



May 15, 2019

✓ **BSE Limited**

Department of Corporate Services,  
P. J. Towers,  
Dalal Street,  
**MUMBAI - 400 001.**

**National Stock Exchange of India Limited**

Exchange Plaza,  
Bandra Kurla Complex,  
Bandra (East),  
**Mumbai - 400 051.**

*Dear Sirs,*

**Sub: Annual Investors Communication.**

Pursuant to Regulation 30(2) read with Schedule III Part A Para A(15) of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, enclosed, is a copy of the presentation being made at the Annual Investors Communication today i.e. Wednesday, May 15, 2019, at Mumbai.

Kindly confirm having received and noted the above.

Thanking you,

Yours faithfully,  
**FOR LUPIN LIMITED**

**R. V. SATAM  
COMPANY SECRETARY**



Encl.: a/a.

LUPIN LIMITED

Registered Office: 3<sup>rd</sup> Floor, Kalpataru Inspire, Off W. E. Highway, Santacruz (East), Mumbai - 400 055 India. Tel : (91-22) 6640 2323.

Corporate Identity Number: L24100MH1983PLC029442

[www.lupin.com](http://www.lupin.com)

**LUPIN LIMITED**

**Annual Investor Meet**

**May 15, 2019**

**50** YEARS  
OF LUPIN



Materials and information provided during this presentation may contain ‘forward-looking statements’. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements.

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.



- **Industry Trends**
- **Progress on Strategic Growth Drivers**
- **Business Performance**
- **Cost Optimization Roadmap**
- **Regulatory Update**
- **Priorities for FY20**

# Industry Trends

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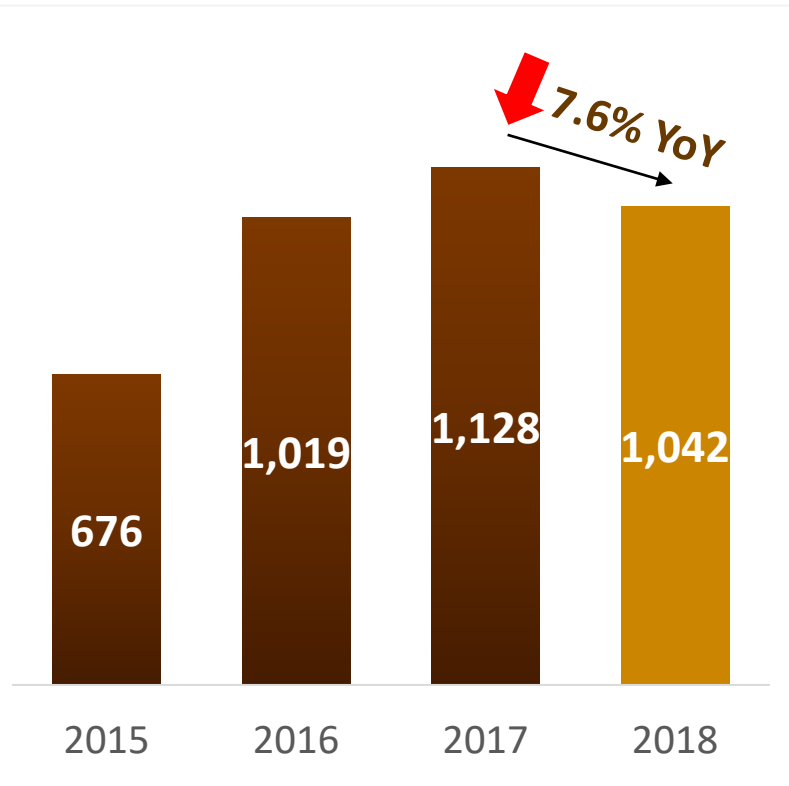
# US generics

## Emerging Signs of Stabilization

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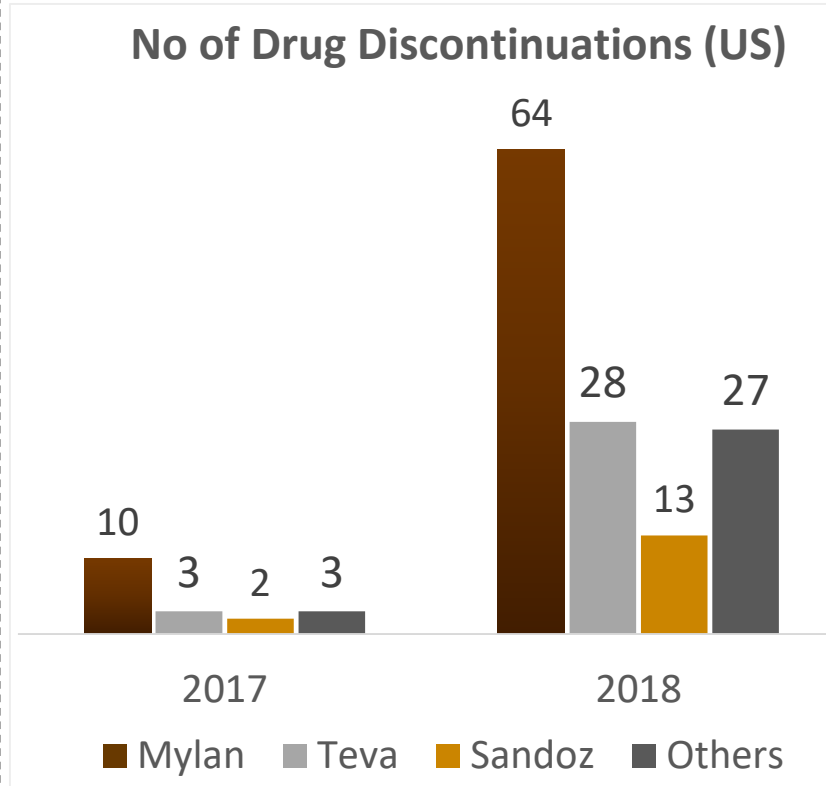


### Slowing ANDA submissions<sup>1</sup>



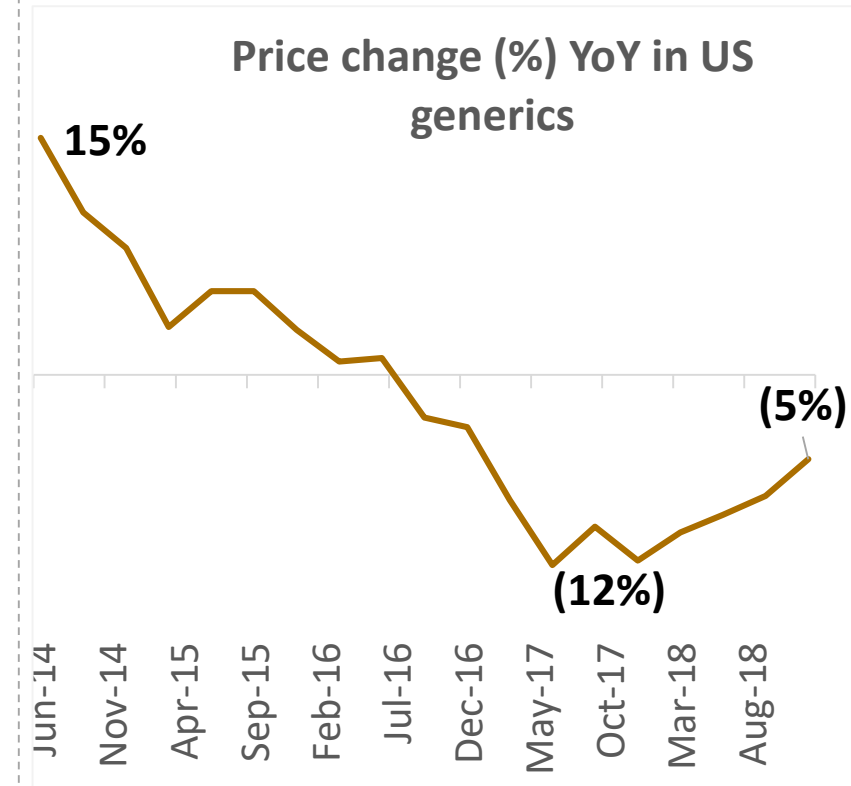
Portfolio rationalization is a recurring theme across players

### Discontinuations by generic majors<sup>2</sup>



Teva, Mylan and Sandoz actively discontinuing non-profitable products

### Stabilizing pricing environment<sup>3</sup>



Price deflation stabilizing at mid single digit bodes well for industry

1. FDA ANDA approval data

2. FDA.gov

3. Nephron Research, Glass Box Analytics, IQVIA

# US generics

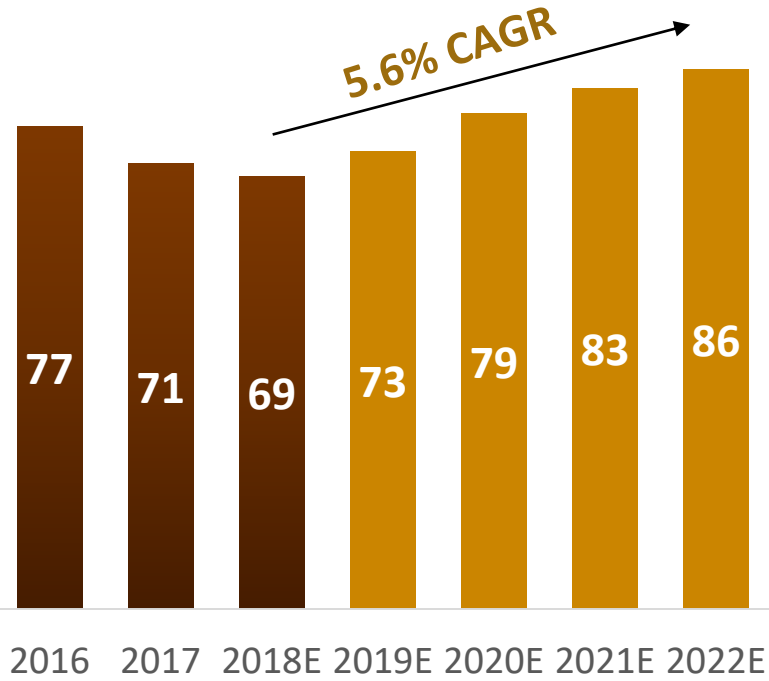
## Emerging Signs of Stabilization

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### US generic market stabilizing

