



# Cipla 2.0: Ready for the next wave of growth

Morgan Stanley's 18<sup>th</sup> Annual India Summit

Presented by: Umang Vohra

Date: 2 June 2016

## Disclaimer

*Except for the historical information contained herein, statements in this presentation and the subsequent discussions may constitute "forward-looking statements". These forward-looking statements involve a number of risks, uncertainties and other factors that could cause actual results to differ materially from those suggested by the forward-looking statements. These risks and uncertainties include, but are not limited to our ability to successfully implement our strategy, our growth and expansion plans, our ability to obtain regulatory approvals, technological changes, cash flow projections, our exposure to market risks as well as other risks. Cipla Limited does not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date thereof.*

**\* DISCLAIMER:** Information relating to any medical products or medical devices contained herein is provided by Cipla for general information purposes only. Information on any of the medical products or medical devices may vary from country-to-country. A reference to a medical product or medical device does not imply that such medical product or medical device is available in your country. The commercial availability of the medical products or medical devices listed herein in each individual country in Europe is dependent on the validity and status of existing patents and/or marketing authorisations related to each. An independent inquiry regarding the availability of each medical product or medical device should be made for each individual country.

The Product information contained herein is not intended to provide complete medical information, and is not intended to be used as an alternative to consulting with qualified doctors or health care professionals.

Nothing contained herein should be construed as the giving of advice or the making of a recommendation and it should not be relied on as the basis for any decision or action. It is important to only rely on the advice of a health care professional.

# Established in 1935, Cipla is a pioneer in the Indian pharmaceutical industry



Today Cipla is a ~\$2bn revenue company with operations in over 100 countries

## 80 YEARS OF CARING

3rd – India Pharma Market Rank

3rd – South Africa Generics Pharma Market Rank

Top 5 in several emerging markets

Top 15 in United States



35+ Manufacturing Facilities



50+ Dosage Forms



1500+ Products



**World's largest** inhalation portfolio



**1 in 3**

HIV patients take Cipla ARVs



**Partner of Choice**

for developed markets e.g. G. Nexium, Pulmicort, Dymista, G. Lexapro



## ***Leading healthcare provider for the emerging world***

Leadership position in India and South Africa; Established platform in Africa and SE Asia

## ***Strong product pipeline backed up by innovation and strategic alliances***

Focused R&D and filing efforts for developed markets in Respiratory, Oncology;  
Alliances formed with global players to strengthen portfolio and market coverage

## ***World class manufacturing infrastructure and quality culture***

35+ accredited plants in India, Africa and Middle East manufacturing 50+ dosage forms;  
Successful track record of USFDA inspections over the past 15 years

## ***Unmatched capabilities in Respiratory***

World's largest inhalation portfolio with products available in over 100 countries;  
Vertically integrated manufacturing process from API to devices

## ***Profitable global access business based on cost leadership and therapy expertise***

Strong passion to bring access to patients in Africa (and elsewhere) for HIV,  
Immunology etc. – ahead of others and profitably

