

### Natco Pharma Limited

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CIN: L24230TG1981PLC003201, www.natcopharma.co.in

16th September, 2016

Corporate Relationship Department M/s.BSE Ltd Dalal Street, Fort Mumbai 400 001 Manager – Listing M/s. National Stock Exchange of India Ltd "Exchange Plaza", Bandra – Kurla Complex Bandra (E) Mumbai 400 051

Scrip Code: 524816 Scrip Code: NATCOPHARM

Dear Sir,

Sub:- Submission of Presentation made to analysts / Investors

We are enclosing herewith a copy of the presentation made to analysts /Investors for the Un-Audited Financial Results of the Company for the quarter ended 30th June, 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:



**Investor Presentation August 2016** 



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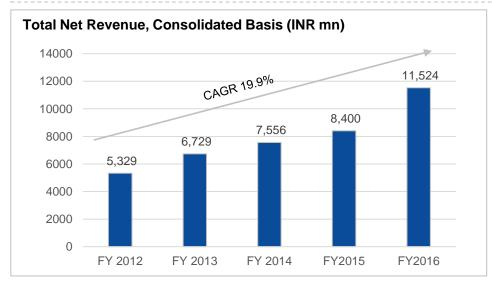
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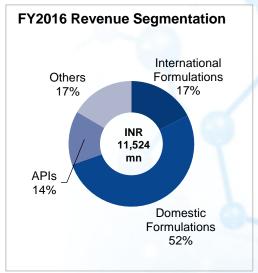
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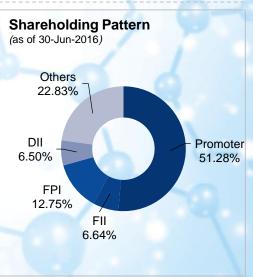


### NATCO Pharma at a Glance

- 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 over 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)
  - Target to file 10+ ANDA's in the US during the next 2 fiscal years.
- Strong position in domestic oncology and gastro hepatology segments
- Portfolio of 27 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 (Sofosbuvir) and its combinations under its brands HEPCINAT and HEPCINAT LP 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

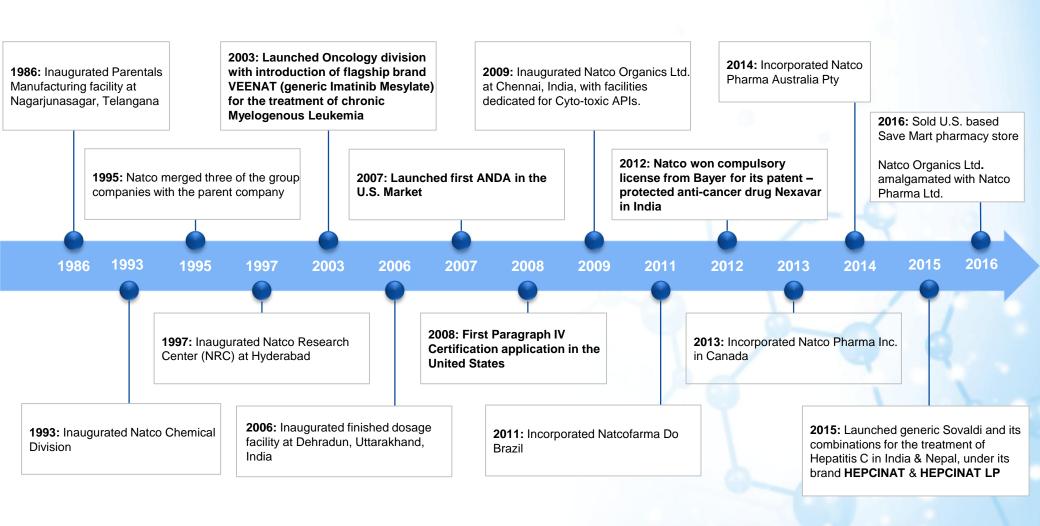








# **Company Evolution**





# **Key Business Segments**

#### **Formulations API Others** (Domestic & Exports) **Domestic** International Portfolio of niche and complex Leading Player<sup>1</sup> in India's 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 and other operating income **FY16 Revenue** INR 1580.10 mn INR 2311.20 mn \* INR 6341.96 mn # INR 1627.08 mn # (INRmn) **FY16 Revenue**