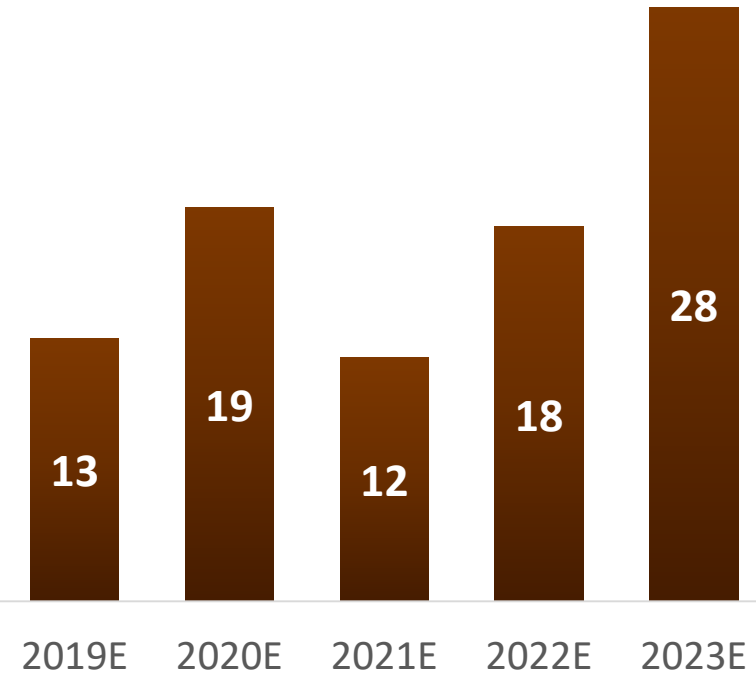
US Generics Market Size<sup>1</sup> (US\$ bn)



US to remain the largest generic pharma market

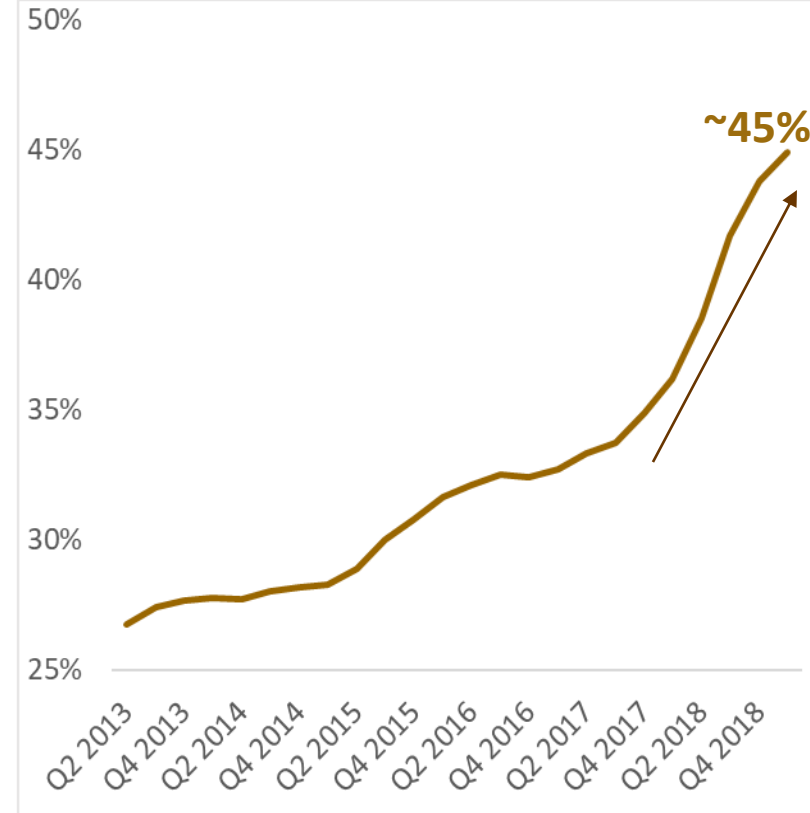
### Substantial opportunities exist

US Small molecule brand LOE<sup>2</sup> (US\$ bn)



Expected impact of losses of exclusivity at ~US\$ 90 bn over 2019-23

### Indian companies gain TRx share<sup>3</sup>



Market share gains by Indian companies accelerated since 2017

1. IQVIA Report Feb 2019

2. IQVIA Market Prognosis Mar 2019 (at invoice price level)

3. IQVIA, Nomura Research

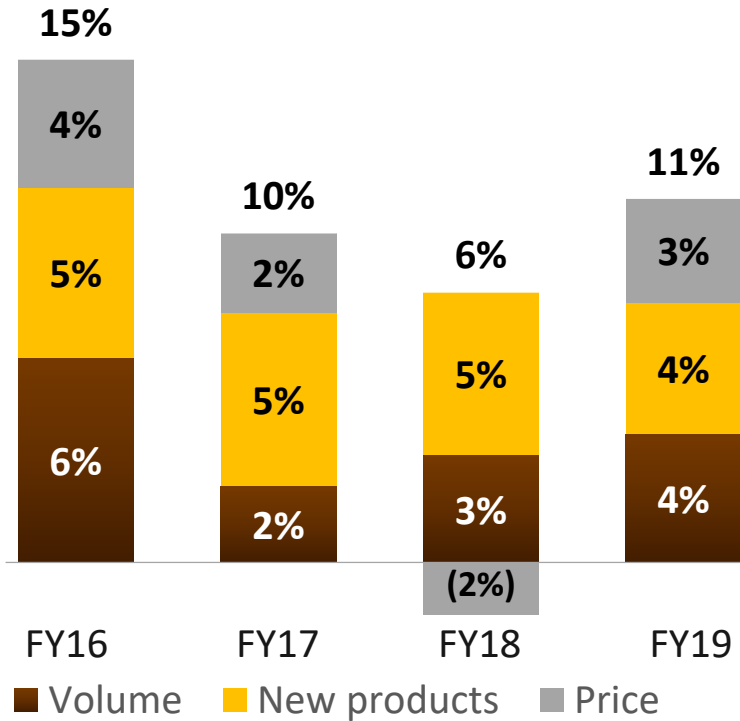
# India Pharma Market (IPM)

Structural growth story intact

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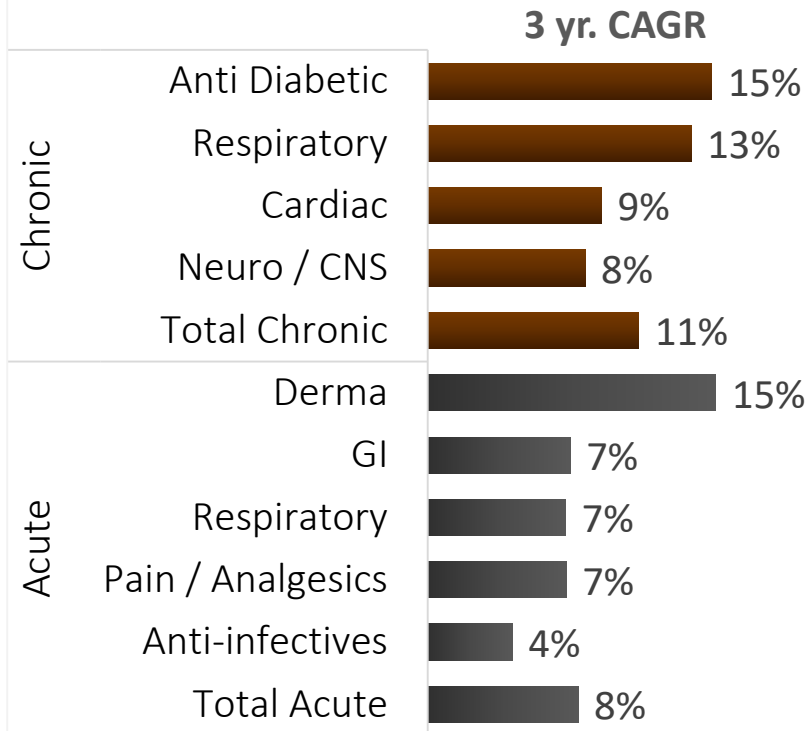


## IPM growth components<sup>1</sup>



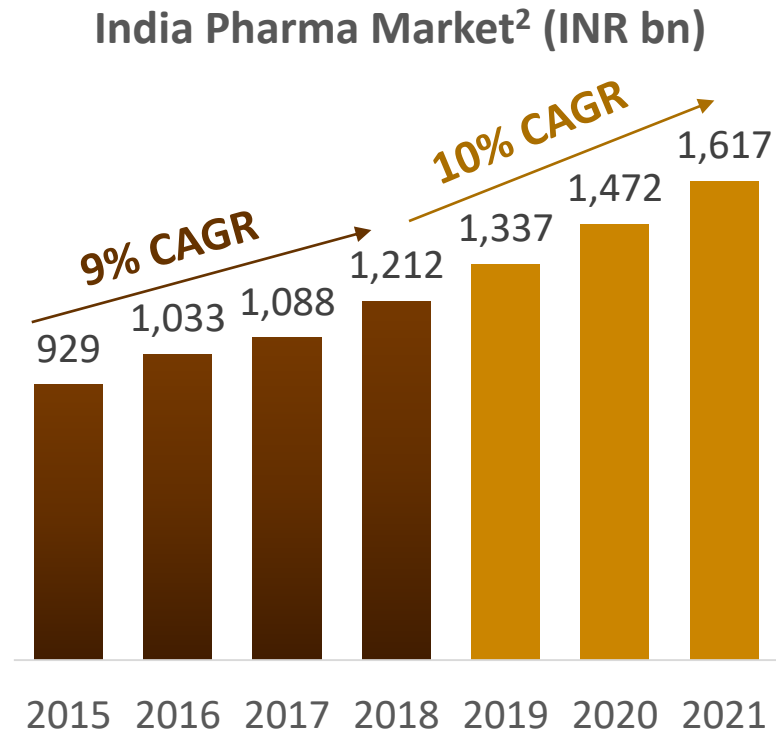
**Volume growth recovering post recent disruptions**

