# Lupin Limited

## FY2015-16 Investor Presentation

May 19, 2016

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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.

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# Global Generics: Industry Trends

**US**
Price Erosion due to channel consolidation
GDUFA goals – FDA approved record ANDAs in 2015

**India**
Policy changes creating uncertainty in the market
Expanding NLEM list and irrational FDC bans

**Japan**
Govt target of Gx penetration for mid-2017: 70%; 2020: 80%
NHI price revisions for 3 years in a row for 2016-18

**M&A**
Record M&A ($500bn in last 2.5 years) for generics and specialty
Eg. Teva - Allergan Gx, Mylan – Meda, Actavis - Allergan

**Biosimilars**
Developed markets pathway emerging
US FDA approving and recommending biosimilars

**Compliance**
Regulatory penalties peaked in 2015 in form of 483's and warning letters by US FDA



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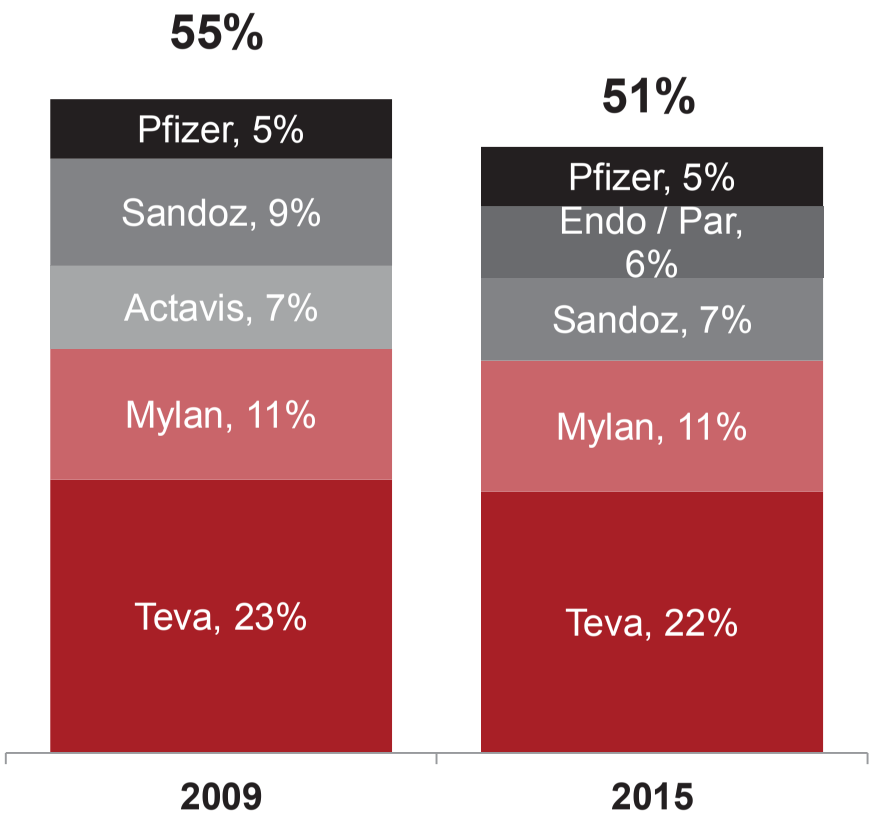
# US Generics – Drivers

## Gx will see further penetration in the US..

- Gx penetration expected to rise from 88% to 92% by 2020
- 2016-20: patent expiries of $92bn
- Generics still underpenetrated in alternative dosage forms
- Generics still fragmented in US: Top 5 share going down despite consolidation

## US Gx Market Share Evolution




Source; IMS Use of Medicines till 2020, Morgan Stanley Research



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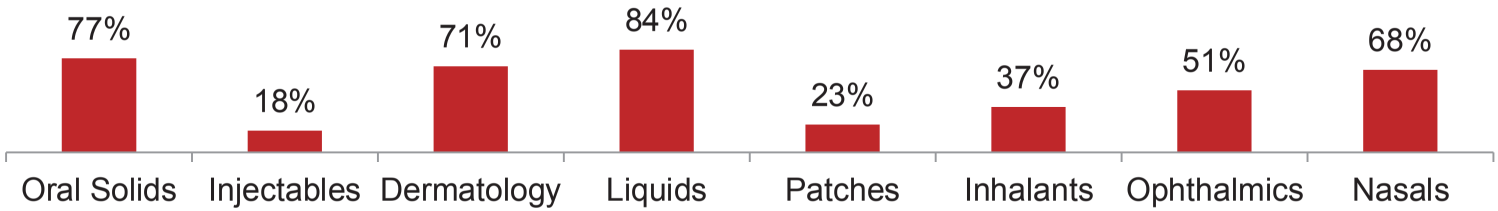
# Complex Generics Opportunity

- **70% of generics market ($68bn) is oral solids and liquids**
- **Majority of companies lack critical mass in alternative dosage forms**
  - Dermatology and injectables have 17 and 14 large players, sized at $6bn and $8bn, respectively
  - Rest of the areas are small ($1-2bn), but are highly concentrated with fewer players

US Gx Penetration (by TRx)




| | Oral Solids | Injectables | Dermatology | Liquids | Patches | Inhalants | Ophthalmics | Nasals |
|---|---|---|---|---|---|---|---|---|
| # of players (>$100mm) | 47 | 17 | 14 | 6 | 6 | 2 | 5 | 3 |
| Market Size ($bn) | 45.0 | 8.4 | 5.9 | 1.9 | 1.5 | 1.7 | 1.3 | 0.5 |

***Complex generics still present an untapped opportunity***

Source; IMS MAT Sep 2015 and Morgan Stanley Research



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# What does this mean for Lupin?

