7**

FY24 Forecast Unchanged: Profit-Share Income from Padagis Agreement to Flow in 2H

1HFY24 result

Acrux reported 1HFY24 total revenue of $5.8m (see Figure 1), which included a Research and Development Tax Incentive payment of $1.3m for FY23 and active pharmaceutical ingredients (API) sales revenue of $3.9m. Notably, under the commercialisation agreement with Padagis, Acrux presently manages the acquisition of the APIs essential for the manufacture of Prilocaine 2.5% and Lidocaine 2.5% cream. These API procurement expenses are documented under cost of goods sold and subsequently billed to Padagis, contributing to the overall sales revenue. As such, while this item is essentially a pass through, it does bode well for product-related revenue in 2HFY24 related to profit-share income associated with Prilocaine 2.5% and Lidocaine 2.5% cream which is marketed by Padagis in the United States (launched in December 2022).

Operating expenses totalled $4.71m, representing a decrease of $1.13m or 19% compared to the previous corresponding period. This decline was mainly due to the timing of external research and development project costs, which vary depending on the stage of project development within the product development cycle. The net loss after tax was $3.2m versus a net loss of $3.3m in 1HFY23. Cash on hand at 31 December 2023 totalled $4.6m, compared with $6.2m at 30 June 2023.

Figure 1: 1HFY24 result: key items

$000's	1H23	1H24	Comments
Product licensing income	954	481	
Sales Revenue - API	467	3,928	Acrux presently manages the acquisition of the API for the commercial production of Prilocaine 2.5% and Lidocaine 2.5% Cream, so this is effectively a pass through item as reflected in the COGS
R&D Incentive Rebate	1,800	1,285	
Interest Received	28	83	
Total revenue	**3,249**	**5,777**	
Cost of Goods Sold	493	3,928	see above
Operating Expenses			
External R&D	1,926	1,147	Decline was mainly due to the timing of external research and development project costs
Employee and NED Benefits	2,934	2,780	
Other Expenses	979	784	
	5,840	4,711	
Profit/(Loss) Before Tax	- 3,083	- 2,862	
Income Tax Expense	211	378	
Profit/(Loss) After Tax	**- 3,294**	**- 3,240**	

Source: Acrux.

Valuation

We value Acrux at $0.25 per share (unchanged), using a DCF methodology on free cash flow (see Figure 2). Key DCF inputs are a beta of 1.22, a 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.

- Prilocaine 2.5% and Lidocaine 2.5% – on the market
- Dapsone 5% gel – imminent launch
- Dapsone 7.5% gel – under review by FDA
- Acyclovir 5% cream – under review by FDA
- Nitroglycerin ointment 0.4% – under review by FDA

We assume each product partner will absorb of 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 average revenue contribution of around $3m per product per annum and development timelines of around 5 years, we note that the contribution to 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-23	Jun-24	Jun-25	Jun-26	Jun-27	Jun-28	Jun-29	Jun-30	Jun-31	Jun-32	Jun-33
EBIT	A$m	(0.3)	(3.9)	2.4	10.3	10.3	10.3	10.3	10.3	10.3	10.3	10.3
Tax at standard rate	A$m	**(0.6)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Post-tax EBIT	A$m	**0.2**	**(3.9)**	**2.4**	**10.3**	**10.3**	**10.3**	**10.3**	**10.3**	**10.3**	**10.3**	**10.3**
Depreciation & Amortization	A$m	0.7	0.7	0.6	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Post-tax cash flow	A$m	**0.9**	**(3.3)**	**2.9**	**10.7**	**10.6**	**10.6**	**10.6**	**10.5**	**10.5**	**10.5**	**10.5**
Less capex	A$m	(0.5)	(0.1)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)
Less change in working capital	A$m	(0.3)	(0.4)	(0.3)	-	-	-	-	-	-	-	-
Free cash flow	A$m	**0.1**	**(3.8)**	**2.4**	**10.5**	**10.3**	**10.3**	**10.3**	**10.3**	**10.3**	**10.3**	**10.3**
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		**(3.4)**	**1.9**	**7.4**	**6.5**	**5.8**	**5.1**	**4.6**	**4.1**	**3.6**	**3.2**

