

Acrux (ASX: ACR)

1H FY18 results

20 February 2018

Forward looking statements

This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Acrux to be materially different from the statements in this presentation.

Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and effects of regulatory actions, the strength of competition, the outcome of legal proceedings and the effectiveness of patent protection.

1H FY18 outcomes

Cash reserves	31 December 2017: \$32.36m 30 June 2017: \$33.97m
Net (Loss)/Profit After Tax	1H 2018: \$(8.69)m includes a non-cash impairment loss of \$(5.65)m 1H 2017: \$6.32m
Royalty revenue	1H FY18: \$2.42m 1H 2017: \$13.97m
Pipeline progress	At end December 2017, Acrux had 10 products in active development all of which are targeting the topical generic market in the United States

Half year profit and loss

	Half Year Ending		
	31 December 2017	31 December 2016	
	\$'000	\$'000	%
Royalty revenue	2,420	13,969	(82.7%)
Interest & other income	323	359	(10.0%)
Total	2,743	14,328	(80.9%)
R&D investment	(5,303)	(3,551)	49.3%
Other operating costs	(1,682)	(936)	79.7%
Non operating costs	(448)	(791)	(43.3%)
Total expenses	(7,433)	(5,278)	40.8%
Operating (loss) / profit before impairment loss and income tax	(4,690)	9,050	(151.8%)
Impairment loss	(5,647)	-	-
Operating (loss)/profit before income tax	(10,337)	9,050	(214.2%)
Income tax benefit / (expense)	1,643	(2,728)	(160.2%)
Net (loss)/profit for the half-year	(8,694)	6,322	(237.5%)
Earnings per share			
Basic (loss)/earning per share	(0.05) cents	0.04 cents	
Cash reserves	32,363	33,974	(4.7)%

- Royalty revenue from Axiron® decreased 84.3% to \$2.2m reflecting a decline in global sales by our partner Eli Lilly and Company due to generic competition and the termination of the licensing agreement
- R&D investment was \$5.30m, up 49.3% on prior half year due to the increase in expenditure on our generic pipeline
- Other operating costs were \$1.68m, up 79.7% on prior half year materially due to non-recurring legal fees of \$0.70 million associated with the Axiron® patent appeal litigation
- Non operating costs are comprised of depreciation and amortisation
- Impairment loss is a result of a reassessment of the estimated future discounted cashflows from Axiron®. The assessment included consideration of termination of Axiron® licensing agreement and U.S. Court of Appeals for the Federal Circuit decision.
- Income tax benefit of \$1.64m is attributable to the lower operating profit (excluding the impairment loss) and the reversal of the deferred tax liability associated with the impaired portion of Axiron® capitalised development costs not being realised as initially contemplated

Half year cash flow

	Half Year Ending		
	31 December 2017	31 December 2016	
	\$'000	\$'000	%
Cash flow from operating activities			
Receipts from product agreements	6,570	10,420	(36.9%)
Payments to suppliers and employees	(7,183)	(5,244)	37.0%
Interest received	253	298	(15.1%)
Income tax paid	(1,069)	(2,924)	(63.4%)
Net cash (used in) / provided by operating activities	(1,429)	2,550	(156.0)%
Cash flow from investing activities			
Payment for property, plant and equipment	(159)	(200)	(20.5%)
Net cash used in investing activities	(159)	(200)	(20.5)%
Net (decrease) / increase in cash and cash equivalents	(1,588)	2,350	(167.6)%
Cash at beginning of half year	33,974	29,360	15.7%
Foreign exchange differences on cash holdings	(23)	8	(387.5)%
Cash and at end of the half year	32,363	31,718	2.0%

- Cash received from product agreements was \$6.57m, down 36.9% on prior half year due to lower Axiron royalty receipts
- Payments to suppliers and employees was \$7.18m up 37% due to increased investment in R&D pipeline and impact of one-off legal costs
- Interest received is down 15.1% on prior year reflective of the maturity timing of invested cash reserves
- Tax payments made during the half year were \$1.07m or 63.4% lower than prior half year reflecting lower operating results across the Group
- Capital expenditure was \$0.16m down 20.5% on prior half year. The Group will continue to carry out upgrades on existing equipment to improve our internal analytical and testing capabilities
- Cash reserves at year end were \$32.36m up 2.0% or \$0.65m on prior half year

Lenzetto® launch progress

Launches
Q1 2016
to
Q2 2017

- Hungary
- Poland
- Czech
- Germany
- Croatia
- Latvia
- Romania
- Bulgaria
- Slovenia
- Slovakia
- Estonia
- Lithuania
- Belgium
- Sweden
- Finland

