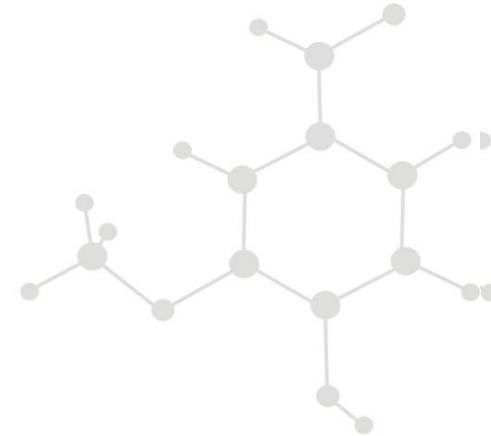


# Glenmark Pharmaceuticals Limited



A new way for a new world

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## **GLENMARK : TRACK RECORD**

**BUSINESS OVERVIEW**

**FINANCIALS**





## Year 2000

- ❖ Consolidated Turnover - Rs 1380 Mn (\$ 31.62 Mn)
- ❖ 2 Formulations Manufacturing Facilities
- ❖ Sales from International operations – 8%
- ❖ Initiation into NCE research

## Year 2014

### Research Driven

- 6 NCEs + NBEs in Clinics
- USD 217 Mn of cash received from NCE/NBE out-licensing deals
- Seven out-licensing deals since 2004

### Global

- Consolidated Turnover - Rs. 60069.35 Mn (\$ 995 Mn)
- Global Operations with more than 20 subsidiaries and over 10,000 employees
- 14 manufacturing facilities in 4 countries
- Front-ends in key markets worldwide

### Integrated

- 3 API plants
- 11 Finished dosage plants
- 6 Research facilities

**GLENMARK : TRACK RECORD**

**BUSINESS OVERVIEW**

**FINANCIALS**



# Glenmark Value Proposition



Glenmark Generics moving down the value chain in to Pure Generics & API space

**Glenmark**

Glenmark Pharma moving up the value chain with Discovery research

Big pharma moving down the value chain by entering the Branded Generics & Pure Generics space

**API Manufacturing**

**Pure Generics Business**

**Branded Generics business**

**Propriety Branded Business**

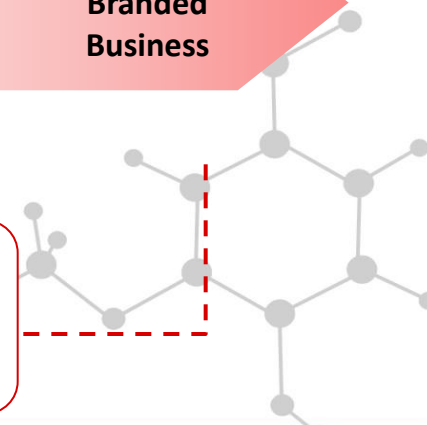
## PHARMACEUTICAL VALUE CHAIN

### Key Requisites

Low cost; low margins  
Forging IP challenges  
"Push" for products  
Efficient distribution

