



RESISTING THE USUAL



NATCO

INVESTOR PRESENTATION

March, 2015



NATCOFARMA Do Brasil Ltda
Brazil

NATCO Pharma (Canada) Inc.
Canada



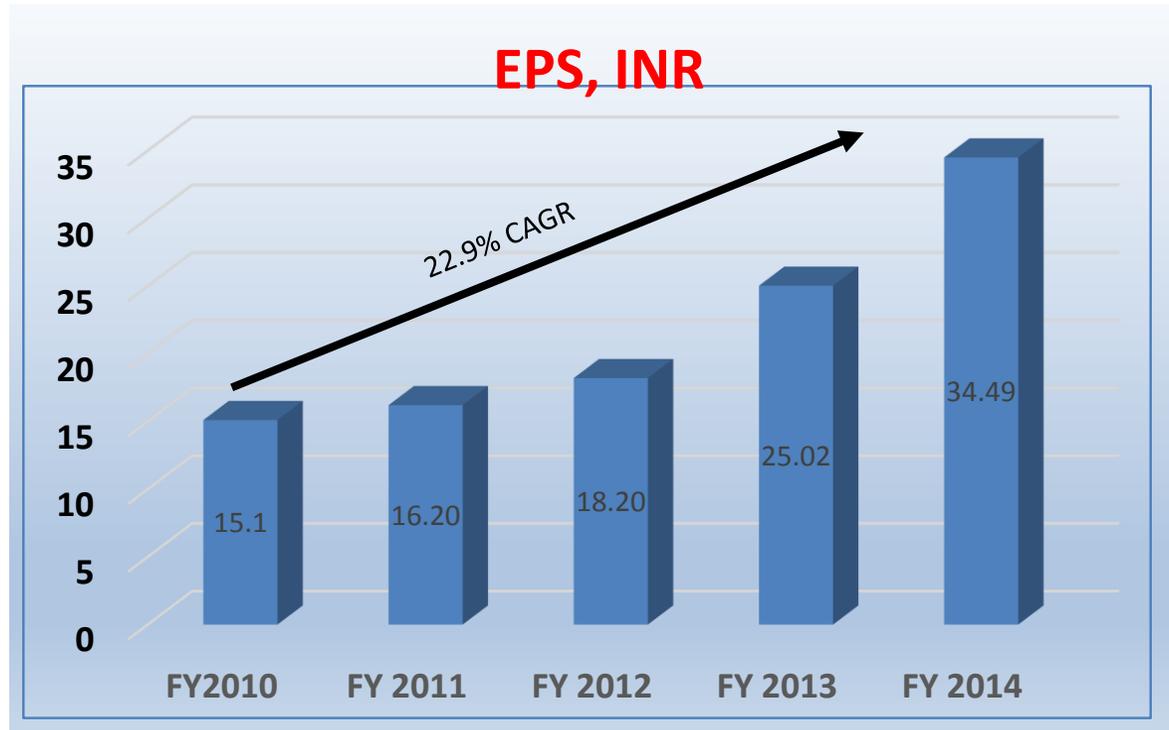
NATCO Pharma Asia Pte Ltd
Singapore

NATCO Pharma Australia Pty Ltd
Australia

NATCO'S MISSION



Quality Medicare at an affordable cost



- Natco at the point of Emergence for sustained long-term growth!
- Solid growth in earning for share-holders over the recent years

- * **Incorporated 1981**
- * **Public listed company**
- * **Revenue**
About \$ 130 million (FY 2013-2014)