## Chronic therapies outpacing acute<sup>1</sup>



**Driven by rising awareness/diagnosis and changing lifestyle patterns**

## IPM to Sustain growth of 10%



**Still Underpenetrated and High growth potential**

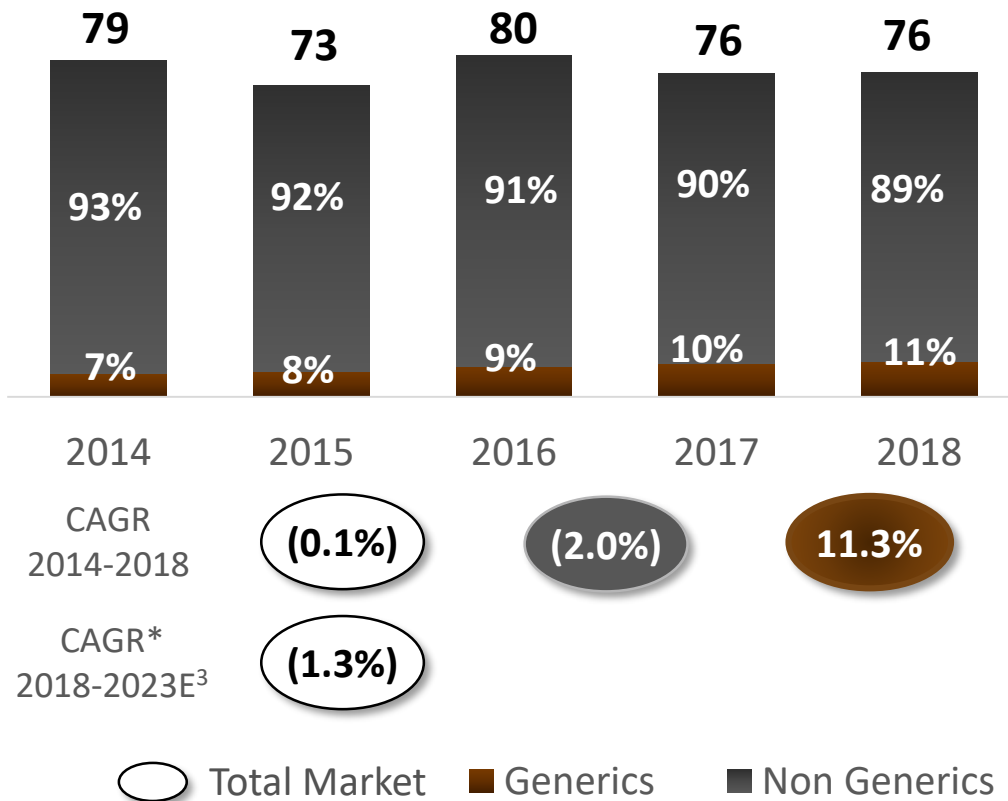


# Other pharma market trends

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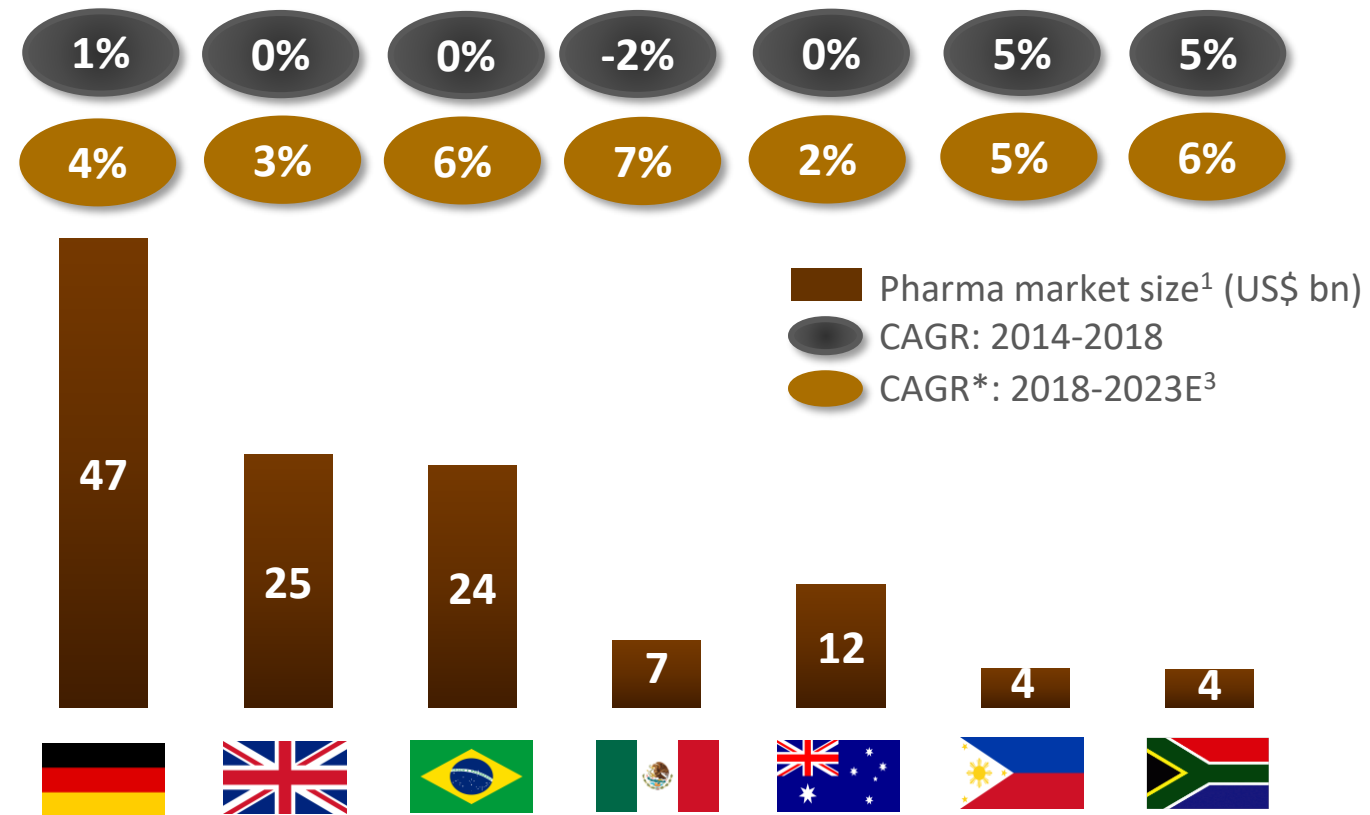


## Japan Pharma Market – by Value<sup>1</sup> (US\$ bn)



Superior generics growth on increasing penetration (69% as of Mar'18<sup>2</sup> vs 47% in Sep'13)

## Modest growth seen across other key pharma markets



Other major emerging markets growth lagged expectations due to pricing pressures, regulatory delays and political instability

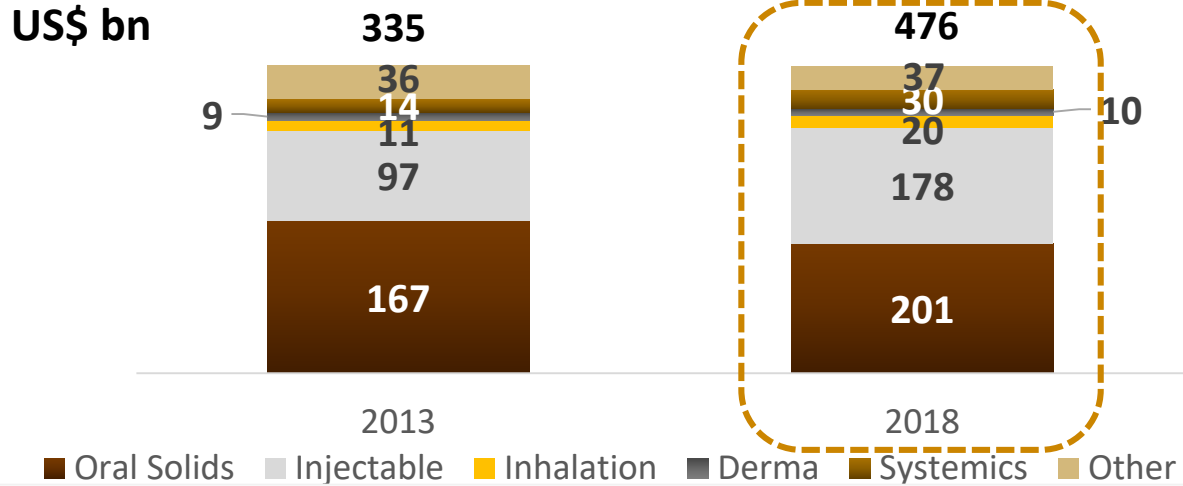
# Complex generics

Sizeable opportunities in the US

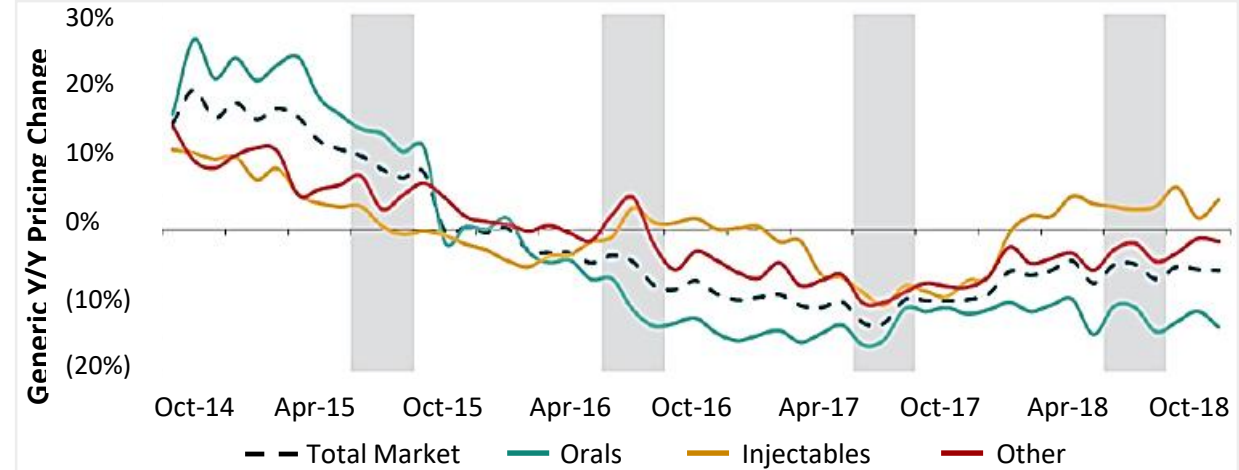
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## Dollar share<sup>1</sup> of Non Oral Solids increasing

