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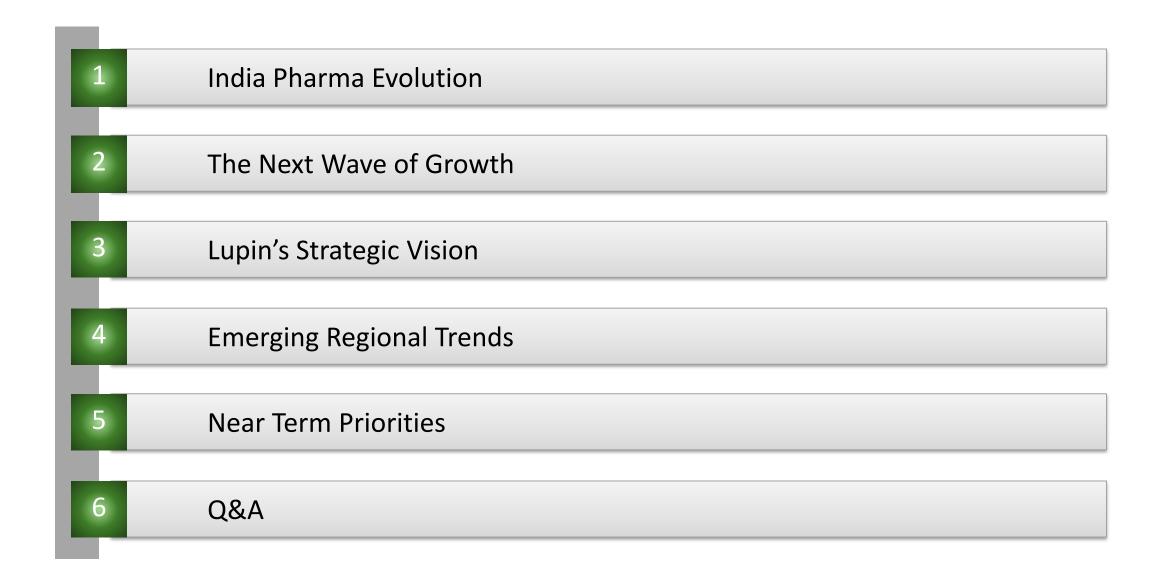
Also, for products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials, and failure to gain market acceptance.

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### Agenda





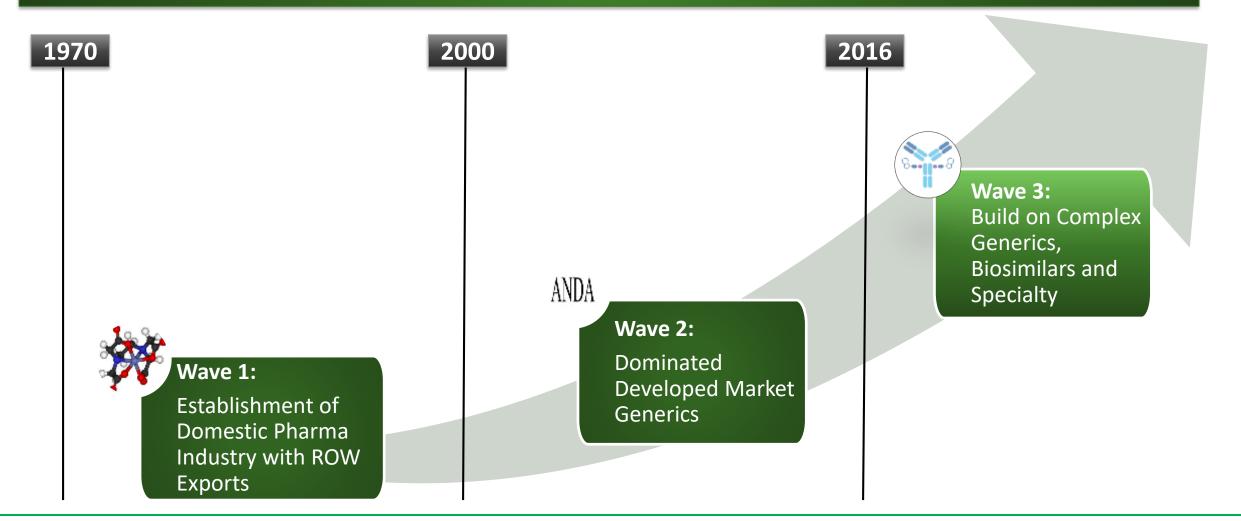
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### **India Pharma Industry Evolution**