Q3 2017

Spain

Q4 2017

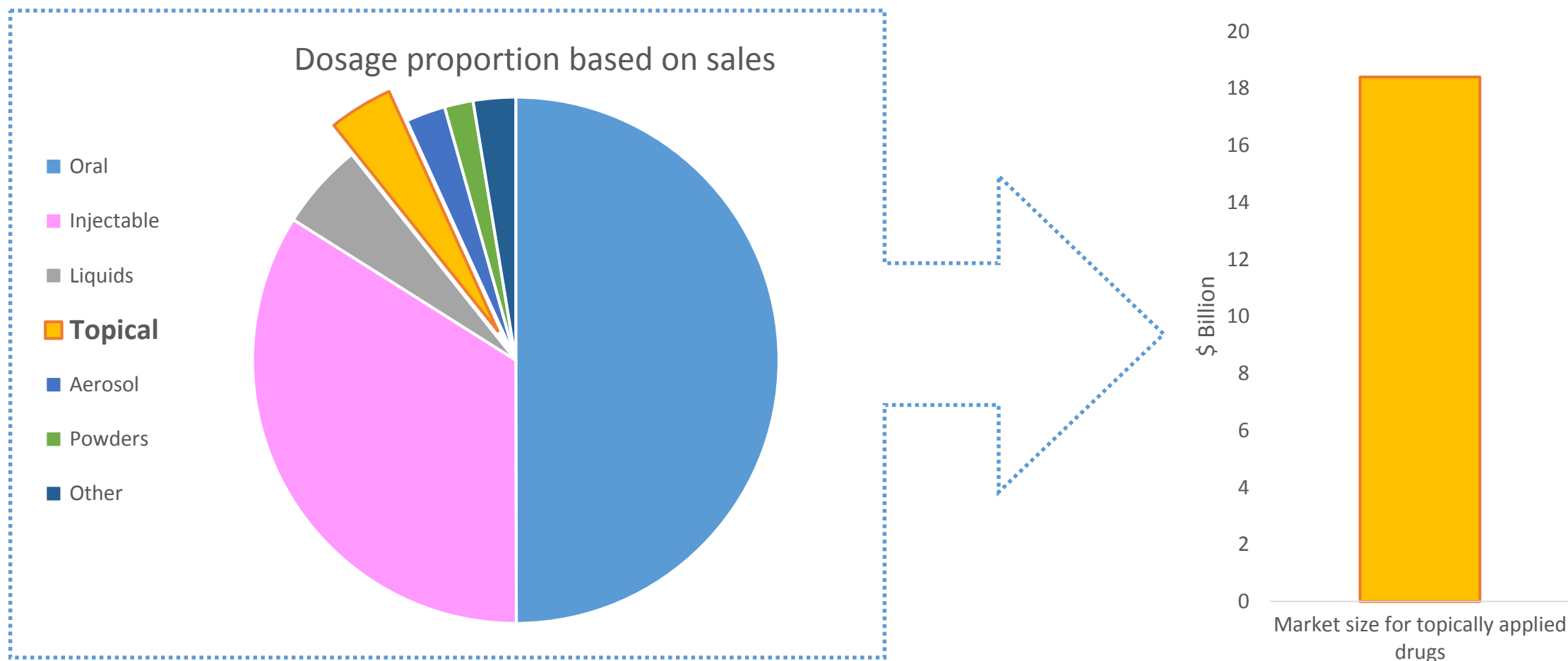
Italy
Denmark

2018+

Additional
