Acrux (ASX: ACR)
Annual General Meeting
26 October 2017

ACRUX
DRUG DELIVERY SOLUTIONS

Introduction:
Ross Dobinson
Non-Executive Chairman

Operational review:
Michael Kotsanis
CEO & Managing Director

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.

Agenda

- Axiron patent litigation and status
- FY2017 outcomes and milestones
- Full year P&L and Cashflow
- Acrux pipeline selection and progress
- Near term milestones

Axiron® timeline and status

May / November 2013
Lilly and Acrux sue Perrigo for patent infringement in May and Actavis in November following initial Axiron generic submissions with Paragraph IV certification against Axiron IP in the United States

December 2014
Lilly and Acrux sue Amneal for patent infringement

March 2015
FDA release third Drug Safety Communication on testosterone. FDA outlined requirement for NDA sponsors to conduct a long term postmarketing (PMR) safety trial. Trial is expected to start late 2017.

May 2015
Lilly and Acrux sue Lupin for patent infringement

August 2016
US District Court decision that formulation and axilla patents are invalid. Lilly and Acrux appeal District Court decision

July / August 2017
Perrigo (July) and Teva/Actavis (August) announce launch of a generic of Axiron

September 2017
Axiron license terminated; Lilly withdrawing product in United States and ceasing sales of Axiron in other markets by December

October 2017
Federal Circuit appeal heard in Washington DC. Decision pending.

2013 2014 2015 2016 2017

Acrux outlook and priorities following Axiron license termination

Cash reserves	At 30th June 2017: $34.0 million
Future royalties	• Axiron royalties cease in line with Axiron license termination • Acrux is pursuing a range of opportunities to realise the value of its intellectual property • Evamist and Lenzetto royalties continue
Onychomycosis (ACR065)	• FDA Pre-IND meeting in October supportive of Acrux proposed clinical program and ethics application submitted for Phase 1 program in Australia • Project will now be suspended to preserve and focus cash on nearer term opportunities in topical generic pipeline
Pipeline focus	• Acrux had 7 generic products in active development in its pipeline at end FY2017 • Acrux plans to have 12 products in its generic pipeline by end FY2018 and will expand this to 19 products by end FY2019 • Acrux plans to submit its first generic dossiers to the FDA mid CY2018

FY2017 outcomes

Cash reserves	2017: $34.0 million 2016: $29.4 million
Net (Loss)/Profit After Tax	2017: $(0.2) million includes a non-cash impairment loss of $10.68 million 2016: $11.1 million
Royalty revenue	2017: $23.3 million 2016: $25.4 million
Pipeline progress	At end June 2017, Acrux had 8 products in active development including 7 generic products and 1 specialty product for onychomycosis

FY2017 milestones

• Scale up activities to manufacture exhibit batches for initial generic products	✓
• Gedeon Richter to continue country specific launches of Lenzetto in the European Union	✓
• Draft and submit patent application for ACR065 for onychomycosis	✓
• Contract manufacturing organisation to be engaged to manufacture multiple generic products	✓
• Commence first bioequivalence study*	**Trial planning on schedule**
• Portfolio of 7 topical generic products in development by end FY17	✓
• Axiron Appeal outcome	**Federal Circuit hearing 5 October 2017**

*a number of products in the Acrux pipeline do not require a clinical study for product approval

Finance review:
Tim Bateman
CFO & Company Secretary

Full year profit and loss

	Full Year Ending 2017 $'000	2016 $'000	%
Royalty revenue	23,321	25,469	(8.4%)
Milestone revenue	-	2,540	(100.0%)
Interest & Other Income	613	548	11.9%
Total revenue and other income	**23,934**	**28,557**	**(16.2%)**
R&D investment	(9,247)	(5,536)	67.0%
Operating costs	(2,198)	(2,390)	(8.0%)
Non operating costs	(1,903)	(2,539)	(25.0%)
Total expenses	**(13,348)**	**(10,465)**	**27.5%**
Operating profit before impairment loss and income tax	**10,586**	**18,092**	**(41.5%)**
Impairment loss	(10,680)	-	-
Operating (loss)/profit before income tax	**(94)**	**18,092**	**(100.5%)**
Income tax expense	(149)	(5,111)	(97.1%)
Net (loss)/profit for the year	**(243)**	**12,981**	**(101.9%)**
Earnings per share			
Basic (loss)/earning per share	**(0.15) cents**	**7.80 cents**	**(7.95) cents**

- Royalty revenue largely comprises Axiron revenue of $22.8m which is 10% down on prior year
- Prior financial year milestone income reflects multiple marketing approvals of Lenzetto in the European Union by our licensee Gedeon Richter
- R&D investment was $9.2m up 67% prior year due to the increase in expenditure on our generics and specialty product pipeline
- Impairment loss is a result of a reassessment of the estimated future discounted cashflows from Axiron®. The assessment included consideration of the current market data for the Testosterone market in the United States and generic market penetration since 6 July 2017
- Income tax expense is $0.1m being 97.1% lower than prior year due to reversal of the deferred tax liability associated with the impaired portion of Axiron® capitalised development costs
- Loss after tax was $0.2m down $13.2m from prior year

Full year cash flow

	Full Year Ending 2017 $'000	2016 $'000	%
Cash flow from operating activities			
Receipts from product agreements	21,822	28,208	(22.6%)
Payments to suppliers and employees	(10,748)	(7,923)	35.7%
Interest received	637	515	23.7%
Income tax paid	(6,335)	(4,294)	47.5%
Net cash provided by operating activities	**5,376**	**16,506**	**(67.4)%**
Cash flow from investing activities			
Payment for property, plant and equipment	(629)	(236)	166.5%
Net cash used in investing activities	**(629)**	**(236)**	**166.5%**
Cash flow from financing activities			
Dividends paid	-	(9,992)	(100.0%)
Net cash used in financing activities	**-**	**(9,992)**	**(100.0)%**
Net increase in cash and cash equivalents	**4,747**	**6,278**	**(24.4)%**
Cash at beginning of year	29,360	23,068	27.3%
Foreign exchange differences on cash holdings	(133)	14	(1050.0)%
Cash and at end of the year	**33,974**	**29,360**	**15.7%**

- Cash received from product agreements was $21.8m, down 22.6% on prior year due to:
  - lower Axiron royalty receipts
  - non recurrence of Lenzetto European approval milestones
- Payments to suppliers & employees was $10.7m up 35.7% due to increased investment in R&D pipeline.
- Interest received is up 23.7% on prior year due to higher average cash reserves held during year
- Tax payments for the financial year were $6.3m or 47.5% higher than prior year reflecting the timing of tax payments
- Capital expenditure was $0.6m up 166.5% on prior year
- Cash reserves at year end were $34.0m up 15.7% or $4.6m on prior year

