

## ACRUX PRESENTS AT BIOSHARES BIOTECH SUMMIT

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Acrux (ASX: ACR) today announced that CEO and Managing Director, Michael Kotsanis presented at the 2017 Bioshares Biotech Summit on 22 July 2017.

The presentation follows this announcement.

### **For further information, contact**

Michael Kotsanis, CEO and Managing Director: 03 8379 0100

### **About Acrux**

Acrux (ASX: ACR) is a pharmaceutical company dedicated to developing and commercialising specialty and generic topical pharmaceuticals. Incorporated in 1998 and using in house facilities and capabilities, Acrux has successfully developed and commercialised through licensees a number of pharmaceutical products in the US and Europe using the Patchless Patch™, a fast-drying and invisible topical application technology. Marketed products include Axiron®, Evamist® and Lenzetto®. More recently, in addition to specialty products, Acrux has identified and initiated development of a range of generic products. Acrux is leveraging its on-site laboratories, GMP manufacturing suite, clinical and commercial experience to bring more products to market. Acrux encourages collaboration and is well positioned to discuss partnering and product development.

For further information on Acrux, visit [www.acrux.com.au](http://www.acrux.com.au)





# Generics – affordable medicine

Michael Kotsanis

CEO and Managing Director, Acrux Ltd

2017 Bioshares Biotech Summit

22 July, 2017

# 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

About generics

Generic facts, figures and impact

Generic market evolution

The Acrux opportunity

# What is a generic drug?

## **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.*

# Agenda

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# Healthcare spending on pharmaceuticals – United States

Figure 1: National healthcare expenditure

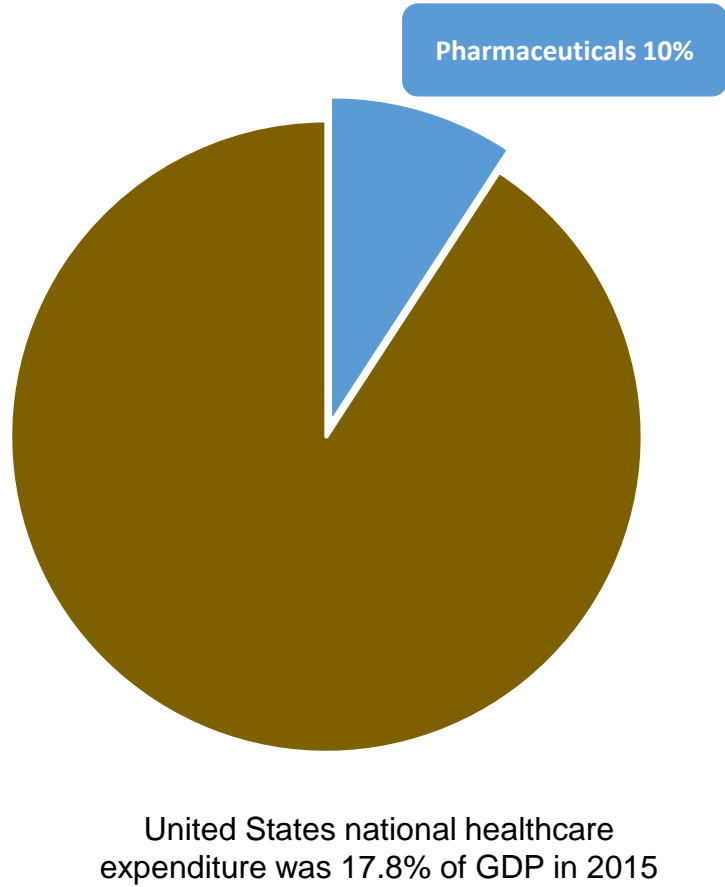
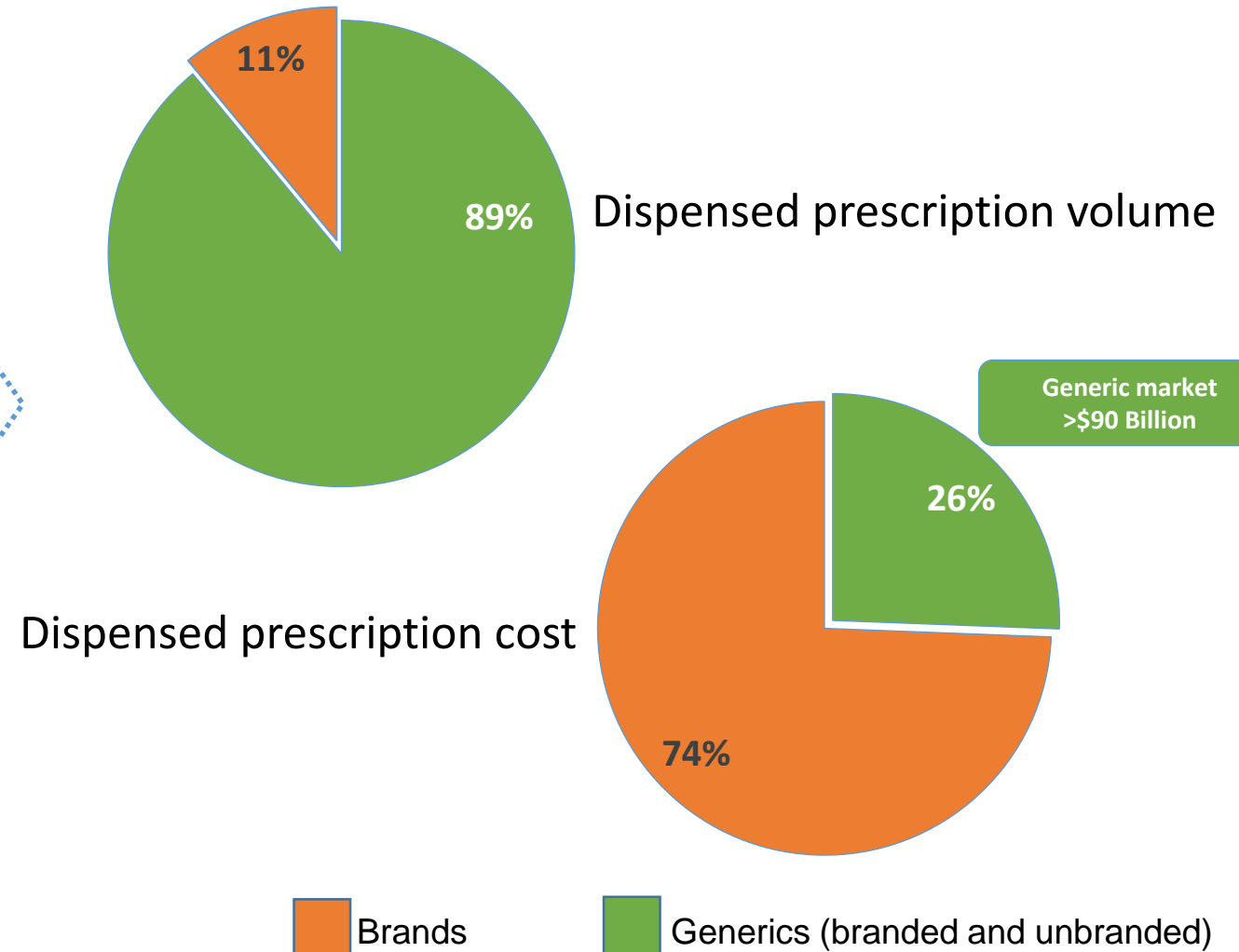