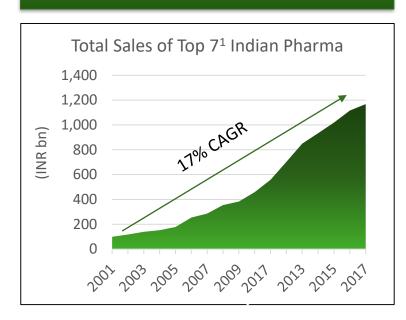
Indian Pharma Industry has evolved from almost being non-existent to one of the world's leading suppliers of generic drugs



### 2001-2016: Golden age of India Pharma Industry

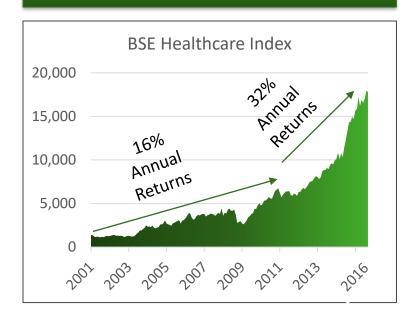


#### Sales mushroomed



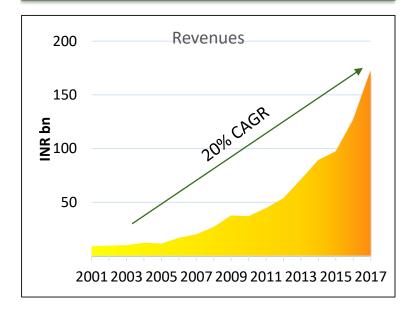
Industry grew at 17% during these 15 years

#### Valuations expanded



Returns doubled from 2010 to 2016

#### Lupin at the forefront



Lupin grew faster than market at 20% CAGR from FY'01 – FY'17

Pharma witnessed 17% CAGR and delivered 16-32% compounded returns Once Lupin entered US, we spearheaded this growth wave

### FY'18 was the toughest year for the Industry



#### Sector witnessed muted revenue growth and margin pressures in FY'18

#### Operating margins contracted



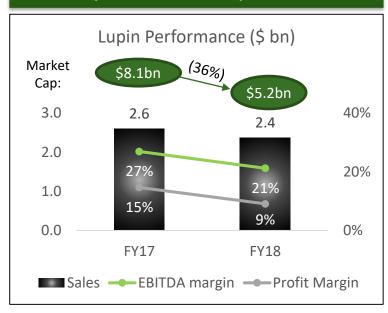
Sales were flat but overall margins declined in FY'18

