

## Natco Pharma Limited

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CIN: L24230TG1981PLC003201, www.natcopharma.co.in

Manager – Listing

2<sup>nd</sup> June, 2016

Corporate Relationship Department The Bombay Stock Exchange Limited Dalal Street, Fort Mumbai 400 001

M/s. National Stock Exchange of India Ltd "Exchange Plaza", Bandra – Kurla Complex Bandra (E) <u>Mumbai 400 051</u>

Scrip Code: 524816 Scrip Code: NATCOPHARM

### Sub:- Submission of Presentation made to analysts / Investors

We are enclosing herewith a copy of the presentation made to analysts /Investors on Audited Standalone and Consolidated Financial Results of the Company for the quarter and year ended 31st March, 2016.

Pease take the same on your records

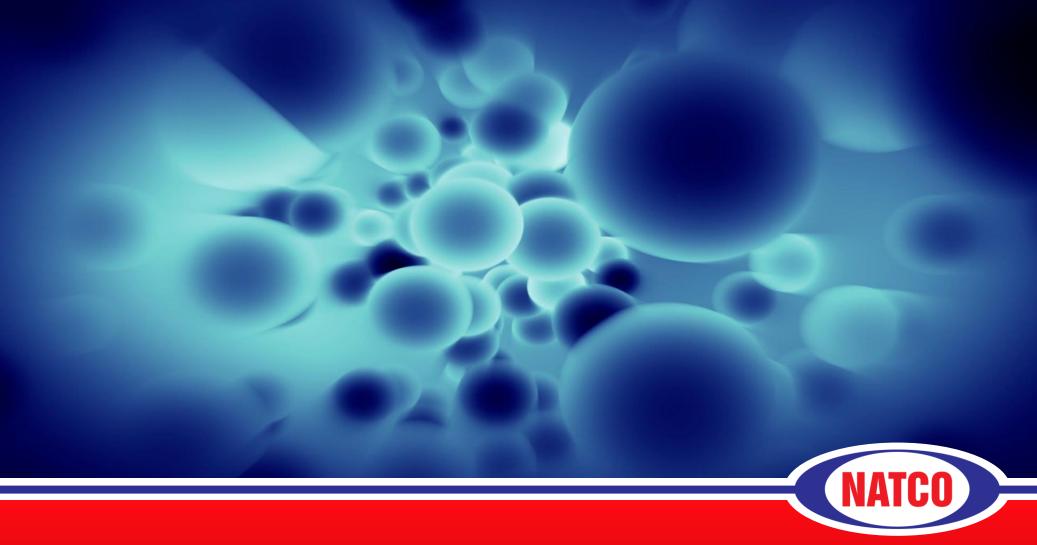
Thanking you,

Yours faithfully, For NATCO Pharma Limited

M. Adinarayana Company Secretary &

V.P.(Legal & Corp. Affairs)

Encl. as above:



# **Natco Pharma Limited**

May 2016
Strictly Private and Confidential

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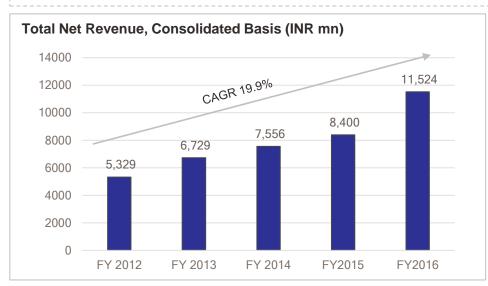
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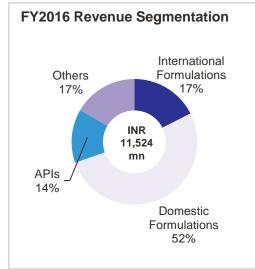
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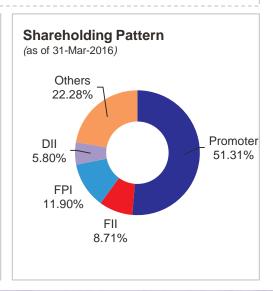


