



LEADING VERTICALLY INTEGRATED GENERIC PLAYER

JP Morgan Healthcare Conference January 10th, 2017



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Executive Summary



- Among the Top-5 listed pharmaceutical companies from India by sales⁽¹⁾ and market capitalization⁽²⁾
- 7th largest generic company by volume in the US; IMS TRx represents greater than 35% growth year over year (3)
- Broad portfolio of diversified dosage forms including Rx and OTC oral solids, liquids, injectables, and ophthalmics
- One of the highest rates of vertical integration, incorporating in-house API in 70% of total formulations, and greater than 90% of oral solids
- Global presence, with critical mass in US and EU markets
- Well entrenched US portfolio of 421⁽⁴⁾ filed ANDAs with 262⁽⁴⁾ final approvals
- Diversified manufacturing footprint spread across multiple regions and sites, offering extended capability and capacity





Emerged into a leading global generic player



	2006	2016
Revenue	US\$ 244 million	US\$ 2.1 billion
EBITDA margin (%)	11.1%	23.1%
Formulations contribution	16%	79%
US Formulations contribution	3%	44%
EU Formulations contribution	3%	22%
Manufacturing facilities	7 facilities including 3 formulation facilities	22 facilities including 11 formulation facilities
Employees	~4500	~16,000

The Journey So Far...



1992-2006

- Commencement of export of APIs
- Initial Public Offering ('95)
- Entered into formulation business ('02)

Pre-2006

API Focus

2006-08

- Acquired UK based Milpharm
- Acquired formulations facility in US
- Investment in building manufacturing, marketing & IPR capabilities

2010-12

- Commenced operations of Unit VII and Aurolife facilities
- First Controlled Substance product approved in US
- Entered into Peptide business

2006 - 2012

Formulation Focus

+
Establishing Global
Footprint

2013

- Commenced marketing specialty injectables in USA
- Building capabilities in Penem and Oncology

2014

- Acquired Western European commercial operations from Actavis
- Acquired Natrol

2015-17

- Focus on differentiated technology platforms
- Entered into Biosimilars and Vaccines

2013-2017

Consolidating
Presence in US & EU

+
Expanding Injectables
& Differentiated
Offerings

Core Strengths



Scale & Leadership

- Large manufacturing facilities inspected by leading regulatory bodies
- Well diversified product portfolio
- Large, World-class R&D Centers for formulations and active pharmaceutical ingredients
- Significant presence in the US and EU (~44% and ~22% of sales in FY16)

Operational Strengths

- High vertical integration
- Robust and highly scalable formulations
- Extensive product pipeline (~159 ANDAs pending final approval*)
- Capability and capacity for large volumes
- Diversity of dosage forms

Customer Centricity

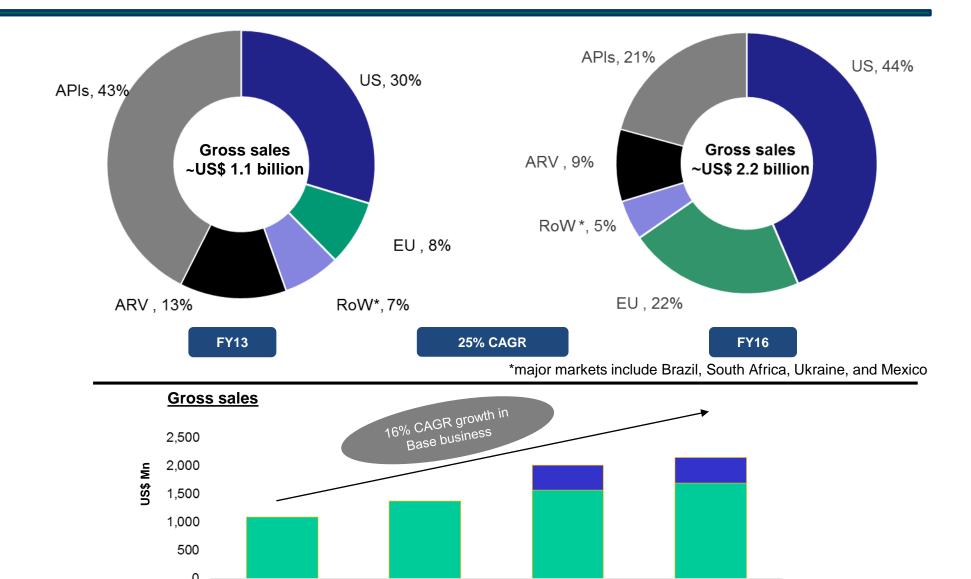
- Global marketing network in over 150 countries
- Customer centric approach and relationship oriented marketing
- Speed and effectiveness in execution