#### Valuations declined



Sector valuations contracted by 16%

#### Lupin also under pressure

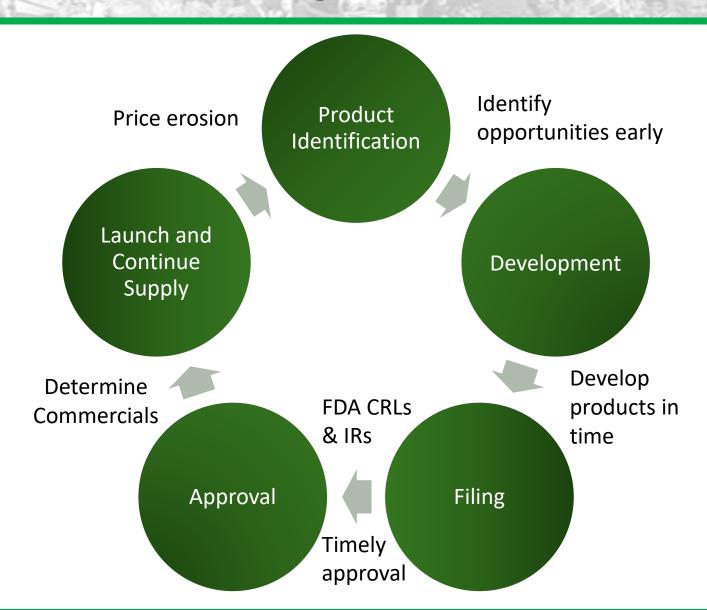


Lupin sales declined 10% but market cap and margin saw much higher decline

FY'18 has brought the outlook of the entire sector into question

### Execution – Running on a Treadmill



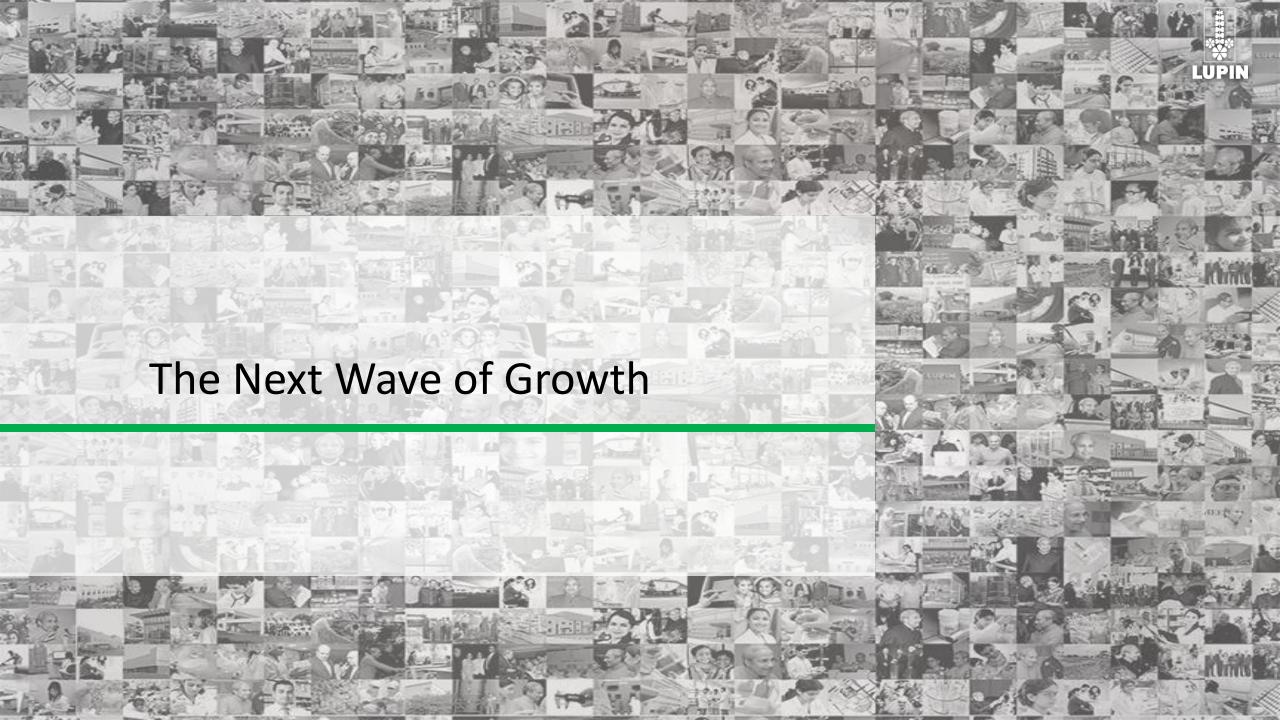


Execution has become very challenging today as high # of uncertainties at each stage

Compliance is an additional challenge

With significant base, Indian companies now need significant new product launches each year just to maintain their position

The Old Model just does NOT work anymore



### **Wave 3: Three Key Drivers of Growth**



#### **Complex Generics**

- Indian companies have only 19% penetration in complex generics compared to 34% penetration in simple generics
- Big classes of Complex products are not genericized or are still semi-exclusive
- Exclusive and Para 4
   opportunities will remain
   lucrative

#### **Biosimilars**

- Current biologics market worldwide is estimated to be ~\$240 bn
- Of this, biosimilars contribute only ~\$4-6 bn
- US and EU are opening up differently due to patent expiries
- Still considerable marketing / regulatory challenges in EU and US

#### **Specialty / Branded**

- Target areas which have unmet needs and provide clinical advantage
- Acquire opportunities which are in late stage of development
- Supplement with internal pipeline eventually
- Focus would be primarily US but also developed markets like Europe and Japan

### India Pharma is at End of Wave 2



We are at the end of Wave 2 and Wave 3 is still to kick in
The Next 12 months are going to be challenging
We are investing for Wave 3 now but Returns will start only in next two years

