

# ZIM LABORATORIES LIMITED INVESTOR PRESENTATION

December 2018

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# **Discussion Summary**



- Business Overview
- Robust Drug Delivery Platforms
- Oral Thin Film Future Game Changer
- Business Strategy & Outlook
- Q2 & H1 FY19 Results Update
- Financial Overview

# ZIM is a Specialty Pharma R&D Company Focused on Innovative Drug Delivery Solutions





**ZIM** leverages on range of **technology based novel drug delivery solutions** and **non-infringing proprietary manufacturing processes** to develop, manufacture and supply wide range of **innovative and differentiated** generic pharmaceutical products

Strong R&D expertise in complex generics and NDDS
(Novel Drug Delivery Solutions)

Robust technology capable to manufacture wide range of therapy-agnostic products

Consistent and high quality supply of complex drugs, zero product failure / recall

Focused on improving convenience and adherence of drug treatment

## ZIM Has a Critical Role to Play in the Global Pharma Landscape





# Rising Importance of NDDS in the Global Pharma Industry

- Rising competition in generics space is driving the focus on differentiated products, complex generics and specialty pharma to enhance competitiveness and increase profitability
- There is an increasing preference for incremental innovation through NDDS over novel drug discovery
- NDDS focuses on innovative drug-device combinations, targeted and controlled drug delivery, convenient routes of drug administration
- NDDS leads to higher drug efficacy, lower dosage frequency, improved bio-availability, minimisation of side effects and increased patient adherence
- The global NDDS market was USD 165.4 Bn in 2015 and is expected to reach USD 202.5 Bn by 2022



# ZIM Bridges the Technology Gap for Manufacturing Complex Generics

- Acts as a single window for multiple proprietary technology platforms offering innovative products
- Specialises in complex generic formulations and complex routes of drug delivery
- · Provides wide range of dosage forms
- Established development partner for various local players in Pharmerging and ROW markets
- Demonstrated proof of concept by selling its own branded formulations across Pharmerging and ROW markets based on indigenously developed technologies

## **Strategic R&D Partner to Global Pharma Companies**



## Robust Therapy-Agnostic Technology Platforms

- Modified Drug Release
- Solubility & Stability Enhancement
- Taste Masking
- Dosage Transformation

Wide-Range of Differentiated Product Offerings

- Pre-formulation Intermediates (PFI) (significant value-addition on APIs)
  - Pellets
  - DC Granules
  - Taste Masked Granules
- Formulations
  - o ODS / OTF
  - o Tablets
  - **Capsules**
  - Dry Syrups

Flexible Customer Engagements

- Product Development & Supply
- Co-Development (MNC Pharma)
- Out-Licensing (in case of ODS)
- Provide support in Registrations (Preparing Dossiers) & Marketing

**Customers / Partners** 

- Exports (Pharmerging & ROW markets)
  - Local manufacturers
  - **Distributors**
  - Marketing agents
- Domestic
  - Hospitals
  - Govt. Institutions

Trusted Partner for Differentiated Products and Complex Generics based on NDDS Technology

# **Wide Range of Therapy-Agnostic Products**



PFI: Pellets, DC Granules, Taste Masked Granules

Formulations: ODS / OTF, Tablets, Capsules, Dry Syrups





















## **Strong Research & Development Capabilities**



# **Experienced Research Team**



111 Research Team5 Doctorates81 Post-Graduates22 Graduates3 Diploma Holders

# Patent Filings Product Registrations



26 Inventions with 54 filings worldwide 302 Registered 427 Applied 83 in Pipeline

# Product Registrations



Dosage Form	Registered	Applied	Pipeline	Total
Capsules	58	76	12	146
ODS	44	141	18	203
Suspension	4	-	-	4
Tablets	185	190	49	424
Others	11	20	4	35
Registrations	302	427	83	812



# Recognitions & Academic Linkages



DSIR Recognized & approved by the Nagpur University for PhD Programs

Co-development projects with IITs, UDCT

### **Awards**



5<sup>th</sup> Annual India Pharma Awards "Excellence in R&D" won in November 2017