- * **Main business**

- ❖ Branded Generics
- ❖ Drug substance Manufacturing
- ❖ Drug Discovery

- * **Approvals**

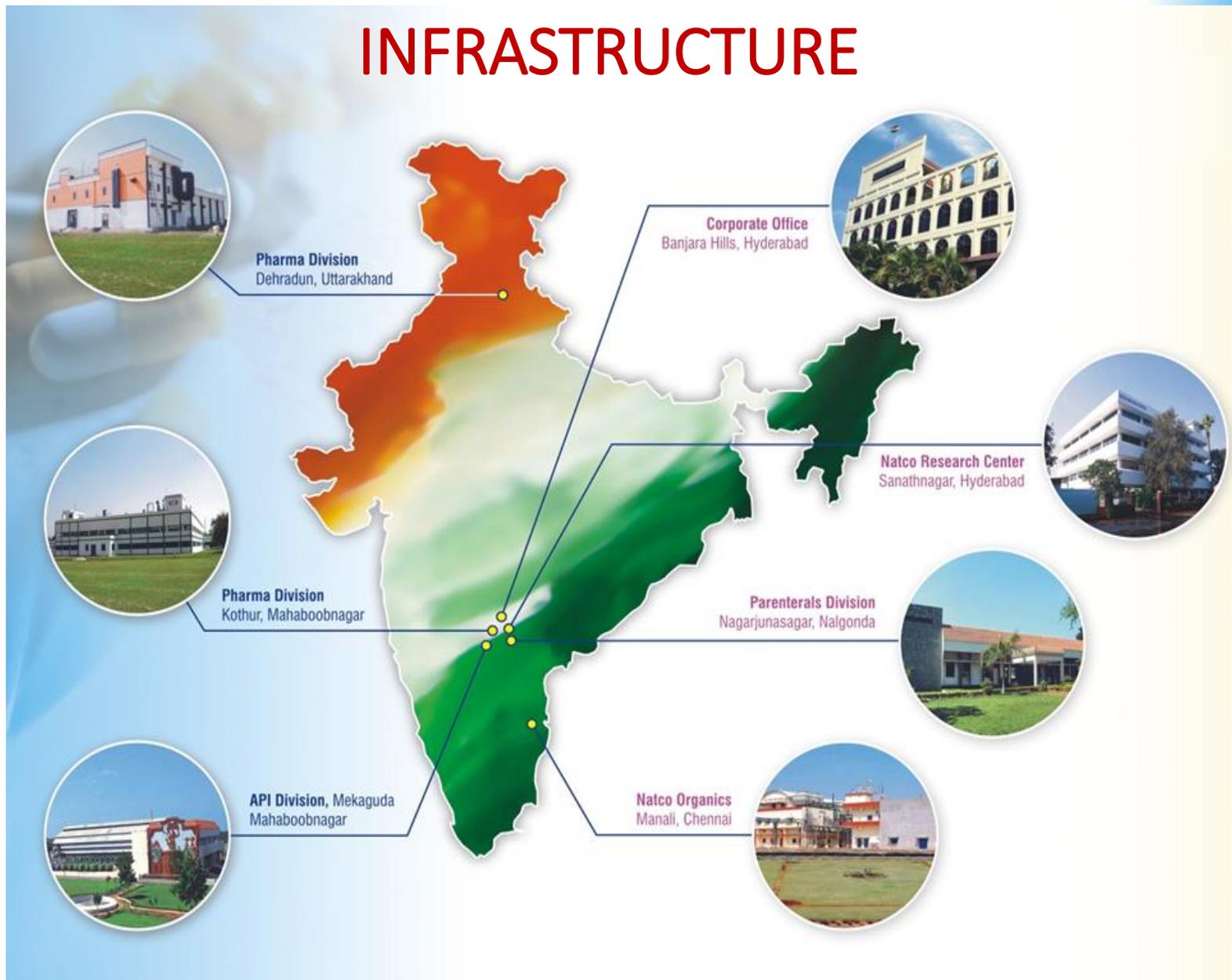
Finished Dosage Plant – USFDA; German Health Authority, Hamburg (EU GMP); TPD Canada; Ministry of Health, Greece; Infarmed, Portugal; ANVISA, Brazil;

API Manufacturing – USFDA; Australia TGA; German Health Authority, Hamburg; Korean Health Authority; PMDA, Japan; Cofepris Mexico.

