



# LUPIN LIMITED

Investor Presentation – May 15, 2018

**FY 2017 - 18**

# Safe Harbor Statement



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Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents obtained by competitors. Challenges inherent in new product development, including completion of clinical trials; claims and concerns about product safety and efficacy; obtaining regulatory approvals; domestic and foreign healthcare reforms; trends toward managed care and healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.

Also, for products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials, and failure to gain market acceptance.

You are cautioned not to place undue reliance on these forward-looking statements, which reflect our opinions only as of the date of this presentation.

The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events, or otherwise.

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# Our Strategic Focus

# Our Strategic Vision: Well-Diversified Pharma business



## Strong Foundation

*Amongst the Top 10 generic companies in the World*

## Complex Generics Focus

*Investing heavily in developing high barrier products*

## Specialty Focus

*Committed to building a strong specialty business*

### Sustain and Grow

- Major revenue contributor currently
- Maximize on capabilities to maintain leadership in US generics
- Continue growth momentum in India and other emerging markets

### Evolve portfolio

- Deliver on key complex generics, esp. Inhalation and Injectables
- Continued filing of P-IV and semi-exclusive generics
- Successfully file and commercialize biosimilars

### Build

- Create a meaningful women's health franchise in US
- Neurology / CNS focus in other developed markets

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# Global Generics Market Trends

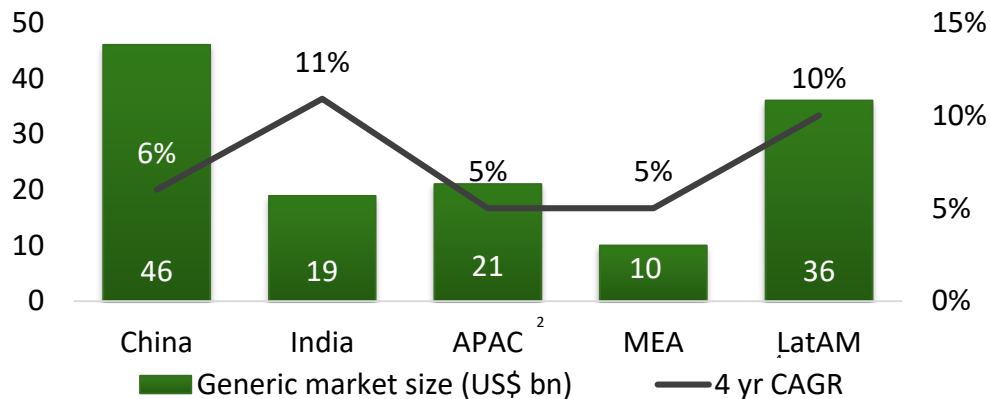


Varying growth trends seen within the ~US\$ 300 bn global generics market

Developed markets exhibiting stronger growth in Specialty<sup>1</sup> except Japan where Gx penetration increased in recent years

Market	Generics		Specialty	
	US\$ bn	4 yr CAGR	US\$ bn	4 yr CAGR
US	68	2%	389	9%
EU5	42	(1%)	105	1%
Japan	8	9%	68	(4%)

Emerging markets continue to show promising growth<sup>1</sup>



Generics industry facing challenges and growth slowing down

## US Generics grew slower than Specialty

- Customer consolidation continues to limit bargaining power
- New generic entrants and ramp-up in approvals exert additional pressure

## India

- Growing well at double digit rates
- Still underpenetrated and high growth potential

## Other

- Emerging markets saw 10% CAGR driven by increasing penetration

Despite challenges, US remains the biggest market

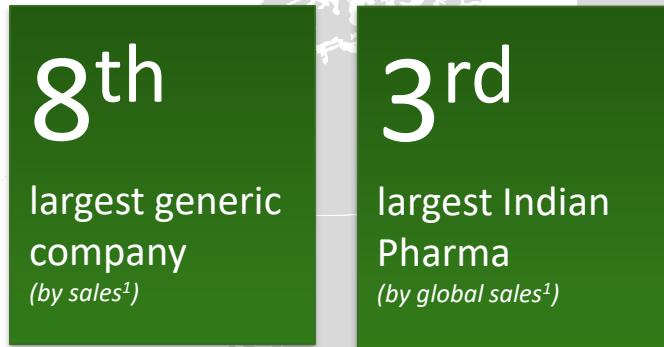
Source:

1. IQVIA MAT DEC 2017; US and Japan Generics include only unbranded products; India includes total market; Rest of the markets include both non-original branded products and unbranded products
2. APAC – ex Japan/China/India

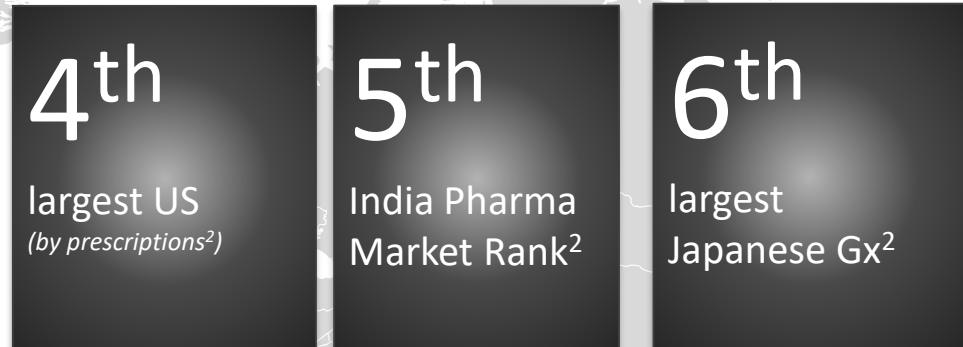
# Lupin - Leadership in Global Generics



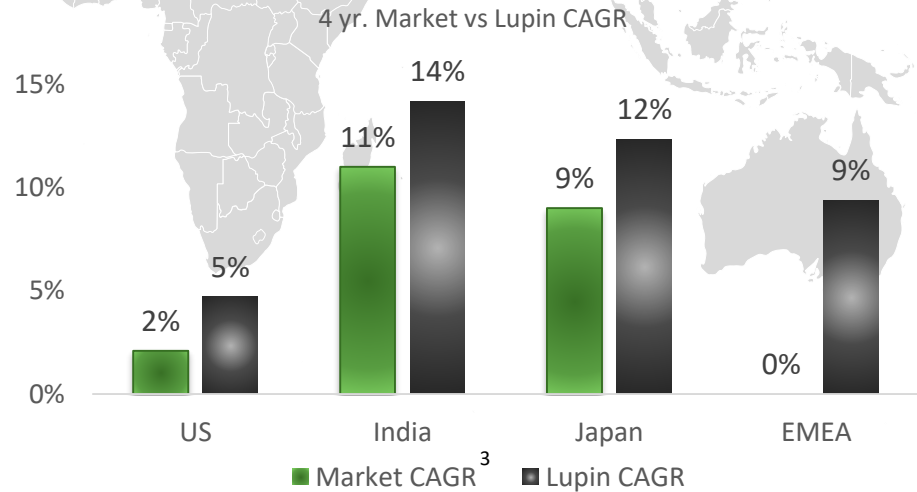
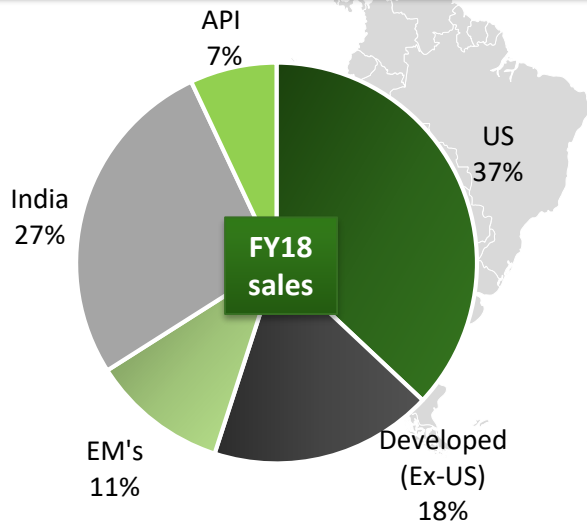
## Globally