# **State-Of-The-Art Manufacturing Facilities**









Solid Oral Dosage (General) Facility			
Manufacturing Capabilities	Tablets, Capsules, DC Granules, Pellets, and Dry Syrup		
Accreditations	EU-GMP, WHO-GMP, ISO 9001		
Area	1,00,000 Sq. Ft		
Began Operations	1989		
Current Manpower	266		

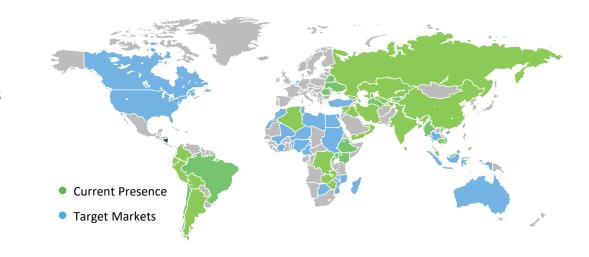
Solid Oral Dosage (Cephalosporin) Facility				
Manufacturing Capabilities Tablets, Capsules, DC Granules				
Accreditations	WHO-GMP, ISO 9001			
Area	16,000 Sq. Ft			
Began Operations	2011			
Current Manpower 51				

Oral Thin Film Facility				
Manufacturing Capabilities	OTF			
Accreditations	WHO GMP, ISO 9001			
Area	6,300 Sq. Ft			
Began Operations	2014			
Current Manpower	176			

## **Diverse Customer Base in Pharmerging & RoW Markets**



- ✓ Presence in 55 Countries
- √ 207 Global Clientele
- ✓ Focus on Pharmerging & ROW markets
- ✓ Exports to SAARC countries, Africa,
   MENA, South-East Asia, Russia & CIS,
   Latin America
- ✓ Status of "Three Star Export House" accorded by DGFT.



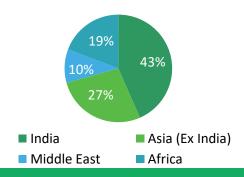
### **Presence Across Countries with Growing Clientele**



#### **Well-Diversified Customer Base**



#### Region wise Revenue Breakup: FY18



## **Experienced Leadership & Management Team**





Dr. Anwar Daud Managing Director (M.Pharm, PhD)

- Incorporated ZIM in 1989
- · Currently, leads the R&D function and is responsible for vision and overall growth strategy of ZIM
- Earlier worked with in various mid size & large pharma companies
- Co-Inventor of 14 process patents
- Felicitated by the Central Institute of Business Management Research & Development, Nagpur for showing leadership, entrepreneurship, and dedicated service to the region (2004)
- Honored for contribution to the pharmaceutical profession by Central India Pharmacy Promotion and Research Association (CIPPARA) – Awarded at the Hands of Shri Nitin Gadkari (2017)



Mr. Zulfiquar Kamal Director – Finance (B.Com, FCA)

- He is a co-promoter of ZIM
- More than 3 decades of experience
- Financial controller overseeing finance, tax, audit & commercial operations of the company



Mr. Niraj Dhadiwal
Director – Business
Development (B.Pharm, DBM)

- Associated with ZIM for 30+ yrs
- He has played a key role in entering new markets for ZIM



Mr. Prakash Sapkal Director – Operations (B.Pharm, MBA)

- Associated with ZIM for 24 yrs
- Currently responsible for Operations, ODS and new strategic initiatives
- He has also filed patents for the technology development of ODS

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## **Modified Drug Release (Pelletization)**





### Niche Technology

- Pelletization requires adoption of a unique manufacturing process
- The end-product is in the form of fine micro granules called pellets





#### **Enables Controlled Release**

- The release of API through Pellets, administered via capsules, is done in a controlled manner and in required quantities
- This enables Delayed Release, Dual Drug Release and Extended Release of Drug in the human body



### **Increased Efficacy & Convenience**

- Timely discharge of pellets improves the drug's bio-availability in the body and circumvents the need to consume multiple dosages
- Convenience to the patient as there is no need to remember the timing of dosage

# **Stability & Solubility Enhancement (DC Granules)**





### **Robust Technology**

 Using co-crystallization, micro emulsification, co-precipitation, inclusion, complexation, miscellar solubilization, adduct formation, nanotechnology and powder coating.