## Natco Pharma at a Glance

- Vertically integrated pharmaceutical company with focus on niche therapeutic areas and complex products in Finished Dosage Formulations ("FDF") and Active Pharmaceutical Ingredients ("APIs")
- Diversified business model with presence across segments including Domestic & International formulations, API manufacturing and drug discovery
  - Products marketed in 40 countries
  - Portfolio of 38 niche ANDA filings in the US including 16 Para IV filings and 33 USDMFs filings (as of 31-Mar-2016)
- Strong position in domestic oncology and gastro hepatology segments
- Portfolio of 28 products (as of 31-Mar-2016) catering to various oncology diseases including breast, brain, bone, lung and ovarian cancer
  - Launched the generic version of Gilead's Sovaldi, under its brand HEPCINAT for the treatment of Hepatitis C
- Strong R&D capabilities supported by two well equipped research centres and seven approved manufacturing facilities (five formulations and two APIs)
- Incorporated in 1981 and headquartered in Hyderabad currently employs over 3,500 employees across all locations

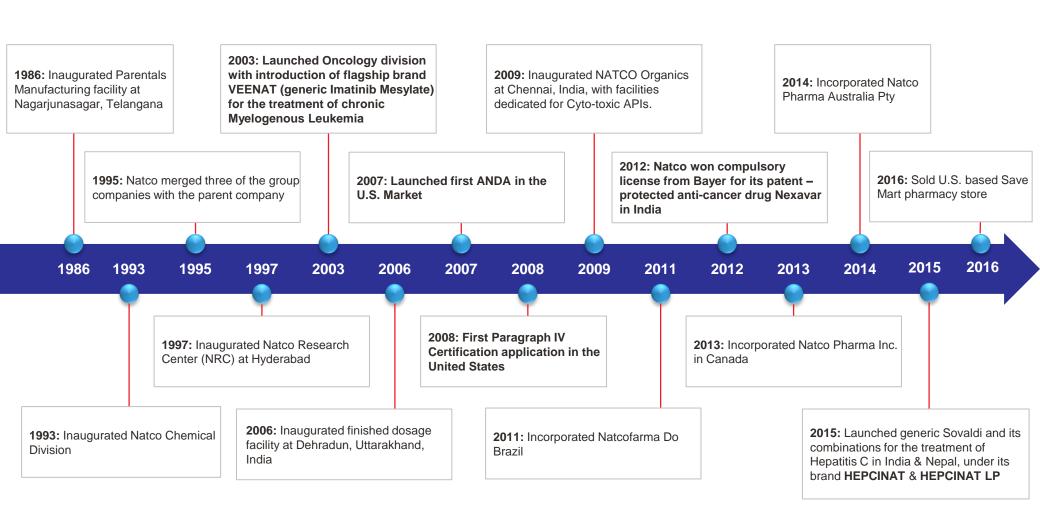








# **Company Evolution**





# **Key Business Segments**

#### **Formulations** API **Others** (Domestic & Exports) **Domestic** International Leading Player<sup>1</sup> in India's Portfolio of niche and complex Filed 33 DMFs in US with Operates one pharmacy store in US (Sold on April 7, 2016) products for US generic oncology space led by over 16 products under flagship brands like Geftinat, development 38 niche ANDA filings in the Operates in Brazil, Canada, Erlonat, Veenat, Sorafenat and Vertically integrated for most Singapore and Australia US Bortenat of its FDF products through following subsidiaries: 16 product approvals Specialist sales force of 200+ (including 3 tentative Exports focused on the US. Natco Farma Do Brazil personnel and over 490 approvals) Europe and Brazil - Natco Pharma (Canada) Inc. Overview distributors 21 products under review Natco Asia Pte Ltd.. Heralds a new beginning in the Emerging presence in Canada, Singapore gastro-hepatology therapy Brazil, Europe, Asia, Australia segment with the launch of Natco Pharma Australia Pty and RoW markets Hepcinat Selective contract manufacturing business **FY16 Revenue** INR 2024 mn INR 6002 mn INR 1597 mn INR 1909 mn (INRmn) **FY16 Revenue** Contribution