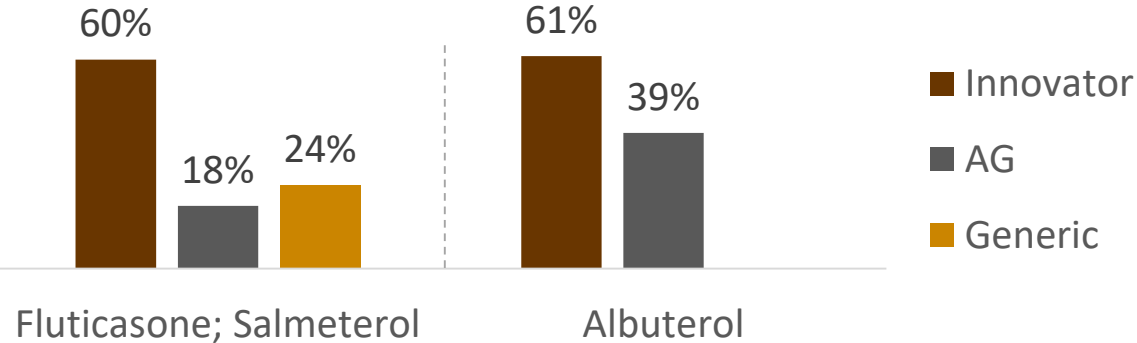


## Lower pricing pressures seen in complex generics<sup>2</sup>

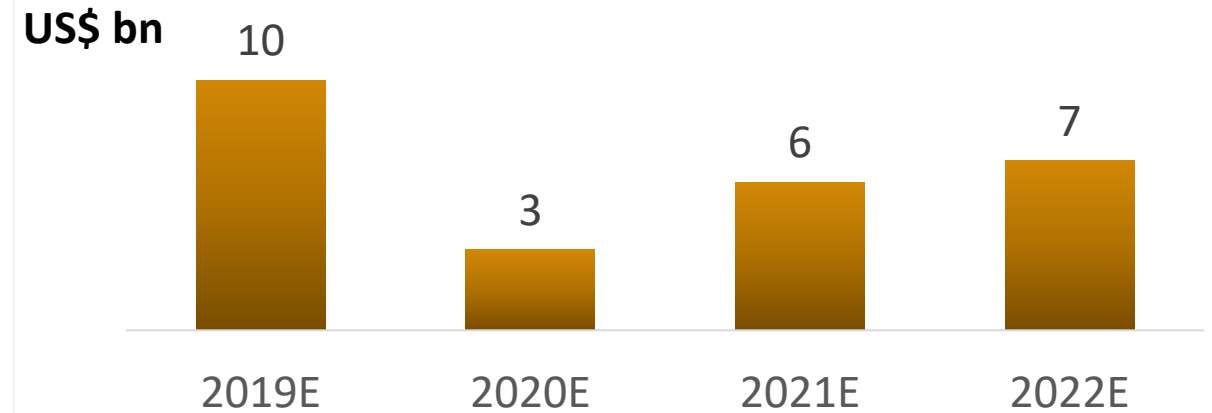


## Inhalation generics gaining acceptance

TRx Market share<sup>1</sup> (%) - 2 months post Gx/AG launch



## Key Inhalation and long acting Injectable opportunities<sup>3</sup>



1. IQVIA, National Sales Perspectives, December 2018

2. Nephron Research, Glass Box Analytics, IQVIA;

3. Industry estimates (US Brand sales at risk), IQVIA

# Biosimilars

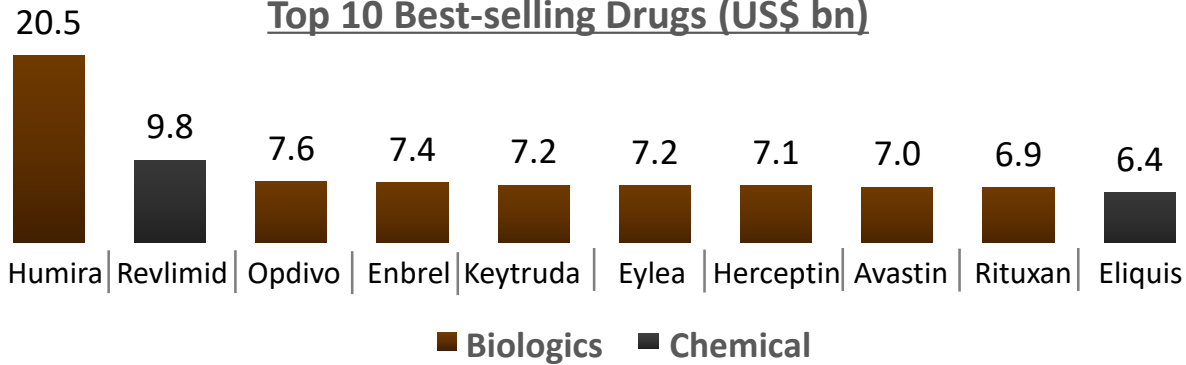
## Market opening up

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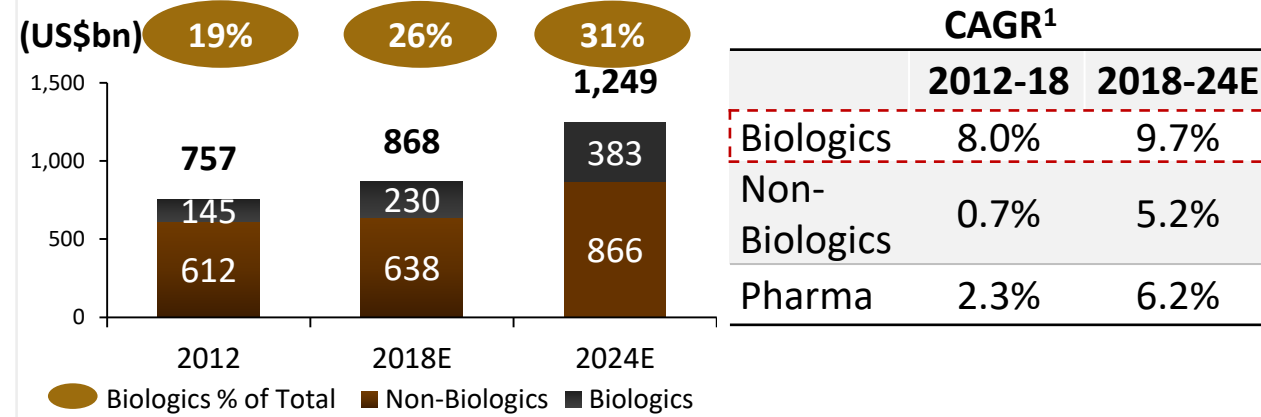


**Biologics Represents a US\$230 bn Global market<sup>1</sup> with 8 out of the Top 10 Best-selling Drugs being Biologics...**

