

RESISTING THE USUAL...

NATCO PHARMA LIMITED

INVESTOR PRESENTATION
September, 2014



Tradition of TRUST & RELIABILITY



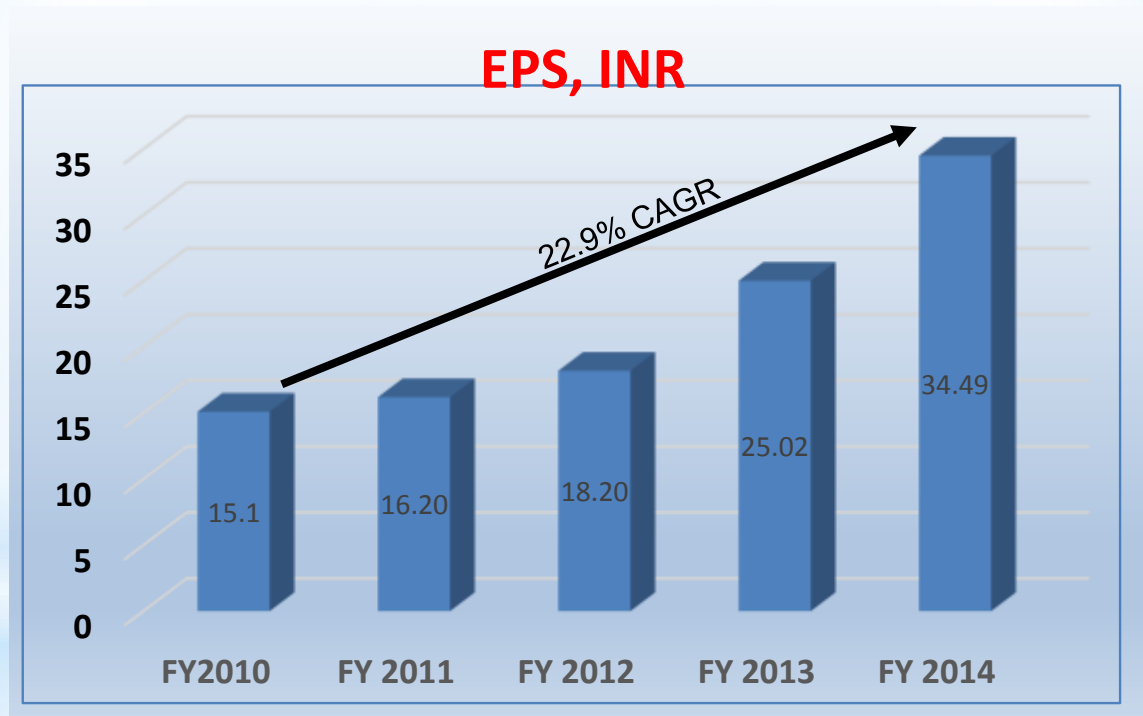
Disclaimer

Except for the historical information contained herein, statements in this presentation and the subsequent discussions, which include words or phrases such as “will”, “aim”, “will likely result”, “would”, “believe”, “may”, “expect”, “will continue”, “anticipate”, “estimate”, “intend”, “plan”, “contemplate”, “seek to”, “future”, “objective”, “goal”, “likely”, “project”, “should”, “potential”, “will pursue” and similar expressions or variations of such expressions 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, obtain regulatory approvals, our provisioning policies, technological changes, investment and business income, cash flow projections, our exposure to market risks as well as other risks. NATCO Pharma Limited does not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date thereof.



NATCO'S MISSION→

Quality Medicare at an affordable cost



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



NATCO GROUP

- * **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 – US FDA, MHRA, German Health Authorities
 - API Manufacturing – US FDA, TGA, German Health Authorities,
Iran GMP, Korean FDA & Mexican FDA.
- * **Total Employees ~3000**



INFRASTRUCTURE



INFRASTRUCTURE- R&D

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- FORMULATIONS

Units 1, 4, 5 & 8 at Kothur
(near Hyderabad)

Unit 6 & 7,
(Dehradun, India)

Unit 2, Parenterals
at Nagarjuna Sagar
(~ 3 hours from Hyderabad)