Contribution

5

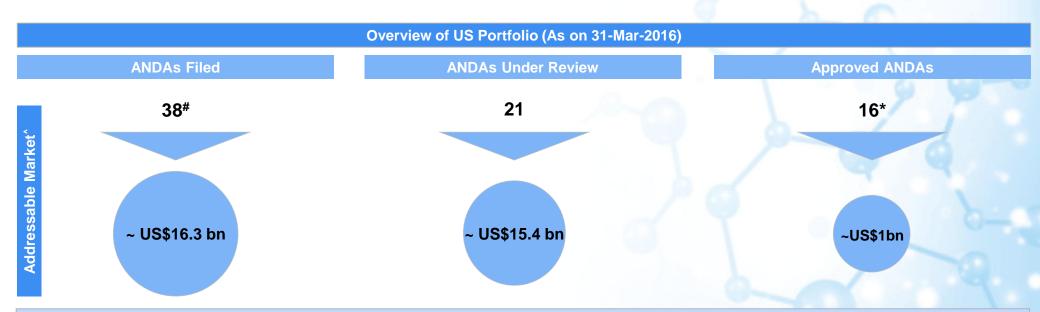
<sup>\*</sup> Including Profit Sharing from marketing partners

<sup>(1)</sup> Source: Report On Pharmaceutical Industry by CARE Ratings, 2015

<sup>#</sup> Gross Rayani

# 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\$16.3 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 Ke	y 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	✓		4,349.60
Gleevac	Imatinib	Cancer - CML	Tablets	✓		2,375.38
Gilenya	Fingolimod	Multiple Sclerosis	Capsules	✓		1,765.16
Treanda	Bendamustine	Leukemia	Injection	✓		709.70
Nuvugil	Armodafinil	Antidepressants	Tablets	✓		482.11
Tamiflu	Oseltamivir Capsules	Influenza Infection	Capsules	✓		402.98
Entocort	Budesonide	Crohn's Disease	Capsules		✓	370.53
Vidaza	Azacitidine	Myelodysplastic syndrome	Injection		<b>✓</b>	238.63
Doxil	Doxorubucin	Cancer, Ovarian	Injection (liposomal)		<b>✓</b>	■ 202.94
Jevtana	Cabazitaxel	Prostate Cancer	Injection	✓		■ 137.28
Fosrenol	Lanthanum Carbonate	End stage renal disease	Tablets	✓		■ 118.56
Tykerb	Lapatinib Ditosylate	Breast Cancer	Tablets	✓		■ 73.89
Revlimid*	Lenalidomide	Multiple Myloma	Capsules	✓		997.94
Nexavar*	Sorafenib	Liver, Kidney 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

Source: IMS; Based on annual sales of products for 12-month period Jan 2015 to Dec 2015 \* Represents REMS product, Market size estimated from respective Innovator's Annual Report



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

### **Mitigation Strategy**

US Market reach and Regulatory Challenges

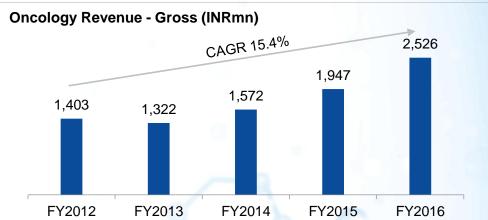
- Adopted and successfully implemented partnership strategy for international formulations product
  - Has product specific partnerships with global generic players at different stages of a potential ANDA filing
  - Entered into de-risked arrangements with marketing partner whereas the partner undertakes 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