(1) Source: Report On Pharmaceutical Industry by CARE Ratings, 2015



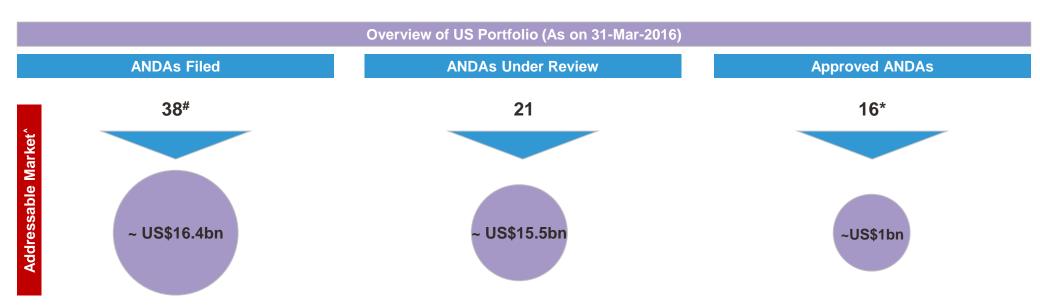
# Key Growth Pillars in Place Supported by a Strong Foundation for Value Creation

**Emerging Expanding US** Presence in **Leading Position** footprint through a Pillars of Europe, Asia and in Domestic differentiated **RoW Markets**; Growth **Oncology &** product pipeline of Launching **Gastro-Hepatology** niche and complex **Hepcinat in RoW** Market products Countries De-risked business model through partnership with global pharmaceutical players **Supported** Strong in-house API development with vertical integration for most of its formulation products by a Strong **Foundation** Strong research and development capabilities and commitment to quality manufacturing and regulatory compliance Spearheaded by an experienced management team



# Expanding US Footprint Through a Differentiated Product Pipeline of Niche and Complex Products

- Pipeline of niche and complex generics products in US
- 38 ANDA filings including 16 Para IV filings with USFDA (as on March 31, 2016) targeting a combined market of over US\$16.4 bn^
- 16 approved ANDAs (including 3 tentative approvals)
- Adopts partnering strategy to develop and market products for the US with globally renowned pharmaceutical companies



Portfolio of 38 ANDAs including 16 Para IV filings some of which are believed to be First-to-file (FTF)

<sup>\*</sup> Includes 3 tentative approvals; ^ Source: IMS; Based on annual sales of products for 12-month period Jan-2015 to Dec-2015; # One ANDA filing withdrawn



# Expanding US Footprint Through a Differentiated Product Pipeline of Niche and Complex Products (Cont'd)

Overview of Key Filings						
Key Brand	Molecule	Therapeutic Segment / Indication	Dosage Form	Para IV	Para III	Market Size (US\$mn)#
Copaxone 20&40mg	Glatiramer 20&40mg	Multiple Sclerosis	PFS	✓		4,350
Gleevac	Imatinib	Cancer, CML	Tablets	✓		2,375
Gilenya	Fingolimod	Multiple Sclerosis	Capsules	✓		1765.16
Treanda	Bendamustine	Leukemia	Injection	✓		709.7
Entocort	Budesonide	Crohn Disease	Capsules		✓	516.17
Nuvugil	Armodafinil	Antidepressants	Tablets	✓		482.11
Tamiflu	Oseltamivir Capsules	Influenza Infection	Capsules	✓		402.98
Vidaza	Azacitidine	Myelodysplastic syndrome	Injection		✓	238.63
Doxil	Doxorubucin	Cancer, Ovarian	Injection (liposomal)		✓	202.94
Jevtana	Cabazitaxel	Prostate cancer	Injection	✓		<b>1</b> 37.28
Fosrenol	Lanthanum Carbonate	End stage renal disease	Tablets	✓		■ 118.56
Tykerb	Lapatinib Ditosylate	Anti cancer	Tablets	✓		73.89
Revlimid*	Lenalidomide	Multiple Myloma	Capsules	✓		997.94
Nexavar*	Sorafenib	Anti cancer	Tablets	✓		■ 72.77
Tracleer*	Bosentan	Hypertension	Tablets		✓	I 40.25