#### **Directly Compressible (DC) Granules**

- Dry and Wet granulation and direct compression are the two methods for preparation of tablets
- Direct compression is more economical since it requires less equipment, lower power consumption, less space, less time and less labour leading to reduced production cost of tablets



### **Increased Stability & Solubility**

- Direct compression is more suitable for moisture and heat sensitive APIs
- Changes in dissolution profiles are less likely to occur in tablets made by direct compression on storage than in those made from granulations

## **Taste Masking**





## **Robust Technology**

ZIM has developed a highly cost-effective technology which can taste
mask bitter products including antibiotics without affecting their shelf
life and maintaining their dissolution and bio-availability requirements



#### **Vital for Bitter APIs**

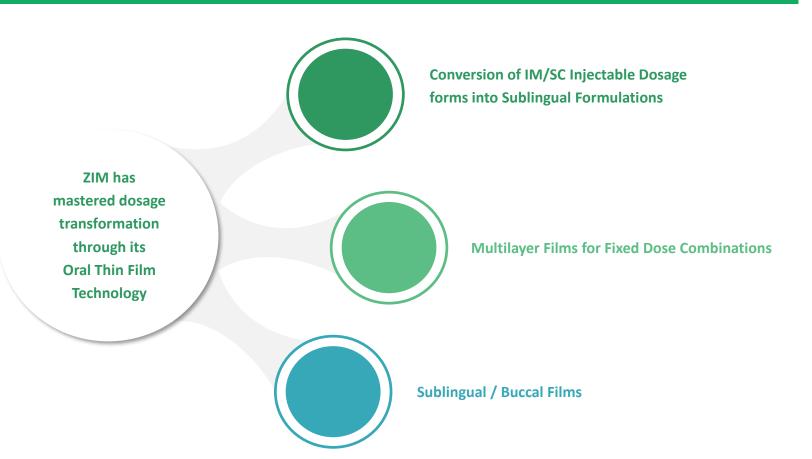
- Taste-masking techniques are applied to mask or overcome the bitter or unpleasant taste of APIS to achieve patient acceptability and compliance
- This is key for patient groups such as paediatrics and geriatrics

## **Taste Masking Techniques**

- Use of ingredients like flavours, sweeteners and amino acids
- Polymer coating, conventional granulation, Ion-exchange resins, Spray congealing with lipids
- Use of gelatin, liposomes, lecithins, surfactants, salts and polymeric membranes

# **Dosage Transformation**





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# **OTF** - Versatile Drug Delivery Platform





### **Thinoral**®

- ✓ ZIM's indigenously developed Oral Thin Film (OTF) Technology is patented as Thinoral®
- ✓ It has 25 product/process patents for oral thin films globally
- ✓ OTF is a rapidly dissolving, non-sticky film which can have a drug loading capacity as high as 100 mg of the active drug. The faster release profile alleviates the solubility issues in poorly soluble drugs
- ✓ The Thinoral® strips are flexible and offer ease of storage and transportation
- ✓ Thinoral® technology could also be used for delivery of drugs through sublingual and buccal absorption routes, showing improved bioavailability by avoiding first pass metabolism







## **OTF** - Versatile Drug Delivery Platform



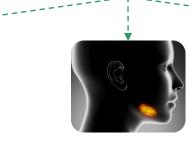


## ZIM has developed range of OTF products offering various clinical and customer advantages





- Non invasive mode of administration
- Large molecules of proteins (incl. complex generics) can be formulated