- * **Total Employees over 3500**



INFRASTRUCTURE



INFRASTRUCTURE- R&D

NATCO

A Center Recognized by DSIR*, India



* Dept of Scientific and Industrial Research

NATCO Research Centre (NRC),
Hyderabad, India

INFRASTRUCTURE- R&D



Function	No. of Laboratories	No. of Scientists
Process Research	12	80
Discovery – NCEs (Anti-cancer segment)	4	15
Analytical development	5	45
Therapeutic Peptides	3	15
Total	24	155

Function	No. of Laboratories	No. of Scientists
New formulation	1	10
Cell biology	1	10
Animal house- Toxicology	1	5
Molecular modeling & RDD	1	5
Total	4	30

Function	No. of Laboratories	No. of Scientists
Biotechnology & Fermentation	3	20
Containment labs for high potency products	2	10
Bio-Analytical lab	1	10
Novel Drug Delivery Systems (NDDS) & nano- pharmaceuticals	2	10
Total	7	50

INFRASTRUCTURE- BULK DRUGS

NATCO

1992

2009

Unit III

Mekaguda Chemical Division



- ▶ Spread over 100 acres, largest API facility

Regulatory Approvals-

- ▶ US FDA
- ▶ Australian TGA
- ▶ EU GMP (German Drug Authority)
- ▶ ISO:14001 certified

NATCO Organics

Facility for Cytotoxic APIs at Chennai



- Zero-discharge plant w/ RO plant converting wastewater into potable water

Kothur Formulation Units

NATCO

1983

1998

2009

2012

Unit I

Oral Solid Dosage Forms



Unit IV

Oral Solid Dosage Forms



Unit V

OSDs & Parenterals (Cytotoxic)



Unit VA

OSDs (Non-Cytotoxic)



USFDA; German Health Authority, Hamburg (EU GMP); TPD Canada;
Ministry of Health, Greece; Infarmed, Portugal;
ANVISA, Brazil;

* OSDs – Oral Solid Dosages

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Other Formulation Units

1986



Unit II

Parenteral Formulation facility
at Nagarjuna Sagar



2006



Unit VI

OSDs & Parenteral facility
at Dehradun



2009



Unit VII

Oral Solid Dosage Forms
at Dehradun



* OSDs – Oral Solid Dosages

CORE STRENGTH/CAPABILITIES



- ❖ Complex multi-step synthesis & scale-up (50 steps for one speciality gm-scale API)

- ❖ Semi-synthetic fusion technologies
(Fermentation / Biotech / Synthetic / Separation technologies)

- ❖ Containment / High potency APIs

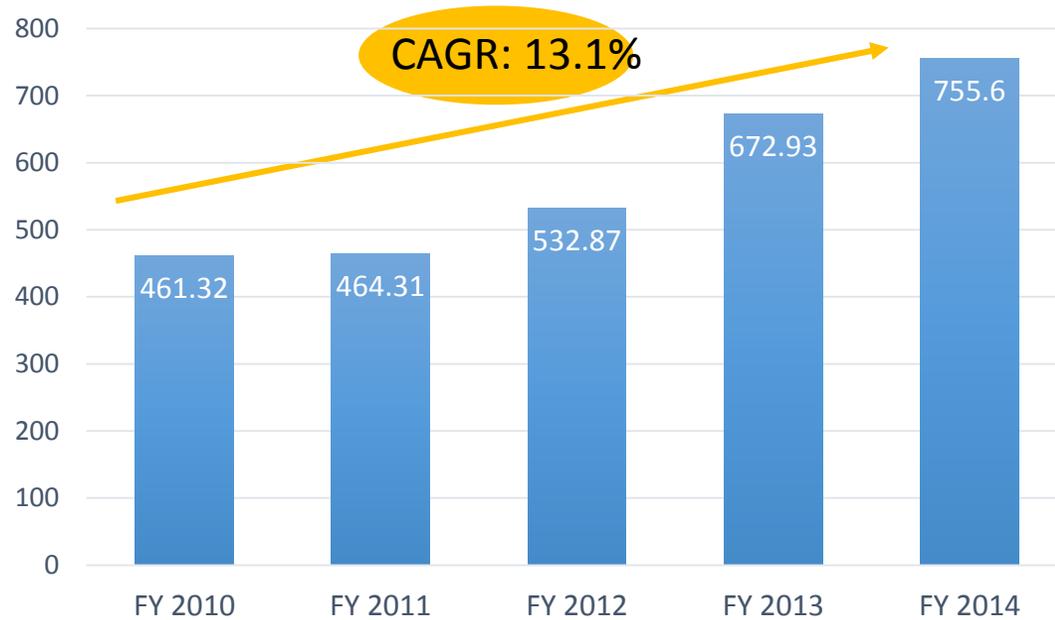
- ❖ Peptide (Solid phase) pharmaceuticals