Operational Report continued:
Michael Kotsanis
CEO & Managing Director

Generic pharmaceuticals…

ACRUX
DRUG DELIVERY SOLUTIONS

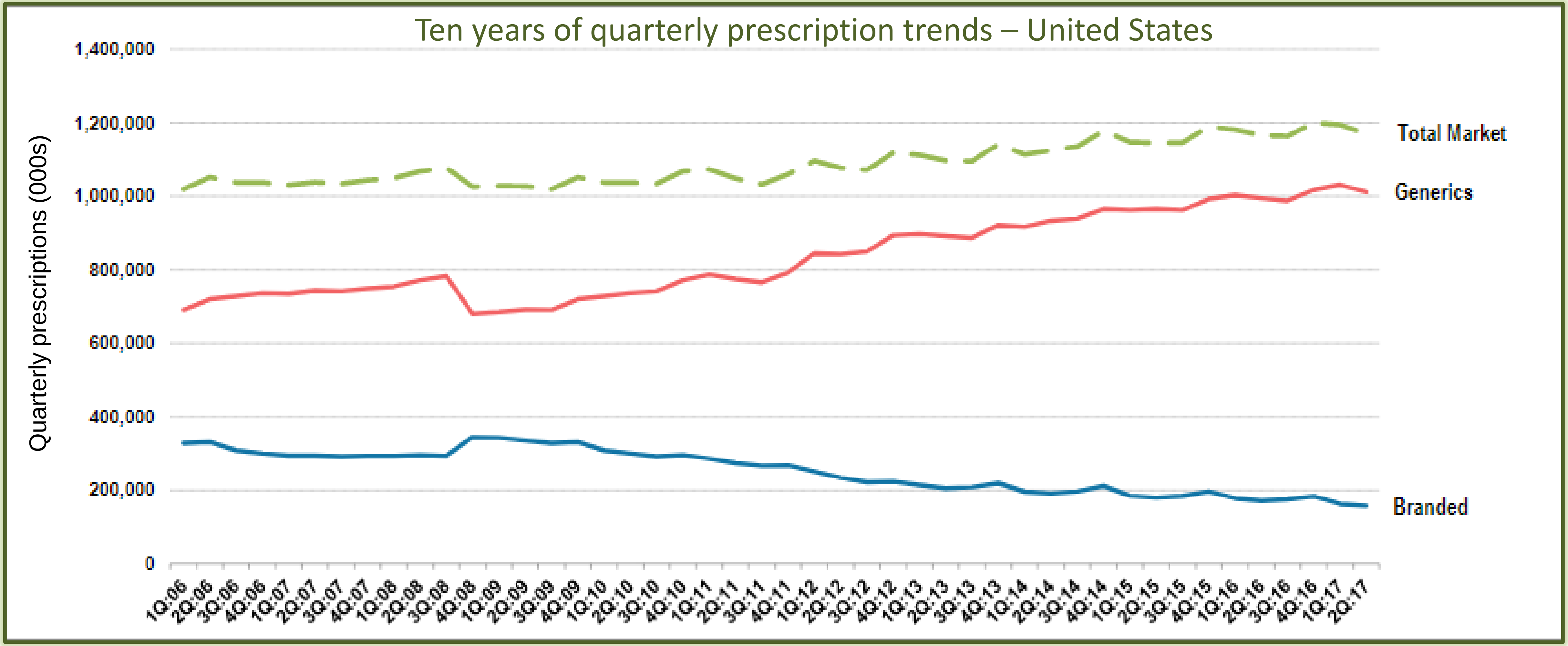
According to the FDA:
"Generic drugs…are just as safe and just as effective as their brand-name counterparts, and they are a cost effective way of achieving substantial savings." "A generic drug is identical or bioequivalent to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use."

According to the American Medical Association (AMA):
"One of the primary ways physicians can practice cost-effective prescribing is by offering patients a generic medicine when one is available."

What is a generic medicine?
Generic drugs contain the same active ingredients, in the very same strength, as brand-name drugs. When a medicine is first developed, the pharmaceutical company that discovers and markets it receives a patent on its new drug. The patent usually lasts for 20 years, to give the originating company a chance to recoup its research investment. After the patent expires, a generic version of the drug may become available. Generics are marketed under the drug's chemical, or "generic," name and meet the same FDA quality and effectiveness standards as the original.