Figure 2. United States generic and branded volume and sales

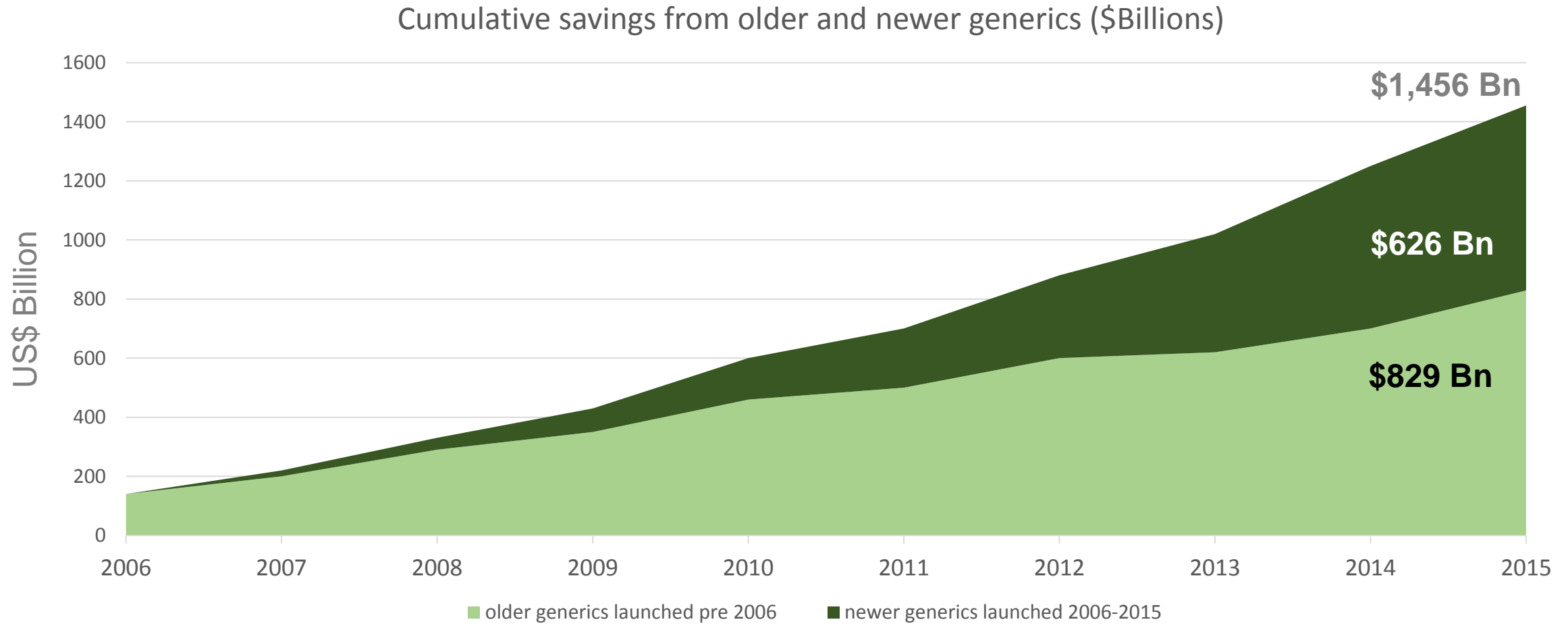


Sources:

Figure 1. Data from Centers for Medicare & Medicaid Services. National Health Expenditure Fact Sheet. 2015

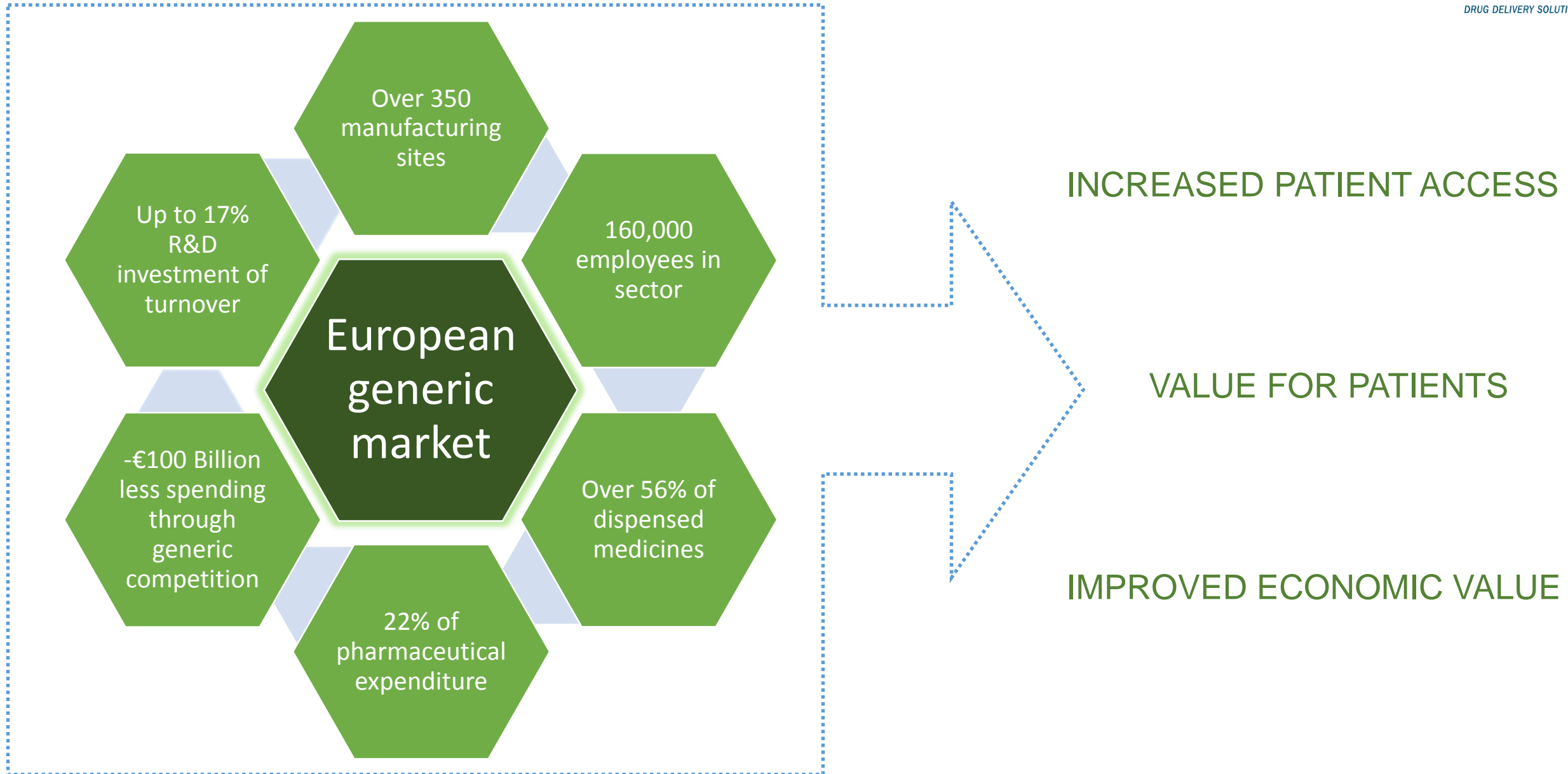
Figure 2. QuintilesIMS MIDAS Q3 2016; QuintilesIMS GPHA February 2017