Sum of discount streams	A$m	38.7	**CAPM**			
Terminal growth	%	0.0%	Risk free rate	%	5.0%	5.0%
Future value into perpetuity	A$m	83.6	Equity beta	x	1.22	1.22
NPV of terminal value	A$m	26.2	Equity risk premium	%	6.0%	6.0%
PV of cash flows	A$m	64.9	Cost of equity	%	12.3%	12.3%
PLUS: Value of investments	A$m	-	Debt	%	0%	0%
LESS: Net debt	A$m	(6.2)	Equity	%	100%	100%
Equity value	**A$m**	**71.1**	Interest rate	%	3.0%	3.0%
Ordinary shares	m	288.7	Tax rate	%	30%	30%
Value per share	**A$**	**0.25**	WACC	%	12.3%	12.3%

Source: MST Access.

Notwithstanding pricing dynamics in each product market, our valuation is most sensitive to assumptions relating to gross margin and discount rate used in our DCF methodology. Figure 3 shows the impact of varying these two elements to our valuation.

Figure 3: Sensitivity matrix – Varying discount rate vs gross margin

Discount rate \ Gross margin	50.0%	60.0%	70.0%	80.0%	90.0%
12.0%	0.18	0.25	0.33	0.36	0.42
12.3%	0.17	0.25	0.32	0.35	0.40
13.0%	0.16	0.23	0.30	0.33	0.38

Source: MST Access estimates.

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 in order 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 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 has 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 results makes it difficult to assess competitor pipelines prior to 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 also allow entry of generic manufacturers and also disrupt pricing dynamics of product target markets.

Lastly, Indian and Chinese generic manufacturers often compete on the basis of 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 the 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 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 to be used as a tax offset for the shareholder.

Funding: Notwithstanding cash of A$4.6m as of 31 December 2023, growing revenues from the launch of new products and 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 sharing of costs.