## Major Markets



## Diversified geographical footprint and strong growth profile



Sources:  
1. LTM sales available as of 31<sup>st</sup> Dec 2017  
2. IQVIA MAT Mar-18 for respective markets

3. QVIA MAT Dec-17



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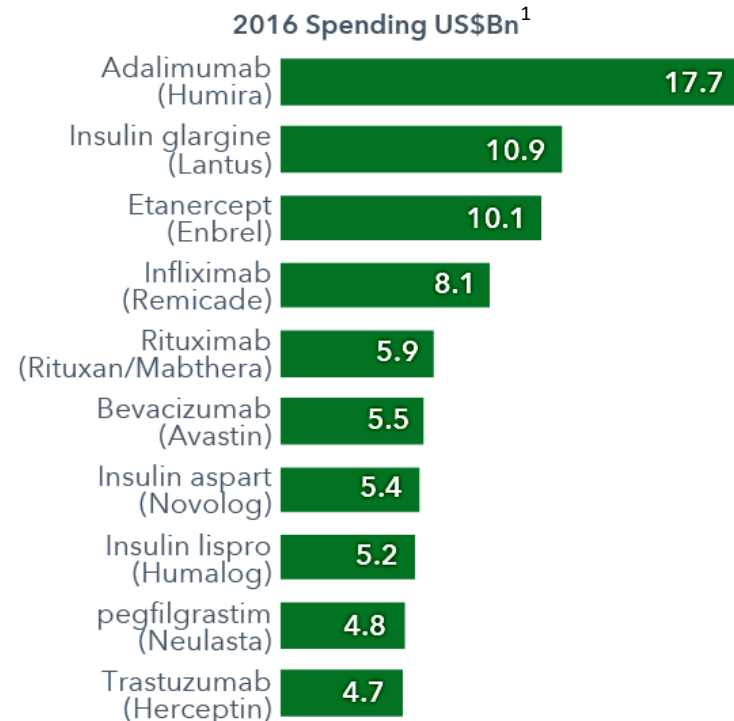
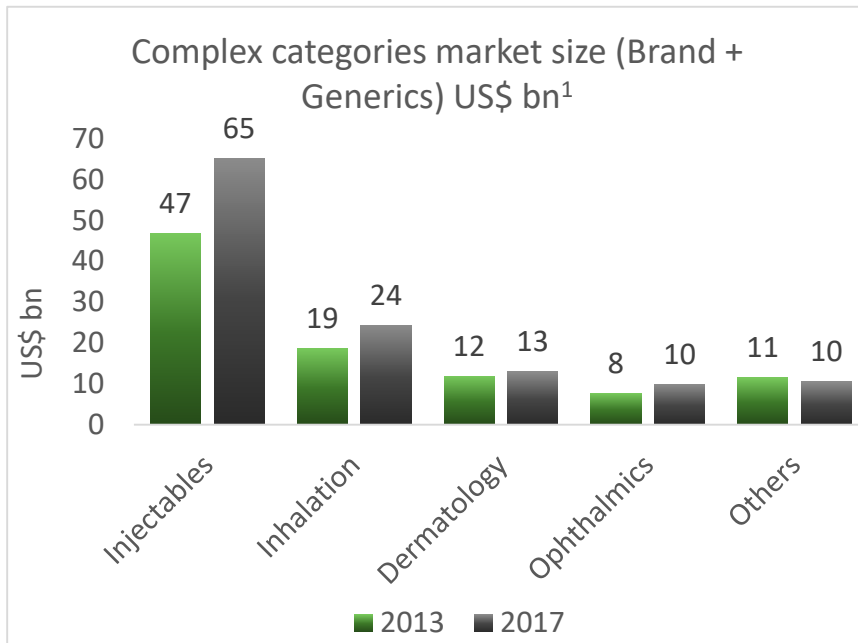
# Complex Generics and Biosimilars Opportunity

Opportunities exist in products with barriers to entry

Potential exists in various categories like

- First to market / first to file opportunities
- Complex molecules in orals
- Complex dosage forms like injectables, inhalation, dermatology and ophthalmics

Global Biosimilars opportunity is evolving as biosimilars have seen good adoption in Europe and gaining adoption in US