# The US healthcare system has saved \$1.46 trillion in the last ten years due to the availability of low cost generics





# Impact of generics in Europe



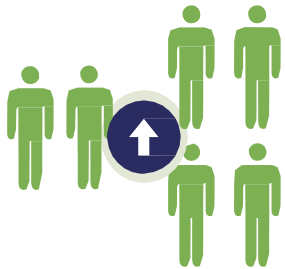
# Value of generic medicines

European Generics Association Health Economics Study

## INCREASED PATIENT ACCESS



### HYPERTENSION



MORE PATIENTS TREATED  
with  
SAME EXPENDITURE



## VALUE FOR PATIENTS

- IMPROVED MEDICATION ADHERENCE
- BETTER PATIENT HEALTH OUTCOMES



### BREAST CANCER



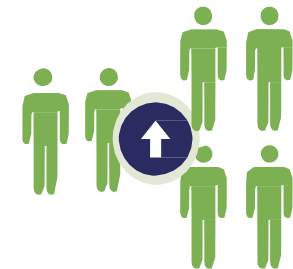
SAME NUMBER OF PATIENTS TREATED  
with  
LESS EXPENDITURE



## IMPROVED ECONOMIC VALUE



### DEPRESSION

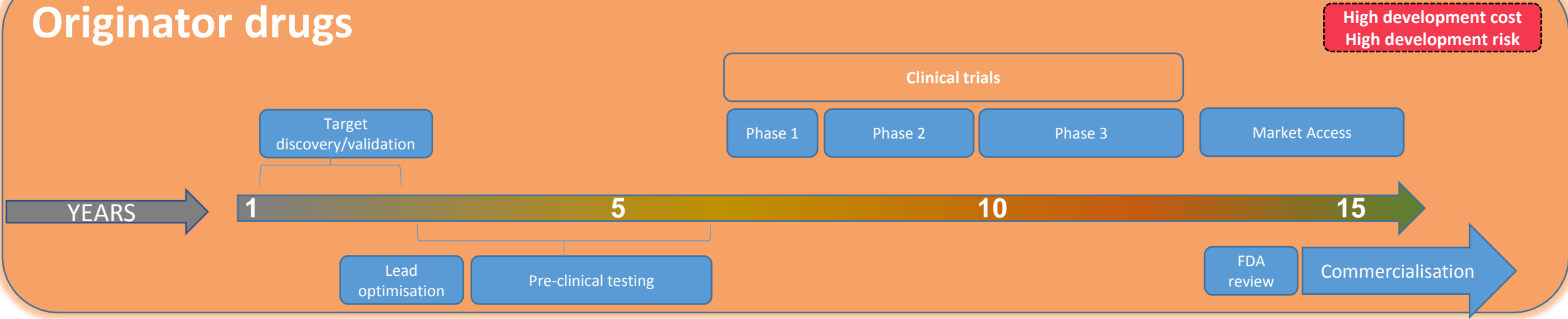


MORE PATIENTS TREATED  
with  
SMALL EXPENDITURE INCREASE

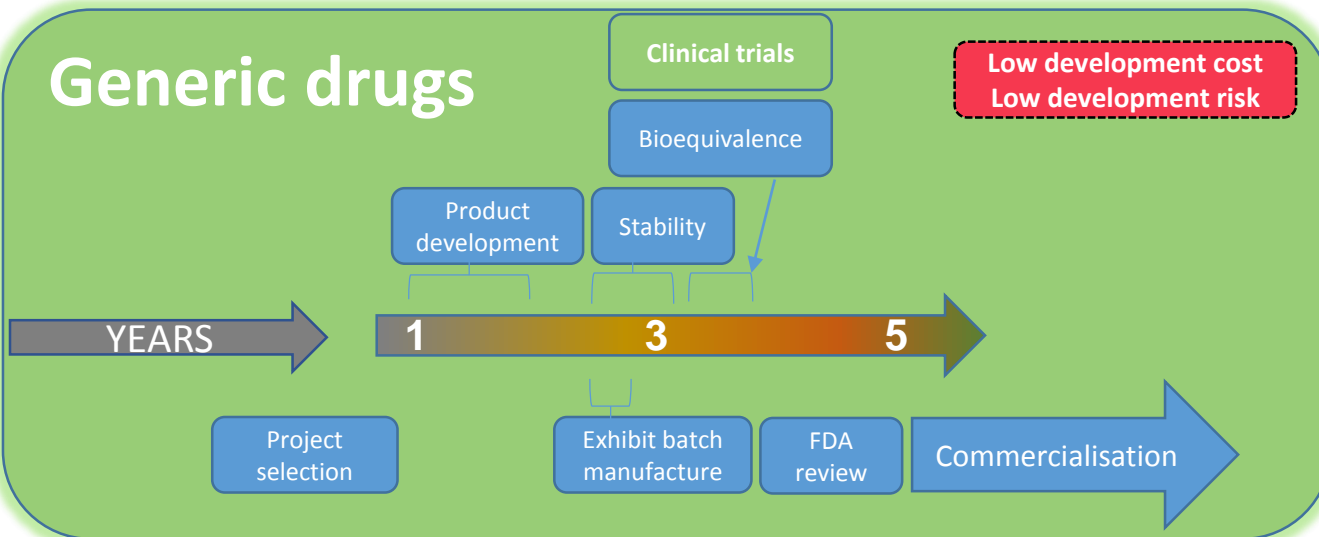


# Timelines for development of originator or generic drugs

## Originator drugs



## Generic drugs



Drug development timelines for generics are substantially shorter than originator drug development

# Agenda

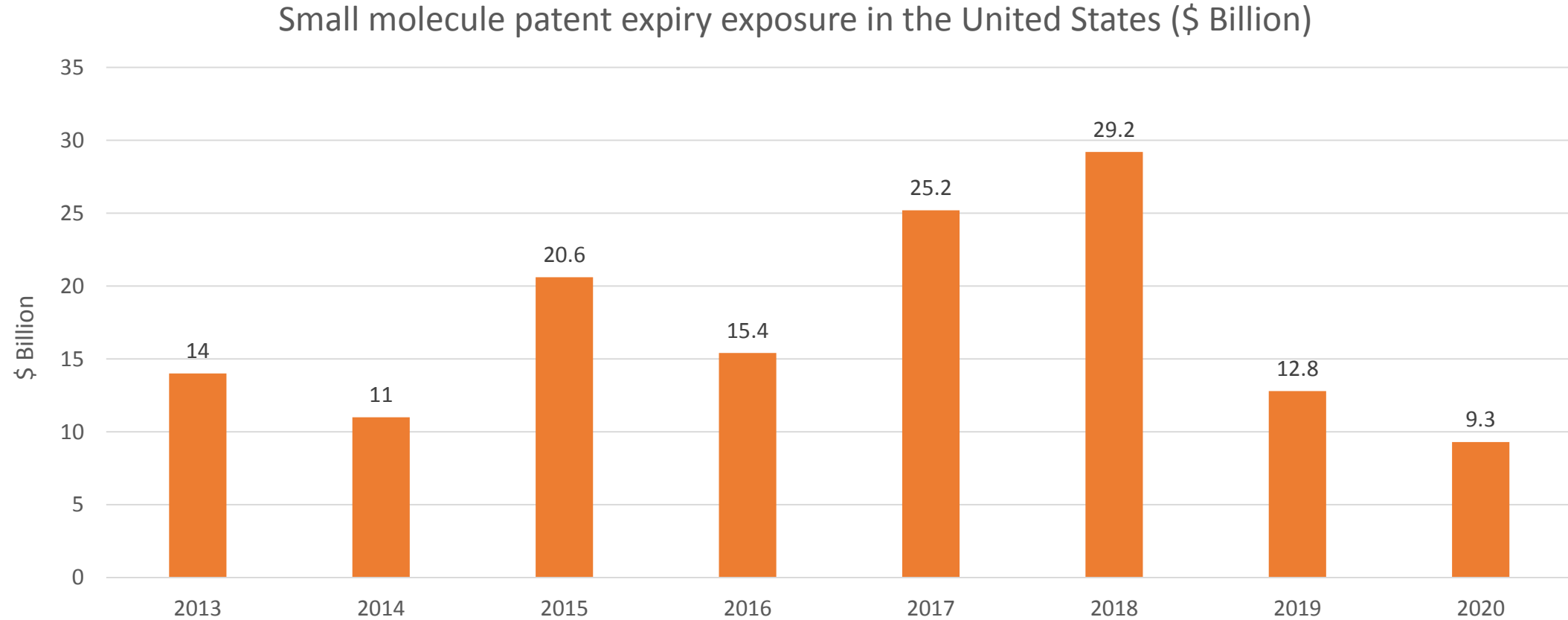
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Generic facts, figures and impact