*As on 31 December 2016

Diversified Revenue Base & Strong Organic growth

FY13





FY15

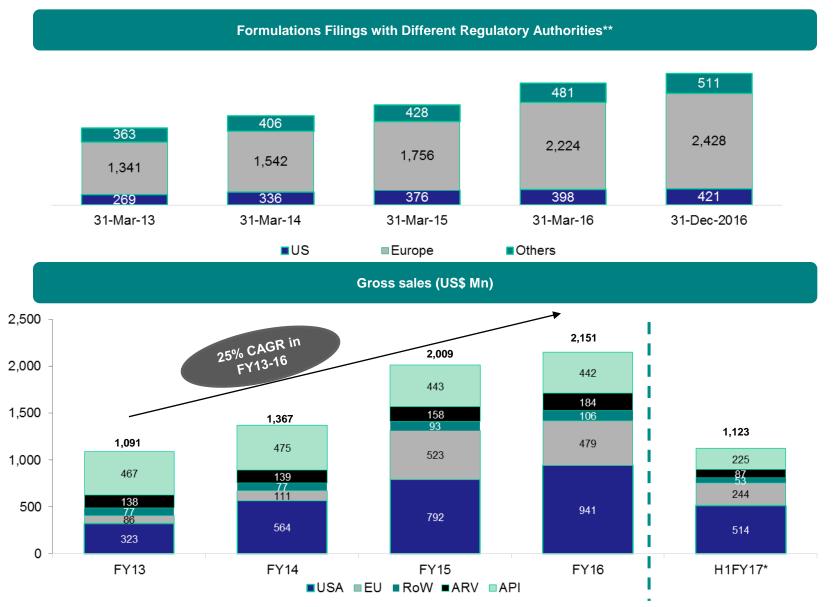
FY16

FY14

■Base business ■Acquisitions

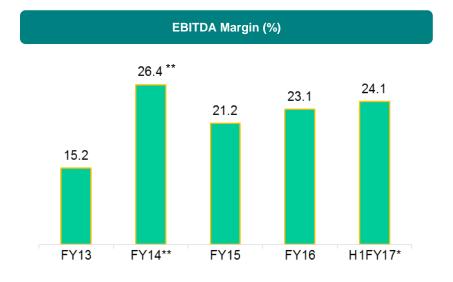
Operational Performance Trend

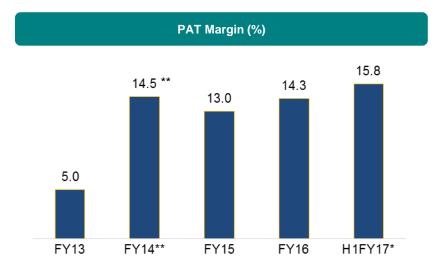


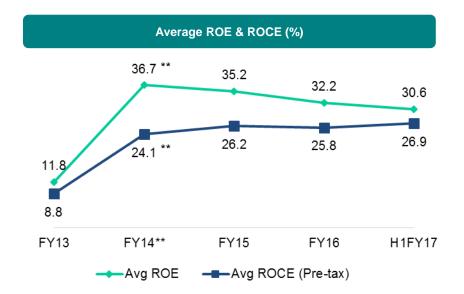


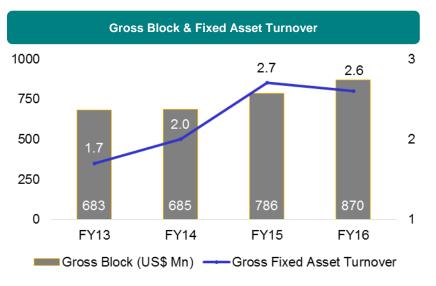
Financial Performance Trend











^{*} As per Indian Accounting Standards (Ind AS) introduced from Q1FY17

^{**}includes sales from limited competition product

Our Business Segments



<u>US</u>

- Ranked 7^{th*} Rx supplier as per IMS total prescriptions dispensed
- Differentiated pipeline with new launches including injectables, ophthalmics, speciality products and controlled substances
- Expanded presence in dietary supplement business through Natrol
- Manufacturing and R&D presence including Controlled substances

