Pharmaceuticals



INSTITUTIONAL RESEARCH

Top 10 US focused companies in our coverage:

Company	Reco	TP
Sun Pharma	BUY	640
Lupin	BUY	1,200
Cadila	BUY	525
Dr. Reddy's Labs	NEU	2,340
Cipla	NEU	565
Aurobindo	BUY	740
Alkem Labs	BUY	2,445
Torrent Pharma	BUY	1,590
Glenmark	BUY	710
Alembic Pharma	NEU	535

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Comeback on the cards...

Beleaguered by regulatory clampdowns, channel consolidation in the US and increased competition, earnings of US-focused Indian pharma companies dropped 30% over FY18. Despite the all-too-visible business challenges, they persisted with higher R&D activity (related to complex generics and specialty business), which aggravated the pain. As a result, the NIFTY Pharma index has corrected ~30% over three years (after 30% CAGR over FY11-15).

We believe FY19 may see a gradual comeback for large cap pharma companies, driven by (1) Actual and likely regulatory resolutions, (2) Moderating price erosion and (3) Several product launches across generic and specialty categories in 2HFY19. We believe earnings have bottomed out, while the base is favourable. Upgrade Sun Pharma to BUY.

What has changed?

- 1. <u>US price erosion moderating:</u> Price erosion has been ever-present in the generics business; however, it has historically been in the range of 5-6% vs. the double digit decline witnessed over FY16-18. Except Glenmark, all major players have seen moderating price erosion during 4QFY18 and have guided for stable single digit price decline ahead.
- 2. <u>Diversified manufacturing base:</u> Three years ago, 50% of US revenues of most Indian pharma majors were contributed by two plants. Since then, they have added plants and diversified filings across multiple facilities. Lupin has seven formulation plants now; SUNP has

- built one more injectable plant while the Mohali plant has also received clearance from the US FDA. CDH, ARBP, TRP and ALPM have also scaled up manufacturing base (both in numbers and capability). This has significantly reduced concentration risk with respect to future regulatory adversity.
- 3. R&D as % of sales has topped out: R&D spend for the 10 companies in this note has increased from Rs 72bn in FY15 to Rs 106bn in FY18. Most of them have guided for flattish R&D spend in FY19. Only SUNP and ARBP are likely to see some scale up owing to fresh clinical trials for novel products and bio-similars. However, we expect R&D spend to remain in the range of 8-9% of revenues over the next two years for most companies.
- 4. Lucrative product launches in FY19/FY20: Absence of niche product launches in the US was a key reason why Indian companies did not perform well over FY16-18. But the filing pipe looks rich and mature enough now. FY19 can be a breakthrough year in terms of niche product opportunities. SUNP (Tildra, Sceiera, Yonsa), LPC (Solosec, Levothyroxine, gRanexa), DRRD (gNuvaring, gSuboxone), CDH (gAsacol HD) and ARBP (Ertapenem) will launch several lucrative products in FY19. Inhalers, bio-similars, trans-dermals and niche injectables launches are expected to start from FY20.
- 5. Aided by these factors and a favorable base (GST & US tax impact), we expect earnings to grow 22%YoY in FY19. Valuations are still attractive for key stocks like LPC, ARBP, and GNP. With five big specialty launches in FY19, SUNP will see back ended returns. But looking at enormous market opportunity, we believe it will get factored in very soon.



Summary

Company	Management Commentary	Our view
Sun Pharma	 Low double digit growth in top line in FY18. Specialty business would be new growth engine for SUNP Specialty business to breakeven in FY20. 	 Earlier than expected resolution in Halol provides further comfort on earnings estimates. We believe launches like Iron sucrose, gVagifem and gSandostatin could contain the expected fall in Taro' business. However, specialty business scale up remains key for re-rating. With Halol resolution we have increased the P/E multiple from 20x to 24x. Upgrade to BUY with TP of Rs 640 (24x FY20E).
Lupin	 Single digit growth in top line in FY19. EBITDA margins to be in the range of 18-20% US price erosion is stabilized. 	 Although gSynthroid approval has been delayed to 2HFY19, we expect LPC's US revenues to grow at least in mid-single digit in FY19, along with strong double digit growth in emerging market segments (incl India). With moderated R&D spend (10% of sales) and lucrative opportunities like gRanexa and gSythroid, we expect LPC to largely maintain EBITDA margin in FY19. Maintain BUY with TP of Rs 1200 (20x FY20E)
Cadila	 FY19 top line to grow despite high base in FY18, driven by several key product opportunities. Base business EBITDA margin to improve 100bps YoY. Witnessing single digit price erosion in the US. 	 While competition in gLialda is inevitable, and base effect is likely to play truant in FY19E, we believe that there are still numerous triggers for CDH. Launches like gAsacol HD, gPrevacid ODT, gToprol XL and gExelon (transdermal patch) will compensate significantly for any drop-off in sales of gLialda. We believe CDH merits a premium multiple considering its robust ANDA pipeline and regulatory status. Maintain BUY with a revised TP of Rs 525 (24x on FY20E EPS).