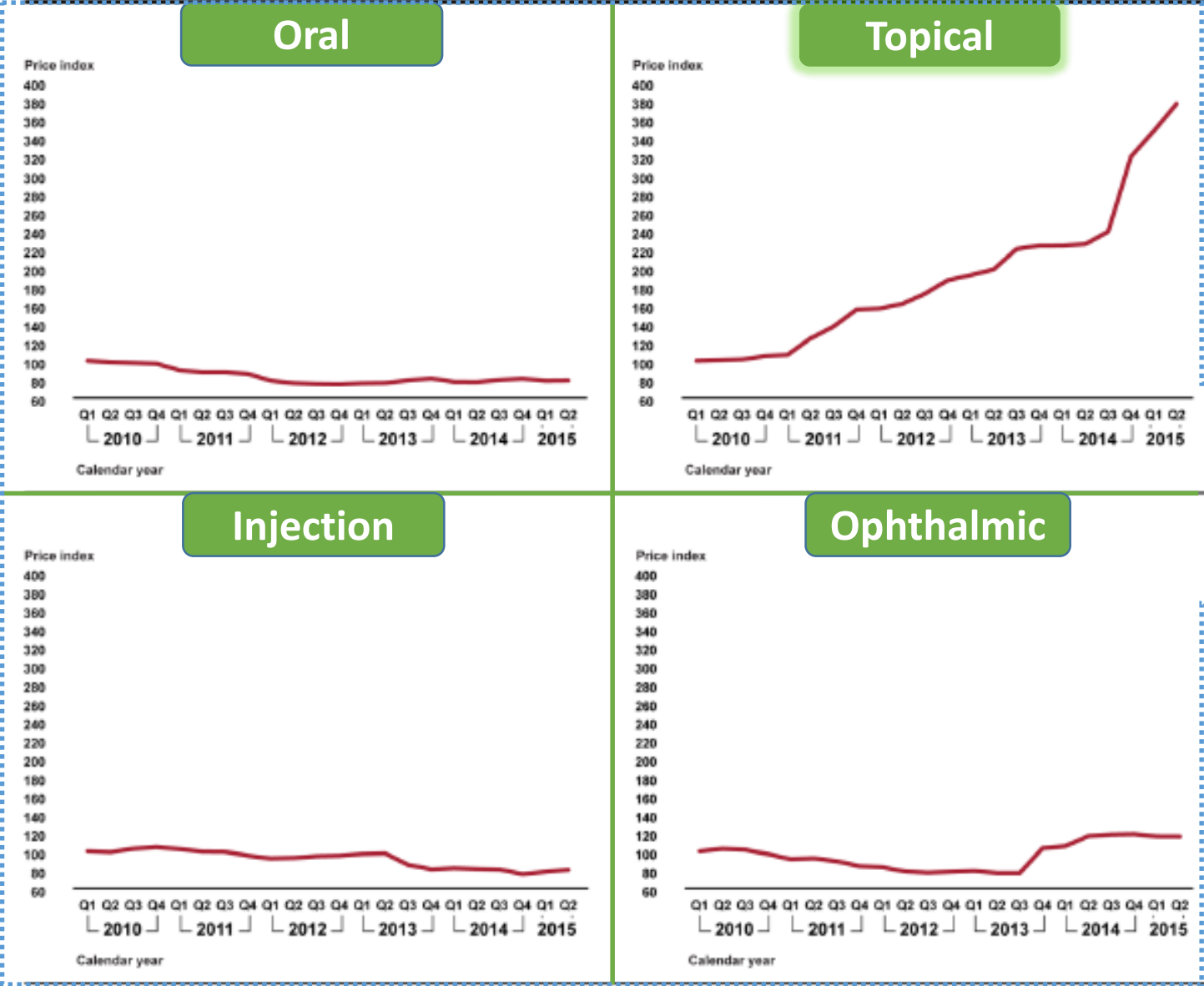
**Generic market evolution**

The Acrux opportunity

# Generic company opportunities - over \$50 billion of branded sales facing loss of exclusivity in coming years

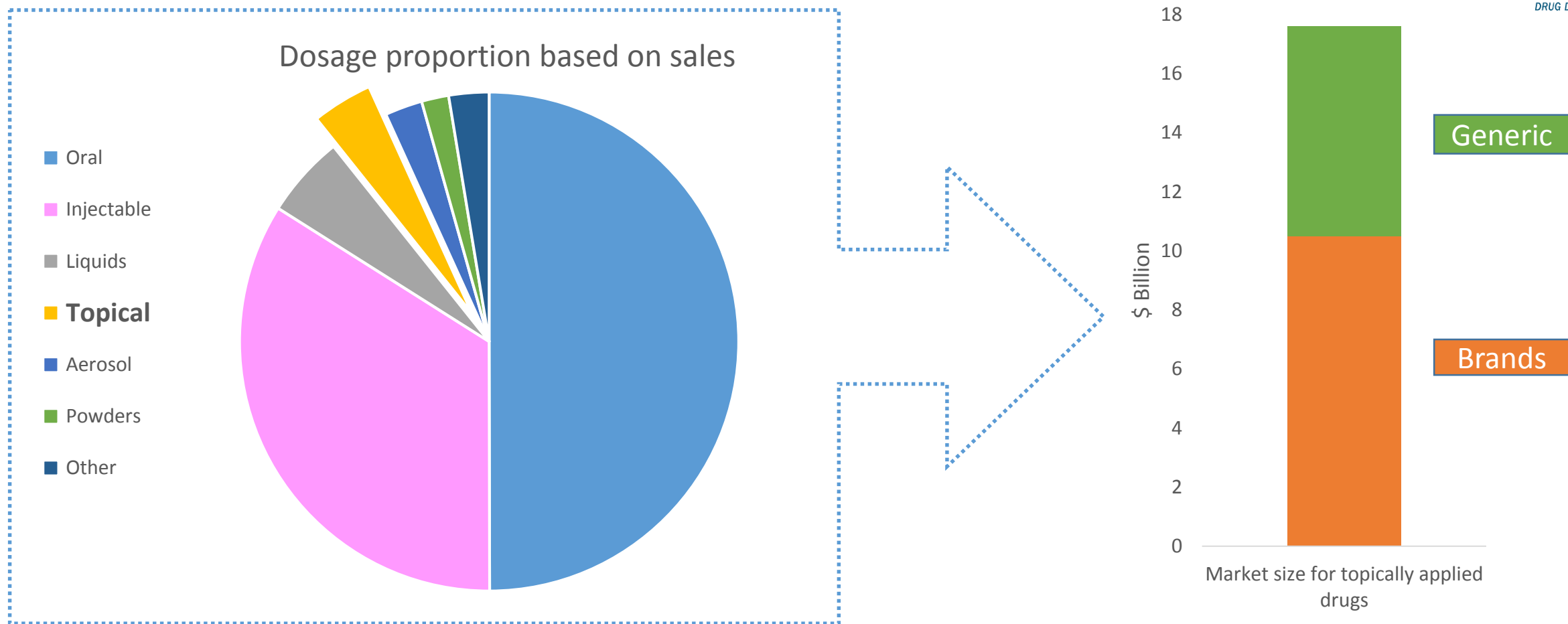


# Changing landscape - United States pricing trends for generics



INCREASED PRICING  
PRESSURE IN  
COMMODITISED SEGMENTS

# 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**

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About generics