# Operating in the right mix of developed and emerging markets

<b>Leadership Position</b>	<b>India</b>	<ul style="list-style-type: none"> <li>■ #3 player by value and by volume<sup>1</sup> ; #1 player in Respiratory, Urology &amp; Paediatrics<sup>1</sup></li> <li>■ 22 brands in Top 300 brands in India Pharma Market; Rank 2<sup>nd</sup> in prescription share</li> <li>■ Continued focus on In-licensing opportunities with global majors</li> </ul>
	<b>South Africa</b>	<ul style="list-style-type: none"> <li>■ #3 generics player with market share of 5%+; #1 player in Respiratory<sup>1</sup></li> <li>■ Establishing status of “Partner of Choice” through alliances such as Teva, SII</li> </ul>
	<b>Other EM</b>	<ul style="list-style-type: none"> <li>■ Front end presence established in 20+ markets with leadership position in markets such as Sri Lanka, Yemen, Kenya and Uganda</li> </ul>
<b>Strategic Position for Growth</b>	<b>USA</b>	<ul style="list-style-type: none"> <li>■ Commercialising 70+ products</li> <li>■ Cipla ranks among the top 3 for 19 of our own sold products</li> <li>■ 100% acquisition of InvaGen Pharmaceuticals Inc. and Exelan Pharmaceuticals Inc.</li> </ul>
	<b>EU</b>	<ul style="list-style-type: none"> <li>■ Launched key Respiratory products (Salmeterol Fluticasone and Mometasone) in select European markets – will continue to build volume market share</li> </ul>
<b>Large partner Markets</b>		<ul style="list-style-type: none"> <li>■ Strong partner relationships established across the globe such as in Australia/New Zealand, Russia/CIS, LATAM</li> </ul>

<sup>1</sup>Source: IMS data 12M ending March'15

## Strong Product Development & Filing Capabilities

- Market leading Respiratory and HIV portfolio with continuous R&D underway
- 200+ drugs under development – Top 50 projects address a market size based on innovator sales of ~\$30bn
- Track record of successful development for partners

## Vibrant Emerging Markets Platform

- Recognized leadership position in India and South Africa, witnessing strong growth trends
- Leverage front-end presence in 20+ globally diversified markets – with leadership position in many

## Upcoming North America franchise

- Aim to grow from current 8% to 20-25% of overall sales by 2020 - through organic and inorganic routes
- Successful transition from pure B2B to Direct+B2B model in the US, backed by our capabilities in Respiratory, HIV, Oncology
- Building Specialty portfolio

## Impeccable Manufacturing capability and Quality focus

- 35+ internationally accredited plants having global scale across different dosage forms
- Best-in-class quality record with successful audit history with USFDA, UK-MHRA etc. over the past 15 years

# Innovation has been an integral part of Cipla's growth story



## Cipla's 30+ World's first products – with a focus on Inhalation Therapies



Iron Chelator for Thalassaemia



3-in-1 Inhaler for COPD



Transparent DPI and single-action, multi dose DPI



3-in-1 cocktails for HIV/AIDS – Triumune



First combination of in a Breath Actuated pMDI

Static-free spacer with valve mechanism

Combination of an antihistamine and an intranasal steroid (INCS) for allergic rhinitis

Tiotropium in pMDI

Generic Pirfenidone, the 1st and only approved therapy for IPF

Generic Sildenafil for PAH

## Complex & differentiated products launched and commercialized



Onco Lyo Inj (Gemcitabine)



Ophthalmic (Travaprost)



Respule (Albuterol)



Nasal spray (Dymista)



Bilayer tablet (T+A)



Injection (Argatroban)



Soft Gel (Isotretinoin)



Oral Suspension (Amox/Clav)



Hydrophilic Matrix (Metformin tab)



Tablet (Alendronate)



Syrup (Zidovudine)



Capsule (Anagrelide, Rivastigmine)



Molten Mass Encap-sulaion (Vancomycin)



Particulate Coating (Kcl caps)



Controlled Substance (Cet/Pseudo)



Hormonal Product (Levonorgstrel)

Cipla has a rich history of R&D and manufacturing partnership with global players for blockbuster products such as: G.Nexium (USA), Dymista Nasal Spray (EU, USA), Pulmicort Respules, G. Lexapro (USA) etc.