**US**
Focus on complex generics
Build specialty internally and via acquisitions/partnerships

**India**
Increase the prescriber base and penetration
New alliances to help accelerate growth

**Japan**
Strategic partnerships with key constituents
Capacity expansion to serve the further genericization

**M&A**
Focus on Brands and Specialty acquisition
Target Niche technology platforms

**R&D**
Enhanced R&D investments in complex generics, specialty and biologics

**Execution**
Continued focus on operational excellence to achieve cost leadership
High quality and compliance standards



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# Our Strategic Direction

## 2016

- Primarily a Generic / Branded Generic Business
- 3 strong geographies

## 2018

- Leading generics player with a larger complex generics and specialty business
- Stronger geographic spread

## 2020+

- Leading generics player with a significant complex generics and specialty business
- Leading global player



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# LUPIN TODAY

# A Journey of Stellar Performance

| Parameter | 2006* | | 2016* |
|---|---|---|---|
| Market Cap | 41bn | CAGR 32% | 667bn |
| Revenues | 16bn | CAGR 24% | 137bn |
| R&D spend | 1bn | CAGR 31% | 16bn |
| *R&D % to sales* | *7%* | | *12%* |
| EBITDA | 3bn | CAGR 29% | 39bn |
| *EBITDA%* | *19%* | | *29%* |
| Net Profit | 2bn | CAGR 29% | 23bn |
| *Net Profit %* | *11%* | | *17%* |

*All figures in INR; "mm" indicates million and "bn" indicates billion


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# Today Lupin is a Globally Dominant Force

## Globally

**7th**
largest generic globally
*(by market cap[1])*

**9th**
largest generic company
*(by sales[2])*

**3rd**
largest Indian Pharma
*(by global sales[2])*

**#1**
in Anti-TB
*(globally)*

## Advanced Markets

**5th**
largest US
*(by prescriptions[3])*

**9th**
Largest Japanese Gx[4]

## Emerging Markets

**8th**
India Pharma Market Rank[5]

**4th**
largest South Africa generics[6]

Sources:
1 Bloomberg EQS, 31 March 2016
2 LTM sales available as of 19-May-16
3 IMS MAT Sep 15 (GPhA presentation)
4 Latest reported FY sales
5 IMS MAT Mar 16
6 IMS MAT Mar 16


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# Lupin – Awards and Accolades

- **Outstanding Company of the Year** by CNBC-TV18
- Lupin Ranked 15th in the Great Places to Work **"Best Companies to Work for in Asia"**
- Lupin in AON **Best Employers India 2016**
- Lupin in Forbes World's Most Powerful Public Companies
- **CNBC TV18 Firm of the year** in Pharma sector: India Risk Management Awards – 2015
- Vinita Gupta, CEO & Nilesh Gupta, MD awarded the Ernst & Young **Entrepreneur of the Year,** India, 2015
- Vinita Gupta awarded "Outstanding Woman Business Leader of the Year" – CNBC-IBLA: FY 2015-16
- Vinita Gupta in **Forbes Asian Businesswomen – Power 50**
- Vinita Gupta amongst The Most Powerful business Women 2015 by Business Today
- Ramesh Swaminathan the **Best CFO** by FinanceAsia
- Lupin #1 in Pharma **in "Best at Investor Relations"** by FinanceAsia; 5th in Overall Ranking