- ❖ In Formulations,
 - ❖ New Drug Delivery Systems (NDDS) strength
 - ❖ Controlled Release Formulations

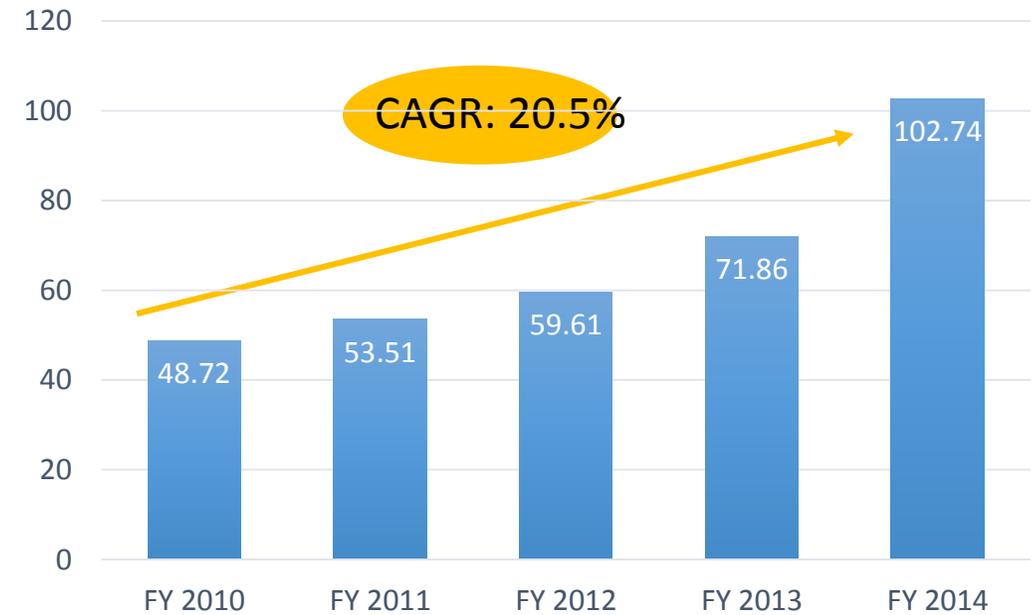
Historical Financial Performance



REVENUE (Crore Rupees)



NET PROFIT (Crore Rupees)



NATCO: STRATEGY



Technology

- Focus on limited hard/complex molecules with targeted markets(USA & Europe) & careful supply strategy. File selective ANDAs

Domestic

- Sustain Leadership position in Oncology
- Strengthen existing business & Institutional sales
- Expand portfolio into other therapeutic areas

International

- Continued focus on entry into regulated markets through strong marketing associations
- Expand to new geographical territories- Brazil, Canada, Singapore, China, etc.