**Top 10 Best-selling Drugs (US\$ bn)**

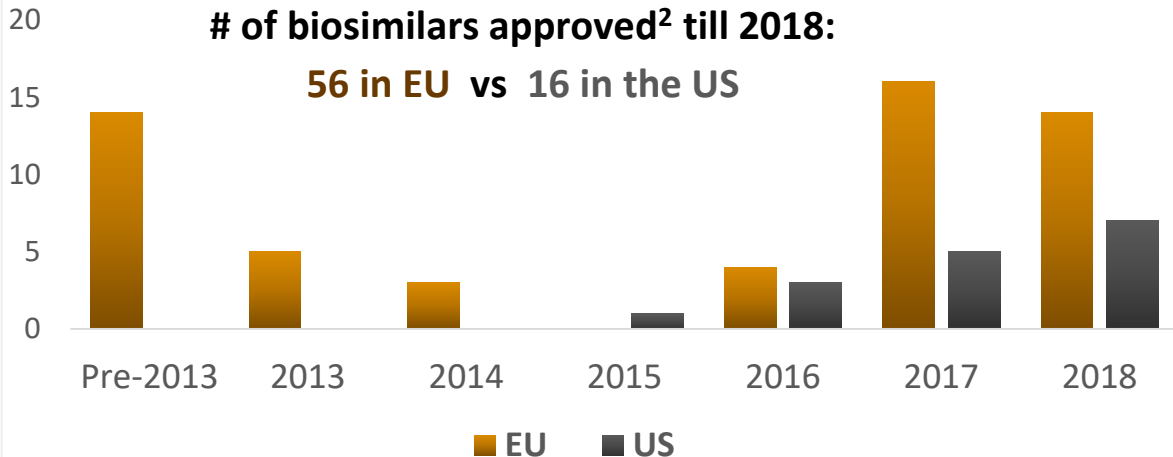


**...and will continue to be the Fastest Growing Segment**

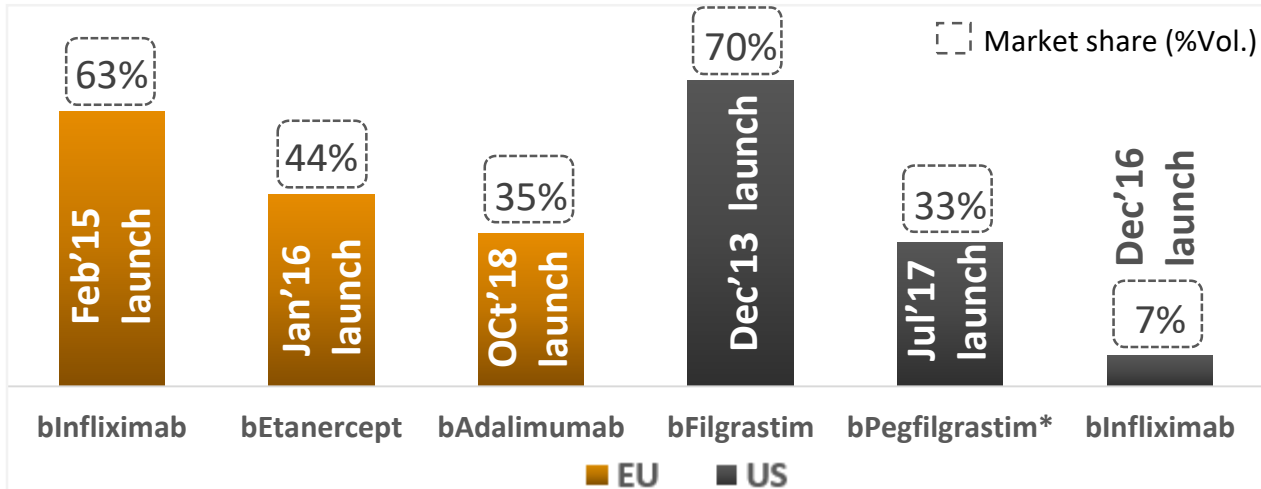


**Biosimilars approvals by U.S. FDA picking-up**

**# of biosimilars approved<sup>2</sup> till 2018:**  
56 in EU vs 16 in the US



**In market performance<sup>3</sup> of biosimilar launches**



1. Evaluate pharma (WW 2018 sales)

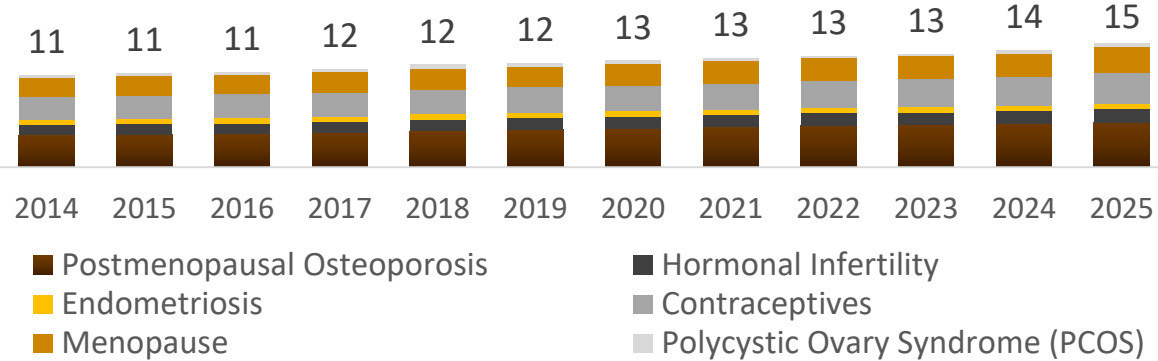
2. U.S. FDA, EMA

3. Company data, IQVIA MAT Dec'18, Bloomberg

Note - \* syringes market

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

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



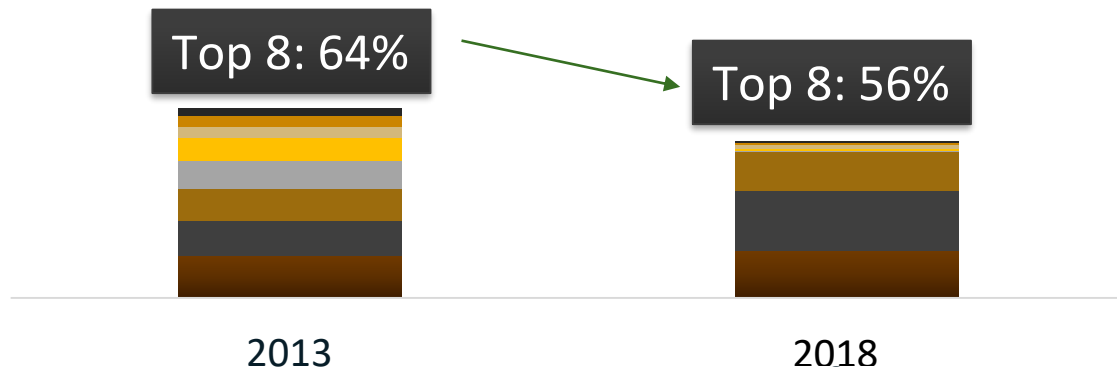
#### Commentary

Large market worldwide and growing steadily

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

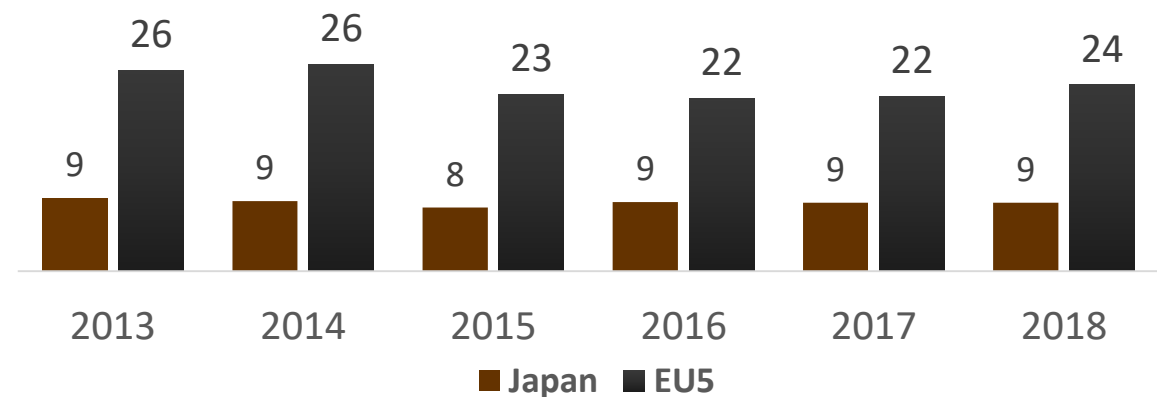
#### Market share of Branded players in WH<sup>1</sup>

Big Pharma defocusing on this segment



#### CNS

#### CNS market size EU5 + Japan (US\$ bn)



# Progress on Strategic Growth Drivers

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# Strategic Vision

Well Diversified Pharma Business

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## Strong Foundation

*Amongst the Top 10 generic companies in the World*

## Complex Generics Focus

*Focus on delivering high barrier products*

## Specialty Focus

*Committed to building a strong specialty business*

### Sustain and Grow

- Major revenue contributor now
- Maximize on capability to maintain leadership in US
- Outperform in India
- Attain scale in other EM's

### Portfolio Execution

- Deliver on key complex generics, esp. Inhalation and Injectables
- Continue filing P4 and semi-exclusive generics
- Execute on biosimilars

### Build

- Create a meaningful Women's Health business in US
- Neurology / CNS focus in other developed markets

**Leadership in Global Generics with a diversified geographical footprint and manufacturing base**

Key Metrics	
Market Cap <sup>(3)</sup>	INR 365 bn
Revenue (FY19)	INR 164 bn
EBITDA (FY19)	INR 32.5 bn

**Globally**

**8th**  
Largest generic company  
*(by sales<sup>1</sup>)*

**3rd**  
Largest Indian Pharma  
*(by global sales<sup>1</sup>)*

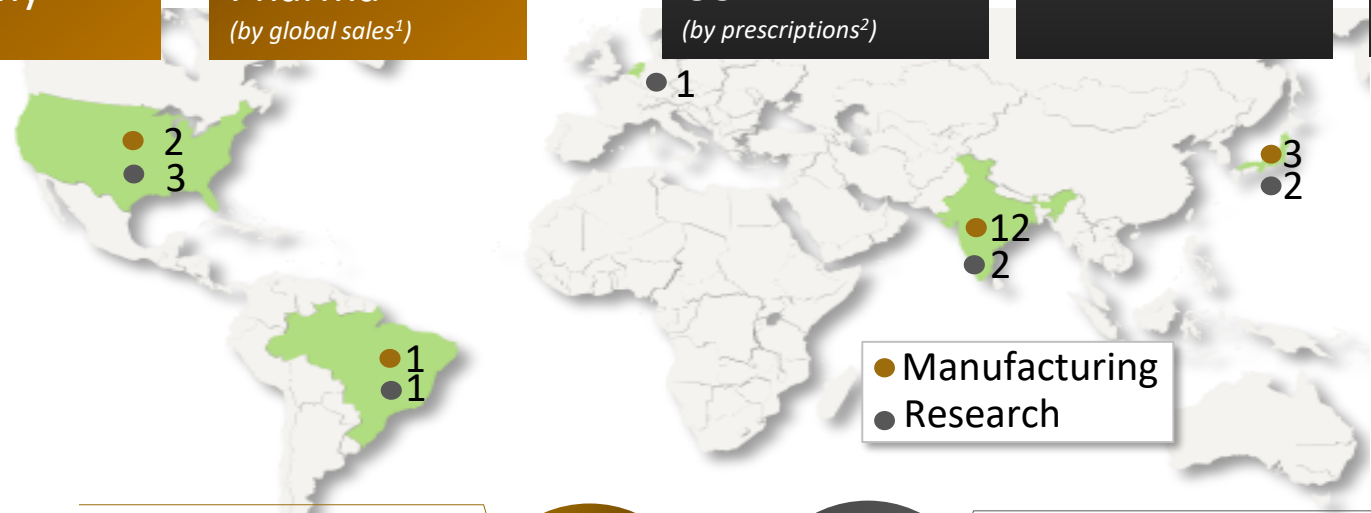
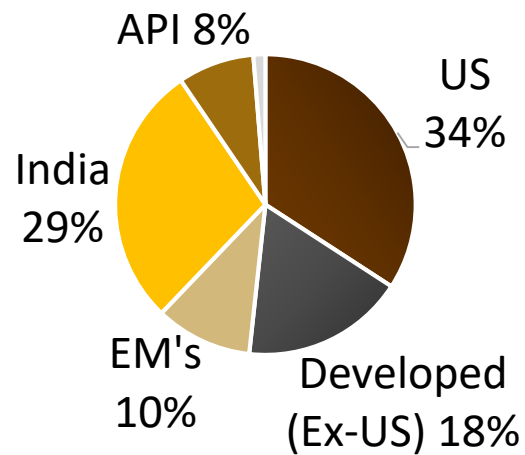
**Major Markets**

**3rd**  
Largest in the US  
*(by prescriptions<sup>2</sup>)*

**5th**  
India Pharma Market Rank<sup>2</sup>

**6th**  
Largest Japanese Gx<sup>2</sup>

**FY19 Revenues split**



- 12 USFDA inspected sites
- 30 bn+ extended unit capacity

**18 Mfg. sites**

- 422 US ANDAs; 265 approved
- 40 pending US First to Files

**9 R&D sites**

1. LTM sales available as of 31<sup>st</sup> Dec 2018

2. IQVIA MAT Mar-19 for respective markets

3. As of 14<sup>th</sup> May 2019

# Complex Generics & Biosimilars

## Pipeline Progress

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Target Market Size <sup>1</sup> (US\$ bn)	Product segment	No. of Products	Pipeline Progress
18	Inhalation	13	<ul style="list-style-type: none"> <li>○ First MDI &amp; DPI filed with more under development                             <ul style="list-style-type: none"> <li>○ Albuterol MDI (gProAir) filing under FDA review – H2 FY20 launch</li> <li>○ Tiotropium DPI (gSpiriva) filed, FTF confirmed</li> <li>○ gBrovana filed in the U.S.</li> </ul> </li> </ul>
29	Biosimilars	6	<ul style="list-style-type: none"> <li>○ bEtanercept approved in Japan; under review in EU – H2 FY20 launch</li> <li>○ Partnered with Mylan (EU, certain other mkts) and Nichi-Iko (Japan)</li> <li>○ bPegfilgrastim - US clinical studies ongoing; advancing other programs</li> </ul>
15	Injectables (incl. Complex Inj.)	>30 (10 depot inj.)	<ul style="list-style-type: none"> <li>○ 4 Injectable products approved; 1<sup>st</sup> launch in H2 FY20</li> <li>○ Advancing multiple Complex Injectable (depot, peptides, iron products)</li> </ul>

**Inhalation, Injectable and Biosimilar platforms well positioned to capitalize potential opportunities**



# U.S. Specialty

Building a Leading Women Health business

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**Single Dose**

Treatment for BV

**10 Years**

Data exclusivity

**93%**

Total Payor Coverage

**70%**

Unrestricted Coverage

**133**

Dedicated WH reps

**7 years**

Average WH exp

**Focus to add more WH assets**



**Unique Positioning**



**Managed Care access**



**Specialized Sales force**



**Business Development**

**Established top notch Women's Health team, Solosec launched successfully  
Foundation in place to build a leading Women's Health business**

# Specialty update (Ex-US)

CNS focus

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**Orphan  
Drug**

**+181% YoY**  
FY19 sales



**Launched**  
Via own front end



**Partnering**  
discussions ongoing

**Co-promotion**  
agreement with Yoshitomi  
(170+ MRs)

**66 MR's**  
Directly engaged

**NaMuscla**  
MEXILETINE

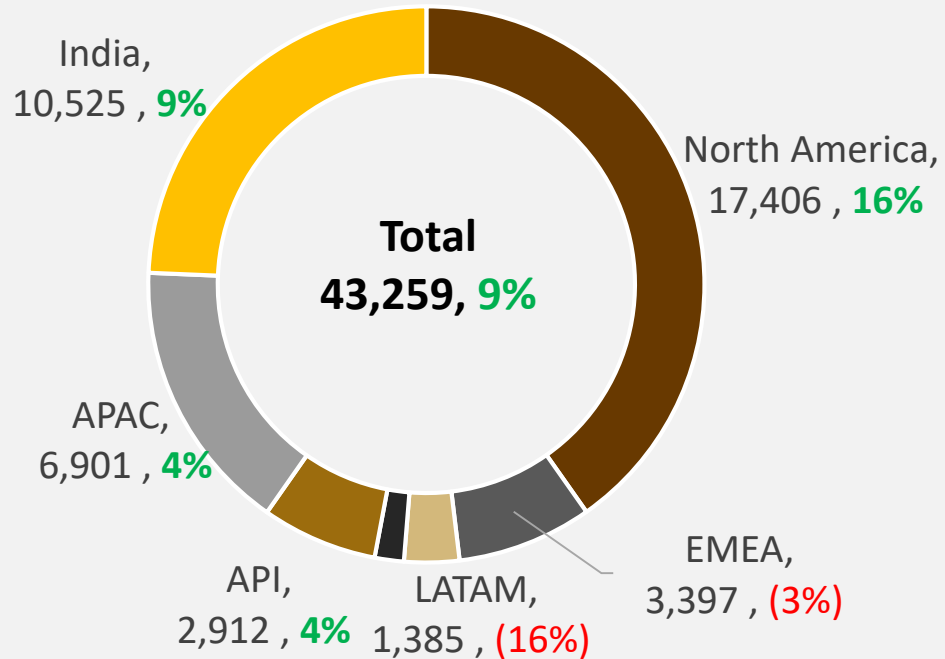


# Business Performance

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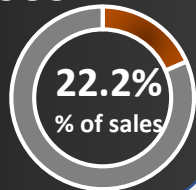