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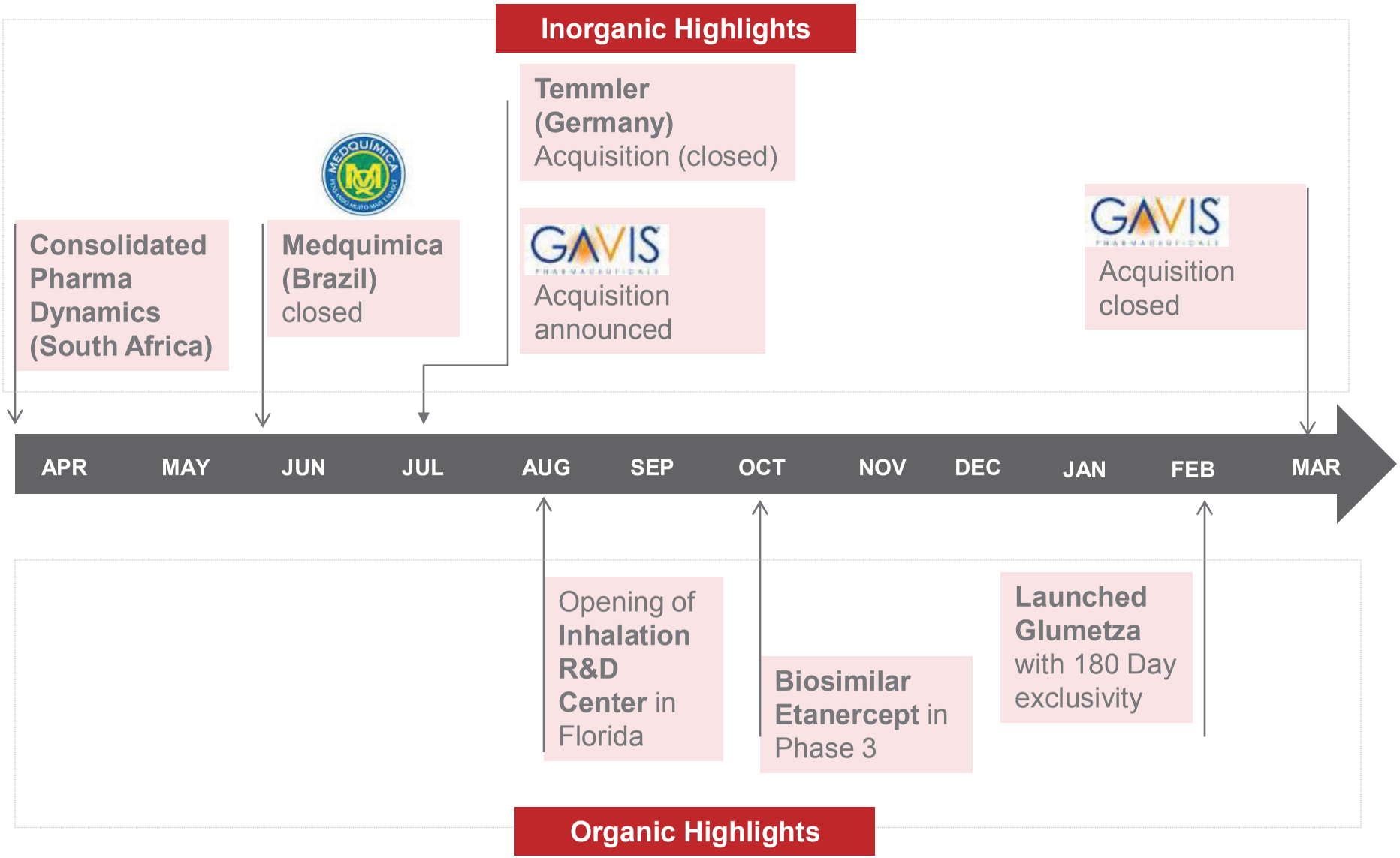
# 2016 - Year of Enhancing Global Footprint



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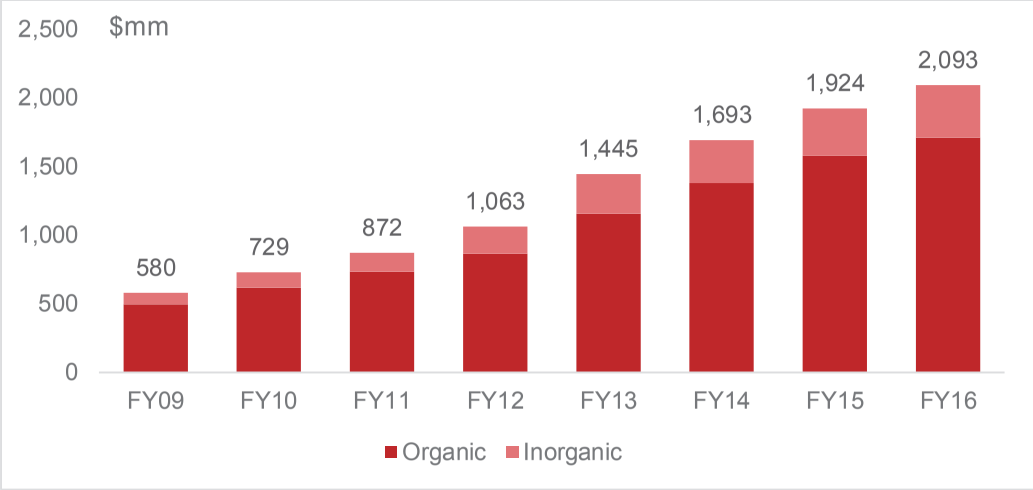
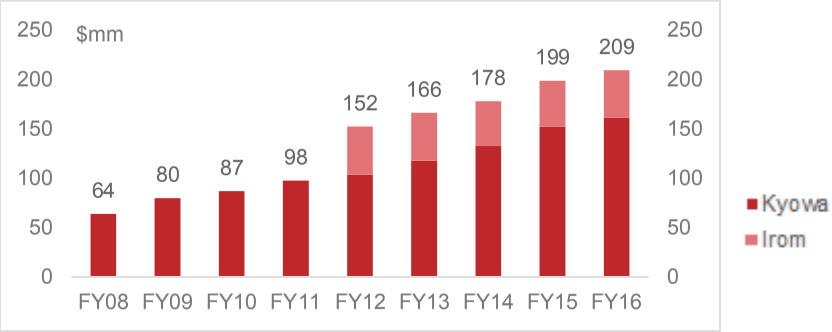
# Strong Track Record of Organic & Inorganic Growth

**~20% of Lupin's FY16 Revenue is derived from acquisitions**

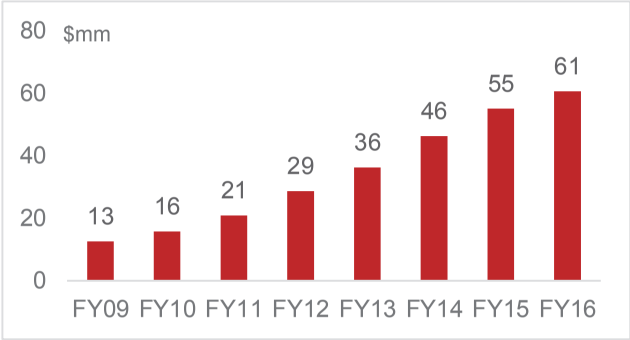



**KYOWA / Japan Acquisition**




- Kyowa's performance improved from an operating loss to one of the highest Gx margins in JP
- Revenue CAGR of 16% since acquisition (constant FX)