Sublingual / Buccal Films

- More accuracy with absorption predictability as compared to sublingual tablets
- Improved bioavailability by avoiding first pass metabolism
- OTFs with anti-infective & antibacterial properties are already developed and Probiotic films are under development



Multilayer Films for Fixed Dose Combinations

- Suitable for incompatible APIs
- APIs with different release profiles can be formulated in one film
- Can be used for trans-mucosal films that require inert backing membranes

### **OTF: Key Advantages**

- ✓ Have large surface area causing quick disintegration, leading to quick reaction
- ✓ Non-obtrusive characteristic enables easier administration to paediatrics, mentally challenged and bed-ridden patients with chronic conditions
- ✓ Allows efficient taste-masking and palatability
- ✓ Enhances patient compliance and convenience
- ✓ Enhances safety with high-precision dosage and lowest excipient load

IM: Intramuscular, SC: Subcutaneous

## **OTF** – Rising Customer Acceptance





# 18 OTF products based on Thinoral® Technology have been launched and supplied to leading global pharma companies







1 Product Launched

5 Product Launched

2 Product Launched







2 Product Launched

2 Product Launched

4 Product Launched





1 Product Launched

1 Product Launched

# ZIM's OTF Technology has Won Several Accolades



ZIM's Fast Dissolving OTF was awarded as the Best Innovation Development of a Solid Dosage Form for the year 2016 by India Pharmaceutical Association



# **Discussion Summary**

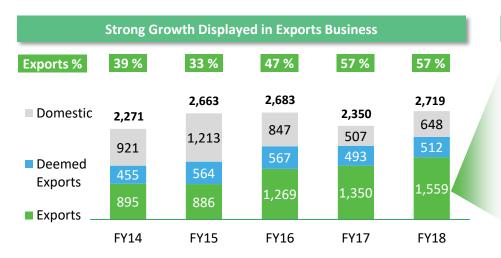


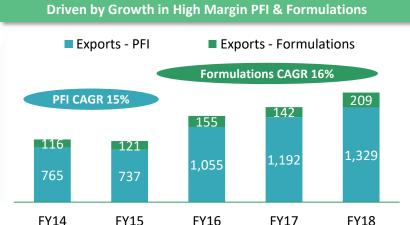
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## **Recalibration of Business to Drive Profitable Growth**









### Rapid growth in the Exports business -

- Consistent increase in sales of PFI and Formulations
- Continued foray into existing and new markets in emerging and developed countries
- PFIs are exported to local manufacturers and formulations are exported to local distributors / marketing agents across Pharmerging & ROW markets

# Conscious reduction in exposure to Deemed Exports and Domestic Government business –

- Low margins in Deemed Exports (to countries with import restrictions). Going forward, this will remain stable at FY18 levels
- In-direct Government business (through agents) was discontinued in FY15 due to low margins and high working capital issues. Going forward, only tender-based Government business will continue and will remain stable at FY18 levels

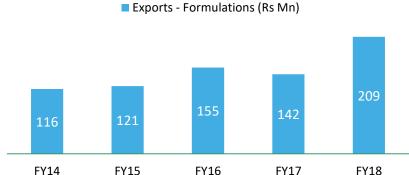
Based on Standalone Financials

## **Expand Registrations Base to Drive Growth in Sale of Formulations**



#### The Registrations Base Significantly Grew Over FY16-FY18; Complete Revenue Potential Yet to Be Realized





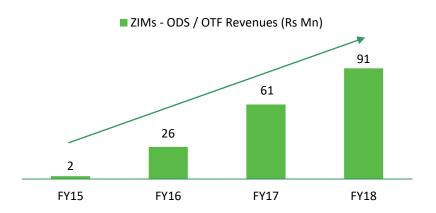
#### Strong Growth Potential in Formulation Exports in Future –