Management Commentary Our view Company The company is likely to complete remediation activities by June-July for both Srikakulam and Duvvada plants. Hence, it is unlikely that we will see The US business should grow with 15+ lucrative approvals coming in from these two plants launches in FY19. in FY19, leading to further erosion in the US base gNuvaring launch delayed to 2HFY19. business. Dr. Reddy's Labs gSuboxone could be an at risk launch upon The niche filings like gNuvaring, gSuboxone and approval. Addressing FDA queries on gCopaxone are also facing challenges on various gCopaxone. fronts, so we are building in these launches in our R&D to be in the range of 11-12% of sales 4QFY19/FY20 estimates. Maintain NEUTRAL with a TP of Rs 2,340 (18x FY20E + 10x on non-core earnings). While the trajectory of the US business is likely to be upwards, we believe that big ticket approvals are likely to come in only from 2HFY19/FY20E. With 3-4 respiratory clinical trials starting in FY19, we The management is confident of one limited expect R&D expenses to increase to 8-9% of sales (v/s competition approval every quarter which ~7% in FY18). This will keep EBITDA margin expansion will drive US revenues in FY19. Cipla in check (~100bps YoY). R&D in FY19 to be 8-9% of sales. On a low base, we foresee 10%/34% Targeting US\$ 1bn sales in India in FY19. revenue/earnings CAGR over FY17-20E. At CMP, valuations remain unsupportive (24.4x FY19E and 18.9x FY20E EPS). Maintain NEUTRAL with a TP of Rs 565 (20x FY20E). Since Unit-4 has been cleared by US FDA, we expect launch momentum to pick up in FY19. The product like Ertapenem, upon approval, would add ~US\$ 60-The mgt also believes that it will continue to 70mn revenues in FY19. deliver strong growth in the injectables Overall, we model 9% top-line growth, 9% EBITDA portfolio in FY19E. growth and 7% earnings growth for ARBP over FY17-Price erosion was 1% QoQ. 20E. At CMP, the stock is trading at 15.3x FY19E and Aurobindo ARBP is guiding for 35+ ANDA launches in 12.4x FY20E. FY19, product opportunities such as While a stock has always traded at significant metoprolol XR, vancomycin and ertapenem discount to peers due to the pure-play generic model, remain key monitorables in 1HFY19. valuations still remains attractive at CMP. Maintain BUY rating, with a revised TP of Rs 732 (16x FY20E).



Company	Management Commentary	Our view
Alkem	 Sees mid to higher single-digit price erosion in general (not for ALKEM specifically). ALKEM is likely to launch 8-9 products in FY19. Mgt commentary on EBITDA margin going forward was cautious, guiding for limited expansion over FY18 margin. 	 Higher R&D spends, increased raw material cost, incremental overheads for fresh capacities will lead to only 50-70bps margin improvement in FY19. The top line growth is likely to be in mid teens driven by double digit growth in both India and the US segments. The long-term story for ALKEM remains on-track and investors should consider any dip in the stock price a an opportunity to add. Maintain BUY with a revised TP of Rs 2,445 (24x FY20E EPS).
Torrent Pharma	 Looking to launch 8-10 products in the US market in FY19, some of which will be 'significant'. The US base business erosion is in single digits. 	 We continue to believe that the UL acquisition has bolstered TRP's standing in the domestic market and will not only help in expanding margins, but will also ensure the sustainability of future cash flows. This will aid TRP's future expansion plans, both organicall and inorganically. Substantial cost synergies are likely to come from lower employee and SG&A spend. Foresee 15%/12% revenue/earnings CAGR over FY17-20E. Maintain BUY with a revised TP of Rs 1,584 (22x FY20E EPS).
Glenmark	 Expects 10-15% top line growth in FY19. Continue to see double digit price erosion in the US. to launch additional 10 products in FY19, which includes 5-6 niche opportunities R&D guidance remains at 11-12%. 	 We continue to believe that GNP's push towards innovation and specialty is strategically sound. However, the capital allocation is weighing heavily of the business. In the absence of lucrative product launches for the US market, the base margins have fallen from 18-19' in FY17 to 13-14% over last two quarters. However, with the recent gWelchol and gProtopic approvals, margins are likely to normalise in 1HFY19. Foresee 6%/10% revenue/earnings CAGR over FY17-20E. Maintain BUY with a revised TP of Rs 710 (16x FY20 and Rs 135/sh for pipeline).