**PHARMADYNAMICS / South Africa Acquisition**




- PBT margin increased 2.3 times since acquisition
- Revenue CAGR of 25% since acquisition (constant FX)

1. Used constant fiscal year ending 2016 average exchange rates



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# Lupin Somerset (Gavis) - Update

- **Acquisition - On Track**
  - Performance on track with the business plan
  - Integration complete
  - Appointed Dr. Kurt Nielsen as President of Lupin – Somerset
  - Launched Methergine® Oral Tablets under Lupin's Women's Health division
  - Launched through Lupin's paediatrics division

- **Strengthens portfolio and Enhances near-term pipeline**
  - Adds 28 marketed products to Lupin's portfolio bringing it to a total of 124
  - Has 9 controlled substances and 1 dermatology product in market
  - Adds 102 cumulative filings of which 58 pending; 66 products in development
  - Received 14 approvals in FY2015-16



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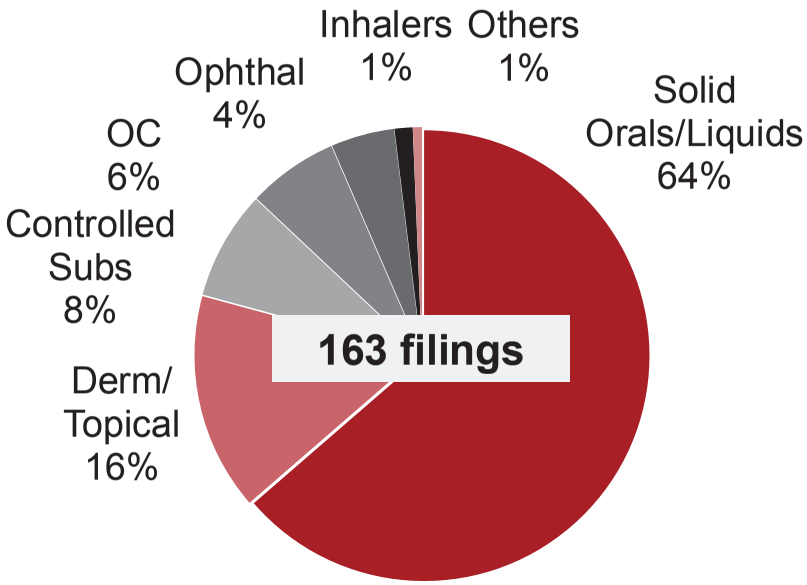
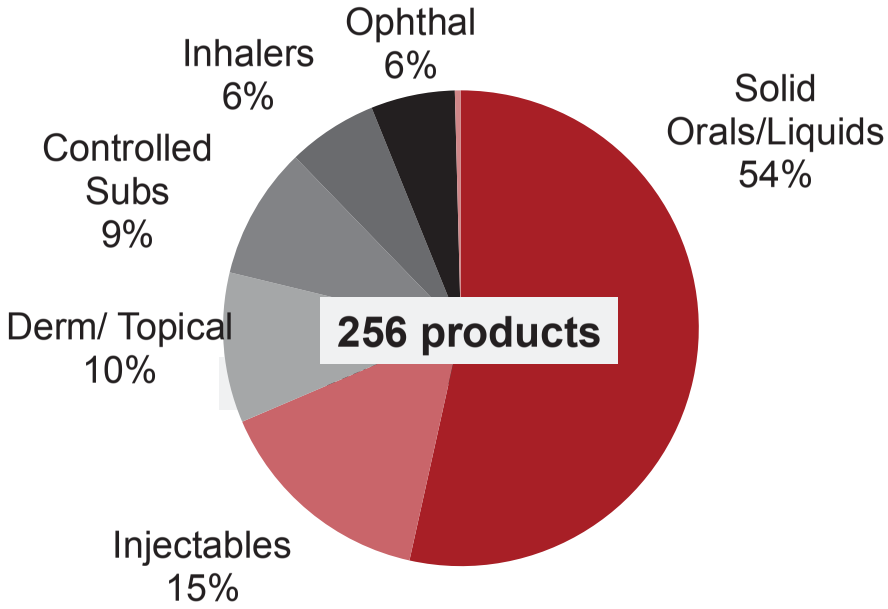
# US: Combined Pipeline Update

## Filed products




| | Lupin | Somerset | Total |
|---|---|---|---|
| **Total** | 241 | 102 | 343 |
| **Approved** | 136 | 44 | 180 |
| **Pending** | **105** | **58** | **163** |

## Products in development




| | Lupin | Somerset | Total |
|---|---|---|---|
| **Total** | **190** | **66** | **256** |



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# Complex Gx / Specialty Update

Complexity

| Focus Areas | FY16 R&D Update | Market Size targeted ($bn)[1] |
|---|---|---|
| NDDDs | Continue development (10 NCEs) | |
| Biosimilars | 10 under development; Etanercept started PhIII in Japan; | 19.1 |
| Respiratory | 2 filings; Clinical trials started for 1 MDI; DPI clinical trials to commence in FY17 | 17.2 / 0.3 |
| Injectables | Nanomi-complex depot inj. dev. ongoing; LRP injectables dev. ongoing | 12.8 |
| Controlled Subst. | Gavis 9 pdts in market; 12 filings; Further Dev ongoing | 7.8 / 4.1 |
| Dermatology | Gavis 1 pdt in market; 24 filings; Dev ongoing | 2.7 / 3.0 |
| Ophthalmology | 2 in market; 7 filings; Continue development | 1.8 / 3.1 |
| OC's | 21 pdts in market; 10 pending approval | 1.2 |