- ZIM started building registrations base in Sri-Lanka during FY13-FY15 which led to ramp-up in formulation exports in FY16
- The registrations obtained during FY16-FY18 should lead to improved formulation sales over near term
- In addition to existing base of 248 registrations, there are another 514 registrations applied and 39 registrations in pipeline across diverse therapies
- Continuous investment in growing the registrations base should lead to significant growth in formulation exports over coming years

## Significant Ramp-up in Sale of ODS / OTF Products



#### ZIM is Market Leader in India in the OTF Space and has Displayed Strong Growth in ODS / OTF Revenues Since Inception



### Global OTF Market (USD Mn)



### **Strong Growth in ODS Sales over FY15-18**

- ODS products are primarily sold domestically under out-licensing model to leading global pharma companies
- ZIM has now also started selling own branded ODS products in domestic & export markets
- Currently 8 products are commercialised, 11 developed and another 22 products in pipeline, available across major therapeutic segments

### Long Runway for Future Growth

- Till date, ~150 Mn has been invested in R&D. As on FY18, 1 machine was installed & running at 20% capacity utilisation (Rs 500 Mn peak revenue potential). The facility has further scope to install another 2-3 machines (each costing only ~Rs 10 Mn due to in-house technology), providing a long growth potential
- According to Transparency Market Research, the global OTF market is expected to grow at 13% CAGR from USD 2.1 Bn in 2017 to USD 6.3 Bn in 2026

Based on Standalone Financials 24

# **Significant Ramp-up in Sale of ODS / OTF Products**



## ZIM has a Robust Portfolio of ODS / OTF Products Addressing Major Therapeutic Applications

Existing Portfolio					
Generic Molecules	Therapeutic Use	Generic Molecules	Therapeutic Use		
Ondansetron (Hydrochloride)	Anti-Emetic	Dextromethrophan Hydrobromide	Anti- Flatulent		
Tadalafil, Sildenafil (Citrate)	Erectile Dysfunction	Simethicone	Anti-Tussive/ Mucolytic/Expectant		
Methylcobalamin, Vitamin D3	Vitamin B12, Vitamin D3	Rizatriptan Benzoate	Anti-Migraine/Anti-Vertigo		
Levocetirizine Dihydrochloride	Anti-Allergic / Nasal Decongestant	Voglibase	Anti-Diabetic		
Montelukast (Sodium)	Anti-Asthmatic/ Anti-Allergic	Zolmitriptan	Anti-Migrane		
Menthol Mouth Freshener	Mouth Freshener (Mint Flavor)	Loperamide Hydrochloride	Anti - Diarrheal		

22 Products in Pipeline Across Following Therapeutic Applications				
Adaptogens	Erectile Dysfunction			
Analgesics (Non - Opioid) & Antipyretics	Opiods Analgesics			
Anti - Gout drugs	Central Nervous System			
Anti- Psychotic & Anti - Emetics	ADHD			
Antihistamine	Sedatives & Hypnotics			
Antispasmodic	Tranquilizers & Antioxidants			
Arthritis/Osteoporasis	Vitamins & Minerals			
Cholinergic Stimulants				

## **Continued Focus on New Product Development**



Focus on Co-Development – particularly in OTF

- Enter into product co-development and supply partnerships with Original Product Manufacturers / Marketing Companies globally across delivery platforms
- Co-develop products using ZIM's Thinoral as alternate delivery platforms for extending product lifecycle, specific customer targeting etc.

Focus on Developing
Products for Developed
Markets

Invest in R&D infrastructure, team, process, systems, studies etc. that assist in the company's plans of registration and supply of differentiated generic products across developed markets

Focus on Developing
New Drug Delivery
Platforms

- Develop more ODS products using Multi-layer film technology
- Work on Electrospun nanofibers which can be spun in an OTF or in powder form in a capsule. Unique
  properties of Electrospun Nanofibers make it highly effective for designing of controlled drug delivery
  systems, tissue engineering and wound healing purposes
- Work on **2D printing** of drug on OTF. Printing technology enables preparation of flexible dosage forms with multiple APIs with complex and tailored release profiles