Appendix: Glossary

Figure 4: Glossary

Term	Abbreviation	Description
Abbreviated New Drug Application	ANDA	An application for a generic drug approval for an existing approved drug, submitted for review to the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs. In order to achieve approval, applicants must demonstrate bioequivalence to the innovator drug. Once approved, an applicant may manufacture and market the generic drug product in the US. All approved products are listed in FDA's Orange Book.
Active pharmaceutical ingredient	API	The therapeutically active component in a medicine's final formulation which is responsible for its physiological action. Also known as active drug substance.
Acyclovir 5%, cream		Indicated in the US for the topical treatment of cold sores.
Addressable market		Total market sales value and volume of a pharmaceutical product in a specific dosage form. This market data is purchased from IQVIA.
Authorized generic drugs		Typically marketed by the brand-name drug company or company with the brand's permission but as a generic at a lower cost, considered a tactic to address generic competition in the first instance.
Bioequivalence/ bioavailability		Bioequivalence studies compare the bioavailability of the proposed drug product with the Reference Listed Drug (RLD) containing the same active ingredient. Bioavailability is the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of drug action. As such, bioequivalence is the absence of a significant difference in the rate and extent to which the drug substance becomes available at the site of drug action when administered at the same dose under similar conditions.
Contract Manufacturing Organisation	CMO or CDMO	Serves other companies in the pharmaceutical industry on a contract basis to provide services that may range from drug development services to commercial manufacturing.
Contract Research Organisation	CRO	Provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. CROs may be involved in all aspects of the clinical development process, from initial drug discovery through preclinical and clinical trials and regulatory approval.
Dapsone gel		Indicated in the US for the topical treatment of acne vulgaris.
Estradiol		A form of estrogen (a female sex hormone produced by the ovaries); used to treat symptoms of menopause.
Evamist®		Brand name for Acrux's unique Estradiol spray product in the US. The Evamist® trademark is owned by Lumara Health and sublicensed to Padagis.
Food and Drug Administration	FDA	The government body that ensures safe and effective drugs are available to improve the health of people in the US. It regulates and supervises prescription, over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals and veterinary products.
Generic Drug User Fee Act	GDUFA	Introduced in 2012 to create an evidence-, research-, and science-based standards-setting program for the FDA. In the first few years of GDUFA, approximately 800 Product-Specific Guidances (PSGs) were published. These documents 'identify the methodology for developing generic drugs and generating evidence needed to support generic approval.' PSGs contain recommendations on complex in-vitro and in-vivo release testing, among other topics.
Gedeon Richter		Acrux's licensee for Lenzetto®; a major international pharmaceutical company headquartered in Hungary.
Good Manufacturing Practice	GM or cGMP (current Good Manufacturing Practice)	The aspect of quality assurance that ensures medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.
In-vitro permeation testing	IVPT	In-vitro permeation testing studies across biological membranes for formulations that are applied to the skin are vital to guide product development and establish product bioequivalence. IVPT is a critical tool for understanding drug delivery into the various layers of skin and can aid in formulation selection.
In-vitro release testing	IVRT	Measurement of drug release from dosage forms applied topically for the purpose of bioequivalence testing. IVRT allows for targeted and systematic drug development and guides the establishment of therapeutic equivalence. IVRT involves subjecting the drug formulation to conditions that will induce drug release across a membrane and quantifying the amount of drug released under those conditions.
IQVIA		A US-based multinational company which provides, on a subscription basis, pharmaceutical industry-leading sales data.
Lenzetto®		Brand name for Acrux's unique Estradiol Spray in the European Union and other countries. The Lenzetto® trademark is owned by Gedeon Richter.
Nitroglycerin 0.4% ointment		Indicated in the US for moderate to severe pain associated with chronic anal fissure.
Orange Book		The publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, identifies drug products approved on the basis of safety and effectiveness by the FDA and related patent and exclusivity information.
Padagis		A pharmaceutical manufacturer that offers high-quality generic and specialised pharmaceutical and OTC products that meet strict standards of quality and safety. Padagis' line of extended topicals includes prescription creams, ointments, suspensions, gels, foams, sprays, patches, nasal, and suppositories and is a market leader in that segment in the US.
Paragraph IV		Under this section of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, a company can seek FDA approval to market a generic drug before the expiration of patents related to the brand-name drug that the generic seeks to copy.

Pooled Development Fund	PDF	The Pooled Development Fund Act 1992 was established by the Australian Government to increase the supply of capital to small and medium-sized Australian enterprises to enable them to grow and develop their own markets, creating industry and jobs for Australia. To incentivise investors, a concessional tax regime was established for those companies that were registered as Pooled Development Funds (PDFs).
Prilocaine 2.5% and Lidocaine 2.5%, Cream		Indicated in the US as a topical anaesthetic for use on normal, intact skin for local analgesia or genital mucous membranes for superficial minor surgery and as pre-treatment for infiltration anaesthesia.
Product-Specific Guidance	PSG	To facilitate generic drug product availability and identify the most appropriate methodology for developing drugs and generating evidence to support ANDA approval, the FDA publishes product-specific guidance describing its current thinking and expectations on how to develop generic drug products therapeutically equivalent to specific reference-listed drugs.
Route of administration – enteral		Includes oral, sublingual, buccal and rectal administration
Route of administration – parenteral		All injections which Includes intravenous, intramuscular, subcutaneous, and intraarterial administration
Route of administration – other		Includes trans-nasal, inhalation, vaginal, transdermal and topical administration. Note that Acrux's focus is on transdermal and topical drugs (including the under-arm route)
Transdermal		A route of administration wherein active pharmaceutical ingredients are delivered across the skin for systemic distribution.
Topical		A route of administration wherein active pharmaceutical ingredients are applied to or affect a localised area of the body.

Source: Acrux, MST Access.

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