- US FDF product portfolio is predominantly focused on high-barrier-to-entry products that are difficult to formulate, difficult to manufacture or may face complex legal and regulatory challenges
- 16 Para IV filings with combined market size of US\$14.0bn¹

Represents REMS product # Source: IMS; Based on annual sales of products for 12-month period Jan 2015 to Dec 2015



# De-risked Business Model through Partnership with Global Pharmaceutical Players

## **Mitigation Strategy**

US Market reach and Regulatory Challenges

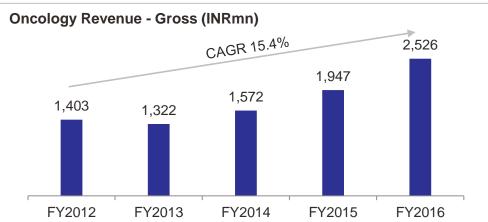
- Adopted and successfully implemented partnership strategy for international formulations product
  - Has product specific partnerships with global generic players at different stages of a potential ANDA filing
  - Entered into de-risked arrangements with marketing partner whereas the partner undertakes the responsibility of lengthy and complex litigation and regulatory issues and securing the ANDA approval
  - Global generic pharmaceutical companies have significant insight into global legal procedures and protocols enabling
    us to draw on their experience to successfully obtain the necessary regulatory approvals and effectively commercialize
    our products.





# **Leading Position in Domestic Oncology Segment**

- Focus on oncology segment in domestic market and hold leading market share in operated portfolio of product
- Entered the segment with launch of Veenat (Imatinib generic version) in 2003
- Progressively widened its oncology product range from 6 in 2003-04 to 27 as on 31-Mar-2016
  - Portfolio catering to Breast, Brain, Bone, Lung, and Ovarian Cancers
- Sales and marketing of the product is supported by strategically located logistics network of 200+ marketing personnel & over 490 distributors



Oncology Portfolio

No. of Active Brands\*

Hematology

11

Solid Tumors 16

INR100mn+ Brands (FY15)

(Veenat)

(Sorafanat)





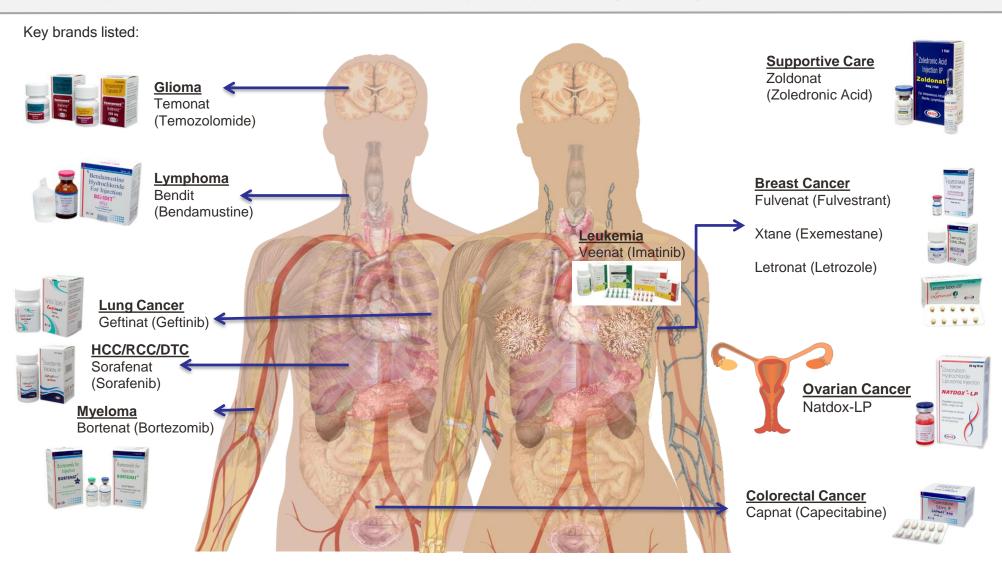


- ✓ Substantial reduction in the treatment cost of Chronic Myeloid Leukemia via launch of generic Imatinib
- ✓ Granted a compulsory license to launch Bayer's patent protected anti-cancer drug Nexavar in India

