

# Natco Pharma (NATPHA)

₹ 952

## USFDA approves gCopaxone for both strengths

In a positive development for Natco, the USFDA has approved the generic version of Teva's Copaxone (Glatiramer Acetate) for both 20 mg/ml (once a day dosage) and 40 mg/ml (three times a week dosage) strengths. The product will be marketed by Mylan in the US. The drug is used to treat relapsing form of multiple sclerosis (MS). While patent for 20 mg/ml has expired on May 5, 2014 the subsequent five patent filed by Teva for the 40 mg/ml strength are supposed to expire in 2030. As per IMS, the brand sales for the Copaxone in the US were at US\$700 million and US\$3.6 billion, for the 20 mg/ml and 40mg/ml, respectively. Due to the successful transition of the MS treatment from the 20 mg/ml strength to 40 mg/ml, Teva continues to dominate the MS market, earning 96% of the overall MS revenues. In September 2009, Mylan had filed a Copaxone 20 mg/ml ANDA with USFDA. Natco/Mylan are second filers for the gCopaxone 20 mg/ml after Sandoz/Momenta.

Teva and Yeda (the innovator of the drug), post the launch of 40 mg/ml strength, have filed patent infringement suits in relation to US patents in a US District Court (Delaware) against Mylan, Momenta, Sandoz, Amneal, Dr Reddy's, Synthon, and Pfizer (Natco was later dismissed from the complaint). The US District Court on January 30, 2017 announced that all asserted claims by Teva and Yeda for four of the five patents in 40 mg/ml to be invalid for obviousness. Post the decision of the US District Court, Teva and Yeda has appealed the District Court's decision to the US Court of Appeals. The future of the Plaintiff's 40 mg/ml Copaxone is now heavily dependent on the decision of the Court of Appeals.

In a separate set of events, the US Patent Trial and Appeal Board (PTAB) held that Mylan and Amneal were able to show that three of the five patents were un-patentable. However, both parties can further raise the PTAB decision in the Court of Appeals.

### Exhibit 1: Chronology of Events

Year	Event
1987	Yeda Grants exclusive worldwide license to Teva to develop Copaxone
2002	Teva gets USFDA approval for 20 mg/ml single dose prefilled syringes
2008	Mylan enters in to license and supply agreement with Natco Pharma for gCopaxone
2009	Mylan files ANDA for generic Copaxone (20 mg/ml strength)
2010	Teva files complaint against Mylan in the US District Court against 4 patent infringement of Copaxone 20mg/ml
2014	Mylan files ANDA for generic Copaxone (40 mg/ml strength)
2015	Teva and Yeda file patent infringement suits against Mylan and other generic players
2015	Mylan and Amneal file petition in US patent office against 3 patents of Copaxone 40 mg/ml
2017	Mylan granted USFDA approval for both gCopaxone 20 mg/ml and 40 mg/ml strength

Source: Company, IMS, ICICIdirect.com Research

### Approval vindicates Natco's capability in complex generics

After a wait of almost eight years, the company has received approval for this complex product. We believe this will be a huge sentimental booster for the company after tanking almost ~30% from its high apparently due to suspense over approval. We expect 20 mg/ml product to be launched soon while the 40 mg/ml product may be launched in FY19. Natco will supply the drug under cost plus profit sharing agreement and Mylan will market it in the US. We arrive at an NPV per share of ₹ 37 and ₹ 253 for the 20 mg/ml and 40 mg/ml, respectively, leading to an overall price target of ~₹ 1065 on an SOTP basis. We upgrade our rating to **BUY**. Any unfavourable decision for Mylan by the US Court of Appeals and incremental USFDA approvals to other players are likely limiting factors to our revised target.

### Rating matrix

Rating	: Buy
Target	: ₹ 1065
Target Period	: 12-15 months
Potential Upside	: 12%

### What's Changed?

Target	Changed from ₹ 955 to ₹ 1065
EPS FY18E	Changed from ₹ 25.5 to ₹ 26.4
EPS FY19E	Changed from ₹ 16 to ₹ 15.8
Rating	Changed from Hold to Buy

### Key Financials

(₹ crore)	FY16	FY17E	FY18E	FY19E
Revenues	1149.2	2049.9	2124.0	1930.5
EBITDA	269.8	668.2	675.8	442.6
Net Profit	157.8	470.9	460.3	276.4
EPS (₹)	9.0	27.0	26.4	15.8