**Factors** 

**Development costs** 

Scientific Expertise

Manufacturing Setup

Front end

Simple generics

Low

Leverage the same expertise

Same

Same

Complex generics

High

Build Additional expertise

Dedicated

Same

Biosimilars & Specialty

Very High

Develop Unique expertise

Not Relevant

Build separate

Not so much about giving up the Old but embracing the New



### **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 capability to maintain leadership in US Generics
- Continue growth in India and other emerging markets

#### Evolve portfolio

- Deliver on key complex generics, especially Inhalation and Injectables
- Continued filing of P4 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

## **Our Strategic Vision: Well-Diversified Pharma business**





### Global Generics Markets – Build on the Strong Foundation



#### 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

	Generics		Specialty		
Market	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>



We have built a solid foundation that we can build on Generics industry facing challenges and growth slowing

#### **US Generics grew slower than Specialty**

- Customer consolidation continues to limit bargaining power
- New generic entrants and ramp-up in approvals exert additional pressure
- However, customers now talking of supply continuity
- Industry leaders talking about unsustainability of price 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 shall remain the biggest market, including the biggest Generic Market

#### Source:

<sup>.</sup> 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

<sup>2.</sup> APAC – ex Japan/China/India

### **Lupin - Leadership in Global Generics**



#### Globally

8<sup>th</sup>

largest generic company (by sales1)

3rd

largest Indian Pharma (by global sales¹)

#### **Major Markets**



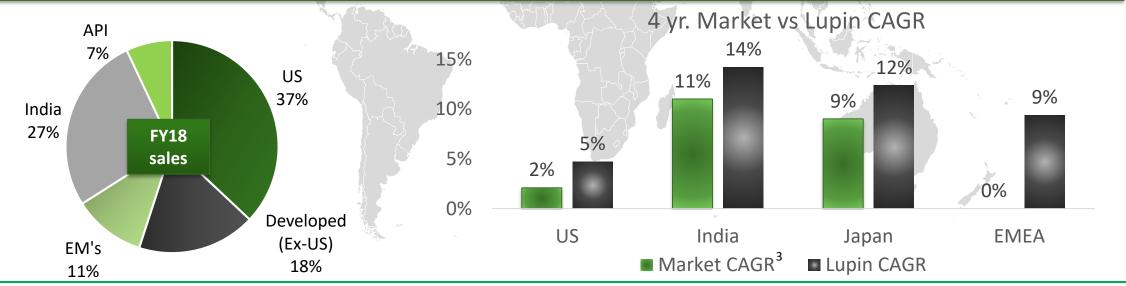
largest US (by prescriptions²)

# 5<sup>th</sup>

India Pharma Market Rank<sup>2</sup> 6<sup>th</sup>

largest Japanese Gx<sup>2</sup>

#### Diversified geographical footprint and strong growth profile



Sources:

1. LTM sales available as of 31st Dec 2017

## **Our Strategic Vision: Well-Diversified Pharma business**





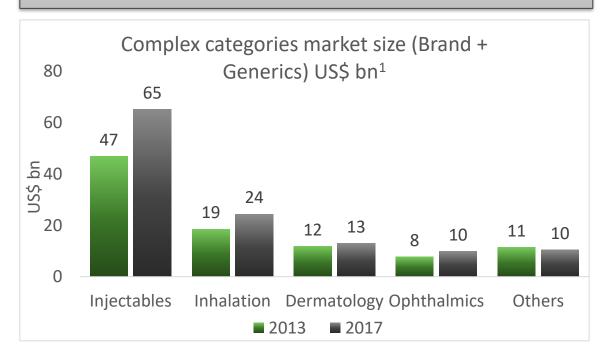
### **Complex Generics and Biosimilars Opportunity**



#### Opportunities exist in products with barriers to entry

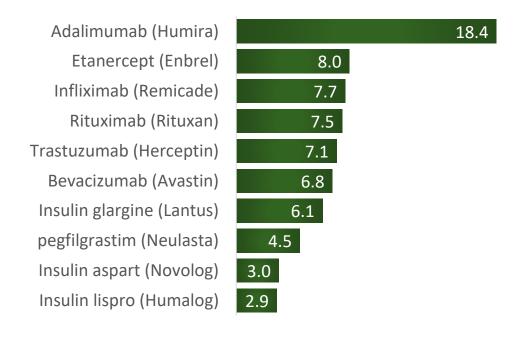
Potential exists in various categories like