\*As on 31-Mar-2016



# Leading Position In Domestic Oncology Segment (Cont'd)





# **Expanding Presence in Domestic Specialty Pharma Segment**

### **Domestic Specialty Pharma**

- Portfolio of 13 products catering primarily to Gastroenterology, Orthopaedics and Critical Care/CNS
- Currently products in oral and injectables dosage forms
- Select contract manufacturing assignments

## **Sovaldi Opportunity**







- Launched generic Sofosbuvir and its combinations for the treatment of Hepatitis C in India & Nepal under its brand HEPCINAT & HEPCINAT LP
  - Medicine used for chronic hepatitis C infection and sold globally by Gilead Sciences, Inc., under its brand Sovaldi
- Non-exclusive licensing agreement with Gilead Sciences for 101 countries including India reaching a target population of 103 million people
- Launched generic Daclatasvir in India under its brand Natdac
- Non-exclusive, royalty free licensing agreement with Medicines Patent Pool (MPP) and Bristol-MyersSquibb to manufacture and sell generic versions of Daclatasvir.
- Is one among the generic manufacturers who are first to launch Sofosbuvir, the combination drug Sofosbuvir+Ledipasvir, and Daclatasvir in India, thus is one of the market share leader in India

### **Overview of Key Non-Hepcinat Products**

Products		Active Ingredient	Dosage Form	Therapeutic Area	
Eddor and Hongard Mangard	Natzold	Zoledronic Acid	Infusion Solution	Orthopaedics, Supportive Care	
	Glatimer	Glatiramer Acetate	Injection	Multiple Sclerosis	
	Teravir	Tenofovir	Tablets	Hepatitis-B	



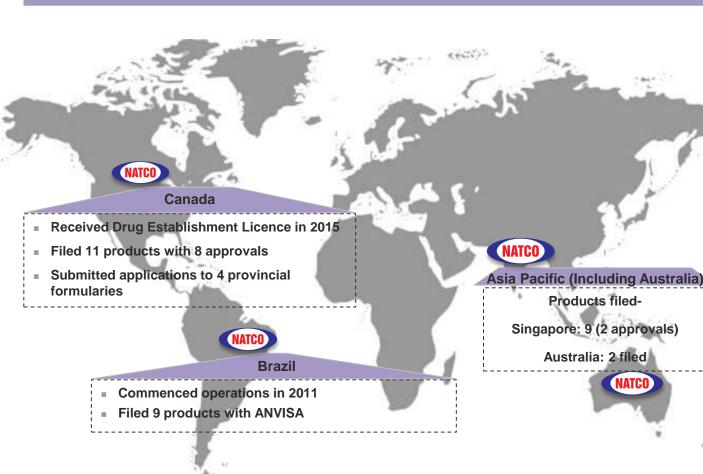
# **Expanding Europe & RoW Presence**

RoW formulation growth to be driven by launches in EU, scale up in Latin America and Canada and phased launch of generic Sovaldi

Products filed-

Singapore: 9 (2 approvals)

Australia: 2 filed



## **Europe**

- Sell our products in Eastern Europe, UK and Germany
- 4 approvals
- Distribution arrangements with our business partner