**Approved by US FDA, UK, MHRA, TGA Australia, Health Canada,
INFARMED Portugal & Byelorussian Health Ministry.**



NATCO

Unit 9, Mirza, Assam

INFRASTRUCTURE- BULK DRUGS



Cyto-toxic Chemicals
Manali, Chennai

Regulatory Approvals-

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

- ▶ Spread over 100 acres, largest API facility



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



Unit 3, API facility
at Mekaguda
(~ 1 hr from Hyderabad)



CORE STRENGTH/CAPABILITIES

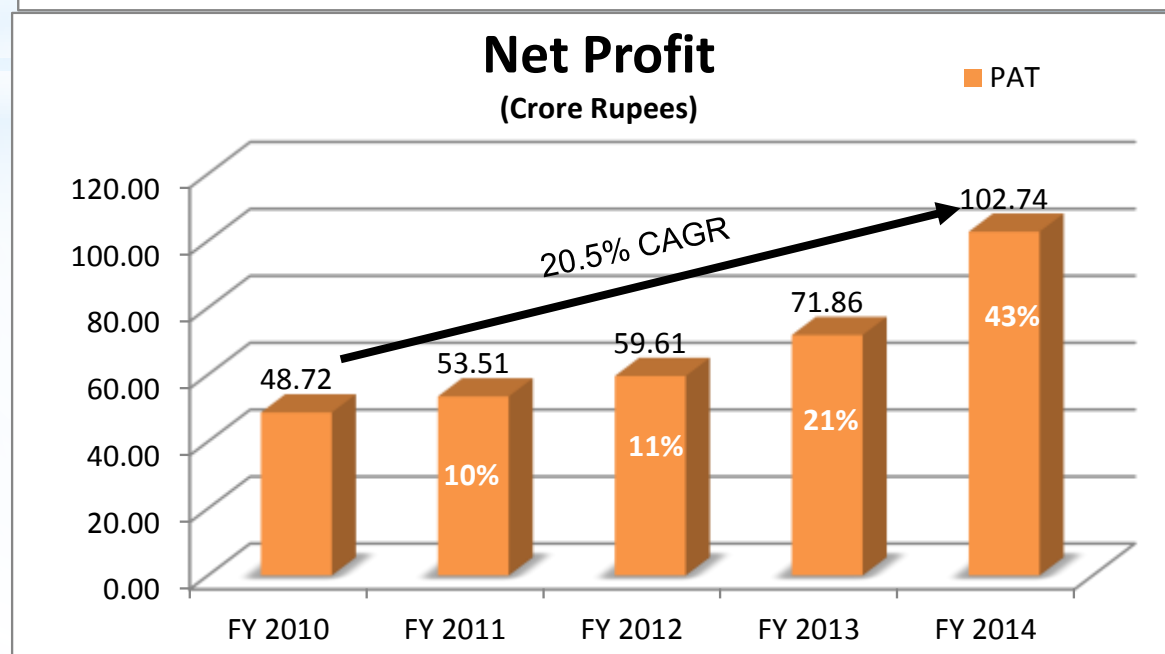
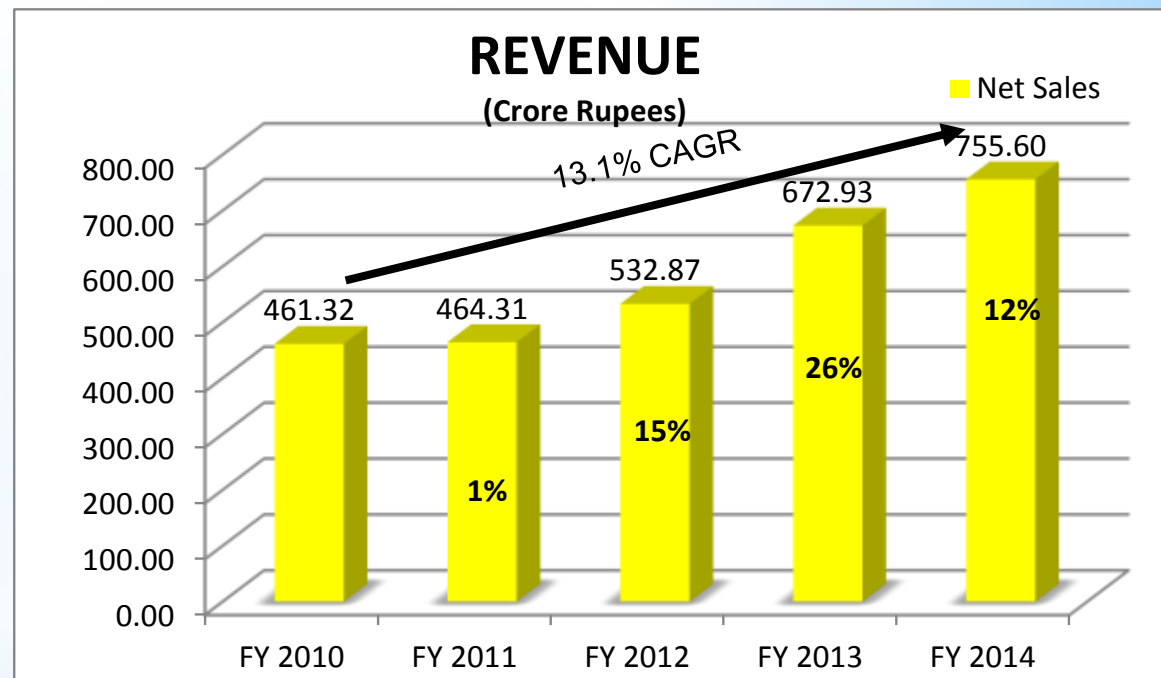
- ❖ Complex multi-step synthesis & scale-up (50 steps for one speciality gm-scale API)
- ❖ Semi-synthetic fusion technologies
(Fermentation / Biotech / Synthetic / Separation technologies)
- ❖ Containment / High potency APIs
- ❖ Peptide (Solid phase) pharmaceuticals
- ❖ In Formulations,
 - ❖ New Drug Delivery Systems (NDDS) strength
 - ❖ Controlled Release Formulations