### Key Requisites

Innovation Brand Building  
"Pull" for products  
Marketing front end





## GLENMARK

### Novel Research & Development

### Specialty Business

### Generics Business

#### FOCUS

- Focus on New Drug Development

- Specialty/ Proprietary Business
- Focus on branded products market

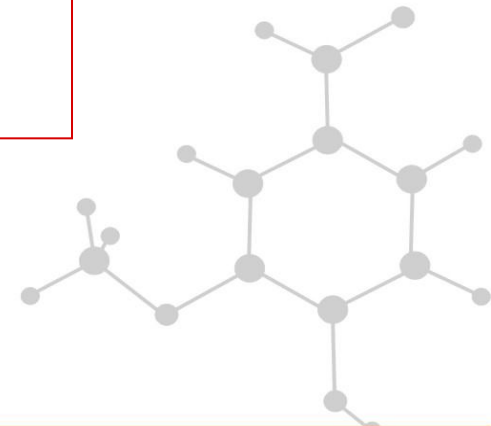
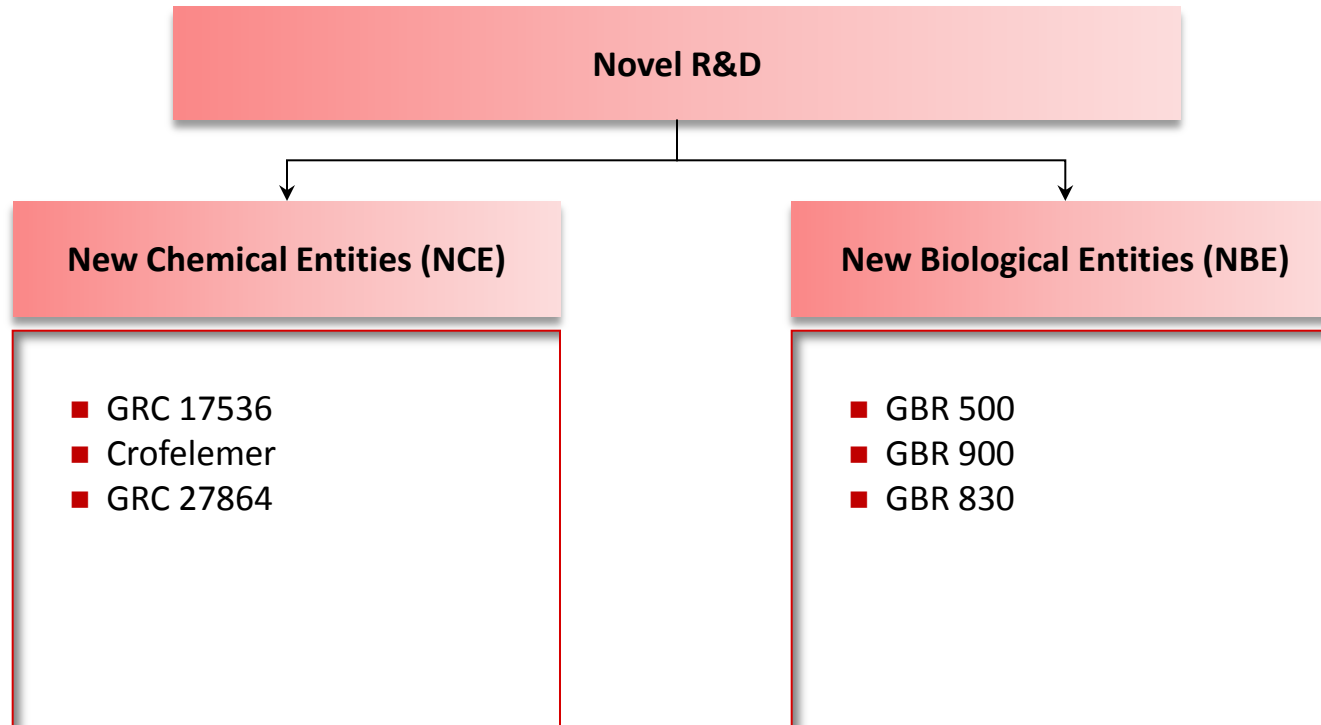
- Pure Generics Business
- Focus on marketing of APIs and generic formulations

#### BUSINESS IMPERATIVES

- Discover First-in-Class or Best-In-Class molecules for unmet medical needs
- Continuously build a pipeline of exciting molecules
- Medical & Clinical studies
- IP Protection

- Brand Building
- Prescription Generation
- Therapy focus
- Create 'pull' for brands
- Marketing fronts in key branded markets
- In-licensing products for markets

- Low cost manufacturing
- Maintaining supply of low-cost API
- Efficient spread of distribution
- Create right 'push' for generic products
- Product selection/ timing and speed of development
- IP Challenge



# Novel R & D Capabilities – Out-licensing deals



## **GBR - 500: Sanofi-Aventis 2011**

- ❖ First novel biologics outlicensing deal for Glenmark
- ❖ Upfront payment of USD 50 mn; Received USD 5 mn in May'14 Total deal size – USD 613 mn