new country
launch plans

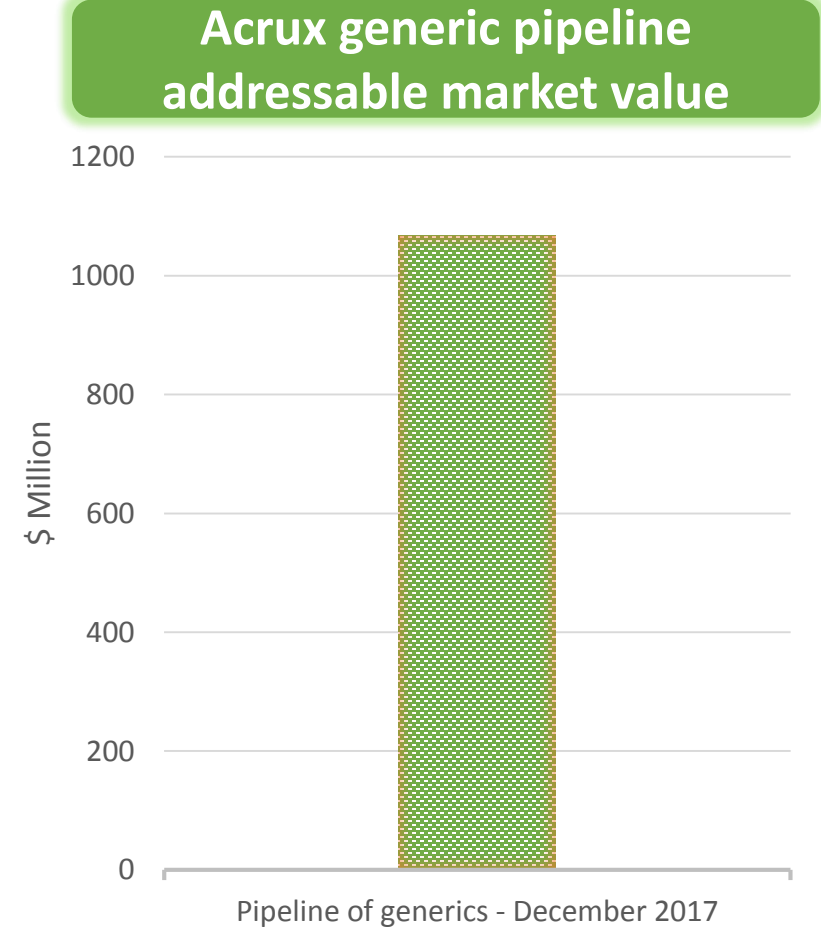
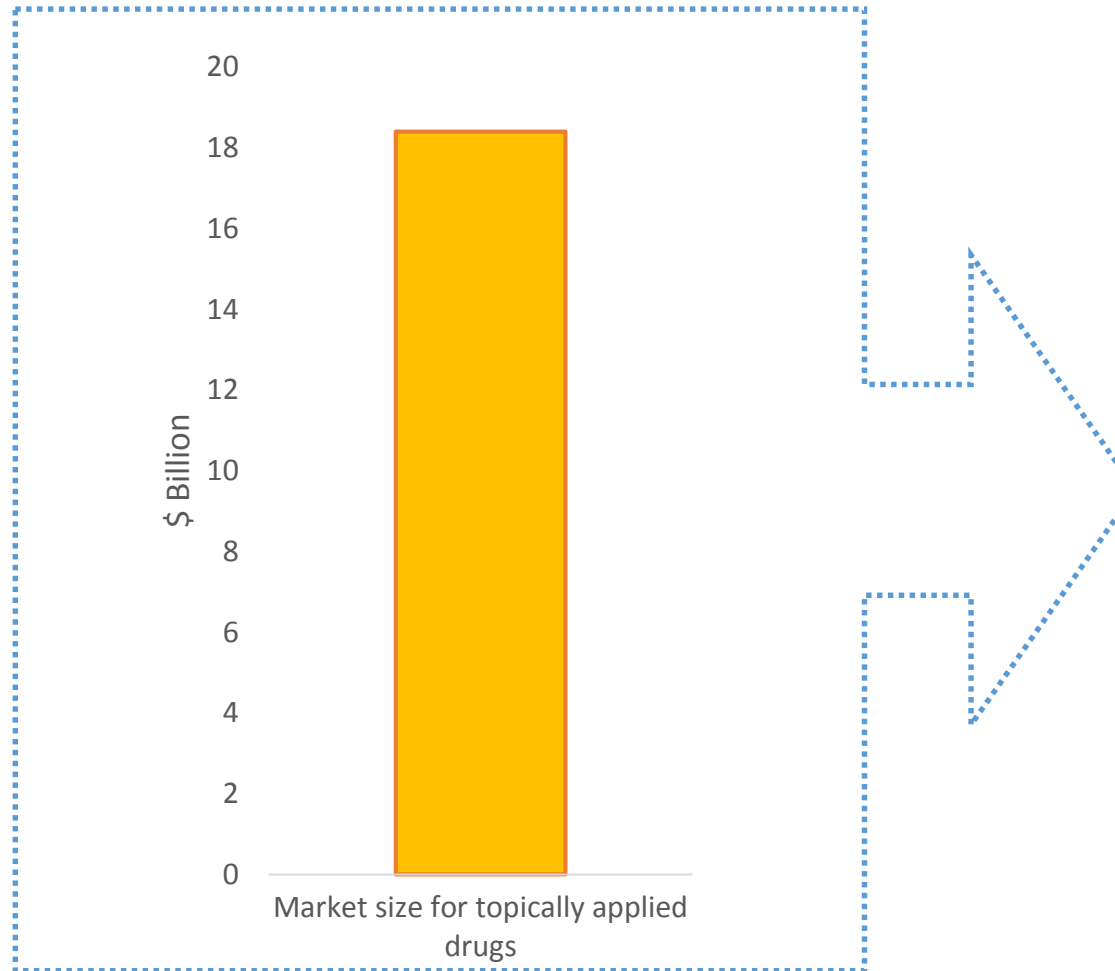