First company in India to obtain compulsory license under the Indian Patent Act



Sorafenib Tosylate is used in the treatment of Liver and Kidney cancers

→ Nexavar, Innovator's Price (Bayer) : Rs. 2.84 lakhs for a one-month therapy

→ NATCO's Price : Rs. 8,800 for a one-month therapy

Estimated number of Liver cancer patients in India : 20,000

Estimated number of Kidney cancer patients in India : 9,000

FINISHED DOSAGE FORMULATIONS (FDPF)

Leading Domestic segment: Oncology

- Entered the segment with launch of Veenat (Imatinib generic version)
- Launched in quick succession, medicines for Breast, Brain, Bone, Lung, and Ovarian Cancers
- Today, Natco holds >25% of market share in their operated portfolio of products in India
- Driven by the motto “No one goes without medicines for want of money”. Natco thrives on decisive therapeutic options affordable to the patients through innovative processes
- The logistics network in India is well knit with about 150 marketing personnel & around 400 distributors in strategic points to ensure easy accessibility all over the country

NATCO, DOMESTIC- ONCO

NATCO

Glioma

TEMONAT (TEMOZOLOMIDE)

Ovarian Cancer

NATDOX-LP

Lymphoma

BENDIT
(BENDAMUSTINE)

Prostate Cancer

X-TRANT
(ESTRAMUS
TINE)

Leukemia

VEENAT (IMATINIB)

Lung Cancer

GEFTINAT (GEFTINIB)

Breast Cancer

ANASTRONAT
(ANASTRAZOLE)

HCC/RCC/DTC

SORAFENAT (SORAFENIB)

Supportive Care

ZOLDONATE
(ZOLEDRONIC ACID)

Myeloma

BORTENAT
(BORTEZOMIB)

Colorectal Cancer

CAPNAT (CAPECITABINE)

HEPCINAT (Sofosbuvir) Domestic Market



2015

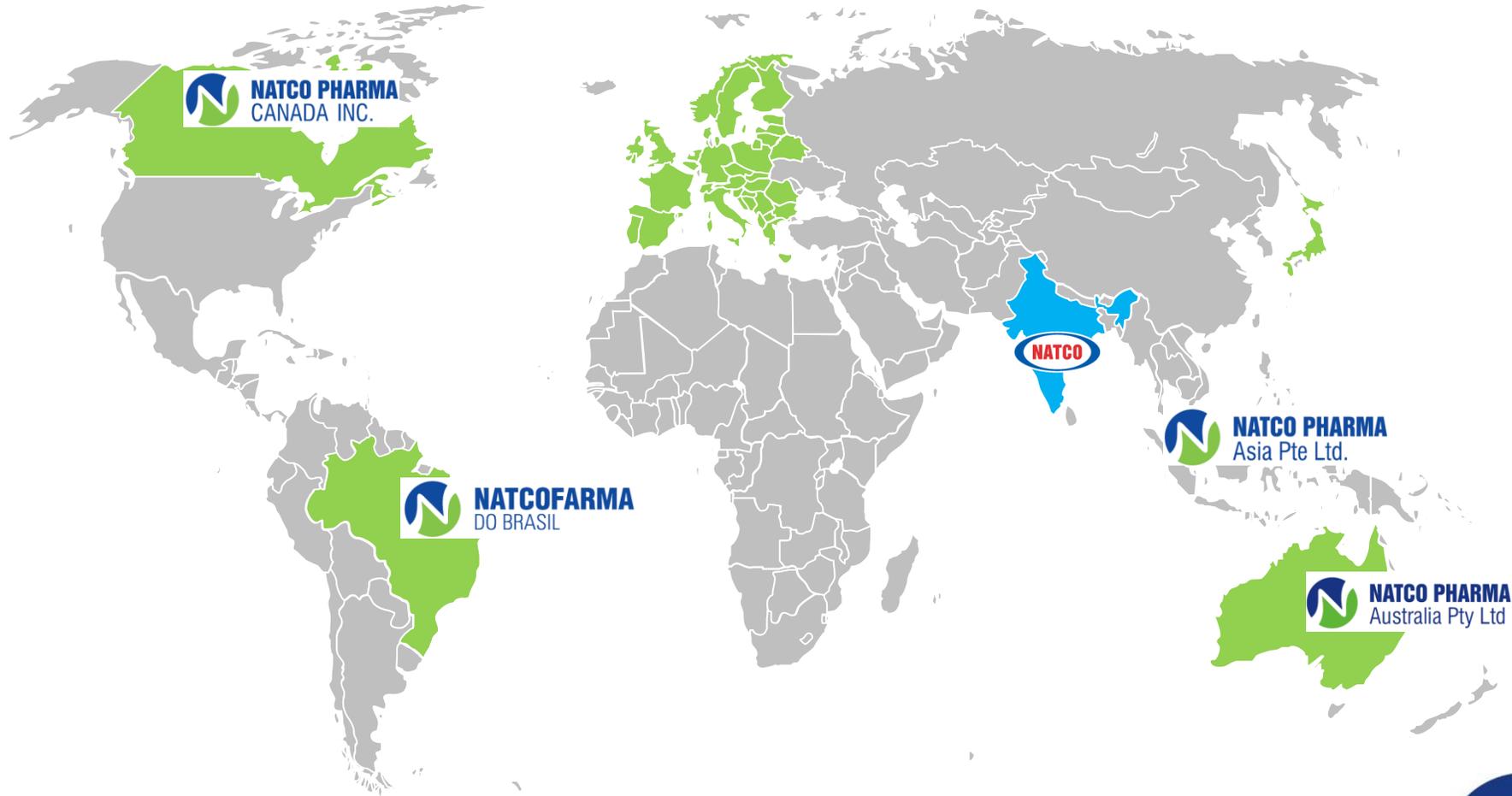
Innovator Brand Name	Name of the Active Ingredient	Dose Form
Sovaldi	Sofosbuvir	Tablets