Development

Filed

Target $73bn[1]

Note: 1. US IMS MAT Dec 2015 Brands + Gx data



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# Lupin Global Capabilities Footprint

***Manufacturing sites: 11 in India; 1 in US; 2 in Japan and 2 in LatAm***

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# US FDA Compliance Record: Goa Update

| Month | Site of Inspection | Outcome |
|---|---|---|
| Jan-15 | Pithampur (Indore), Unit-2 | 483 with 6 observations |
| Mar-15 | Pithampur (Indore), Unit-3 | No observations |
| Mar-15 | Nagpur | No observations |
| Apr-15 | Aurangabad | 483 with 2 observations |
| Jun-15 | DSRM, Mumbai | No observations |
| Jul-15 | Goa | 483 with 9 observations |
| Aug-15 | Pithampur (Indore), Unit-1 | No observations |
| Aug-15 | Tarapur | No observations |
| Aug-15 | LBC, Pune | No observations |
| Jan-16 | Aurangabad | 483 with 3 observations |
| Feb-16 | Mandideep Unit-1 | 483 with 4 observations |
| Mar-16 | Goa | 483 with 9 observations |

- Responded to the Goa observations
- Provided update thereafter
- Working on holistic quality transformation



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# BUSINESS UPDATE



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# P&L Highlights – Q4FY16 YoY

| Particulars (INRmm) | Q4FY16 | % of net sales | Q4FY15 | % of net sales | YoY growth | Q3FY16 | % of net sales | QoQ growth |
|---|---|---|---|---|---|---|---|---|
| **Net sales** | **40,913** | **100.0%** | **30,540** | **100.0%** | ***34.0%*** | **33,577** | **100.0%** | ***21.9%*** |
| Other operating income | 899 | | 241 | | | 1,981 | | |
| **Total revenue** | **41,812** | | **30,781** | | ***35.8%*** | **35,558** | | ***17.6%*** |
| Gross margin *(excl. other operating income)* | 30,176 | 73.8% | 20,977 | 68.7% | *43.9%* | 22,347 | 66.6% | *35.0%* |
| EBITDA | 13,929 | 34.0% | 8,066 | 26.4% | *72.7%* | 9,425 | 28.1% | *47.8%* |
| EBIT | 12,482 | 30.5% | 6,995 | 22.9% | *78.4%* | 8,311 | 24.7% | *50.2%* |
| **Net profit** | **8,071** | **19.7%** | **5,470** | **17.9%** | ***47.5%*** | **5,298** | **15.8%** | ***52.4%*** |

Crossed 4,000 Cr in sales and 800 Cr in profits for the first time in a quarter



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# P&L Highlights – FY16

| Particulars (Rs mn) | FY16 | % of net sales | FY15 | % of net sales | Growth |
|---|---|---|---|---|---|
| **Net sales** | **137,016** | **100.0%** | **125,997** | **100.0%** | ***8.7%*** |
| Other operating income | 5,069 | | 1,703 | | |
| **Total revenue** | **142,085** | | **127,700** | | ***11.3%*** |
| Gross margin *(excl. other operating income)* | 93,922 | 68.5% | 84,427 | 67.0% | *11.2%* |
| EBITDA | 39,412 | 28.8% | 38,593 | 30.6% | *2.1%* |
| EBIT | 34,777 | 25.4% | 34,246 | 27.2% | *1.5%* |
| PBT | 34,330 | 25.1% | 34,148 | 27.1% | *0.5%* |
| **Net profit** | **22,707** | **16.6%** | **24,032** | **19.1%** | ***(5.5%)*** |

PBT maintained at previous years' level despite challenging first half and enhanced R&D investments



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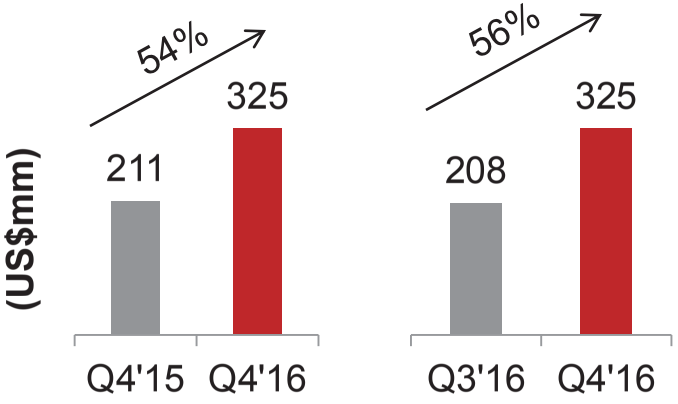
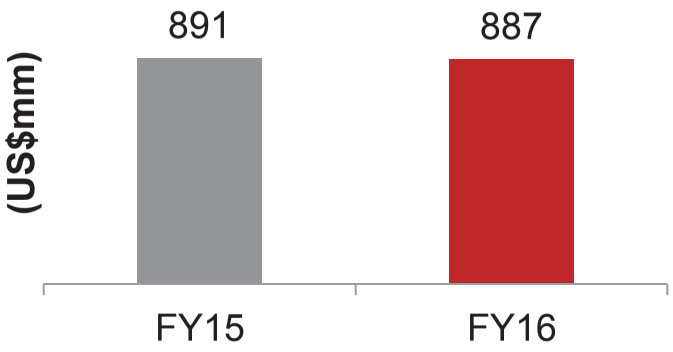
# US