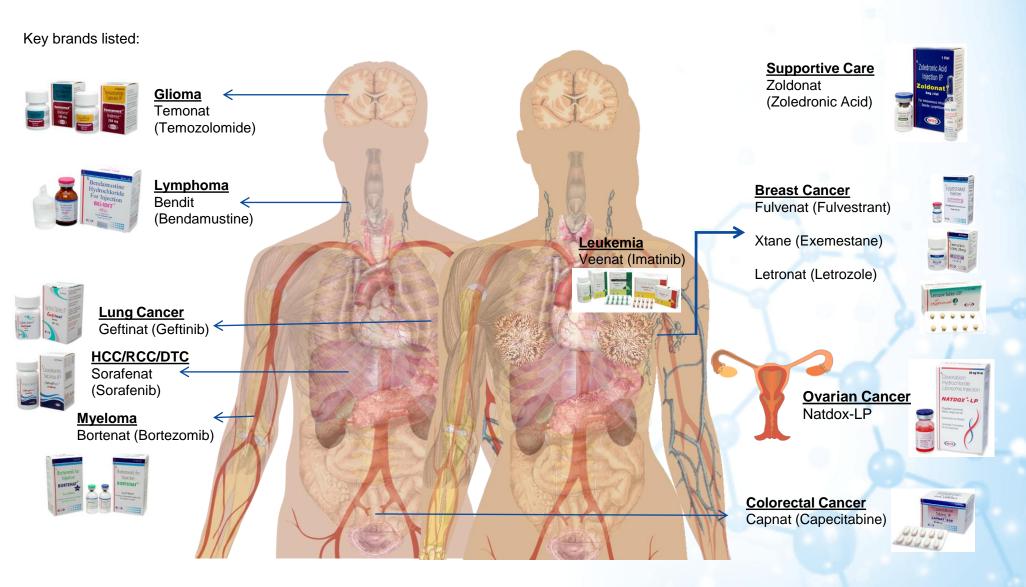


- ✓ Substantial reduction in the treatment cost of Chronic Myeloid Leukemia via launch of generic Imatinib
- ✓ Granted a compulsory license to launch Bayer's patent protected anti-cancer drug Nexavar in India





# 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 amongst the market share leaders in India

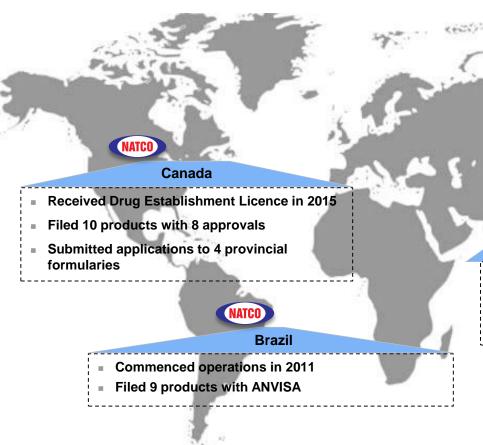
### **Overview of Key Non-Hepcinat Products**

	Products	Active Ingredient	Dosage Form	Therapeutic Area
Deduce and Handle Handl	Natzold	Zoledronic Acid	Infusion Solution	Orthopaedics, Supportive Care
Samuel of	Glatimer	Glatiramer Acetate	Injection	Multiple Sclerosis
Total Sales	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



### NATCO

Asia Pacific (Including Australia)

Products filed-

Singapore: 9 (2 approvals)

Australia: 2 filed

NATCO

### **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**

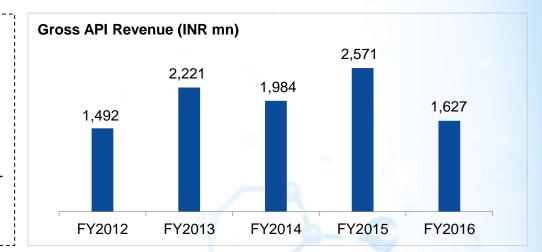
- Indian sub-continent
- Middle East

All data as of March 31, 2016.