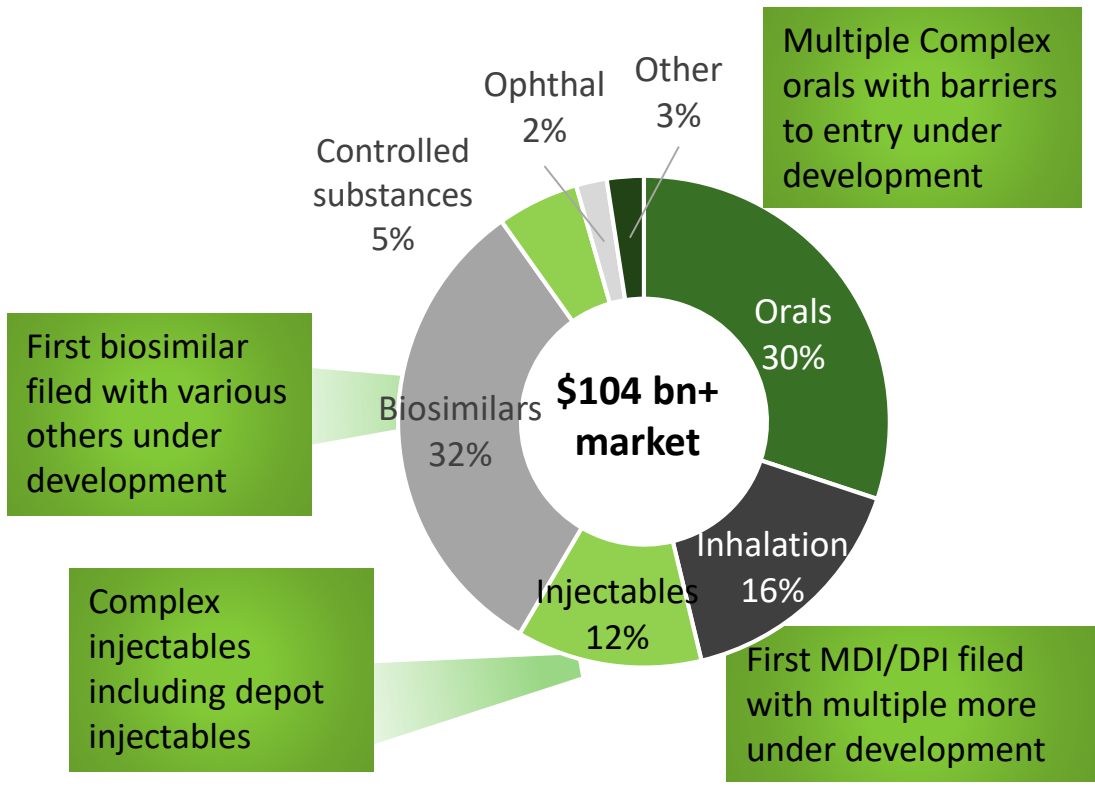


# Lupin - Complex generics and Biosimilars Overview

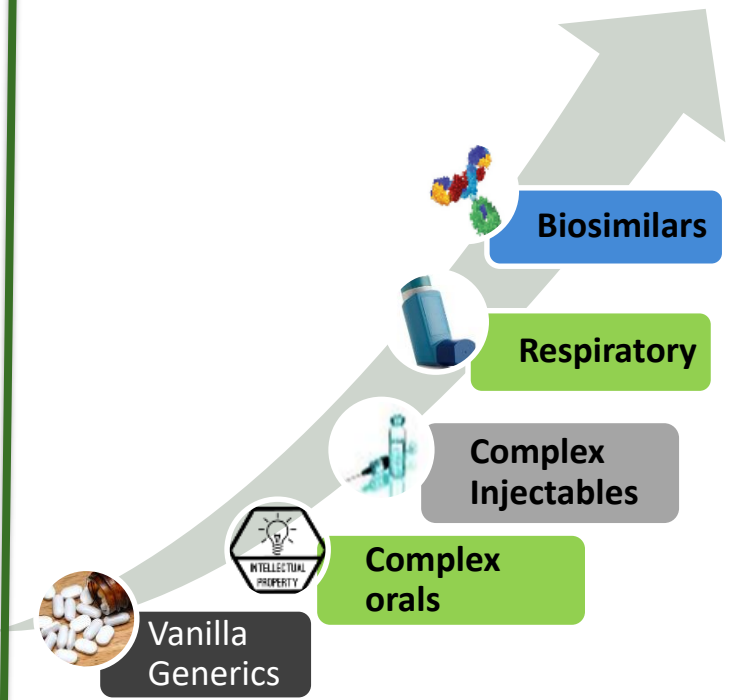
Accelerating investments towards complex generics and global biosimilars

- Prioritizing complex generics pipeline
- Products in development target US\$ 104 bn of which complex categories account for ~70%
- Inhalation, biosimilars first filings done

## Pipeline under development - Market Size Split<sup>1</sup>



## Lupin Focus Shift



1. Sales: IQVIA MAT Jan 2018 / Company reported sales



# Progress on US Inhalation Pipeline

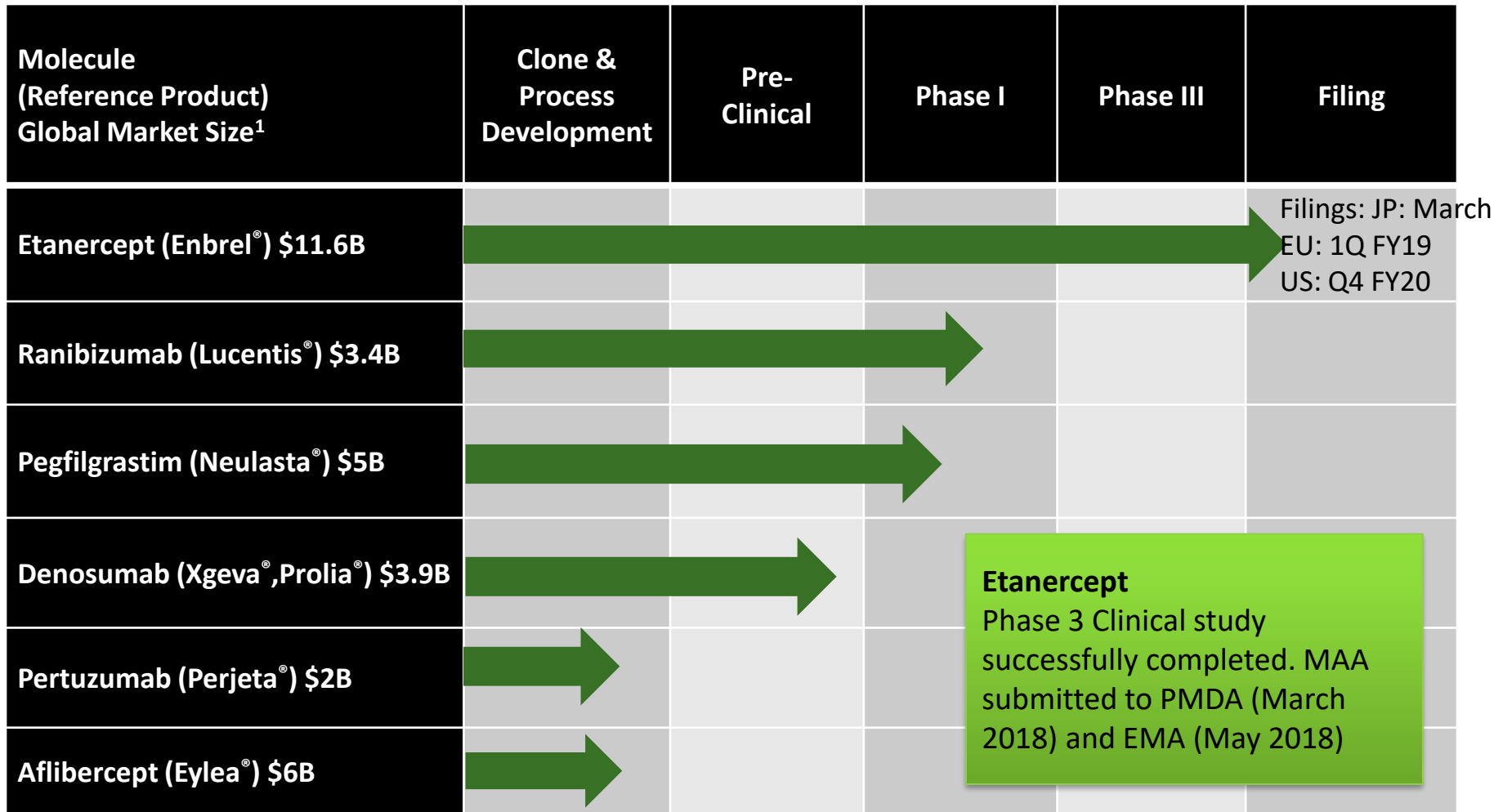
Product (Market Size <sup>1</sup> )	Formulation	PK Study	PD Study	Filing
Tobramycin Sol. (\$ 100 mn+)	→			FY 16 Filed & Approved
Albuterol MDI (\$3 bn)	→			FY 17 Filed
Budesonide susps <sup>2</sup> (\$1 bn)	→			FY 18 Filed
Tiotropium DPI (\$ 2 bn+)	→			Q1 FY19 Filed
Advair DPI (\$ 4 bn+)	→			
MDI 1 (\$ 1 bn)	→			
MDI 2 (\$ 1 bn)	→			
MDI 3 (\$ 1 bn)	→			
MDI 4 (\$ 3 bn)	→			
MDI 5 (\$ 1 bn+)	→			

- Submitted Tiotropium DPI ANDA on completion of PD study on 377 patients
- Responded to all FDA's queries for Albuterol ANDA

Total Inhalation target market size of ~US\$ 17 bn

Note:  
 1. IQVIA MAT Dec 17  
 2. Biowaiver product

# Progress on Biosimilar Pipeline



Total Biosimilar target market size of ~US\$ 33 bn

Sources:  
1. IQVIA MAT Oct 17 and Annual Reports

# Progress on US Injectables Pipeline



## Nanomi Pipeline

Product (Market Size) <sup>1</sup>	Formulation	Clinical Phase	Filing
Risperdal Consta (\$0.4 bn)			Developing multiple depot injectables
Depot 2 (\$1.7 bn)			
Depot 3 (\$0.4 bn)			

## LRP Complex injectables Pipeline

Product Name (Market Size) <sup>1</sup>	API/RM/PM sourcing	Q1/Q2 status	Formulation and characterization	Validation	Registration batches	Clinical	Submission
Product 1 (\$0.7 bn)				<ul style="list-style-type: none"> <li>Advancing other injectables pipeline out of India which includes various complex products;</li> <li>Filed 4 in FY18 ; Expected to file 5+ in FY19 with Mihan plant commissioning</li> </ul>			
Product 2 (\$0.3 bn)							
Product 3 (\$0.3 bn)							
Product 4 (\$0.2 bn)							

Complex Injectables market size ~US\$ 4 bn in depot; >US\$ 1.5 bn in other complex injectable

