



## INDIA



## India pharma: Recommendations

Company code	Mkt Cap (USD bn)	Rating	TP (Rs)	CMP (Rs)	Upside (%)
SUNPIN	19.4	UP	440	540	-18%
LPC IN	7.3	N	1,022	1,049	-3%
DRRD IN	6.0	N	2,500	2,385	5%
CIPLA IN	7.2	N	632	611	3%
CDH IN	7.7	UP	415	491	-16%
GNP IN	2.6	OP	728	607	20%
JUBILANT IN	1.6	OP	900	636	42%
STR IN	1.2	OP	1,100	875	26%

\*Prices as of October 18, 2017

Source: Bloomberg, Macquarie Research, October 2017

## We are well below street across our coverage

EPS (Rs)	% variation (Macq vs consensus)		
	FY18E	FY19E	FY20E
Sun	↓ -13%	↓ -14%	↓ -7%
Lupin	↓ -11%	↓ -15%	↓ -10%
DRRD	↓ -16%	↓ -15%	↓ -10%
Cipla	↓ -3%	↓ -2%	↓ -1%
Cadila	↓ -23%	↓ -17%	↓ -14%
Glenmark	↓ -2%	↓ -5%	↓ -9%
Jubilant	↔ 0%	↓ -5%	↓ -16%

Source: Bloomberg, Macquarie Research, October 2017

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Macquarie Capital Securities India (Pvt) Ltd

## India pharmaceuticals

## Be careful what you wish for

## We see downside risk to consensus earnings forecasts

We initiate coverage on the Indian pharma sector with a cautious stance, particularly on large caps. We expect companies to remain exposed to elevated US pricing erosion (10-12% YoY; led by channel consolidation, higher competition) and margin pressure due to increased R&D spends. While street estimates suggest these issues will be sorted out soon (our FY19/20 EPS estimates are up to 15-20% lower), this assumption is fraught with risks. Our analysis of specialty timelines suggests that it is unlikely to fill the void in the core business, at least for the next 18-24 months. Notwithstanding ~30% under-performance of BSE Healthcare Index vs Sensex over the past 1 year, we find the recent 15% rally inexplicable. We have an **Underperform** rating on Sun Pharma and Cadila Healthcare. Our top picks are Jubilant Life, Strides and Glenmark.

## Legacy players in the US at risk, India steady for now

We segregate our coverage broadly into two halves—the incumbents and the challengers in the US. We believe pricing concerns are unlikely to fade away easily, with intense scrutiny under the Trump regime and the latest WBAD-Econdisc alliance. In our view, another stumble in the USD1bn+ US business for Sun, DRRD and Lupin remains a possibility. We expect companies that have a relatively smaller US presence (<USD500m) and strong compliance track record to be better placed. India business, with EBITDA margins of 30-35%, is a major contributor to profitability of Indian companies. With 39% revenues from India and improving US growth, Cipla would be an attractive play, were valuations not so rich. We believe regardless of favourable demographics, stricter regulations is a key factor to monitor, and will shape India growth trajectory.

## Complex/specialty transition easier said than done

Our analysis of revenue accrual timelines of specialty drugs suggests that predictability can be a big challenge, which has led to let-downs in the past. Also, we are sceptical about the upside from complex/ specialty compensating the generics erosion, at least for the next 18-24 months. With higher focus on approvals for complex generics, under the new FDA commissioner, revenue arbitrage of complex molecules could reduce. Even as hopes are pinned on a recovery on the back of increasing contribution from specialty and complex generics for legacy companies, timelines are sketchy. We believe uncertain approval timelines for specialty need to be captured in valuation multiples.

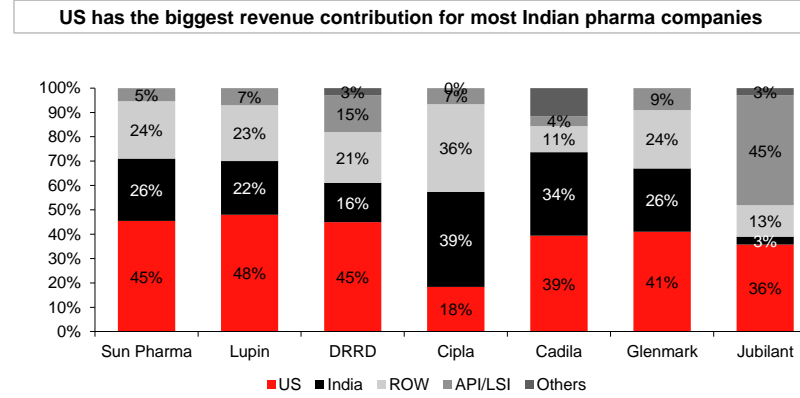
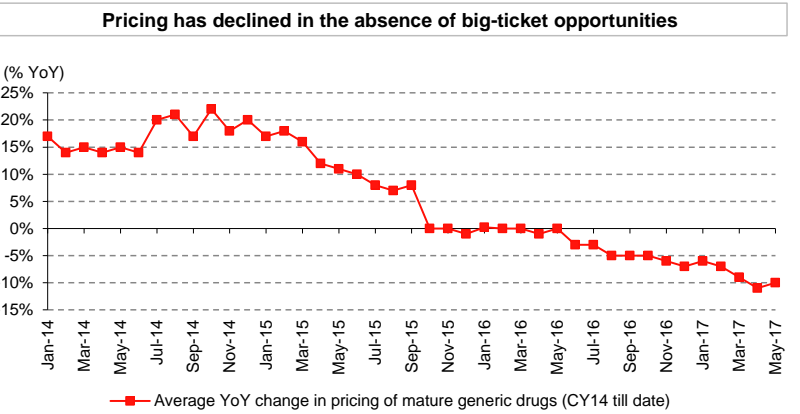
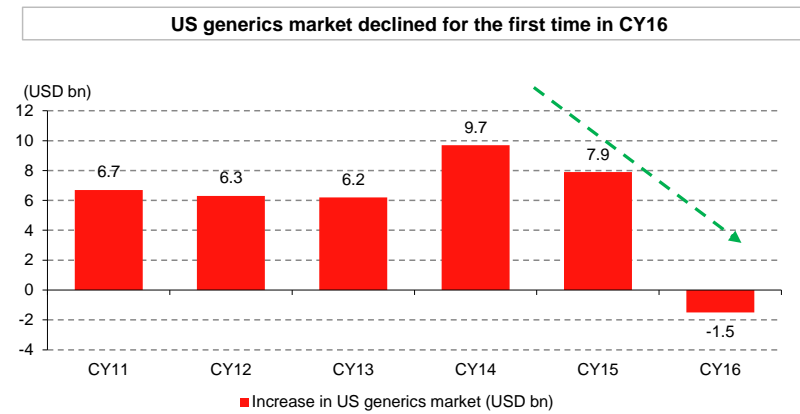
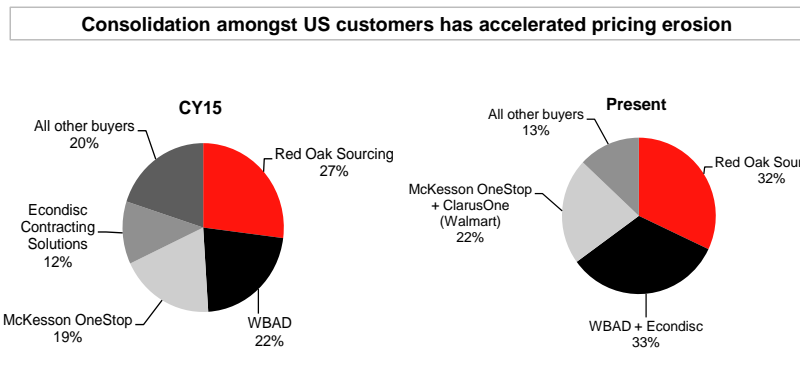
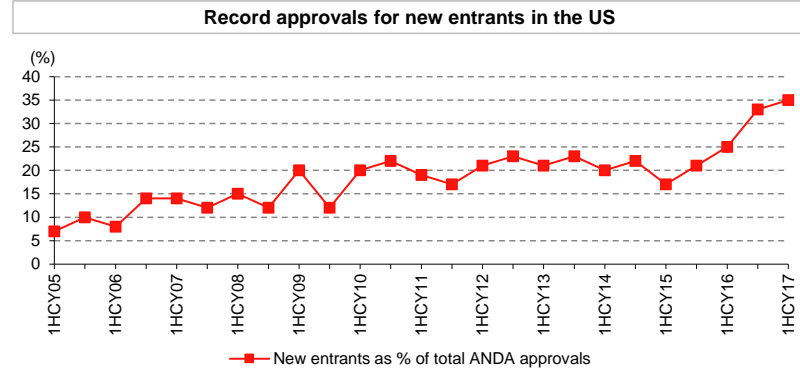
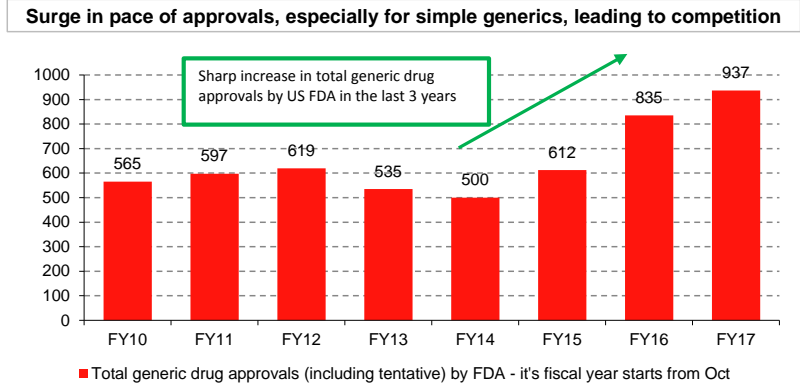
## Increasing R&amp;D &amp; compliance costs—is there a choice?

In order to fill the void created by delayed launches due to pending quality issues, we believe it has become imperative for generics companies to step up their R&D spends. Due to resultant operating deleverage, we expect combined ROCEs for our coverage to drop below 15% in FY19 vs 20%+ in FY15. We expect only a gradual margin recovery as R&D returns will be back-ended.

## Key risks to our cautious stance

US FDA resolution of key facilities like Halol for Sun and Srikakulam API, Duvvada for DRRD could boost sentiment. However, fundamental improvement based on these resolutions, especially Halol, will be very gradual. Faster approvals of key molecules could lead to upgrades. Further INR depreciation could also lift earnings (~1-1.5% EPS change for every Rs1 move).

**Fig 1 At a glance – Key charts indicating how pricing issues in the US market are impacting Indian pharma companies**



Source: Company data, IMS, US FDA, Bloomberg, Drug Channels, Industry, Macquarie Research, October 2017

**Fig 2 Recent commentary on US generics business by leading pharma companies**

<b>Mylan</b>	<ul style="list-style-type: none"> <li>•Witnessing increasing pricing pressure in the US. High single-digit price erosion outlook in North America generics (up from mid-single digit erosion seen in March 2017).</li> </ul>
<b>Teva</b>	<ul style="list-style-type: none"> <li>•Deflation will accelerate in the second half of FY18.</li> </ul>
<b>Perrigo</b>	<ul style="list-style-type: none"> <li>•Price erosion is unknown's unknowns. We are going to continue to experience a tough pricing environment at least going forward for a little while.</li> </ul>
<b>Par Pharma</b>	<ul style="list-style-type: none"> <li>•US generic business declined 34% YoY, due in part, to annualization of 2016 competitive events and product discontinuances; Price erosion in line with company's previous expectations.</li> </ul>
<b>Sanofi</b>	<ul style="list-style-type: none"> <li>•The company will be exiting its generics business in the US by CY18 end. The company has however, reiterated its commitment to its generic business in other parts of the world, and will sharpen its focus on emerging markets.</li> </ul>
<b>Sun Pharma</b>	<ul style="list-style-type: none"> <li>•Pricing pressure is across large number of products in US.</li> </ul>
<b>Lupin</b>	<ul style="list-style-type: none"> <li>•FY20 is when we think things could be much better for us.</li> </ul>
<b>Dr. Reddy's</b>	<ul style="list-style-type: none"> <li>•In addition to increased competitive intensity, enhanced customer erosion has led to price erosion beyond company's earlier estimates.</li> </ul>
<b>Glenmark</b>	<ul style="list-style-type: none"> <li>•Witnessing 10-12% price erosion in US base business.</li> </ul>
<b>Aurobindo</b>	<ul style="list-style-type: none"> <li>•Pricing erosion in remaining part of FY18 would fluctuate between high single digits to low teens.</li> </ul>
<b>Cipla</b>	<ul style="list-style-type: none"> <li>•Erosion is more than what people have expected. Pricing pressure from higher competition could possibly continue for 1.5-2 years until there is a shake up and few companies exit.</li> </ul>
<b>Cadila</b>	<ul style="list-style-type: none"> <li>•What we need to do and what we have decided is that when there will be pressures on pricing, we have to make sure our operational efficiency improves significantly in order for us to maintain our margins.</li> </ul>
<b>Natco Pharma</b>	<ul style="list-style-type: none"> <li>•Not as bullish about US like in the past. It has become very very difficult to do business in the US if there are 5-6 competitors for a product. Unless, there is a product which is so special that there is limited competition or shortage, companies cannot make money in the US.</li> </ul>
<b>Jubilant Life</b>	<ul style="list-style-type: none"> <li>•There has been increased pricing led competition in the US generics market.</li> </ul>

Source: Company filings, concall transcripts, media interviews, Macquarie Research, October 2017

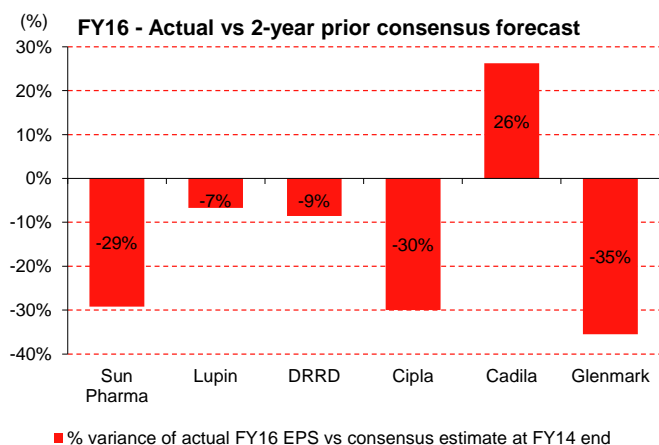
### Our earnings estimates are below consensus across our coverage

**Fig 3 Macquarie vs Consensus estimates – We are below street for all stocks across FY18-20**

EPS (Rs)	Macquarie EPS estimates (Rs)			Consensus EPS (Rs)			% variation (Macq vs consensus)		
	FY18E	FY19E	FY20E	FY18E	FY19E	FY20E	FY18E	FY19E	FY20E
Sun	13.0	18.6	25.4	15.1	21.7	27.2	↓ -13%	↓ -14%	↓ -7%
Lupin	38.7	47.6	59.9	43.4	55.9	66.7	↓ -11%	↓ -15%	↓ -10%
DRRD	66.8	108.5	141.5	79.5	128.4	158.0	↓ -16%	↓ -15%	↓ -10%
Cipla	20.3	26.5	31.0	20.9	27.1	31.4	↓ -3%	↓ -2%	↓ -1%
Cadila	15.1	20.4	23.2	19.7	24.6	27.0	↓ -23%	↓ -17%	↓ -14%
Glenmark	39.1	43.8	47.2	39.7	46.0	52.0	↓ -2%	↓ -5%	↓ -9%
Jubilant	43.1	55.4	64.6	43.3	58.3	77.2	↔ 0%	↓ -5%	↓ -16%
Strides	28.7	45.7	59.4	41.6	61.8	88.2	↓ -31%	↓ -26%	↓ -33%

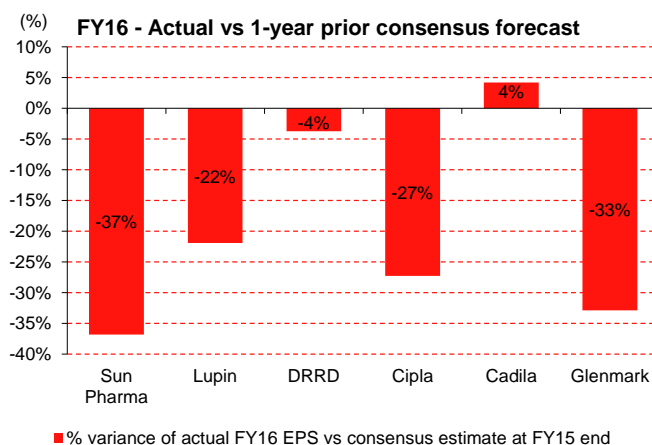
Source: Bloomberg, Macquarie Research, October 2017

**Fig 4 FY16 – Actual performance vs 2-year prior consensus forecast**



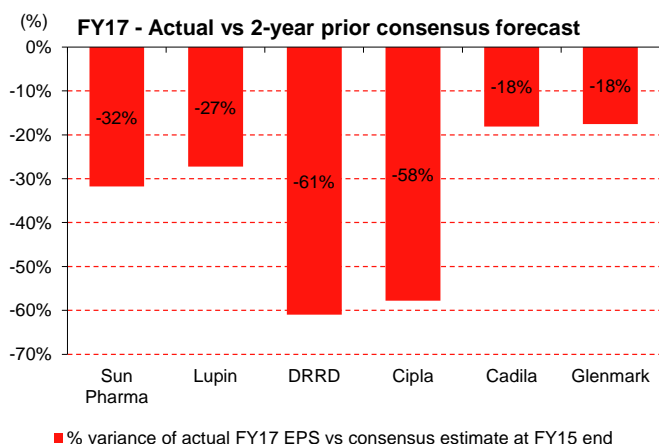
Source: Bloomberg, Macquarie Research, October 2017

**Fig 5 FY16 – Actual performance vs 1-year prior consensus forecast**



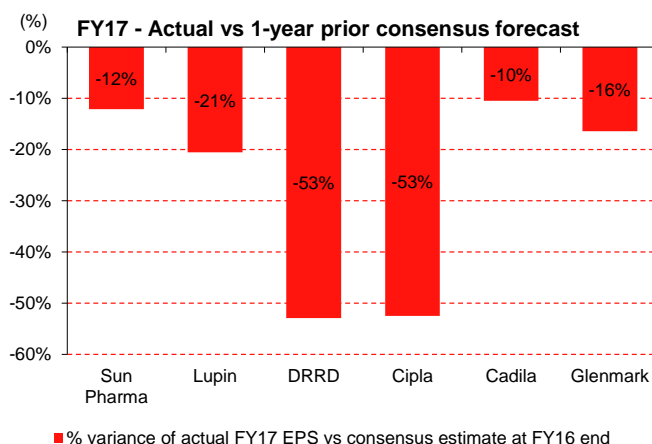
Source: Bloomberg, Macquarie Research, October 2017

**Fig 6 FY17 – Actual performance vs 2-year prior consensus forecast**



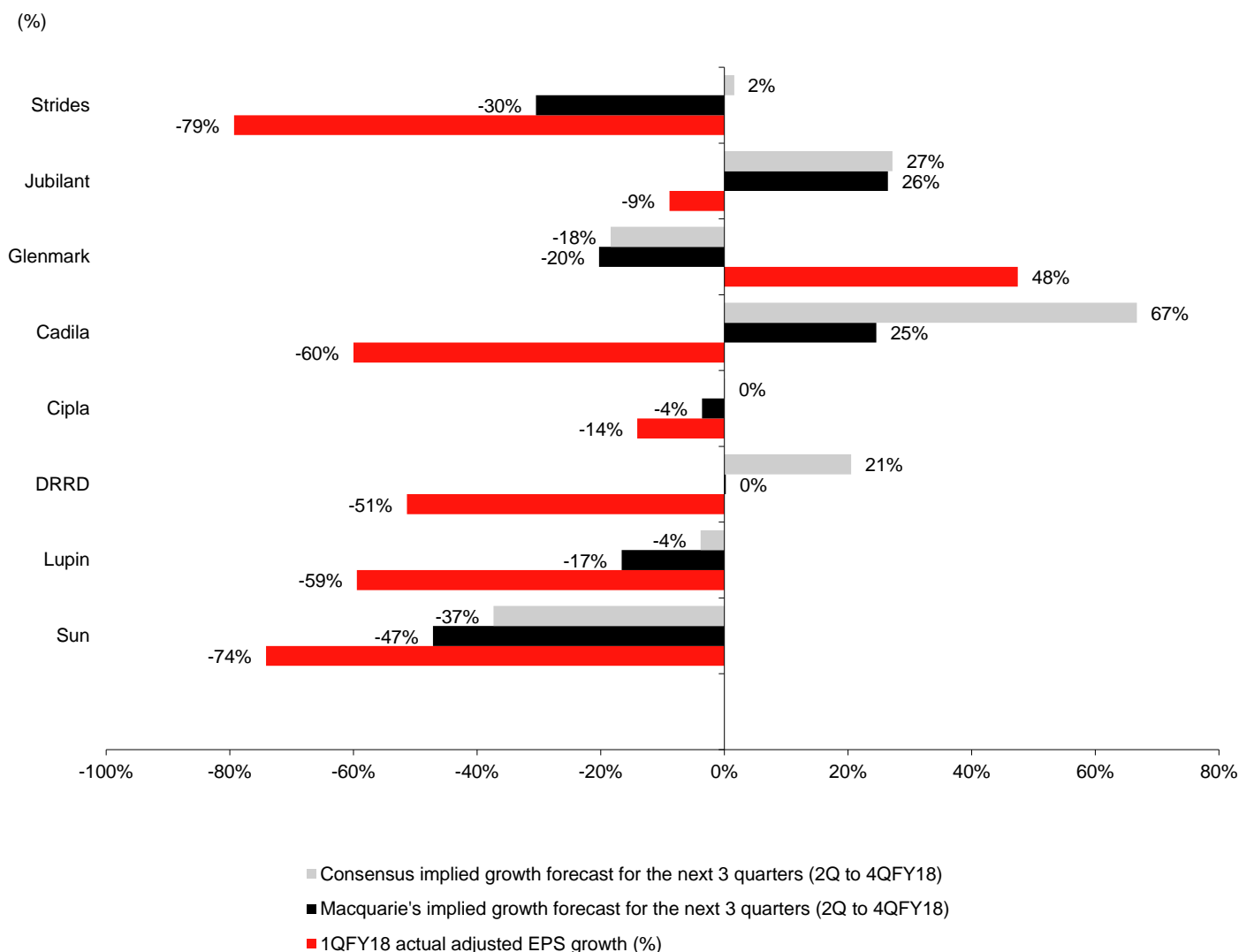
Source: Bloomberg, Macquarie Research, October 2017

**Fig 7 FY17 – Actual performance vs 1-year prior consensus forecast**



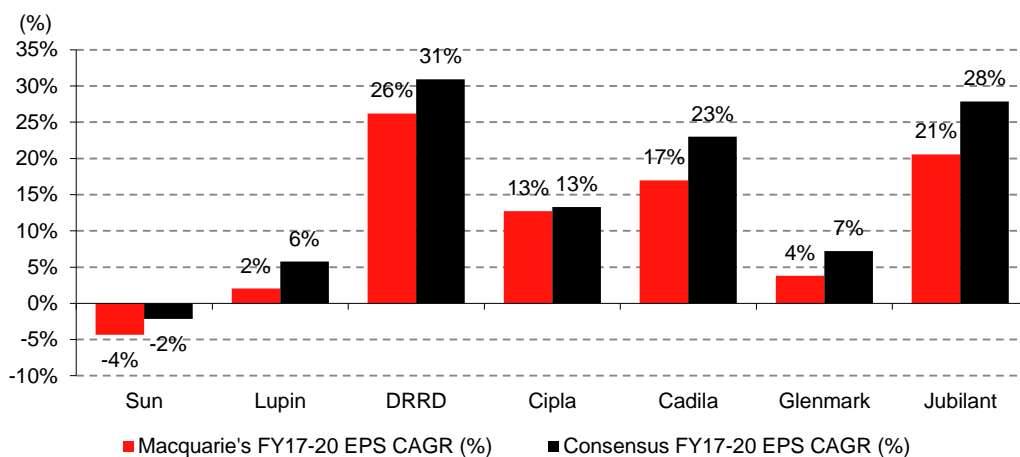
Source: Bloomberg, Macquarie Research, October 2017

**Fig 8 As per street's estimates, asking rate for rest of FY18 is still too high**



Source: Bloomberg, Macquarie Research, October 2017

**Fig 9 Comparison of our and Consensus EPS CAGR over FY17-20E**



Source: Bloomberg, Macquarie Research, October 2017

**Inside**

Be careful what you wish for	7
Dust unlikely to settle soon in the US	12
Ongoing transition easier said than done	21
India – Steady, barring regulatory overhang	26
R&D, compliance costs to impede margins	33
Appendices	36
Sun Pharma	39
Lupin	54
Dr. Reddy's Laboratories	64
Cipla	75
Cadila Healthcare	86
Glenmark Pharmaceuticals	97
Jubilant Life Sciences	109
Strides Shasun	119

# Be careful what you wish for

## Valuations and Recommendations

### Recommend against bottom-fishing at current price points

***In the absence of any clear signals, assuming issues like US price erosion, increasing competition, transition to specialty, pending compliance concerns will be sorted out soon, is fraught with risks.***

Even as stock prices of most pharma companies have collapsed in the past two years, pricing erosion could intensify further with intense scrutiny under the Trump regime and WBAD-Econdisc alliance. In the absence of any clear signals, assuming issues like US price erosion, increasing competition, transition to specialty, pending compliance concerns will be sorted out soon, is fraught with risks. While these issues are well-flagged, street earnings estimates still reflect lot of optimism. We are sceptical about the upside from specialty compensating the generic price erosion, at least for the next 18-24 months. Even though we have built in ample earnings recovery in FY19/20, our EPS estimates across our coverage universe are significantly lower than street estimates. We note that notwithstanding ~30% under-performance of BSE Healthcare Index vs Sensex over the past 1 year, we find the recent 15% rally in BSE Healthcare Index inexplicable.

### Multiples need to reflect timing uncertainty and lower growth, margins & ROCEs

During FY14-FY16, higher multiples for the sector were led by street extrapolating the strong US performance over the preceding years. By increased scrutiny on pricing, channel consolidation, higher competition coming in from new US, Indian and Chinese manufacturers, US FDA compliance issues and sharp increase in R&D spends, return ratios of companies have tanked considerably. Due to resultant operating deleverage, we expect combined ROCEs for our coverage to drop below 15% in FY19 vs 20%+ in FY15. Approval timelines for specialty molecules are sketchy and we believe these need to be captured in valuation multiples as well. Hence, we are comfortable with our 16-22x Sept-19 PER multiples for our universe. With much lower return ratios and limited scope for a sharp earnings recovery in the next 12-15 months, we have a cautious view on the sector.

### Prefer midcaps in the Indian pharma space

We segregate our coverage universe broadly into two halves – the legacy players and the challengers in the US. With increasing competition in the base portfolio, we believe disappointment in the US base business for the legacy players still remains a distinct possibility. On the other hand, pharma companies having a relatively smaller US presence now (<USD500m), stand in good stead. We also remain positive on companies with a strong compliance track record and niche businesses. Accordingly, we prefer mid-caps with niche businesses in regulated markets like Jubilant Lifesciences and Strides Shasun. Owing to valuation comfort, we have an Outperform rating on Glenmark. We are particularly guarded on large-caps due to their high US base and have an Underperform recommendation on Sun Pharma and Cadila Healthcare. We note these companies also have a strong compliance track record. Despite improving US traction, we have a Neutral rating on Lupin, DRRD and Cipla due to fair valuations. Despite elevated valuations, Cipla with 39% revenues from India and improving US growth, could provide investors a place to hide.

**Fig 10 ROCEs have deteriorated significantly for most companies**

Company	FY11-14			FY17-20E		
	% EPS CAGR	FY14 ROCE (%)	Average PER multiple (x)	% EPS CAGR	FY20E ROCE (%)	Target PER multiple (x)
Sun Pharma	20.8%	30.0%	19	-4.4%	14.5%	20
Lupin	28.5%	28.8%	18	2.0%	13.4%	19
DRRD	25.8%	23.6%	18	26.2%	16.6%	20
Cipla	13.5%	17.4%	18	35.3%	17.3%	22
Cadila	4.9%	16.8%	22	16.9%	21.2%	19
Glenmark	25.2%	18.3%	18	3.8%	16.0%	16
Jubilant	13.9%	9.3%	10	20.5%	17.3%	15

Source: Company data, Macquarie Research, October 2017

## Global peer valuation snapshot

Fig 11 Global generic pharma peer valuation comparison

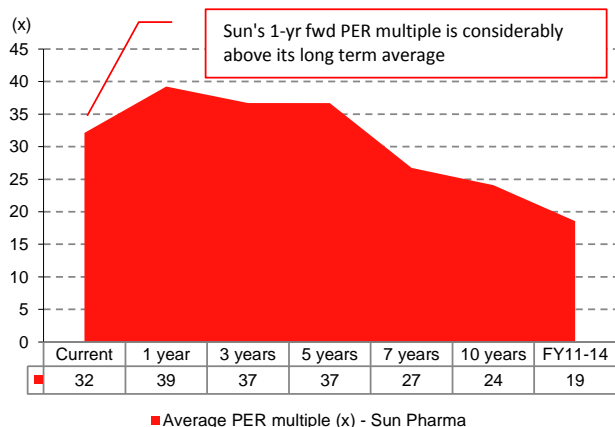
Company	BBG code	Mkt Cap (USD bn)	6m ADTV (USD m)	Rating	TP (1cy)	CMP (1cy)	Upside (%)	PER (x)			EV/sales (x)		FY17 ROE (%)	Dividend Yield (%)
								FY18E	FY19E	FY20E	FY18E	FY19E		
<b>Covered Indian pharma cos</b>														
Sun Pharma	SUNP IN	19.4	45.9	Underperform	440	540	-18%	41.4	29.0	21.3	4.2	3.8	19.4	0.6
Lupin	LPC IN	7.3	32.1	Neutral	1,022	1,049	-3%	27.1	22.0	17.5	3.1	2.8	20.8	0.7
Dr. Reddy's	DRRD IN	6.0	24.7	Neutral	2,500	2,385	5%	35.7	22.0	15.1	2.9	2.9	9.6	0.8
Cipla	CIFLA IN	7.2	11.9	Neutral	632	611	3%	30.2	23.0	19.7	3.3	2.9	8.3	0.3
Cadila Healthcare	CDH IN	7.7	10.3	Underperform	415	491	-16%	32.5	24.0	21.2	5.0	4.4	24.2	0.7
Glenmark	GNP IN	2.6	10.4	Outperform	728	607	20%	15.5	13.9	12.8	2.2	2.1	31.5	0.3
Jubilant Lifesciences	JUBILANT IN	1.6	5.1	Outperform	900	636	42%	14.8	11.5	9.8	1.8	1.5	18.0	0.5
Strides Shasun	STR IN	1.2	5.8	Outperform	1,100	875	26%	30.5	19.1	14.7	2.7	2.6	12.5	0.5
<b>Average</b>								<b>28.5</b>	<b>20.6</b>	<b>16.5</b>	<b>3.2</b>	<b>2.9</b>	<b>18.0</b>	<b>0.6</b>
<b>Uncovered Indian pharma cos</b>														
Aurobindo Pharma	ARBP IN	6.6	34.7	Not Rated	NA	756	NA	16.7	15.1	14.0	2.8	2.5	27.6	0.4
Torrent Pharma	TRP IN	3.3	3.6	Not Rated	NA	1,386	NA	25.9	20.6	17.4	3.9	3.4	23.8	1.0
Alkem Labs	ALKEM IN	3.4	1.1	Not Rated	NA	1,831	NA	26.8	19.9	17.1	3.4	2.9	21.9	0.6
Divi's Labs	DIVI IN	3.5	29.4	Not Rated	NA	877	NA	25.1	21.6	19.2	5.6	5.1	22.0	1.6
Biocon	BIOS IN	3.4	19.0	Not Rated	NA	382	NA	41.1	30.1	23.3	5.2	4.3	NA	0.7
Natco Pharma	NTCPH IN	2.6	6.3	Not Rated	NA	991	NA	33.9	23.8	21.2	8.1	6.4	33.0	0.4
Ajanta Pharma	AJP IN	1.6	4.6	Not Rated	NA	1,196	NA	22.7	18.6	12.1	5.0	4.3	36.7	0.9
Alembic Pharma	ALPM IN	1.4	0.6	Not Rated	NA	500	NA	22.6	18.2	14.4	2.7	2.4	23.0	0.9
Ipca Labs	IPCA IN	1.0	2.7	Not Rated	NA	493	NA	30.4	20.1	14.6	2.0	1.7	8.3	0.4
<b>Average</b>								<b>27.2</b>	<b>20.9</b>	<b>17.0</b>	<b>4.3</b>	<b>3.7</b>	<b>24.5</b>	<b>0.8</b>
<b>International pharma cos</b>														
Teva	TEVA US	16.1	16.0	Not Rated	NA	15	NA	3.5	3.9	3.5	2.4	2.5	-23.9	4.1
Mylan	MYL US	20.6	218.7	Not Rated	NA	39	NA	8.4	7.2	6.5	2.9	2.8	5.7	0.0
Perrigo	PRGO US	12.6	123.5	Not Rated	NA	89	NA	19.3	17.3	15.1	3.2	3.2	-36.9	0.7
Hikma	HIK LN	3.7	17.7	Not Rated	NA	1,186	NA	16.0	15.0	NA	2.3	2.2	6.9	2.0
<b>Average</b>								<b>11.8</b>	<b>10.8</b>	<b>8.4</b>	<b>2.7</b>	<b>2.7</b>	<b>-12.0</b>	<b>1.7</b>