## Commentary

- US business grew YoY by 59% in INR terms to Rs. 21,871 mm (including IP) in Q4FY16
- QoQ growth was 56%
- **Lupin now has 5.6% Rx share and retains 5th rank[1]**
- 39 approvals in FY16
- 9 new product launches during the quarter
- **Lupin supplies four of the Top 10 most commonly dispensed medicines in US**
- **Portfolio of 124[2] products (28 Somerset)**
- **US Market Share: No. 1 in 44 & top 3 in 79 products[3]**
- Total of 343[2] ANDA filings till date (102 Somerset), of which 180[2] (44 Somerset) have been approved

Note:
1 IMS MAT Sep 2015
2 As of 31-Mar-16
3 IMS MAT Mar 2016



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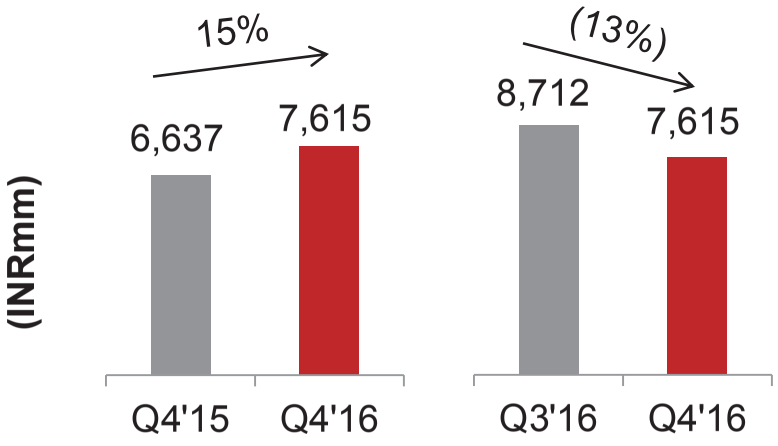
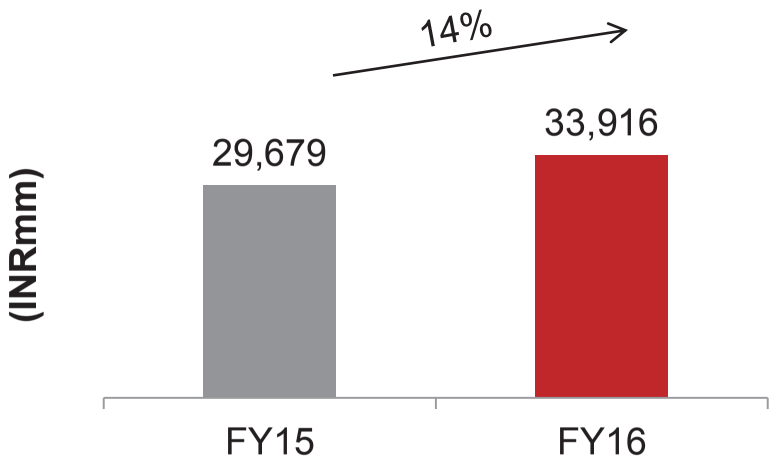
# India




## Commentary

- India business growth of 14% to Rs. 33,916 mm
- Ranked 8th in the IPM[1]
- Added 1,000 reps in FY15; Total sales force > 6,600
- Launched 5 new divisions to cater to high growth therapies
- Climbed to #3 ranking in Respiratory
- Launched 19 brands in FY16
- Chronic: 58%; Semi-chronic: 29% of sales in FY16

Note:
1 IMS MAT Mar 2016



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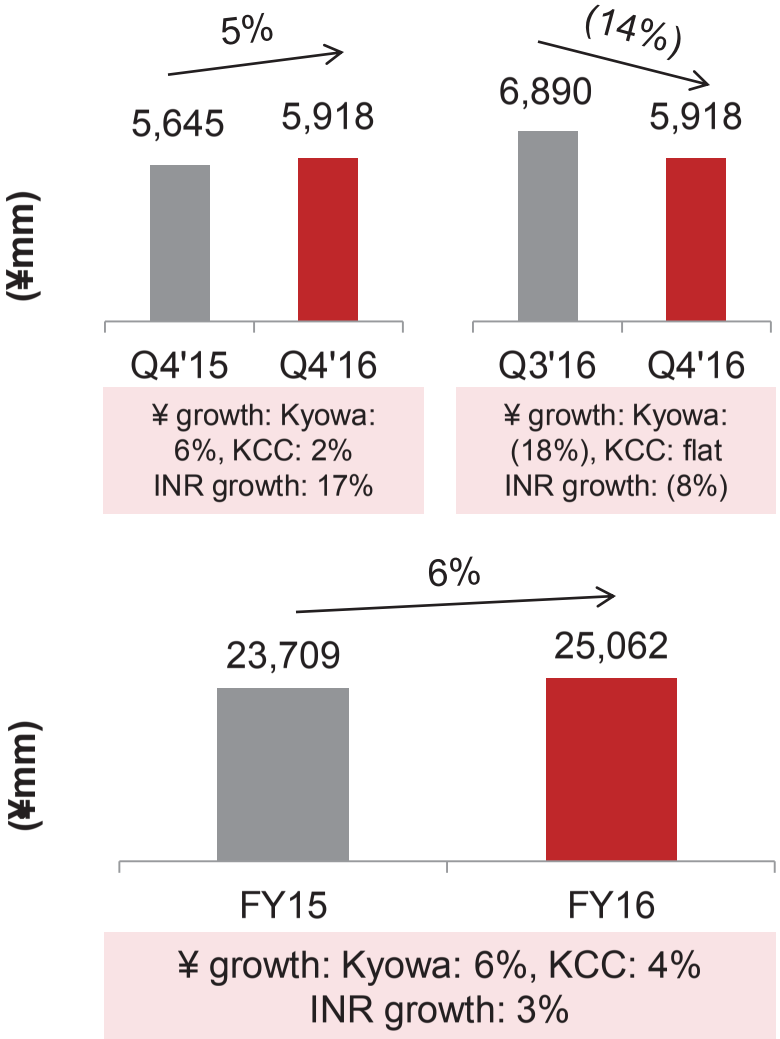
# Japan