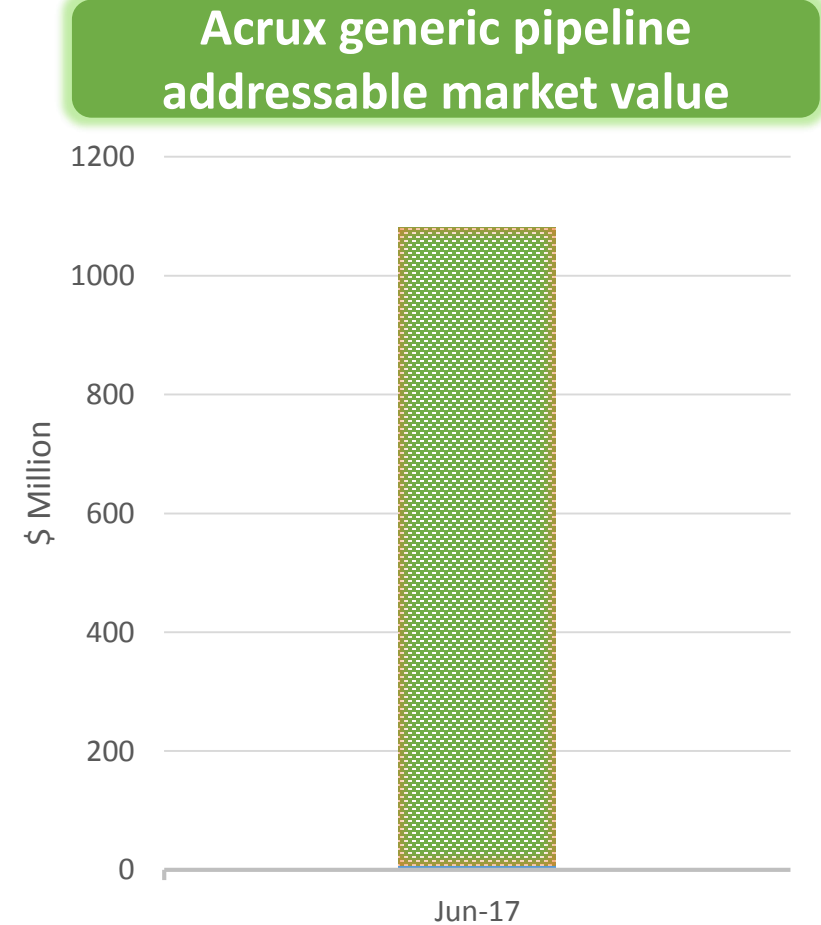
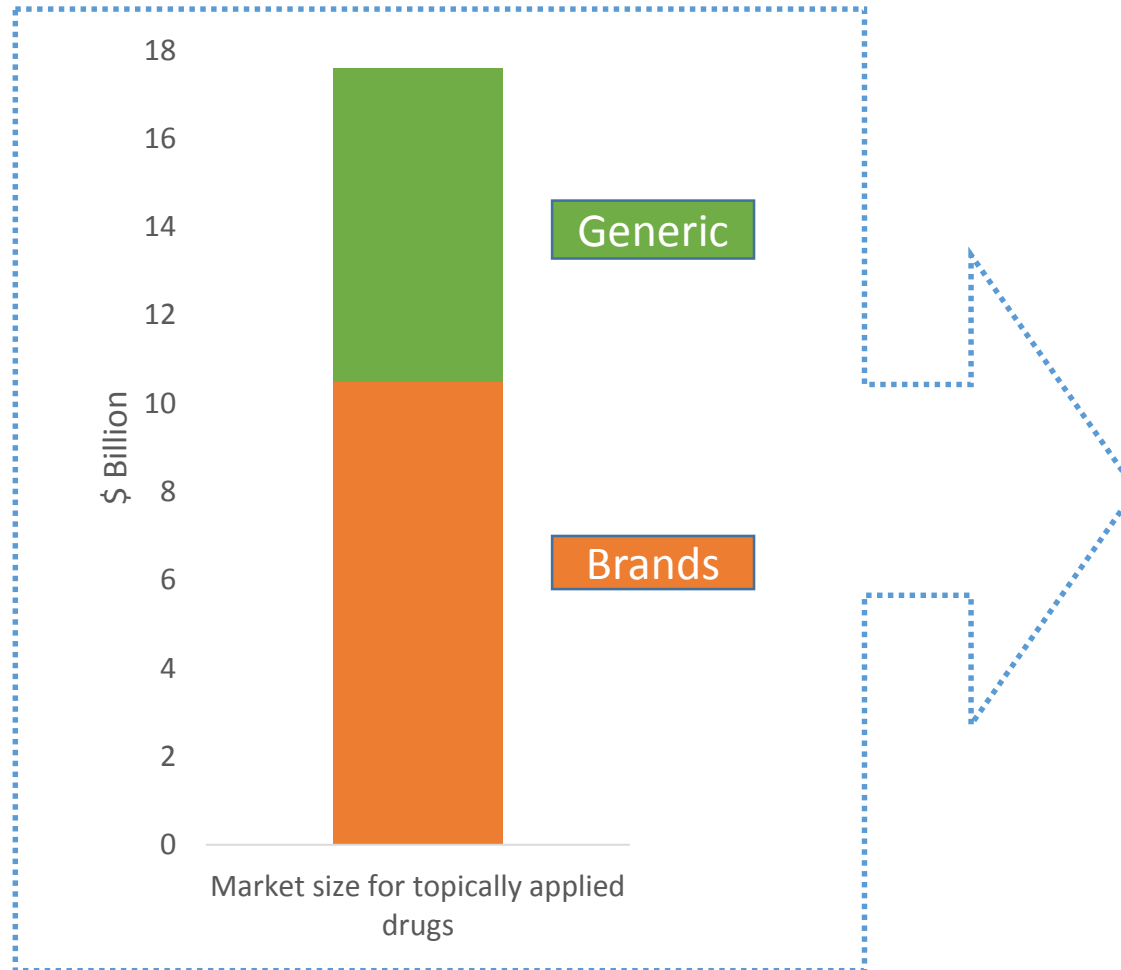
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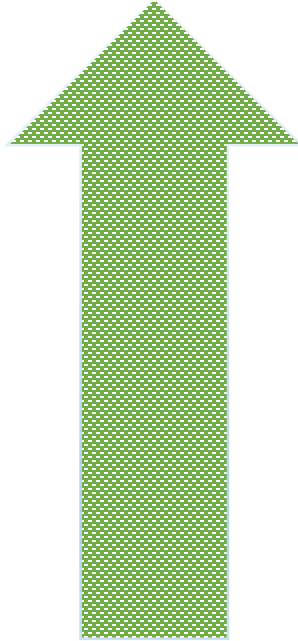


# The Acrux market opportunity



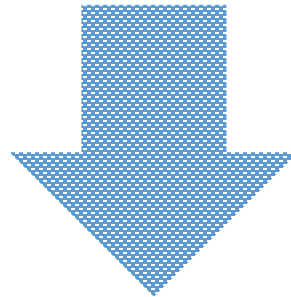
**Acrux has 7 generic products in active development**  
**Acrux expects to increase this to 12 generic products in active development by end FY18**

# Acrux opportunities and challenges ahead



## Opportunities

- Low project risk for generic pipeline compared to branded products
- Considered project selection including products with biowaiver potential or Paragraph IV opportunity
- Avoid commoditised market segments with significant pricing pressure
- Commercialise a diversified broad topical generic portfolio
- FDA costs lower for ANDAs compared to 505(b)(2) or NDA submissions



## Challenges

- Undisclosed pipelines for generic companies

**Acrux plans to file ANDA regulatory submissions mid 2018 for its initial generic products**