HISTORICAL

FINANCIAL

PERFORMANCE



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.



NATCO, DOMESTIC

First company in India to obtain compulsory license under the Indian Patents 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



NATCO, DOMESTIC 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

Glioma
TEMONAT (TEMOZOLOMIDE)



Lymphoma
BENDIT
(BENDAMUSTINE)



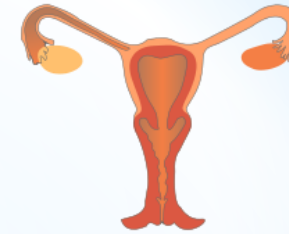
Lung Cancer
GEFTINAT (GEFTINIB)



HCC/RCC/DTC
SORAFENAT (SORAFENIB)



Myeloma
BORTENAT
(BORTEZOMIB)



Ovarian Cancer
NATDOX-LP



Leukemia
VEENAT (IMATINIB)

Prostate Cancer
X-TRANT
(ESTRAMUSTINE)

Breast Cancer
ANASTRONAT
(ANASTRAZOLE)



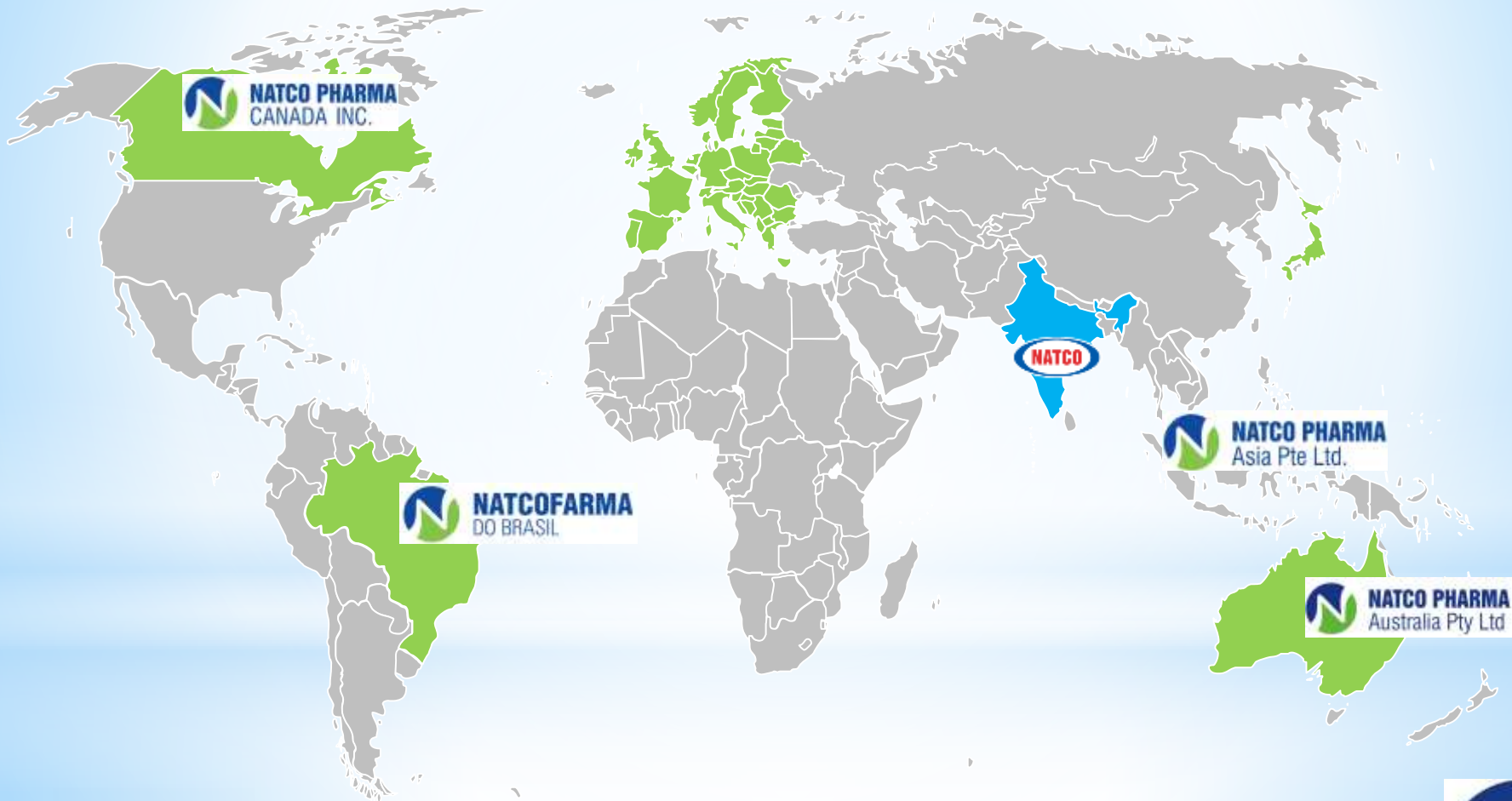
Supportive Care
ZOLDONATE
(ZOLEDRONIC ACID)

Colorectal Cancer
CAPNAT (CAPECITABINE)



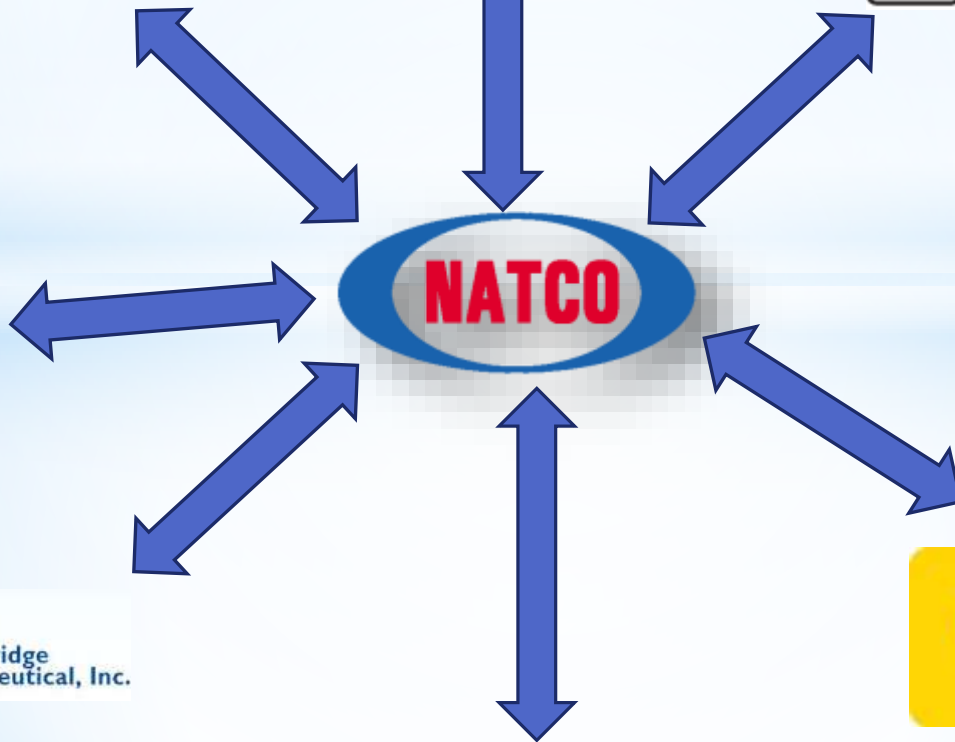
NATCO, INTERNATIONAL (Subsidiaries)