- First to market / first to file opportunities
- Complex molecules and formulations 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

2017 Sales US \$bn<sup>2</sup>

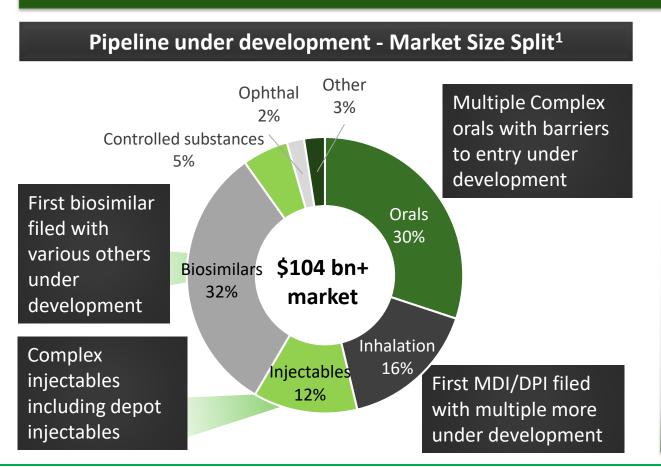


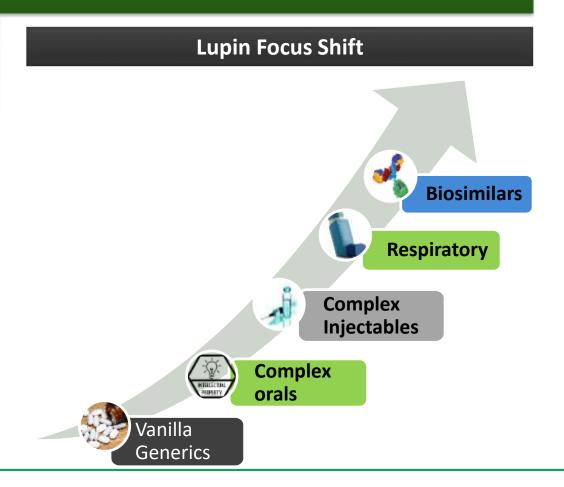
### **Lupin - Complex generics and Biosimilars Overview**



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





## **Our Strategic Vision: Well-Diversified Pharma business**

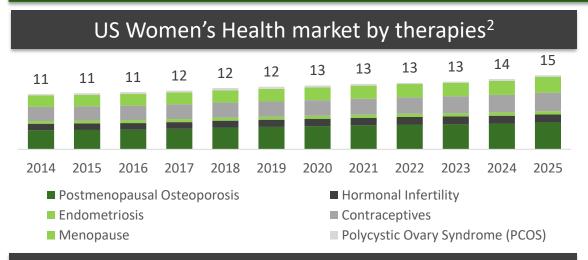




### **Specialty: Women's Health and CNS**

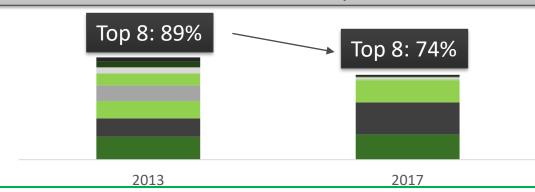


#### Women's health represents large market with areas of unmet needs



#### 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



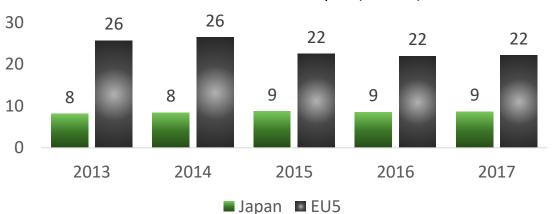
#### Commentary

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

#### **CNS**





### **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>

- Recently launched in the US
- 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)

Lupin capabilities

#### Medical

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

**Business Development** 

**R&D** and Manufacturing

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

<sup>5.</sup> BilardiJE et al. PLoSOne. 2013;8:1-11 BrotmanRM et al. JID. 2010:1907-1915.