# Focus on several innovative platform technologies for the future pipeline



Nanotechnology	Liposome Injections	Inhalation technology	Microsphere Injections	Sprinkles
 <p data-bbox="112 592 295 625">Nanotechnology</p> <p data-bbox="73 658 369 719">Paclitaxel, Fenofibrate, Siromilus</p>	 <p data-bbox="517 592 639 625">Liposomal</p> <p data-bbox="566 658 741 719">Doxorubicin, Amphotericin</p>	 <p data-bbox="832 592 1070 625">Inhalation technology</p> <p data-bbox="838 658 1118 719">MDIs and Dry Powder Inhaler</p>	 <p data-bbox="1193 592 1402 625">Microencapsulates</p> <p data-bbox="1199 691 1489 719">Leuprolide, Triptorelin</p>	 <p data-bbox="1647 592 1750 625">Sprinkles</p> <p data-bbox="1669 658 1862 719">Paediatric care products</p>

### Sustained release formulations

- Core/Coat technology
- Hydrophilic Matrix
- OROS Technology
- MUPS Technology

### Stemcells

- Strategic alliance with Stempeutics which produces stem cell based medicinal products

### Characterization Science including Biosimilars

- 4 disruptive in-house Biosimilars & 1 insulin product currently under development
- Aim to focus on access and affordability

- 1 Over 100 patents granted including respiratory
- 2 Over 1500 dedicated and talented scientists

Patent filing includes drug substances & products, platform technologies, polymorphs and crystals & medical devices

Developing new drug delivery systems with an aim to improve compliance and convenience

Developing proprietary medical devices for respiratory medicines



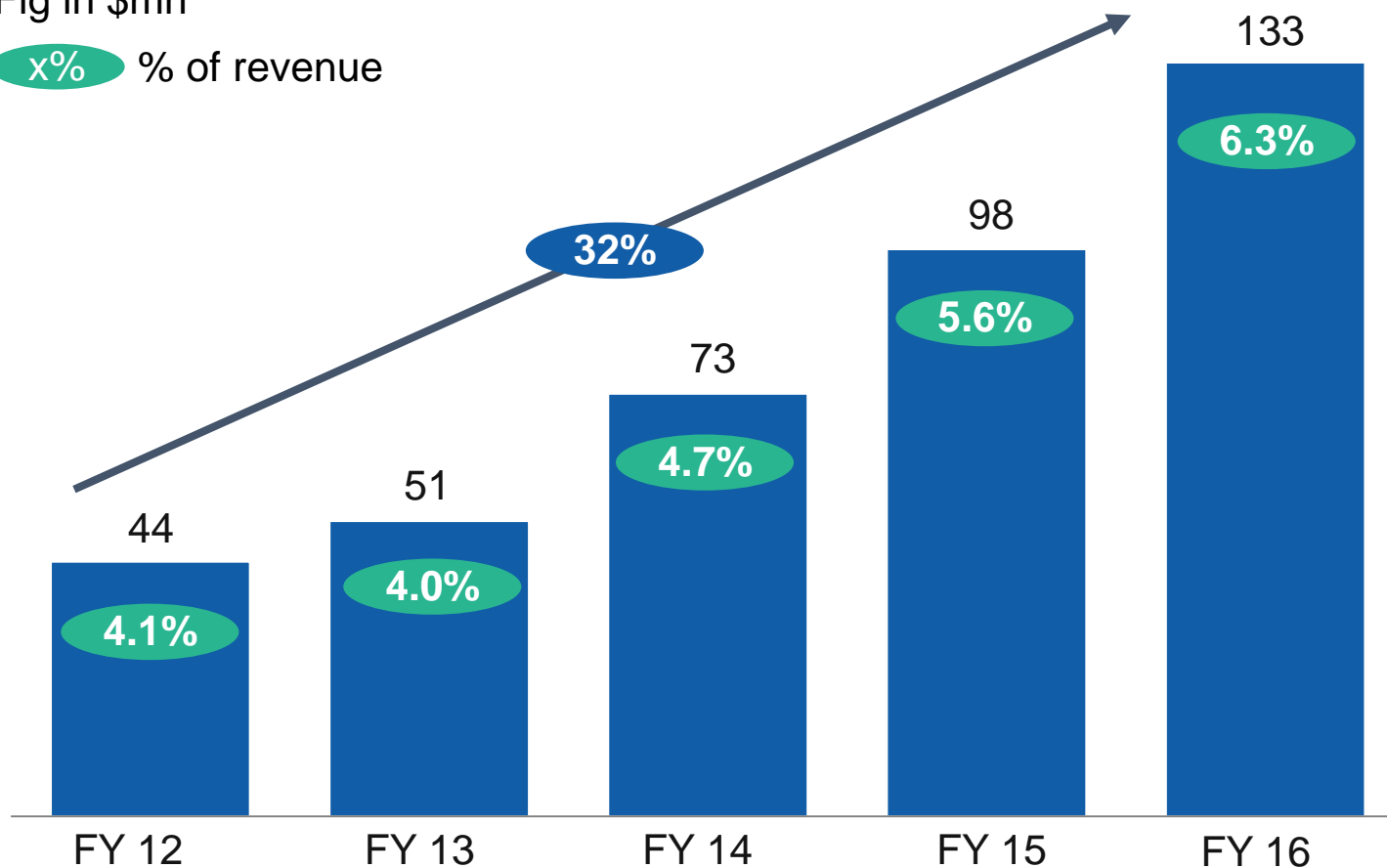
1. Strong Product Development & Filing Capabilities