United States market – sales by dosage form



Topically applied drugs generate \$18 billion in sales in the United States
Acrux pipeline is focussed on the development of generic topical/transdermal products

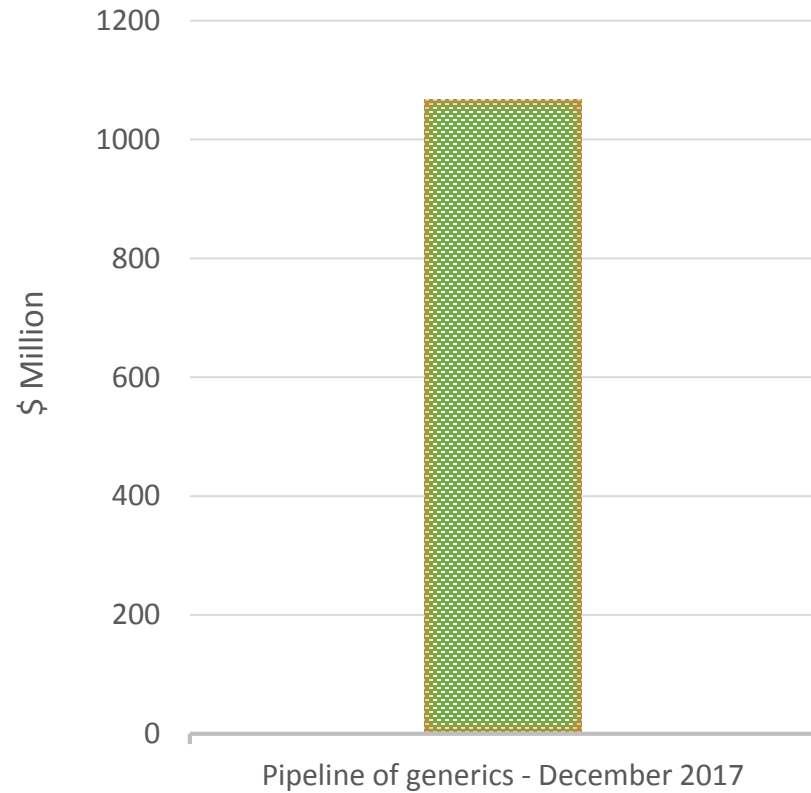
The Acrux market opportunity



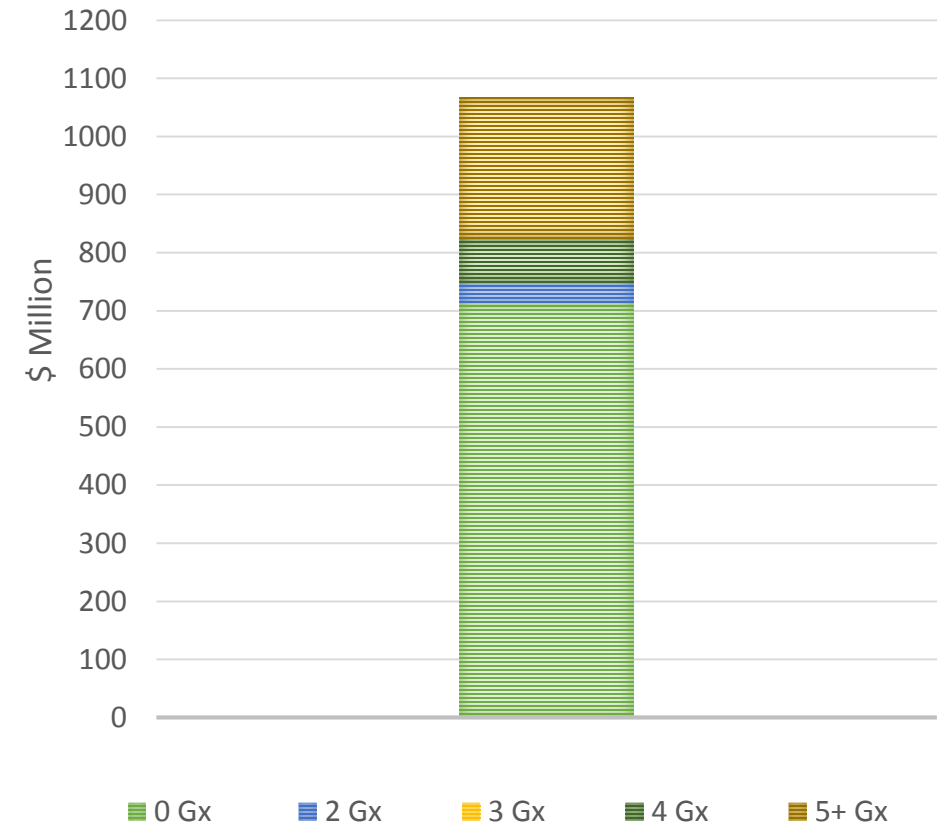
Acrux had 7 generic products in active development at end FY2017
Acrux currently has 10 generic products in active development
Acrux plans to increase this to 12 generic products in active development by end FY18