## **mPGES-1 Inhibitors Forest Labs 2012**

- ❖ Received USD 15 million payment from Forest labs on an option agreement.
- ❖ Forest has the first right to refusal after Phase I completion

## **GRC 15300: Sanofi-Aventis 2010**

- ❖ Received \$25 million in upfront and milestone payments for development & commercialization rights of a first in class TRPV3 antagonist
- ❖ Phase II trial did not meet the Primary endpoint in May'14

## **GRC 6211: Eli Lilly 2007**

- ❖ Eli Lilly acquired the rights to a portfolio of TRPV1 antagonist molecules
- ❖ Received an upfront fee of \$45 million
- ❖ Development of the lead compound GRC 6211 has been stalled

## **Melogliptin: Merck KGaA 2006**

- ❖ A deal worth \$ 250 Mn in October 2006. Received total payments of \$ 31 Mn
- ❖ Due to a reduced R&D focus on Diabetes, Merck returned the molecule to Glenmark in April 2008
- ❖ Melogliptin completed Phase II b trials and is ready to enter Phase III

## **Oglemilast: Forest Labs 2004**

- ❖ A deal worth \$190 Mn on Oglemilast US Rights
- ❖ Received \$35Mn as upfront and milestone payments

## **Oglemilast: Teijin Pharma 2005**

- ❖ A \$ 53 Mn deal for Oglemilast Japan rights
- ❖ Teijin Pharma paid an up-front payment of \$6Mn

**GPL has completed seven out-licensing deals since 2004, with a cumulative payment of \$ 217 Mn received in terms of upfront and milestone payments.**