US - Focus on base business while capitalizing on the differentiated product portfolio EU – 2nd largest Gx market for the company

<u>EU</u>

- Among top 15** Gx companies by sales
- Focus markets are France, Germany, Netherlands, Spain, UK, Portugal and Italy
- Augment position through new product launches and extension to selected Eastern Europe markets

<u>API</u>

- Cost effective with vertical integration of around 70% of API requirement sourced internally
- One of the leading supplier of APIs from India - serves as a source for various Gx and branded drugs
- Strong regulatory capability with 214*** US DMF filings

API - The Vertically Integrated Business

ARV & Growth Markets

ARV – Institutional

- Focus on global tenders; availability across >100 countries
- Maintain competitiveness through development of new products
- First company to receive FDA approval for Dolutegravir 50 mg under PEPFAR program

Growth Markets

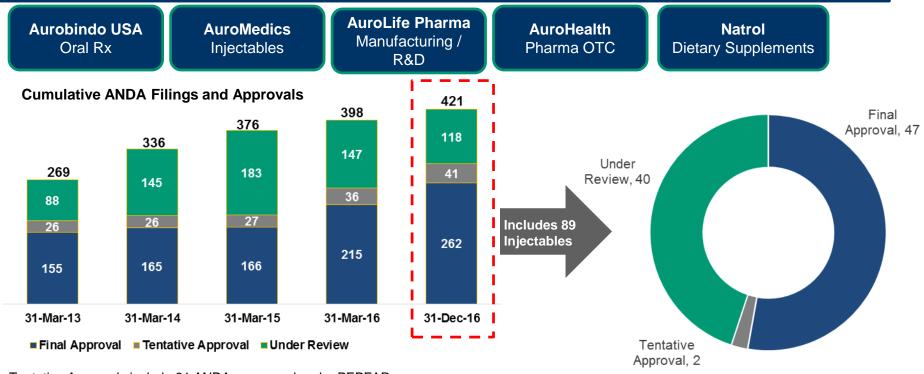
- Focus on major markets: Brazil, South Africa, Ukraine, and Mexico
- Expansion into select markets of Asia Pacific, Africa & Middle East

^{*}Source: IMS National Prescription Audit, Total Prescriptions Dispensed, Twelve months ending April 2016

^{**}Source: Market Reports, ***as on 31 Dec 2016

US Business Overview





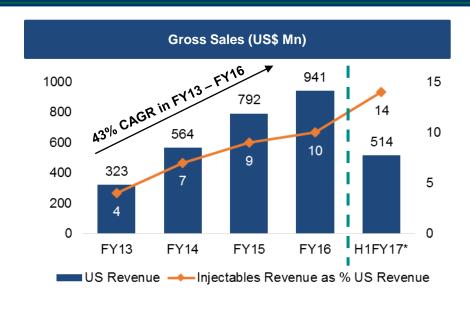
Tentative Approvals include 21 ANDAs approved under PEPFAR

Unit wise ANDA	Filings as on	31-December-2016

Site	Details	Final Approval	Tentative Approval	Under Review	Total
Unit III	Oral Formulations	99	16	10	125
Unit IV	Injectables & Ophthalmics	38	2	35	75
Unit VIB	Cephalosphorins Oral	11			11
Unit VII (SEZ)	Oral Formulations	79	23	56	158
Unit X	Oral Formulations			2	2
Unit XII	Penicillin Oral & Injectables	19		1	20
Aurolife USA	Oral Formulations	16		10	26
AuroNext	Penem Injectables			4	4
Total		262	41	118	421

US: Expanding Portfolio Mix Towards Differentiated Products

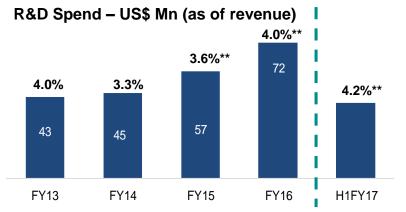




Growth Drivers in the next 3-4 years

- Broadening portfolio with more balance through accelerated growth in injectable, OTC, and higher complexity products
- Increasing collaboration across the global customer base
- Operational efficiencies and cost leadership in API and formulation manufacturing, supply chain planning and distribution

Focus on building differentiated product portfolio



Significant investment in research initiatives (new labs, experienced scientists)

Future pipeline will include Oncology Products, Hormones, Depot injections, Peptides, Inhalers, Patches, Films, Vaccines, and Biosimilars, and Differentiated Oral delivery Products