Addressable market for Acrux generic pipeline

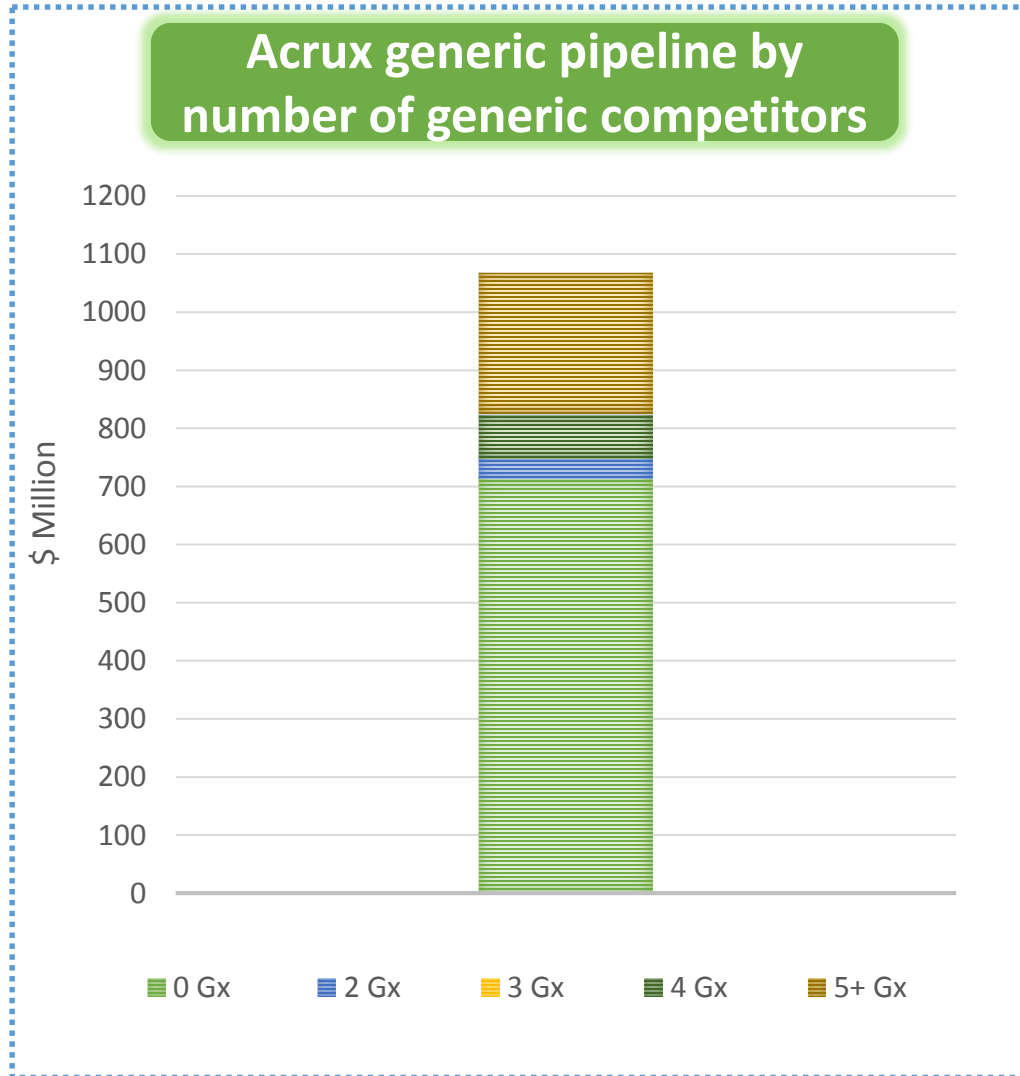
Acrux generic pipeline
addressable market value