#### Venezuela

Sell our FDF products (oncology) to third parties

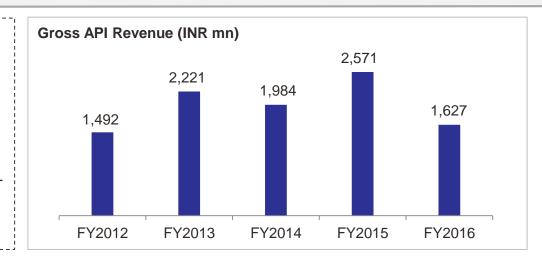
## **Other Geographies**

- Indian sub-continent
- Middle East



# Strong In-House API Development with Vertical Integration for Key Formulation Products

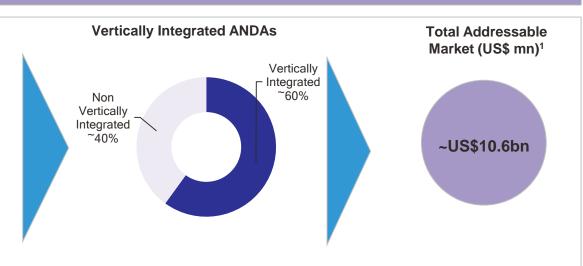
- Strategically important business develops APIs primarily for captive consumption of its FDF portfolio as well as third party sales
- Portfolio of 33 USDMFs with over 16 products under development
- Focuses on complex molecules in oncology and CNS segments
  - Other therapeutic areas of focus includes Anti-asthmatic, Antidepressant, Anti-migraine, Anti-osteoporosis and G I Disorders
- Exports are focused on the US, EU, Canada, Latin America and South-East Asia
- Vertical integration for several APIs a key competitive advantage



## Strategic Advantage with Backward Integration in Critical APIs

## **API Strengths**

- ✓ Complex multi-step synthesis & scale-up
- ✓ Semi-synthetic fusion technologies
  - Fermentation / Biotech / Synthetic / Separation technologies
- ✓ Containment / High potency APIs
- ✓ Peptide (Solid phase) pharmaceuticals



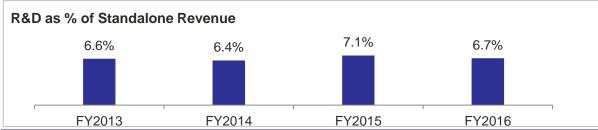
(1) Source: IMS. Denotes size of FDF markets of vertically integrated ANDAs



# Strong Research & Development Capabilities

Strong R&D capabilities demonstrated by its complex and niche product filings in formulations and API segments

- Two well equipped research facilities with capabilities across synthetic chemistry, biotech & fermentation, nano pharmaceuticals, new drug discovery & cell biology
  - Currently engaged in discovery and development of drugs NRC-AN-019 (brain tumour, pancreatic cancer and CML) and NRC-2694 (Breast Cancer); NRC-019 has received orphan drug status in USA



Function	No. of Labs	No. of Scientists
Process Research	10	80
Discovery - NCEs (Anti-cancer segment)	2	10
Analytical Development	5	45
Therapeutic Peptides	3	15
New formulation / Cell Biology / Animal house Toxicology / Molecular modeling & RDD	5	40
Biotechnology & Fermentation	3	15
Containment labs for high potency products	2	10
Bio-Analytical lab	2	10
NDDS & nano-pharmaceuticals	2	15
Development & Quality Assurance	1	10

## 16 ANDAs Approved

(including 3 tentative approvals)

16 Para IV Filings

33 US DMFs Filed

Over 16 API products Under

Development

181 International Patents Filed114 International Patents Granted

177 Indian Patents Filed81 Indian Patents Granted



# Commitment to Manufacturing Excellence with a Culture of Quality and Compliance

## **Formulations Manufacturing Facilities**

### **Kothur Facility**



- Capability: Tablets, Capsules, Pellets, Injectables
- Key Regulatory Approvals:
   GMP, USFDA, German Health
   Authority, ANVISA
- USFDA audit: Last approval -July 2014; Most recent audit -March 2016 (awaiting approval)

## Nagarjuna Sagar Facility



- Capability: Ampoules, Vials, Lyophilized vials, Parenterals, Sterile Dry Powders
- Key Regulatory Approvals: GMP

### **Dehradun Unit 6 Facility**



- Capability: Tablets, Capsules, Injectables
- Key Regulatory Approvals: GMP

### **Dehradun Unit 7 Facility**



- Capability: Tablets, Capsules
- Key Regulatory Approvals:
   GMP, Public Health Service of the Netherlands (EU GMP)