Company	Management Commentary	Our view
Alembic Pharma	 Mgmt guided for higher than market growth for India formulation segment The US business will also grow in FY19. To file 25+ ANDAs this year. The green field oral oncology plant and derma plant are ready to get commissioned in FY19. Filings should start from 4QFY19. Oncology injectable and general injectable plants will also get completed by 1HFY19. 	 We strongly believe that the significant benefits from the recent investments are back-ended and will be realized from 2HFY20. Lucrative ANDA filings in the US will begin only in 4QFY19 and launches thereafter. In the meanwhile, we expect the company's elevated cost structure to keep EBITDA margin under pressure. The impact of this pressure will be exacerbated in FY19 with growing depreciation and interest cost. Especially, when the material launches in the US are too few and far in-between. Maintain NEUTRAL with a revised TP of Rs 535 (18x FY20E EPS).

FY19 to be a breakthrough year with several key launches for many companies

SUNP to have 7 new specialty products in their portfolio by FY19 end – Tildra, Yonsa, Odomzo, Seceira, Bromsite, Elepsia and Xelpros.

Lupin's Solosec is likely to be a significant opportunity with 4mn patient pool and US\$ 100 revenue realization per patient for LPC

Niche Product Launches In FY19

		Peak Revenue Potential (US\$ mn)	Peak sales year	EPS (Rs/sh)	As % of FY18 EPS
SUNP	Tildra	450	FY22	3.5	26.7
	Yonsa	100	FY20-21	0.8	5.9
	Odomzo	150	FY21	1.2	8.9
	Seceira	200	FY21	1.5	11.9
	gSanodostatin LAR	100	FY20	1.3	10.4
LPC	Solosec	100	FY21	4.1	10.8
	Levothyroxin	100	FY20	6.1	16.1
	Ranexa	120	FY20	8.6	22.7
DRRD	Nuvvaring	60	FY20	8.4	13.9
	Suboxone	100	FY20	13.9	23.2
CDH	Asacol HD	140	FY19-20	4.4	34.2
ARBP	Ertapenem	70	FY19	3.8	11.1



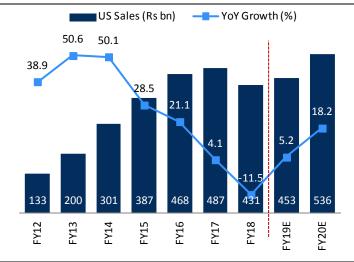
US revenues for top 10 US focused companies to grow in single digit in FY19E after ~12% drop witnessed in FY18

Improving US business environment and launch momentum to benefit high exposure US companies and beaten down stocks

Over last two years, all the companies have invested heavily to expand their capabilities both in manufacturing and R&D side

Top 10 US focussed companies (Key Charts)

US Revenue: Growth Returns In FY19



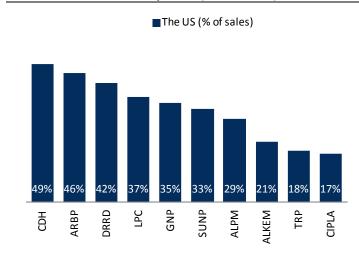
Source: Company, HDFC sec Inst Research

Scale Up In Formulation Units For Key Players

·	FY16	FY19
Sun Pharma	6	8
Dr. Reddy	4	7
Cipla	2	2
Aurobindo	7	10
Lupin	5	7
Glenmark	5	6
Cadila	6	9
Alkem	2	3
torrent	1	3
Alembic	1	5

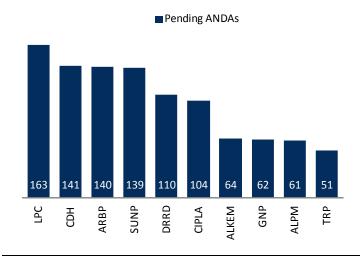
Source: Company, HDFC sec Inst Research

US Contribution In Top Line (% Of Sales)



Source: Company, HDFC sec Inst Research

Pending ANDA Approvals



Source: Company, HDFC sec Inst Research



Top 10 US focused companies to deliver double digit top line growth in FY19E (growth will be largely back ended)

EBITDA margin likely to remain flat in FY19 as 1HFY19 is likely to be soft for many companies