Source: http://www.gphaonline.org/about/generic-medicines

…dominate the United States market



9 out of 10 scripts dispensed are generic

Source: QuintilesIMS, Morgan Stanley Pharma Rx chart, Oct, 2017

The value of generic medicines to patients and the economy…

ACRUX
DRUG DELIVERY SOLUTIONS

INCREASED PATIENT ACCESS

HYPERTENSION

MORE PATIENTS TREATED
with
SAME EXPENDITURE

PATIENT-RELATED VALUE

- IMPROVED MEDICATION ADHERENCE
- BETTER PATIENT HEALTH OUTCOMES

BREAST CANCER

SAME NUMBER OF PATIENTS TREATED
with
LESS EXPENDITURE

OVERALL ECONOMIC VALUE

DEPRESSION

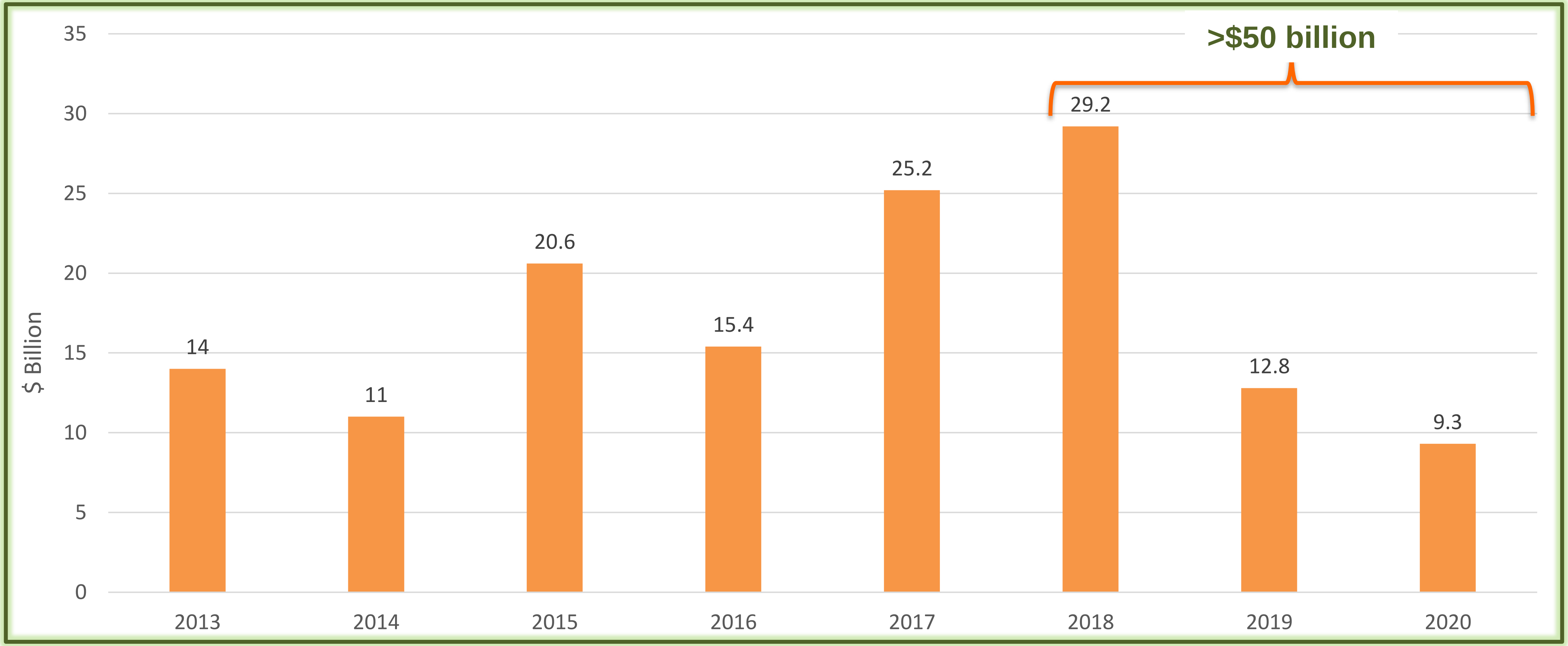
MORE PATIENTS TREATED
with
SMALL EXPENDITURE INCREASE

Source: European Generics Medicines Association / Medicines For Europe, Health Economics Study, October 2015

…will grow as more products face patent expiry

ACRUX DRUG DELIVERY SOLUTIONS

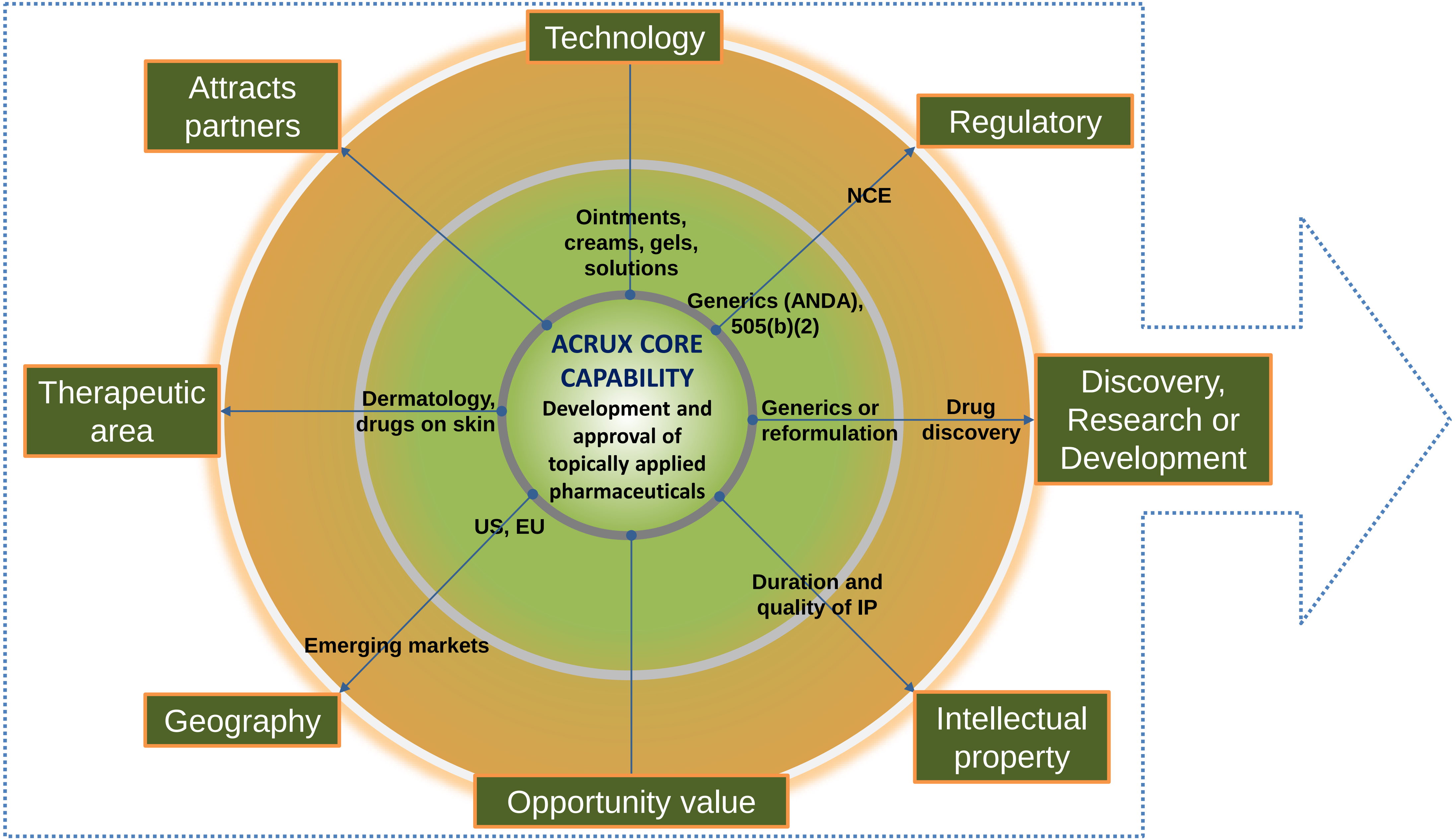
Small molecule patent expiry exposure in the United States ($ Billion)



Over $50 billion of branded sales facing loss of exclusivity in the United States in coming years