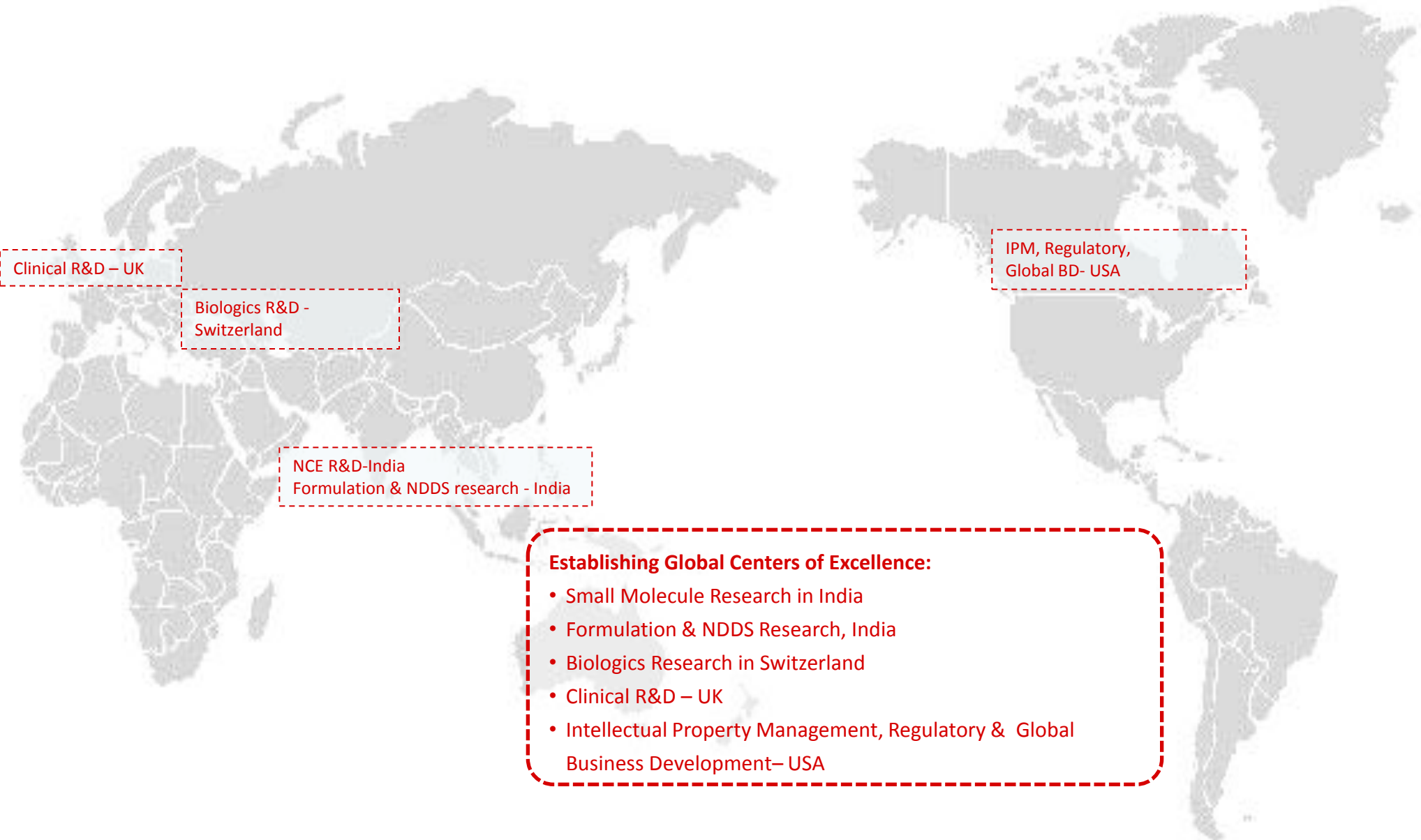


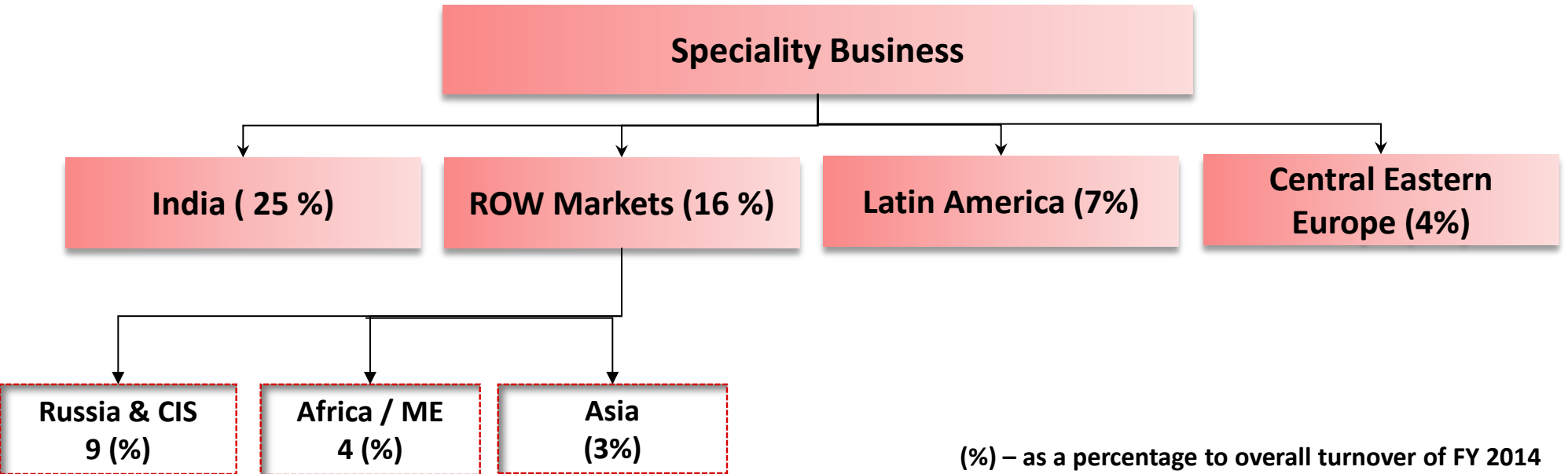
# Novel Drugs Pipeline



Compound	Primary Indications	Target	Pre Clinicals	Phase I	Phase II a	Phase II b	Phase3	Approval	
<b>Crofelemer</b>	HIV related Diarrhea	CFTR Inhibitor	[Progress bar: 100%]						In-licensed for ROW Markets
	Adult Acute Infectious Diarrhea including Cholera	CFTR Inhibitor	[Progress bar: 100%]						In-licensed for ROW Markets
<b>GRC 17536</b>	Neuropathic Pain	TRPA1 Inhibitor	[Progress bar: ~75%]						
	Respiratory disorders	TRPA1 Inhibitor	[Progress bar: ~75%]						
<b>GRC 27864</b>	Chronic Inflammatory conditions including Pain	mPGES-1 Inhibitor	[Progress bar: ~25%]						Option agreement with Forest Laboratories
<b>Vatelizumab (mAb)</b>	Multiple Sclerosis	VLA-2 Antagonist	[Progress bar: ~50%]						Out-licensed to Sanofi
<b>GBR 900*</b>	Chronic Pain	TrkA Antagonist	[Progress bar: ~10%]						