\*Prices as of October 18, 2017, Bloomberg consensus forecasts used for uncovered cos

Source: Bloomberg, Macquarie Research, October 2017

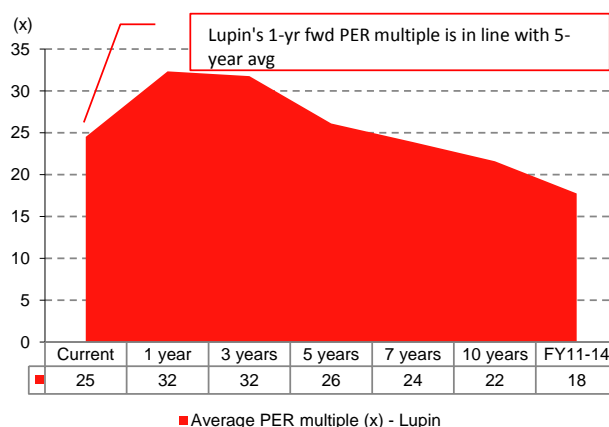


**Fig 12 Sun's 1-yr fwd PER multiple on Consensus earnings over various time frames across last 10 years**



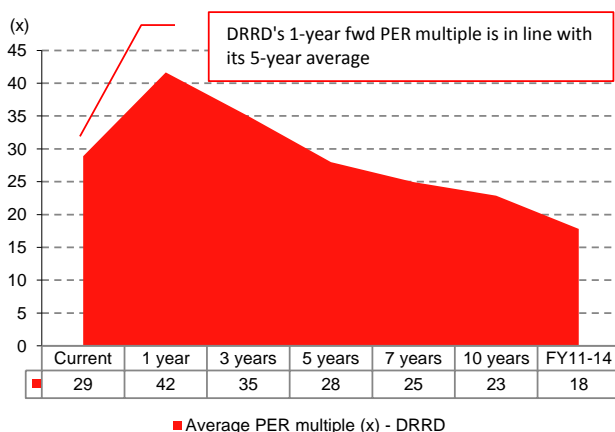
Source: Bloomberg, Macquarie Research, October 2017

**Fig 13 Lupin's 1-yr fwd PER multiple on Consensus earnings over various time frames across last 10 years**



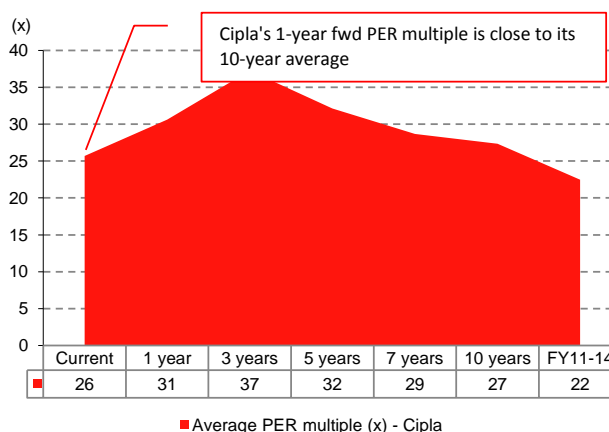
Source: Bloomberg, Macquarie Research, October 2017

**Fig 14 DRRD's 1-yr fwd PER multiple on Consensus earnings over various time frames across last 10 years**



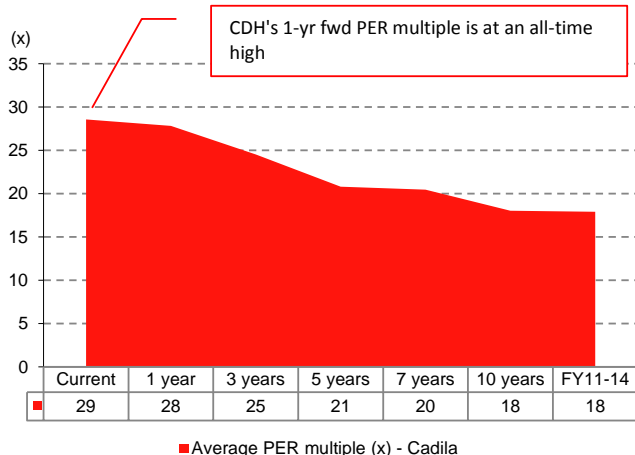
Source: Bloomberg, Macquarie Research, October 2017

**Fig 15 Cipla's 1-yr fwd PER multiple on Consensus earnings over various time frames across last 10 years**



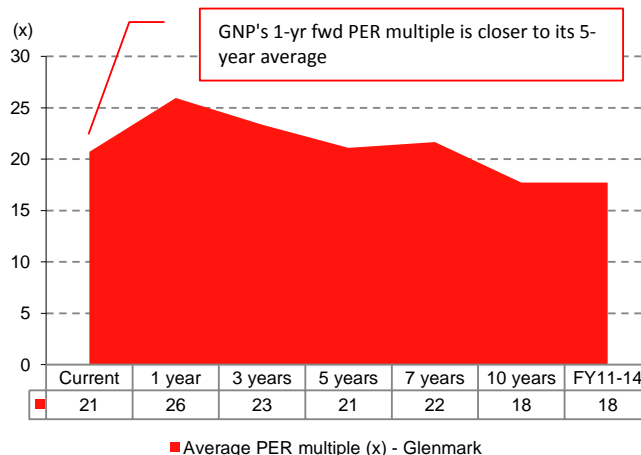
Source: Bloomberg, Macquarie Research, October 2017

**Fig 16 Cadila's 1-yr fwd PER multiple on Consensus earnings over various time frames across last 10 years**



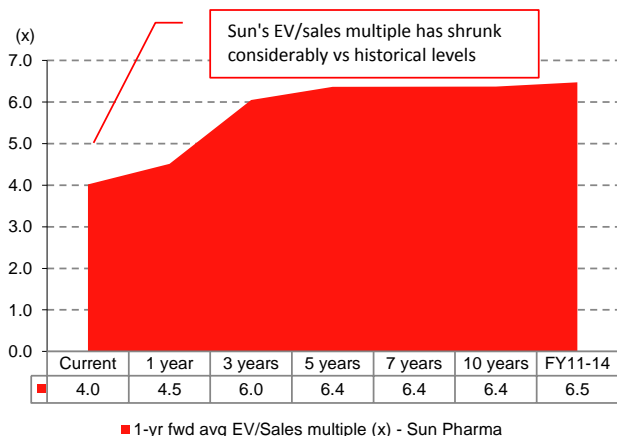
Source: Bloomberg, Macquarie Research, October 2017

**Fig 17 GNP's 1-yr fwd PER multiple on Consensus earnings over various time frames across last 10 years**



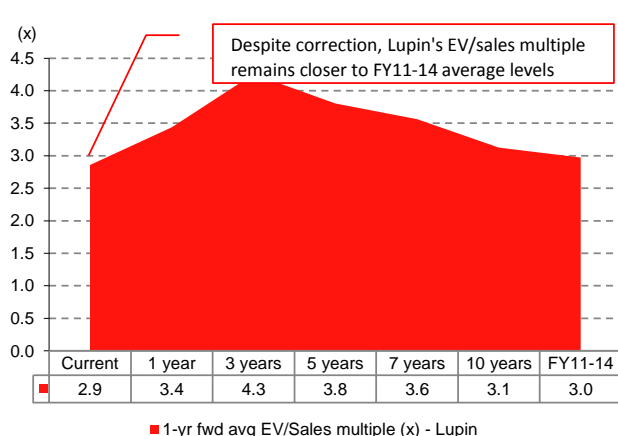
Source: Bloomberg, Macquarie Research, October 2017

**Fig 18 Sun's 1-yr fwd EV/sales on Consensus forecasts over various time frames across last 10 years**



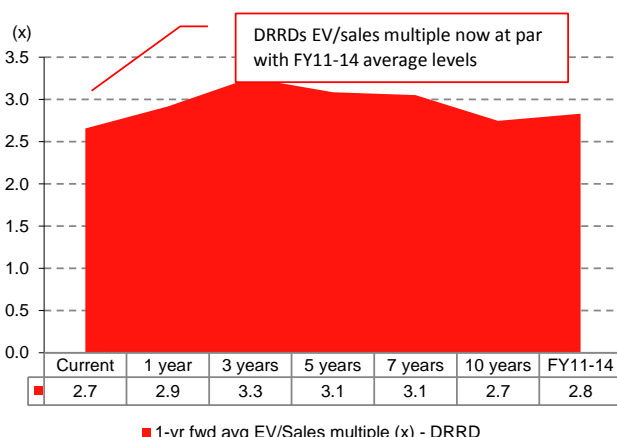
Source: Bloomberg, Macquarie Research, October 2017

**Fig 19 Lupin's 1-yr fwd EV/sales on Consensus forecasts over various time frames across last 10 years**



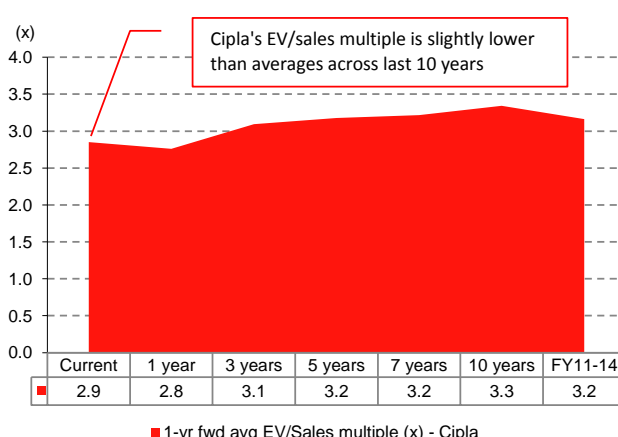
Source: Bloomberg, Macquarie Research, October 2017

**Fig 20 DRRD's 1-yr fwd EV/sales on Consensus forecasts over various time frames across last 10 years**



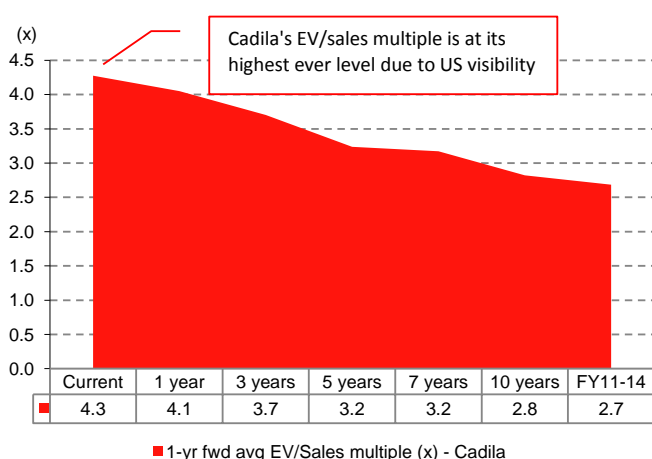
Source: Bloomberg, Macquarie Research, October 2017

**Fig 21 Cipla's 1-yr fwd EV/sales on Consensus forecasts over various time frames across last 10 years**



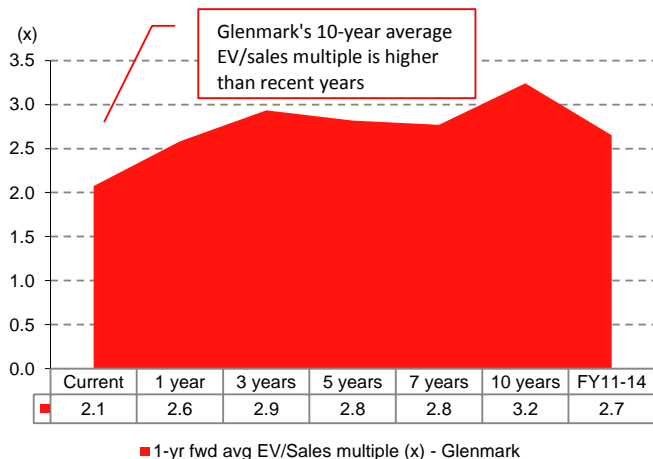
Source: Bloomberg, Macquarie Research, October 2017

**Fig 22 Cadila's 1-yr fwd EV/sales on Consensus forecasts over various time frames across last 10 years**



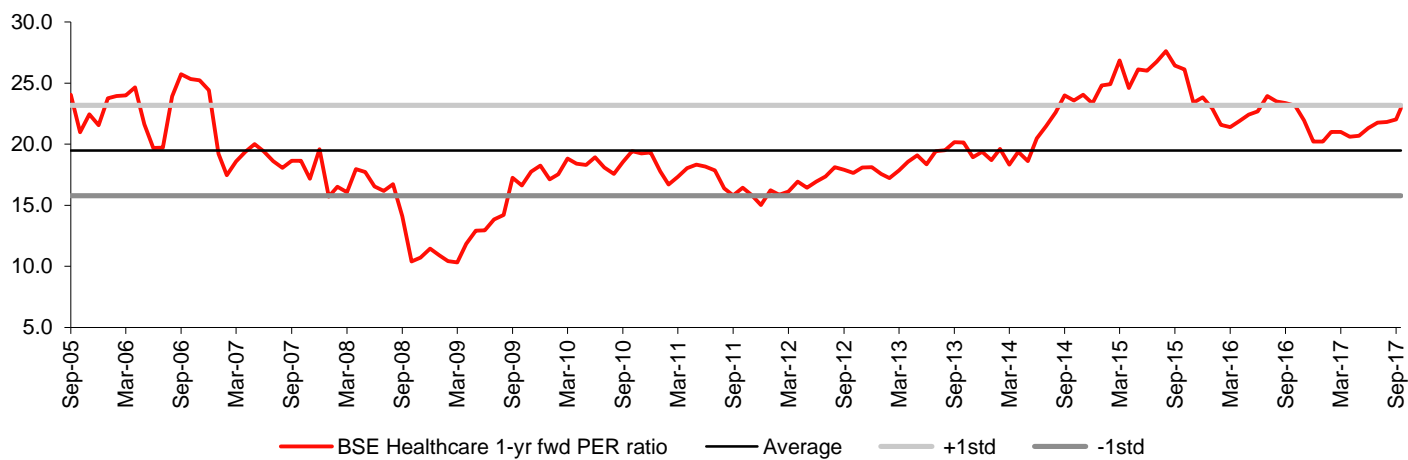
Source: Bloomberg, Macquarie Research, October 2017

**Fig 23 GNP's 1-yr fwd EV/sales on Consensus forecasts over various time frames across last 10 years**



Source: Bloomberg, Macquarie Research, October 2017

**Fig 24** Despite correction in stock prices, BSE Healthcare Index trades at 1 std deviation above long-term mean



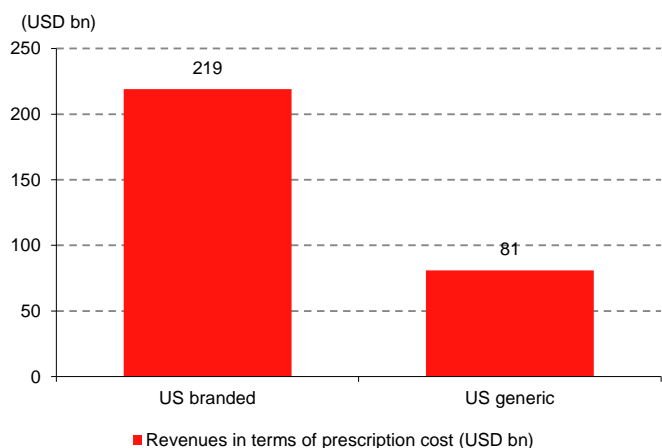
Source: Bloomberg, Macquarie Research, October 2017

# Dust unlikely to settle soon in the US

**The unbranded US generics market stood at USD68bn in CY15. Indian companies have ~30-35% market share by volumes of the overall unbranded US generics industry.**

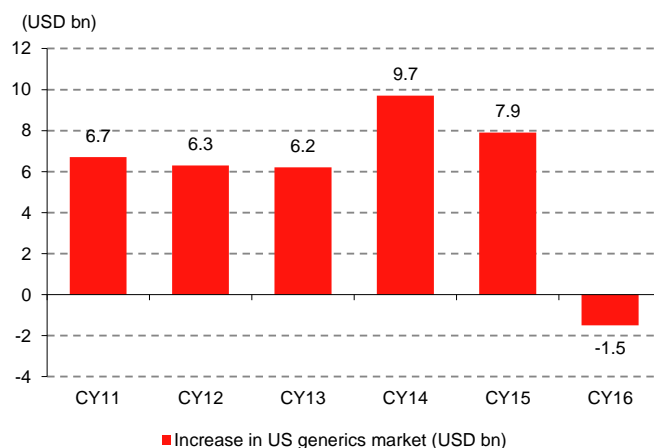
With a size of ~USD350bn (innovator plus generics), US is still the most lucrative pharma market in the world. US generics market (including branded generics) stood at USD114bn in CY15, up from USD106bn in CY14. The unbranded US generics market stood at USD68bn in CY15. Indian companies have ~30-35% market share by volumes of the overall unbranded US generics industry. Channel consolidation, rising competitive intensity from smaller generic players due to faster approvals post GDUFA-II, increased scrutiny on price hikes by drug-makers in the US and higher frequency/stringency of US FDA inspections has created pricing as well as supply issues for generics companies. While increased pace of approvals is generally positive, implementation of GDUFA is a double-edged sword and net impact is likely to be negative for larger companies due to the threat of new generic competition. Given that ~90% of the US generics market is now controlled by three buying consortiums, pricing issues in the US are structural. In our view, Indian pharma companies with a large US presence, will have to adjust to this new pricing normal. Developing complex generics and specialty products is challenging due to need for heavy investments and lengthy/uncertain timelines. Here, we believe, niche M&As are helping plug an important gap.

**Fig 25 US pharma market size**



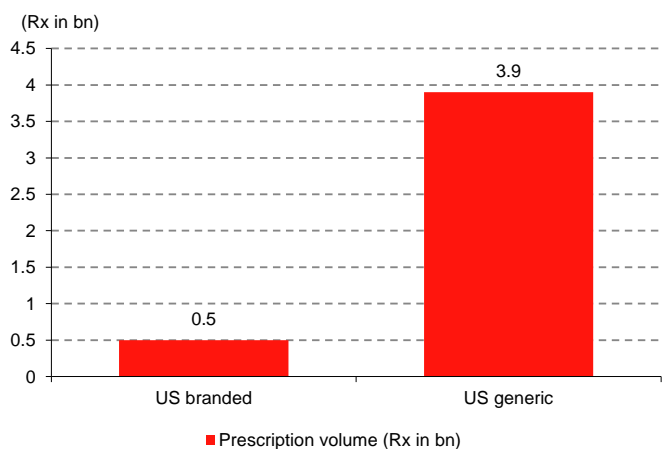
Source: Mylan, Macquarie Research, October 2017

**Fig 26 US generic market declined in CY16**



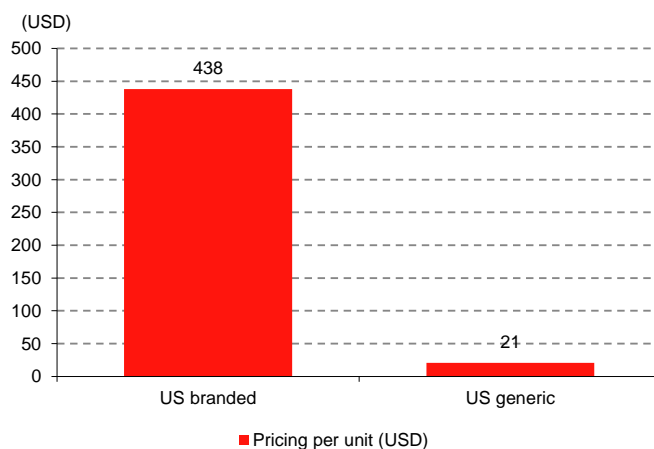
Source: IMS, Industry, Macquarie Research, October 2017

**Fig 27 US drug prescription volumes (Rx)**



Source: Mylan, Macquarie Research, October 2017

**Fig 28 Stark avg pricing gap b/w branded and generic**



Source: IMS, Macquarie Research, October 2017

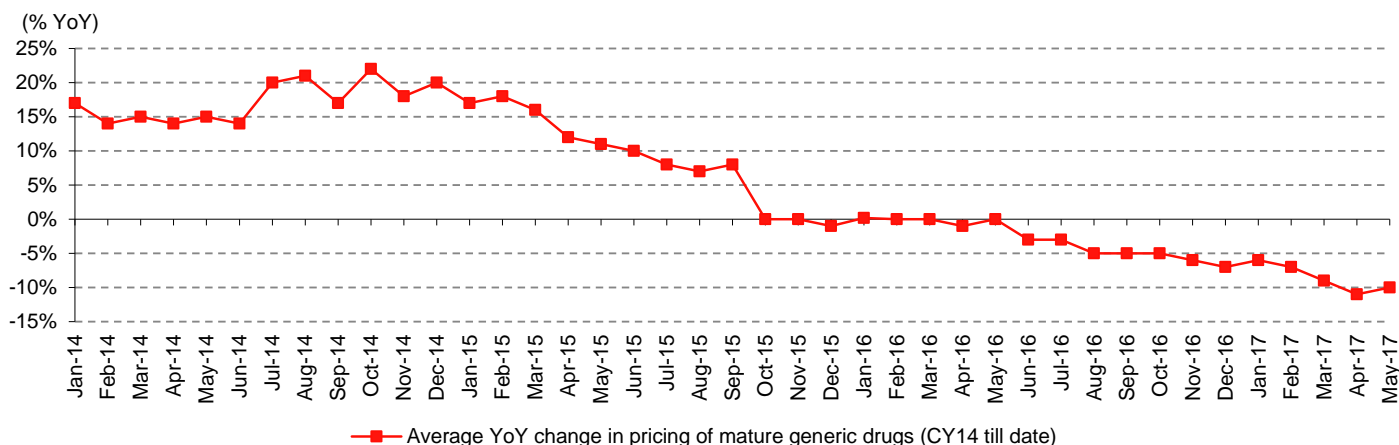
### Opportune price hikes taken in prior years have accelerated erosion

Apart from customer consolidation and increased pace of approvals, increased noise about drug price hikes has limited the control of generic pharma companies on drug pricing. Pricing of mature generics is under increasing scrutiny from payers and policy makers. Leading Indian companies like Sun, DRRD and Cadila are also party to an ongoing US Congress probe on high drug pricing taken in CY14. Between CY12-CY15, the US generics industry benefitted from high generic price inflation. Key factors leading to this inflation were: (i) Production issues faced by some manufacturers, (ii) curtailed production of few molecules by some companies (iii) slower ramp-up of the GDUFA program which led to backlog on approvals for new generics (iv) Consolidation of manufacturers and (v) Aggressive portfolio management by generics companies.

**CY16 was the first year of decline for the overall US generic industry with ~2% YoY fall.**

Led by channel consolidation, US FDA’s push towards faster ANDA approvals under GDUFA and increasing clamour about rising generic drug prices in the US, the pricing inflation started correcting CY15 onwards. As a result, CY16 was the first year of decline for the overall US generic industry with ~2% YoY fall. To add to the woes of the generic pharma companies, first-to-file (FTF) products, even during exclusivity, are also witnessing pricing issues due to rampant launches of authorized generics (AGs).

**Fig 29 On a high base, pricing started moderating in 2HFY16 in the absence of big-ticket opportunities**



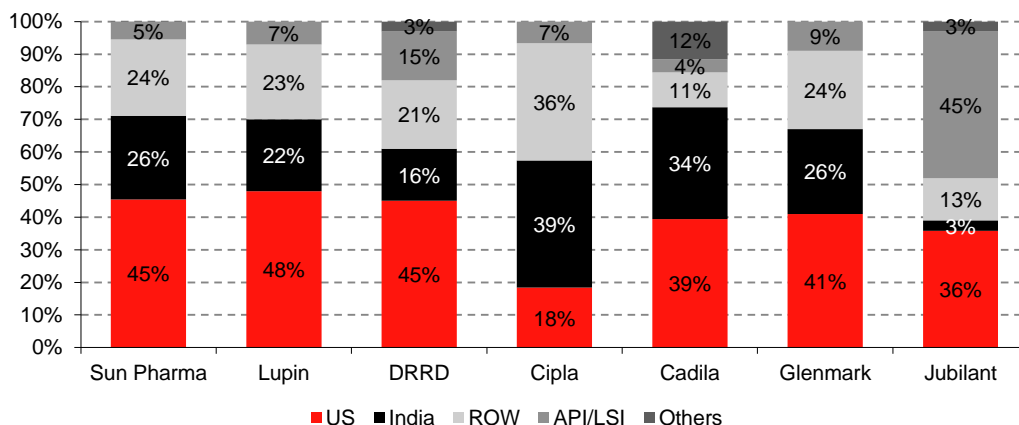
Source: Drug Channels, Macquarie Research, October 2017

### Legacy players in the US still at a disadvantage

**Amongst the large-caps, Cipla has the least contribution from US at 18%, while Lupin has the highest at 48%, followed by Sun Pharma and DRRD at 45% each.**

US generic business margins remain under tremendous stress. We segregate our coverage broadly into two halves – the legacy players and the challengers in the US. We believe large cap pharma companies do not have material sustainable competitive advantage in the US, especially with regard to plain-vanilla generics. In a move to lower drug prices in the US, FDA has specifically stated that it will work towards expediting approvals for products which have few competitors in the US. Our checks suggest that there are at least 100 companies, which are awaiting their first ANDA approval from US FDA. While most of these are likely to target plain-vanilla Para III opportunities, this indicates the extent of competition prevalent in the US generics market. Even as hopes are pinned on a recovery on the back of increasing contribution from specialty and complex generics, timelines are sketchy. More the delay in launching complex/specialty molecules, lower is the opportunity size. Despite these issues, we believe it still makes sense for Indian pharma companies to invest in their US business; however diversification into non-US is imperative as well. Amongst the large-caps, Cipla has the least contribution from US at 18%, while Lupin has the highest at 48%, followed by Sun Pharma and DRRD at 45% each.

**Fig 30 Geography-wise sales breakup of Indian pharma companies**



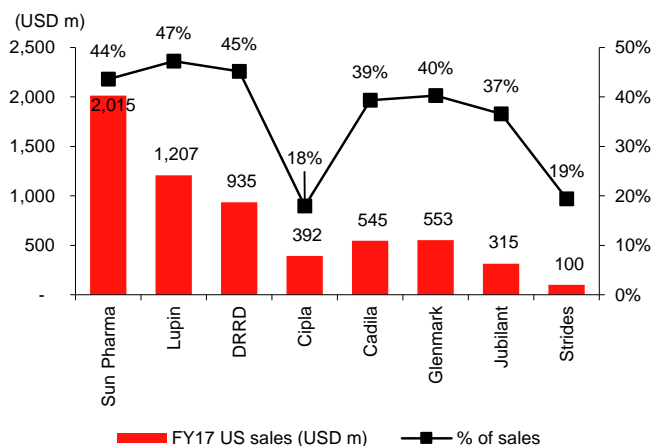
Source: Company, Macquarie Research, October 2017

**US business recovery to be gradual at best**

*Amongst the large caps in our coverage, we expect Cipla and Cadila to report the best traction in the US*

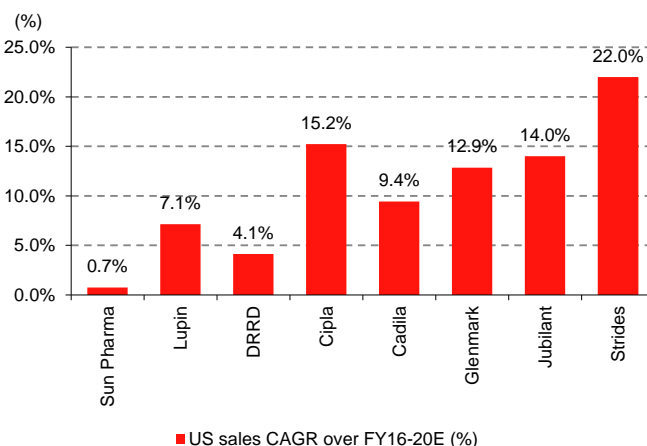
Looking at Consensus estimates, we believe the street continues to be optimistic of a hasty recovery, which we think is extremely unlikely. We believe there is limited reason to believe a turnaround is just round the corner. Especially for the large-caps like Sun Pharma, DRRD and Lupin, US growth is likely to be muted. Sun’s US sales have already been flattish over FY15-17 despite opportunities like Gleevec due to pressure in US base business, particularly Taro, and delay in approvals as Halol continues to be stuck with a US FDA warning letter. As we build Halol resolution in FY19 and ramp-up of its specialty pipeline including Tildrakizumab, we are forecasting decent 10% and 15% US sales growth for Sun in FY19 and FY20 respectively. Similarly, we expect Lupin’s and DRRD’s FY16-20E US sales CAGR to be impacted by a lack of big approvals and high product concentration. Amongst the large caps in our coverage, we expect Cipla and Cadila to report the best traction in the US – Cipla on a smaller base and Cadila benefitting from pent-up approvals from its stuck-up Moraiya facility.

**Fig 31 High US base biz for Sun, LPC and DRRD**



Source: Company, Macquarie Research, October 2017

**Fig 32 Tepid FY16-20E US sales CAGR for large-caps**



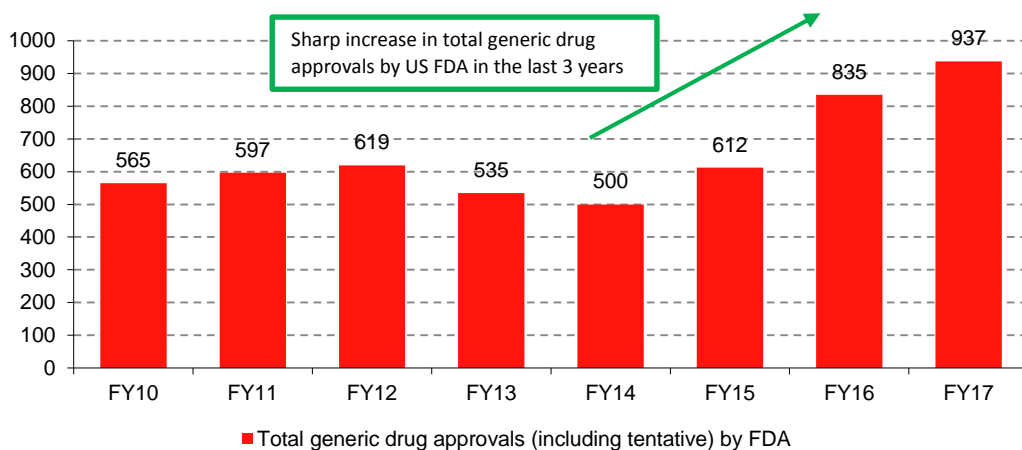
Source: Company, Macquarie Research, October 2017

**Our checks suggest that there are ~100 companies, which are awaiting their first ANDA approval from US FDA.**

## Increased pace of approvals by US FDA leading to competition

As smaller generic pharma companies build scale in the US, the US FDA is helping their cause by increasing the pace of approvals. Under Generic Drug User Fee Amendments (GDUFA), US FDA is actively working on clearing a backlog of generic approvals. Our checks suggest that there are ~100 companies, which are awaiting their first ANDA approval from US FDA. While most of these are likely to target plain-vanilla Para III opportunities, this indicates the extent of competition prevalent in the US generics market. Late entrants got 40% of the total ANDA approvals in 1HCY17, higher than 35% in 1HCY16. Out of these, there are many smaller companies from various countries including India and China, which are now spreading their wings in the US. There is limited difference in technical capabilities across pharma companies in the simple generics business. This has led to increased competition in the US generics business. As a result, total generic drug approvals (including tentative) have surged in the last 3 years, up from 500 approvals in FY14 (US FDA's fiscal year is from October to September) to 937 approvals in FY17.