# **Discussion Summary**



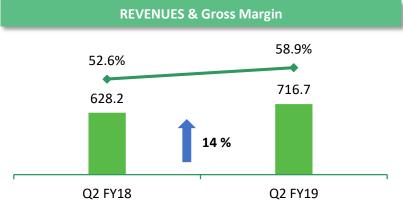
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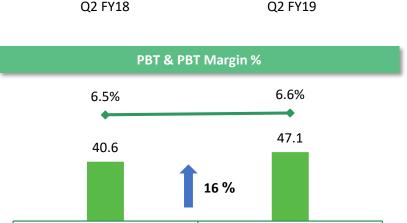
# **Q2 FY19: Key Highlights**

Q2 FY18

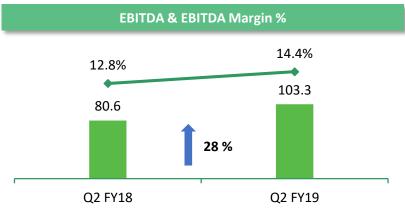


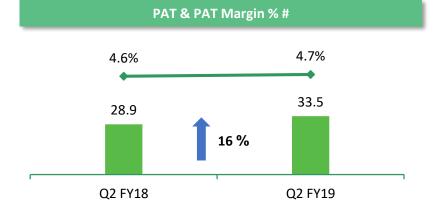






Q2 FY19

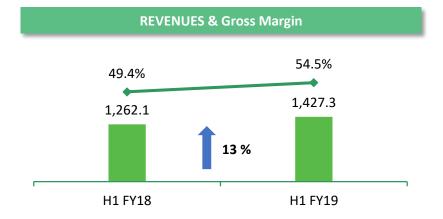


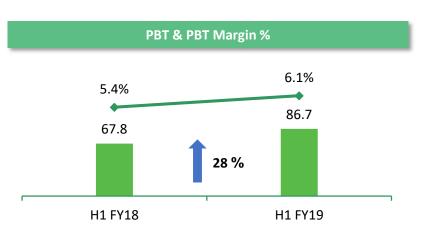


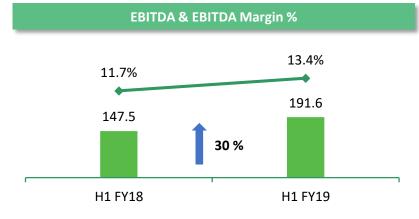
# H1 FY19: Key Highlights

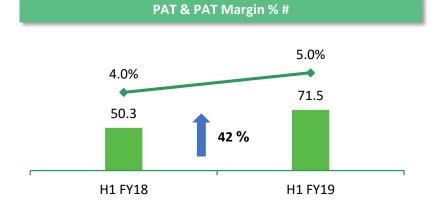


In Rs Mn





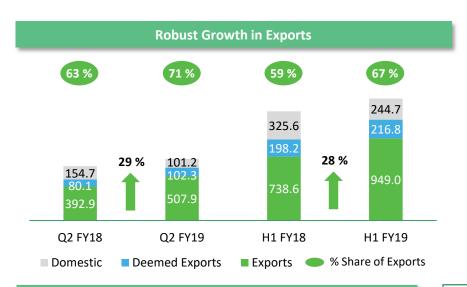


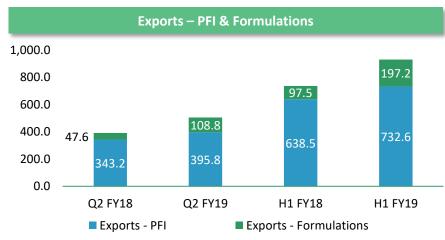


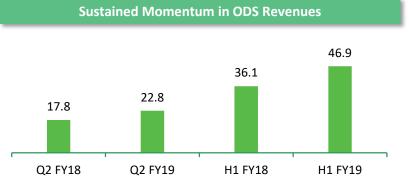
## Q2 & H1 FY19: Revenue Analysis











- Revenue growth was in line with the company's business recalibration strategy marked by strong growth in high margin exports, strong traction in ODS /OTF sales, stable deemed exports and reduction in low margin domestic government business and API trading
- Export revenues witnessed strong traction in both PFI sales and Formulation sales (driven by growing registrations base)
- Gross margin thus increased from 52.6% to 58.9% in Q2 FY19 and EBITDA margin from 12.8% to 14.4%