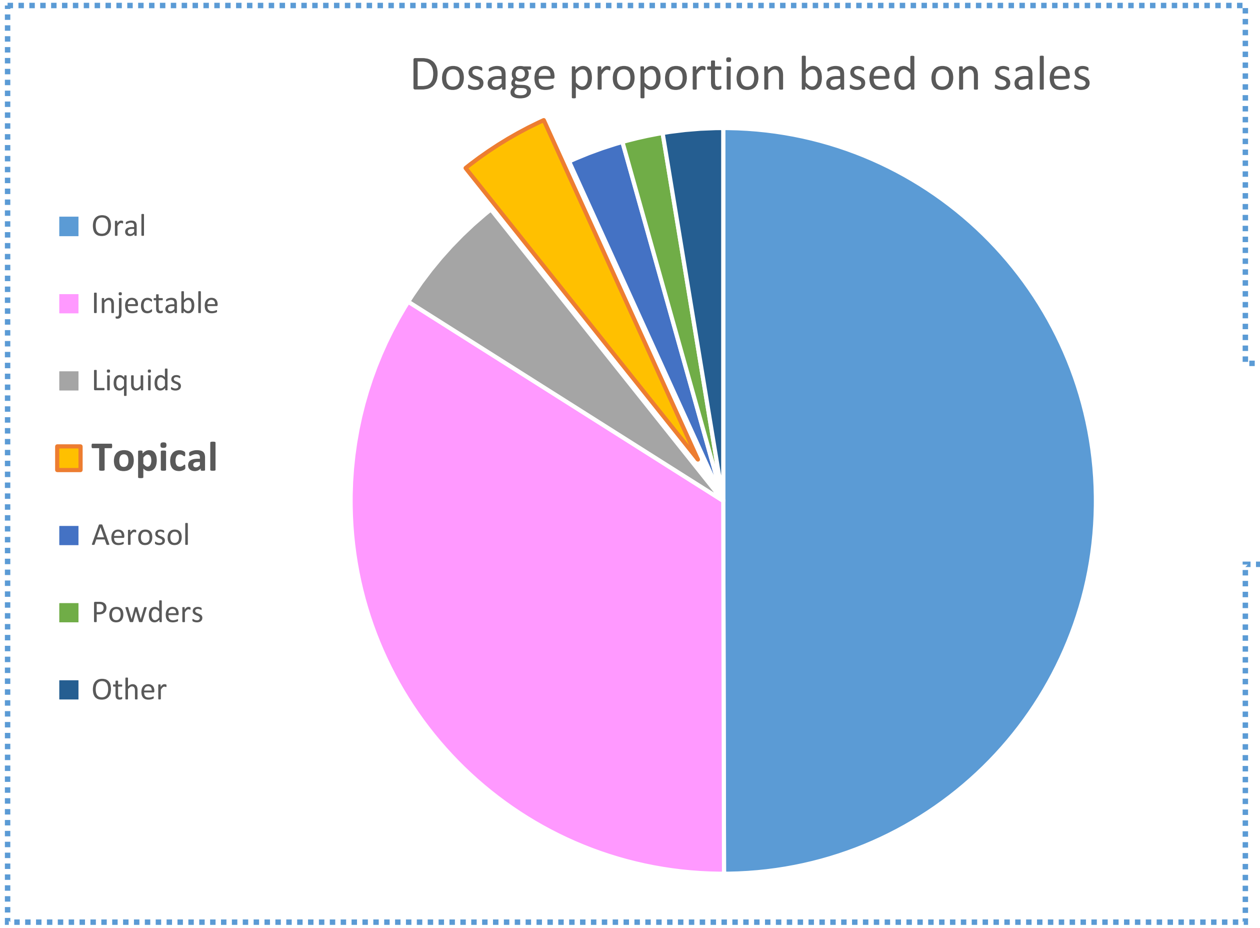
Source: QuintilesIMS, National Sales Perspectives, Sep 2016, US$
Sales in year prior to expiry used for years 2013-16; sales in MAT Sep 2016 used for years 2017-20