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

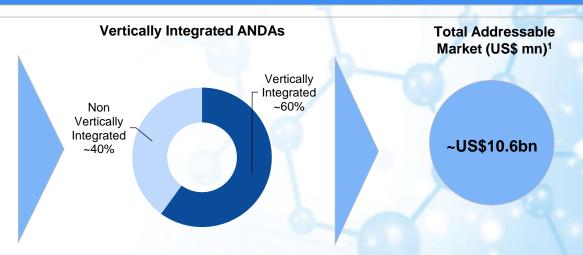
- Strategically important business develops APIs primarily for captive consumption of its FDF portfolio as well as third party sales
- Portfolio of 33 USDMFs with over 16 products under development
- Focuses on complex molecules in oncology and CNS segments
  - Other therapeutic areas of focus includes 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

NATCO

All data as of March 31, 2016.

# 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 two key molecules which are in clinical phase studies - NRC-AN-019 (brain tumour, pancreatic cancer and CML) and NRC-2694 (Breast Cancer); NRC-019 has received orphan drug status in USA

# R&D as % of Standalone Revenue 6.6% 6.4% 7.1% 6.7% FY2013 FY2014 FY2015 FY2016

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 Filed
114 International Patents Granted

177 Indian Patents Filed 81 Indian Patents Granted

All data as of March 31, 2016.



# 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 August 2016

### 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

### Formulations Facility Under Progress

#### **Vishakapatnam Facility**



- Located in a Special Economic Zone (SEZ)
- Capability: Cytotoxic & other Oral Solid Dosages
- Targeted towards US & other International regulated markets

### **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: Last approval August 2016



# **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



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. S.V.V.N.Appa Rao *CFO* 

- 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

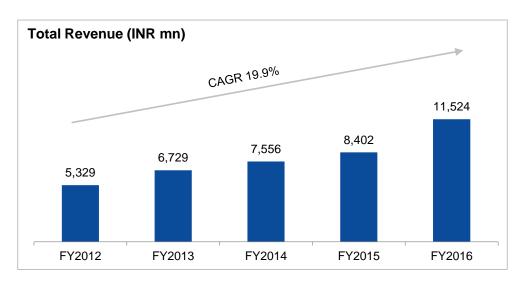


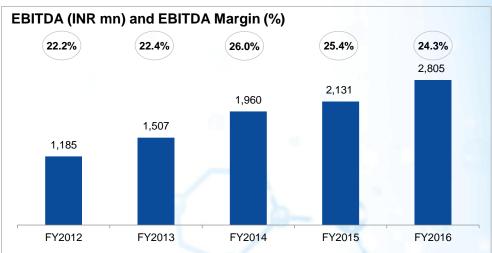
Mr. Rajesh Chebiyam Vice President - Business Development & Corp Support

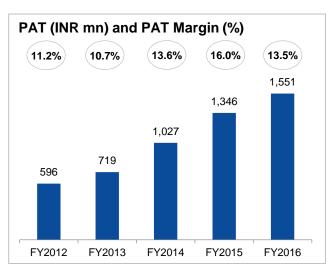
- Holds MBA from Babson College (USA) and Masters degree in Chemical Engineering from University of Rhode Island
- 20+ years of experience across supply chain, operations, business development, sales and strategy

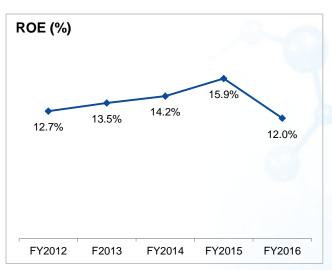


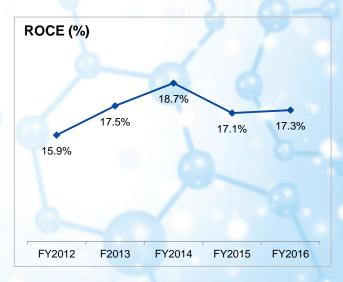
# Demonstrated Track Record of Topline and Earnings Growth