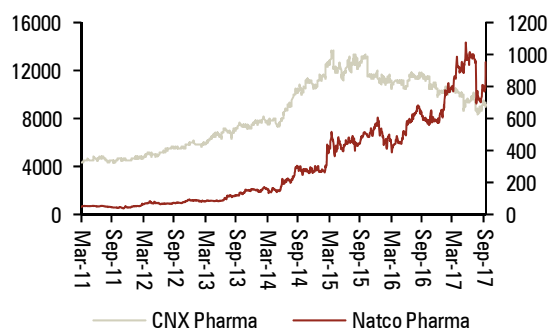
### Valuation summary

	FY16	FY17E	FY18E	FY19E
PE (x)	105.0	105.0	36.1	60.1
Target PE(x)*	43.8	14.7	15.0	25.0
EV to EBITDA (x)	61.7	61.7	24.9	37.6
Price to book (x)	12.8	12.8	8.4	7.6
RoNW (%)	12.2	12.2	23.2	12.6
RoCE (%)	16.0	16.0	28.1	16.0

### Stock data

Particular	Amount
Market Capitalisation	₹ 16601 crore
Debt (FY17)	₹ 222 crore
Cash (FY17)	₹ 24 crore
EV	₹ 16798 crore
52 week H/L (₹)	1090/495
Equity capital	₹ 34.9 crore
Face value	₹ 2

### Price Chart



### Research Analyst

Siddhant Khandekar  
siddhant.khandekar@icicisecurities.com  
Mitesh Shah  
mitesh.shah@icicisecurities.com  
Harshal Mehta  
harshal.mehta@icicisecurities.com

**Exhibit 2: Copaxone 40 mg/ml Patent Litigation**

Nos	Patent	Patent Expiry	PTAB/ District court decision	Current status
1	US8232250	19/08/2030	District Court: Held invalid	District Court: Decision appealed to the Court of Appeals
2	US8399413	19/08/2030	PTAB: Held unpatentable	PTAB: Decision to be reheard
3	US8969302	19/08/2030		
4	US9155776	19/08/2030	District Court: Held invalid PTAB: Filed inter partes review	District Court: Decision appealed to the Court of Appeals
5	US9402874	19/08/2030	District Court: Infringement suit filed	District Court: Ongoing

*Source: USFDA, IMS, ICICIdirect.com Research*

## Financial summary

Profit and loss statement		₹ Crore			
(Year-end March)	FY16	FY17E	FY18E	FY19E	
Revenues	1,149.2	2,049.9	2,124.0	1,930.5	
Growth (%)	39.3	78.4	3.6	-9.1	
Raw Material Expenses	329.2	627.3	608.6	579.1	
Employee Expenses	184.2	242.7	269.6	306.1	
Other expenses	366.1	511.7	570.0	602.6	
Total Operating Expenditure	879.5	1,381.7	1,448.2	1,487.9	
EBITDA	269.8	668.2	675.8	442.6	
Growth(%)	26.4	147.7	1.1	-34.5	
Depreciation	50.9	54.4	60.0	84.2	
Interest	22.9	18.4	25.6	11.7	
Other Income	9.7	13.9	15.7	18.6	
PBT	206.2	609.3	605.9	365.3	
Total Tax	49.2	139.4	144.4	87.7	
PAT before MI	156.9	469.9	461.5	277.6	
Minority Interest	-1.4	-1.1	1.2	1.2	
Adjusted PAT	157.8	470.9	460.3	276.4	
Growth(%)	4.3	198.4	-2.3	-40.0	
EPS (Adjusted)	9.0	27.0	26.4	15.8	

Source: Company, ICICIdirect.com Research

Cash flow statement		₹ Crore			
(Year-end March)	FY16	FY17E	FY18E	FY19E	
Profit/(Loss) after taxation	158.3	470.9	460.3	276.4	
Add: Depreciation	50.9	54.4	60.0	84.2	
(Inc)/dec in Current Assets	-296.7	-253.2	-87.4	89.9	
Inc/(dec) in CL and Provisions	195.6	10.4	70.6	-32.9	
CF from operating activities	108.1	282.5	503.5	417.6	
(Purchase)/Sale of Fixed Assets	-137.3	-298.5	-350.0	-180.0	
(Increase)/Decrease in Investmen	-19.3	-11.2	-20.0	-20.0	
Others	0.5	14.4	1.2	1.2	
CF from investing activities	-156.2	-295.2	-368.8	-198.8	
Inc / (Dec) in Equity Capital	317.1	0.1	0.0	0.0	
Inc / (Dec) in Loan	-4.8	14.1	0.0	0.0	
Dividend & Dividend tax	-23.1	-117.7	-115.1	-69.1	
Others	-209.4	95.6	0.0	-100.0	
CF from financing activities	79.8	-8.0	-115.1	-169.1	
Net Cash flow	31.8	-20.7	19.7	49.8	
Opening Cash	13.4	45.1	24.4	44.1	
Closing Cash	45.1	24.4	44.1	93.8	
Free Cash Flow	-29.2	-16.0	153.5	237.6	