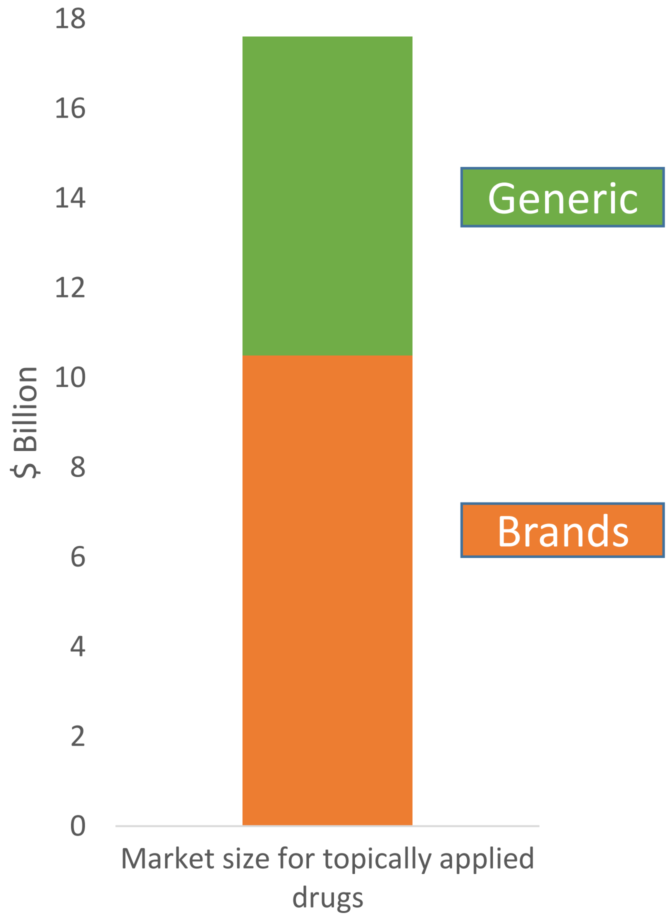
The Acrux pipeline…



…leverages core Acrux skills

United States market – sales by dosage form

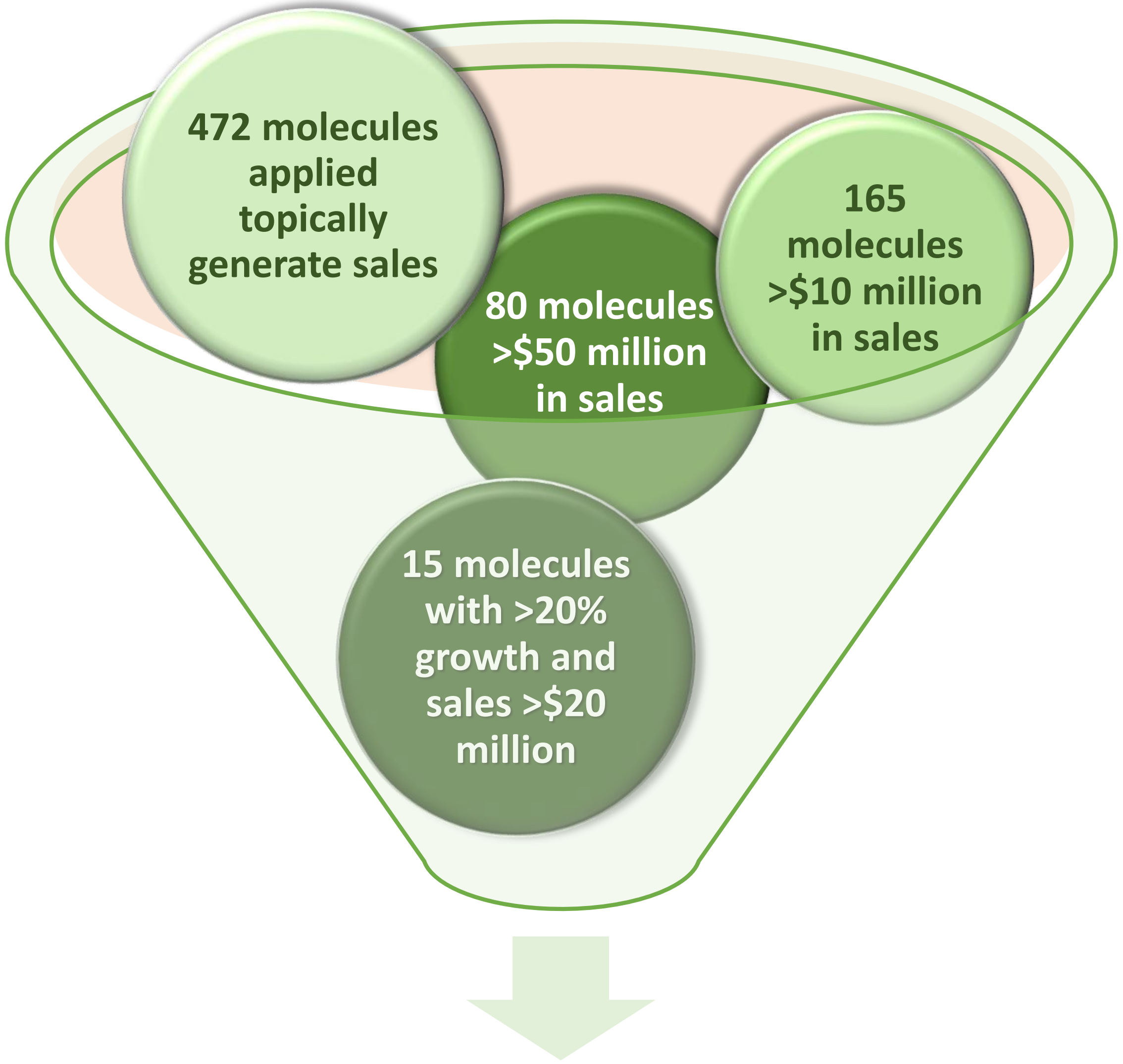




Topically applied drugs generate almost $18 billion in sales in the United States
Acrux pipeline is focussed on the development of generic topical/transdermal products

Source: US market by dosage form, IMS Q2, 2015 MAT. US market sales. US$. Market size for topically applied drugs IMS Q1, 2017 MAT US$