## Sales (INR mn, YoY growth)



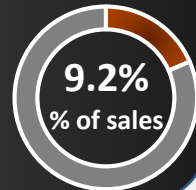
### EBITDA

INR 9,588 mn



### R&D

INR 3,963 mn



## Important developments

### Commercial

- 8 new product launches incl. exclusive gRanexa, gSolodyn launches
- Higher gTamiflu sales due to seasonality
- Monetization of Complex Generics underway with Levothyroxine launch
- Continue to outpace IPM growth

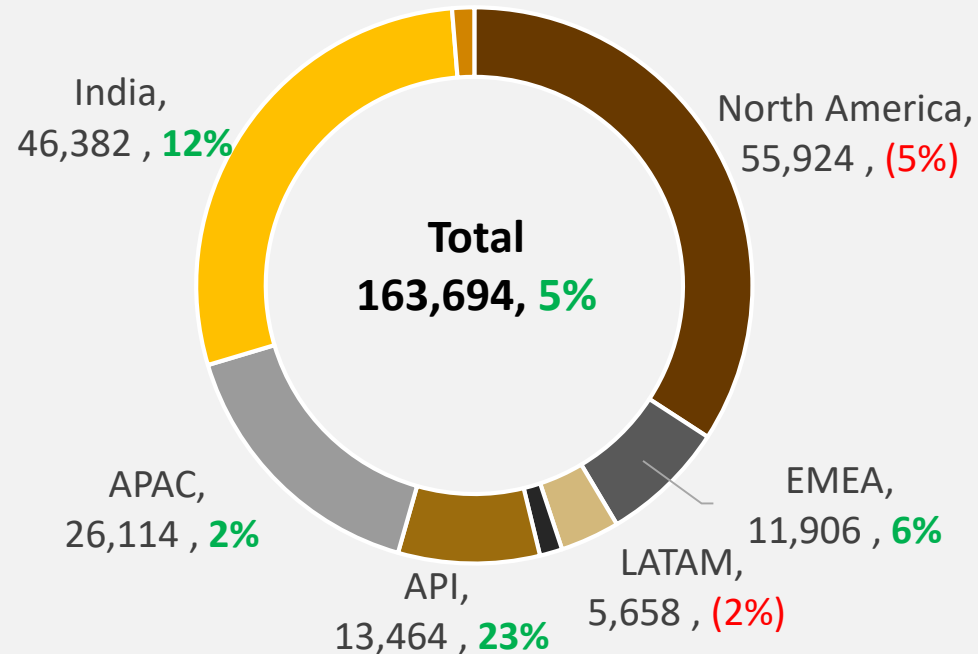
### Regulatory

- Warning Letter update – Pithampur (Unit 2) and Goa re-inspected
- Pithampur (Unit 2), Mandideep (Unit 1), Somerset facilities classified as OAI

### Pipeline

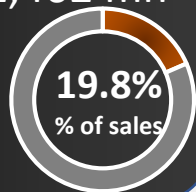
- PMDA (Japan) approval for bEtanercept
- 12 filings including gBrovana
- Approval for 7 ANDAs including Levothyroxine and an injectable

## Sales (INR mn, YoY growth)



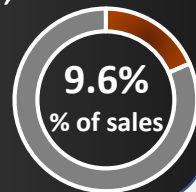
### EBITDA

INR 32,462 mn



### R&D

INR 15,731 mn



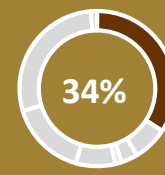
## Important developments

### Commercial

- Monetization of Complex Generics underway
- Successfully launched Solosec on the Specialty front
- Expanded partnership with BI and Lilly for 3 anti-diabetic drugs in India
- Etanercept commercialization agreements with Mylan, Nichi-Iko
- MALT1 Inhibitor program licensed to AbbVie for potential milestone payments of up to US\$ 947mn (US\$ 30mn upfront)

### Pipeline

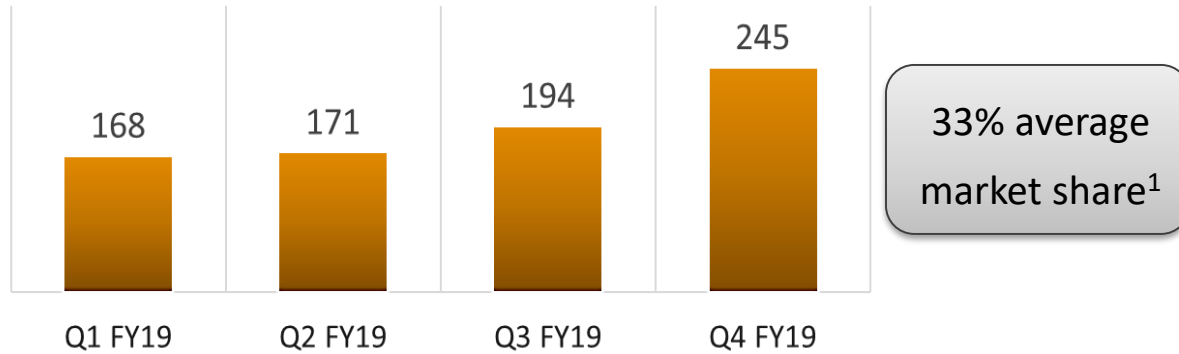
- 28 filings incl. 11 FTF's; Received approval for 30 ANDAs
- 2 Inhalation Gx filing incl. FTF on our first DPI – gSpiriva in US
- Biosimilar Etanercept approved in Japan; under review in Europe
- NaMuscla™ approved for treatment of myotonic disorders in Europe, with an orphan drug designation; launched in UK, Germany and France



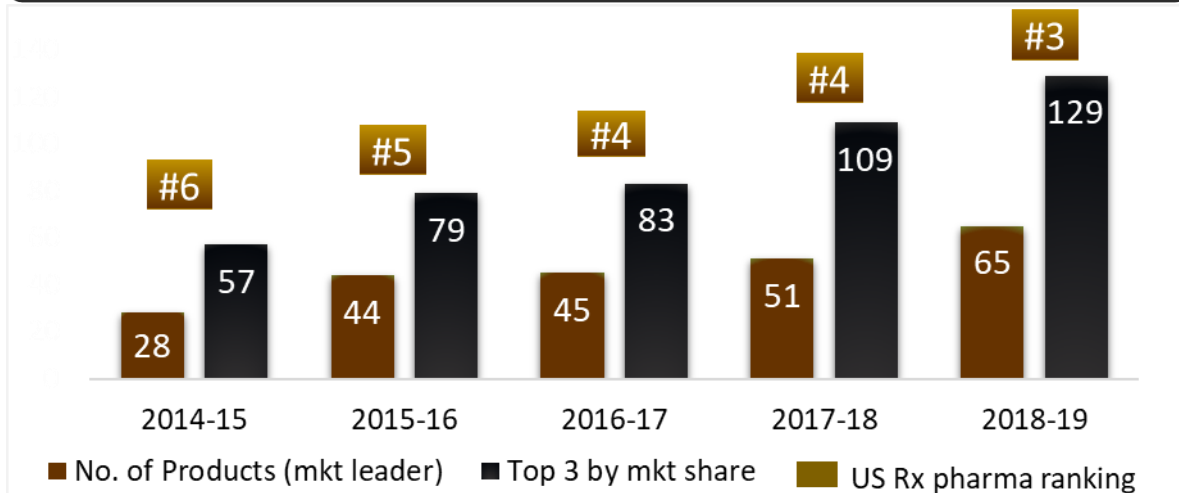
Q4FY19	
YoY	QoQ
↑ 16.1%	↑ 22.8%

### US revenues getting back on growth mode

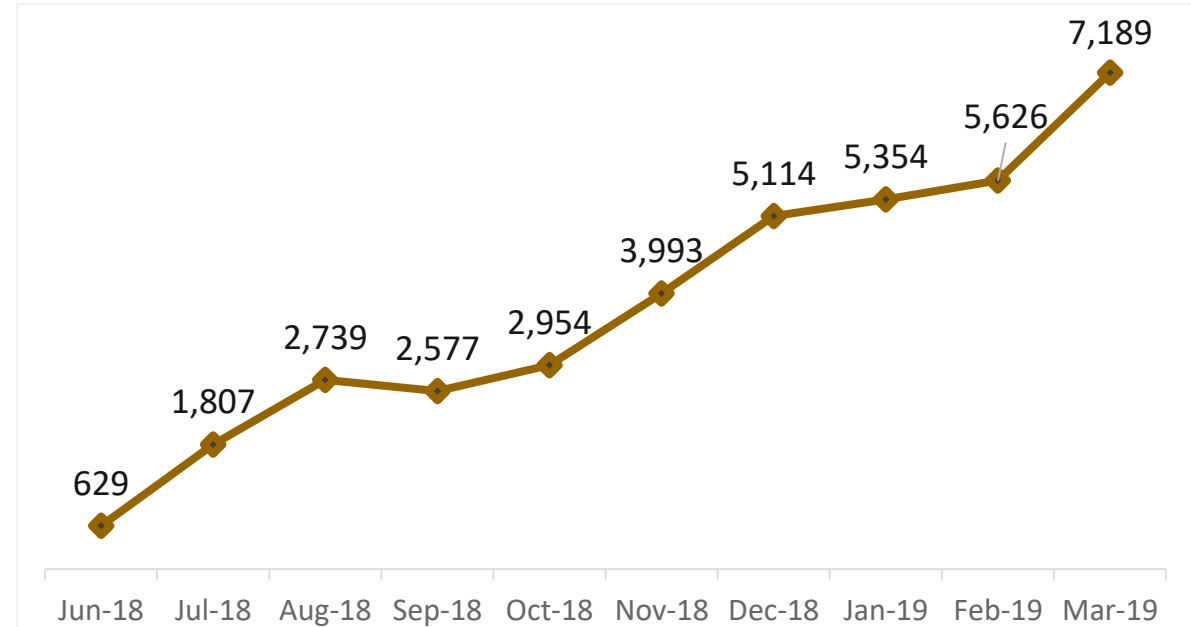
US quarterly sales (\$ mn)



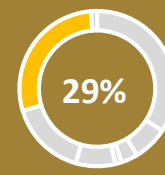
### Lupin consolidating its position in US<sup>1</sup>