### **Guwahati Facility**



- GMP Compliant Facility
- Capability: Tablets, Capsules

#### **API Manufacturing Facilities**

#### **Mekaguda Facility**



- Key Regulatory Approvals: GMP, USFDA, German Health Authority, PMDA (Japan), Cofepris (Mexico)
- USFDA audit: Last approval January 2015

#### **Chennai Facility**



- Key Regulatory Approvals: GMP
- USFDA audit: Most recent audit February 2016 (awaiting approval)



# **Experienced Management**



Mr. V.C Nannapaneni Chairman and Director



Over 42 years of experience in the Pharmaceutical Industry



Mr. Rajeev Nannapaneni Vice Chairman & CEO

- Holds bachelors degree in Quantitative Economics and History from Tufts University, Boston, USA
- Holds wide experience and exposure in General Management and Product Development



Dr. A.K.S Bhujanga Rao President (R&D and Technical)

- Awarded Ph.D.in Synthetic Organic Chemistry from the Indian Institute of Science (IISc), Bangalore
- Wide expertise in technology transfer to commercial scale, quality control regulatory affairs and Patents



**Dr. Linga Rao**President (Technical Affairs)

- Holds Masters degree in Science (Applied Chemistry) & Ph.D in Chemistry from JNTU, Hyderabad
- Over 35 years of experience in the pharmaceutical industry and has been working with Natco for over 21 years



Mr. P.S.R.K Prasad Executive Vice President

- Holds B.E. Mech. Engg. from Andhra University, Visakhapatnam
- Responsible for looking after the general administration, engineering, regulatory, training, environmental matters, safety, health, production and maintenance activities of the Company



Mr. S.V.V.N.Appa Rao

- Over 25 years of experience including 20 years within the Company covering areas of accounting, financial controller, treasury
- Responsible for finance and treasury functions at the Company



M. Adinarayana Company Secretary & VP-Legal & Corporate Affairs

- Bachelors in Commerce and Bachelors in Law from Andhra University, Fellow Member of Institute of Company Secretaries of India
- 22+ years of experience within the Company in legal, secretarial and patent litigation areas

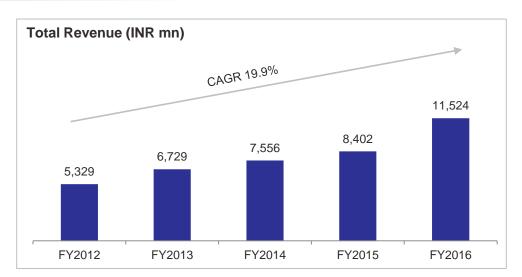


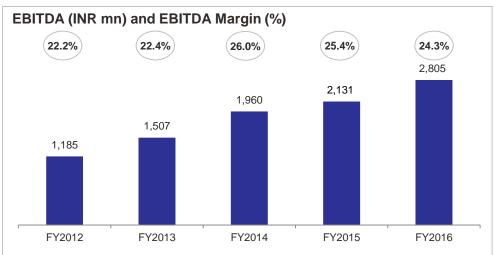
Mr. Rajesh Chebiyam Vice President - Business Development & Corp Support

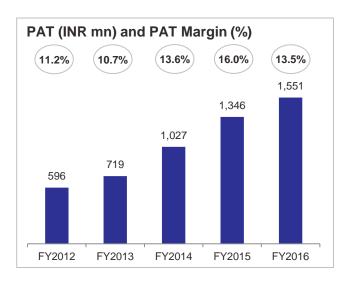
- Holds MBA from Babson College (USA) and Masters degree in Chemical Engineering from University of Rhode Island
- 20+ years of experience across supply chain, operations, business development, sales and strategy