**Fig 33 Surge in pace of approvals, especially for simple generics**



Source: US FDA, Macquarie Research, October 2017 \*US FDA's fiscal year is from October to September

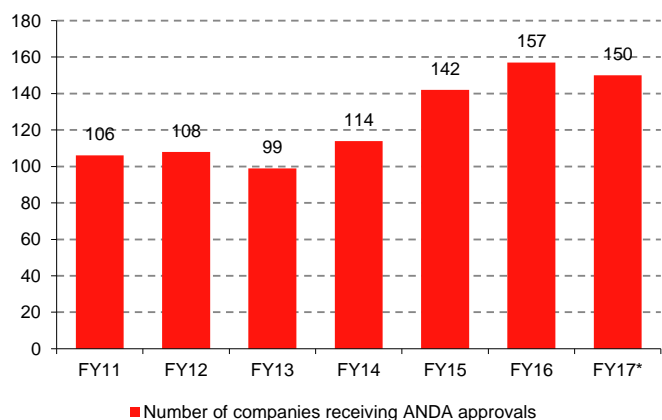
**Total generic drug approvals (including tentative) have surged in the last 3 years, up from 500 approvals in FY14 (US FDA's fiscal year is from October to September) to 937 approvals in FY17.**

Companies like Natco Pharma have recently commented that due to high competition in the US, the same product has the potential to generate higher sales in geographies like India than in the US. While we do not believe that the situation is so alarming for most other pharma companies, we believe companies like Sun, DRRD and Lupin, with a large US business (>USD1bn) and high product concentration, are indeed being negatively impacted due to increased pace of approvals by US FDA. These companies have also not benefited much from overall higher pace of approvals due to pending quality issues. Especially for complex molecules, US FDA is issuing more Complete Response Letters (CRLs), with multiple review cycles, which is delaying approvals. Under GDUFA II, we await faster conversions of these CRLs into approvals.

### Increasing competition amongst manufacturers is a key focus for Dr Gottlieb

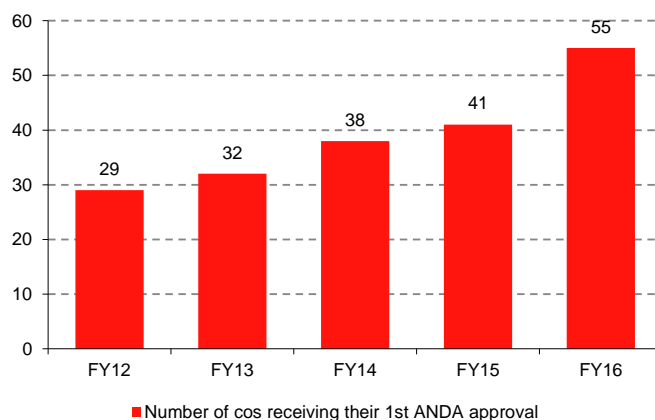
Under its new Commissioner, Dr Scott Gottlieb, the US FDA has formed a Drug Competition Action Plan which could further increase competition for established Indian generics companies. Dr Gottlieb has mentioned that the FDA is looking to create competition where there isn't any. Under this Plan, FDA will prioritise its review of generic drug applications until there are three approved generics for a given drug. With higher focus on approvals for complex generics as well, the revenue arbitrage of complex molecules could reduce. In the long run, this could also lead to generic drug manufacturers withdrawing their low-margin drugs or refraining from launching such drugs altogether. We believe a lower ROI could thus trigger a shortage of drugs over the long term, which should support pricing. For example, a lower ROI has contributed to shortages of generic injectables in the last 1-2 years in the US. However, we expect this cycle to play out only after at least 1.5-2 years of pricing disruption.

**Fig 34 Competition is inching in US generics space**



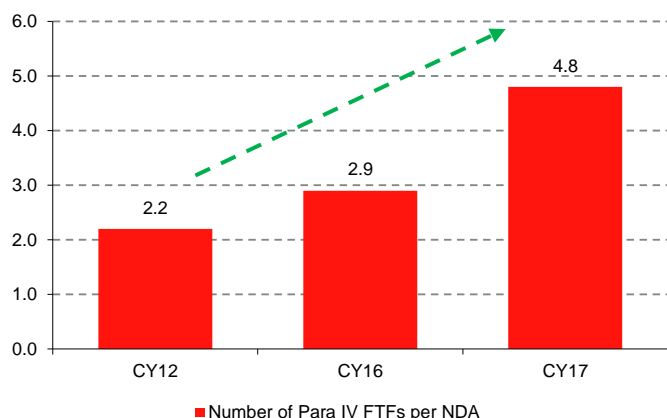
\*Estimate for FY17, US FDA's fiscal year ends in Sept  
 Source: US FDA, Company data, Macquarie Research, October 2017

**Fig 35 Increasing number of companies entering the US generics market**



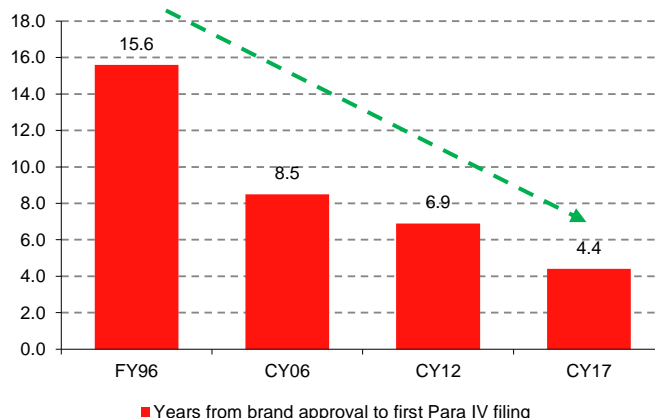
Source: US FDA, Macquarie Research, October 2017

**Fig 36 Players within a particular drug have been increasing**



Source: US FDA, Macquarie Research, October 2017

**Fig 37 Exclusivity period is coming down heavily for innovator drugs**



Source: US FDA, Macquarie Research, October 2017

**Channel consolidation in the US - A key driver of pricing erosion**

***Given that ~90% of the US generics market is now controlled by 3 buying consortiums, we believe pricing issues in the US are structural.***

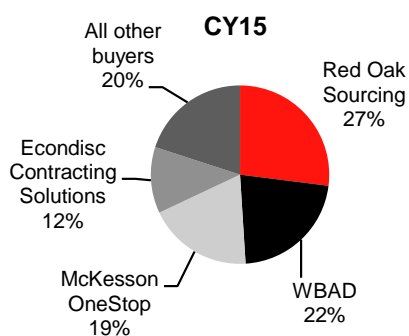
Horizontal as well as vertical consolidation amongst US distributors, retailers and PBMs has accelerated pricing pressure for generic pharma companies. Distributors and retail chains have struck alliances to form generic purchasing consortia like Walgreens Boots Alliance Development (Walgreens and AmerisourceBergen), Red Oak Sourcing (CVS Health and Cardinal Health), and the purchasing tie-up between McKesson and Walmart. This has created an alignment between the largest pharma distributors, pharmacy business managers (PBMs) and pharmacy retail chains in the US. Amazon's anticipated entry in this space could lead to further disruption in the drug buying scenario in the US. Given that ~90% of the US generics market is now controlled by 3 buying consortiums, we believe pricing issues in the US are structural. Generic pharma companies will have to adjust to this new pricing normal.



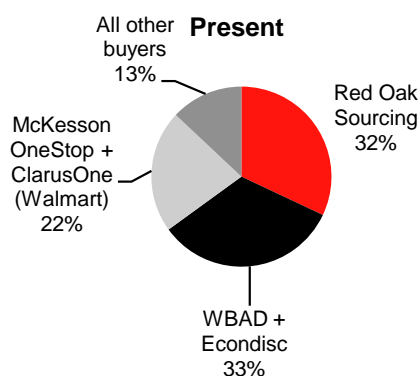
**Latest round of consolidation could further dent bargaining power of pharma cos**

In May 2017, Express Scripts' Econdisc agreed to partner with Walgreens Boots Alliance Development (WBAD), leading to further consolidation amongst the buying groups in the US. With the latest deal, the 3 largest buyers now account for ~90% of total generic drug purchases in the US. This is likely to add to the pricing woes during negotiations in FY18. These 3 top buyers are Red Oak Sourcing (CVS Health-Cardinal Health), WBAD-Econdisc (Walgreens Boots Alliance with AmerisourceBergen and Econdisc) and McKesson OneStop and ClarusOne (with Walmart). Earlier, US-based Walgreens had acquired Switzerland-based Alliance Boots to form WBAD. WBAD has 3 divisions: (i) Retail Pharmacy in US (Walgreens) (ii) Global Retail Pharmacy (Boots) and (iii) Pharma Distribution in Europe (Alliance Healthcare). The three leading public PBMs - Express Scripts, CVS Caremark and UnitedHealth's OptumRx control ~75-80% of the PBM market. There are ~60,000 pharmacies in the US, out of which ~38,000 are part of retail chains and 22,000 are independent pharmacies. The largest pharmacies in US include CVS, Walgreens, Express Scripts and Walmart. Both chargebacks and rebates have also been accelerating for Indian pharma companies due to increase in customer consolidation in the US.

**Fig 38 Market share of consortiums in CY15**



**Fig 39 Market share of consortiums at present**



Source: Macquarie Research, October 2017

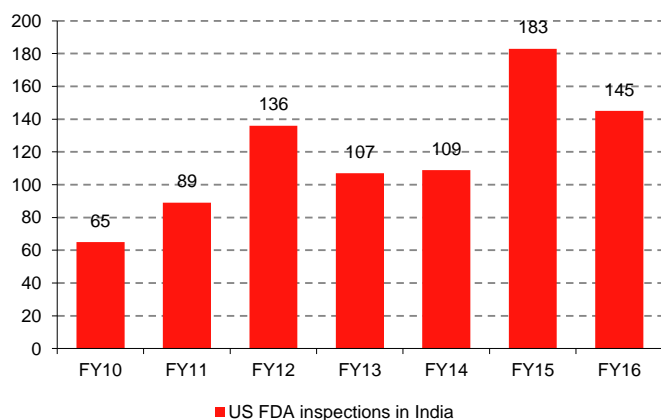
Source: Macquarie Research, October 2017

**Heightened scrutiny by FDA – Indian companies getting a fix**

***Our discussions with US FDA experts suggest that US FDA has upped its compliance requirements and a significant overhaul of legacy systems is underway for most Indian pharma companies.***

Delay in approvals due to ongoing remediation activities at their key facilities has taken a toll on several Indian pharma companies. Our discussions with US FDA experts suggest that US FDA has upped its compliance requirements and a significant overhaul of legacy systems is underway for most Indian pharma companies. This holds true especially for companies, which are foraying into specialty products. Evolution towards automatic data acquisition and recording systems is an important step towards compliance. Currently, most entries are still captured manually and possibility of errors increase significantly with manual entries. Gradually, Indian pharma companies are transitioning to automated data retrieval by embedding data, e-batching records and digital log books. We believe a conscious effort is required to make this transition. Spate of US FDA issues over the last few years has certainly expedited this transition. We believe this is a continuous journey and the series of serious observations across companies in the last few years are gradually resulting in better compliance standards and reduction in number of serious Form 483 observations.

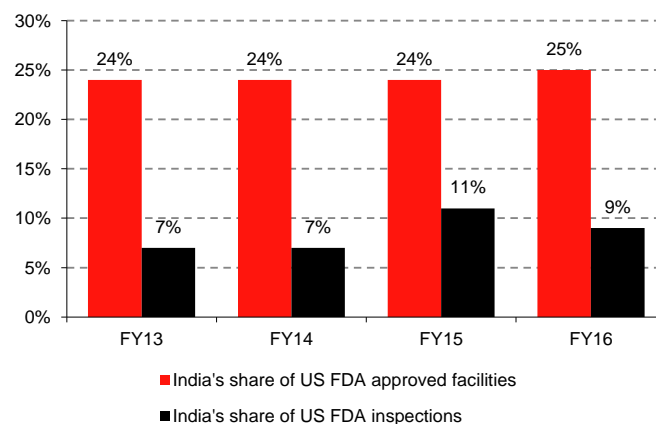
**Fig 40 US FDA inspections in India have increased in last 2 years**



\*US FDA's fiscal year is September ending

Source: Companies, US FDA, Macquarie Research, October 2017

**Fig 41 Proportion of US FDA inspections are still lower in India compared to other non-US countries**



\*US FDA's fiscal year is September ending\*US FDA's fiscal year is September ending

Source: Companies, US FDA, Macquarie Research, October 2017

***No company under our coverage appears close to making meaningful revenues from biosimilars in the US, at least for the next 2-3 years.***

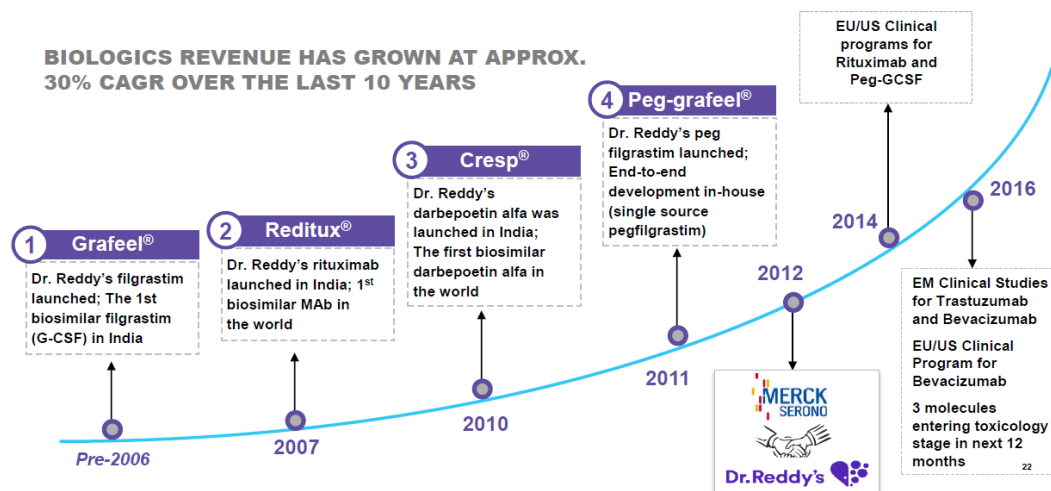
### Indian companies still long way from US biosimilar opportunity

In the US, there are currently ~50 biosimilars under development and we expect a significant chunk of them to reach the US market in the next 5 years. Lack of FDA guidance on interchangeability has created a slower uptake environment for biosimilars in the US as compared to the small molecule generic market. This has resulted in biosimilars needing to compete with brands to be first choice by providers. The first biosimilar (Zarxio – filgrastim) in the US was approved in March 2015 and launched in August 2015. Price erosion for biosimilars has been lower than initial expectations, at least till the second competitor became available. We believe uncertainties around biosimilars are much higher than generics which are dissuading early market entrants from reducing prices rapidly. As per IMS, market dynamics around biosimilars are likely to revolve around reimbursement, substitution, competition and litigation.

- **Reimbursement:** Different reimbursement policies under PBMs versus medical benefits with less direct insurer influence
- **Substitution:** Automatic substitution driven by regulatory status and pharmacy rules
- **Competition:** Number of biosimilars will impact price discount levels offered by competing companies.
- **Litigation:** More complex litigation process could delay launch of biosimilars

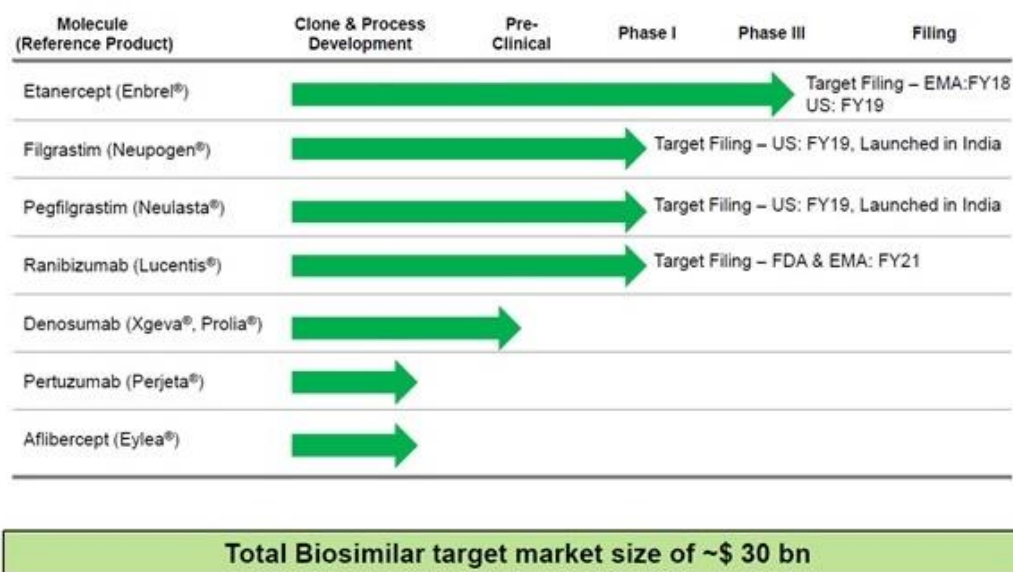
Development of biosimilars involves significant investment in time and money. Since biosimilars are biologics and the manufacturing process is the same, they are expensive to develop. It takes 8 to 10 years and costs USD100-200m to develop a biosimilar. On the other hand, developing a small-molecule generic drug takes 3 to 5 years and costs between USD1-5m. Unlike in the past, when manufacturing drugs were relatively easier to copy during the patent cliff, going ahead, a meaningful chunk of drugs going off-patent are biologics. A large number of biosimilar medicines are in development and can be expected to reach the market in the U.S. by 2021. Still, there are significant uncertainties as many applications are not yet filed, regulatory reviews are not yet a frequent occurrence for FDA or the applicants, and almost all biosimilars will face litigation from originators. Amongst our coverage universe, DRRD and Lupin have made some headway in the US biosimilar opportunity. DRRD has one molecule (Bevacizumab) in Phase 3, another (Pegfilgrastim) in Phase 1 and Trastuzumab in pre-clinical. Lupin has Etanercept undergoing Phase 3 trials. Neither appear close to making meaningful revenues from biosimilars in the US, at least for the next 2-3 years.

**Fig 42 DRRD's progress in biologics**



Source: Company, Macquarie Research, October 2017

**Fig 43 Lupin's global biosimilar pipeline**



Source: Company website, Macquarie Research, October 2017

Fig 44 Biosimilars expected to be available in the US by CY21

Therapy area	Molecule	Admin Route	Number of biosimilars by CY21	Comments
<b>Insulins</b>	<b>Insuline glargine</b>	SC	1 approved currently (1-2 additional)	Approved, launch Dec 2016; Original insulins widely influenced by insurer non-medical incentives, biosimilars expected to follow similar patterns
<b>Autoimmune</b>	<b>Infliximab</b>	IV	1 approved currently (1-2 additional)	Approved; Infused and reimbursed through medical benefit with significant provider incentives who are able to purchase for less than reimbursement level
	<b>Adalimumab</b>	SC	7-10	Self-administered but while expensive, most patients are insulated from cost through generous plan designs or coupons; Little switching due to cost between originators; In the absence of FDA approved interchangeability, patient financial incentives to choose biosimilars would be required to drive significant uptake. Patent litigation pending, biosimilars asserting 2018, originator 2022.
<b>AMD</b>	<b>Ranibizumab</b>	Intra-ocular	1-2	Biosimilars for ranibizumab would require interchangeability and to discount similar to bevacizumab biosimilars. Interchangeability unlikely considering typical regulatory scrutiny of ophthalmic formulations.
<b>Oncology Supportive Care</b>	<b>Filgrastim</b>	IV	2 marketed currently (1-4 additional)	Non-original versions of Filgrastim including Granix and Zarxio have reached 40% of volume, growing slowly initially but accelerating with the addition Zarxio as the second competitor
	<b>Pegfilgrastim</b>	IV	2-3	The pegfilgrastim market is much larger than the filgrastim market and once a biosimilar or other non-original version is available similar uptake is expected
	<b>Epoetin alfa</b>	IV/SC	1-2	EPO usage in the U.S. is largely limited to chronic kidney disease with treatment paid for with bundled payments, making lower cost biosimilar an attractive financial option for providers
<b>Oncology Therapeutics</b>	<b>Bevacizumab</b>	IV	3-4	Widely used across multiple tumours, these cancer biologics will likely see similar uptake as that seen by Filgrastim to date.
	<b>Trastuzumab</b>	IV	2-3	
	<b>Rituximab</b>	IV	2-3	Off-label use of original bevacizumab in AMD likely to continue and biosimilar bevacizumab expected in 2019, a year before ranibizumab biosimilars.

Source: IMS, Macquarie Research, October 2017

# Ongoing transition easier said than done

## Complex/specialty evolution to be gradual

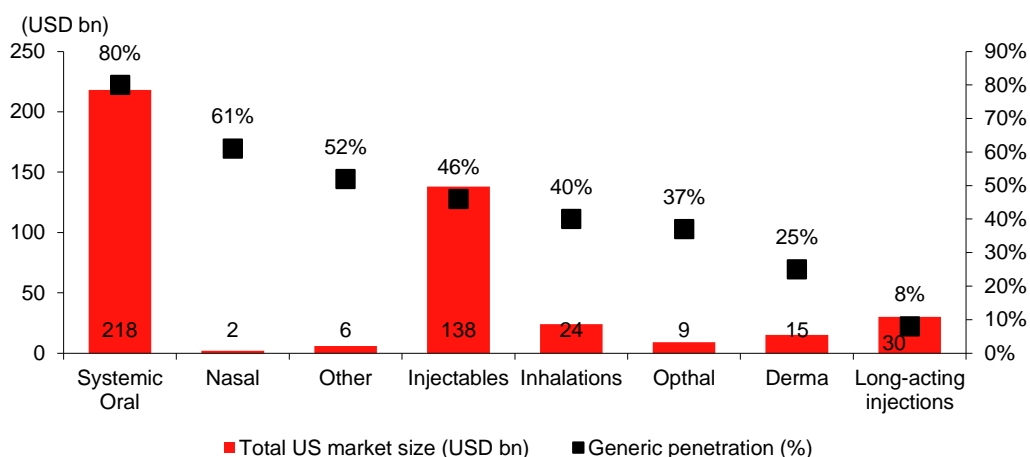
### Increasing focus on complex molecules/specialty pharma

**Even as hopes are pinned on a recovery on the back of increasing contribution from specialty and complex generics, timelines are sketchy.**

Investments on the complex molecules/specialty pharma side have increased considerably across our coverage universe as well. All companies are trying various avenues to mitigate pricing challenges in the US. Risk-mitigating strategies include aiming to move up the value curve by focusing more on specialty and complex generics and increasing penetration in non-US geographies. Even as hopes are pinned on a recovery on the back of increasing contribution from specialty and complex generics, timelines are sketchy. More the delay in launching complex/specialty molecules, lower is the opportunity size. Developing complex generics and specialty products is challenging due to need for heavy investments and lengthy/uncertain timelines. We remain guarded whether the upside from specialty will be enough to compensate for the generic price erosion, at least for the next 18-24 months. Here, we believe, niche M&As are helping plug an important gap for generic pharma companies.

Penetration of generics in difficult-to-manufacture therapies like complex injectables, derma, transdermals and respiratory is low. In the US, Indian pharma companies have 19% penetration in complex generics, much lower than the 34% in simple generics.

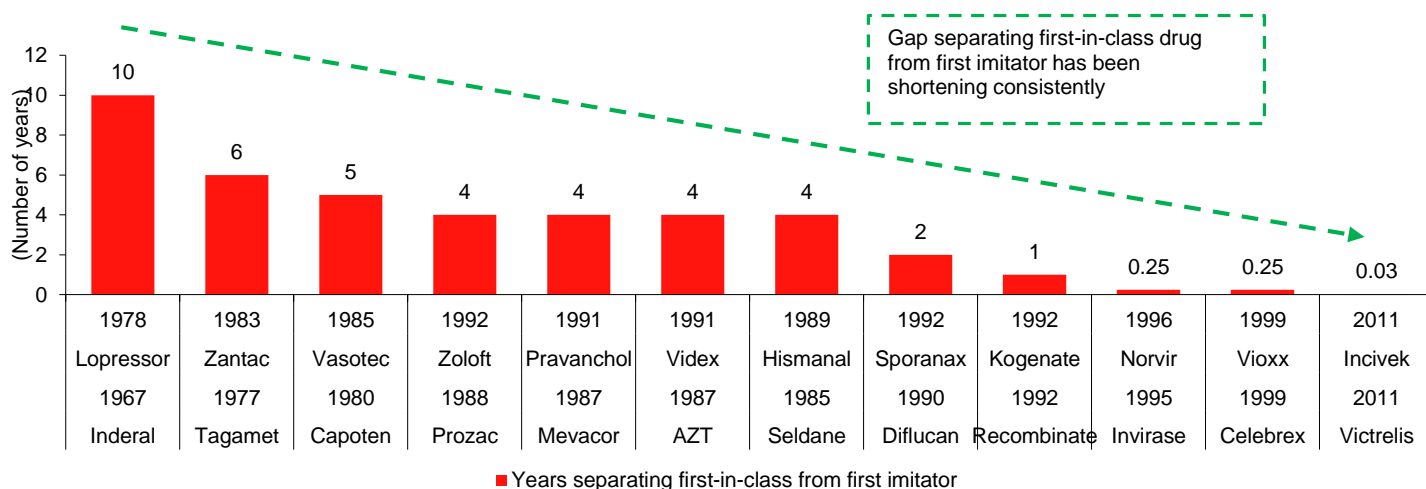
**Fig 45 Complex generics opportunity in US**



Source: IMS, Lupin, Macquarie Research, September 2017

Specialty drugs are often injectable, high-cost, biologics, or require cold-chain distribution. These are often initiated by specialists for treatment of cancer and other chronic conditions. Typically, specialty medicines require lot of patient follow-up and monitoring. Spending on specialty drugs has been increasing driven primarily by treatments for hepatitis, autoimmune diseases and oncology. Specialty therapies are likely to become more significant in developed markets. IMS expects spends on specialty drugs to continue witnessing a surge till CY21, particularly in developed countries. In emerging markets, growth of specialty medicines could be constrained by cost, access controls and a greater focus on assessments of value. As per IMS data, US net spending on medicines (adjusted for rebates and price concessions) stood at USD310bn in CY15. Out of this, specialty drug spending was USD121bn. Specialty accounts now for more than 36% of non-discount drug spending in the US, a sharp increase from 24% in CY10.

**Fig 46 Competitor drugs are entering at a faster clip, thereby dropping exclusivity periods**



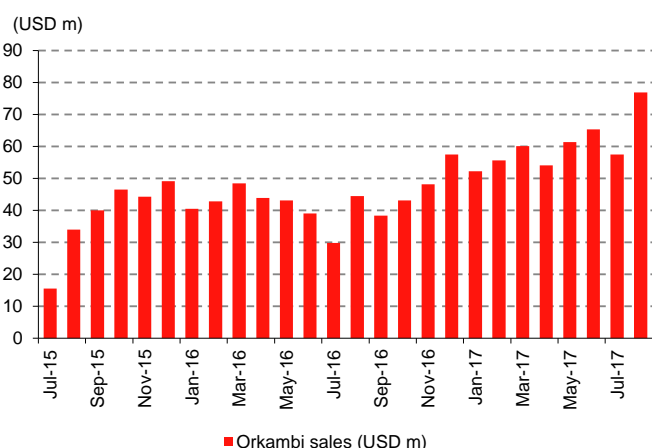
Source: PhRMA, The Wilkerson Group, Macquarie Research, October 2017

### Taking cue from historical evidence of specialty ramp-up

**Key challenges in succeeding in specialty are setting up the distribution network, creating awareness through a strong sales-force, reimbursement and cost density issues.**

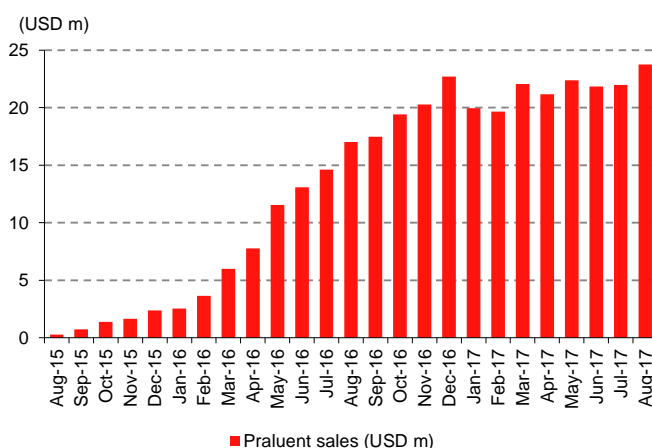
We scrutinize the revenue ramp-up of leading specialty drugs globally. Typically, most specialty products achieve peak sales within 5-6 years. The key challenges are setting up the distribution network, creating awareness amongst various market participants through a strong sales-force, managing reimbursement issues and cost density issues (cost of certain specialty molecules has to be born upfront as opposed to an elongated time-frame for most other drugs). As per Sun Pharma, if a company is very aggressive in building up its infrastructure and sales force and incurs a significant buildup cost, then peak sales can be achieved as early as three years. We provide charts highlighting gradual sales ramp-up of 4 big specialty drugs – Orkambi, Praluent, Ibrance and Cosentyx (competitor to Sun Pharma’s Tildrakizumab) in the US below. All these drugs were launched in CY15 and their monthly revenue run rate suggests that the drugs are still ramping up.

**Fig 47 Orkambi monthly sales**



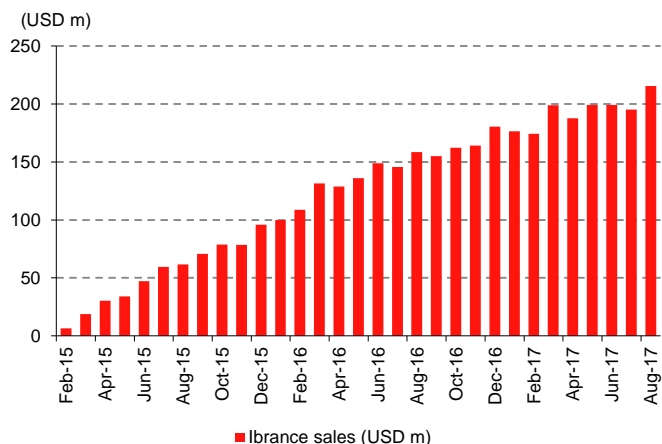
Source: Symphony data, Macquarie Research, October 2017

**Fig 48 Praluent monthly sales**



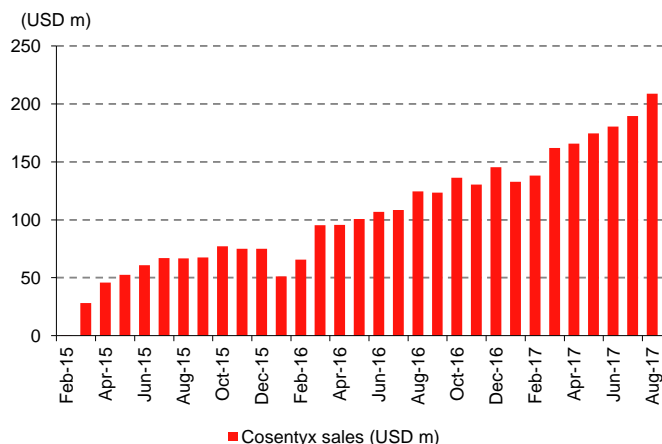
Source: Symphony data, Macquarie Research, October 2017

**Fig 49 Ibrance monthly sales**



Source: Symphony data, Macquarie Research, October 2017

**Fig 50 Cosentyx monthly sales**



Source: Symphony data, Macquarie Research, October 2017

### Throwing caution to the specialty winds

While the above cases have been fairly successful launches with a near-linear revenue offtake, the transition to specialty is also fraught with risks – both in terms of timelines as well as revenue potential. We present two case studies to emphasize that the revenue upside from specialty products can be difficult to forecast and sometimes, the outcome could be very different from the blue-sky scenarios being forecasted by the street.

#### Specialty Case Study I: Pfizer’s Exubera becomes a non-starter

***We present two case studies to emphasize that the revenue upside from specialty products can be difficult to forecast and sometimes, the outcome could be very different from the blue-sky scenarios being forecasted.***

Exubera was the first inhaled insulin product and was aimed to be a replacement to injections for treatment of patients with Type 1 and Type 2 diabetes. It was approved by US FDA in CY06 and launched commercially by Pfizer in CY07. The then Pfizer CEO had guided that the drug would achieve annual sales of USD1.5bn in CY10. Pfizer failed to roll out an aggressive physician education program, or even a direct-to-consumer advertising effort. Finally, in October 2007, Pfizer stopped manufacturing of Exubera as it failed to gain acceptance amongst patients and physicians. The company had to eventually take a write-off of USD2.8bn for the drug. We note that another similar attempt in marketing an inhaled insulin product, Afrezza, by Sanofi and Mannkind in CY15, has also not succeeded.