Note:  
 1. IQVIA MAT Jan 18  
 2. Biowaiver product



# Our Strategic Vision: Well-Diversified Pharma business



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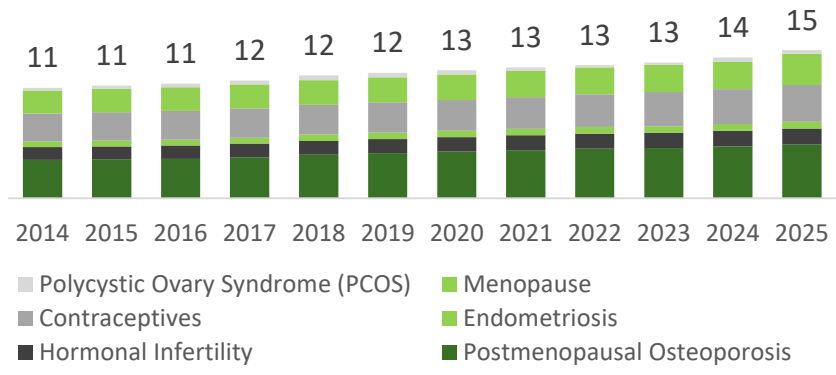
## Specialty Focus

*Committed to building a strong specialty business*

# Specialty: Women's Health and CNS

Women's health represents large market with areas of unmet needs

## US Women's Health market by therapies<sup>2</sup>



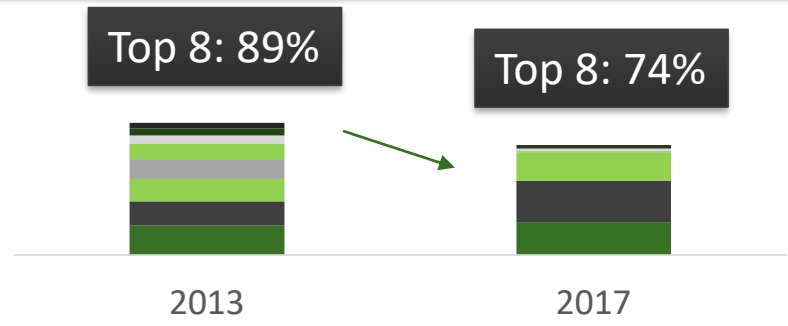
## Commentary

Large market worldwide and growing steadily

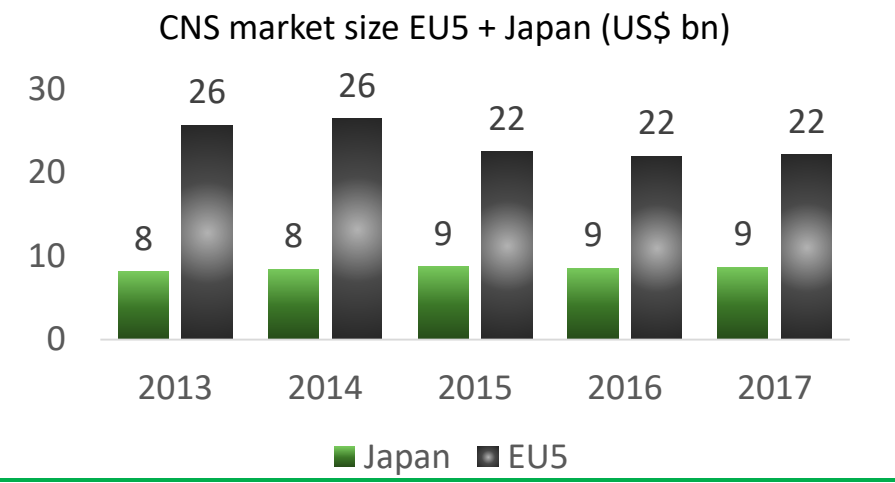
- US market estimated at about ~US\$ 12 bn and growing
- Global market at US\$ 31- 35 bn now growing at single digit to as much as US\$ 45 - 50 bn by 2025

## Market share of Branded players in WH<sup>1</sup>

Big Pharma defocusing on this space; Top 8 share declined from 89% to 74% in last 4 years



## CNS



Sources:  
1. IQVIA MAT Dec 17  
2. Grand View Research 2025

# Solosec: Opportunity and Launch Plan



## Bacterial Vaginosis: Scope of the Problem

- Most prevalent US gynecological infection<sup>1</sup>
- Prevalence: 29.2%
- 22 million US women aged 14-49<sup>1</sup>
- High recurrence rate: 43% at 3 months, 58% at 12 months<sup>2,3</sup>
- >4 million women treated annually<sup>4</sup>
- Large untreated population
- Significant impact to QOL<sup>5</sup> and has serious health consequences<sup>6</sup>



- Launching in the US in June 2018
- First and only BV treatment designed to deliver a complete course of therapy in just one oral dose
- Designated as a Qualified Infectious Disease Product (QIDP) with 10 years of exclusivity



### Commercial

- 166 Field Sales Reps calling on WH Providers
- 70% of # of reps have WH experience (Average ~7 years)

### R&D and Manufacturing

Lupin  
capabilities

### Medical

- Leadership: MDs with clinical practice experience and WH expertise
- MSLS focused on other medical activities

### Business Development

1. KoumansEH, et al. *Sex TransmDis*.2007;34:864-9.  
2.NagarajaP. *Indian J Med Microbiol*. 2008;26:155-157.  
3.Ferris MJ et al. *BMC Infect Dis*. 2004;4:1-8

4. IQVIA LRx, Dx, 2014  
5. BilardiJE et al. *PLoSOne*. 2013;8:1-11.  
6. BrotmanRM et al. *JID*. 2010:1907-1915.



# Specialty: Namuscla (EU) and Bipresso (Japan)



## Namuscla

- Acquired rights with Temmler acquisition
- Filed Namuscla (Mexiletine), an orphan drug indicated for Myotonia symptoms (neurology) in EU in 1Q FY18
- Myotonia is a rare genetic neuromuscular movement disorder
- Prevalence: ~80,000 – 90,000 patients
- **Namuscla value proposition:** Treatment of choice for myotonia symptoms:
  - Rapid response
  - Lower side effects, which are transient and manageable
  - Most cost effective



## Bipresso®

- Exclusively in-licensed CNS specialty product Bipresso® (Quetiapine ER tablets) from Astellas
- Launched in Japan in 3Q FY18
- Bipresso® is highly recommended atypical Anti-Psychotic in Japan and across several international treatment guidelines<sup>1</sup>
- Patient enrollment for Bipresso has been trending favorably; growing 58% m-o-m since launch