## Commentary

- Japan business grew YoY by 3% to Rs.13,646 mm
- 9th largest generic company Strong presence in Central Nervous System, Cardiovascular, Gastroenterology & Injectables
- A new dedicated manufacturing site for oral solids
- New injectable line in KCC
- Strategic partnership with national distributor

1 IMS MAT Mar 16 – Peer companies universe



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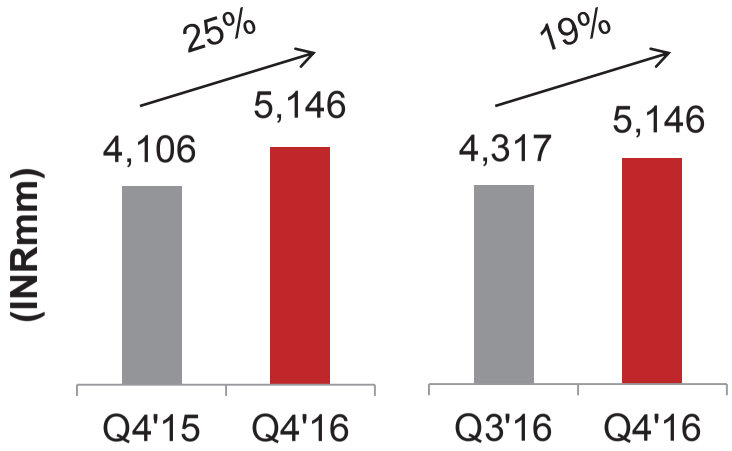
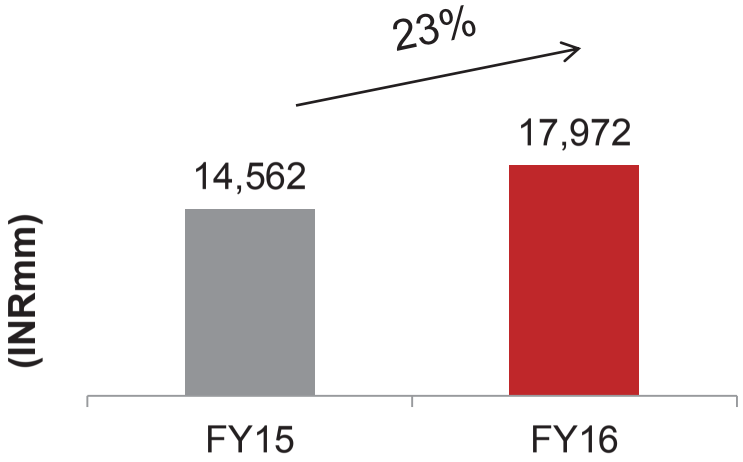
# Rest of Business




## Commentary

### South Africa

- YoY growth of 10% in ZAR
- 4th largest generic company[1] & #1 CVS player[1]

### Philippines

- YoY growth of 42% in PHP
- Multicare IMS growth of 44%[2] vs industry growth of 9%[2]
- Rank: 22[2]

### LatAm

- **Mexico:** 2nd largest ophthal (by volume); IMS growth of 18% vs 5% market growth[3]
- **Brazil:** IMS growth of 15% vs market growth of 8%[4]

### Europe

- All businesses growing strongly
- Foray into Branded / Specialty segment with the acquisition of Temmler portfolio in Germany

Note:
1 SA IMS MAT Mar 16
2 Philippines IMS MAT Mar 16
3 Mexico IMS Mar 16
4 Brazil IMS MAT Dec 15
5 Rest of Business: Includes Europe, ROW (South Africa, Philippines, Mexico, Australia and Brazil)