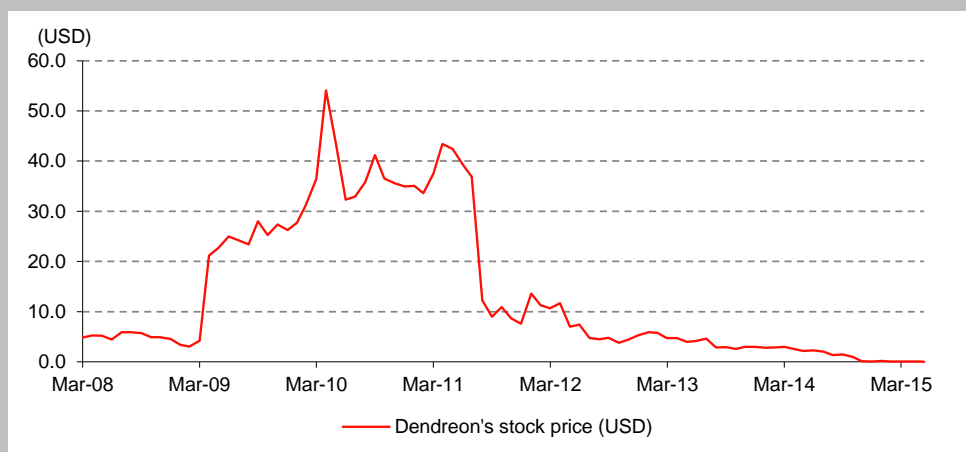
#### What went wrong?

Physicians were uncertain about the working of the inhaler device. Additionally, lung-function tests had to be done to make certain Exubera was an appropriate therapy for patients. A key reason for the drug’s failure was its large drug delivery device, which was inconvenient to carry. Also, over time, diabetes needles became very tiny and hence self-injection became convenient. Inhaled insulins are costly as well as the inhalers use much more insulin than syringes. Despite the higher price, Exubera was less effective as compared to existing injectable treatments.

## Specialty Case Study II: The collapse of Dendreon

Dendreon is a US-based biotech company focussed on novel active cellular immunotherapy for treatment of cancer. Its flagship product was Provenge, a cell-based cancer immunotherapy for prostate cancer. In May 2010, following the US FDA approval for Provenge, the market capitalisation of Dendreon had reached USD7.5bn. Prior to its 2QCY11 (first full quarter of Provenge launch) conference call, Dendreon had guided for USD350-400m annual sales in CY11 from Provenge. The company could only manage to report USD50m sales in 2QCY11 and another USD19m sales in July, which was substantially lower than internal projections. The stock fell ~66% on the day of 2QCY11 results. The earlier guidance was revised substantially to 'modest sequential growth' in Provenge's sales. Ultimately, Provenge ended up achieving USD220m and USD322m sales in CY11 and CY12, considerably lower than earlier guidance. In November 2014, Dendreon filed for Chapter 11 bankruptcy and Valeant Pharma took over the company in February 2015. In June 2017, Sanpower Group, a private Chinese conglomerate, acquired Dendreon from Valeant Pharma for USD820m.

**Fig 51 Dendreon's stock price collapse is a reflection of sky-high expectations**



Source: Symphony data, Macquarie Research, October 2017

### What went wrong?

The reasons for the huge gap between actual performance and street estimates ranged from supply constraints, reimbursement issues, high cost density (the molecule was priced highly at USD100k for a course of 3 infusions), failure of physicians in identifying patients eligible for Provenge and the novelty of the product, which needed a unique supply chain. Another issue was that this product could be prescribed by both oncologists and urologists. While oncologists were used to infusion-based medicines, urologists were not and had to be educated in that area. We highlight that such issues could hold true for other specialty drugs as well. Unless the companies are well-prepared, there could be a mismatch in performance.

### Takeaways:

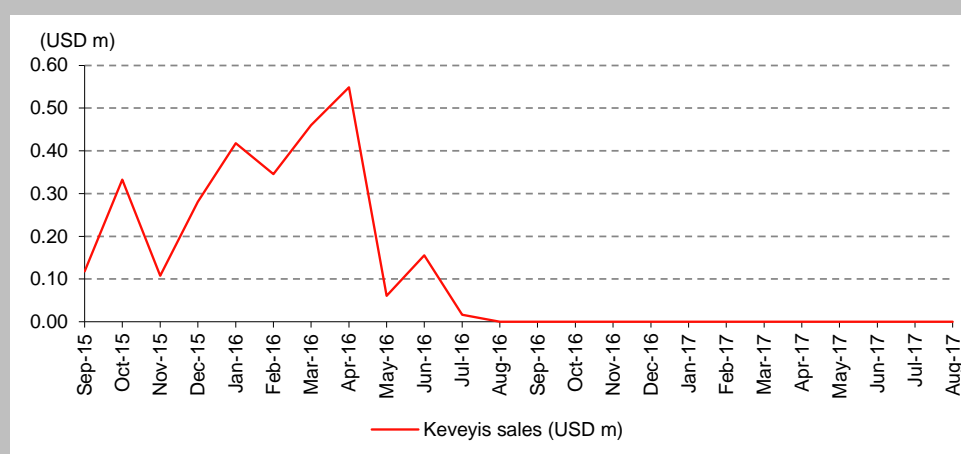
- It can be difficult to quantify the revenue potential and timelines of specialty drugs, even for management.
- Creating a market for the drug could be challenging and educating medical specialists could also be a challenge.
- Impact of cost density could hamper demand.



## Specialty case Study III: Keveyis – Big gap between reality and USD100m+ street expectations

Keveyis, an orphan drug by Sun Pharma's US subsidiary, Taro, was the first to get approval for the treatment of periodic paralysis. Periodic paralyses are a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis. Many patients often endure decades of diagnostic 'missteps,' with a significant delay between the onset of symptoms and diagnosis. Among the 5,000 people estimated to be living with Periodic Paralysis in US, fewer than 1,500 are believed to have been diagnosed. The drug was launched in September 2015 in US. Post the commercial launch, the product never took off. There was a significant mismatch between the sales and costs, which could not be bridged. Realising that it could not sustain the losses, Taro decided to make the product available free of cost to distributors from May 2016.

**Fig 52 Sales data for Keveyis suggests it never took off commercially**



Source: Symphony data, Macquarie Research, October 2017

### What went wrong?

Although Taro expected to treat only a few hundred patients with Keveyis, reaching such a small pool of people proved to be more difficult than previously anticipated by the company. The company spent a lot in creating patient awareness, support services, medical education and awareness of pediatric paralysis. However, since this is an ultra-rare disease, the patient population was very small. Despite extensive pre-launch diligence, revenues from Keveyis at <USD1m since launch were much lower than the company's and street's expectations.

### Takeaways:

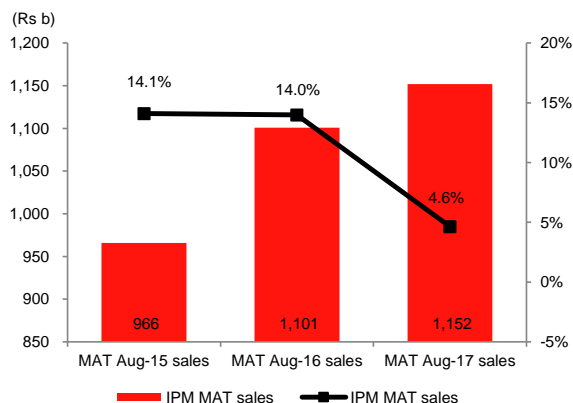
- For orphan specialty drugs, patient population size itself could limit market potential.
- Also, patient outreach could be a big challenge especially as marketing spends would not be cost effective.

# India – Steady, barring regulatory overhang

## We build India sales recovery to 10-13% YoY across cos in FY19/20

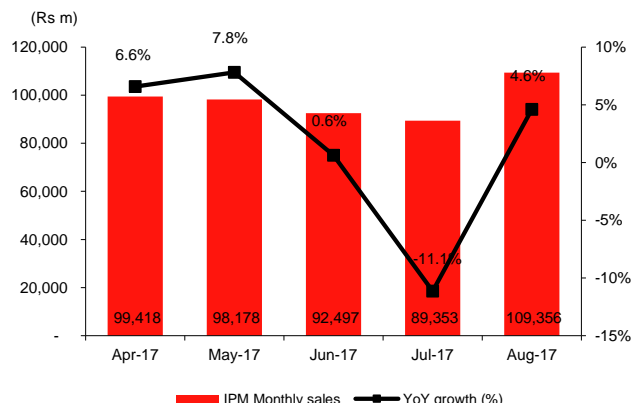
After US, India is the second-largest market for most Indian pharma companies. Spending on healthcare in India remains low by international standards, accounting for ~5-6% of GDP. Government contributions account for just 30% of total healthcare spending. IMS expects the Indian pharma market to grow at a CAGR of 11% between CY16-CY21 to reach Rs1,983bn.

**Fig 53 India pharma MAT sales growth**



Source: IMS, Company data, Macquarie Research, October 2017

**Fig 54 India pharma monthly sales**



Source: IMS, Company data, Macquarie Research, October 2017

**Fig 55 IPM – companies’ sales and market share – top 25 companies enjoy ~71% market share**

(Rs m)	MAT sales			MAT sales growth(YoY)		Monthly sales growth (YoY)						Market share MAT Aug-17 sales
	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	MAT Aug-16 sales	MAT Aug-17 sales	Mar-17	Apr-17	May-17	Jun-17	Jul-17	Aug-17	
IPM	965,872	1,100,897	1,152,015	14.0%	4.6%	10.6%	6.6%	7.8%	0.6%	-11.1%	4.6%	100.0%
SUN	77,815	87,521	93,491	12.5%	6.8%	12.6%	7.8%	8.3%	-0.8%	-9.8%	5.2%	8.1%
ABBOTT	62,709	69,762	74,424	11.2%	6.7%	10.8%	7.4%	11.5%	0.0%	-3.8%	8.2%	6.5%
CIPLA	50,865	57,550	60,049	13.1%	4.3%	11.7%	6.9%	12.0%	-2.8%	-8.9%	2.2%	5.2%
MANKIND	34,665	42,028	44,025	21.2%	4.8%	10.0%	7.6%	5.8%	10.8%	-11.8%	8.7%	3.8%
ALKEM	32,700	38,356	39,304	17.3%	2.5%	8.3%	6.5%	5.7%	-5.7%	-20.8%	0.1%	3.4%
LUPIN	31,339	34,953	38,929	11.5%	11.4%	17.6%	14.8%	16.0%	8.9%	-8.2%	6.7%	3.4%
GSK	33,204	36,257	37,323	9.2%	2.9%	12.8%	11.0%	8.0%	0.6%	-13.2%	6.7%	3.2%
MACLEODS	30,383	35,425	36,792	16.6%	3.9%	9.7%	6.4%	5.9%	-1.7%	-15.0%	4.0%	3.2%
CADILA	34,232	37,352	37,153	9.1%	-0.5%	4.5%	-1.0%	-1.5%	-4.4%	-17.0%	1.8%	3.2%
INTAS	26,781	31,057	32,719	16.0%	5.4%	9.7%	5.4%	7.1%	0.4%	-7.7%	11.0%	2.8%
PFIZER	27,876	29,853	27,900	7.1%	-6.5%	-5.4%	-9.8%	-6.0%	-9.2%	-23.1%	-8.0%	2.4%
ARISTO	21,587	26,260	27,526	21.6%	4.8%	13.5%	7.3%	10.0%	4.2%	-17.1%	-2.2%	2.4%
TORRENT	23,934	25,272	27,260	5.6%	7.9%	13.3%	10.5%	8.8%	3.1%	-1.8%	9.6%	2.4%
DRRD	23,152	26,322	25,713	13.7%	-2.3%	7.6%	-2.7%	-2.5%	-11.8%	-9.4%	-1.5%	2.2%
SANOFI	22,255	25,075	26,191	12.7%	4.4%	5.2%	4.1%	8.7%	5.1%	-1.1%	6.2%	2.3%
GLENMARK	19,293	23,237	25,362	20.4%	9.1%	14.5%	14.5%	11.6%	0.7%	-4.8%	6.8%	2.2%
EMCURE	22,129	25,136	25,149	13.6%	0.1%	5.3%	3.5%	3.9%	-0.3%	-12.6%	0.5%	2.2%
U S V	19,018	22,119	24,168	16.3%	9.3%	14.7%	9.4%	12.2%	4.3%	4.0%	12.4%	2.1%
MICRO LABS	15,895	17,845	18,686	12.3%	4.7%	13.0%	8.6%	11.0%	3.3%	-21.3%	1.8%	1.6%
ALEMBIC	15,887	17,526	17,895	10.3%	2.1%	11.7%	7.1%	7.2%	-4.9%	-19.4%	-1.2%	1.6%
WOCKHARDT	14,537	17,266	16,960	18.8%	-1.8%	-4.4%	3.8%	4.2%	-4.4%	-23.2%	3.1%	1.5%
IPCA LABS	14,187	15,991	16,556	12.7%	3.5%	12.3%	2.3%	5.7%	-4.8%	-19.6%	1.3%	1.4%
UNICHEM	10,487	11,553	12,069	10.2%	4.5%	12.8%	7.7%	8.5%	0.7%	-12.4%	7.1%	1.0%
FDC	10,994	12,447	12,574	13.2%	1.0%	6.0%	3.0%	3.8%	-5.0%	-13.5%	4.1%	1.1%
NOVARTIS	10,646	11,397	11,691	7.1%	2.6%	5.3%	-5.2%	1.7%	-1.0%	-4.5%	9.8%	1.0%
BIOCON	3,449	3,586	3,745	4.0%	4.4%	12.4%	8.9%	1.8%	4.4%	-5.5%	9.2%	0.3%

Source: IMS data, Macquarie Research, October 2017

While the private share of total healthcare spending is declining, out-of-pocket payments by patients continue to account for 63-65% of total healthcare expenditure. Dispensing of prescription drugs without a doctor’s prescription remains common, although a new campaign seeks to raise awareness and limit over-the-counter sale of antibiotics without a prescription. Close relationships between prescribers and nearby pharmacies mean substitution rates tend to be relatively low. The key therapies in India include anti-infectives, cardiac, gastro intestinal and anti-diabetic (fastest growing despite a high base).

**Fig 56 Indian pharma – top therapies sales and market share**

(Rs m)	MAT sales			MAT sales growth (YoY)		Monthly sales growth (YoY)						Market share MAT Aug-17 sales
	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	MAT Aug-16 sales	MAT Aug-17 sales	Mar-17	Apr-17	May-17	Jun-17	Jul-17	Aug-17	
IPM	965,872	1,100,897	1,152,015	14.0%	4.6%	10.6%	6.6%	7.8%	0.6%	-11.1%	4.6%	100.0%
Anti-infectives	132,764	149,805	141,900	12.8%	-5.3%	1.5%	-0.3%	0.6%	-5.9%	-28.1%	-9.4%	12.3%
CARDIAC	114,527	128,689	136,363	12.4%	6.0%	10.0%	5.7%	7.2%	1.5%	-4.2%	9.0%	11.8%
Gastro Intestinal	103,841	117,418	123,202	13.1%	4.9%	11.7%	7.5%	8.3%	-1.7%	-11.1%	5.4%	10.7%
Anti Diabetic	76,680	91,625	106,320	19.5%	16.0%	22.4%	17.1%	20.8%	10.4%	7.0%	16.1%	9.2%
Pain / Analgesics	79,065	88,255	91,210	11.6%	3.3%	8.0%	4.6%	5.0%	-0.8%	-13.3%	3.2%	7.9%
Respiratory	74,820	85,010	89,685	13.6%	5.5%	11.2%	6.1%	7.1%	-0.8%	-8.5%	6.7%	7.8%
Vitamins	75,363	86,343	88,678	14.6%	2.7%	10.8%	8.7%	11.5%	-0.3%	-21.2%	-4.8%	7.7%
Derma	62,610	72,812	84,052	16.3%	15.4%	23.7%	15.8%	15.7%	8.5%	0.7%	20.7%	7.3%
Neuro / CNS	57,223	65,643	69,543	14.7%	5.9%	11.0%	6.5%	7.8%	-0.6%	-9.0%	6.4%	6.0%
Gynaec	48,027	54,152	55,866	12.8%	3.2%	7.7%	3.5%	3.2%	1.0%	-11.1%	5.9%	4.8%
Ophthal	18,385	20,596	22,383	12.0%	8.7%	16.3%	11.7%	14.0%	2.9%	-8.2%	8.4%	1.9%
VACCINES	19,206	19,808	21,126	3.1%	6.7%	8.8%	10.9%	16.8%	11.9%	2.4%	15.7%	1.8%
Hormones	15,865	18,355	20,214	15.7%	10.1%	18.3%	11.1%	11.1%	3.8%	-6.6%	10.4%	1.8%
Urology	17,079	18,934	18,562	10.9%	-2.0%	-0.6%	-2.9%	-3.8%	-7.2%	-13.0%	1.3%	1.6%
Oncology	13,457	16,494	16,766	22.6%	1.7%	1.2%	-8.7%	-4.7%	7.3%	-5.6%	13.4%	1.5%
Others	9,875	11,066	11,612	12.1%	4.9%	12.5%	10.5%	8.7%	-1.7%	-8.5%	11.0%	1.0%
Hepatoprotective	8,496	11,905	11,451	40.1%	-3.8%	-2.0%	-5.4%	-5.2%	-5.8%	-15.3%	2.4%	1.0%
Blood Related	10,104	11,068	10,849	9.5%	-2.0%	3.2%	-3.9%	1.5%	-3.0%	-10.3%	7.9%	0.9%
Antivirals	5,682	7,862	8,739	38.4%	11.2%	25.8%	21.4%	16.4%	1.8%	-4.3%	12.4%	0.8%
Stomatologicals	5,856	6,634	7,071	13.3%	6.6%	12.4%	7.3%	8.8%	-0.1%	-5.3%	15.1%	0.6%
Anti malarials	5,286	6,265	5,042	18.5%	-19.5%	-14.1%	-25.9%	-19.3%	-23.0%	-46.6%	-23.9%	0.4%
Anti-TB	4,115	4,048	3,828	-1.6%	-5.4%	-4.8%	-5.7%	-3.5%	-5.2%	-18.4%	-4.5%	0.3%
Anti-Parasitic	3,496	3,799	3,522	8.7%	-7.3%	1.2%	-1.4%	-6.9%	-16.8%	-26.3%	-5.6%	0.3%

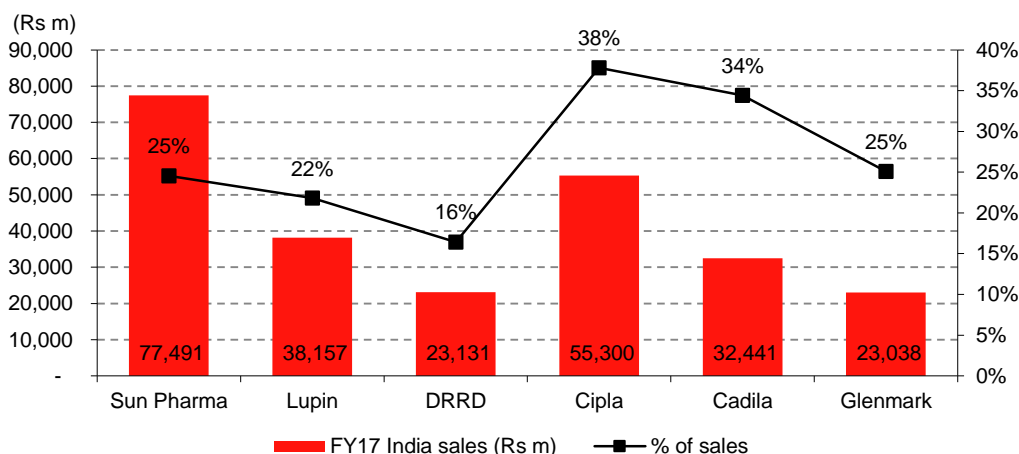
Source: IMS data, Macquarie Research, October 2017

**India remains a strong cash cow for Indian pharma companies**

The revenue contribution from India for our coverage universe ranges from as low as 16% for DRRD to as high as 38% and 34% for Cipla and Cadila respectively in FY17. India market also remains a major contributor to profitability of Indian pharma companies with high gross margins of 70-75% and EBITDA margins of 30-35%. Apart from this, working capital requirements and taxes are lower, which boost ROCEs.

**India market also remains a major contributor to profitability of Indian pharma companies with high gross margins of 70-75% and EBITDA margins of 30-35%.**

**Fig 57 India is the second largest market for most pharma companies**

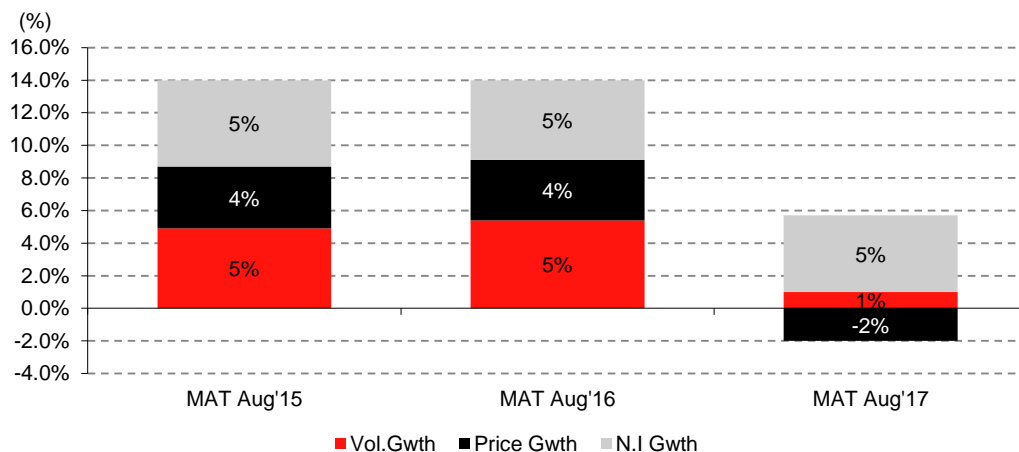


Source: Company, Macquarie Research, October 2017

*The domestic pharma industry growth has been largely driven by volumes and new launches in the past, with the value component of growth in low single digits.*

The domestic pharma industry growth has been largely driven by volumes and new launches in the past, with the value component of growth in low single digits. New introductions (NI) have been consistently contributing ~500bps to industry growth over the last three years.

**Fig 58 Growth in India sales has been largely volume and NI led**

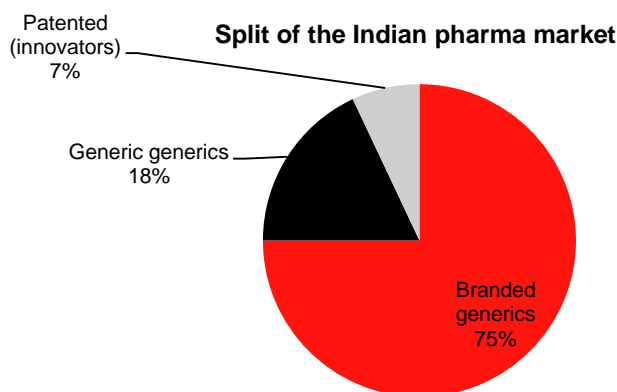


Source: IMS data, Macquarie Research, October 2017

**Indian pharma market dominated heavily by branded generics**

As per IMS data, branded generics constitute ~75% of the ~Rs 1 trillion Indian pharma market. Patented drugs (innovators) constitute ~7% of the market, whereas the rest ~18% is contributed by generic generics.

**Fig 59 Revenue split of the Indian pharma market**



Source: IMS, Industry data, Macquarie Research, October 2017

**Regulatory risks cast doubts on strong predictability of the business**

In the past few years, there have been too many disruptions, cumulatively shaving off few basis points growth from the Indian pharma market. These include the 2013 Drug Price Control Order (DPCO), NLEM list, FDC ban, demonetisation and GST related disruption in the supply chain.

*In the past few years, there have been too many disruptions, cumulatively shaving off few basis points growth from the Indian Pharma market.*

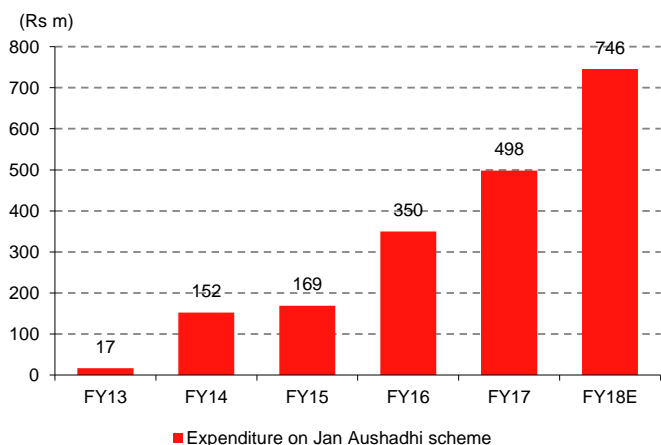
- **Price control:** Price controls on drugs in India were expanded significantly with the implementation of the 2013 Drug Price Control Order (DPCO), and their scope was increased further following the updates of NLEM, bringing the total number of drugs subject to price controls to 821. The government intends to update the NLEM list regularly in the future, which is an overhang. Even in the draft pharma policy, citing high out-of-pocket expenses, the government has reiterated its intent of continuing to regulate healthcare prices. Other related pricing disruptions include the pricing caps on coronary stents and knee implants.
- **FDC ban:** In March 2016, following a review of ~5,500 fixed-dose combinations (FDCs), the Ministry of Health and Family Welfare (MOHFW) announced a ban on the sale of 344 FDCs. In December 2016, the Delhi High Court struck down the ban. The MOHFW has lodged a petition with the Supreme Court, challenging the Delhi High Court's decision. The case is currently ongoing in the Supreme Court. In total, FDCs contribute ~40% of the total Indian pharma market (Rs400bn).
- **Demonetisation:** The note ban (withdrawal of all Rs500 and Rs1,000 notes to curtail black market) by the Central government in November 2016 was another disruption for the Indian pharma industry, which impacted industry growth for 3-4 months.
- **GST-related disruption:** In June 2017, normal inventory levels for the industry, which used to be ~45 days had come down to 25 days due to GST destocking. Currently, inventory levels have increased slightly to 30-35 days. There are also issues in availing GST credit, which has increased working capital requirements for pharma manufacturers. In the long run, we expect GST to simplify the supply chain and it could be a consolidation trigger across all levels of the pharma market.

*There has been a thrust on increasing the distribution of Jan Aushadhi stores across the country.*

**Increasing government focus on affordable healthcare can pinch pharma cos**

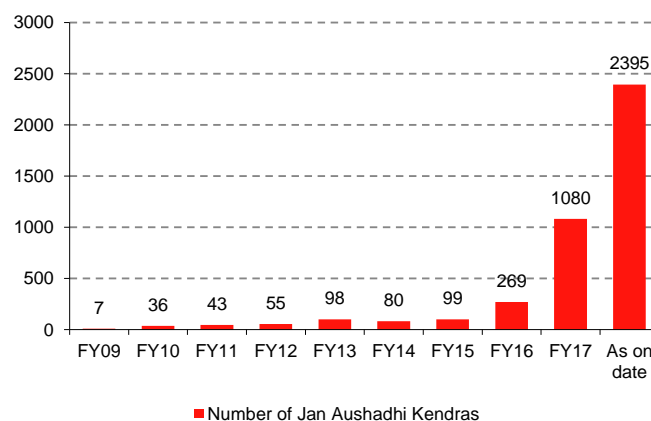
The stated objective of the Indian government is improving access of medicines and providing affordable healthcare to the masses. Accordingly, there has been a thrust on increasing the distribution of Jan Aushadhi stores (government stores selling generic drugs) across the country. Currently, the Jan Aushadhi program is in its expansion phase. If the expansion continues at the same pace for the next few years, the branded pharma business of Indian companies could start feeling the pinch. However, the Jan Aushadhi program first needs to sort out supply constraints and quality issues to have a meaningful impact.

**Fig 60** Though miniscule, expenditure on Jan Aushadhi scheme is increasing



Source: Union Budget, Macquarie Research, October 2017

**Fig 61** Number of Jan Aushadhi Kendras



Source: [www.janaushadhi.gov.in](http://www.janaushadhi.gov.in), Macquarie Research, October 2017

The Indian government had last attempted genericisation in 1978, which was then shelved after it was challenged in court. Our discussions with industry experts lead us to believe that genericisation is difficult to implement given various issues. These issues include (i) bioequivalence (ii) labeling and packaging (iii) prescription and substitution (iv) patient acceptance and (v) quality standards. As per our discussions with pharma consultants, there is a big gap in the quality standards of US FDA-approved facilities and non US FDA-approved facilities in India. Hence, implementation of complete genericisation is extremely difficult.

**Fig 62 A Jan Aushadhi store in Pune**



Source: Government of India, Justdial, Macquarie Research, October 2017

### Expect newsflow around the pharma policy for the next few years

***Our discussions with industry players suggest that we could see the refined version of the draft pharma policy (very close to the final version) in the next few months.***

The Indian government has been focussing on improved access to affordable medicines and promoting local manufacturing of drugs. Accordingly, the government prepared the Draft Pharma Policy in August 2017. Currently, the government is engaged in discussions with various stakeholders in finalising the policy. Our discussions with industry players suggest that we could see the refined version of the policy (might not be the final version yet) in the next few months. We note that the policy has been silent on requirement of doctors to prescribe molecule/salt names (except for public procurement), which is a relief for pharma companies. Also, higher focus on quality standards, is beneficial for pharma companies under our coverage as these have already been maintaining stricter checks on quality. Smaller players could be at a disadvantage if stringent quality checks are put in place. However, measures like restrictions on API sourcing and loan-licensing are negatives for all pharma companies.

Key objectives of the draft pharma policy as laid down by the government are:

⇒ **Making essential drugs accessible at affordable prices to the common masses**

The government endeavours to streamline the price regulation mechanisms and regulating trade margins. The policy also proposes public procurement of generic generics by their salt name. The government aims to address the issue of unethical marketing practices deployed by manufacturers and marketing companies. The policy has raised the point of all-expense paid trips to educational conventions being used to circumvent advertisement of a drug.

⇒ **Providing a longer-term stable policy environment for the pharmaceutical sector**

As per the policy, the government will prepare the list of drugs under pricing regulations, while National Pharmaceutical Pricing Authority (NPPA) will fix the actual ceilings and will be responsible for enforcing the lower prices. While this will simplify the price regulation mechanism, it can lower top-line growth and impact margins for pharma companies. The government intends to prescribe the level of trade margins to create a level playing field for the Industry and to bring down prices. Institutions receiving supplies directly from manufacturers/distributors or retailers will also be covered under the trade margin reforms.

⇒ **Making India sufficiently self-reliant in end to end indigenous drug manufacturing**

The government plans to promote domestic manufacturing by giving preference to formulations manufactured from indigenous APIs and intermediates in government manufacturing. Such formulations will be exempted from price controls for five years. An enabling environment will be created for setting up mega API parks with common facilities for pollution control and effluent treatment. According to Pharmaceuticals Export Promotion Council (Pharmexcil), India imports APIs worth ~USD6bn. The policy mentions about high dependence for APIs on 1-2 countries. It proposes change in sourcing policies for APIs and levying higher custom duties, which would increase costs given that more than 60% APIs are imported (largely from China). In some specific APIs, the dependence on imports is 80-90%.

⇒ **Ensuring world class quality of drugs for domestic consumption & exports**

The policy proposes making bio-availability and bio-equivalence tests mandatory, including future renewals of manufacturing licenses for drugs. The government also plans to ensure that WHO's GMP and Good Laboratory Practices (GLP) are followed at all facilities. The government is considering allowing self-certification of manufacturing units as an effective mechanism till such time that Central Drug Regulator develops capacity for annual inspections. The Draft Pharma Policy has proposed to disallow loan licensing except in case of biologics. If implemented, this could be a serious negative for Indian pharma companies. As per industry estimates, more than 30% of total volumes are manufactured using loan-licensing. The government has also proposed alternatives like phasing out loan licensing over three years or limit it to WHO approved facilities or limit it to 10% of the company's total production capacity.