R&D spend increased from ~4.1% of revenue in 2011-12 to 6.3% of revenue for FY 2015-16



Fig in \$mn

x% % of revenue



INR/\$=65

1. Strong Product Development & Filing Capabilities

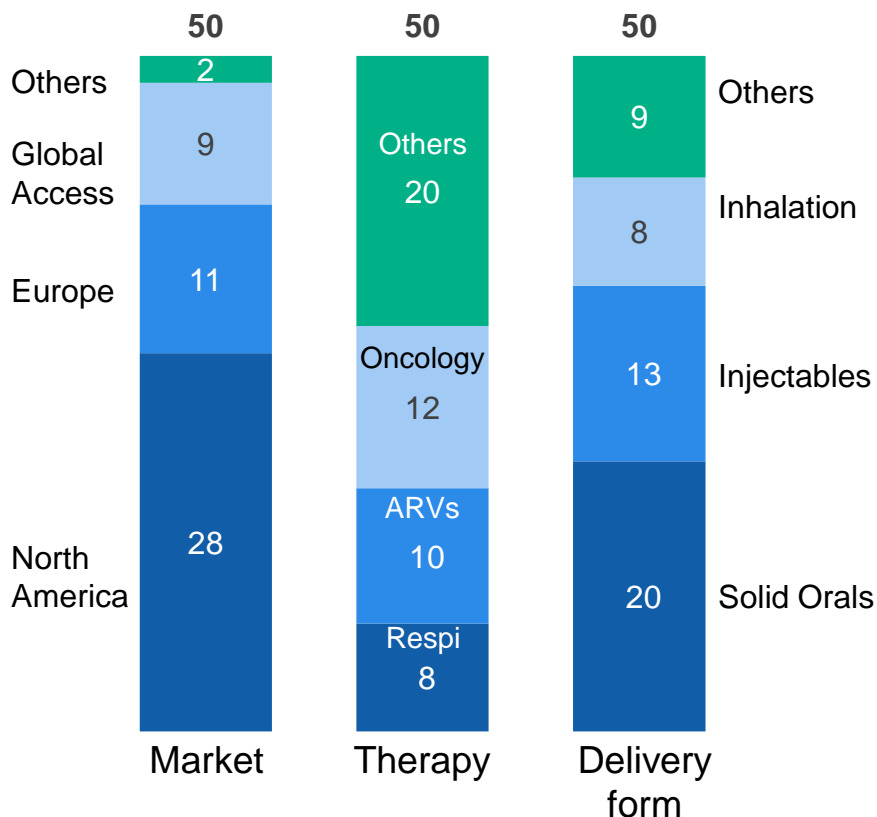
**Over the next 3 years filings are targeted in areas of limited competition**