<b>GBR 830 (mAb)</b>	Autoimmune Disorders	OX 40 Antagonist	[Progress bar: ~10%]						

\* GBR 900 is a monoclonal antibody inlicensed from Lay Line Genomics, Italy. With this, Glenmark has the exclusive target license to commercialize monoclonal antibodies against TrkA receptor for pain





- Key markets are India, Russia, and Brazil.
- Build expertise around focus therapeutic areas across all operating regions viz. Dermatology, Respiratory and Oncology
  - 1-2 additional therapeutic areas in each region



## Specialty Business

*Global Therapeutic focus on Dermatology, Oncology and Respiratory*

India (25 %)

- ❖ Growth driven by new brand introductions and focused strategy of divisionalisation
- ❖ Cardiometabolic, Respiratory and Dermatology continue to register growth

ROW Markets (16 %)

- ❖ Russia is the largest subsidiary
- ❖ Presence in several African markets
- ❖ Power Brand strategy drives growth in Asia

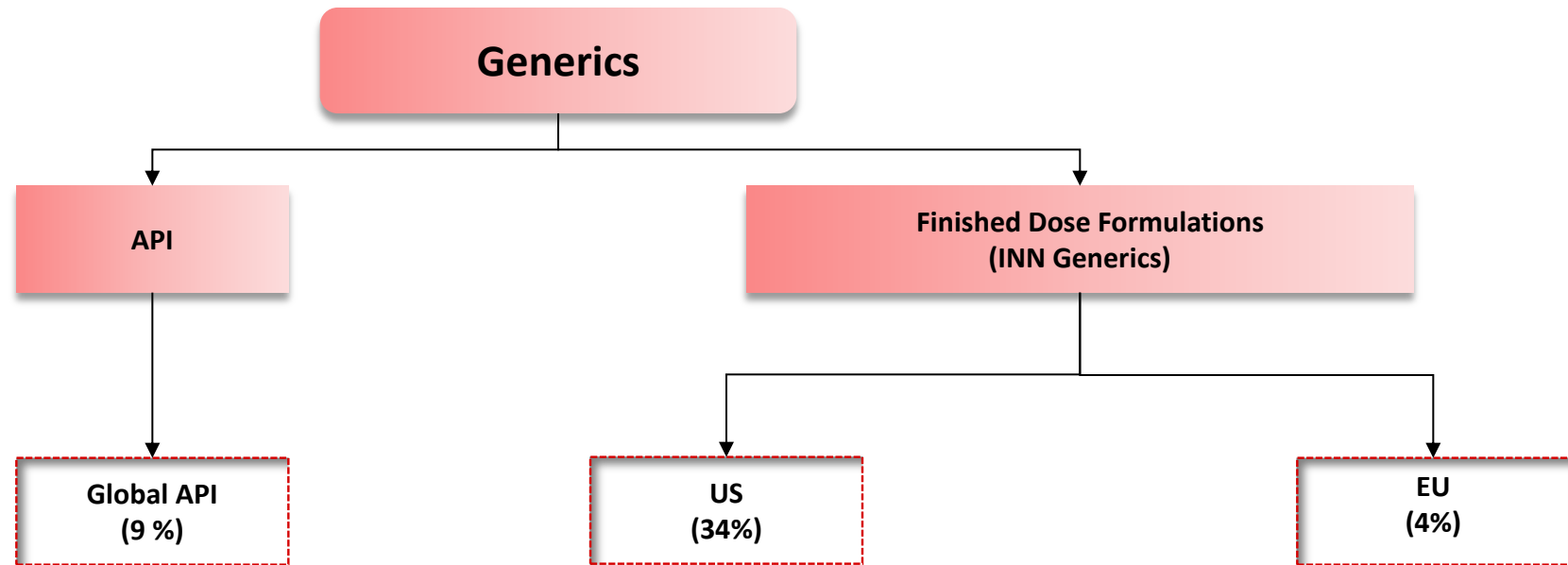
Latin America (7%)