⇒ **Creating an environment for R&D to produce innovator drugs**

For Novel Drug Delivery Systems (NDDS), there will be concessional customs duty rate of 0-5% on the import of R&D-related specified goods and services. A major grievance of the industry is that the approval of a new drug is a long drawn-out process and the average time taken is two years. The policy lays emphasis on standardising the drug approval process and shortening it to a maximum of six months.

***The Draft Pharma Policy has proposed to disallow loan licensing except in case of biologics. As per industry estimates, more than 30% of total volumes are manufactured using loan-licensing.***

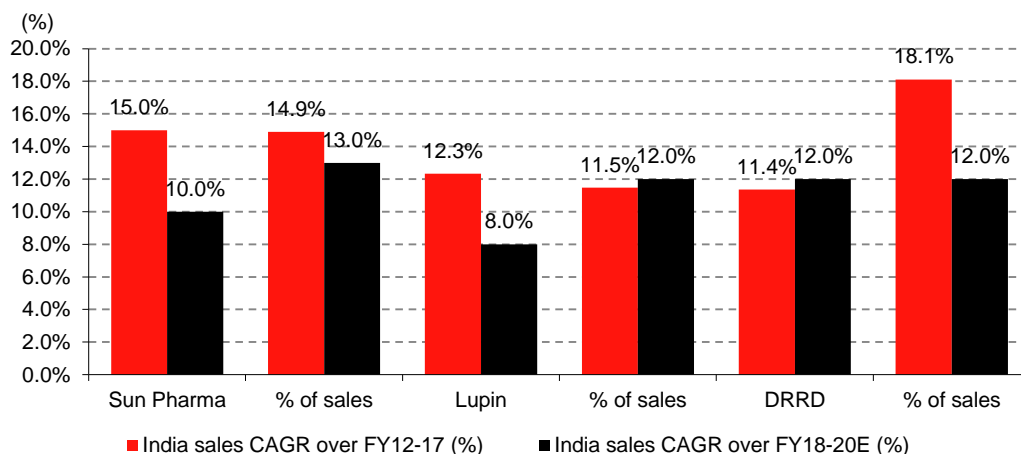
**Few other countries like Brazil have tried to convert from branded generics to generic-generic. However, the ramp-up of generic-generic market share has been extremely gradual.**

**Why is genericisation difficult to implement quickly in India?**

We believe any move by the government towards genericisation could pose risk to the medium-term growth outlook of Indian pharma market. With the industry already reeling under the impact of NLEM, FDC ban, demonetisation and GST-disruption, this could be a further headwind for the Indian pharma industry. However, in our view, stringent GMP regulations for Indian facilities are a must before generic prescriptions are made mandatory as quality standards could significantly vary across manufacturers. Existing regulatory framework does not provide egalitarian opportunities for all the pharma companies. Quality systems and infrastructure are different across companies. There is not a level playing field for companies. A regulatory framework is required to ensure that every drug approved has the same level of safety, efficacy and reliability. In our view, the drug regulatory governance structure has to be streamlined. In India, a key impediment in implementation of a stable regulatory framework is that there is a Central Regulatory Authority and various state regulatory authorities. Ensuring the quality of drugs remains a critical aspect for the Indian government to address. The same standards are not implemented at the State level and healthcare is a state subject. Few other countries like Brazil have tried to convert from branded generics to generic-generic. However, the ramp-up of generic-generic market share has been extremely gradual.

We expect industry margins to be largely capped as price controls are expanded and prices are cut under the DPCO. In addition, trade margins, including both wholesaler and retailer margins, could be subject to stricter regulation in future.

**Fig 63 Despite regulatory overhang, we are building improvement in FY19-20**



\*Sun's estimates adjusted for Ranbaxy acquisition  
 Source: Company, Macquarie Research, October 2017



## R&D, compliance costs to impede margins

### Gross margins to improve steadily in FY19-20

Average price erosion in the US was ~5% between FY13-FY17, which has now increased to high single digits to low double digits. From 2HFY19, we are building in reasonable stability (settling to 9-10% annually) in pricing erosion in the base business. Also, we expect the impact of the latest round of channel consolidation to be reflected till then. We also expect early signs of specialty ramp-up to be visible for larger companies. Accordingly, we are building improvement in gross margins in FY19-20.

**Fig 64 Gross margin schematic - Building expansion in FY19-20**

Rs m	FY15	FY16	FY17	FY18E	FY19E	FY20E
Sun Pharma	75.4%	77.1%	74.3%	68.0%	69.0%	70.5%
Lupin	67.4%	69.7%	71.4%	70.2%	71.1%	72.1%
DRRD	57.6%	59.6%	55.6%	55.5%	58.5%	60.0%
Cipla	63.1%	63.1%	63.7%	62.0%	62.9%	62.8%
Cadila	63.1%	66.7%	63.5%	66.0%	68.0%	68.5%
Glenmark	70.8%	69.1%	71.5%	70.5%	70.5%	70.7%
Jubilant	52.4%	35.9%	33.3%	44.0%	44.0%	43.5%
Strides	54.0%	52.2%	56.2%	54.5%	57.0%	57.5%

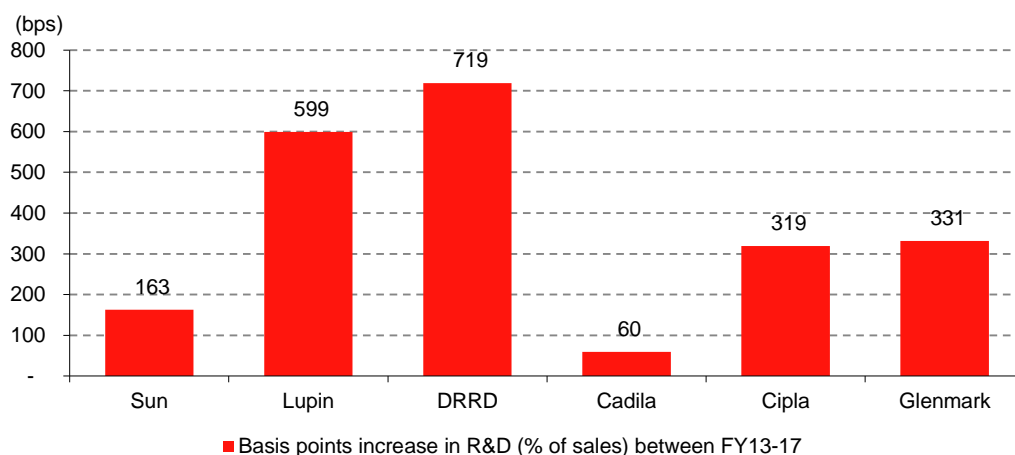
Source: Company data, Macquarie Research, October 2017

### Increasing R&D spends – Is there a choice?

**Given the pressure in the US base business, we believe it has become imperative for Indian pharma companies to step up their investments in complex generics and specialty.**

R&D spends across our coverage universe have increased as companies increasingly invest in specialty and complex generics. Companies, which have traditionally underinvested in R&D, are now trying to close the gaps in their portfolio by increasing R&D spends. Especially for DRRD and Lupin, there has been sharp increase in R&D spends between FY13-17. R&D spends have been increasing for most pharma companies due to the ongoing transition to specialty, which have taken a toll on margins. For example, only ~25% of Mylan's R&D spends in CY17 is expected to be towards its base generics business. The rest would be towards development of complex products, respiratory and biosimilars (Mylan has invested ~USD3.1bn cumulatively between CY13-17 towards R&D). Especially for specialty molecules, clinical trials are a key reason for higher R&D spends. Depending on the molecule, as per Lupin, cost of clinical trials can range from USD6m to USD60m. Given the pressure in the US base business, we believe it has become imperative for Indian pharma companies to step up their investments in complex generics and specialty considerably in the last few years.

**Fig 65 Impact on EBITDA margins due to increase on R&D spends between FY13 and FY17**



Source: Company data, Macquarie Research, October 2017

**Fig 66 R&D (% of sales) has been generally increasing across pharma companies**

Rs m	R&D (% of sales)						
	FY14	FY15	FY16	FY17	FY18E	FY19E	FY20E
Sun	6.2%	6.7%	8.0%	7.6%	9.5%	9.2%	9.2%
Lupin	8.4%	8.7%	11.7%	13.5%	13.0%	12.8%	12.6%
DRRD	9.4%	11.8%	11.5%	13.9%	14.6%	14.0%	13.2%
Cipla	5.2%	5.9%	5.9%	7.4%	8.0%	8.0%	8.0%
Cadila	6.3%	6.5%	7.7%	8.0%	8.0%	8.0%	8.0%
Glenmark	10.0%	9.1%	10.7%	11.6%	11.3%	11.0%	11.0%

Source: Company data, Macquarie Research, October 2017

Due to weak topline and higher R&D, compliance and specialty-related costs, EBITDA margins have been under pressure. We are building in gradual improvement in margins in FY19-20.

**Fig 67 EBITDA margin schematic – We are building improvement in FY19-20**

Rs m	FY14	FY15	FY16	FY17	FY18E	FY19E	FY20E
Sun Pharma	44.7%	29.0%	29.4%	31.9%	20.5%	23.8%	26.9%
Lupin	26.6%	28.3%	26.4%	25.7%	20.9%	22.6%	24.3%
DRRD	24.7%	23.6%	26.6%	17.9%	17.4%	21.3%	23.4%
Cipla	21.1%	19.1%	18.0%	16.9%	18.3%	20.1%	20.5%
Cadila	16.6%	20.3%	24.2%	20.2%	22.0%	25.5%	26.2%
Glenmark	21.5%	21.4%	18.7%	22.2%	21.1%	22.1%	22.3%
Jubilant	17.4%	14.5%	21.7%	23.0%	21.0%	20.2%	20.6%
Strides	20.6%	20.7%	18.2%	20.6%	17.4%	22.0%	22.9%

Source: Company data, Macquarie Research, October 2017

*Return ratios are likely to improve gradually in FY19 and FY20.*

Return ratios of most companies has deteriorated materially over FY15-18E.

**Fig 68 ROEs have deteriorated materially for most companies**

ROE (%)	FY15	FY16	FY17	FY18E	FY19E	FY20E
Sun Pharma	17.2%	15.0%	19.4%	7.5%	10.1%	12.5%
Lupin	30.4%	22.9%	20.8%	12.3%	13.6%	15.1%
DRRD	19.9%	15.6%	9.6%	9.0%	13.4%	17.2%
Cipla	11.3%	12.0%	8.3%	12.3%	14.3%	14.5%
Cadila	30.2%	31.8%	24.2%	20.4%	23.2%	22.0%
Glenmark	15.8%	16.1%	31.5%	22.0%	20.2%	18.2%
Jubilant	9.1%	13.2%	18.0%	17.9%	19.4%	18.9%
Strides	14.2%	9.3%	12.5%	9.1%	13.1%	15.0%

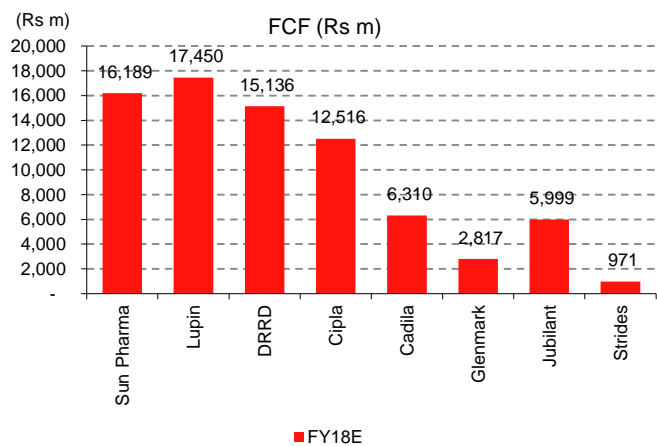
Source: Company data, Macquarie Research, October 2017

**Fig 69 Despite forecasting expansion, ROCEs for most cos are only in mid-teens**

ROCE (%)	FY15	FY16	FY17	FY18E	FY19E	FY20E
Sun Pharma	37.4%	27.9%	22.6%	9.2%	11.8%	14.5%
Lupin	31.2%	17.6%	14.0%	8.9%	10.9%	13.4%
DRRD	21.1%	21.8%	8.9%	7.8%	13.0%	16.6%
Cipla	14.8%	14.7%	8.6%	11.9%	15.2%	17.3%
Cadila	21.5%	25.5%	18.8%	15.8%	20.1%	21.2%
Glenmark	17.2%	15.0%	20.8%	15.8%	16.4%	16.6%
Jubilant	6.4%	9.6%	12.5%	13.2%	15.8%	17.7%
Strides	15.1%	11.7%	11.1%	8.7%	12.7%	14.4%

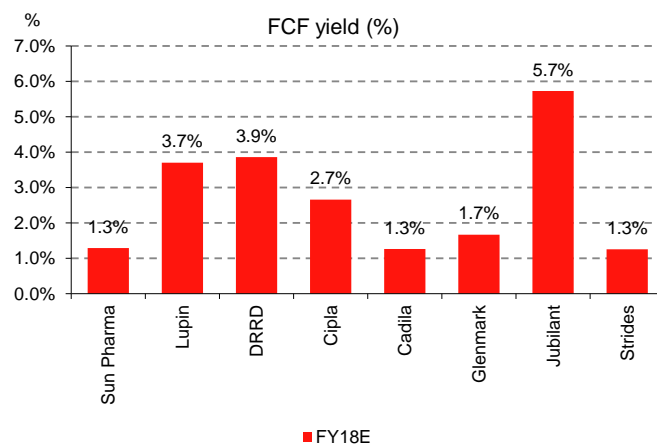
Source: Company data, Macquarie Research, October 2017

**Fig 70 Estimated free cash generation in FY18**



Source: Macquarie Research, October 2017

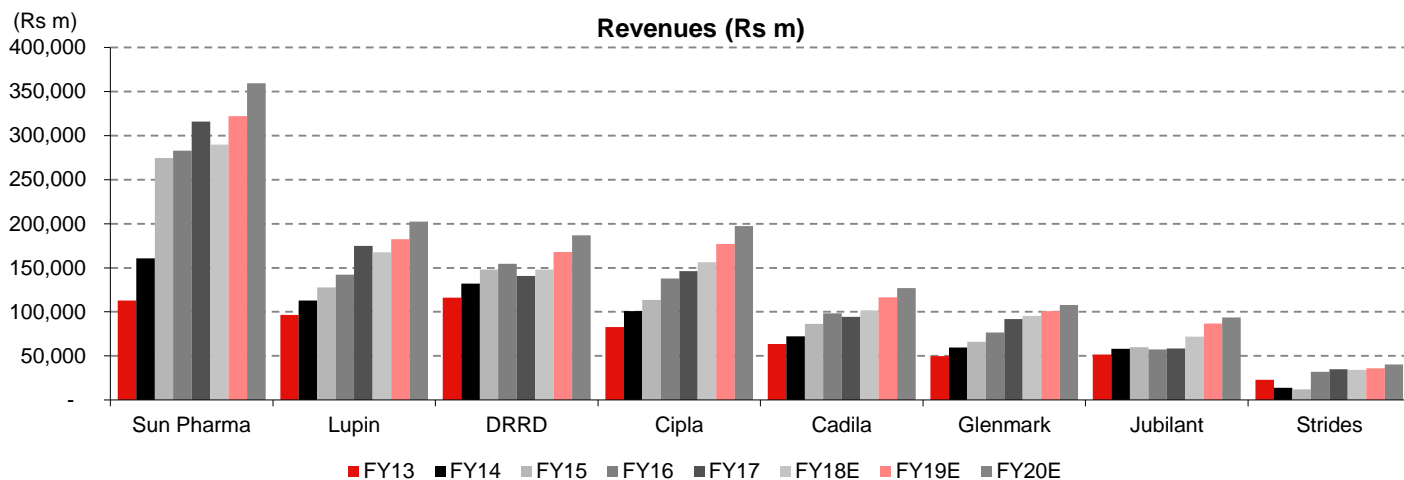
**Fig 71 FCFE yield – FY19E (%)**



Source: Macquarie Research, October 2017

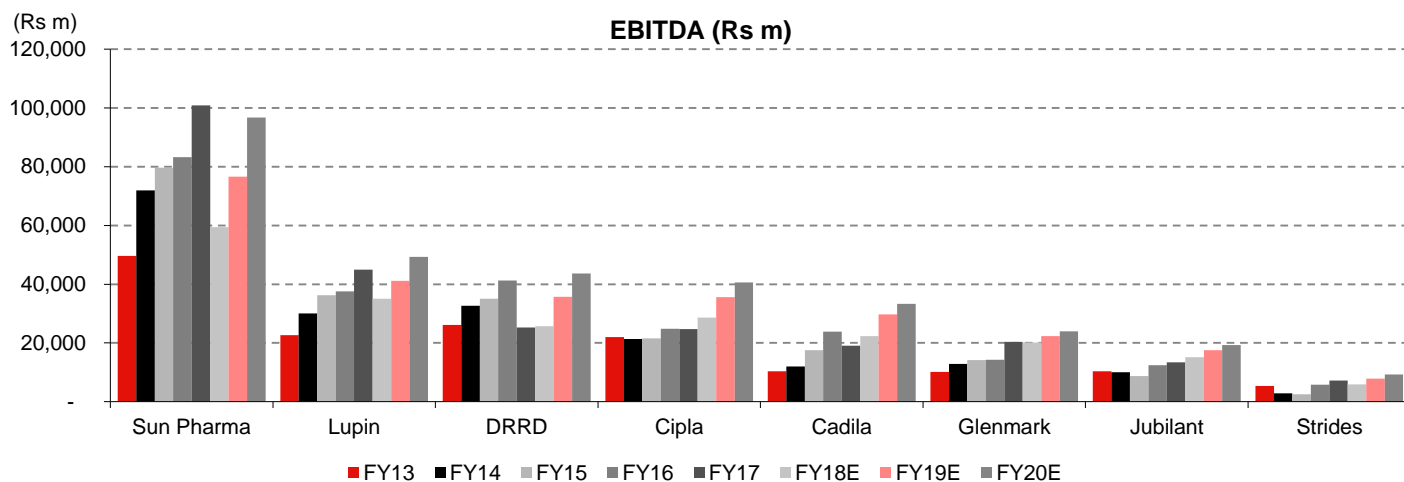
# Appendices

**Fig 72 Revenue comparison of our pharma coverage universe**



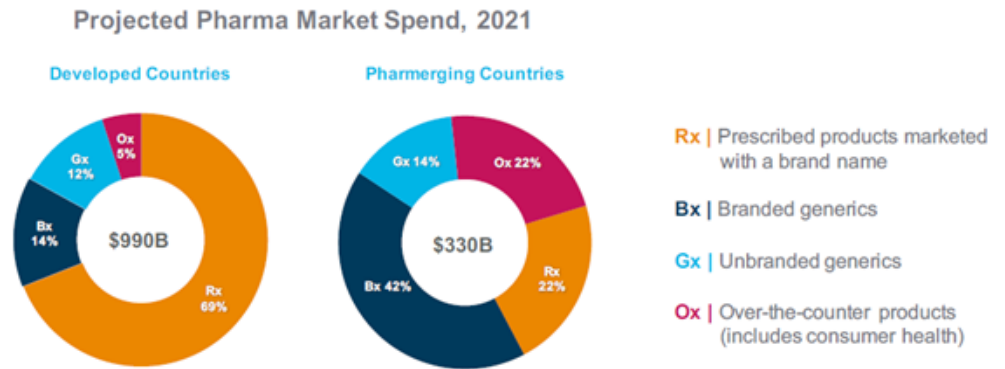
Source: Company, Macquarie Research, October 2017

**Fig 73 EBITDA comparison of our pharma coverage universe**



Source: Company, Macquarie Research, October 2017

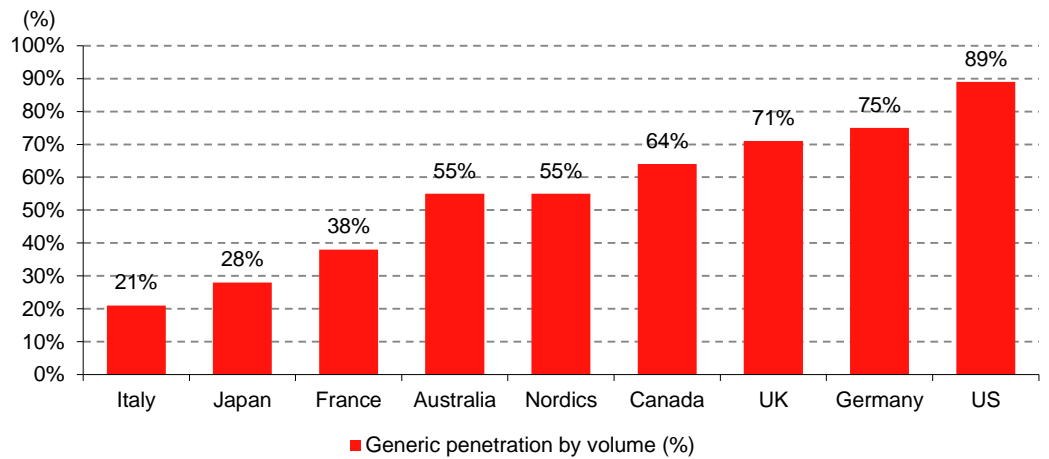
**Fig 74 Estimated size of the global pharma market by CY21**



Source: IMS, Mylan, Macquarie Research, October 2017

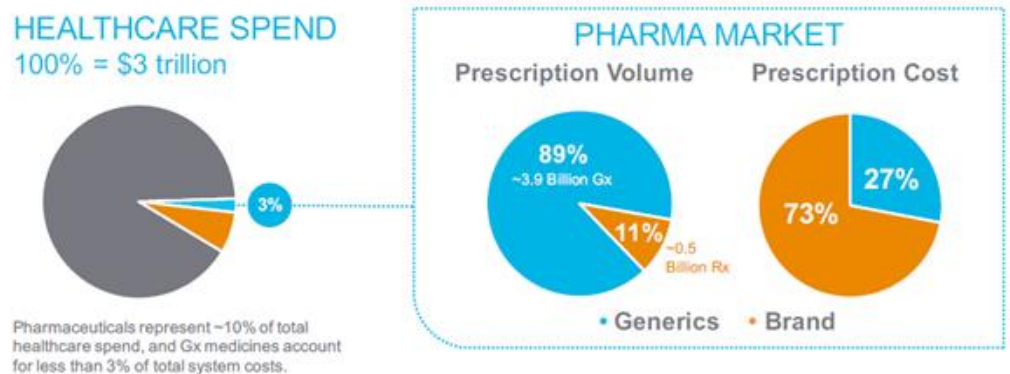
**US remains the most lucrative market for Indian generics companies.**

**Fig 75 US has the highest generic penetration by volume**



Source: IMS, Macquarie Research, October 2017

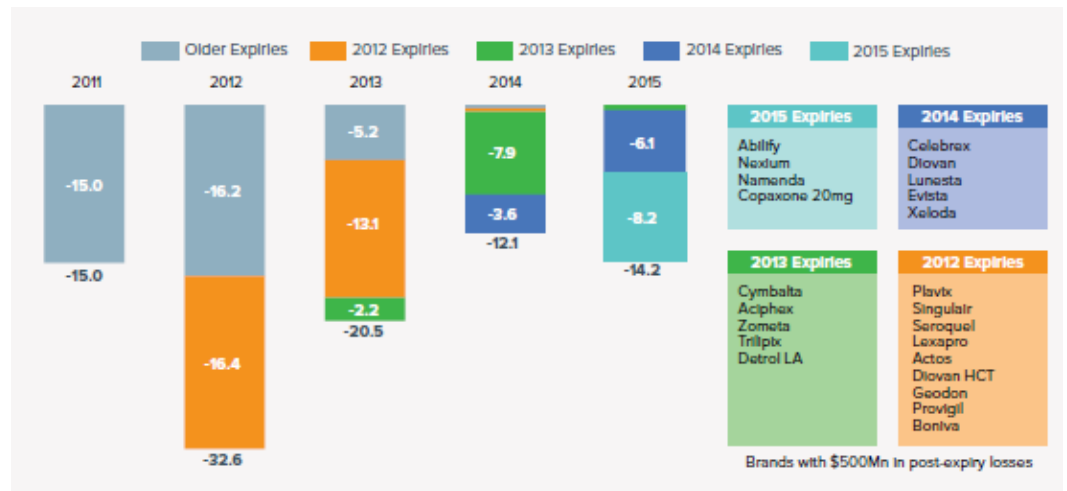
**Fig 76 Size of the US pharma market**



Source: Mylan, Macquarie Research, October 2017

*Indian generics companies benefitted immensely between CY12-CY15 due to high patent expiries of branded drugs in the US.*

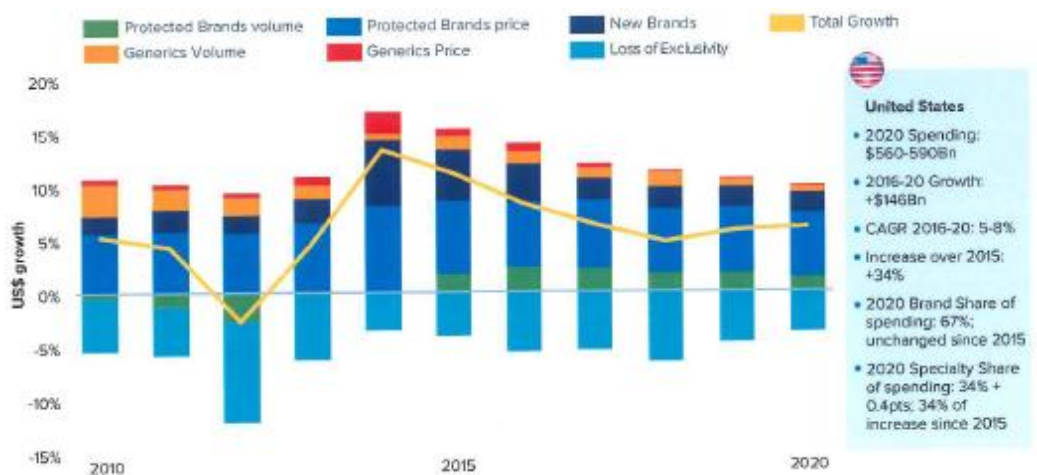
**Fig 77 Decline in brand spending in US from loss of exclusivity (USD bn)**



Source: IMS, Macquarie Research, October 2017

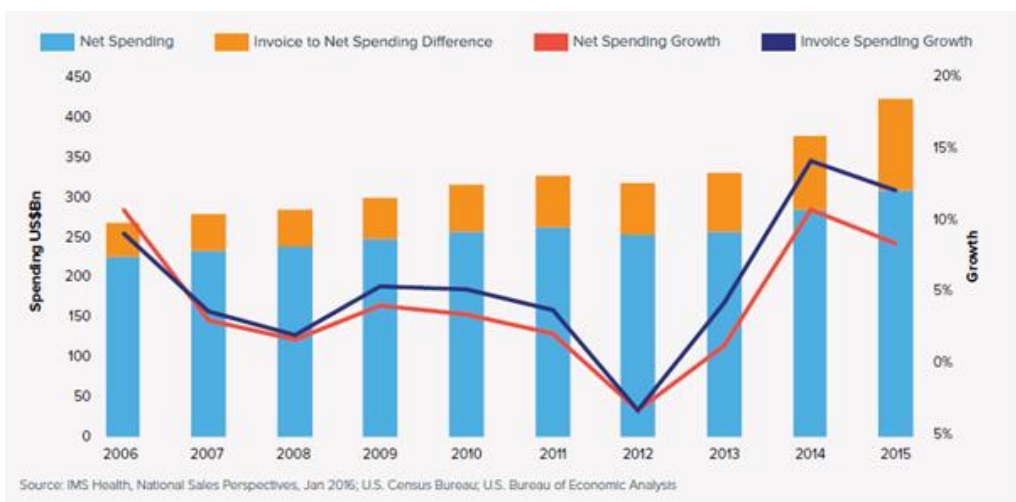
*For the next 5 years, patent expiries of branded drugs in US is expected to be similar in absolute terms to the previous 5 years. This could restrict growth for generics companies.*

**Fig 78 IMS forecast for US pharma market suggests contracting growth**



Source: IMS, Macquarie Research, October 2017

**Fig 79 Sharp increase in drug spending from CY13-15 due to price hikes**



Source: IMS, Macquarie Research, October 2017

## INDIA

SUNP IN Underperform

Price (at 12:58, 18 Oct 2017 GMT) Rs540.20

Valuation	Rs	440.00
- PER		
12-month target	Rs	440.00
Upside/Downside	%	-18.5
12-month TSR	%	-17.8
Volatility Index		Low/Medium

## GICS sector

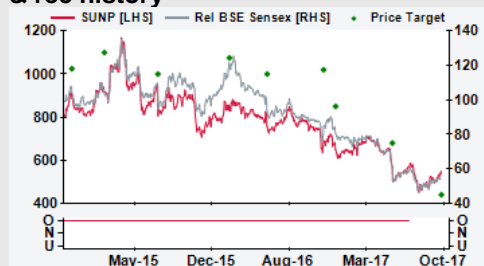
Pharmaceuticals, Biotechnology &amp; Life Sciences

Market cap	Rsbm	1,296
Market cap	US\$m	20,277
Free float	%	44
30-day avg turnover	US\$m	44.1
Number shares on issue	m	2,399

## Investment fundamentals

Year end 31 Mar		2017A	2018E	2019E	2020E
Revenue	bn	315.8	289.7	321.9	359.4
EBIT	bn	88.2	46.4	63.1	83.2
EBIT growth	%	20.7	-47.4	36.0	31.8
Recurring profit	bn	90.6	48.9	66.1	87.2
Reported profit	bn	69.6	23.5	44.7	60.9
Adjusted profit	bn	69.6	31.3	44.7	60.9
EPS rep	Rs	29.03	9.79	18.64	25.39
EPS rep growth	%	48.0	-66.3	90.5	36.2
EPS adj	Rs	29.03	13.04	18.64	25.39
EPS adj growth	%	29.2	-55.1	43.0	36.2
PER rep	x	18.6	55.2	29.0	21.3
PER adj	x	18.6	41.4	29.0	21.3
Total DPS	Rs	3.50	4.00	4.50	4.50
Total div yield	%	0.6	0.7	0.8	0.8
ROA	%	14.2	6.9	9.4	11.5
ROE	%	19.4	7.5	10.1	12.5
EV/EBITDA	x	12.1	20.5	15.9	12.6
Net debt/equity	%	-16.5	-18.1	-20.5	-23.5
P/BV	x	3.2	3.0	2.8	2.5

## SUNP IN rel BSE Sensex performance, &amp; rec history



Note: Recommendation timeline - if not a continuous line, then there was no Macquarie coverage at the time or there was an embargo period.

Source: FactSet, Macquarie Research, October 2017  
(all figures in INR unless noted)

## Analyst(s)

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23 October 2017

Macquarie Capital Securities India (Pvt) Ltd

# Sun Pharma

## A long, hot summer

### Conclusion

- Sun Pharma's US business has been severely impacted by heightened pricing pressure especially in Taro's portfolio, muted organic growth (ex-Taro) and a delay in the resolution of the Halol facility. The impact of pricing erosion on Sun has been magnified due to its high base (US\$2.1bn FY17 US sales, the highest among Indian peers). Its medium-term margin outlook is fraught with challenges due to operating leverage and incremental spend towards its specialty pipeline. While we concur with the street that Sun remains relatively better placed to succeed in specialty, we believe any specialty upside will be protracted. Until then, there will be a mismatch, denting margins. Absent any fundamental catalysts, we expect the stock to remain under pressure. We initiate with Underperform and a TP of Rs440 (20x Sept-19E EPS).

### Impact

- Operating de-leverage:** Sun has guided for a challenging FY18, with single-digit overall revenue decline (Macq: 8% drop). We expect Sun's US base business revenues to remain depressed as a result of a continued delay in the resolution of the Halol facility and increasing pricing pressure on its organic portfolio. Apart from the impact of negative operating leverage, margins are also being impacted due to ongoing R&D and SG&A investments in rolling out its specialty franchise. This is despite the US\$300m Ranbaxy synergy benefits.
- Market share loss in key products is concerning:** Sun's key existing products like Doxil, Sumatriptan and Decitabine have been losing share due to supply constraints and increasing competition. Due to an inordinate delay in the resolution of the Halol facility, Sun has lost ground for some of its upcoming launches as the opportunity size is gradually reducing. Even if Halol is reinspected in 2HFY18, lifting of the warning letter is likely only in 1HFY19.
- Specialty benefits to be back-ended:** We expect Tildrakizumab (despite a crowded market) and Seciera together could generate US\$500-600m in revenue at peak (launches in 2HFY19 and early-FY20, respectively). While the company is ticking the right boxes in terms of its specialty prowess and related investments, we wonder whether these investments are sufficient to meaningfully compensate for the price erosion and Taro's margin pressure. Even if we assume no delay in launches, we expect ramp-up of specialty revenues to be gradual.