Selecting a topical generic portfolio

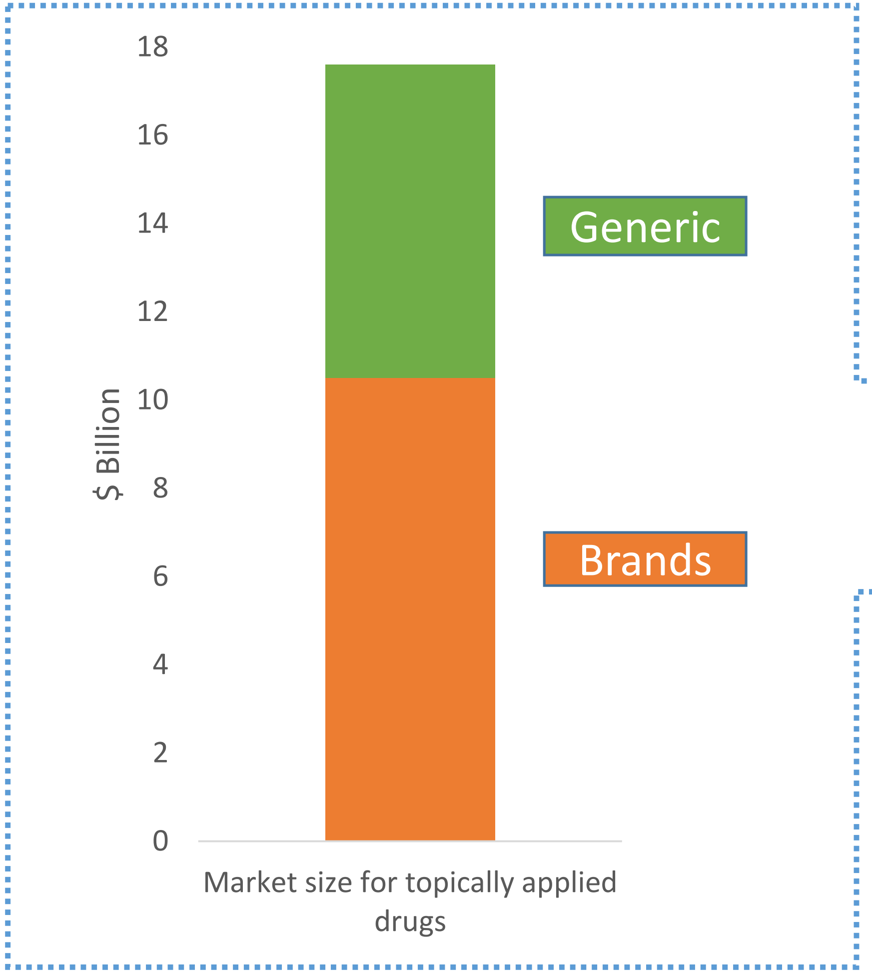


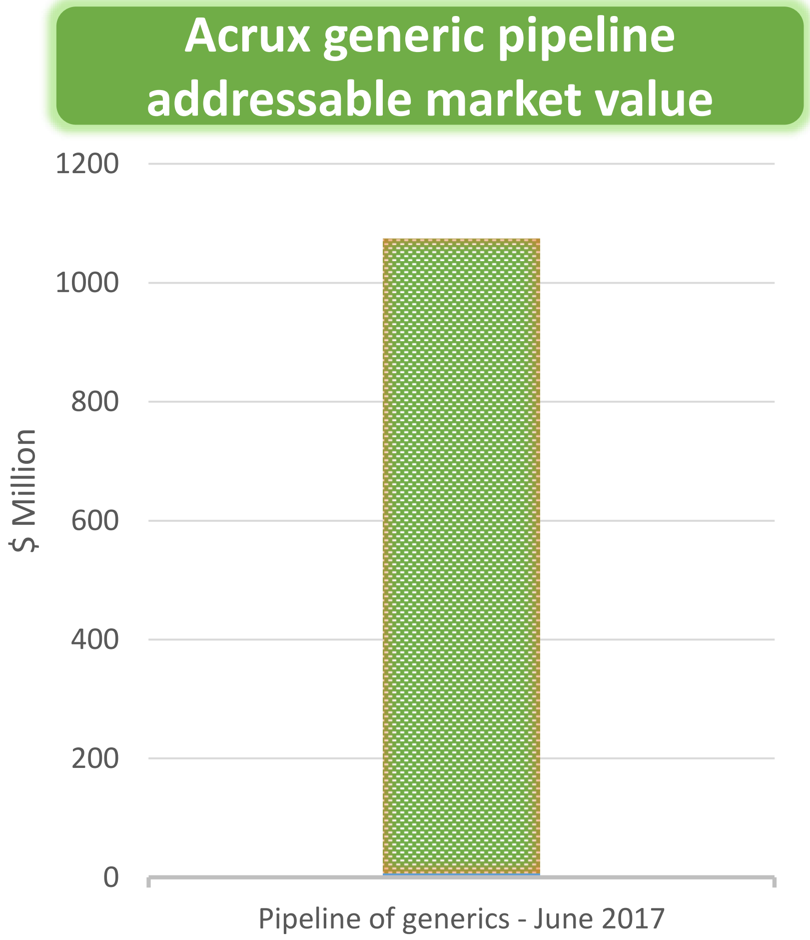
Significant number of topical opportunities for Acrux to target

- Acrux is targeting molecules with low to modest competition
- Drugs often have more than one presentation (including creams, gels, ointments, solutions, lotions, patches)
- Competition, pricing and sales of relevant skus are considered in business case
- Complexity and cost and any clinical program is a factor considered in all business cases

Source: Acrux analysis. IMS March 2017 MAT. US transdermal and topical generic and branded market segments. US$