- ❖ Brazil: To focus on Dermatology, Oncology & Respiratory
- ❖ Differentiated branded generic pipeline for key markets – Mexico, Venezuela, Peru

Central Eastern Europe (4%)

- ❖ Focus on CNS and Cardiology Segments
- ❖ A mix of in-licensing and in-house developed products targeted for launch

(%) – as a percentage to overall turnover of FY 2014



(%) – as a percentage to overall turnover of FY 2014



## GGL

### US (34 %)

- ❖ Focus on niche/limited competition products rather than me-too opportunities
- ❖ Portfolio of nearly 90 generic products
- ❖ Pipeline of at least 65 ANDAs with a high proportion of differentiated molecules

### Europe (4%)

- ❖ Pursuing multiple revenue streams – Dossier licensing, third party supplies and direct sales (own front end)
- ❖ Direct sales presence established in the UK
- ❖ Subsidiary established in Germany and the Netherlands

### API (9%)

- ❖ Focus has been to transition the business from ROW markets to Regulated markets
- ❖ Over 50 DMFs filed
- ❖ Launched several new products in last few years
- ❖ Market leadership in Perindopril, Lecanidipine, Telmisartan and Amiodarone

(%) – as a percentage to overall turnover of FY 2014

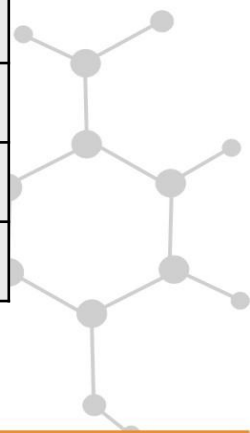




Niche / Focus Area	Pending Approval	Authorized to Distribute	Total Filings	Market Size (\$Mn)
<b>Immediate Release</b>	29	46	75	\$20,135
<b>Hormones</b>	13	11	24	\$2,203
<b>Modified Release</b>	5	8	13	\$ 1,028
<b>Dermatology</b>	8	22	30	\$ 1,361
<b>Complex Injectables</b>	1	0	1	\$ 200
<b>Immunosuppressants</b>	2	0	2	\$ 1011
<b>Controlled Substances</b>	0	4	4	\$ 916.2
<b>Oncology – Injectables</b>	6	0	6	\$2,884
<b>Total</b>	<b>64</b>	<b>91</b>	<b>155</b>	<b>\$29,738</b>
<b>Para IV filings</b>	<b>29</b>	<b>0</b>	<b>29</b>	<b>15988</b>

Source Data: IMS World Review Molecule Dec 2013

Pipeline as on April 2014



# Generics : FTF Opportunities



- ❖ Sole FTF opportunity for all products
- ❖ All below mentioned Para IV litigations settled except Azelaic Acid Gel