### Earnings and target price revision

- We rate the stock Underperform with a TP of Rs440, at 20x Sept-19E EPS.

### Price catalyst

- 12-month price target: Rs440.00 based on a PER methodology.
- Catalyst: Resolution of Halol, key specialty launches.

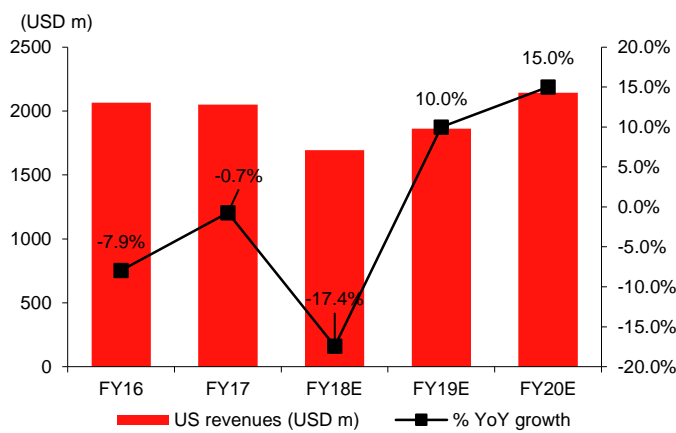
### Action and recommendation

- We believe re-rating triggers are elusive and it is very difficult to ignore the medium-term pain. A key risk to our Underperform recommendation is the resolution of Halol in 2HFY18, which would likely boost sentiment. However, fundamental improvement due to the Halol resolution will be very gradual.

### Uncertainty in the US business to persist

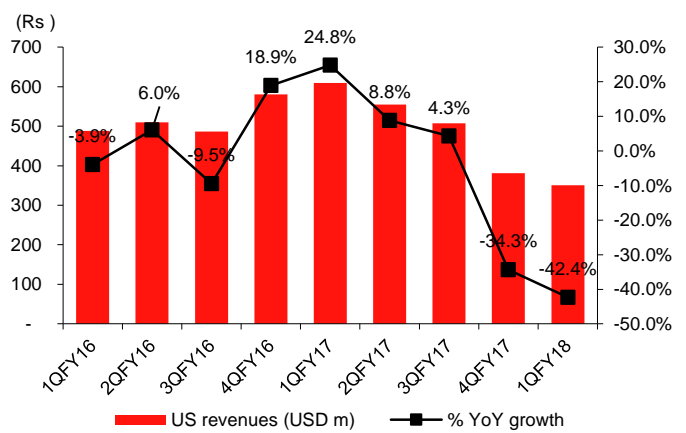
Sun's US business has been severely impacted by heightened pricing pressure especially in Taro's portfolio, muted organic growth (ex-Taro) and a delay in the resolution of the Halol facility. Any major US recovery for Sun (the fourth-largest generic company in the US) in the next two to three years hinges on the resolution of Halol by end-FY18 and the success of key launches like Tildrakizumab, Seciera, Elepsia and Xelpros. We expect Sun's specialty franchise to start contributing meaningfully only from FY20/21. Sun's key existing products like Doxil, Sumatriptan and Decitabine have been losing share due to supply constraints and increasing competition. Increased competition for Doxil from DRRD (launched in 1QFY18) has led to Sun losing market share. Due to an inordinate delay in the resolution of the Halol facility, Sun has also lost ground on some of its upcoming launches as the opportunity size is gradually reducing. For example, despite approval of Glumetza in August 2016, the company is yet to launch the product.

**Fig 1 Sun's annual US sales**



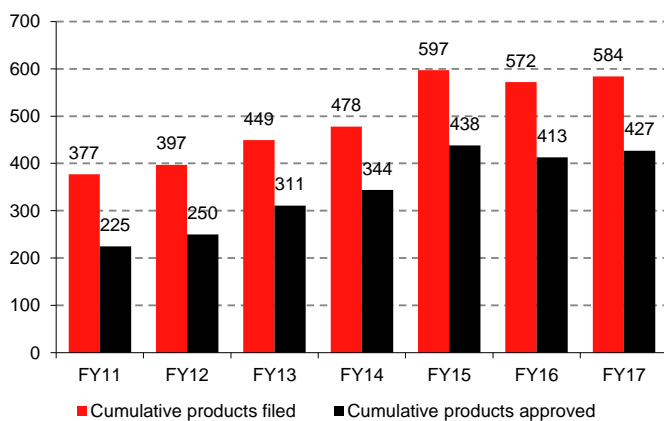
Source: Company data, Macquarie Research, October 2017

**Fig 2 Sun's quarterly US sales**



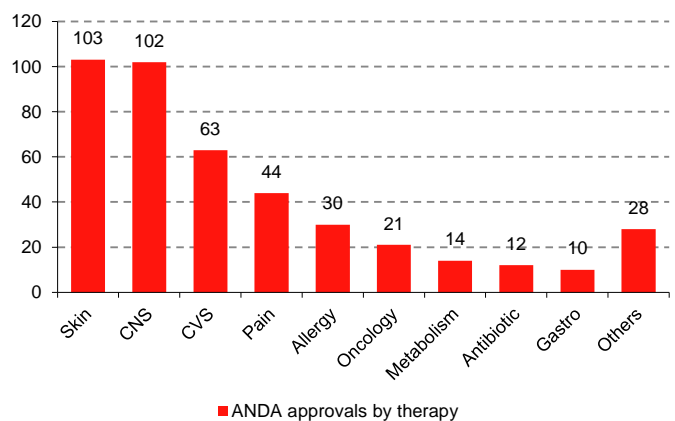
Source: Company data, Macquarie Research, October 2017

**Fig 3 ANDAs filed and approved**



Source: Company data, Macquarie Research, October 2017

**Fig 4 ANDA approvals by therapy**



Source: Company data, Macquarie Research, October 2017

Sun has a basket of 584 ANDAs and 41 NDAs filed. As of FY17 end, Sun had 157 ANDAs and five NDAs awaiting approval. Sun has more than 427 approved products in the US; 36 NDAs have been approved across multiple therapies.

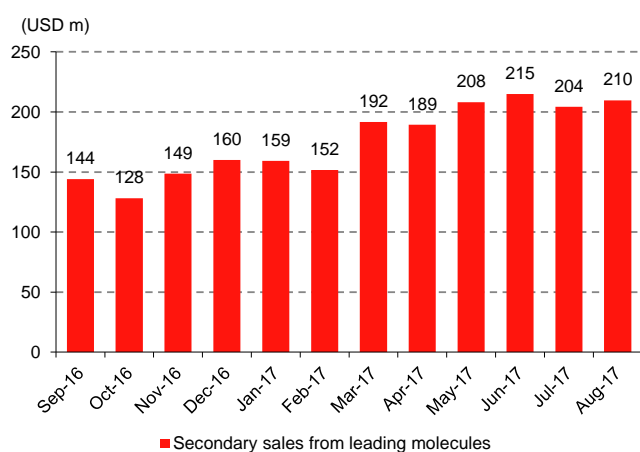


**Fig 5 Sun’s leading molecules in the US**

Secondary sales (USD m)	Sep-16	Oct-16	Nov-16	Dec-16	Jan-17	Feb-17	Mar-17	Apr-17	May-17	Jun-17	Jul-17	Aug-17
ABSORICA	32	30	31	36	36	37	53	55	64	67	60	63
% Change MoM	-9%	-4%	1%	17%	0%	3%	43%	4%	16%	4%	-9%	4%
% Change YoY							15%	32%	63%	75%	79%	81%
IMATINIB MESYLATE	75	68	65	69	66	62	72	68	69	64	61	61
% Change MoM	-21%	-9%	-3%	5%	-4%	-7%	16%	-6%	2%	-7%	-4%	-1%
% Change YoY							-19%	-20%	-18%	-32%	-31%	-36%
OLMESARTAN MEDOXOMIL	0	1	33	38	41	38	43	40	39	35	34	35
% Change MoM				16%	8%	-9%	15%	-7%	-3%	-9%	-5%	3%
% Change YoY							NA	NA	NA	NA	NA	NA
HYDROXYCHLOROQUINE SULFATE	5	6	7	9	10	10	19	21	25	26	25	26
% Change MoM	15%	20%	16%	25%	6%	4%	80%	14%	19%	0%	-1%	2%
% Change YoY							353%	407%	511%	561%	534%	458%
DOXYCYCLINE HYCLATE	32	23	12	8	6	5	5	5	11	23	24	26
% Change MoM	-7%	-30%	-48%	-35%	-25%	-18%	6%	0%	116%	113%	2%	9%
% Change YoY							-87%	-86%	-70%	-37%	-32%	-26%
<b>Secondary sales from leading molecules</b>	<b>144</b>	<b>128</b>	<b>149</b>	<b>160</b>	<b>159</b>	<b>152</b>	<b>192</b>	<b>189</b>	<b>208</b>	<b>215</b>	<b>204</b>	<b>210</b>
% Change MoM	-15%	-11%	16%	8%	-1%	-5%	26%	-1%	10%	3%	-5%	3%
% Change YoY							8%	13%	28%	24%	26%	24%

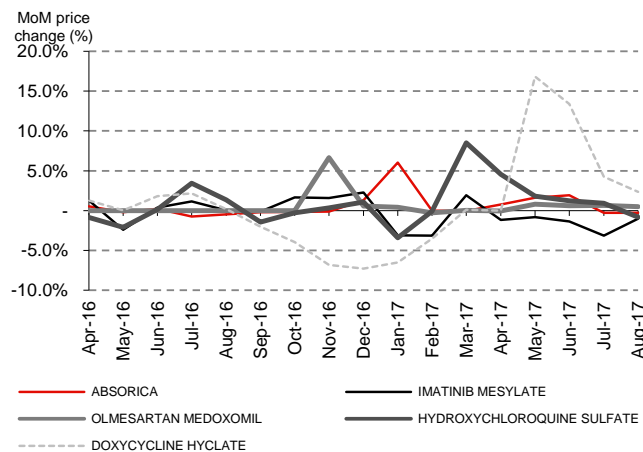
Source: Symphony data, Bloomberg, Macquarie Research, October 2017

**Fig 6 Secondary sales from leading molecules**



Source: Symphony data, Bloomberg, Macquarie Research, October 2017

**Fig 7 Price trends for leading molecules**

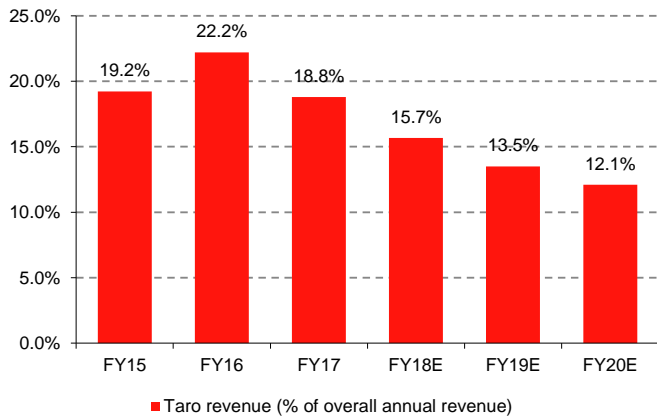


Source: Symphony data, Bloomberg, Macquarie Research, October 2017

**Taro’s margins remain elevated despite recent collapse**

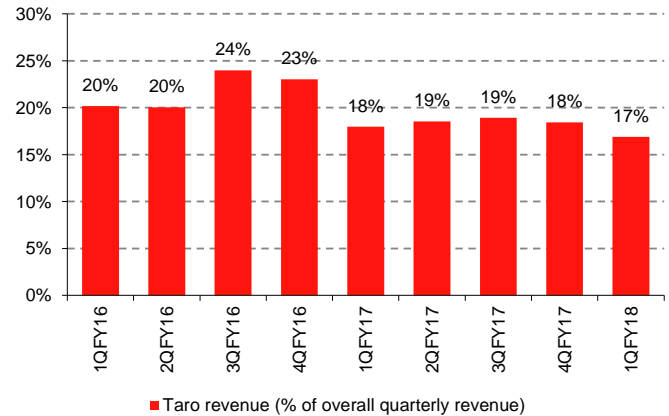
Taro continues to invest in building its US pipeline and has a total of 35 ANDAs awaiting FDA approval, including five tentative approvals. ~70% of FY17 R&D spends by Taro were on generics. Taro’s topicals/derma portfolio continues to witness incremental competition due to a faster US FDA approval rate, which is leading to elevated pricing pressure. US contributed ~89% to Taro’s revenues in FY17. Other generic companies have also commented about increasing competition and resultant pricing pressure in their derma portfolios. We expect pressure on the Taro business to continue given expected increase in pace of US FDA approvals within derma. Also, between FY14-16, Taro had been a beneficiary of supply constraints by taking price hikes and enjoying industry-leading margins. While Taro still enjoys an edge over peers due to lower competition in derma portfolio, the gap in margins could reduce.

**Fig 8 Annual Taro sales contribution**



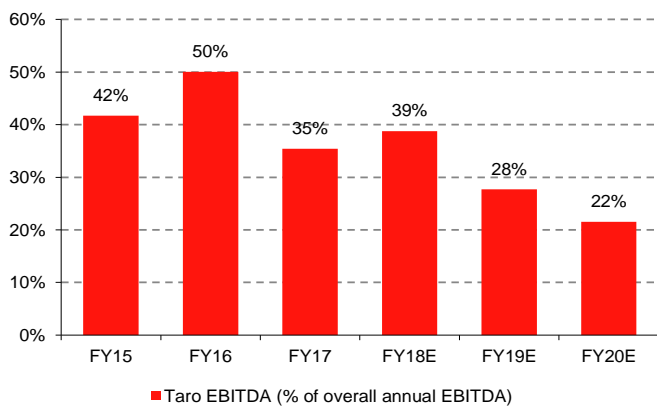
Source: Company data, Macquarie Research, October 2017

**Fig 9 Quarterly Taro sales contribution**



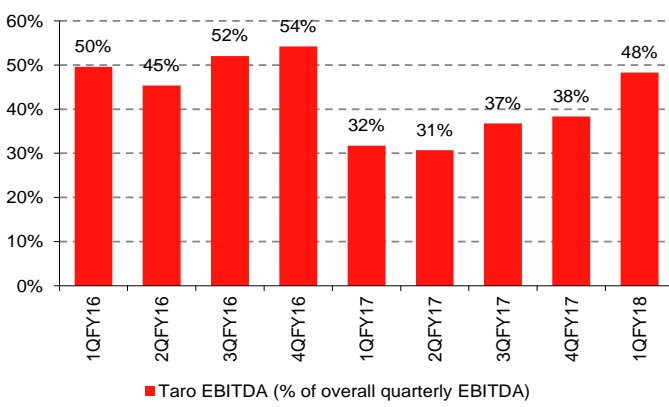
Source: Company data, Macquarie Research, October 2017

**Fig 10 Annual Taro EBITDA contribution**



Source: Company data, Macquarie Research, October 2017

**Fig 11 Quarterly Taro EBITDA contribution**



Source: Company data, Macquarie Research, October 2017

### Heavily banking on its specialty pipeline

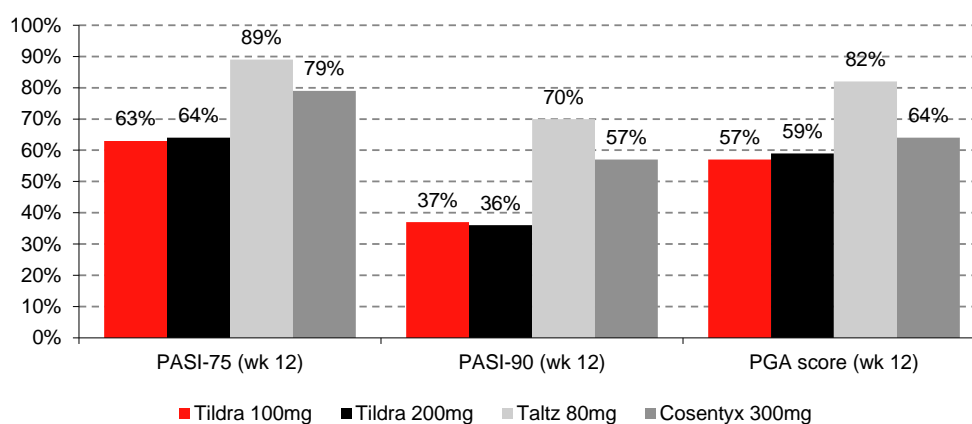
Sun has adapted the acquisition route to boost its specialty and complex portfolio. The company is investing ~50% of its R&D spends in building its specialty business in the dermatology, ophthalmology, oncology and CNS segments. While the company is ticking the right boxes in terms of its specialty prowess and investments in that direction, we wonder whether these investments will be sufficient to meaningfully compensate for the erosion in the base business. Sun expects its specialty portfolio to breakeven in FY20. We expect MK-3222 (despite a crowded market; launch in 2HFY19) and Seciera (launch in early FY20) put together to generate US\$500-600m revenues at peak for Sun. Specialty products launched in 2HFY17 include Odomzo and BromSite. Sun maintains that there has been a good ramp-up for both Odomzo and BromSite.

#### Sun's unfolding specialty pipeline includes:

- MK3222 (Tildrakizumab) for the treatment of plaque psoriasis:** It is an anti-IL-23p19 monoclonal antibody that works by selectively targeting IL-23 (interleukin-23), specifically the p19 component of the cytokine. Blocking this key cytokine helps control the pathogenic cells responsible for the inflammatory process of psoriasis and hence is likely to offer high rates of clearance of psoriatic lesions. Earlier generation TNF inhibitors (such as Enbrel and Humira) may be associated with more adverse side effects, such as systemic infections, because they target immune systems of the patient more broadly. The co-primary efficacy endpoints of the placebo-controlled studies were the PASI 75 response and PGA score (physicians' global assessment) at week 12 and 28. (1) PASI 75 (i.e. 75% skin clearance) was achieved by 63%/77% of patients by week 12/28 with a 100mg dose. (2) PGA score of "clear" or "minimal" psoriasis was achieved by 57%/66% of patients by week 12/28 with a 100mg dose. With a 200mg dose at week 12/28, the PASI score was 64%/78% and PGA score was 59%/69%. While the molecule's efficacy remains lower than IL17's, safety profile and dosing are in favour of Tildrakizumab.

- ⇒ **What is the potential and competitive dynamics:** Stelara (targets IL12/23), marketed by Janssen for psoriasis, currently generates ~US\$2bn in annual sales. IL17 inhibitors have been approved (Taltz and Cosentyx), and these could gain share in the psoriasis market given superior efficacy (but they do lack long-term safety data that the IL23 inhibitors enjoy). Data for Tildrakizumab is largely in line with expectations though not best-in-class. Tildrakizumab enjoys the advantage of dosing – six a year vs ~17 a year for Cosentyx. With a dosing advantage as at week 28 of the trials, Tildrakizumab is able to achieve fully clear skin (PASI 100) for 30% of patients vs. ~46% for Cosentyx at week 52. Notwithstanding a crowded market, Tildrakizumab has the potential to generate ~US\$300-350m revenues at peak for Sun. The company has partnered with Alimirall in Europe for this molecule.
- ⇒ Tildrakizumab's filing has been accepted by both US FDA as well as EMA for the US and European markets respectively. Sun plans to gradually file Tildrakizumab in all key markets in the next few quarters.

**Fig 12 Efficacy gap between Tildra, Taltz and Cosentyx**

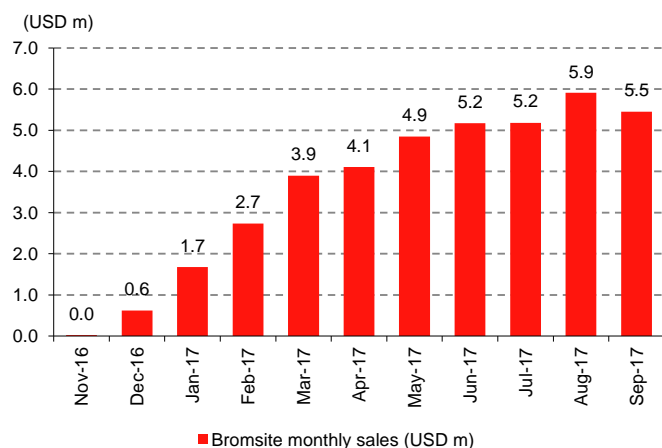


Source: Company data, Macquarie Research, October 2017

- **Seciera:** In January 2017, Sun announced successful Phase 3 confirmatory clinical trial results for Seciera, an aqueous solution for the treatment of dry eye disease. Seciera is a clear, preservative-free, aqueous solution used for the treatment of dry eyes. It is patented (covered by patents until at least 2033), novel, proprietary nanomicellar formulation of cyclosporine A 0.09%. Seciera is being developed by Ocular Technologies, a company acquired by Sun in October 2016 for US\$40m (acquisition completed in December 2016). Sun owns exclusive, worldwide rights to Seciera and is developing it to commercialize for global markets including US, Europe, and Japan, as well as several emerging markets. Seciera could be a competition to Allergan's blockbuster dry eye syndrome drug, Restasis, which has annual US sales of ~US\$1.4bn. Along with Restasis, the only other drug in the similar category is Shire's Xiidra, which received FDA approval in July 2016. In comparison with Restasis, Xiidra works faster and is less stinging. As compared to both Restasis and Xiidra, Seciera has the advantage of early onset of action and addresses both tear production and inflammation of the ocular surface. Sun remains on track to file the NDA for Seciera by 3QFY18.
  - ⇒ **Trial details:** In a 12-week Phase 3 confirmatory study, 744 dry eye patients were treated either with Seciera, or its vehicle. After 12 weeks of treatment, as compared to vehicle, Seciera showed statistically significant improvement in the primary end-point.
  - ⇒ **Result highlights:** Time to efficacy of Seciera at 12 weeks is much lower than 24 weeks for Restasis. Seciera also has a better side effect profile compared to Restasis. Additionally, several key secondary endpoints showed statistically significant improvements compared to vehicle with some showing an even earlier onset of action. Adverse events reported in the trial were mild to moderate in nature and similar to other approved drugs in the category. Based on published data, the efficacy and safety endpoints in these trials compared favourably to other formulations of cyclosporine A with the advantage of early onset.

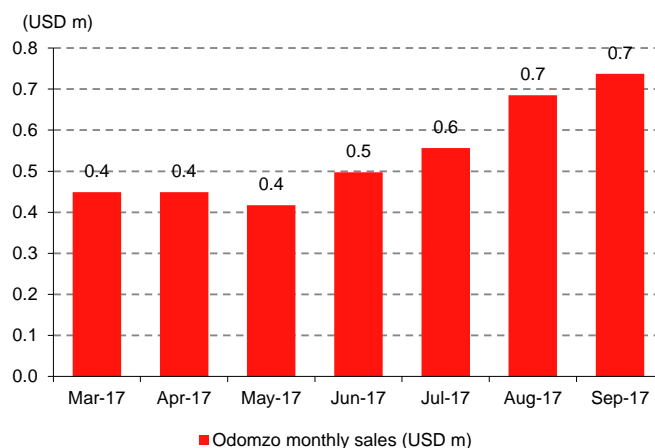
- **Elepsia XR:** Sun has announced a licensing arrangement with SPARC for **Elepsia XR** (Levetiracetam Extended Release tablets 1000mg and 1500mg). SPARC will receive an upfront payment of US\$10m from Sun and is also eligible for sales-driven additional milestone and royalties. Elepsia (pending approval, given Halol warning letter) is a novel once-a-day formulation of Levetiracetam using SPARC's proprietary Wrap Matrix technology that uses a laser drill to achieve a controlled release with minimal excipients. It will help reduce pill burden for epilepsy patients, improving convenience and compliance, according to the company.
  - ⇒ **What is the edge and potential?** Pill burden in epilepsy patients remains high. More than 55% patients are at >6 pills per day, as >80% patients need daily dosage of 1000mg-3000mg. Elepsia XR (1000 and 1500mg once-a-day formulation) represents a new therapeutic option to reduce pill burden for epilepsy patients, thereby differentiating it amongst other competing products. Levetiracetam products currently have ~9 million prescriptions dispensed annually for epilepsy in the US with sales of ~ US\$450m. Given Elepsia XR significantly reduces pill burden and increases compliance, we believe opportunity exists to price Elepsia at a premium to generics. **We believe this could ramp up to ~US\$50m product at peak** (UCB's Keppra XR levetiracetam 500mg and 750mg had reached US\$150m in annual sales in 2011), **assuming ~ 5-10% share at peak, with a premium pricing.** Reimbursement challenges do remain; given the availability of generics. Composition and dose-specific patents have been granted in the US with last patent expiry in 2027.
- **BromSite:** BromSite is the first bromfenac ophthalmic solution formulated in **DuraSite technology**, which is a polymer-based formulation that can be used to improve solubility, absorption, bioavailability and residence time in the eye as compared to conventional topical therapies. Sun launched BromSite in US in November 2016. The product is being marketed by Sun Ophthalmics and has a dedicated marketing and sales team for optimal customer service. BromSite is Sun's first branded ophthalmic product used for treatment of ocular pain in patients undergoing cataract surgery. As per the company, BromSite is gradually ramping up.
  - ⇒ **What is the edge and potential?** It is the first non-steroidal anti-inflammatory drug (NSAID) approved by the USFDA to prevent pain & treat inflammation in the eye for patients undergoing cataract surgery vs. other NSAIDs in this class currently indicated for the treatment of inflammation & reduction of pain. Approval was supported by two Phase-3 studies in which a significantly higher proportion of BromSite treated patients were pain-free at Day 1 post-surgery (77% and 82%) compared to patients treated with vehicle control (48% and 62%). Additionally, a significantly higher proportion of subjects administered BromSite were inflammation-free at day 15 post-cataract surgery (57% and 38%), compared to a vehicle control group (19% and 22%). The U.S. NSAID Ophthalmic market is ~US\$400m in sales with about 4 million prescriptions (Trx) annually. Reimbursement challenges do remain given the availability of generics. **Assuming a 5-10% Trx market share at peak and realization of US\$200/Trx, this could ramp up to US\$40-80m product at peak.** The patent expires in 2029.
- **Odomzo:** Odomzo is Sun's first branded oncology product with a global market size of US\$200m. Odomzo was acquired by Sun from Novartis in December 2016. Sun plans to leverage the marketing strength of its derma and oncology sales team in US to ramp up Odomzo's sales. The company has indicated that the peak sales for Odomzo could be ~US\$150m at par with Erivedge (Roche's competing brand). Sun expects Odomzo's market size to grow as well. The company is also looking to add new indications, which can help the product to grow further.

Fig 13 Ramp-up of both BromSite and Odomzo...



Source: Symphony data, Macquarie Research, October 2017

Fig 14 ...has been gradual



Source: Symphony data, Macquarie Research, October 2017

- **Xelpros** (pending approval, given Halol warning letter), the glaucoma product (latanoprost BAK free eye drops) with **peak potential of ~ US\$50m (likely launch in FY19)**.
- **DexaSite** (0.1% dexamethasone ophthalmic solution) is likely to be launched in FY19 for treatment of non-bacterial blepharitis with peak potential of **~US\$80-100m**.
- **InfuSMART** is a proprietary technology of Sun in which intravenous cytotoxic drugs are developed in a Ready-To-Administer (RTA) bag. Standardized doses of the drugs are used for ranges (or “bands”) of doses calculated for individual patients. While Gemcitabine is the first drug being launched using InfuSMART delivery, Sun has additional 5 oncology products in the pipeline stable on this technology to be rolled out.

⇒ **What is the Edge and potential?** Currently, compounding of oncology products is done at hospitals (in-house) or outsourced to compounding pharmacies making it a time-consuming and potentially hazardous process. Using the RTA InfuSMART bag (i) reduces risk of contamination, (ii) provides a long stable compounded medicine with a 24-month shelf life (iii), is available in 5 different volumes to cover all the dosing needs for Oncologists, (iv) safety of healthcare workers is improved as there is less exposure to toxic products with time savings all around (patients+ healthcare professionals), (v) cuts waste and its associated costs with compounding, and (vi) eliminates the risk of dose calculation error. Sun believes given the superior delivery profile almost 60-80% of the Gemcitabine market can shift to this ready to use bag over the next 2-3 years. If the product is priced competitively to the currently available generics, a large part of the volumes could shift to InfuSMART. InfuSMART is patented and the roll-out begins with a European launch this year. Additional products being launched (5 in the pipeline) and newer geographies could help scale the InfuSMART franchise into a sizeable commercial opportunity (**our view could be ~ US\$80-100m at peak**).

### Inability to resolve Halol has been a big setback for Sun

Before the warning letter received in December 2015 (after inspection in September 2014), Halol used to contribute ~8-9% of US sales for Sun. Inordinate delay in resolution of the Halol plant's warning letter has been a key disappointment for investors. Apart from being the highest contributor to US sales, several key approvals like Elepsia, Xelpros, Vagifem, Focalin XR and Makena have been held hostage to this issue. Sun has completed the remediation efforts at Halol and now it is up to the FDA to come and re-inspect the facility. Sun doesn't expect to receive any approvals from Halol until a successful re-inspection occurs.

Even if Halol is resolved by FY18 end, ramp-up from this facility will be slow due to many existing products being delayed and competition coming in. For new approvals, ramp-up will be gradual. In our view, the company was caught on the wrong foot and did not anticipate the extent of delay in Halol's resolution. The company initiated product site transfers (mainly new products which are pending approval) quite late, and now believes in the strategy of hedging US FDA facility clearance risks by manufacturing key pending ANDAs and Xelpros and Elepsia from alternate sites as well. Sun is looking to file stability files for Xelpros and Elepsia in the next one to two quarters for site transfer.

### Fig 15 Nine observations during Halol's re-inspection from 17 November to 1 December 2016

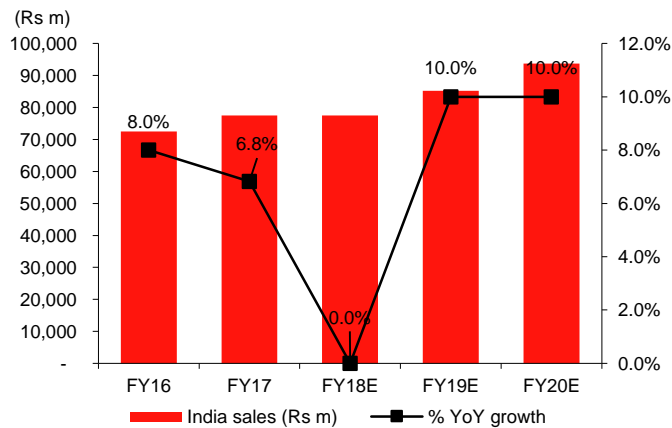
#### Sr. No. Observation details

- 1 Field alert reports were not submitted with three working days of receipt of information concerning bacteriological contamination and significant chemical, physical, or other change or deterioration in a distributed drug product
- 2 Lack of appropriate stability data
- 3 Inadequate design of testing programs to assess stability characteristics of drugs
- 4 Test procedures not adequately reviewed and approved by quality control unit
- 5 Accuracy test methods not established
- 6 Appropriate lab control mechanisms not established to conform to appropriate standards of identity, strength, quality and purity
- 7 Responsibilities and procedures applicable to the quality control unit are not fully followed
- 8 Changes to written procedures are not drafted, reviewed and approved by the appropriate organizational units
- 9 Appropriate controls not exercised to assure that changes to documents related to the manufacture of drug products are instituted only by authorized personnel

Source: US FDA, Macquarie research, October 2017

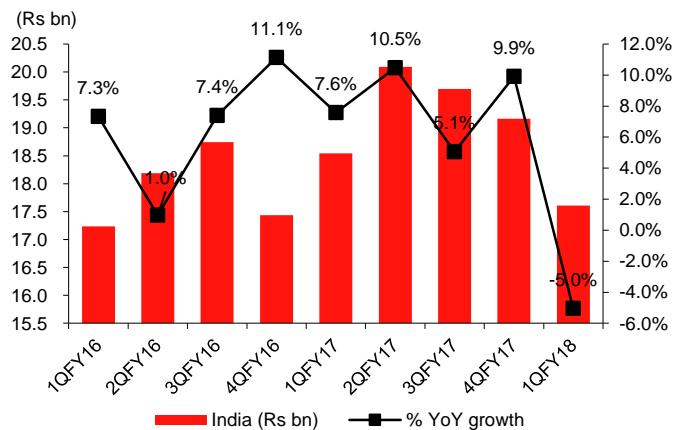
FDA had also issued a Form 483 to Sun's Dadra plant in April 2017 with 11 observations. We estimate Dadra to contribute low to mid single digit of Sun's US sales. On 11 October 2017, Sun received an EIR for Dadra facility. Following the lifting of the import alert in Mohali plant in March 2017, Sun can now supply approved products from Mohali to US. However, certain conditions of the consent decree will continue to be applicable to the Mohali facility. Between FY10-FY13, Ranbaxy had expensed ~Rs20bn as R&D spends from its P&L, bulk of which had Mohali as the manufacturing facility. With the resolution, Sun expects to resume filings from this facility.