### Solosec monthly TRx ramp up



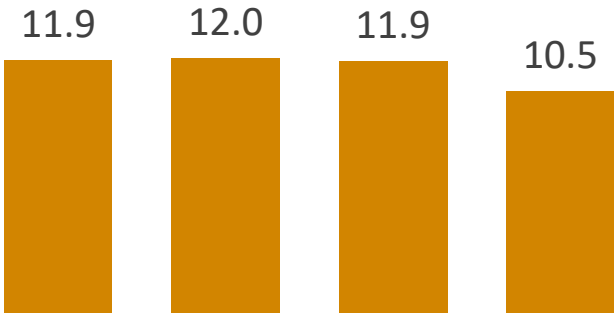
- Strong momentum in Solosec ending FY19
- With nearly one year of performance behind us, managed care coverage is now well-characterized and has led to new targeting and focus for the field sales team
- Medi-Cal, BCBS of Tennessee and other formulary wins



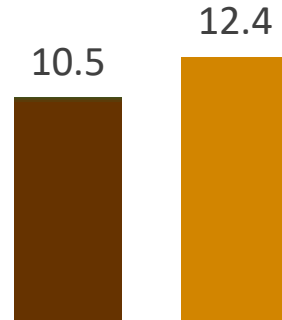
Q4FY19	
YoY	QoQ
↑ 9.1%	↓ 11.6%

### Healthy YoY growth

India quarterly Sales (INR bn)



YoY Growth (%)



Q1 FY19 Q2 FY19 Q3 FY19 Q4 FY19

IPM<sup>1</sup> FY19

### Strong portfolio

**2** brands in Top 100

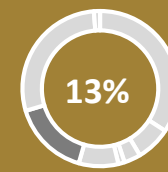
**8** brands in Top 300

BRANDS	RANK (MAT Mar'19)
GLUCONORM-G	32
HUMINSULIN	51
BUDAMATE	111
TONACT	177
GIBTULIO	192
RABLET – D	224
ONDERO	247
IVABRAD	289

### Continue to outpace industry growth

Therapy	CAGR FY15-19 <sup>1</sup>		Lupin Rank <sup>1</sup>	
	Market	Lupin	MAT Dec-15	MAT Dec-19
Acute	9%	8%	14	12
Chronic	12%	14%	5	4
Cardiac	10%	10%	2	3
Anti-diabetics	16%	22%	5	3
Respiratory	10%	16%	6	2

- **5<sup>th</sup>** rank in the IPM<sup>1</sup>; 60% Chronic contribution<sup>1</sup>
- India business maintained outperformance with **11.3% growth in Q4FY19** (vs 7.7% for IPM)
- PCPM improved to INR 0.7 mn per month in FY19 (INR 0.63 mn in FY18; INR 0.56 mn in FY17)
- Rich in-licensed portfolio of 34 brands
- **>6,900** domestic sales force strength



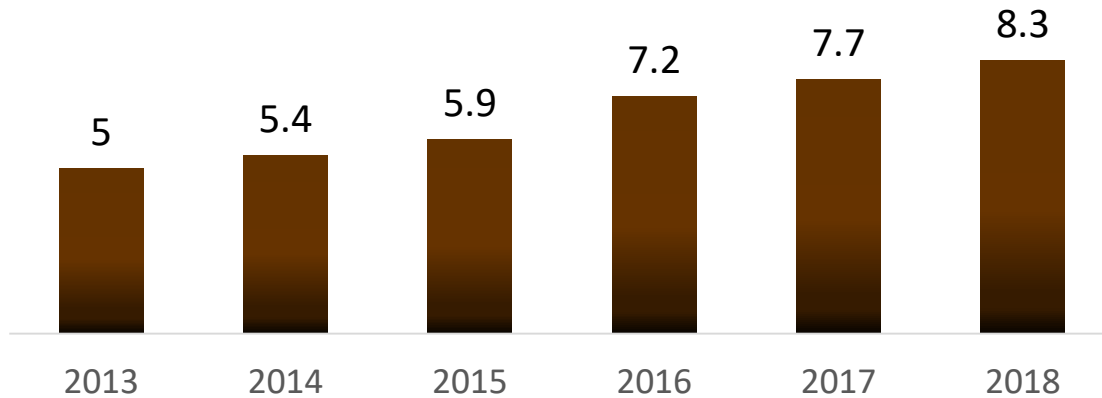
Q4FY19	
YoY	QoQ
↑ 8.6%	↓ 4.0%

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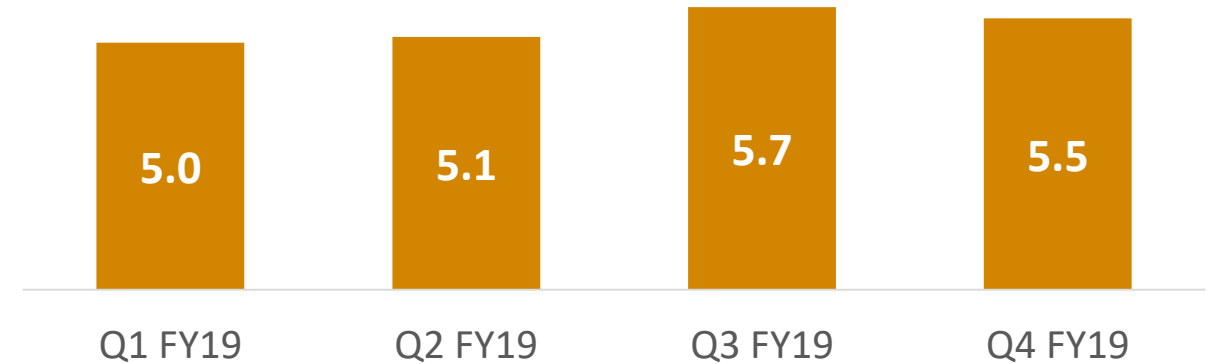


## Pricing regulation changes hurt Japan pharma growth

Japan Generics Market<sup>1</sup> (US\$ bn)



## Japan sales evolution (INR bn)



## Japan Generics Market Update

- Generics segment is expected to grow at a slower pace than past years
- Patent expiration and government pro-Gx measures will continue to drive volume increase. However, pricing pressure will weigh on growth.

## Performance highlights

- bEtanercept approved by PMDA
- Bipresso<sup>®</sup> Q4 sales up 125% QoQ ; Entered into co-promotion agreement for Bipresso with Yoshitomi that has strong CNS marketing capabilities with 170+ MRs
- Focused on research and manufacturing efficiencies



Developed

EU5

- Germany: EUR 7.1 mn sales in Q4FY19; EUR 28.7 mn sales in FY19
- ARV's, Women's Health and CNS are the key focus therapeutic segments
- NaMuscla™ - Launched with Orphan drug designation in UK, Germany and France

Australia

- 5<sup>th</sup> largest Gx player<sup>1</sup>; FY19 revenues up 7.4% YoY to AUD 47 mn

Emerging markets

South Africa

- 4<sup>th</sup> largest generics player
- Q4FY19 revenues grew 10% YoY to ZAR 342 mn; FY19 revenues up 11% YoY to ZAR 1.2 bn
- Market leader in CVS space

LatAm

- BRL 36 mn sales in Q4FY19; BRL 145 mn sales in FY19
- MXN 178 mn sales in Q4FY19; MXN 674 mn sales in FY19
- Grin is #4 ophthalmic player

API + Global Institutional

- Q4FY19 revenues grew 4% YoY; FY19 revenues up 23% YoY to INR 13.5 bn
- Leadership in TB institutional business

# R&D spend optimized

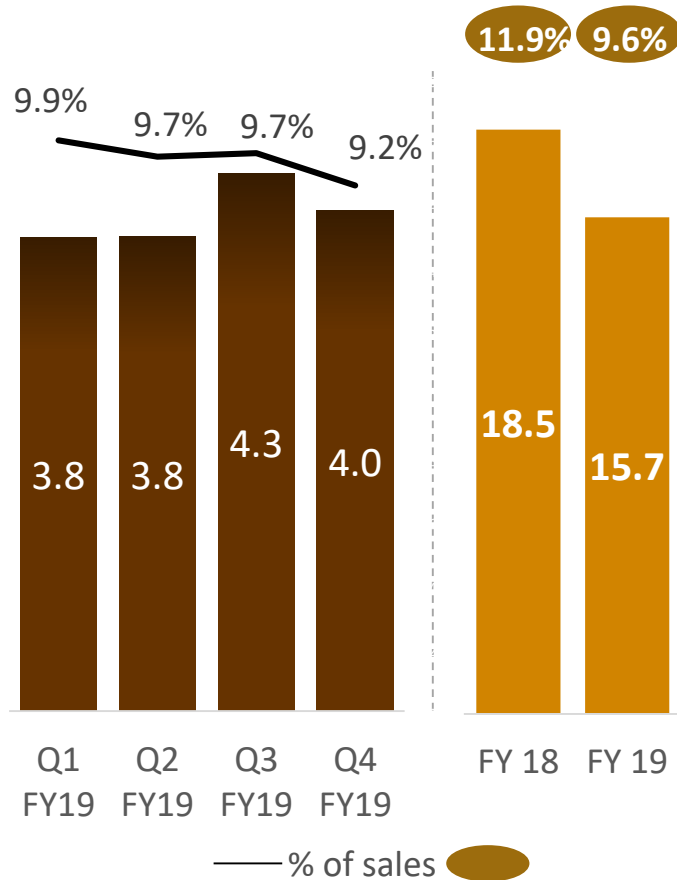
Higher focus on complex products and FTFs

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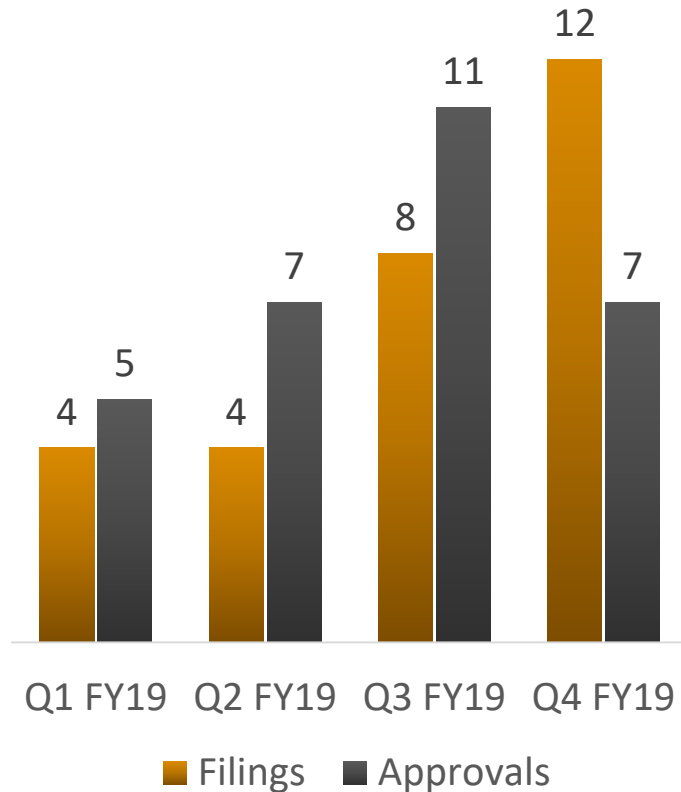