- Estimated patients with Hep C in India: 15 million
- Non-exclusive licensing agreement with Gilead Sciences, Inc for 91 countries including India
- Competitive landscape



NATCO, INTERNATIONAL (Subsidiaries)

WIDENING THE MARKET



Our Subsidiaries

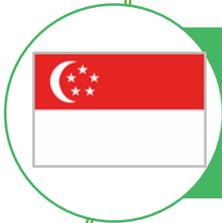
NATCO



Natcofarma do Brazil commenced operations in 2011, currently over 40 employees with 3 business divisions (Pharma, OTC & Distribution)



NATCO Pharma (Canada) established in 2012 with regulatory, sales & marketing, customer service capabilities



NATCO Asia established with Singapore as head quarter, product registrations initiated



NATCO Pharma Australia incorporated in September 2014; product registrations commenced

Our Key US Partners

NATCO



PIPELINE: Para IV filing (USA market)

S. No	Innovator Brand Name	Name of the Product	Dose Form	FTF	Market Size (Millions)
1	Fosrenol	Lanthanum Carbonate	Tablets	Yes	\$ 125
2	Copaxone	Glatiramer Acetate	PFS	No	\$ 3,000
3	Revlimid	Lenalidomide	Capsules	Yes	\$ 3,500
4	Tamiflu	Oseltamivir	Capsules	Yes	\$ 600
5	Tykerb	Lapatinib	Tablets	No	\$ 125
6	Nuvugil	Armodafinil	Tablets	No	\$ 450
7	Treanda	Bendamustine	Injection	Yes	\$ 600
8	Jevtana	Cabazitaxel	Injection	Yes	\$ 120
9	Zortress	Everolimus, Lower Strength	Tablets	Yes	\$ 30
10	Gilenya	Fingolimod	Capsules	Yes	\$ 1,200
11	Nexavar	Sorafenib Tosylate	Tablets	Yes	\$ 48

Market Size Estimates, per IMS. Actual Sales data could vary

PIPELINE: Para III filing (USA market)



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S. No	Innovator Brand Name	Name of the Product	Dose Form	Market Size (Millions)	Likely Launch Year
1	Prevacid	Lansoprazole OTC	Capsules	\$ 300	2015
2	Entocort	Budesonide CR	Capsules	\$ 400	2016
3	Vidaza	Azacitidine	Injection	\$ 315	2016
4	Tracleer	Bosentan	Tablets	\$ 585	2016