Product	Brand name	Plaintiff	Sales* (MAT Jun 2013)	Likely Launch date
Ezetimibe	Zetia	Schering Plough	USD 1.3 bn	Dec 2016
Azelaic Acid Gel 15 %	Finacea	Intendis/Bayer	USD 95 mn	
Hydrocortisone Butyrate Cream	Locoid Lipocream	Triax and Astellas	USD 38 mn	Launched Dec 2013
Fluticasone Lotion 0.005%	Cutivate	Nycomed	USD 49 mn	Launched Mar 2012
Atovaquone & Proguanil HCl	Malarone	Glaxosmithkline	USD 64 mn	Launched Sep'11



# Financials : Sales Breakup

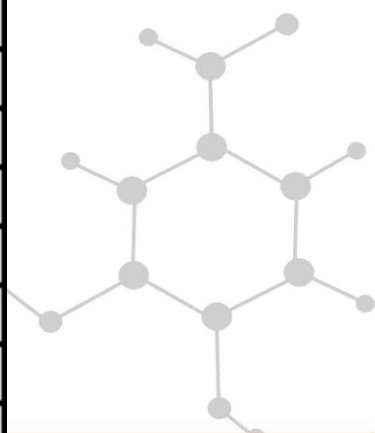


In INR mn	Q4: FY 14	Q4: FY 13	Growth %	FY 14	FY 13	Growth %
India	3,829.96	3,550.32	7.88%	15,104.89	13,095.79	15.34%
US	5,008.52	4,291.36	16.71%	20,270.24	16,887.40	20.03%
ROW	3,425.34	2,293.84	49.33%	9,869.01	8,493.00	16.20%
Europe	1,932.00	1,491.78	29.51%	5,060.70	3,723.68	35.91%
Latin America	1,061.74	792.73	33.93%	4,045.54	3,467.91	16.66%
API	1,530.63	938.58	63.08%	5,353.46	3,976.41	34.63%
<b>Total</b>	<b>16,788.19</b>	<b>13,358.61</b>	<b>25.67%</b>	<b>59,703.84</b>	<b>49,644.19</b>	<b>20.26%</b>
OutLicen. Rev	247.41	-		365.51	493.03	
<b>Consol Rev.</b>	<b>17,035.60</b>	<b>13,358.61</b>	<b>27.53%</b>	<b>60,069.35</b>	<b>50,137.22</b>	<b>19.81%</b>

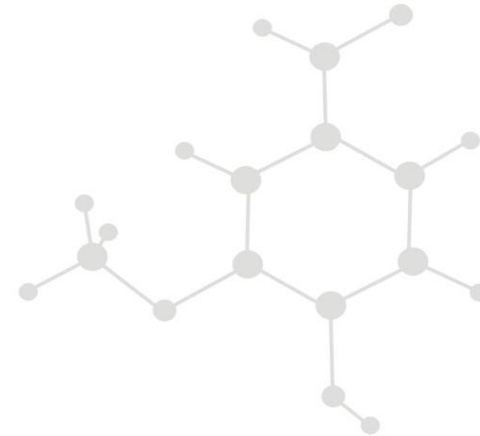
  

IN USD mn	Q4: FY 14	Q4: FY 13	Growth %	FY 14	FY 13	Growth %
India	63.83	59.17	8%	251.75	218.26	15%
US	83.48	71.52	17%	337.84	281.46	20%
ROW	57.09	38.23	49%	164.48	141.55	16%
Europe	32.20	24.86	30%	84.35	62.06	36%
Latin America	17.70	13.21	34%	67.43	57.80	17%
API	25.51	15.64	63%	89.22	66.27	35%
<b>Total</b>	<b>279.80</b>	<b>222.64</b>	<b>26%</b>	<b>995.06</b>	<b>827.40</b>	<b>20%</b>
OutLicen. Rev	4.12	-		6.09	8.22	-26%
<b>Consol Rev.</b>	<b>283.93</b>	<b>222.64</b>	<b>28%</b>	<b>1,001.16</b>	<b>835.62</b>	<b>20%</b>

*\*Conversation Rate taken is Rs.60/USD 1*



Thank You



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