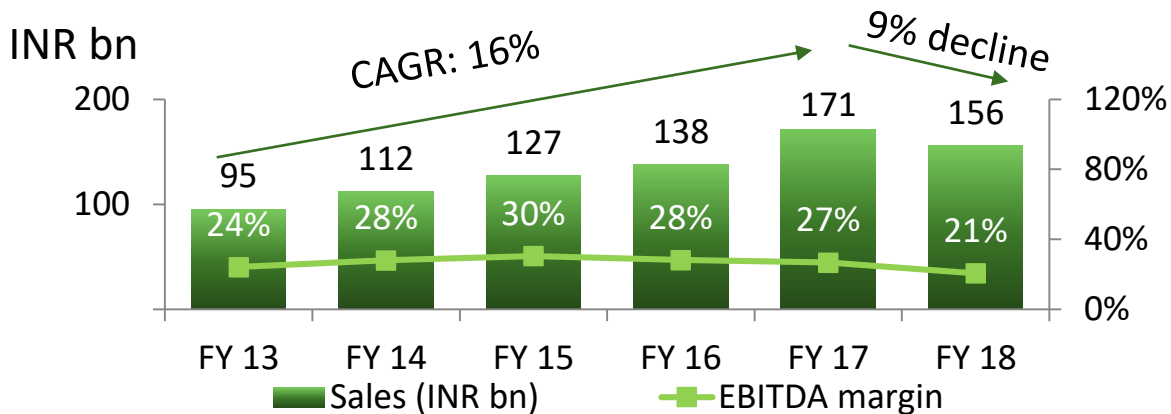
# Business Performance

# FY18 Financial Performance



After 5 years of consistent revenue growth at 16% CAGR, 9% decline in FY18

## Sales and EBITDA Evolution



FY18

- Declined 9% YoY to INR 156 bn

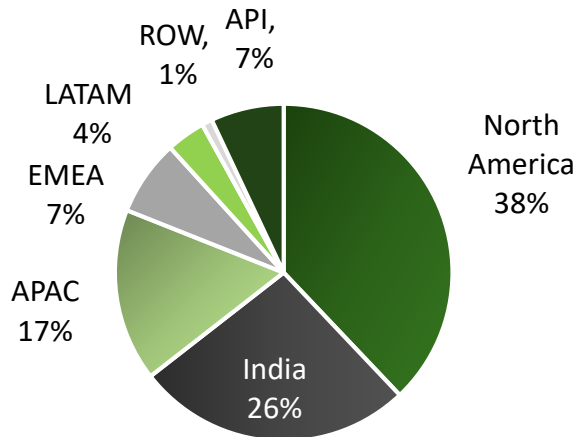
US decline

- 27% YoY sales decline
- Salience declined from 48% to 37%

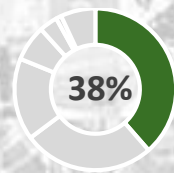
Rest of World grew

- 14% sales growth in ex-US export formulations
- India business grew by 11%<sup>1</sup>

## FY18 Business Split



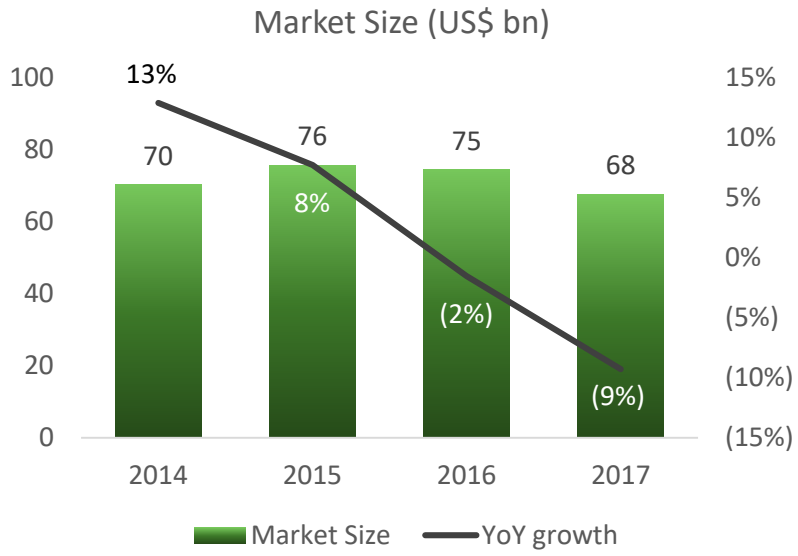




	Q4FY18	
FY18	YoY	QoQ
↓ 29%	↓ 21%	↑ 5%

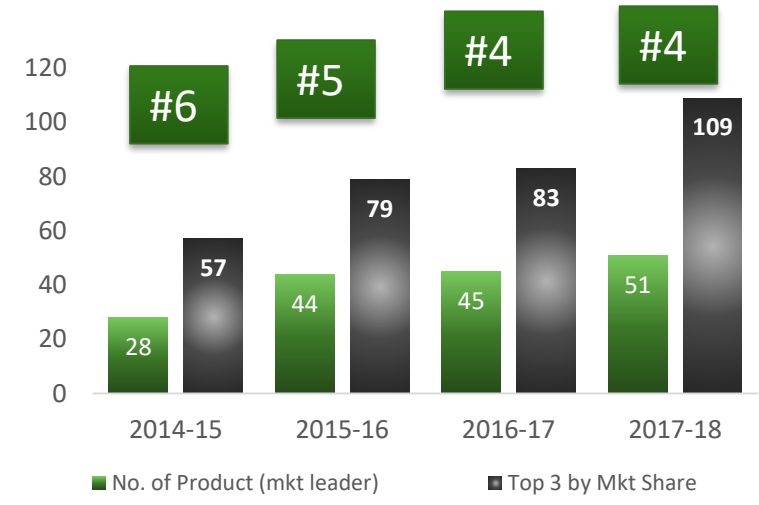


## US Generics market declined

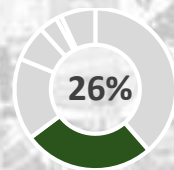


- Customer consolidation and new competition has led to continued pressure
- Increased price competition was seen in the same molecules

## Lupin has consolidated its position in US



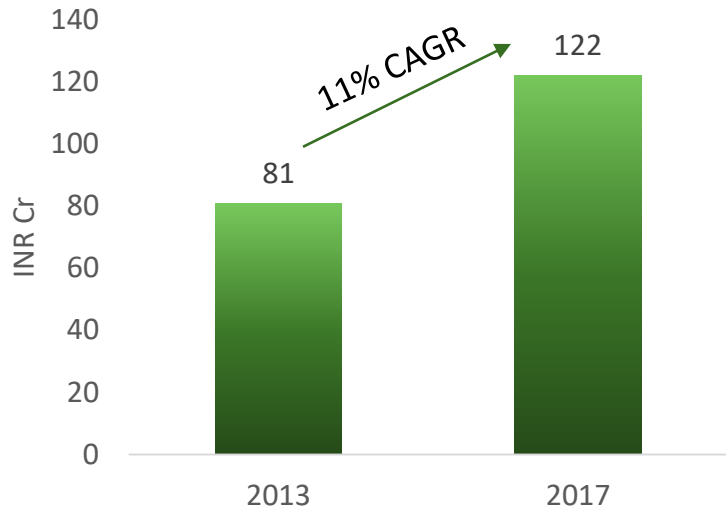
- Moved from #6 to #4 by prescriptions in US
- Launched 23 products in FY18 with record 11 launches in Q4 FY18
- Brands share increased to 10% in FY18 (up 16% YoY) from 6% in FY17
- High approval to launch ratio in US



	Q4FY18	
FY18	YoY	QoQ
↑ 11% <sup>3</sup>	↑ 14% <sup>3</sup>	↓ 10%



India market has grown at 11% CAGR<sup>1</sup>



3 therapies have crossed INR 500 cr annual sales and jumped multiple ranks<sup>2</sup>

Therapy	CAGR FY 14-18 <sup>2</sup>		Lupin Rank <sup>2</sup>	
	Market	Lupin	FY14	FY18
Acute	10	13	13	11
Chronic	13	22	6	4
Cardiac	11	15	3	3
Anti-diabetics	17	40	7	4
Respiratory	10	20	6	2
Gynaecology	9	26	16	9

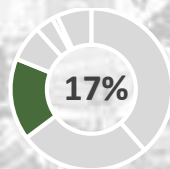
- Growth driven by increasing penetration in Tier I to Tier IV markets which grew faster than total market
- Disruptions like GST and demonetization led to 5% volume decline in 2017

- **PCPM** tracking at **INR 6.3 lakhs per month** in FY18 (INR 5.6 lakhs per month in FY17)
- **8 brands enter top 300** in March 2018 as compared to 5 brands for FY17
- Ranked #2 amongst **new introductions** in FY18
- **Softovac OTC** gaining market share amongst bulk laxatives; Launched **Corcal OTC** brand

Note:  
 1. IQVIA MAT Mar'14 – Mar'18  
 2. Data corresponds to IQVIA MAT Mar 2018