COPAXONE (Glatiramer)



2015

Name of the Product / Molecule	Innovator brand name	Dosage Form	Therapeutic use	Status of P-IV /First to File	Patent Litigation Status	ANDA ownership	Date of Approval
Glatiramer prefilled injection	Copaxone of Teva	Pre Filled Injection	Multiple Sclerosis	Para IV	In process	Mylan	Not yet approved

- Exclusive supply agreement with Mylan, Inc., for generic version of Copaxone (Glatiramer Acetate)
- Expecting 2015 launch (ANDA approval awaited)
- Competition:
 - Sandoz & Momenta
 - DRL and Synthon

Global Mkt
estimated US\$5 B
USA mkt- \$3.0B



Revlimid (Lenalidomide)



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Name of the Product / Molecule	Innovator brand name	Dosage Form	Therapeutic use	Status of P-IV /First to File	Patent Litigation Status	ANDA ownership	Date of Approval
Lenalidomide	Revlimid of Celgene	Capsules	Multiple Myeloma	Para IV/FTF	Still Due	Natco Pharma Ltd	Not yet approved

Drug used in the treatment of Multiple Myeloma

Global Mkt est
US \$3.0 Billion



Actavis

Fosrenol (Lanthanum Carbonate)



~2015

Name of the Product / Molecule	Innovator brand name	Dosage Form	Therapeutic use	Status of P-IV /First to File	Patent Litigation Status	ANDA ownership	Date of Approval
Lanthanum Carbonate tablets 500mg, 750mg and 1000mg	Fosrenol of Shire US	Tablets	End stage renal disease	Para IV/ FTF	*	Natco Pharma Ltd	Not yet approved

Lanthanum Carbonate

Shared First to file opportunity (Para IV ANDA)	Probable launch in 2015
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Global Mkt est
US \$115 million



Glivec (Imatinib)

2016

Name of the Product / Molecule	Innovator brand name	Dosage Form	Therapeutic use	Status of P-IV /First to File	Patent Litigation Status	EU Dossier ownership	Date of Approval
Imatinib	Novartis	Tablets	CML	NA	No	Helm	Not yet approved

Market size ~ EU \$1.5B & USA 2.1B

Patent expires in most regulated markets of Europe: 2016

Global Mkt est
>US \$4 B



TREANDA (Bendamustine)



2015

Name of the Product / Molecule	Innovator brand name	Dosage Form	Therapeutic use	Status of P-IV /First to File	Patent Litigation Status	ANDA Ownership	EU Dossier ownership	Date of Approval
Bendamustine	Treanda by Cephalon	Vial	Chronic Lymphocytic Leukemia	P-IV	*	BPI	Helm	Not yet approved

- Competitive Landscape (~10 players)
- market size: USA \$600M, EU \$170M
Regulated market approval
- USA- ANDA, Para IV, filed through Breckenridge

Global Mkt est
US \$927 M




Tykerb (Lapatinib)

Name of the Product / Molecule	Innovator brand name	Dosage Form	Therapeutic use	Status of P-IV /First to File	Patent Litigation Status	ANDA ownership	Date of Approval
Lapatinib Tablets	Tykerb of GSK	Tablets	Anti cancer	Para IV/FTF	*	Lupin	Not yet approved

- Litigation yet to start;
- Not yet approved
- Limited Competition

Global Mkt est
>US \$125 M



Tamiflu (Oseltamivir)



Name of the Product / Molecule	Innovator brand name	Dosage Form	Therapeutic use	Status of P-IV /First to File	Patent Litigation Status	ANDA ownership	Date of Approval
Oseltamivir	Tamiflu of Roche Laboratories Inc.	Capsules	Treatment of influenza infection	Para IV/FTF	Pending Infringement suit before federal circuit	Natco Pharma Ltd	Mar 14, 2014 Tentative approval