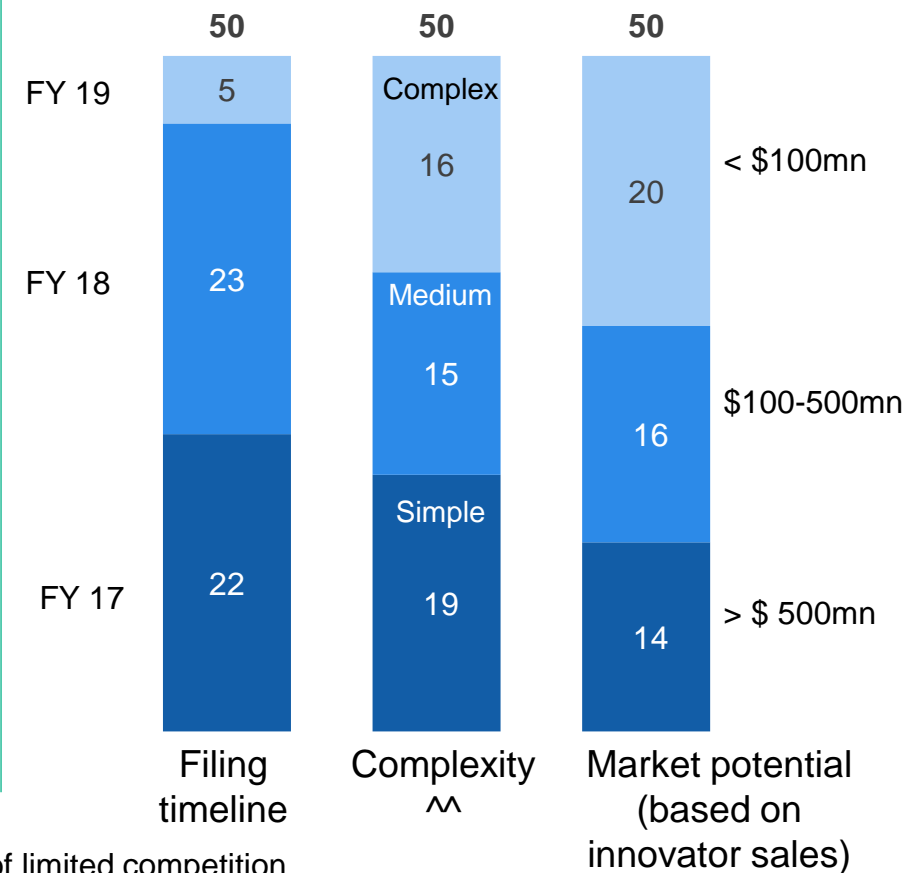
**>200 development projects underway: Top 50 projects address a market size based on innovator sales of ~\$30bn**

**Filing intensity ramping up with a focus on complex products; over 14 developments target products with market potential >\$500mn**

Split of Top 50 R&D projects by market, therapy and delivery form



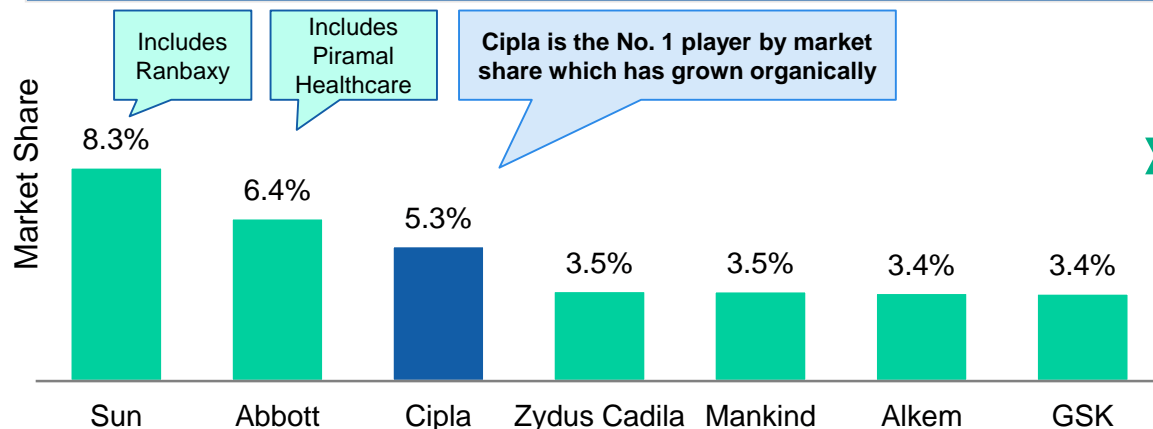
Split of Top 50 R&D projects by filing timelines, complexity and market potential