WIDENING THE MARKET



NATCO, INTERNATIONAL

Collaborative Agreements



PIPELINE: Para IV /Complex molecule filing **(USA market)**

S. No	Name of the Product
1	Lanthanum Carbonate tablets 500mg, 750mg and 1000mg
2	Glatiramer prefilled injection
3	Lenalidomide capsules 5 mg, 10 mg, 15 mg and 25 mg
4	Oseltamivir Capsules , 75 mg
5	Lapatinib Tablets, 250 mg
6	Armodafinil Tablets
7	Lansoprazole OTC
8	Budesonide
9	Everolimus, Lower Strength

- Additional four molecules, undisclosed, on recent filings



2014

Copaxone (Glatiramer)

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 2014 launch (ANDA approval awaited)

Competition:

Sandoz & Momenta
DRL and Synthon



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



Revlimid (Lenalidomide)

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 capsules 5, 10, 15, 25 mg	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



~2015

Fosrenol (Lanthanum Carbonate)

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



Global Mkt est
US \$115 million



2014

Prevacid (Lansoprazole OTC)

Name of the Product / Molecule & ANDA #	Innovator brand name	Dosage Form	Therapeutic use	Status of P-IV /First to File	Patent Litigation Status	ANDA ownership	Date of Approval
Lansoprazole, 15mg	Prevacid 24 HR of Novartis	DR Capsules	Anti-ulcer	Para III	No	Actavis	Not yet approved

Advantage
Own API

Global Mkt est
US \$300 million



Glivec (Imatinib) - EUROPE

Name of the Product / Molecule & ANDA #	Innovator brand name	Dosage Form	Therapeutic use	Year of Approval
Imatinib, 100mg, 400mg	Novartis	Tablets	CML	NA



Europe market size ~ \$1.5B

Patent expires in most regulated markets of Europe: 2016

Global Mkt est
>US \$4 B



2015

TREANDA (Bendamustine)

Name of the Product/ Molecule	Dosage Form	Therapeutic use
Bendamustine injection	Vial	Chronic Lymphocytic Leukemia

Competitive Landscape (~10 players)

Europe market size: \$140M
Regulated market approval

USA- ANDA, Para IV,
filed through Breckenridge

Global Mkt est
US \$860 M



2016

Entocort (Budesonide)

Name of the Product / Molecule	Innovator/ brand name	Dosage Form	Therapeutic use
Budesonide	Astrazeneca/ Entocort	Capsule	Crohn's Intestine disease

Limited Competition



USA market size
US \$400M



TYKERB (Lapatinib)

Name of the Product / Molecule & ANDA #	Innovator brand name	Dosage Form	Therapeutic use	Status of P- IV /First to File
Lapatinib Tablets, 250 mg (203007)	TYKERB of GSK	Tablets	Anti cancer	Para IV/ FTF

**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 Capsules , 75 mg Amendment – 30 and 45 mg	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)

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, 0.25 mg, 0.5mg, 0.75mg	Zortress of Novartis AG	Tablets	Immuno-suppressant	Para IV/ FTF	Pending	Breckenridge	Pending

Limited Competition

USA Mkt est
US \$45 M





Regulated Market FILINGS

Area	Granted		Application	
	India	Foreign	India	Foreign
NCE	1	65	7	114
API	64	10	68	73
Formulation	15	2	6	34
Total	80	77	81	221

<u>Therapeutic Segment</u>	DMF, USA
Oncology	12
Anti Depressant	3
Anti Migraine	6
GI-Disorders	3
Others	12
Total	36

31 ANDA's filed

21 ANDA's under review

EUROPE:
ASMF- 31
CEP- 10 (9 approved)



Natco has also filed in several other ROW countries

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



KEY TAKE-AWAYS

- 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