Source: Company, ICICIdirect.com Research

Balance sheet		₹ Crore			
(Year-end March)	FY16	FY17E	FY18E	FY19E	
Equity Capital	34.8	34.9	34.9	34.9	
Reserve and Surplus	1,263.5	1,603.1	1,948.3	2,155.6	
Total Shareholders funds	1,298.3	1,638.0	1,983.2	2,190.5	
Total Debt	98.4	221.6	221.6	121.6	
Deferred Tax Liability	14.4	15.0	15.0	15.0	
Minority Interest / Others	5.7	4.9	6.1	7.3	
Long Term Provisions	12.5	21.9	21.9	21.9	
Total Liabilities	1,429.3	1,901.4	2,247.8	2,356.3	
Gross Block - Fixed Assets	977.2	1,154.3	1,504.3	1,684.3	
Accumulated Depreciation	272.6	327.0	387.0	471.2	
Net Block	704.6	827.3	1,117.3	1,213.1	
Capital WIP	211.8	336.3	336.3	336.3	
Total Fixed Assets	916.4	1,163.6	1,453.6	1,549.4	
Net Intangible Assets	8.9	5.8	5.8	5.8	
Investments	21.0	32.2	52.2	72.2	
Inventory	357.3	348.9	585.2	527.5	
Debtors	261.6	475.2	326.3	294.1	
Loans and Advances	103.8	78.7	78.7	78.7	
Cash	45.1	24.4	44.1	93.8	
Other Current Assets	43.5	116.6	116.6	116.6	
Total Current Assets	811.3	1,043.8	1,150.9	1,110.7	
Creditors	275.5	262.7	333.3	300.4	
Provisions	4.9	1.8	1.8	1.8	
Other Current Liabilities	114.2	140.4	140.4	140.4	
Total Current Liabilities	394.6	404.9	475.5	442.6	
Net Current Assets	416.8	638.9	675.4	668.1	
LT L & A & Other Non CA	66.1	60.9	60.9	60.9	
Application of Funds	1,429.2	1,901.4	2,247.8	2,356.3	

Source: Company, ICICIdirect.com Research

Key ratios					
(Year-end March)	FY16	FY17E	FY18E	FY19E	
Per share data (₹)					
Adjusted EPS	9.0	27.0	26.4	15.8	
BV per share	74.4	93.9	113.7	125.5	
Dividend per share	1.3	6.7	6.6	4.0	
Cash Per Share	2.6	1.4	2.5	5.4	
Operating Ratios (%)					
Gross Profit Margins	71.4	69.4	71.3	70.0	
EBITDA Margins	23.5	32.6	31.8	22.9	
PAT Margins	13.7	23.0	21.7	14.3	
Inventory days	113.5	62.1	100.6	99.7	
Debtor days	83.1	84.6	56.1	55.6	
Creditor days	87.5	46.8	57.3	56.8	
Asset Turnover	1.2	1.8	1.4	1.1	
EBITDA Conversion Rate	40.1	42.3	74.5	94.4	
Return Ratios (%)					
RoE	12.2	28.8	23.2	12.6	
RoCE	16.0	33.0	28.1	16.0	
RoIC	19.0	39.9	33.0	18.6	
Valuation Ratios (x)					
P/E	105.0	35.3	36.1	60.1	
EV / EBITDA	61.7	25.2	24.9	37.6	
EV / Net Sales	14.5	8.2	7.9	8.6	
Market Cap / Sales	14.5	8.1	7.8	8.6	
Price to Book Value	12.8	10.1	8.4	7.6	
Solvency Ratios					
Debt / EBITDA	0.4	0.3	0.3	0.3	
Debt / Equity	0.1	0.1	0.1	0.1	
Current Ratio	1.9	2.5	2.3	2.3	

Source: Company, ICICIdirect.com Research

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**Pankaj Pandey**

**Head – Research**

**pankaj.pandey@icicisecurities.com**

**ICICIdirect.com Research Desk,  
ICICI Securities Limited,  
1st Floor, Akruiti Trade Centre,  
Road No 7, MIDC,  
Andheri (East)  
Mumbai – 400 093  
research@icicidirect.com**

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