^{*}As per Indian Accounting Standards (Ind AS) introduced from Q1FY17

^{**} calculated on revenues Ex acquired Actavis business

Enhanced Research & Development Capabilities



5 R&D centers in Hyderabad, India

- Focused on difficult to develop API, niche oral, sterile and specialty injectable
- Concentrating on wide range of Oncology, Hormonal products, Penems, Enzymes, Biocatalysts, vaccines and Peptides
- Developing diverse pipeline of biosimilars in Oncology and Immunology. CHO-GS based cell lines with productivity of ~ 4.0 g/L
- Developing various Biosimilar products and vaccines.
- In the preventive healthcare area, working on various OTC and Dietary Supplement products
- Dedicated solid state characterization lab involving powder characterization capabilities
- New chemical technology has been adopted to improve the productivity and efficiency of the existing processes
- Two of the R&D centres has been audited by USFDA

1 R&D center in Dayton, New Jersey

- Developing microsphere technology based specialty injection products.
- Concentrating on development of various niche oral formulation and controlled substances
- Focus on developing tamper/abuse-resistant technology based products

1 R&D center in Raleigh, North Carolina

- Developing various respiratory and nasal products, including DPIs and MDIs
- Dermal Delivery portfolio including transdermal and topical products





EU Business Overview



France

Germany

Netherlands

Spain

UK

Portugal

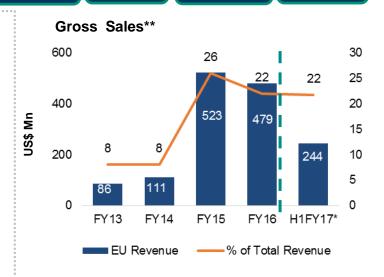
Italy Romania

Belgium

- India's Leading Gx company with strong footprint in Europe
 - Operations in 9 countries with full fledged sales force & support infrastructure
 - Significant presence and position in Top 5 EU markets led by France & Germany
 - > Commercialized over 450 INNs across 9 countries of operation
- Presence across Gx, TGx, BGx and Hx segment with established commercial and hospital sales infrastructure
- Expanded analytical testing facilities for sterile and non-sterile products in Malta
- Pipeline of over 200 products under development

Growth Drivers in the next 3-4 years

- Consolidate presence & improve position among Top 10 players in each market
- Expanding into new geographies viz. Poland and Czech Republic
- Portfolio Expansion through targeted Day 1 launches; Orals, Hormones & Penems, Oncology Products, Niche Injectables, Low volume Injectables
- Lower generics penetration in Italy, Spain, Portugal & France offer future growth potential as share of generics improves



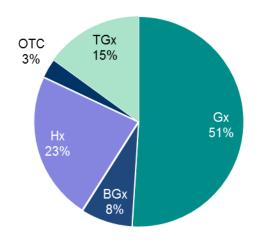
APL's position in Top 5 EU countries

Country	Market size (US\$ Bn)	APL Presence	APL's position
Germany	41	>	8 th
UK	28	\	11 th
Italy	25	\	10 th
France	31	√	6 th
Spain	19	✓	9 th

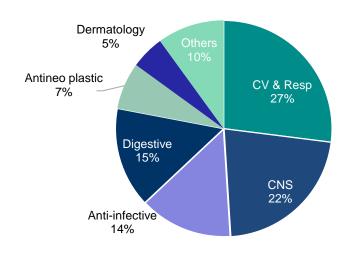
EU: Portfolio Mix Across Channels



Sales split by Channel



Sales split by Therapeutic Profile



Channels	Gx	BGx	ОТС	Hx	TGx
Geographies	All 9 countries	7 countries	6 Countries (DE, ES, FR, NL, PT, IT)	All 9 countries	Germany, Spain & Netherlands
# of Products	761 (primarily tablets & capsules)	34	74 (branded and generic)	343 (predominantly injectables)	765 (including Gx products)
Other Highlights	Amongst top 10 in most markets	Includes leading brands such as Neotigason, Floxapen, Bezalip among others	Tool to support customer acquisition	Focus on high value areas including oncology	Tender based business