#### **US – Well Positioned**





#### US generics opportunity remains significant



- Small molecules still form 72% of exclusivity expirations (~US\$ 76 bn) over next 5 years
- Severe pricing pressure to subside as customers additionally factor in consistent supply rather than price alone

#### Lupin continues to consolidate its position



- Moved from #6 to #4 in US (Rx terms)
- Launched 23 products in FY18 with record 11 launches in Q4 FY18
- Lupin to continue to outpace market growth with monetization of complex generics - Inhalation and Injectables
- 36 FTF's incl. 15 exclusive awaiting approval

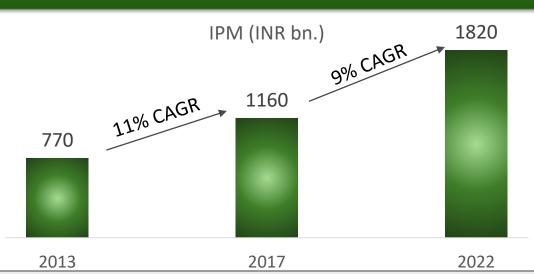
Source: IQVIA, Company website

### **India – Outpacing Industry Growth**





#### India market to witness 9% CAGR<sup>1</sup>



- Affordability is expanding the market
- Increasing new patented drug launches and partnerships among Indian and innovator companies seen
- India is witnessing significant regulatory changes in-line with global trends
- Increasing awareness and trend of self-medication for common disease areas to expand OTC market

#### 3 therapies have crossed INR 500 cr annual sales

	CAGR FY 14-18 <sup>2</sup>		Lupin Rank <sup>2</sup>	
Therapy	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 I	10	20	6	2
Gynaecology	9	26	16	9

#### Lupin continues to strengthen its position

- PCPM tracking at INR 6.3 lakhs per month in FY'18 (INR 5.6 lakhs per month in FY'17)
- 8 brands enter top 300 in March 2018 as compared to 5 brands for FY'17
- Rich in-licensed portfolio of 32 brands
- Ranked #2 amongst new introductions in FY'18
- Softovac OTC gaining market share amongst bulk laxatives; Launched Corcal OTC brand

Moto:

IQVIA MAT Mar'14 – Mar'1

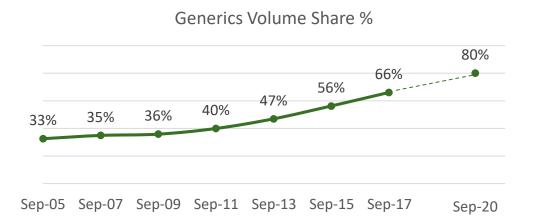
<sup>2</sup> Calendar Year

### Japan – Focus On Operational Efficiencies



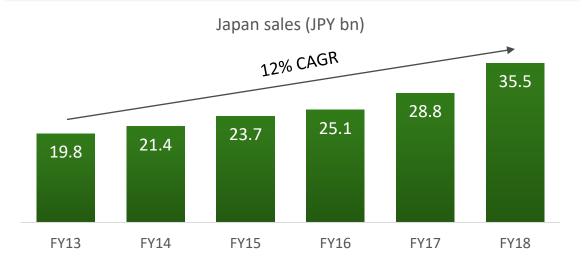


Generics Market expected to grow in volume as it reaches 80% penetration targeted by Government



- Generics' market volume share has risen around
   20% in the last three years alone
- New pricing rules, annual price declines and LLPs addition to pricing rules expected to result in 12-14% price cuts for major generics
- Discount pricing not sustainable now as resulting in low margins

#### Lupin's Japan business witnessed 12% CAGR



- Lupin has recorded steady growth
- LLP price reforms affected 4 of 18 brands
- Enhanced focus on research and manufacturing efficiencies
- Successfully launched Bipresso exclusively inlicensed CNS specialty product from Astellas

#### Other markets



Developed

EU5

Germany: EUR 31 mn sales in FY'18; 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 FY'18; 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 FY'18; 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 FY'18: up 21% YoY on new product launches
- Grin is #4 ophthalmic player