**Fig 16 Sun's annual India sales**



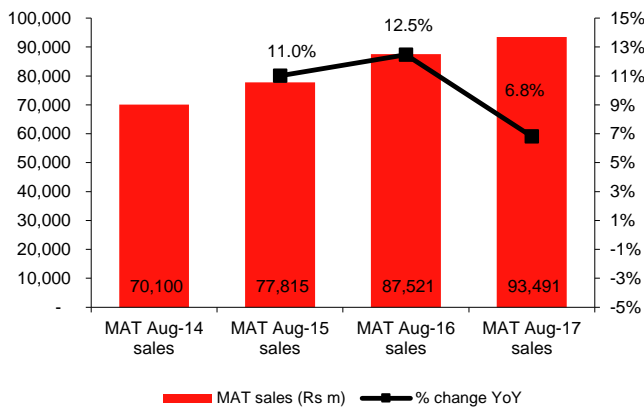
Source: Company data, Macquarie Research, October 2017

**Fig 17 Sun's quarterly India sales**



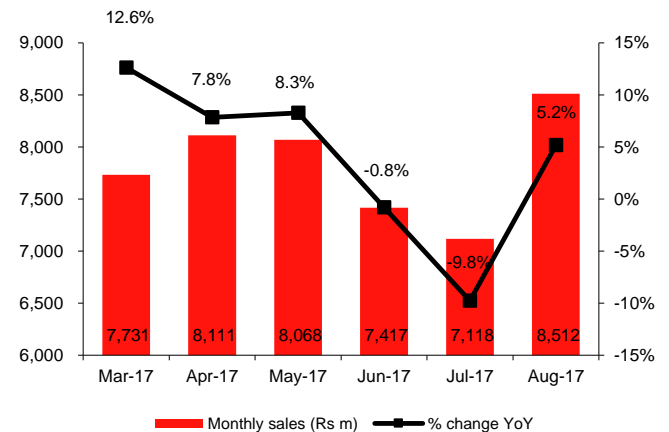
Source: Company data, Macquarie Research, October 2017

**Fig 18 Sun Pharma domestic MAT sales (Aug-17)**



Source: IMS data, Macquarie Research, October 2017

**Fig 19 Sun Pharma domestic monthly sales (Aug-17)**



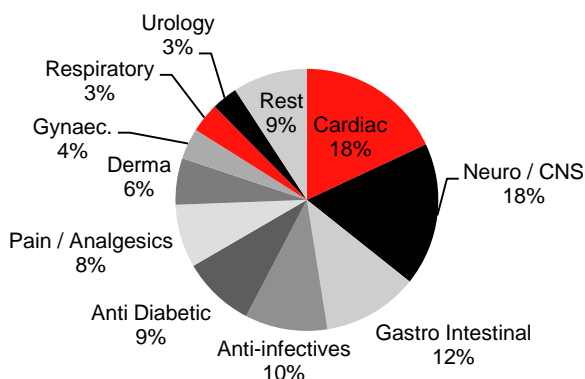
Source: IMS data, Macquarie Research, October 2017

**Fig 20 Key therapeutic drivers - Neuro, Cardiac, and GI driving growth in India**

(Rs m)	MAT sales				MAT sales growth (YoY)		
	MAT Aug-14 sales	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	Aug-15	Aug-16	Aug-17
Cardiac	11,657	13,309	15,513	16,869	14.2%	16.6%	8.7%
Neuro / CNS	10,564	12,574	14,826	16,520	19.0%	17.9%	11.4%
Gastro Intestinal	7,554	8,849	10,081	11,012	17.1%	13.9%	9.2%
Anti-infectives	9,125	9,857	10,659	9,494	8.0%	8.1%	-10.9%
Anti Diabetic	5,377	6,498	7,435	8,373	20.9%	14.4%	12.6%
Pain / Analgesics	6,550	6,861	7,042	7,295	4.7%	2.6%	3.6%
Derma	3,259	3,906	4,381	5,366	19.8%	12.2%	22.5%
Gynaec.	3,058	3,051	3,465	3,569	-0.2%	13.6%	3.0%
Respiratory	2,505	2,812	3,152	3,412	12.3%	12.1%	8.3%
Urology	1,967	2,313	2,714	2,992	17.6%	17.3%	10.2%

Source: IMS data, Macquarie Research, October 2017

**Fig 21 Sun’s domestic therapeutic split – Cardiac, Neuro, Anti-infectives and GI key focus areas (MAT Aug-17)**



Source : IMS data, Macquarie Research, October 2017

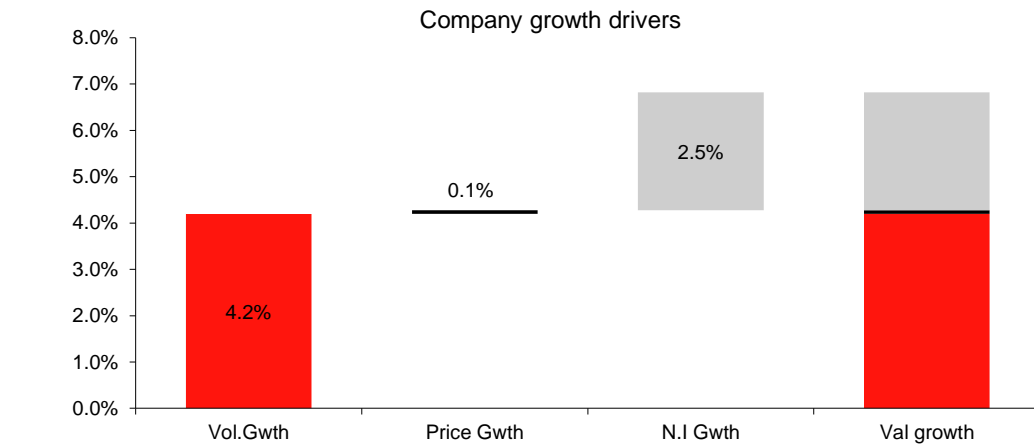
**Fig 22 Sun top-25 brands - contribute ~31% of domestic sales, and grew ~6% YoY (MAT Aug-2017)**

	MAT sales				MAT sales growth (YoY)		
	MAT Aug-14 sales	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	Aug-15	Aug-16	Aug-17
VOLINI	2,487	2,445	2,444	2,384	-1.7%	0.0%	-2.5%
ROSUVAS	1,108	1,412	1,746	1,943	27.4%	23.6%	11.3%
LEVIPIL	998	1,325	1,706	1,925	32.7%	28.8%	12.8%
GEMER	1,081	1,261	1,515	1,793	16.6%	20.2%	18.3%
ISTAMET	756	1,099	1,375	1,671	45.4%	25.1%	21.5%
SUSTEN	1,020	1,222	1,444	1,569	19.8%	18.1%	8.7%
PANTOCID	1,162	1,284	1,381	1,540	10.5%	7.5%	11.6%
PANTOCID-D	916	1,115	1,254	1,369	21.6%	12.5%	9.2%
REVITAL H	-	541	1,516	1,328	NA	180.4%	-12.4%
SPORIDEX	1,111	1,179	1,307	1,310	6.1%	10.9%	0.3%
MOX	1,376	1,300	1,454	1,192	-5.5%	11.9%	-18.0%
MOXCLAV	758	976	1,138	1,119	28.9%	16.5%	-1.7%
ROZAVEL	543	676	830	954	24.5%	22.8%	15.0%
AZTOR	817	939	1,077	910	14.9%	14.7%	-15.5%
MONTEK-LC	528	643	762	889	21.9%	18.5%	16.6%
STORVAS	1,050	1,108	1,079	846	5.6%	-2.7%	-21.6%
CARDIVAS	477	574	689	757	20.4%	19.9%	9.8%
GLUCORED	689	706	736	743	2.5%	4.2%	1.0%
RIFAGUT	373	482	619	727	29.3%	28.5%	17.4%
OXETOL	456	542	613	709	18.9%	13.0%	15.7%
PROLOMET-XL	467	527	627	694	12.8%	19.1%	10.5%
ENCORATE CHRONO	440	528	621	691	19.9%	17.7%	11.3%
URSOCOL	465	533	606	685	14.8%	13.6%	13.1%
LULIFIN	105	212	158	669	102.1%	-25.4%	323.7%
CIFRAN	932	624	753	657	-33.0%	20.6%	-12.7%
<b>Top 25 products as % of total sales</b>	<b>28.7%</b>	<b>29.9%</b>	<b>31.4%</b>	<b>31.1%</b>			

Source: IMS data, Macquarie Research, October 2017



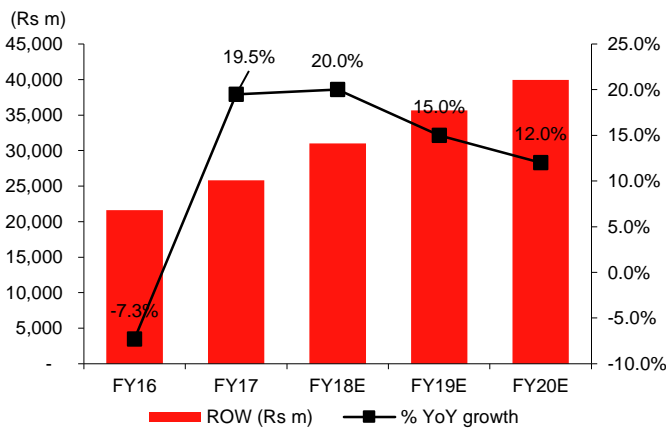
**Fig 23 Sun's domestic growth is largely volume led**



NI Growth: New introduction growth

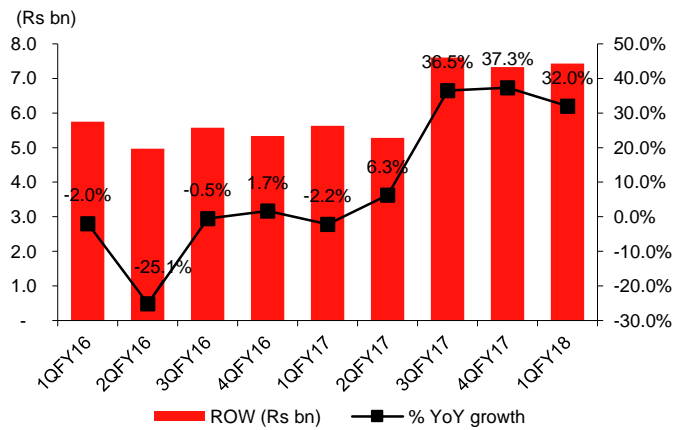
Source: IMS data, Macquarie Research, October 2017

**Fig 24 Sun's annual ROW sales**



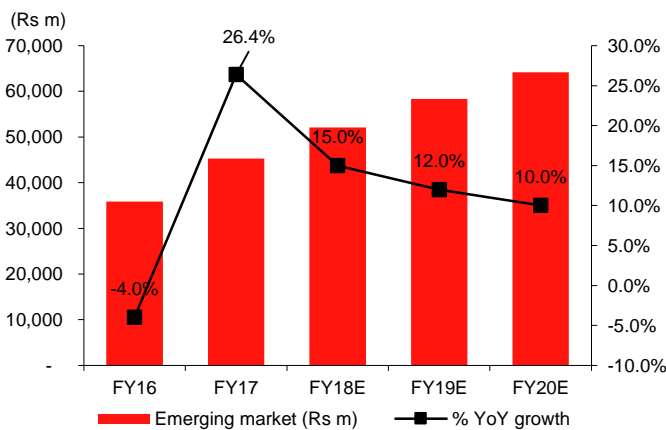
Source: Company data, Macquarie Research, October 2017

**Fig 25 Sun's quarterly ROW sales**



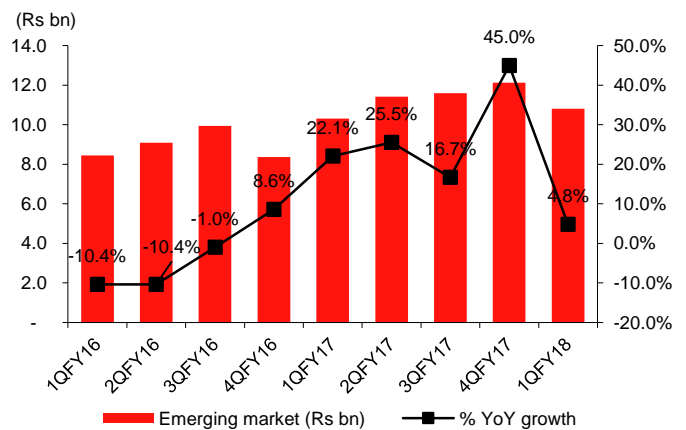
Source: Company data, Macquarie Research, October 2017

**Fig 26 Sun's annual EM sales**



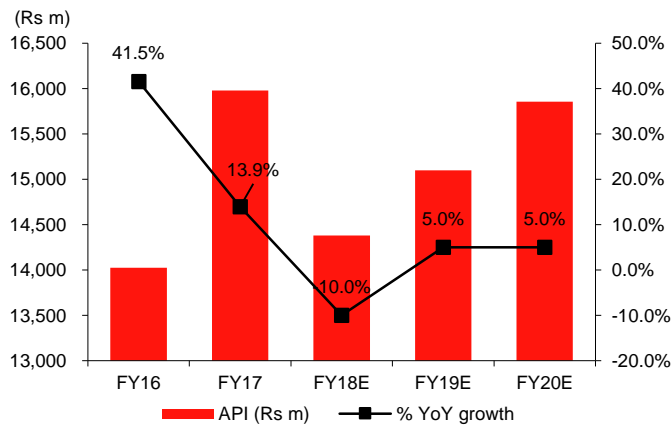
Source: Company data, Macquarie Research, October 2017

**Fig 27 Sun's quarterly EM sales**



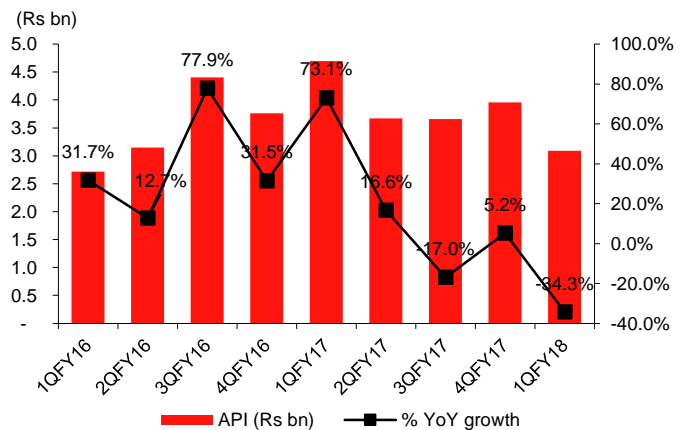
Source: Company data, Macquarie Research, October 2017

**Fig 28 Annual API sales**



Source: Company data, Macquarie Research, October 2017

**Fig 29 Quarterly API sales**

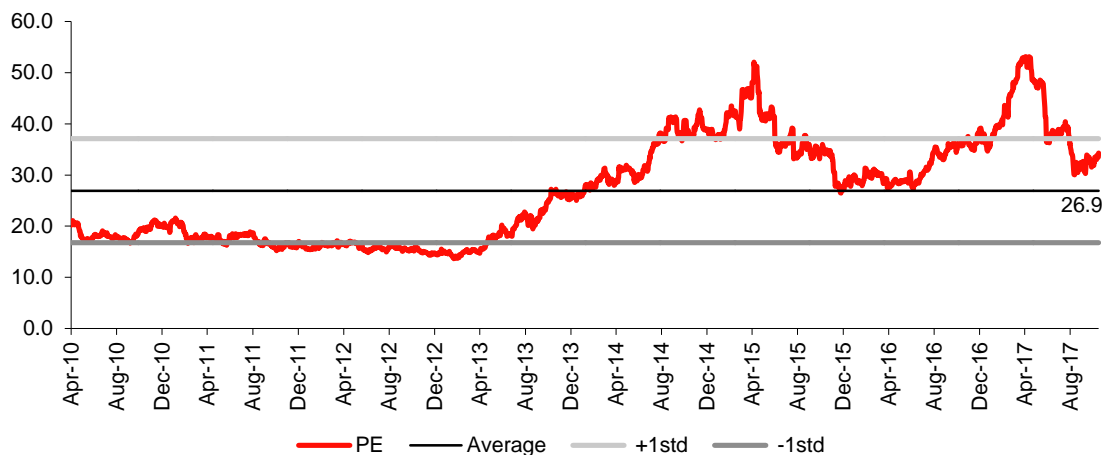


Source: Company data, Macquarie Research, October 2017

**Re-rating triggers remain elusive**

We believe re-rating triggers are elusive and it is very difficult to ignore the medium-term pain. A key risk to our Underperform recommendation is the resolution of Halol in 2HFY18, which would likely boost sentiment. However, fundamental improvement due to the Halol resolution will be very gradual. We rate the stock Underperform with a TP of Rs440, at 20x Sept-19E EPS.

**Fig 30 Sun is trading closer to one standard deviation above its mean**



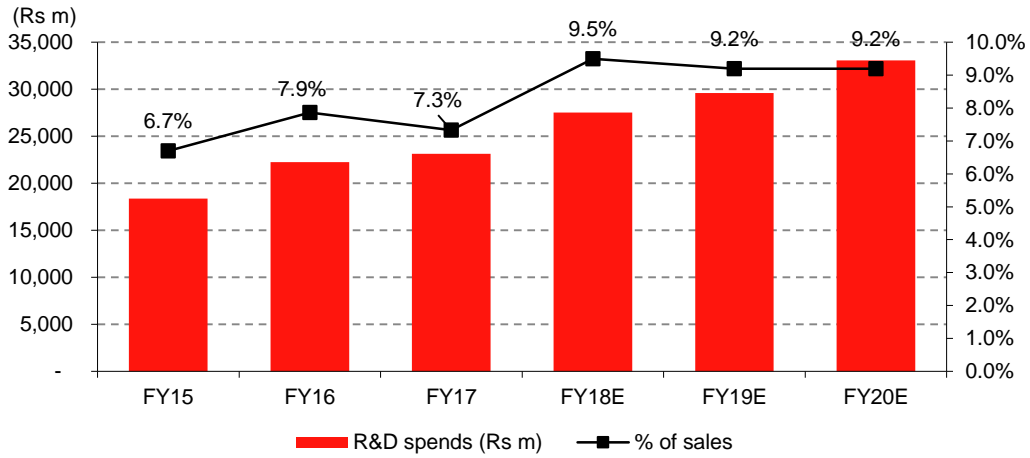
Source: Bloomberg, Macquarie Research, October 2017

**Margins to be depressed due to operating leverage**

Apart from the impact of negative operating leverage, margins are also being impacted due to ongoing R&D and SG&A investments in building its specialty franchise. In FY18, there will be investment in creating a field-force for anticipated Tildrakizumab launch. Similarly, in FY19, there will be investment in creating a new field-force for Seciera, as its field force will be different from that of BromSite. While investments in specialty are likely to yield results from FY20/21, the costs are front-ended, which creates a mismatch and will take a toll on FY18 and 1HFY19 margins as well.

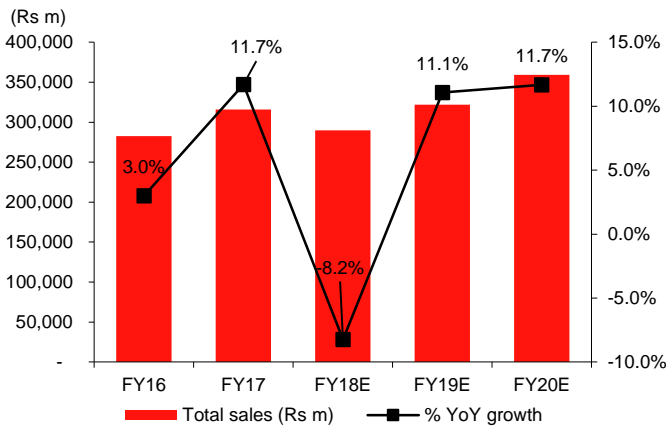
As of FY17 end, Sun had achieved US\$200m synergies out of the total estimated synergy benefits from the Ranbaxy integration. At least until new launches from Halol facility meaningfully pick up, we expect operating leverage and specialty investments to hurt margins. In addition, inability to gain market share in new launches is a concern. In a bid to assuage investor concerns on the tremendous margin collapse, Sun has given an EBITDA margin guidance for the first time (20-22% EBITDA margin in 2HFY18). The management has guided for FY18 R&D at 9-10% of sales (7.6% in FY17), with the increase being driven largely by specialty.

**Fig 31 R&D spends have been increasing for Sun**



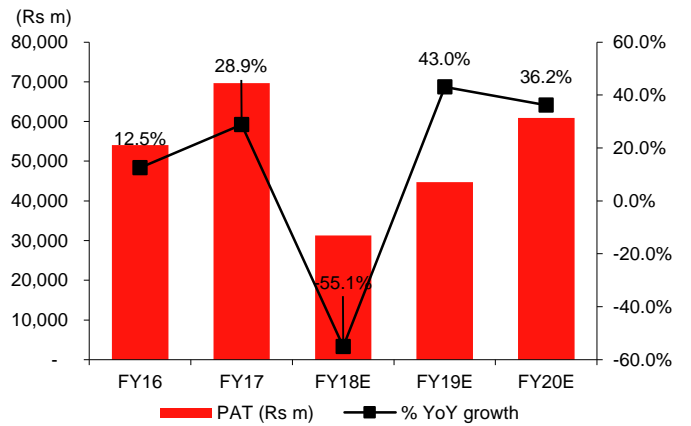
Source: Company data, Macquarie Research, October 2017

**Fig 32 Annual total sales**



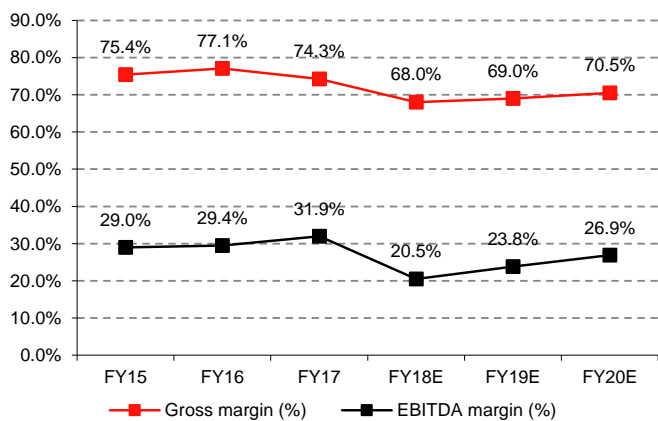
Source: Company data, Macquarie Research, October 2017

**Fig 33 Annual PAT trend**



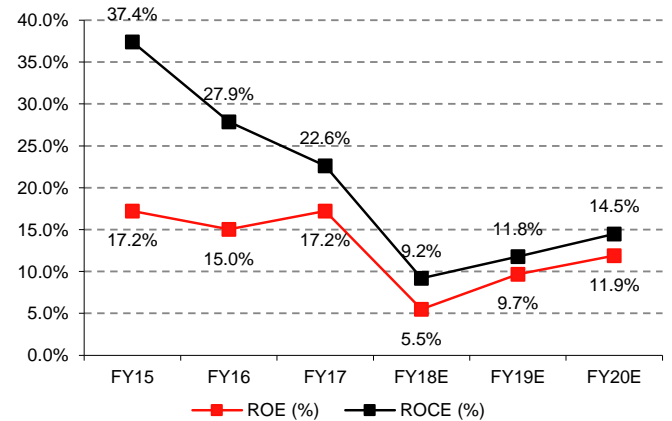
Source: Company data, Macquarie Research, October 2017

**Fig 34 Gross and EBITDA margin trend**



Source: Company data, Macquarie Research, October 2017

**Fig 35 Return ratio profile – much below peak**



Source: Company data, Macquarie Research, October 2017

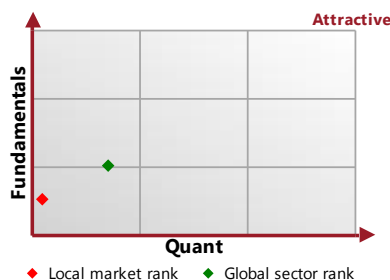
## Macquarie Quant View

The quant model currently holds a strong negative view on Sun Pharmaceutical Industries. The strongest style exposure is Growth, indicating this stock has good historic and/or forecast growth. Growth metrics focus on both top and bottom line items. The weakest style exposure is Price Momentum, indicating this stock has had weak medium to long term returns which often persist into the future.

**665/867**

Global rank in  
Pharma, Biotech & Life Sciences

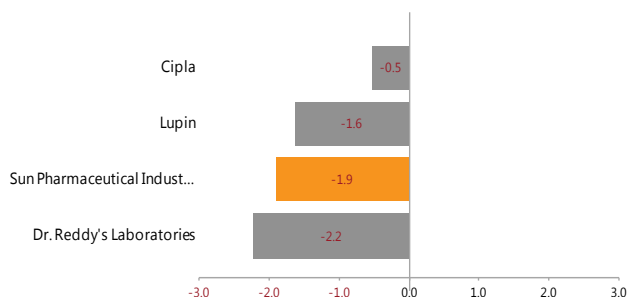
**% of BUY recommendations** 39% (15/38)  
**Number of Price Target downgrades** 2  
**Number of Price Target upgrades** 4



Displays where the company's ranked based on the fundamental consensus Price Target and Macquarie's Quantitative Alpha model.  
Two rankings: Local market (India) and Global sector (Pharma, Biotech & Life Sciences)

## Macquarie Alpha Model ranking

A list of comparable companies and their Macquarie Alpha model score (higher is better).



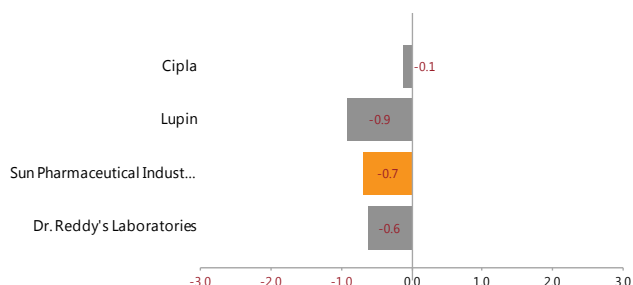
## Factors driving the Alpha Model

For the comparable firms this chart shows the key underlying styles and their contribution to the current overall Alpha score.



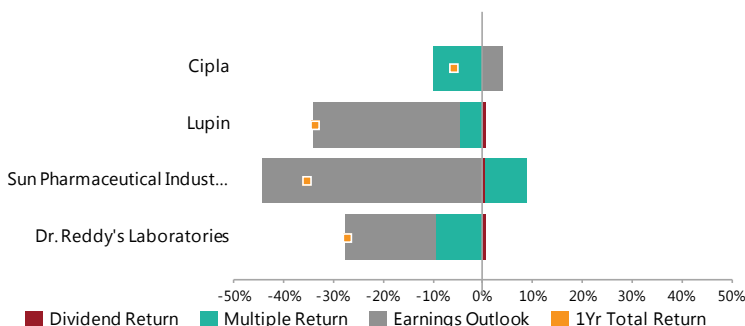
## Macquarie Earnings Sentiment Indicator

The Macquarie Sentiment Indicator is an enhanced earnings revisions signal that favours analysts who have more timely and higher conviction revisions. Current score shown below.



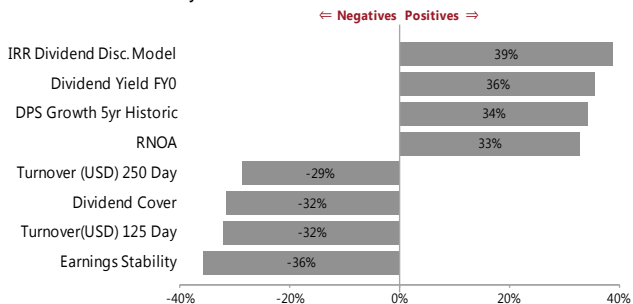
## Drivers of Stock Return

Breakdown of 1 year total return (local currency) into returns from dividends, changes in forward earnings estimates and the resulting change in earnings multiple.



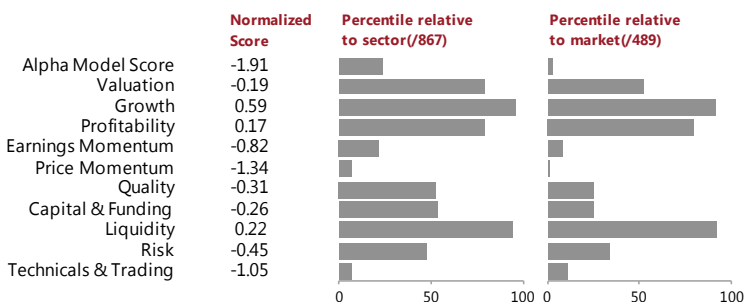
## What drove this Company in the last 5 years

Which factor score has had the greatest correlation with the company's returns over the last 5 years.



## How it looks on the Alpha model

A more granular view of the underlying style scores that drive the alpha (higher is better) and the percentile rank relative to the sector and market.