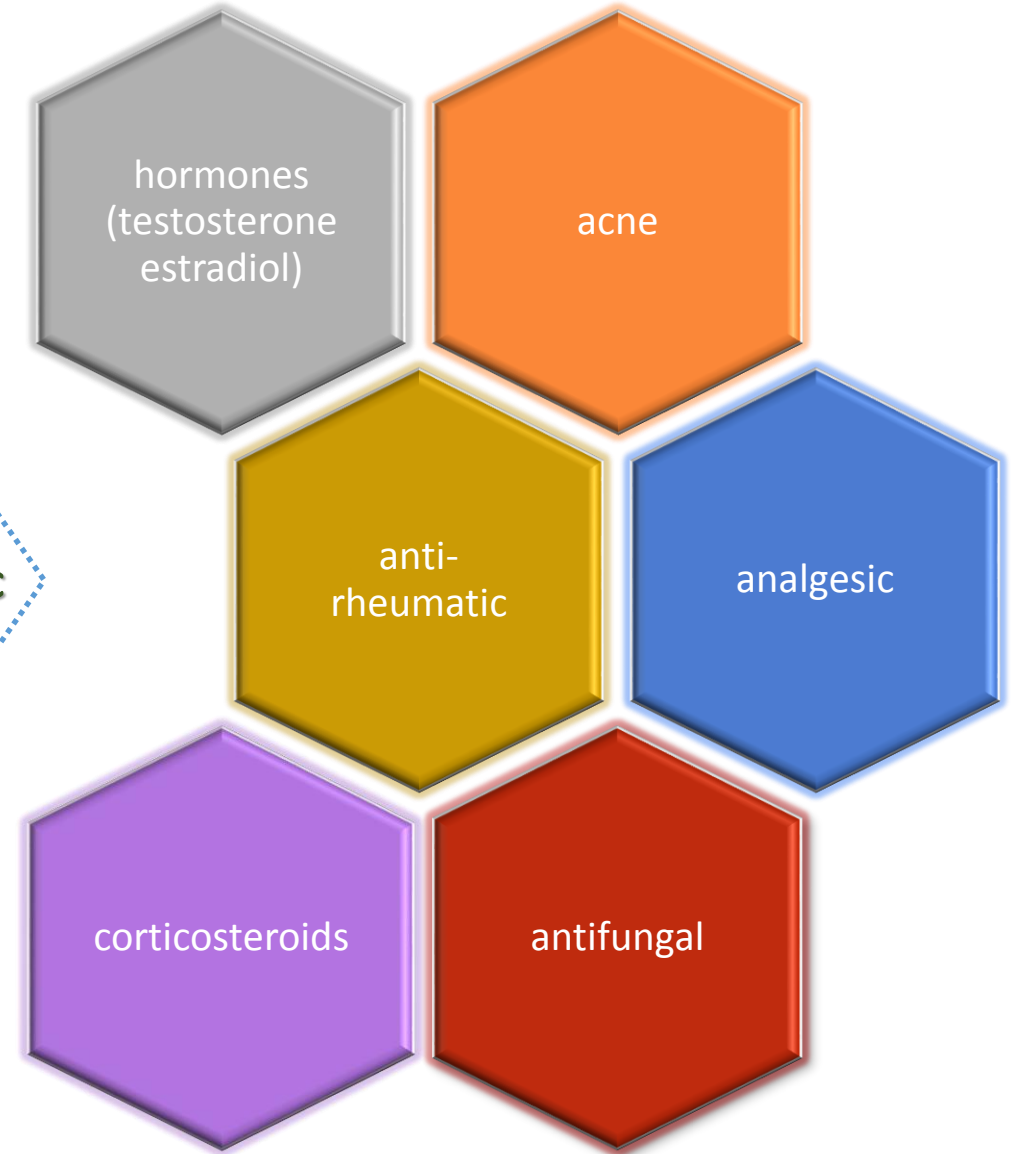
Acrux generic pipeline by
number of generic competitors