Invested INR 15.7 bn or 9.6% of sales on R&D in FY19 at 9 R&D sites globally

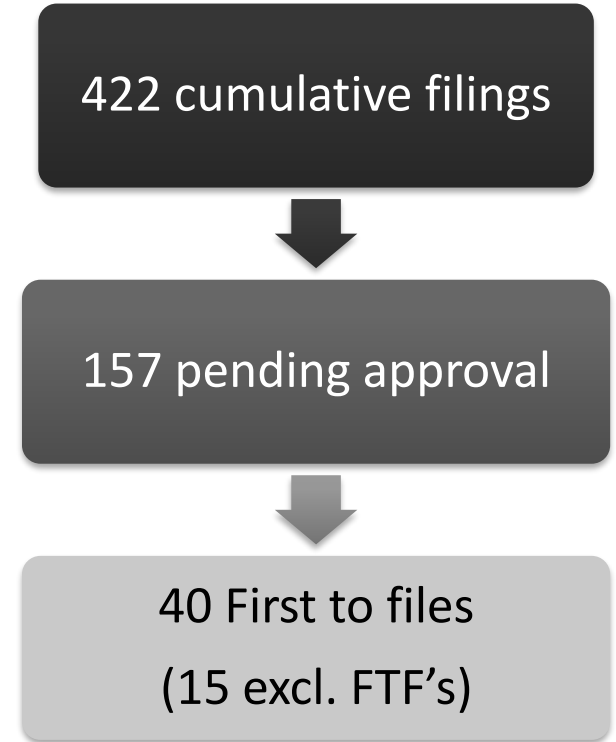
## Optimizing R&D spend (INR bn)



## Filings and Approvals (US)



## US Pipeline



**11 FTF's filed in FY19**

# P&L Highlights – Q4 FY19

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Amount in INR mn	Q1 FY19	Q2 FY19	QoQ Growth	Q3 FY19	QoQ Growth	Q4 FY19	QoQ Growth	Q4 FY18	YoY Growth
<b>Net sales</b>	<b>37,746</b>	<b>38,909</b>	<b>3.1%</b>	<b>43,779</b>	<b>12.5%</b>	<b>43,259</b>	<b>(1.2%)</b>	<b>39,785</b>	<b>8.7%</b>
Other operating income	814	601		1,269		804		553	
<b>Total revenue</b>	<b>38,560</b>	<b>39,510</b>		<b>45,048</b>		<b>44,063</b>		<b>40,338</b>	<b>9.2%</b>
Gross Profit*	23,304	24,981	7.2%	27,770	11.2%	29,181	5.1%	26,159	11.6%
<i>Gross Profit Margin</i>	<i>61.7%</i>	<i>64.2%</i>	<i>246 bps</i>	<i>63.4%</i>	<i>(77 bps)</i>	<i>67.5%</i>	<i>402 bps</i>	<i>65.8%</i>	<i>171 bps</i>
<b>EBITDA</b>	<b>7,112</b>	<b>7,803</b>	<b>9.7%</b>	<b>7,960</b>	<b>2.0%</b>	<b>9,588</b>	<b>20.5%</b>	<b>8,536</b>	<b>(11.0%)</b>
<i>EBITDA Margin</i>	<i>18.8%</i>	<i>20.1%</i>	<i>121 bps</i>	<i>18.2%</i>	<i>(187 bps)</i>	<i>22.2%</i>	<i>398 bps</i>	<i>21.5%</i>	<i>71 bps</i>
PBT**	3,835	4,410	15.0%	4,364	(1.0%)	5,925	35.8%	5,223	(11.8%)
<i>PBT Margin</i>	<i>10.2%</i>	<i>11.3%</i>	<i>117 bps</i>	<i>10.0%</i>	<i>(137 bps)</i>	<i>13.7%</i>	<i>373 bps</i>	<i>13.1%</i>	<i>57 bps</i>
<b>Net Profit**</b>	<b>2,028</b>	<b>2,660</b>	<b>31.2%</b>	<b>1,905</b>	<b>(28.4%)</b>	<b>2,874</b>	<b>50.9%</b>	<b>3,586</b>	<b>24.8%</b>
<i>Net Profit Margin</i>	<i>5.4%</i>	<i>6.8%</i>	<i>146 bps</i>	<i>4.4%</i>	<i>(249 bps)</i>	<i>6.6%</i>	<i>229 bps</i>	<i>9.0%</i>	<i>(237 bps)</i>

Note: \* Excludes other operating income

\*\* Before exceptional items

# P&L Highlights – FY19

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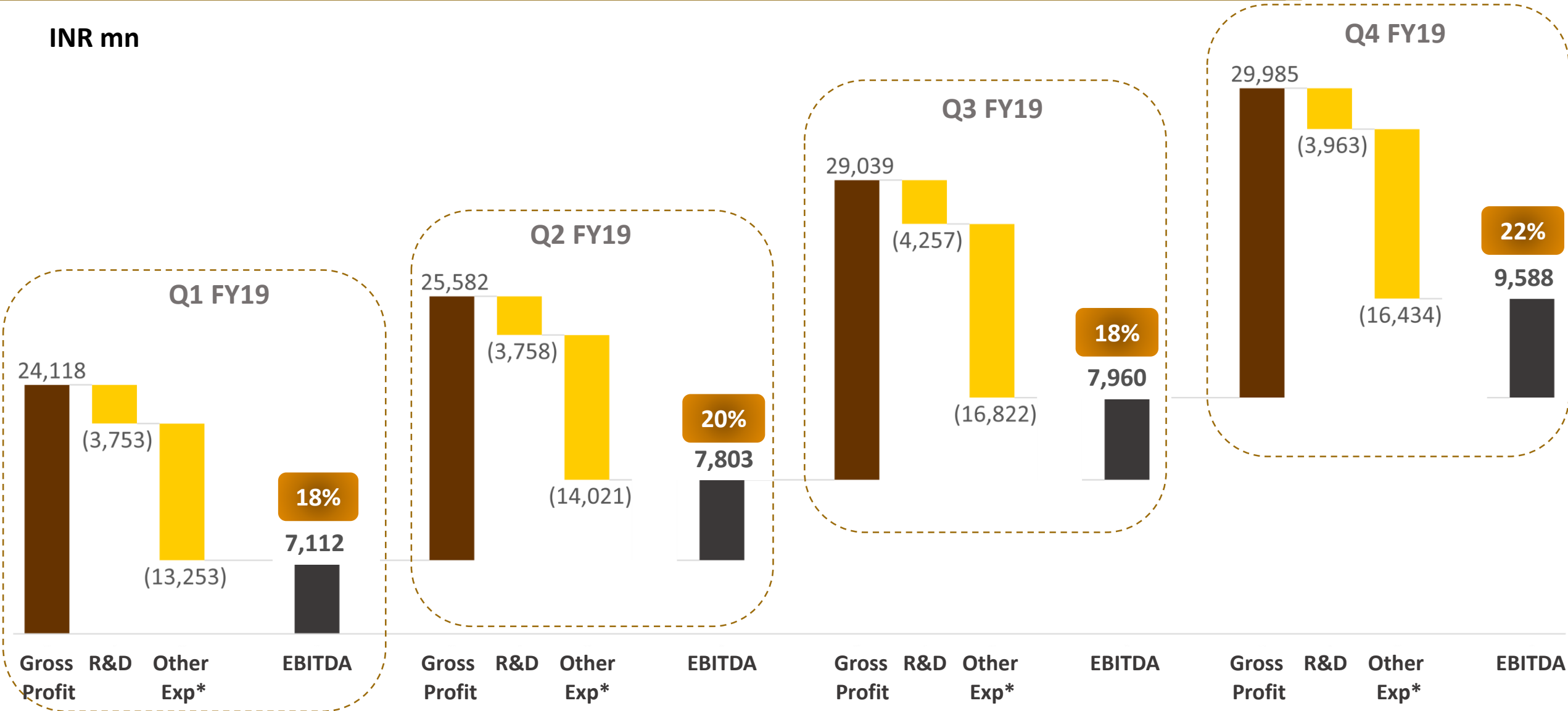
Amount in INR mn	FY19	% of sales	FY18	% of sales	YoY growth
Net sales	163,694	100.0%	155,598	100.0%	5.2%
Other operating income	3,488		2,443		
<b>Total revenue</b>	<b>167,182</b>		<b>158,041</b>		<b>5.8%</b>
Gross Profit (excl. other operating income)	105,236	64.3%	102,854	66.1%	2.3%
<b>EBITDA</b>	<b>32,462</b>	<b>19.8%</b>	<b>32,979</b>	<b>21.2%</b>	<b>(1.6%)</b>
PBT*	18,534	11.3%	20,077	12.9%	(7.7%)
<b>Net profit*</b>	<b>9,466</b>	<b>5.8%</b>	<b>13,934</b>	<b>9.0%</b>	<b>(32.1%)</b>

# EBITDA evolution

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INR mn



Note: \* - Other exp. is net of other income

# Cost Optimization Roadmap

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# Focus on Cost Optimization

Key execution tracks to improve profitability

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Align organization structure to future strategic direction

- Sharp focus on US and India
- Improve R&D productivity
- Build agility in supply chain



- Procurement efficiencies
- Throughput improvement
- Optimize cost base
- Center of excellence for Support Services

# Regulatory Update

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# US Regulatory update

WL issued to Goa and Pithampur (Unit 2)

Nov 2017

Monthly WL updates to USFDA through Jul 2018

Nagpur facility inspected with 0 '483

Mandideep Unit 1 received 18 '483's; Unit 2 issued 4 '483's post inspection  
Somerset facility issued 6 '483's  
EIR for Pithampur (unit 3)

Pithampur (Unit 2) retained OAI status  
EIR for Pithampur (unit 3)  
Pune Bioresearch center inspected with 0 '483

Apr-May '18

Jul 2018

Aug 2018

Sep 2018

Oct 2018

Nov 2018

Dec 2018

EIR for Pithampur (Unit 1)  
Nagpur facility inspected with 0 '483

Final WL update to USFDA  
EIR for Nagpur facility  
Tarapur facility inspected with 1 '483

Pithampur (unit 3) issued 5 '483's

EIR for Nagpur and Tarapur facilities

Mandideep (Unit 1) and Somerset facilities classified as OAI

Jan 2019

Feb 2019

Mar 2019

Apr 2019

May 2019

Pithampur (unit 2) issued 6 '483's post re-audit

Goa facility issued 2 '483's post re-audit

EIR for DSRM unit  
Aurangabad facility issued 3 '483's

# Priorities for FY20

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# Near term priorities

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- Focus on productivity
- Deliver on identified cost saving measures
- Sharp focus on resource allocation

**Cost Optimization**

**Strong Generics Foundation**

- Ensure regulatory compliance – Warning letter & OAI resolution
- Execute on Levothyroxine and 20+ planned launches in the US
- Maintain growth momentum in India, emerging markets

**Goals for FY20**

- Scale up Solosec
- Build scale in WH space in US through BD (Licensing/M&A)
- Build Namuscla in EU, and Ramp up Bipresso in Japan

**Specialty**

**Complex Generics**

- EU approval of Etanercept
- Etanercept launch in JP/EU
- File additional inhalation and injectable products
- Timely gProAir launch upon approval

**THANK YOU**

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