3. Adjusted for excise duty



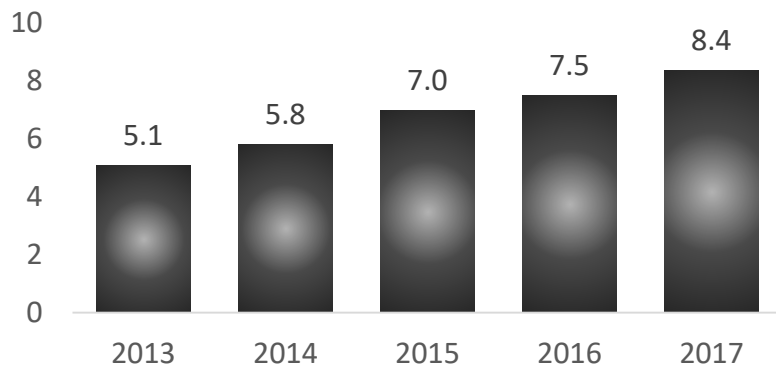


	Q4FY18	
FY18	YoY	QoQ
↑ 14%	↑ 8%	↓ 2%

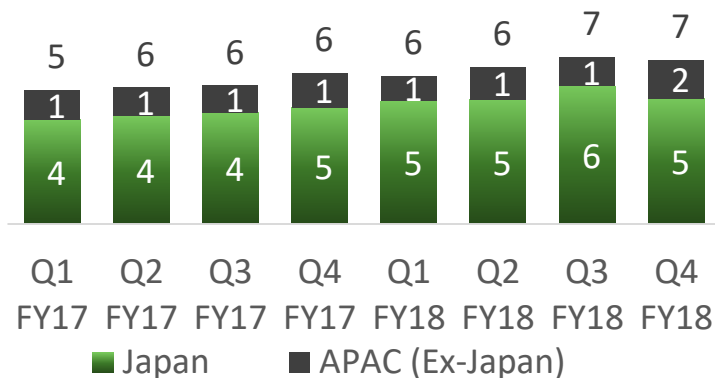


## Japan market saw decline in 2017 due to channel dis-incentivization

Japan Generics Market (US\$ bn)



APAC Sales Evolution (INR bn)



### Japan Generics Market Update

- Generics substitution market witnessed lower growth in last year due to channel dis-incentivization
- Generics price cuts announced to the tune of 12-14% for major generics
- LLPs inclusion in price reforms

### Performance highlights

#### Japan

- Lupin has recorded steady growth
- Successfully launched Bipresso
- LLP price reforms affected 4 of 18 brands
- Focused on research and manufacturing efficiencies

#### APAC ex Japan

- Australia grew 28% YoY led by new launches

## Developed

EU5

- Germany: EUR 31 mn sales in FY18; up 18% YoY
- ARV's, Women's Health and CNS are the key focus therapeutic segments
- Filed Namuscla (Mexiletine), orphan drug for movement disorder

Canada

- CAD 17 mn sales in FY18; up 57% YoY
- Focus on specialty GI and Women's Health with dedicated specialty field force

## Emerging markets

South Africa

- 4<sup>th</sup> largest generics player & #3 generic company by prescriptions
- Market leader in CVS space

Brazil

- BRL 157 mn sales in FY18; up 25% YoY led by branded generics segment
- Making inroads into niche cosmeceutical segment
- Focus to strengthen portfolio through organic route/strategic alliances

Mexico

- MXN 643 mn sales in FY18: up 21% YoY on new product launches
- Grin is #4 ophthalmic player

API + Global Institutional

- Enhanced focus on mainstay product APIs
- Leadership in TB institutional business
- Robust ARV pipeline under development

# P&L Highlights – Q4 FY18



Particulars (INR mn)	Q4 FY18	% of sales	Q3 FY18	% of sales	QoQ growth	Q4 FY17	% of sales	YoY growth
Net sales	39,785	100.0%	39,004	100.0%	2.0%	41,619	100.0%	(4.4%)
Other operating income	553		753			914		
<b>Total revenue</b>	<b>40,338</b>		<b>39,757</b>		<b>1.5%</b>	<b>42,553</b>		<b>(5.2%)</b>
Gross profit (excl. other operating income)	26,159	65.8%	25,077	64.3%	4.3%	29,768	71.5%	(12.1%)
<b>EBITDA</b>	<b>8,536</b>	<b>21.5%</b>	<b>7,168</b>	<b>18.4%</b>	<b>19.1%</b>	<b>8,267</b>	<b>19.9%</b>	<b>3.3%</b>
PBT (before Exceptional item)	5,223	13.1%	3,824	9.8%	36.6%	5,187	12.5%	0.7%
PBT (after Exceptional item)	(9,421)	(23.7%)	3,824	9.8%	(346%)	5,187	12.5%	(282%)
<b>Reported Net profit</b>	<b>(7,835)</b>	<b>(19.7%)</b>	<b>2,217</b>	<b>5.7%</b>	<b>(453%)</b>	<b>3,802</b>	<b>9.1%</b>	<b>(306%)</b>
<b>Net Profit before exceptional items</b>	<b>3,586</b>	<b>9.0%</b>	<b>2,217</b>	<b>5.7%</b>	<b>61.8%</b>	<b>3,802</b>	<b>9.1%</b>	<b>(5.7%)</b>

# P&L Highlights – FY18



Particulars (Rs mn)	FY18	% of net sales	FY17	% of net sales	YoY growth
<b>Net sales</b>	<b>155,598</b>	<b>100.0%</b>	<b>171,198</b>	<b>100.0%</b>	<b>(9.1%)</b>
Other operating income	2,443		3,745		
<b>Total revenue</b>	<b>158,041</b>		<b>174,943</b>		<b>(9.7%)</b>
Gross profit <i>(excl. other operating income)</i>	102,854	66.1%	121,184	70.8%	(15.1%)
<b>EBITDA</b>	<b>32,979</b>	<b>21.2%</b>	<b>45,997</b>	<b>26.9%</b>	<b>(28.3%)</b>
PBT (before Exceptional items)	20,077	12.9%	35,350	20.6%	(43.2%)
PBT (after Exceptional items)	5,433	3.5%	35,350	20.6%	(84.6%)
<b>Reported Net profit</b>	<b>2,513</b>	<b>1.6%</b>	<b>25,575</b>	<b>14.9%</b>	<b>(90.2%)</b>
<b>Net Profit before exceptional items</b>	<b>13,934</b>	<b>9.0%</b>	<b>25,575</b>	<b>14.9%</b>	<b>(45.6%)</b>

## Gavis Impairment

- Significant pressure in US generic pricing, particularly in the opioid space (large part of Gavis' portfolio) resulted in reassessment of the fair value of Gavis
- All products where the carrying value was higher than the value in use have been impaired to the extent of such difference, following conservative accounting principles
- Exceptional impairment provision of INR 14.6 bn (US\$ 227.2 mn) for 4Q FY18 and FY18

## Effective Tax Rate

Reported Effective Tax Rate for FY18 stood at 53.1% as:

- Deferred tax for 4Q FY18 and FY18 includes deferred tax asset of INR 3.2 bn created on difference between tax & book value of certain intangible assets of Gavis
- Re-measurement of deferred tax assets/liabilities pertaining to US operations on enactment of the new tax regime amounted to INR 405 mn charge for 4Q FY18 and INR 766 mn for FY18