Based on Standalone Financials

# **Consolidated Profit & Loss Statement**



Particulars (in Rs. Mn.)	Q2 FY19	Q2 FY18	YoY%	H1 FY19	H1 FY18	YoY%	FY18
Revenue from Operations (net of taxes)	716.7	628.2	14.1%	1,427.3	1,262.1	13.1%	2,728.0
COGS	294.9	297.8	-1.0%	648.9	638.3	1.7%	1,408.9
Gross Profit	421.8	330.4	27.7%	778.4	623.7	24.8%	1,319.1
Gross Margin (%)	58.9%	52.6%	626 bps	54.5%	49.4%	512 bps	48.4%
Employee Expenses	118.5	105.4	12.4%	234.8	191.7	22.5%	408.0
Other Expenses	200.0	144.5	38.5%	352.0	284.5	23.7%	563.2
EBITDA	103.3	80.6	28.2%	191.6	147.5	29.9%	347.8
EBITDA Margin (%)	14.4%	12.8%	159 bps	13.4%	11.7%	174 bps	12.8%
Other Income	1.9	13.2	-85.3%	5.3	15.8	-66.3%	34.2
Finance Costs	29.7	29.5	0.7%	56.0	49.0	14.3%	93.4
Depreciation	28.5	23.7	20.1%	54.3	46.6	16.6%	97.9
Exceptional Items	-	-	-	-	-	-	58.6
РВТ	47.1	40.6	16.1%	86.7	67.8	27.8%	249.4
PBT Margin (%)	6.6%	6.5%	11 bps	6.1%	5.4%	70 bps	9.1%
Taxes	13.6	11.7	16.1%	15.2	17.5	-13.3%	58.3
PAT	33.5	28.9	16.1%	71.5	50.3	42.2%	191.1
PAT Margin (%)	4.7%	4.6%	8 bps	5.0%	4.0%	102 bps	7.0%
Earnings Per Share (EPS) – Basic	2.08	1.79	16.2%	4.43	3.12	42.0%	11.87

# **Consolidated Balance Sheet**



Particulars (In Rs Mn)	Sep-18	Mar-18
Assets		
Non-Current Assets		
Property, Plant and Equipment	1,022.4	929.3
Capital work in progress	56.3	47.7
Intangible Assets	12.7	12.2
Intangible Assets under development	48.4	35.2
Financial Assets		
Investments	0.5	0.5
Other financial assets	11.5	16.2
Deferred Tax Assets (Net)	37.3	36.8
Current Tax Assets	12.1	11.3
Other non-current assets	59.1	151.3
	1,260.4	1,240.5
Current Assets		
Inventories	605.9	515.6
Financial Assets		
Trade receivables	903.6	892.2
Cash & cash equivalents	32.0	14.7
Balance with Banks	34.6	20.6
Loans	1.7	0.9
Other financial assets	10.7	10.8
Other current assets	378.9	287.5
	1,967.5	1,742.4
Total Assets	3,228.0	2,982.9

Particulars (In Rs Mn)	Sep-18	Mar-18
Equities & Liabilities		
Equity		
Equity share capital	80.6	80.6
Other Equity	1,349.8	1,285.4
	1,430.4	1,366.0
Liabilities		
Non-Current Liabilities		
Financial Liabilities		
Borrowings	244.8	202.8
	244.8	202.8
Current Liabilities		
Financial Liabilities		
Borrowings	488.3	495.6
Trade Payables	745.0	662.6
Other financial liabilities	217.9	208.7
Other current liabilities	83.0	42.8
Provisions	7.9	4.3
Current tax liabilities (net)	10.7	-
	1,552.8	1,414.0
Total Equity & Liabilities	3,228.0	2,982.9