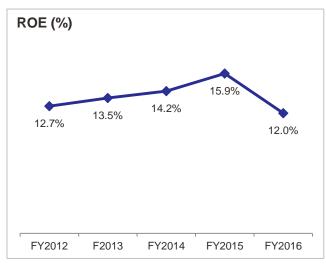


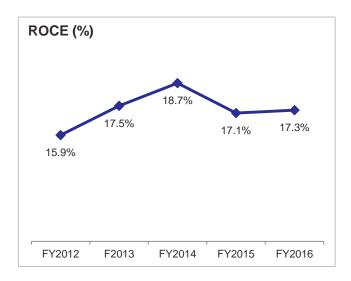
# Demonstrated Track Record of Topline and Earnings Growth













# **Historical Financials**

## Consolidated Profit & Loss Statement (INR Mn)

Particulars	31-Mar- 14	31-Mar- 15	31-Mar- 16
Revenue from operations (gross)	7,447	8,382	11794
Less : Excise duty	58	129	378
Revenue from operations (net)	7,389	8,253	11,416
Other income	167	149	108
Total revenue	7,556	8,402	11524
Expenses			
Cost of material consumed	1,601	1,673	3,037
Purchase of stock in trade	889	843	891
Change in Inventory	(158)	(92)	(517)
Employee benefits	1,128	1,369	1.867
Finance costs	366	317	229
Depreciation	304	473	510
Other expenses	2,135	2,325	3,441
Prior period expenses	0	1	0
Total expenses	6,266	6,908	9,228
Profit before exceptional items and tax	1,290	1,493	2,066
Exceptional item	-	151	-
Profit before tax	1,290	1,342	2,066
Current Tax	323	351	503
Deferred Tax Benefit	(14)	(312)	25
PAT (Before Minority interest)	981	1,303	1,538
Minority Interest	(46)	(43)	(13)
PAT (After Minority interest)	1,027	1,346	1,552

## **Consolidated Balance Sheet (INR Mn)**

Particulars	31-Mar-14	31-Mar-15	31-Mar- 16
Share Capital	331	332	348
Reserves and Surplus	6,928	8,128	12,635
Net Worth	7,259	8,461	12,983
Minority Interest	69	50	49
Long-term borrowings	955	970	-
Deferred Tax Liabilities	431	119	144
Other Non-Current Liabilities	10	8	8
Long-term Provisions	111	95	125
Total Current Liabilities	1,507	1,192	277
Short-term borrowings	986	1,685	984
Trade Payables	1,098	1,253	2,755
Other current liabilities	1,022	1,186	1,142
Provisions	17	13	49
Current Liabilities	3,123	4,137	4,929
Total Liabilities	11,957	13,840	18,238
Tangible Assets	6,127	6,640	7,046
Intangible Assets	320	459	89
CWIP	1,238	1,290	2,118
Non-current Investments	16	16	1
Long Term Loans & Advances	542	570	619
Other Non-Current Assets	32	35	42
Non Current Assets	8,276	9,011	9,915
Current Investments	3	1	210
Inventories	1,811	2,200	3,573
Sundry Debtors	1,188	1,924	2,616
Cash and Bank Balances	110	134	451
Loans and Advances	543	551	1,038
Other Current Assets	25	19	435
Current Assets	3,681	4,830	8,323
Total Assets	11,957	13,840	18,238

## Consolidated Cash Flow Statement (INR Mn)

	31-Mar-14	31-Mar-15	31-Mar-16
Profit Before Tax	1,290	1,342	2,066
Add: Depreciation and Amortization	304	473	510
Less: Change in Working Capital	(161)	(860)	(1500)
Others (inc Tax & Other Adjustments)	7	(29)	(52)
Cash flow from operations	1,440	927	1,024
Net Capex	(1,104)	(1,192)	(1,393)
Others	14	45	(362)
Cash Flow from Investing	(1,089)	(1,148)	(1,755)
Proceeds from Equity	1,085	-	3,344
Net Borrowings	(911)	714	(1,993)
Dividend Paid	(193)	(199)	(261)
Finance Cost Paid	(343)	(299)	(246)
Movement in minority interest	10	75	12
Cash Flow from Financing	(353)	291	856
Effect of currency adjustments	4	(48)	(8)
Net Increase/Decrease in Cash	3	22	117
Opening Balance	100	102	124
Closing Balance	102	124	242