The Acrux market opportunity

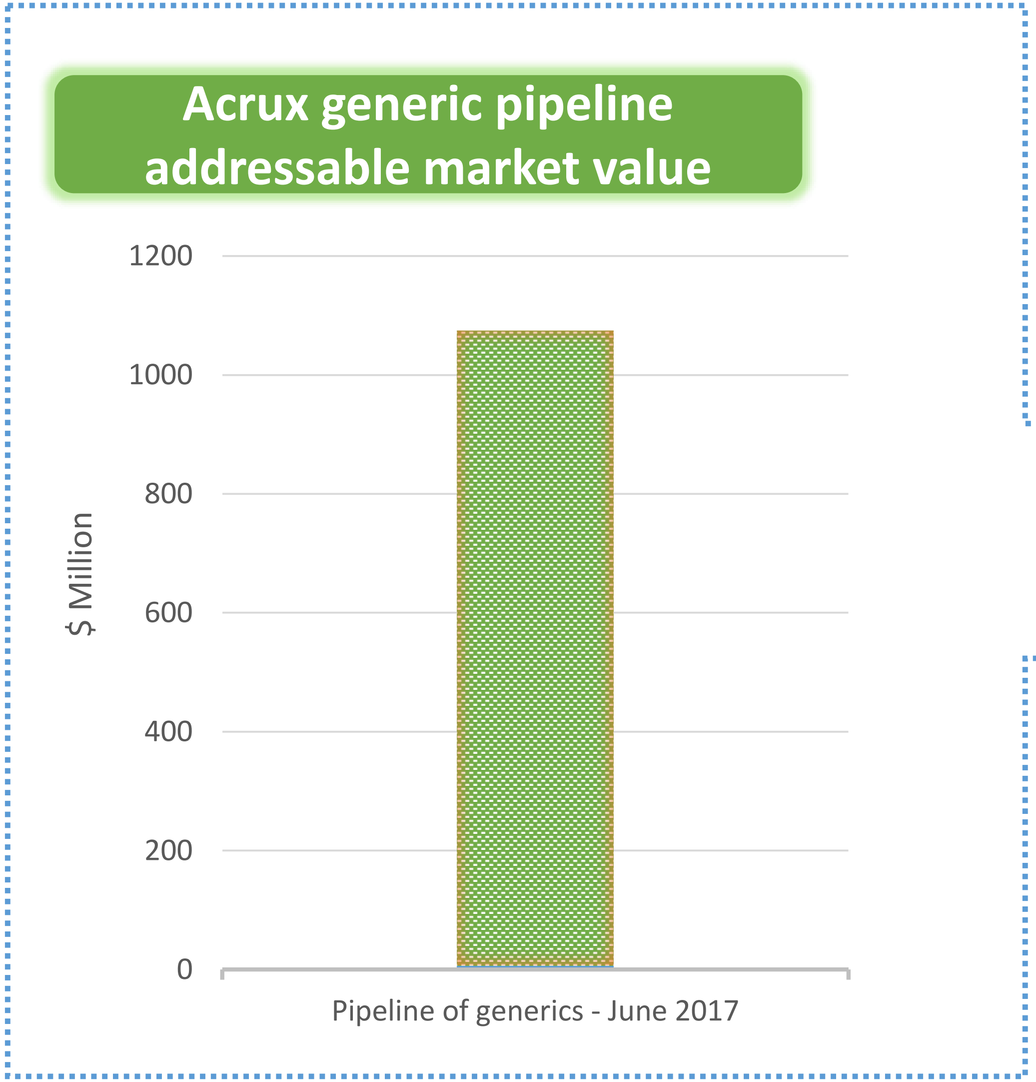


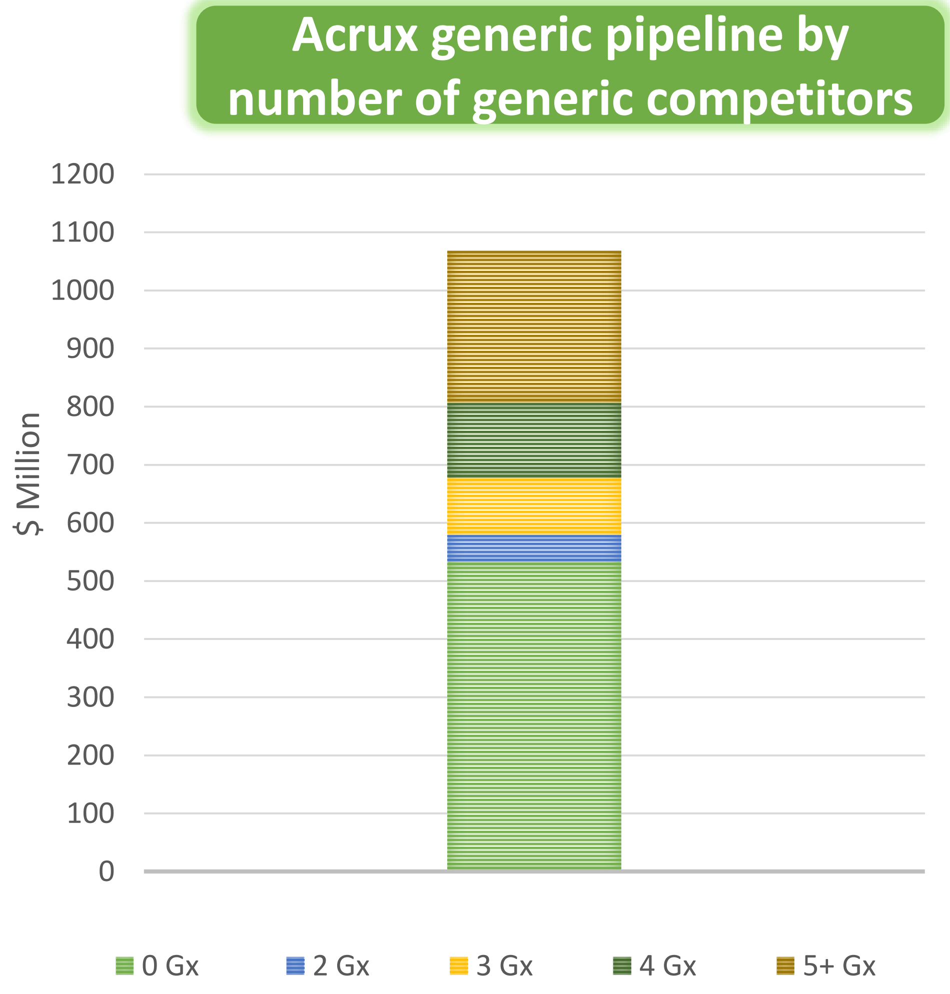


Acrux had 7 generic products in active development at end FY2017
Acrux currently has 9 generic products in active development
Acrux plans to increase this to 12 generic products in active development by end FY18

Source: IMS Q1, 2017 MAT. US market sales. US$

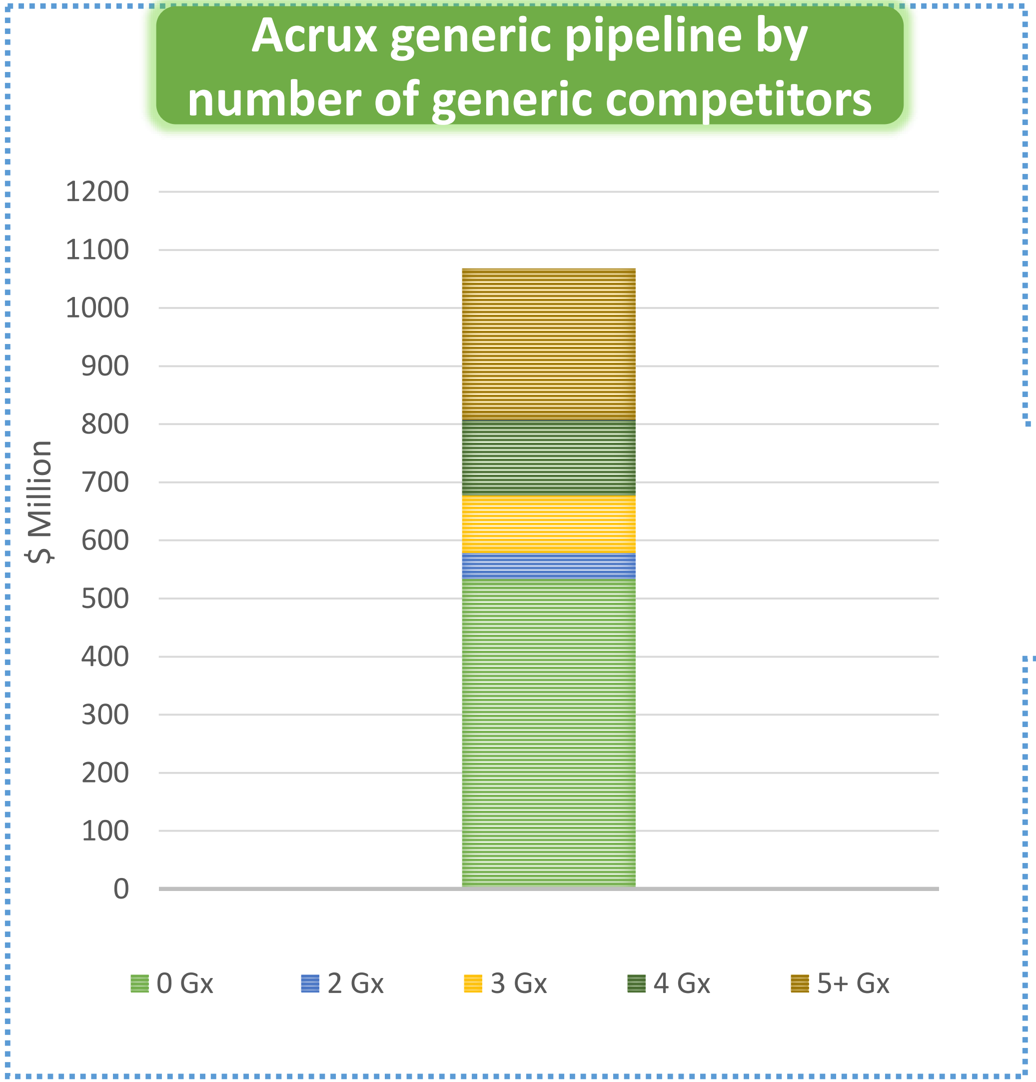
Addressable market for Acrux generic pipeline