Addressable market for Acrux generic pipeline

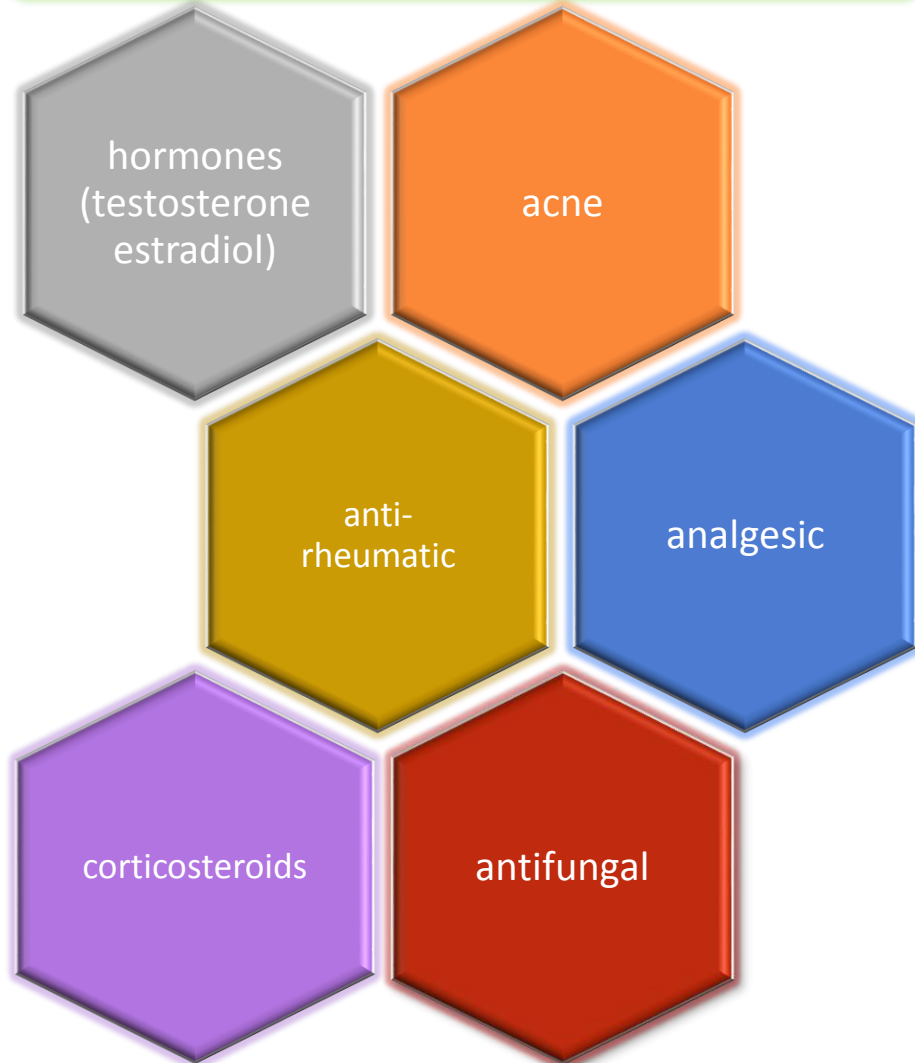


Example
therapeutic
areas

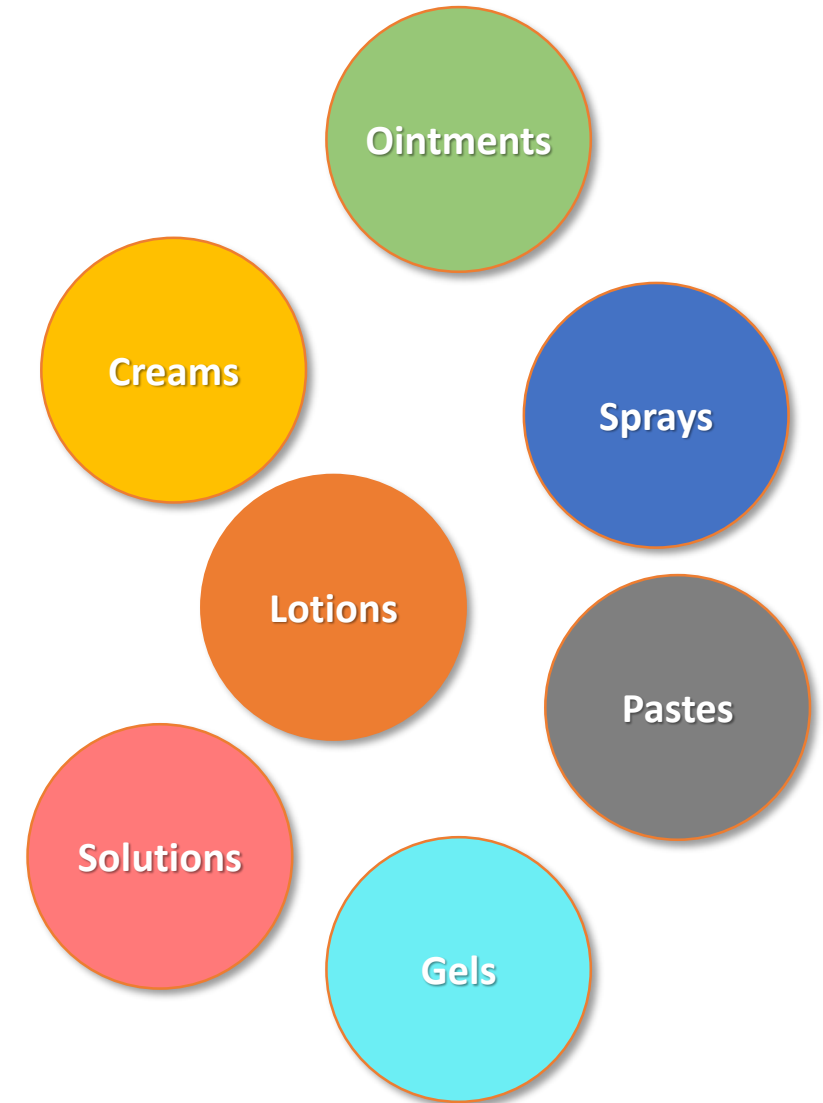


Dosage forms for Acrux generic pipeline

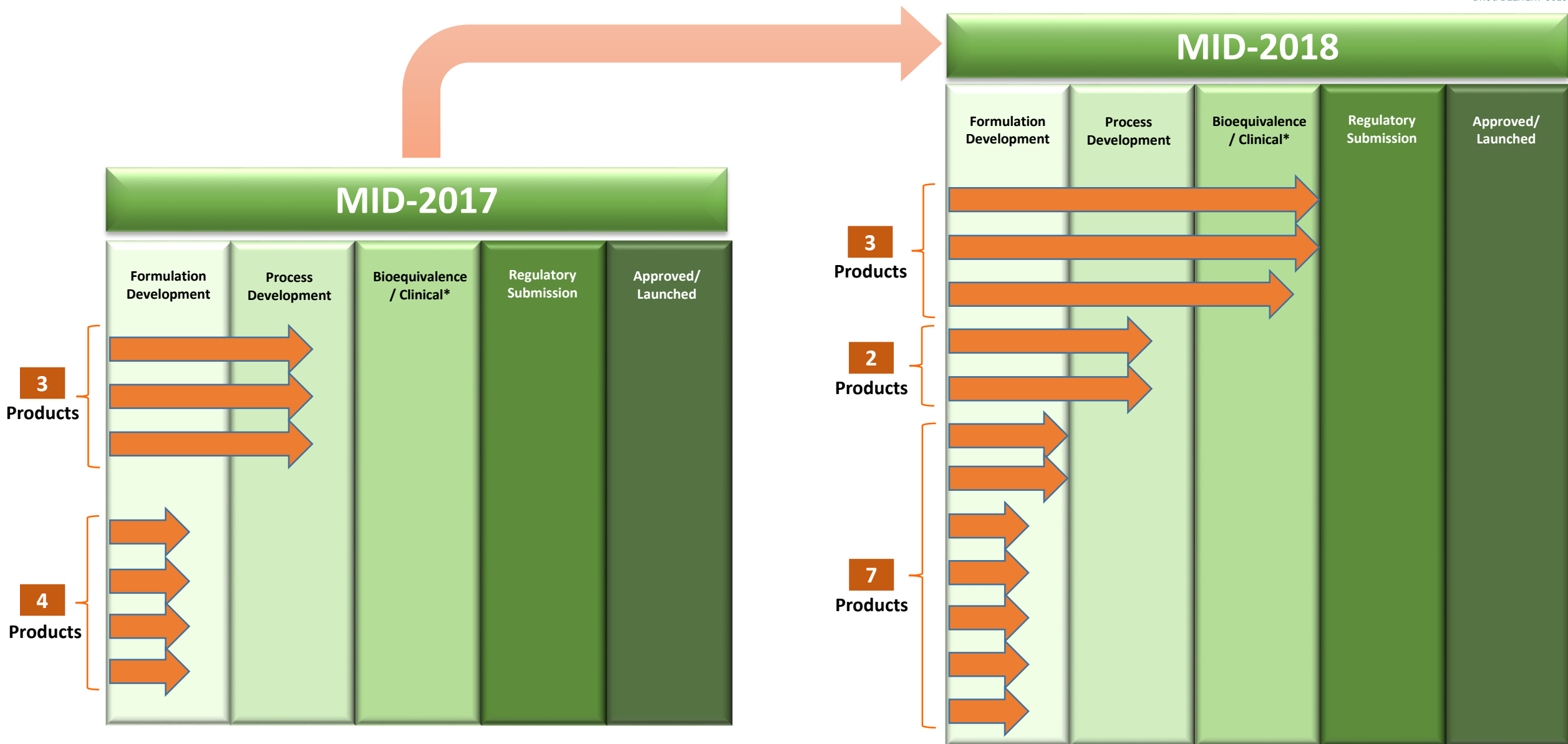
Example therapeutic areas for topically applied pharmaceuticals



Example dosage forms




Advancing our generic pipeline to create value



*based on FDA Guidance, a number of products in the Acrux generic pipeline do not require a clinical study for product approval

Future milestones

Milestone	Update
<ul style="list-style-type: none">Plans to submit first generic dossiers to FDA for review mid CY2018	First dossier planned for submission mid 2018. Other dossiers to follow.
<ul style="list-style-type: none">Initial revenue from generic pipeline expected CY2019	
<ul style="list-style-type: none">Portfolio of 12 topical generic products in development by end FY2018	On track
<ul style="list-style-type: none">Portfolio of 19 topical generic products in development by end FY2019	



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