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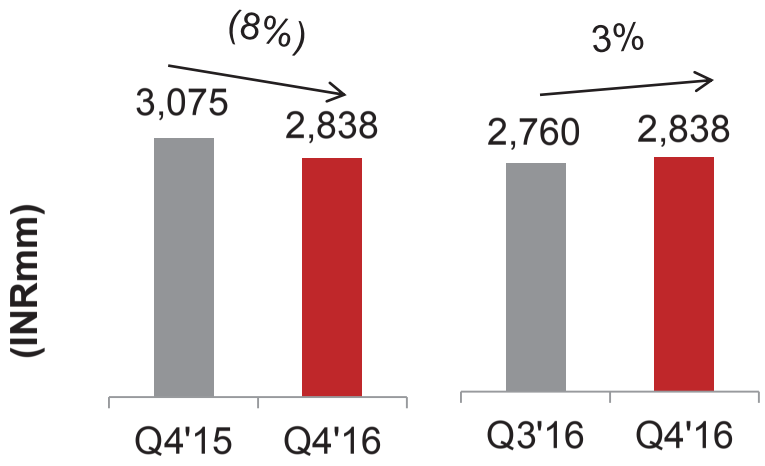
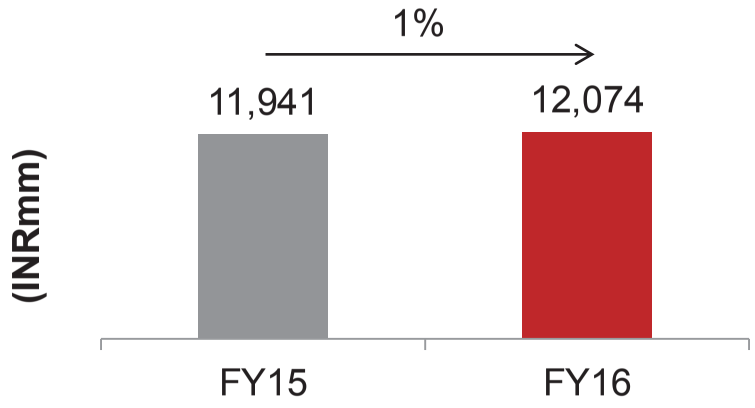
# API




## Commentary

- API business flat YoY at Rs. 12,074mm
- Enhanced focus on pipeline of complex and first-to-file APIs
- 172 US DMFs with 16 filings in FY16



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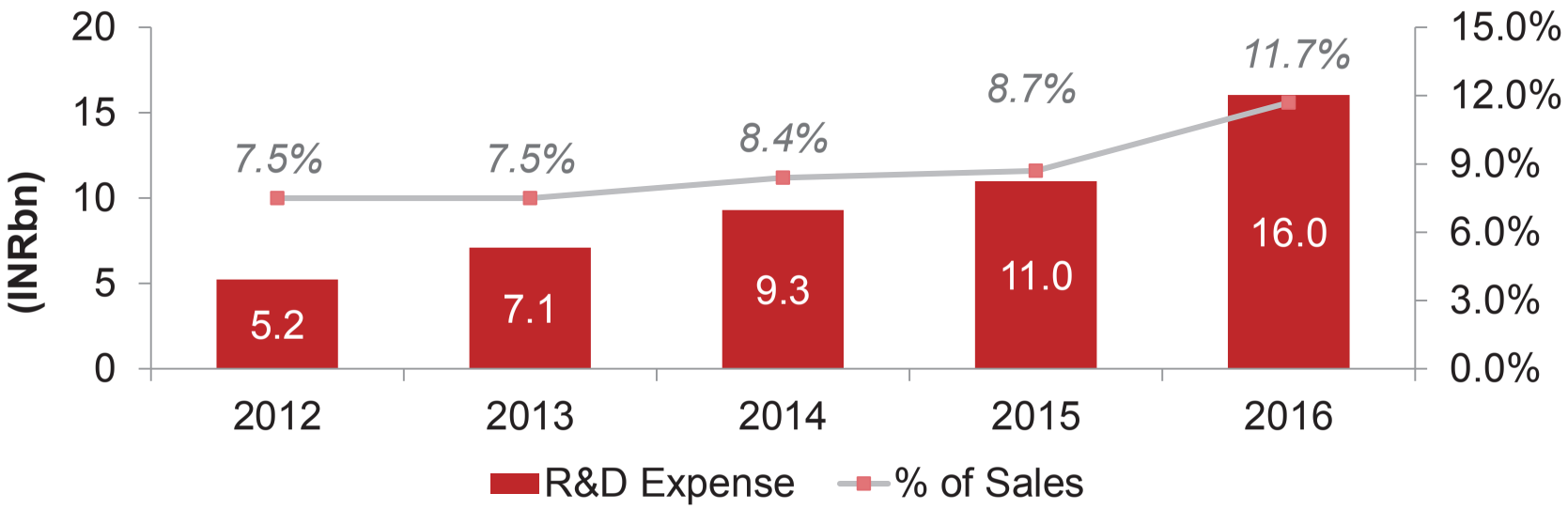
# R&D Expenses




- R&D expenses for Q4FY16 were Rs. 5,113 mm, at 12.5% of net sales vs 3,096 mm, 10.1% of net sales in Q4FY15
- Talent pool of 1,700+ scientists at R&D centers across the globe
- FTFs - 45 filings till date (US$ 11.9 bn[1]) with 35 exclusives (US$ 4.4 bn[1])
- Total of 343[2] ANDA filings till date (102 Gavis), of which 180[2] (44 Gavis) have been approved (25 Lupin + 14 Gavis approvals in FY16)

1. IMS MAT Sep 2015
2. As of 31-Mar-16



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# 2017 Expectations

## Generics — Strong Organic Growth in Key Markets

- Grow US and Japan by new launches and grow base business
- Increase penetration in emerging markets

## Specialty — Continue Efforts to Build Specialty

- Add specialty via acquisitions of assets, brands and companies
- Create specialty pipeline (File NDAs, 505b2)

## R&D — Global R&D centers

- Deliver on the pipeline by filing across geographies
- Evolve complex generics and specialty pipeline

## Op. Ex. — Global Operations

- Focus on operational excellence to achieve cost leadership

## Compliance — High thrust on compliance



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