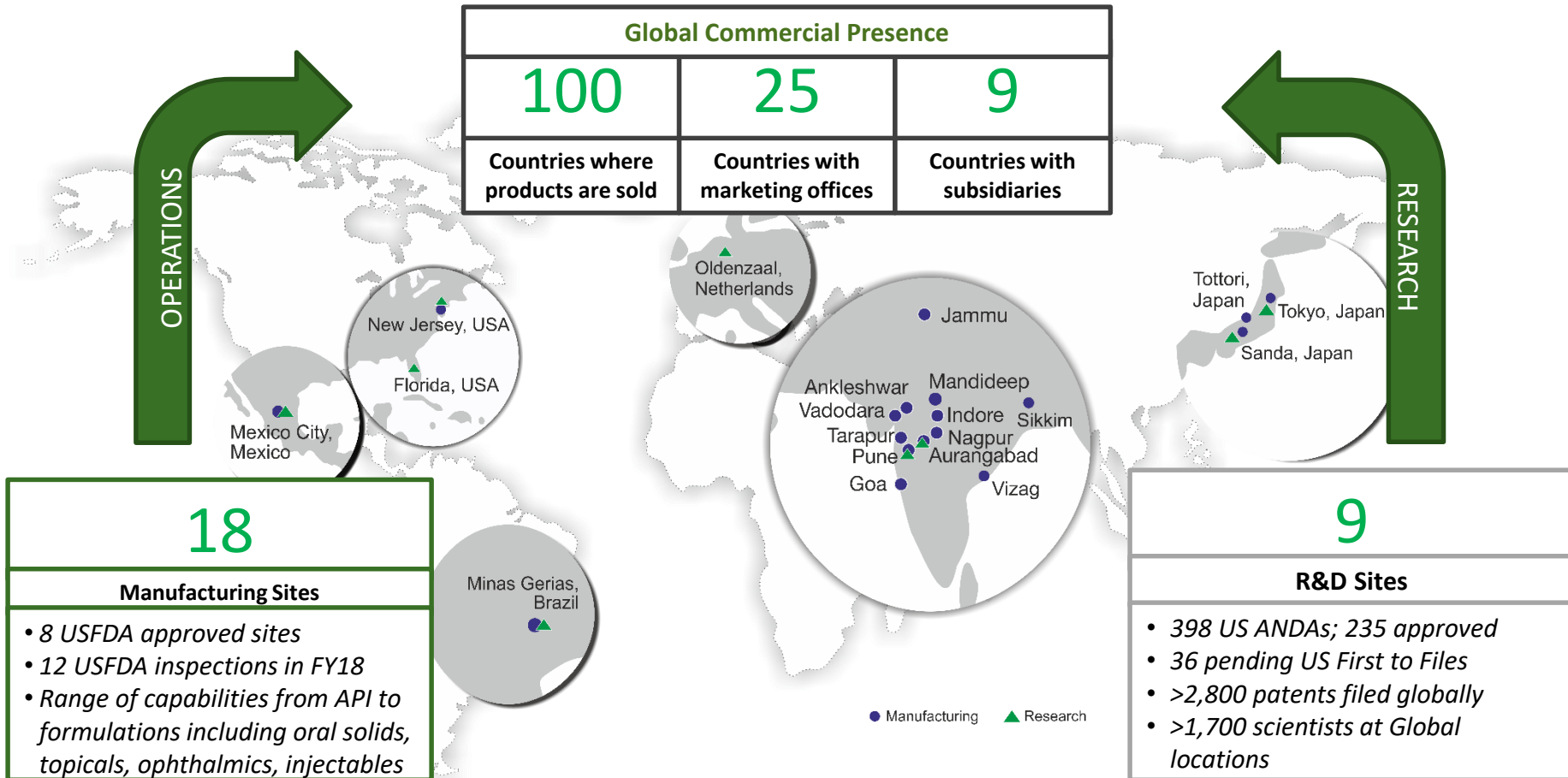
**Adjusted for the above two items, Effective Tax Rate for FY18 stood at 26.3%**



# Global Operational Footprint

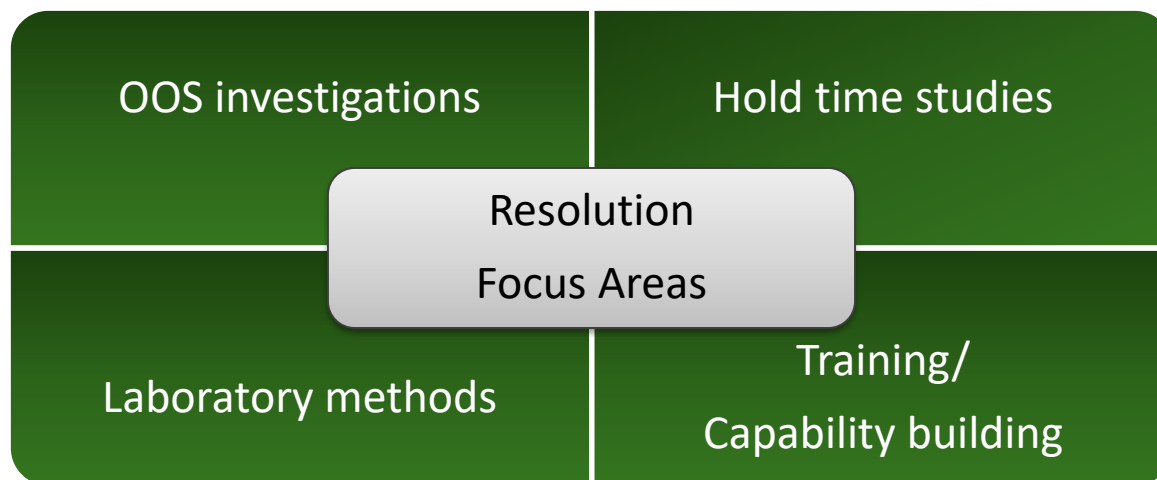
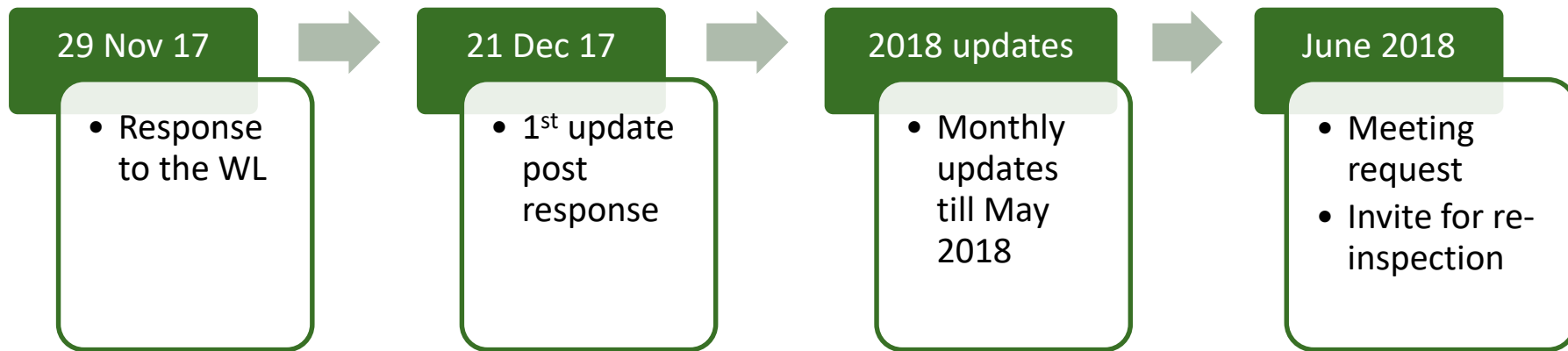


# Manufacturing and R&D – Diverse Global Network



# Warning Letter update

Created a holistic action plan to tackle the WL cited issues at all FDA inspected plants