(^^) Medium and Complex product developments will be in areas of limited competition

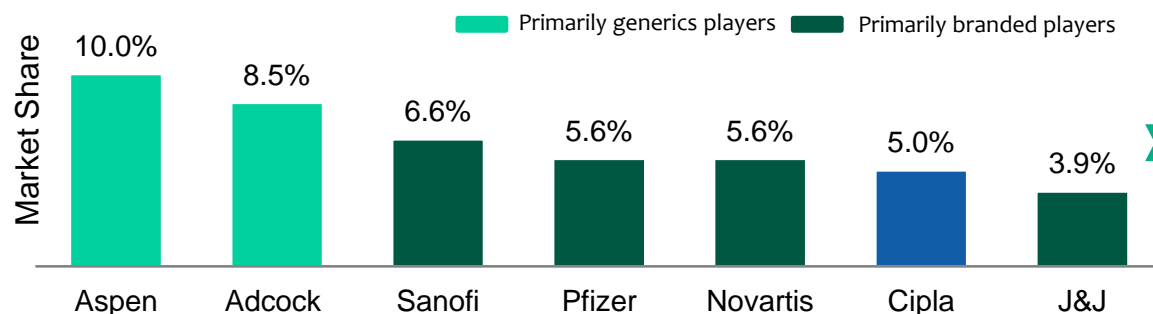
# Stronghold in Emerging Markets – India, S. Africa and others

## 3<sup>rd</sup> largest player in Indian Pharmaceutical Market



- #1 player in Respiratory, Urology & Paediatrics; Amongst Top 5 players in Cardiology and Ophthalmology
- Market share of 5.27% in FY 2014-15<sup>1</sup>
- 22 brands in Top 300 brands in India Pharma Market
- Rank 2<sup>nd</sup> in prescription share at Physicians; 85% of Indian Drs. prescribe at least one Cipla product

## #1 Indian player and 3<sup>rd</sup> largest generic player in South Africa Pharmaceutical Market



- #1 player in Respiratory; Amongst Top 5 players in CNS and Oncology
- Market share of 5% private market in FY 2014-15<sup>1</sup>
- Over 70% business focused on private market across pharma, nutrition, vet etc.
- “Partner of Choice” for Teva, SII etc.

## 20+ Front-end markets established across Africa, S.E. Asia and Middle East

- #1 player in Sri Lanka and established presence in Malaysia, Vietnam, Philippines, Nepal, Myanmar and Pakistan
- #1 player in Yemen and significant presence in Middle East countries like Oman, UAE, Iraq
- #1 supplier of ARVs to Uganda Ministry of Health and reputed player in countries such as Kenya, Tanzania
- Recently established direct presence in North African countries of Morocco and Algeria

<sup>1</sup>Source: IMS data 12M ending March'15

## Levers in place to accelerate scale up of North America business

### Continue R&D Focus

- Maintain momentum of filing >15 ANDAs every year
- Target 7+ limited competition own launches in FY 2017
- 3 limited competition partner launches

### Fructify inorganic growth

- Successfully launch Invagen pipeline and realize synergies
- 30 pipeline products pending approval; additional ~20 products under development
- 5 first to file opportunities that represent a market potential of ~\$8bn

**Aim to grow North America business from current 8% to 20-25% of overall sales by 2020**

### Leverage key partner relationships

- Continue to build on successful partnerships for launch of first-to-market and differentiated generics e.g. Esomeprazole, Dymista Nasal Spray, Budesonide Respules, Escitalopram, Finasteride etc.