# **Historical Financials**

### Consolidated Profit & Loss Statement (INR Mn)

Particulars	31-	31-	31-
Revenue from operations (gross)	Mar-16 11794	Mar-15 8,382	Mar-14 7,447
Less : Excise duty	378	129	58
Revenue from operations (net)	11,416	8,253	7,389
Other income	108	149	167
Total revenue	11524	8,402	7,556
	11324	0,402	7,550
Expenses			
Cost of material consumed	3,037	1,673	1,601
Purchase of stock in trade	905	843	889
Change in Inventory	(530)	(92)	(158)
Employee benefits	1.867	1,369	1,128
Finance costs	229	317	366
Depreciation	510	473	304
Other expenses	3,441	2,326	2,135
Prior period expenses	0	1	0
Total expenses	9,458	6,908	6,266
Profit before exceptional items and tax	2,066	1,493	1,290
Exceptional item	-	151	-
Profit before tax	2,066	1,342	1,290
Current Tax	448	325	323
Deferred Tax Benefit	31	(310)	(14)
PAT (Before Minority interest)	1,538	1,303	981
Minority Interest	(13)	(43)	(46)
PAT (After Minority interest)	1,552	1,346	1,027

### Consolidated Balance Sheet (INR Mn)

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

### Consolidated Cash Flow Statement (INR Mn)

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



# Historical Financials (contd.)

### Segmental Breakdown (INR Mn)

Revenue Division	Q1 – FY17	Q1 – FY16	Q1 - FY15
API, Domestic	8.2	7.4	51.6
API, Exports	21.2	38.7	29.8
API Gross Revenue	29.5	46.2	81.4
Formulations, Exports	38.6	35.9	35.5
Formulations Onco	73.2	62.4	43.2
Formulations, Brand Pharma Non Onco	134.4	27.5	1.6
Formulations, 3rd party, & miscel	20.9	17.3	4.2
Formulations Gross Revenue	267.1	143.1	84.5
Total Net Revenue (including service income minus excise duty)	282.0	186.2	162.0
Profit sharing Income	12.6	2.7	5.2
Other Operating & Non-Operating Income	19.8	8.0	15.2
Stand-Alone Total Net Revenue	314.4	196.9	182.4
Total Revenue, all subsidiaries	16.0	28.7	29.1
Consolidated Total Net Revenue	330.4	225.5	211.5

### **Consolidated Financial Results (INR Mn)**

	Q1 - FY17	Q1 - FY16	Q1 - FY15
Total Revenues	330.4	225.5	211.5
		100	
EBITDA	82.4	59.1	58.7
EBITDA Margin (%)	24.9%	26.2%	27.8%
PAT, after minority interest	47.7	28.1	33.5
PAT Margin (%)	14.4%	12.5%	15.8%

The Company adopted Indian Accounting Standards ("Ind AS") from 1 April 2016 and prior period figures have been reclassified wherever required to conform to the classification of the current period.



### Q1 – FY17 Highlights

(April – June 2016)



- The High Court of Madras vide its Order dated 28th April, 2016, sanctioned the Scheme of Amalgamation of NATCO Organics Limited, a Wholly Owned Subsidiary of the Company with NATCO Pharma Limited.
- Natco's marketing partner, Mylan Inc. received a tentative approval for its Abbreviated New Drug Application (ANDA) for Sorafenib Tablets, 200mg, with the U.S. Food and Drug Administration (USFDA). This product is the generic version of NEXAVAR®, which is indicated for the treatment of certain types of cancers including unresectable hepatocellular carcinoma and advanced renal cell carcinoma.

### **Financial Highlights**

Oncology

Oncology formulations revenue in India recorded about 17 % growth compared to Q1 of FY16.

**Branded Pharma** 

Branded pharma formulations revenue in India exceeded 300 % growth compared to Q1 of FY16 primarily driven by blockbuster launches of generic Hepatitis C medicines.

**Exports** 

Exports formulations revenue (including profit sharing arrangement) showed a growth of around 30 % compared to Q1 of FY16.