R&D spend to remain in the range of 8-9% of sales for the select 10 companies

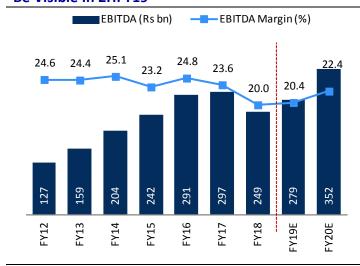
Earnings growth in FY19 will driven by both top line growth and few one-time factors in FY18 like GST impact and higher effective tax rate due to US region

Top line: Growth Returns In FY19



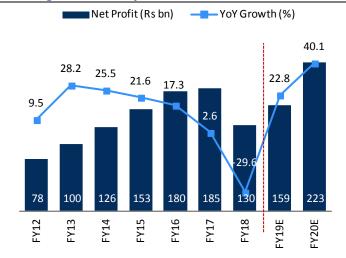
Source: Company, HDFC sec Inst Research

EBITDA Margin: Profitability Improvement Would Be Visible In 2HFY19



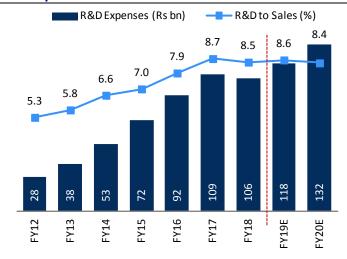
Source: Company, HDFC sec Inst Research

Earnings To Grow By 23%YoY In FY19E



Source: Company, HDFC sec Inst Research

R&D Spend As % Of Sales To Remain Flat



Source: Company, HDFC sec Inst Research

Valuation Matrix

	Мсар	CMP	Dana	eco TP	Adj EPS (Rs/sh)		P/E (x)			RoE (%)			
	(Rs bn)	(Rs/sh)	Reco		FY18	FY19E	FY20E	FY18	FY19E	FY20E	FY18	FY19E	FY20E
Sun Pharma	1,300	540	BUY	640	13.0	16.4	24.6	41.7	32.9	22.0	9.1	12.3	14.8
Cipla	455	567	NEU	565	17.5	23.2	30.0	32.4	24.4	18.9	10.5	12.4	14.3
Cadila Healthcare	390	380	BUY	525	12.9	15.2	21.9	29.6	25.0	17.4	16.8	16.6	20.6
Lupin	384	855	BUY	1,200	38.0	39.6	59.7	22.5	21.6	14.3	12.7	12.5	16.8
Dr Reddy's Labs	372	2,191	NEU	2,340	59.2	75.5	102.1	37.0	29.0	21.4	7.8	9.5	11.5
Aurobindo Pharma	349	596	BUY	740	34.4	39.0	48.0	17.3	15.3	12.4	19.1	17.9	18.6
Divi's Labs	282	1,064	NEU	1,095	33.0	44.6	51.4	32.2	23.9	20.7	15.5	18.7	18.9
Torrent Pharma	238	1,404	BUY	1,590	40.1	52.4	72.0	35.1	26.8	19.5	15.1	17.9	21.1
Alkem Laboratories	237	1,983	BUY	2,445	57.6	76.8	101.9	34.4	25.8	19.5	14.8	17.6	20.1
Glenmark	166	588	BUY	710	17.5	27.0	38.8	33.7	21.8	15.2	9.4	12.8	16.1
Jubilant Life Sciences	123	791	BUY	1,060	46.6	65.5	80.4	17.0	12.1	9.8	19.3	22.4	22.5
Alembic Pharma	97	514	NEU	535	21.9	22.1	29.7	23.5	23.3	17.3	20.0	17.5	20.4
Dishman Carbogen Amcis	49	301	BUY	450	9.6	13.6	19.9	31.4	22.2	15.1	3.1	4.2	5.9
Strides Shasun	33	363	NEU	420	12.7	18.4	26.3	28.6	19.7	13.8	4.4	6.5	8.7
Granules India	21	85	BUY	115	5.2	7.1	9.6	16.1	11.9	8.8	12.0	13.1	16.1
Neuland Labs	6	724	BUY	1,000	11.0	28.9	62.3	66.0	25.1	11.6	2.2	5.5	11.1

Source: HDFC sec Inst Research



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Rating Definitions

BUY : Where the stock is expected to deliver more than 10% returns over the next 12 month period NEUTRAL : Where the stock is expected to deliver (-)10% to 10% returns over the next 12 month period SELL : Where the stock is expected to deliver less than (-)10% returns over the next 12 month period

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