### Build Specialty Portfolio

- Launch Cipla's own differentiated respiratory and oncology pipeline in near future
- Enhance R&D focus on building specialty portfolio

## Global quality and scale across different dosage forms



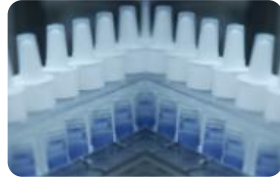
**Tabs and Caps –  
23 Billion units**



**Aerosols pMDI –  
75 Million units**



**Nasal Sprays –  
30 Million units**



**Liquid Injection –  
10 Million units**



**Respules –  
400 Million units**



**Lyo. Injection –  
5 Million units**



**3 Pc Eye drops –  
20 Million units**



**FFS Eye drops –  
60 Million units**



**UNIMS –  
60 Million units**



**Oral Liquids –  
35 Million units**



**Creams –  
65 Million units**



**Bulk Drugs –  
950 Tons**



### Regulatory agencies' approvals (*non-exhaustive*)

Sites ( <i>non-exhaustive</i> )	USFDA	MHRA - UK	WHO – Geneva	TGA - Australia	MCC – S. Africa	Japan	Brazil - Anvisa
Goa, India	✓ (5)	✓ (5)	✓	✓	✓	✓	✓
Patalganga, India	✓ (3)	✓ (1)	✓	✓	✓	✓	✓
Kurkumbh, India	✓ (2)	✓ (1)	✓	✓	✓	✓	✓
Indore, India	✓ (3)	✓ (2)	✓	✓	✓	✓	✓
Baddi, India			✓	✓	✓		

(##) Indicates number of inspections by the regulatory authority in the past 5 years

# Well-defined roadmap to leverage capabilities and achieve multi-fold growth by 2020

## 1 Strong Product Development & Filing Capabilities

### Continue to invest in pipeline

- Ensure on-track progress for development and filing timelines of top 50 projects
- Accelerate execution plan for in-house biologics – clinical trial for Bevacizumab, proof-of-concept for 2-3 other products
- Target R&D spend to continue to increase, up to ~8% of sales

## 2 Vibrant Emerging Markets Platform

### Enhance leadership position in key Emerging Markets

- India growth plan to target above market rate of growth, with focus on in-licensing and new product introductions
- Retain momentum in South Africa and continue to focus on building private market share
- Retain leadership in key front-ends, such as Yemen, Sri Lanka, North Africa and Iran, with focus on respiratory, oncology and global access segments

## 3 Upcoming North America franchise

### Accelerate scale-up of US business

- Enhance scale of US DTM play through seamless integration of InvaGen and Exelan businesses
  - Launch 5-7 products in InvaGen pipeline
  - Launch 8-10 products from Cipla pipeline, including some in limited-competition areas
  - Target filing of 20-25 ANDAs in 2016-17, including some respiratory and oncology filings
- Continue to build on successful partnerships for launch of first-to-market and differentiated generics

## 4 Impeccable Manufacturing capability and Quality focus

### Maintain quality track record

- Maintain best-in-class quality record with key regulatory entities

## Contact Details

### Registered Office :

Cipla Limited, Cipla House,  
Peninsula Business Park,  
Ganpatrao Kadam Marg, Lower  
Parel, Mumbai 400 013

For any general queries, Reach us  
at [contactus@cipla.com](mailto:contactus@cipla.com)

For more information please visit  
[www.cipla.com](http://www.cipla.com)