ARV Business Overview

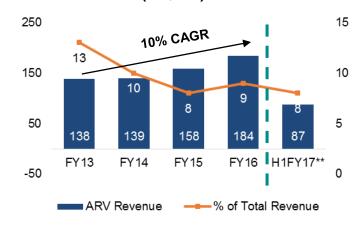


- Focus on global tenders floated by Multi-Lateral Organizations like Global Fund, USAID/PEPFAR and Country specific MOH tenders; currently caters to 2.2 million HIV+ patients
- Well integrated supply chain management services and logistics for ARV supplies (29 products) catering to over 100 countries
- Filed over 1,100 ARV dossiers for registrations across the globe

Growth Driver in the next 3-4 years - Dolutegravir (DTG)

- Aurobindo is the first generic company to sign license with ViiV Healthcare for the next generation Integrase Inhibitor – DTG
 - Received the USFDA approval for DTG 50mg under the PEPFAR program
 - WHO announced this drug as a 1st line reserve drug in its 2015 HIV treatment guidelines
 - Play a collaborative role in upgrading millions of patients to the latest "best-in-class" ARV drug
- Filed an ANDA application for a Triple drug combination containing DTG
- Market size is expected to be US\$ 500m in 2018 for DTG and combinations @50% conversion*

Gross Sales (US\$ Mn)



Products

Efavirenz + Lamivudine + Tenofovir

Zidovudine + Lamivudine + Nevirapine Tabs

Lopinavir + Ritonavir Tabs

Lamivudine + Zidovudine Tabs

Abacavir Sulfate Tabs

Efavirenz + Emtricitabine + Tenofovir Tabs

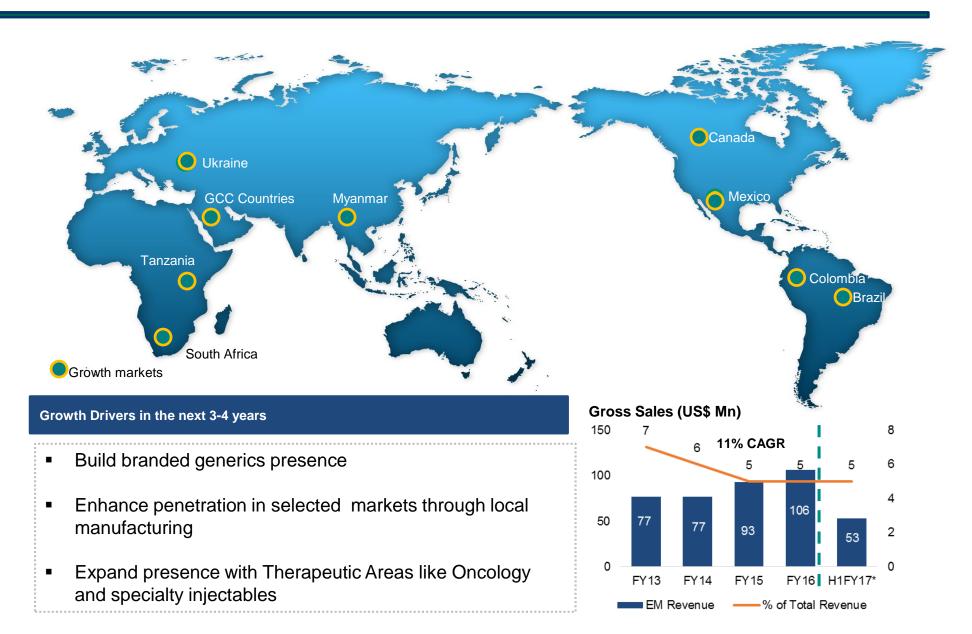
Lamivudine Tabs

^{**}As per Indian Accounting Standards (Ind AS) introduced from Q1FY17

^{*}Source: as per HSBC market report

Growth Markets Business Overview



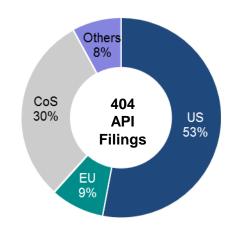


The Base Business: API

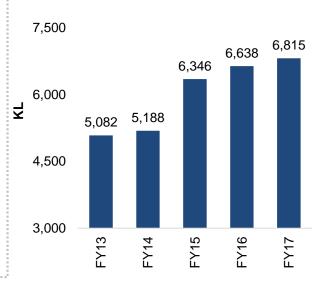


- API business continue to focus on high value, specialty, small/midsize products with a limited competition
- Ensures quality & Reliability of supplies and ability to command cost efficiencies as well as economies of scale
- Focus on continuous improvement of manufacturing process to meet cost and environmental challenges
- Continue to have sustained growth in more advanced regulated markets (EU, Japan & USA)
- API facilities meet advanced market requirements like USFDA, UK MHRA, EU, Japan PMDA, Mexico COFEPRIS, Brazil-ANVISA, Korea FDA etc.
- Manufacturing reaction volumes has been increased over 30% in last 3 years and would further grow in same proportions.
- Additional processing capacities / capabilities would be created in Oncology and allied areas.
- Conventional manufacturing process are migrated into environmentally friendly process and products based on green chemistry.