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- Financial Overview

## **Last 5 years Summary**

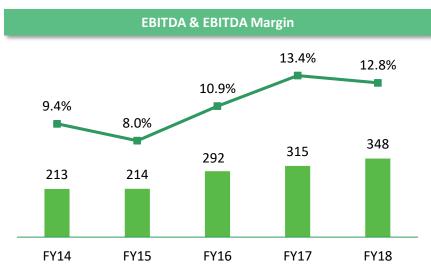


#### In Rs Mn

### **Revenue & Gross Margin** 49.0% 48.4% 41.4% 35.3% 31.8% 2,728 2.663 2,685 2,350 2,271 FY14 FY15 FY16 FY17 FY18



- Exports business (PFI & Formulations) grew at CAGR of 17% leading to improvement in gross margins.
- Revenue Share of Exports business increased from 39% to 57%
- Conscious reduction in Deemed Exports and Domestic Government business

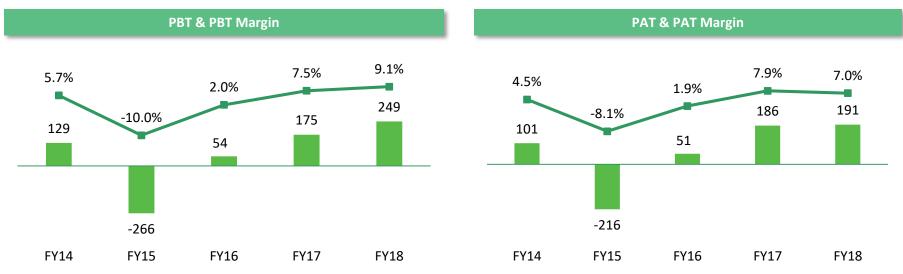


- EBITDA grew at CAGR of 13%. EBITDA margin improved in line with higher gross margin, partially offset by increase in R&D spend
- R&D expense in P&L as % of Revenues increased from 0.7% in FY14 to 3.4% in FY18
- EBITDA margin declined in FY18 vs. FY17 due to spill-over of certain Government orders from FY17 to FY18

## **Last 5 years Summary**



In Rs Mn

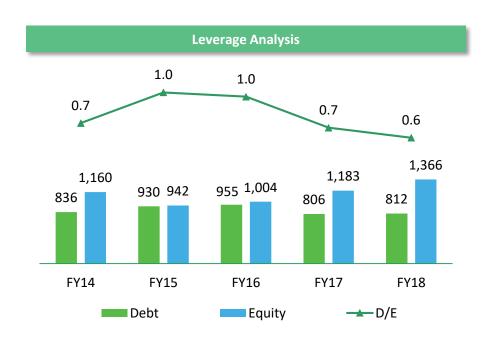


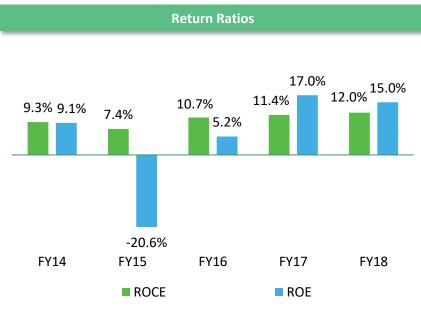
- PBT grew at CAGR of 18%. PBT excl. exceptional items grew at 10% CAGR
- Exceptional Items:
  - The company had made net provisions of Rs 330 Mn in FY15 and Rs 53 Mn in FY16 on account of discontinuation of indirect (agent-based) Government business in FY15. This has impacted the PBT during FY15 and FY16
  - In FY18, the company has written back net provisions of Rs 59 Mn, made earlier on doubtful receivables
- PAT grew at CAGR of 17%

# **Last 5 years Summary**













# Zeal & Innovation in Medicine



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