# 12 USFDA inspections in FY18



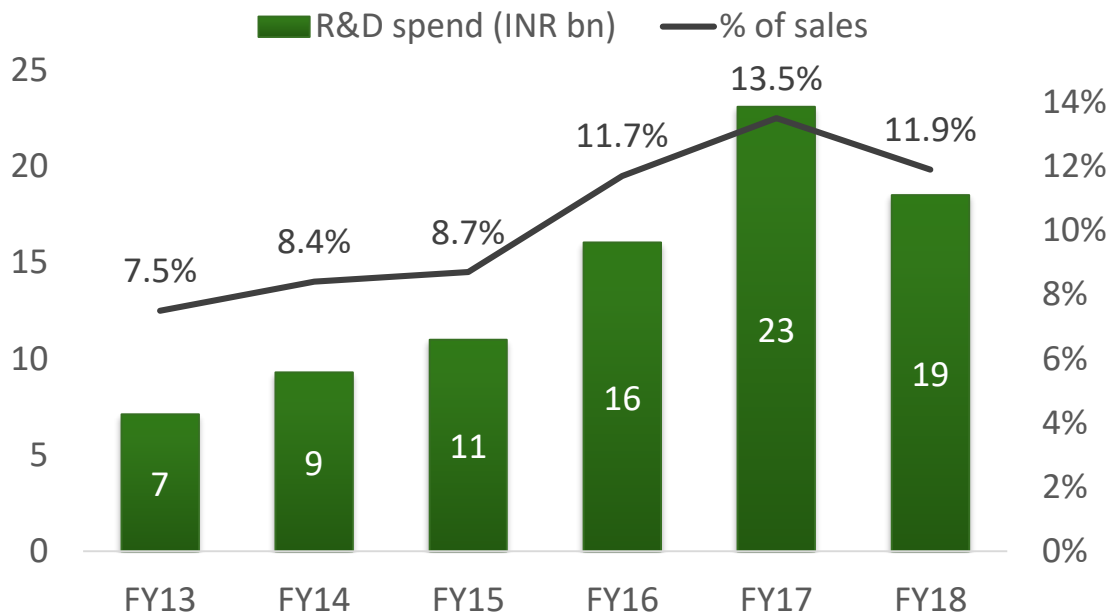
Facility	Type	Capabilities	Last Inspection	Remarks
Nagpur	Formulations	Oral solids	May 2018	No observations
Visakhapatnam	API	NA	Aug 2017	EIR received
Pithampur (Unit 1)	Formulations	Oral solids	Jul 2017	EIR received
Aurangabad	Formulations	Oral solids/liquids	Jul 2017	EIR received
Goa	Formulations	Oral solids	Jul 2017	Pre-approval inspection. No observations
Pithampur (Unit 3)	Formulations	Derma, Inhalation	Jun 2017	EIR awaited
Lupin Bioresearch center (Pune)	NA	NA	Jun 2017	No observations
Pithampur (Unit 3)	Formulations	Derma, Inhalation	Jun 2017	Pre-approval inspection. No observations
Pithampur (Unit 2)	Formulations	Oral solids, Sterile ophthalmic	Jun 2017	Pre-approval inspection. No observations
Nagpur	Formulations	Oral solids	May 2017	No observations
Pithampur (Unit 2)	Formulations	Oral solids, Sterile ophthalmic	May 2017	Received warning letter in Nov'17. Resolution being undertaken
Aurangabad	API	NA	Apr 2017	EIR received
Goa	Formulations	Oral solids	Apr 2017	Received warning letter in Nov'17. Resolution activities underway



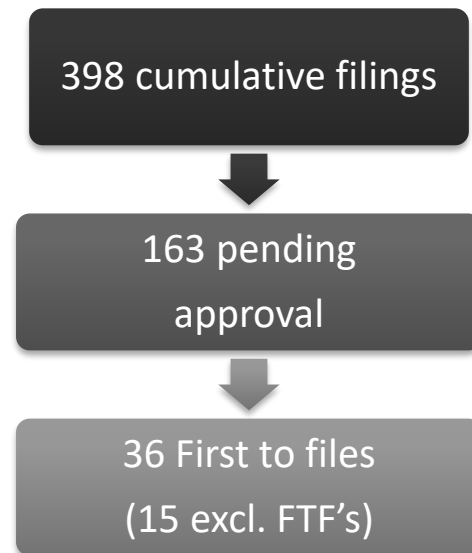
# R&D investment for the future

Invested INR 18.5 bn or 11.9% of sales on R&D in FY18 at 9 R&D sites globally

## R&D spend



## Generics filings Pipeline



## Optimizing R&D spend

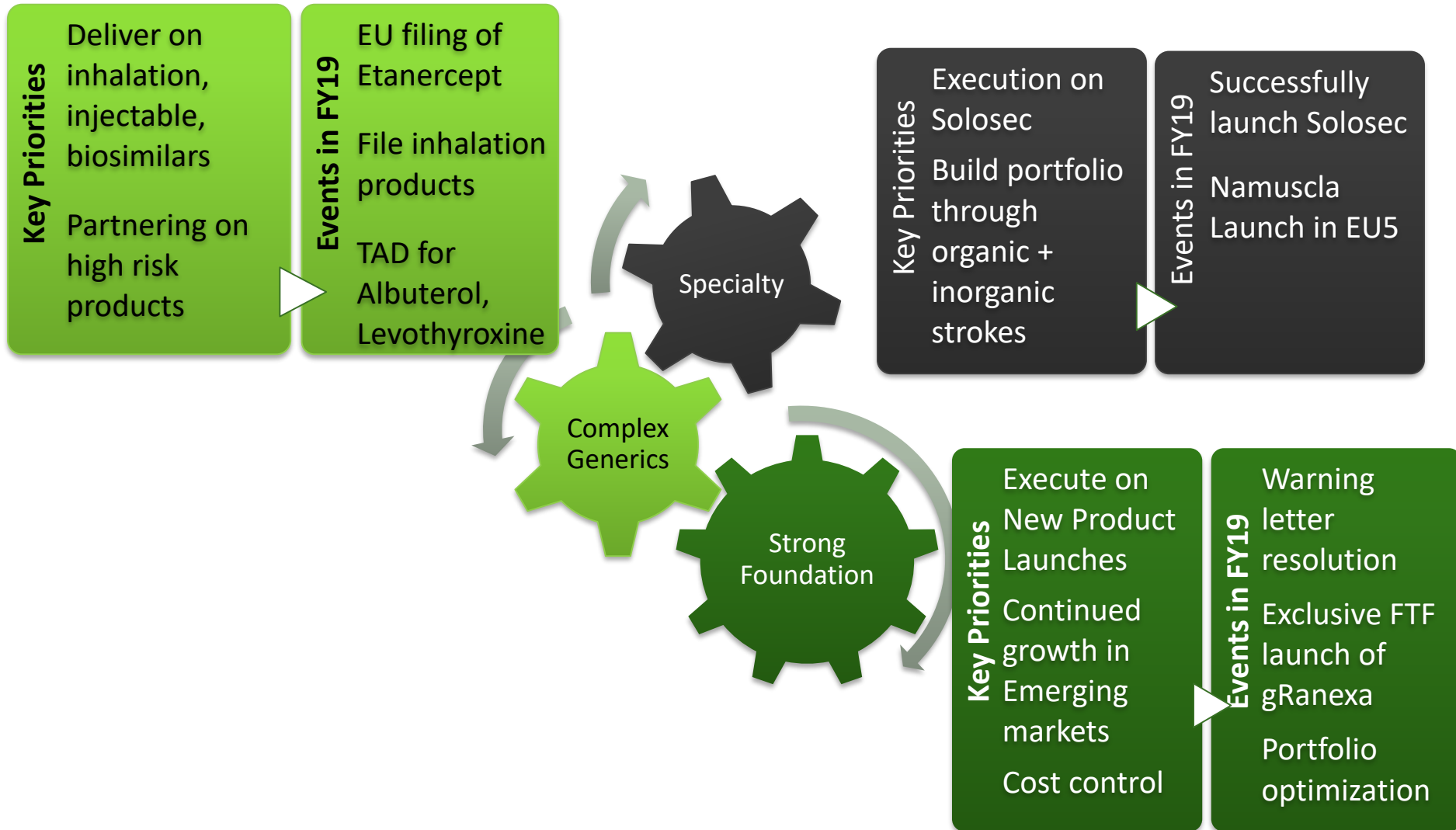
Targeting >US\$ 180 bn brand + generics sales, of which

- Filed products target US\$ 77 bn and
- Products in development target US\$ 104 bn of which complex categories account for ~70%
- 36 First-to-Files (FTF) filings including 15 exclusive FTF opportunities targeting US\$ 23 bn



# Near term priorities

# Near Term Focus on Execution







Thank You