Strong Regulatory Capability*



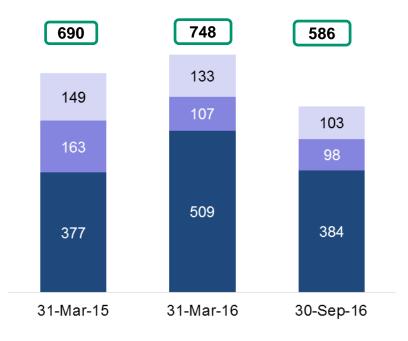
Significant increase in reaction volumes



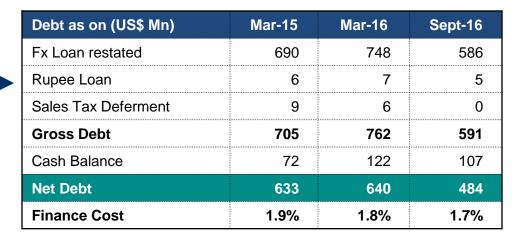
Debt Profile



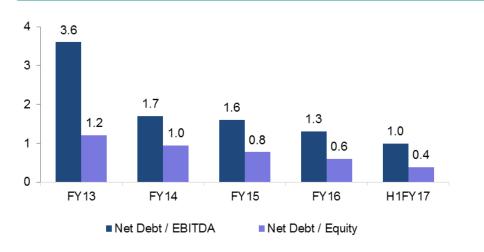
Fx Loan US\$ Mn



- Other Term Loans (Subsidiaries) &Unsecured Loans
- ECB APL
- Working Capital



Net Debt / EBITDA & Net Debt / Equity



Initiatives to Support Sustainable Future Growth



Short Term

Focus on strengthening the Portfolio, Capability and Capacity as Growth Drivers

New facilities and distribution center

- 3 manufacturing facilities in Naidupet, Vizag and Jedcherla, all in India.
- New automated distribution center in the US
- Tripling production capacity of controlled substances in US

R&D centers

- Increase control substance filings to at least 7 per year for future growth
- Fully operational R&D center in North Carolina; filings in inhalation and topical therapies

Peptides

 4 DMF filings upto FY17. Plans to file upto 15 DMFs. Commercial supplies to increase considerably

ARV

• Full impact of Dolutegravir and its combination

Oncology and Hormones

■ File around 30+ products

OTC

Strengthening the US OTC portfolio

US Branded Products Portfolio

 Build a portfolio of 505b2 products in select therapeutic areas and initiate development work

Medium Term

<u>Commercial Drivers: Focus on launches</u> Peptides

Additional product launches

Oncology and Hormones

- 20+ more products to be filed
- Product launches and commercialization starts April '19

Microspheres (Depot Injections)

 All 4 products which are under development will be filed and commercialization begins

<u>Inhalers</u>

- Development work to commence for 4 more products
- First set of product launches and commercialization starts

Vaccines

 2019 - Commercial launch of Bx of pneumococcal conjugate vaccine with an addressable market size of US\$ 6 Bn.

Increased Filing for Sustainable Future Growth Biosimilars

- Commence of manufacturing facility
- Start filing Biosimilars globally
- Commercialization to begin for EMs from FY20

US Branded Products - Filing

- Filing 1-2 505b2 NDAs per year
- Accelerate in-licensing differentiated products and technologies
- Diversify the portfolio target specific patient population to meet unmet medical needs

Long Term

Focus on increasing and sustaining the number of filings on and launches of high-value products

Inhalers

· Focus on product launches

Vaccines

· Strengthen the portfolio

Biosimilars

 Commercialization to begin for Advanced markets

Branded Products - Launches

- · Launch 1-2 branded product per year
- Secure exclusivity

Branded Products - Filings

• Increase the number filings

OTC Brands

• Target 2-3 launches per year



Thank You



For updates and specific queries, please visit our website **www. aurobindo.com**

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