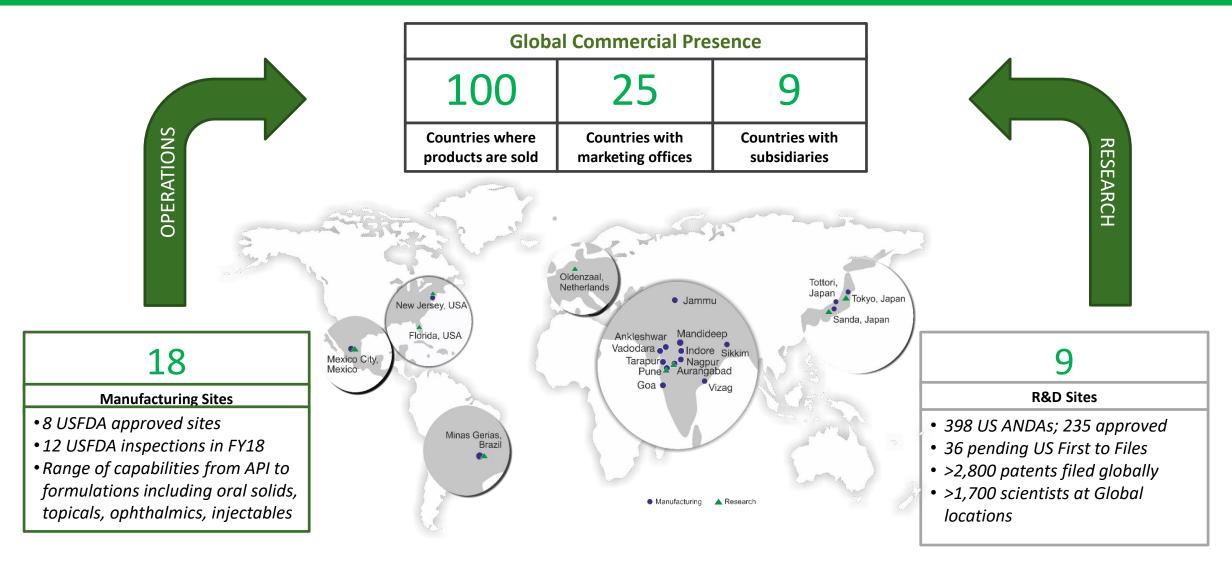
API + Global Institutional

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



### Manufacturing and R&D – Diverse Global Network

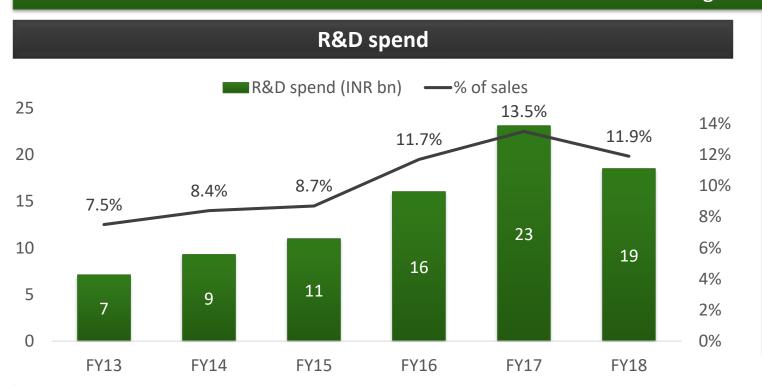


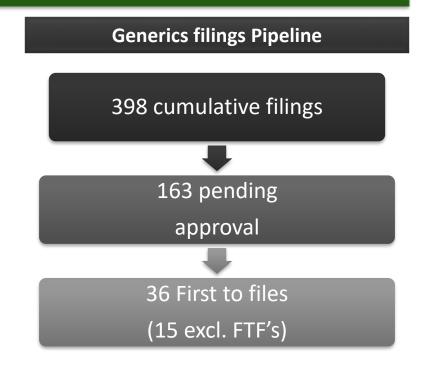


#### **R&D** investment for the future



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





#### 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 Focus on Execution**



Deliver on **Priorities** inhalation, injectable, biosimilars

> Partnering on high risk products

EU filing of **FY19** Etanercept

**Events** 

File inhalation products

TAD for Albuterol, Levothyroxine

Solosec

through
organic + Specialty inorganic strokes

Complex

Generics

Execution on Build portfolio

Successfully scale up Solosec Namuscla Launch in EU5

Execute on New Product Launches Strong Foundation

Continued growth in Emerging Markets

Cost control

Warning letter resolution

**Exclusive FTF** launch of gRanexa

> Portfolio optimization