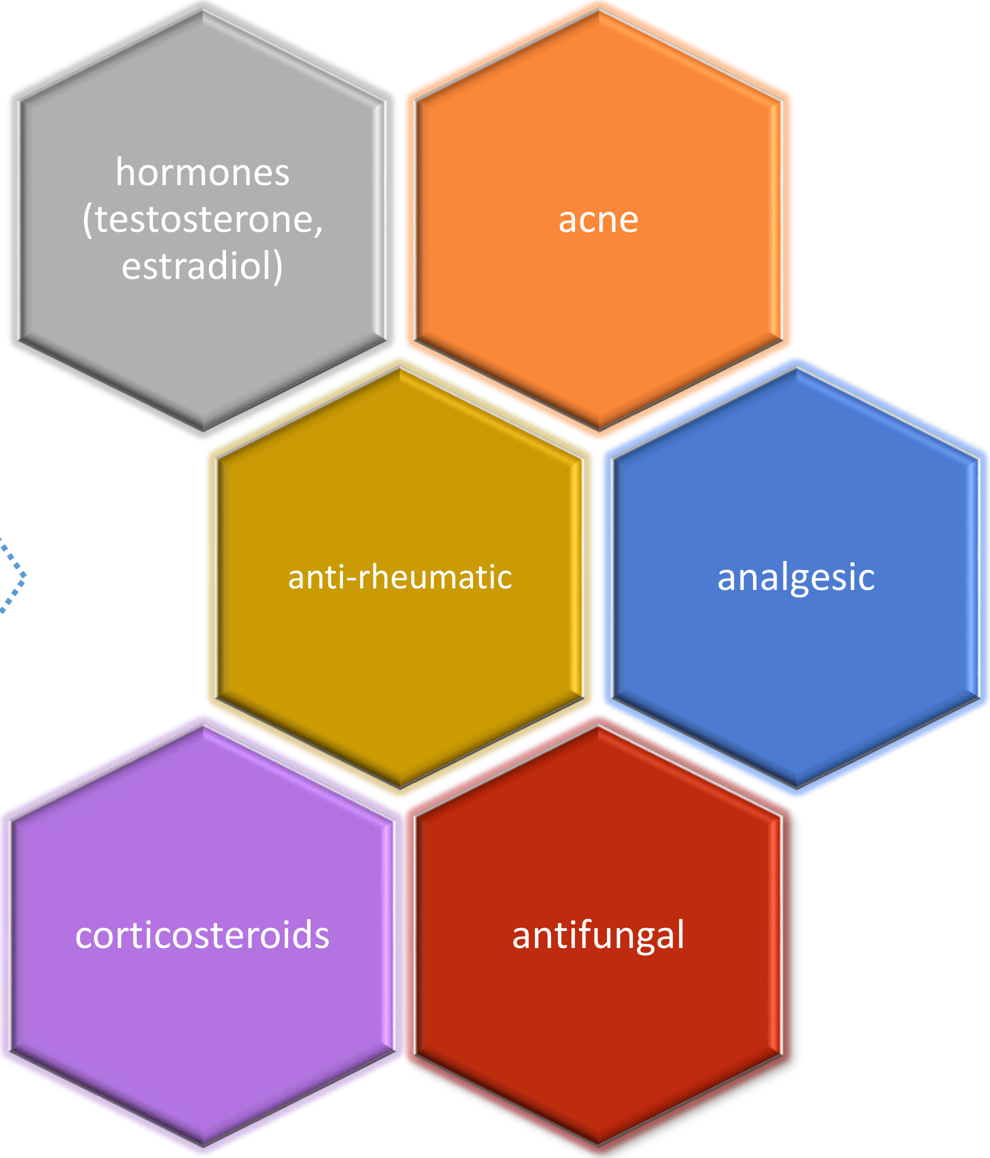


Source: IMS Q1, 2017 MAT. US market sales. US$

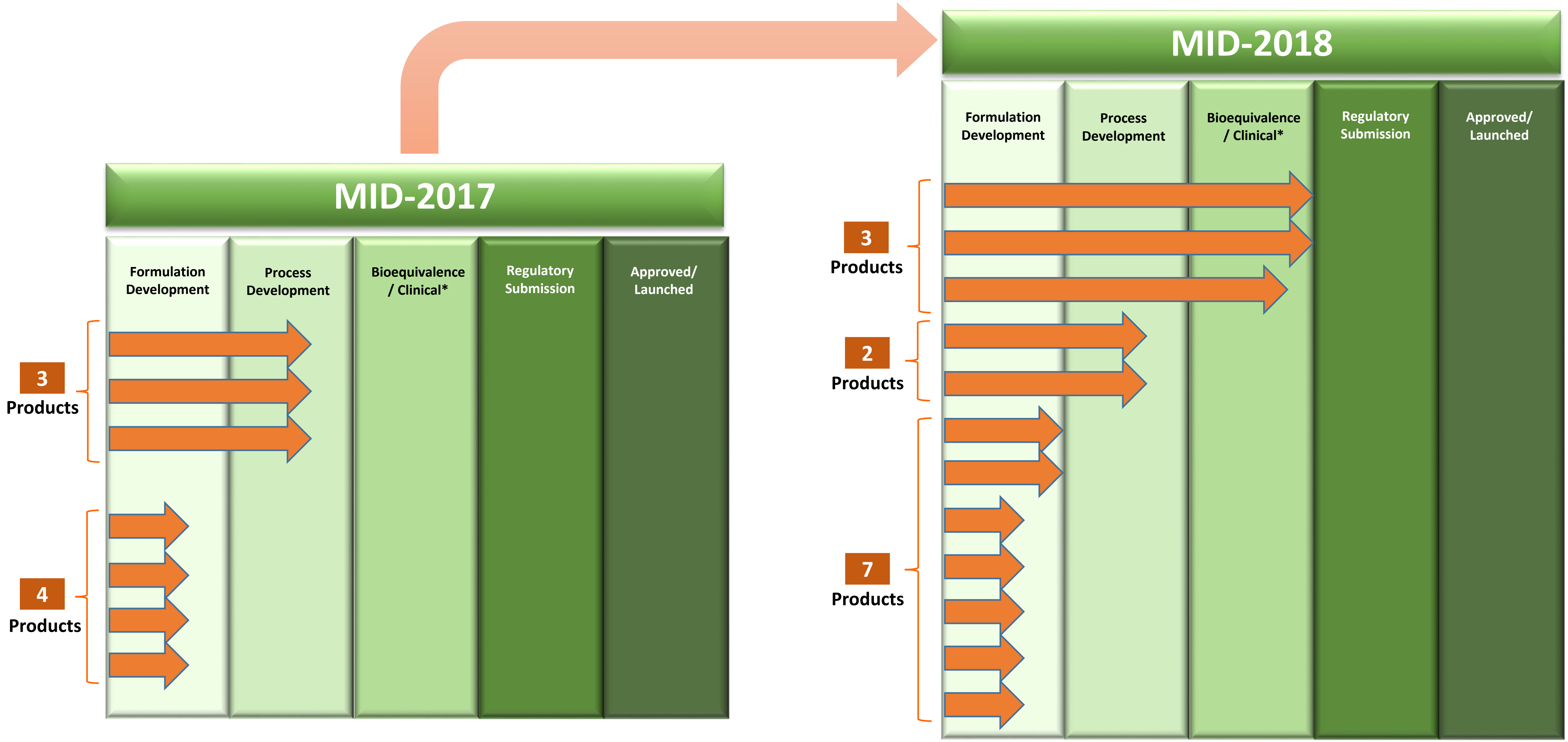
Addressable market for Acrux generic pipeline



Example therapeutic areas



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

- Plans to submit first generic dossiers to FDA for review mid CY2018
- Axiron Appeal outcome
- Initial revenue from generic pipeline expected CY2019
- Portfolio of 12 topical generic products in development by end FY2018
- Portfolio of 19 topical generic products in development by end FY2019

Acrux (ASX: ACR)

Annual General Meeting

26 October 2017