➤ Patent expires 2017; Limited Competition

Global Mkt est
>US \$500 M



Zortress (Everolimus, LS)



NATCO

Name of the Product / Molecule	Innovator brand name	Dosage Form	Therapeutic use	Status of P-IV /First to File	Patent Litigation Status	ANDA ownership	Date of Approval
Everolimus	Zortress of Novartis AG	Tablets	Immuno-suppressant	Para IV/FTF	Pending	Breckenridge	Pending

➤ Limited Competition

USA Mkt est
US \$45 M



Jevtana (Cabazitaxel)



2017

Name of the Product / Molecule	Innovator brand name	Dosage Form	Therapeutic use	Status of P-IV /First to File	Patent Litigation Status	ANDA ownership	Date of Approval
Cabazitaxel	Jevtana by Sanofi	Vial	Hormone-refractory prostate cancer	Para IV	*	BPI	Not yet approved

➤ Limited Competition



USA market size
US \$120M



Gilenya (Fingolimod)

Name of the Product / Molecule	Innovator brand name	Dosage Form	Therapeutic use	Status of P-IV /First to File	Patent Litigation Status	ANDA ownership	Date of Approval
Fingolimod	Gilenya by Novartis	Capsule	Multiple Sclerosis	Para IV	*	*	Not yet approved

➤ Limited Competition



USA market size
US \$1.2B

Nexavar (Sorafenib)



Name of the Product / Molecule	Innovator brand name	Dosage Form	Therapeutic use	Status of P-IV /First to File	Patent Litigation Status	ANDA ownership	Date of Approval
Sorafenib	Nexavar by Bayer; Onyx	Tablets	Kidney & Liver Cancer	Para IV	*	Mylan	Not yet approved

➤ Limited Competition



USA market size
US \$48M



Intellectual Property & Regulatory Filings

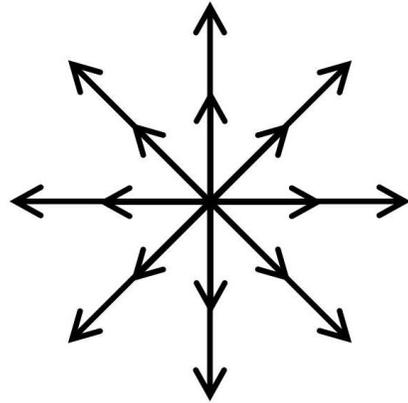


80 Indian patents granted

77 International patents granted

30 USDMFs filed

10 USDMFs under filing



161 total Indian patents filed

298 total International patents filed

34 ANDAs filed

22 ANDAs under review

Discovery & Development of NRC-019 & NRC2694



NRC-019: Chronic Myeloid Leukemia
works on Imatinib resistant strains

- Glioblastoma
- Pancreatic

Orphan Drug status
granted to NRC 19 –
for three indications

NRC-2694: NSCLC resist strains
HER-2 (+) Breast cancer

Evaluating feasibility of
Phase I Clinical trials

- NATCO is at the point of Emergence for a sustainable growth phase
 - Strong pipeline of products for next 5 years
- Technology focus on 'selective' and complex molecules for regulated markets in USA & Europe
- Strong domestic (India) position in Oncology market
- Expansion to new geographies- Canada, Brazil, Singapore, China, etc.

Thank You



NATCO



Forward-looking statements

This document contains statements about expected future events and financial and operating results of Natco Pharma Limited.

By their nature, forward-looking statements require the Company to make assumptions and are subject to inherent risks and uncertainties. There is significant risk that the assumptions, predictions and other forward-looking statements will not prove to be accurate.

Readers are cautioned not to place undue reliance on forward-looking statements as a number of factors could cause assumptions, actual future results and events to differ materially from those expressed in the forward-looking statements.

Accordingly, this document is subject to the disclaimer and qualified in its entirety by the assumptions, qualifications and risk factors.