Source (all charts): FactSet, Thomson Reuters, and Macquarie Research. For more details on the Macquarie Alpha model or for more customised analysis and screens, please contact the Macquarie Global Quantitative/Custom Products Group ([cpq@macquarie.com](mailto:cpq@macquarie.com))

## Sun Pharmaceutical Industries (SUNP IN)

Quarterly Results					Profit & Loss						
	1Q/18A	2Q/18E	3Q/18E	4Q/18E		2017A	2018E	2019E	2020E		
<b>Revenue</b>	m	69,539	72,437	72,437	75,334	<b>Revenue</b>	m	315,784	289,747	321,864	359,417
<b>Gross Profit</b>	m	47,287	49,257	49,257	51,227	<b>Gross Profit</b>	m	234,477	197,028	222,086	253,389
Cost of Goods Sold	m	22,253	23,180	23,180	24,107	Cost of Goods Sold	m	81,307	92,719	99,778	106,028
<b>EBITDA</b>	m	14,256	14,850	14,850	15,444	<b>EBITDA</b>	m	100,893	59,398	76,604	96,683
Depreciation	m	3,120	3,250	3,250	3,380	Depreciation	m	12,648	13,000	13,500	13,500
Amortisation of Goodwill	m	0	0	0	0	Amortisation of Goodwill	m	0	0	0	0
Other Amortisation	m	0	0	0	0	Other Amortisation	m	0	0	0	0
<b>EBIT</b>	m	11,136	11,600	11,600	12,064	<b>EBIT</b>	m	88,245	46,398	63,104	83,183
Net Interest Income	m	-960	-1,000	-1,000	-1,040	Net Interest Income	m	-3,998	-4,000	-4,000	-4,000
Associates	m	0	0	0	0	Associates	m	99	0	0	0
Exceptionals	m	-9,505	0	0	0	Exceptionals	m	0	-9,505	0	0
Forex Gains / Losses	m	0	0	0	0	Forex Gains / Losses	m	0	0	0	0
Other Pre-Tax Income	m	1,560	1,625	1,625	1,690	Other Pre-Tax Income	m	6,232	6,500	7,000	8,000
<b>Pre-Tax Profit</b>	m	2,231	12,225	12,225	12,714	<b>Pre-Tax Profit</b>	m	90,578	39,393	66,104	87,183
Tax Expense	m	-1,702	-1,773	-1,773	-1,844	Tax Expense	m	-12,116	-7,091	-12,560	-17,437
<b>Net Profit</b>	m	529	10,452	10,452	10,870	<b>Net Profit</b>	m	78,462	32,302	53,544	69,747
Minority Interests	m	-2,116	-2,205	-2,205	-2,293	Minority Interests	m	-8,819	-8,819	-8,819	-8,819
<b>Reported Earnings</b>	m	-1,588	8,247	8,247	8,577	<b>Reported Earnings</b>	m	69,644	23,484	44,725	60,928
<b>Adjusted Earnings</b>	m	7,507	7,819	7,819	8,132	<b>Adjusted Earnings</b>	m	69,644	31,278	44,725	60,928
EPS (rep)		-0.66	3.44	3.44	3.57	EPS (rep)		29.03	9.79	18.64	25.39
EPS (adj)		3.13	3.26	3.26	3.39	EPS (adj)		29.03	13.04	18.64	25.39
EPS Growth yoy (adj)	%	-55.1	-55.1	-55.1	-55.1	EPS Growth (adj)	%	29.2	-55.1	43.0	36.2
						PE (rep)	x	18.6	55.2	29.0	21.3
						PE (adj)	x	18.6	41.4	29.0	21.3
EBITDA Margin	%	20.5	20.5	20.5	20.5	Total DPS		3.50	4.00	4.50	4.50
EBIT Margin	%	16.0	16.0	16.0	16.0	Total Div Yield	%	0.6	0.7	0.8	0.8
Earnings Split	%	24.0	25.0	25.0	26.0	Basic Shares Outstanding	m	2,399	2,399	2,399	2,399
Revenue Growth	%	-8.2	-8.2	-8.2	-8.2	Diluted Shares Outstanding	m	2,399	2,399	2,399	2,399
EBIT Growth	%	-47.4	-47.4	-47.4	-47.4						
<b>Profit and Loss Ratios</b>					<b>Cashflow Analysis</b>						
		2017A	2018E	2019E	2020E		2017A	2018E	2019E	2020E	
Revenue Growth	%	11.7	-8.2	11.1	11.7	<b>EBITDA</b>	m	100,893	59,398	76,604	96,683
EBITDA Growth	%	21.2	-41.1	29.0	26.2	Tax Paid	m	-20,571	-7,091	-12,560	-17,437
EBIT Growth	%	20.7	-47.4	36.0	31.8	Chgs in Working Cap	m	-4,092	-246	-629	-3,916
Gross Profit Margin	%	74.3	68.0	69.0	70.5	Net Interest Paid	m	-286	-4,000	-4,000	-4,000
EBITDA Margin	%	31.9	20.5	23.8	26.9	Other	m	-5,121	0	0	0
EBIT Margin	%	27.9	16.0	19.6	23.1	<b>Operating Cashflow</b>	m	70,822	48,061	59,415	71,330
Net Profit Margin	%	22.1	10.8	13.9	17.0	Acquisitions	m	0	0	0	0
Payout Ratio	%	12.1	30.7	24.1	17.7	Capex	m	-35,904	-31,872	-35,405	-39,536
EV/EBITDA	x	12.1	20.5	15.9	12.6	Asset Sales	m	0	0	0	0
EV/EBIT	x	13.8	26.3	19.3	14.7	Other	m	-6,312	6,500	7,000	8,000
<b>Balance Sheet Ratios</b>						<b>Investing Cashflow</b>	m	-42,216	-25,372	-28,405	-31,536
ROE	%	19.4	7.5	10.1	12.5	Dividend (Ordinary)	m	-2,889	-9,597	-10,797	-10,797
ROA	%	14.2	6.9	9.4	11.5	Equity Raised	m	0	0	0	0
ROIC	%	26.2	10.3	13.2	16.2	Debt Movements	m	8,371	0	0	0
Net Debt/Equity	%	-16.5	-18.1	-20.5	-23.5	Other	m	-28,336	0	0	0
Interest Cover	x	22.1	11.6	15.8	20.8	<b>Financing Cashflow</b>	m	-22,854	-9,597	-10,797	-10,797
Price/Book	x	3.2	3.0	2.8	2.5	<b>Net Chg in Cash/Debt</b>	m	5,752	13,092	20,214	28,997
Book Value per Share		168.5	178.3	192.4	213.3	<b>Free Cashflow</b>	m	34,918	16,189	24,010	31,794
						<b>Balance Sheet</b>		2017A	2018E	2019E	2020E
						Cash	m	153,717	85,899	106,113	135,110
						Receivables	m	72,026	74,309	75,042	79,607
						Inventories	m	68,328	57,635	58,203	61,744
						Investments	m	0	0	0	0
						Fixed Assets	m	248,129	267,001	288,907	314,942
						Intangibles	m	91,799	91,799	91,799	91,799
						Other Assets	m	68,154	72,316	72,707	75,141
						<b>Total Assets</b>	m	702,154	648,959	692,770	758,344
						Payables	m	43,954	44,116	44,551	47,261
						Short Term Debt	m	66,549	0	0	0
						Long Term Debt	m	14,361	0	0	0
						Provisions	m	0	0	0	0
						Other Liabilities	m	135,076	130,419	131,048	134,962
						<b>Total Liabilities</b>	m	259,940	174,535	175,599	182,223
						Shareholders' Funds	m	404,305	427,697	461,625	511,757
						Minority Interests	m	37,909	46,727	55,546	64,364
						Other	m	0	0	0	0
						<b>Total S/H Equity</b>	m	442,214	474,424	517,171	576,121
						<b>Total Liab &amp; S/H Funds</b>	m	702,154	648,959	692,770	758,344

All figures in INR unless noted.

Source: Company data, Macquarie Research, October 2017

## INDIA

LPC IN Neutral

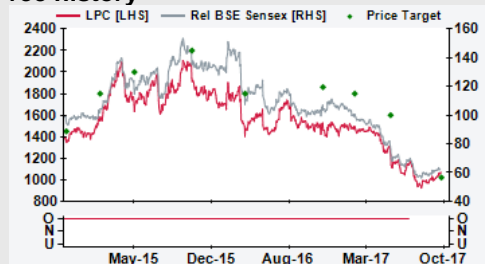
Price (at 13:06, 18 Oct 2017 GMT) Rs1,049.20

<b>Valuation</b>	<b>Rs</b>	<b>1,022.00</b>
- PER		
<b>12-month target</b>	<b>Rs</b>	<b>1,022.00</b>
<b>Upside/Downside</b>	<b>%</b>	<b>-2.6</b>
<b>12-month TSR</b>	<b>%</b>	<b>-1.9</b>
<b>Volatility Index</b>		<b>Low/Medium</b>
<b>GICS sector</b>		
<b>Pharmaceuticals, Biotechnology &amp; Life Sciences</b>		
<b>Market cap</b>	<b>Rsm</b>	<b>474,029</b>
<b>Market cap</b>	<b>US\$m</b>	<b>7,444</b>
<b>Free float</b>	<b>%</b>	<b>51</b>
<b>30-day avg turnover</b>	<b>US\$m</b>	<b>24.5</b>
<b>Number shares on issue</b>	<b>m</b>	<b>451.8</b>

## Investment fundamentals

Year end 31 Mar		2017A	2018E	2019E	2020E
Revenue	bn	174.9	167.5	182.3	202.6
EBIT	bn	35.8	24.7	30.0	37.5
EBIT growth	%	8.8	-31.1	21.8	24.8
Recurring profit	bn	35.3	24.3	29.9	37.6
Reported profit	bn	25.5	17.5	21.5	27.1
Adjusted profit	bn	25.5	17.5	21.5	27.1
EPS rep	Rs	56.40	38.65	47.63	59.92
EPS rep growth	%	12.3	-31.5	23.2	25.8
EPS adj	Rs	56.40	38.65	47.63	59.92
EPS adj growth	%	12.3	-31.5	23.2	25.8
PER rep	x	18.6	27.1	22.0	17.5
PER adj	x	18.6	27.1	22.0	17.5
Total DPS	Rs	7.50	7.50	7.50	7.50
Total div yield	%	0.7	0.7	0.7	0.7
ROA	%	14.6	9.0	10.2	11.7
ROE	%	20.8	12.3	13.6	15.1
EV/EBITDA	x	11.5	14.8	12.6	10.5
Net debt/equity	%	38.0	22.1	10.4	-1.4
P/BV	x	3.5	3.2	2.8	2.5

## LPC IN rel BSE Sensex performance, &amp; rec history



Note: Recommendation timeline - if not a continuous line, then there was no Macquarie coverage at the time or there was an embargo period.

Source: FactSet, Macquarie Research, October 2017

(all figures in INR unless noted)

## Analyst(s)

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23 October 2017

Macquarie Capital Securities India (Pvt) Ltd

# Lupin

## Testing times

### Conclusion

- We expect FY18 and FY19 to be challenging years for Lupin. Factors leading to this are pressure on Glumetza/Fortamet in the US, the absence of blockbuster molecules and pricing issues in Japan due to changes in the pricing structure. On the flipside, we note that product concentration risk is gradually coming down for the company. Lupin remains focussed on building a strong portfolio of specialty products and complex generics, which should aid its growth from FY20 onwards. The full potential of its complex/specialty pipeline is likely to be realised starting FY21. A strong India franchise and regulatory capabilities are positives. In the absence of any near- to medium-term triggers, we initiate coverage with a Neutral and a Rs1,022 target price.

### Impact

- US to remain under pressure in FY18...**LPC has planned 30+ small to mid-size launches in the US in FY18; however, sharp pricing erosion in Glumetza and Fortamet is unlikely to be fully offset by these. New launches in FY18 include Minastrin, Epzicom (both launched in 1QFY18), Hydrocodone APAP (launched in 2Q), Bupropion XL, Levothyroxine (end FY18), Lanthanum Carbonate, Tamiflu and Quetiapine XR. Overall, we expect rising competition and delay in key launches to lead to 18% YoY decline in US sales in FY18.
- ...launches to pick up in FY19:** FTF launches in FY19 are Ranexa, Minocycline, Moxeza and Moviprep. In our view, Sevelamer, Lialda and Apriso are other important opportunities likely to be launched in FY19. Over the next 1-2 years, Lupin expects to launch Toprol XL, controlled release and derma products. Among products not filed but in the pipeline are Asacol HD, Pentasa and Canasa. LPC's ongoing R&D investment in Topicals, Inhalation, complex injectables and biosimilars provide us with comfort on the growth outlook from FY20. On the respiratory front, Lupin filed ProAir in January 2017. We expect this to be followed by filing of Spiriva in end FY18.
- Margins to remain under pressure:** Even as there are challenges in the US business over the next two years, management remains committed to investing in complex generics, biosimilars (via partners) and specialty businesses. We note that absolute R&D spend could inch up in FY19 and FY20 due to higher spend on clinical trials. In the absence of big launches and continued investment in R&D, we expect margins to remain suppressed. Another overhang on margins is the possibility of Japan moving to annual price cuts from biennial revisions currently.

### Earnings and target price revision

- We initiate on the stock at Neutral with a TP of Rs1,022 at 19x Sept-19E EPS (a notch lower than large-cap peers due to limited big-ticket opportunities).

### Price catalyst

- 12-month price target: Rs1,022.00 based on a PER methodology.
- Catalyst: Pick-up in big US FDA approvals

### Action and recommendation

- We await recovery in US sales and margins and rate the stock Neutral.

### US business in need of catalysts

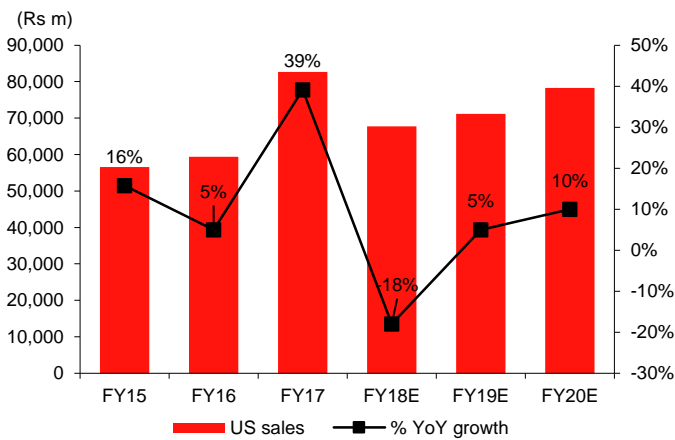
Lupin is the market leader in 45 products in the US generics market and is amongst the Top 3 in 83 of its marketed products (per IMS US March data). Lupin had 368 US ANDA filings, out of which 154 approvals are pending as of FY17 end, with total brand market size of US\$76bn. The company (including Somerset) expects to file 35-40 ANDAs in FY18.

### US business recovery to be delayed

Lupin's FY17 US sales benefitted from an unexpected exclusivity run of 11 months for Glumetza. Since the launch of authorized generic of Glumetza by Valeant in February 2017, Lupin has been facing severe pricing and market share pressures on this product. There has been pricing erosion in Fortamet as well since Mylan launched in 4QFY17. Lupin has guided for a QoQ dip in US sales as the negative impact of Glumetza competition continues in 2QFY18.

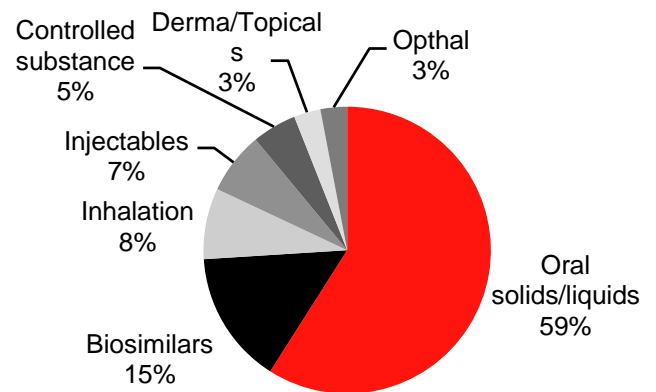
LPC has planned 30+ small- to mid-size launches in the US in FY18 however high pricing erosion in Glumetza and Fortamet is unlikely to be fully offset by these, in our view. In the base business (excluding Glumetza and Fortamet), Lupin is witnessing single digit price erosion. Methergine, in the women's healthcare specialty area from the Gavis portfolio, was launched in April 2017. Methergine is witnessing a strong ramp-up (sales up 48% QoQ in 1QFY18). New launches in FY18 include Minastrin (6-month exclusivity ended in September 2017), Epzicom (both launched in 1QFY18), Hydrocodone APAP (launch in 2QFY18), Bupropion XL, Levothyroxine (end FY18), Lathanum Carbonate (in partnership with Natco), Tamiflu and Quetiapine XR. We note that PAIs for Levothyroxine and Tamiflu were conducted in Indore and Aurangabad, respectively in 1QFY18. We expect rising competition in the US and a delay in a few key launches to lead to a 18% decline in US sales in FY18. In addition, there could be additional pricing erosion once the impact of the WBAD-Econdisc tie-up comes into play.

**Fig 1 Lupin's annual US sales**



Source: Company data, Macquarie Research, October 2017

**Fig 2 Market size split of R&D projects (FY17 end)**



Source: Company data, Macquarie Research, October 2017

### Somerset portfolio to provide some respite in FY18

The company has increased its capacity in Somerset 10x, which should be a key driver of Gavis sales in FY18, in our view. Also, existing products are building market share, especially products launched in 4QFY17. As a result, the company is guiding for a sharp pick-up in Gavis sales, from US\$110m in FY17 to US\$200m in FY18 (Macq estimate: US\$180m).

**Lot of new product launches planned over the next 2-3 years**

FTF launches in FY19 are Ranexa, Minocycline, Moxeza and Moviprep. In our view, Sevelamer/ Colesevelam (late FY19), Lialda and Apriso are other important opportunities likely to be launched in FY19. Over the next 1-2 years, Lupin expects to launch Toprol XL, additional controlled release products and derma products. Lupin has received one query each for Lialda and Apriso from the US FDA, which the company plans to answer later in FY18. Among products not filed and in the pipeline are Asacol HD, Pentasa and Canasa. Ongoing R&D investments in Topicals, Inhalation, complex injectables and biosimilars provide us with comfort on the growth outlook from FY20. On the respiratory front, Lupin filed ProAir in January 2017. We expect filing of Spiriva by FY18 end, followed by Advair, Symbicort, and Qvar. Lupin is focussed on building a strong portfolio of specialty products and complex generics, which should aid its growth from FY20, in our view. Lupin expects to file its first complex injectables product, Risperdal Consta, in FY19, with a likely launch in FY21. In biologics, Lupin has opted for a financing partner for the US market to share some of the risks involved.

**Fig 3 Key US-FDA approved facilities of Lupin with last inspection status**

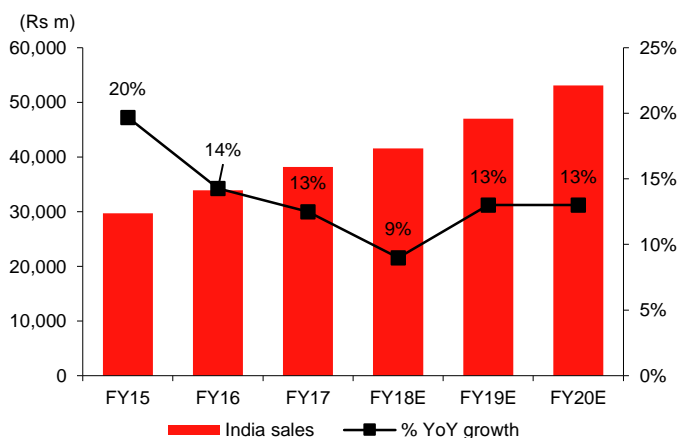
Facility	Type	Last inspection	Status
Mandideep	API and Formulations	Feb-16	Received EIR
Dabhasa	API	Jul-16	2 observations with VAI
Goa	Formulations	Apr-17	3 observations
Aurangabad	Formulations	Apr-17	8 observations
Indore	Formulations	Apr-17	6 observations
Pithampur Unit II	Formulations	May-17	6 observations
Pithampur Unit III	Formulations	Jun-17	4 observations
Pithampur Unit I	Formulations	Jul-17	Zero observations

Source: Company data, Macquarie Research, October 2017

**Underlying growth in India business remains strong**

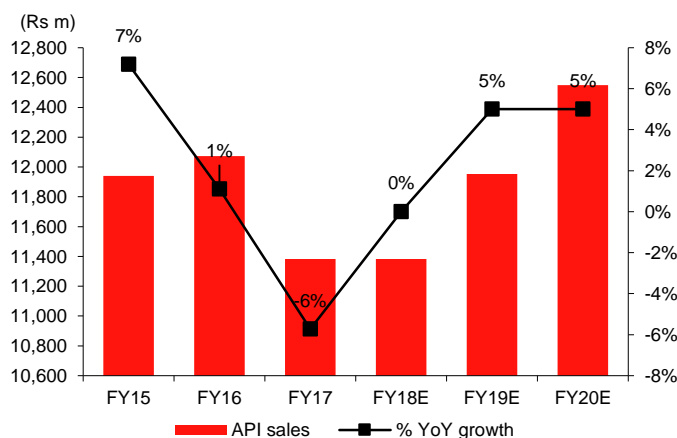
In India, ~80% of Lupin’s portfolio is in the chronic and semi-chronic space. The balance is in the anti-infective and acute areas. Barring the GST-related disruption in FY18, Lupin’s India business remains strong.

**Fig 4 Lupin’s annual India sales**



Source: Company data, Macquarie Research, October 2017

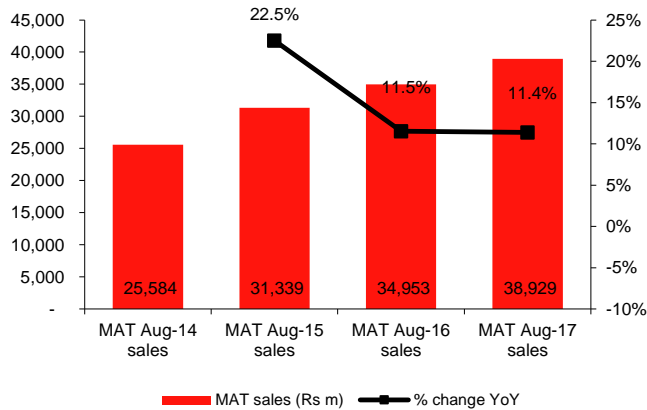
**Fig 5 Lupin’s annual API sales**



Source: Company data, Macquarie Research, October 2017

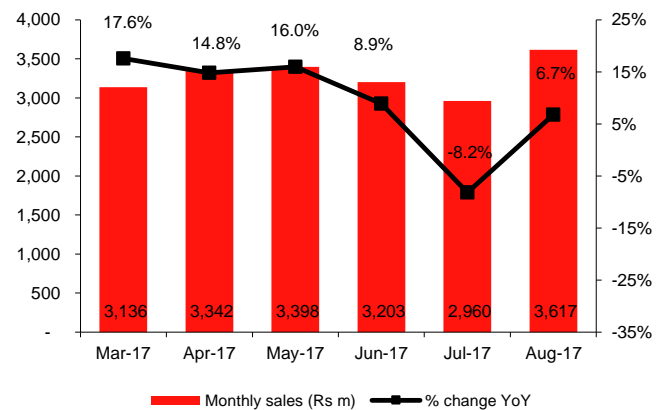


**Fig 6 Lupin India MAT sales**



Source: IMS data, Macquarie Research, October 2017

**Fig 7 Lupin India monthly sales**



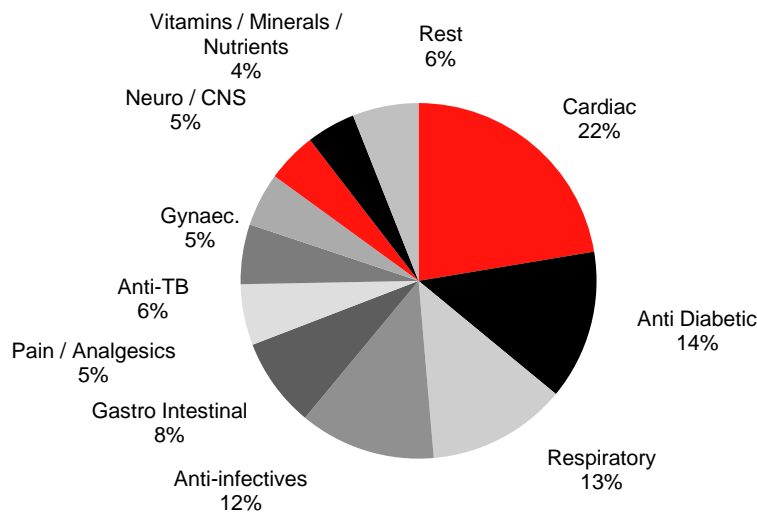
Source: IMS data, Macquarie Research, October 2017

**Fig 8 Anti-diabetic, respiratory and GI driving Lupin’s growth in India**

(Rs m)	MAT sales				MAT sales growth (YoY)		
	MAT Aug-14 sales	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	Aug-15	Aug-16	Aug-17
Cardiac	6,159	7,605	8,192	8,709	23.5%	7.7%	6.3%
Anti Diabetic	2,582	3,355	3,926	5,297	29.9%	17.0%	34.9%
Respiratory	2,907	3,647	4,240	4,928	25.5%	16.3%	16.2%
Anti-infectives	3,933	4,413	4,917	4,817	12.2%	11.4%	-2.0%
Gastro Intestinal	1,879	2,364	2,711	3,167	25.8%	14.7%	16.8%
Anti-TB	2,076	2,350	2,257	2,161	13.2%	-4.0%	-4.2%
Pain / Analgesics	1,448	1,772	1,942	2,117	22.4%	9.6%	9.0%
Gynaec.	798	1,123	1,449	1,900	40.7%	29.0%	31.1%
Neuro / CNS	1,298	1,500	1,623	1,768	15.6%	8.2%	8.9%
Vitamins / Minerals / Nutrients	1,432	1,657	1,734	1,729	15.7%	4.7%	-0.3%

Source: IMS data, Macquarie Research, October 2017

**Fig 9 Lupin domestic therapeutic split – Cardiac, Anti-diabetic and respiratory (Aug-17)**



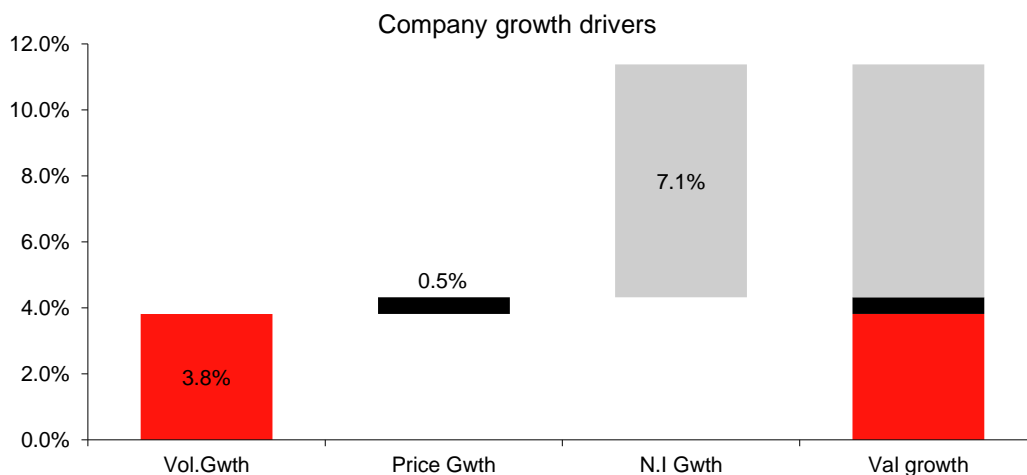
Source: : IMS data, Macquarie Research, October 2017

**Fig 10 Lupin’s top 25 brands contribute 34% of domestic sales and grew ~10% YoY (MAT Aug-2017)**

	MAT sales				MAT sales growth (YoY)		
	MAT Aug-14 sales	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	Aug-15	Aug-16	Aug-17
GLUCONORM-G	1,060	1,348	1,544	1,868	27.1%	14.5%	21.0%
BUDAMATE	590	744	865	962	26.1%	16.1%	11.2%
TONACT	823	918	993	920	11.5%	8.2%	-7.4%
RABLET-D	394	507	595	692	28.8%	17.4%	16.3%
TAZAR	380	431	533	572	13.2%	23.7%	7.3%
RABLET	358	458	504	551	27.9%	10.1%	9.4%
IVABRAD	237	318	403	503	34.5%	26.6%	24.9%
TELEKAST-L	349	414	439	492	18.9%	5.8%	12.2%
MEROTROL	386	398	454	491	3.2%	14.0%	8.3%
CETIL	309	397	467	481	28.7%	17.5%	2.9%
ESIFLO	344	423	438	465	22.9%	3.6%	6.1%
R-CINEX	407	472	461	460	16.0%	-2.4%	-0.1%
LUPISULIN-M	277	324	365	439	16.9%	12.6%	20.3%
SIGNOFLAM	283	371	397	435	30.8%	7.1%	9.7%
GLUCONORM-PG	294	437	431	432	48.8%	-1.3%	0.2%
RAMISTAR	461	508	485	402	10.0%	-4.5%	-17.1%
ONDERO	-	-	150	399	NA	NA	165.6%
NOVASTAT	257	339	377	380	31.8%	11.4%	0.6%
CLOPITAB-A	246	291	347	368	18.3%	19.0%	6.1%
CLOPITAB	329	362	374	359	10.3%	3.3%	-4.2%
NEBISTAR	239	285	323	355	19.1%	13.2%	10.2%
TONACT-TG	289	328	339	347	13.6%	3.3%	2.5%
ODOXIL	255	262	301	312	2.4%	15.0%	3.8%
RCIFAX	160	203	255	306	26.7%	25.4%	20.0%
SOFTOVAC	167	225	273	302	34.9%	21.1%	10.8%
Top 25 products as % of total sales	34.8%	34.3%	34.7%	34.2%			

Source: IMS data, Macquarie Research, October 2017

**Fig 11 Lupin’s existing domestic portfolio continues to grow as well**

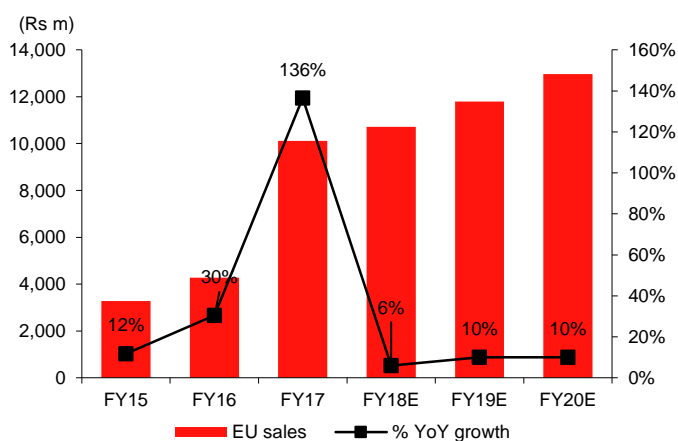


Source: IMS data, Macquarie Research, October 2017

### Structural changes in Japan market vital to monitor

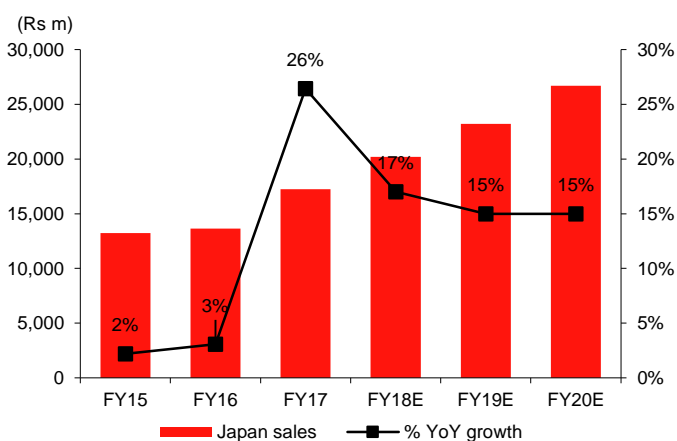
Starting August 2016, Lupin has a strategic asset purchase agreement with Japanese pharma company Shionogi to acquire 21 long-listed products, effective December 1, 2016 for ~US\$150m. The combined annual sales of these brands belonging to different therapeutic categories were US\$90m. The product portfolio acquired from Shionogi covers therapy areas like the Central Nervous System (CNS), Oncology, Cardiovascular and Anti-infectives. Lupin is now the sixth-largest generic player in Japan. There have been a number of proposals from the Japanese government to keep the total healthcare budget under control. The government is contemplating an annual price cut vs the current structure of a price cut every two years. There are changes currently being effected in the copay regime as well. As a result of these structural changes, Lupin has been focussed on moving to a hybrid and then to a specialty strategy in Japan.

**Fig 12 Lupin's annual EU sales**



Source: Company data, Macquarie Research, October 2017

**Fig 13 Lupin's annual Japan sales**



Source: Company data, Macquarie Research, October 2017

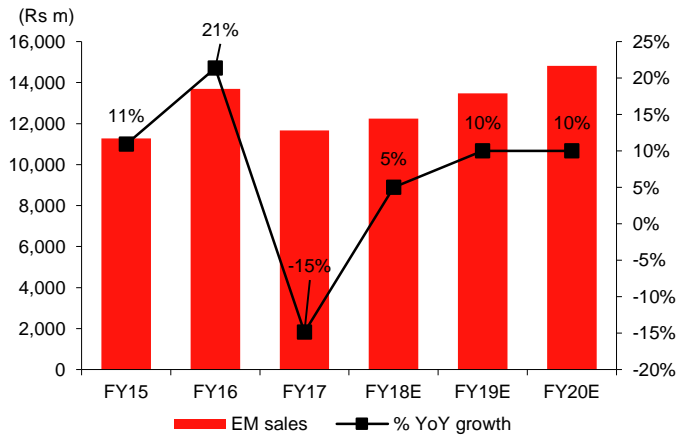
### Eyeing niche acquisitions

The company's M&A strategy is primarily focused on the specialty brand side. Management believes the bulk of the company's investments in complex generics has been made and the emphasis will be on execution over the next few years. On the specialty front, Lupin plans to build its expertise through product acquisitions over the next two years. Within therapies, the key focus areas for Lupin are Women's health, Pediatrics and CNS.

### Other business highlights:

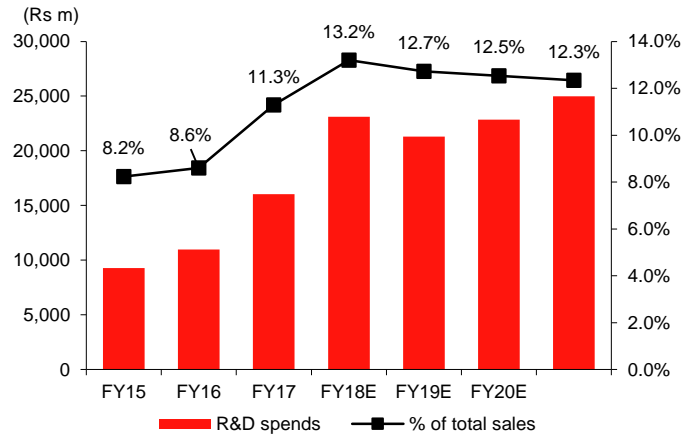
- Lupin's South African business has been doing well, with 21% YoY growth in FY17. The company expects that business to do well in FY18.
- 75% of Lupin's API production quantity is consumed in house.
- The company has a fairly decent track record of US FDA compliance owing to putting lot of emphasis on quality standards.

**Fig 14 Lupin’s annual EM sales**



Source: Company data, Macquarie Research, October 2017

**Fig 15 R&D spend has increased significantly**



Source: Company data, Macquarie Research, October 2017

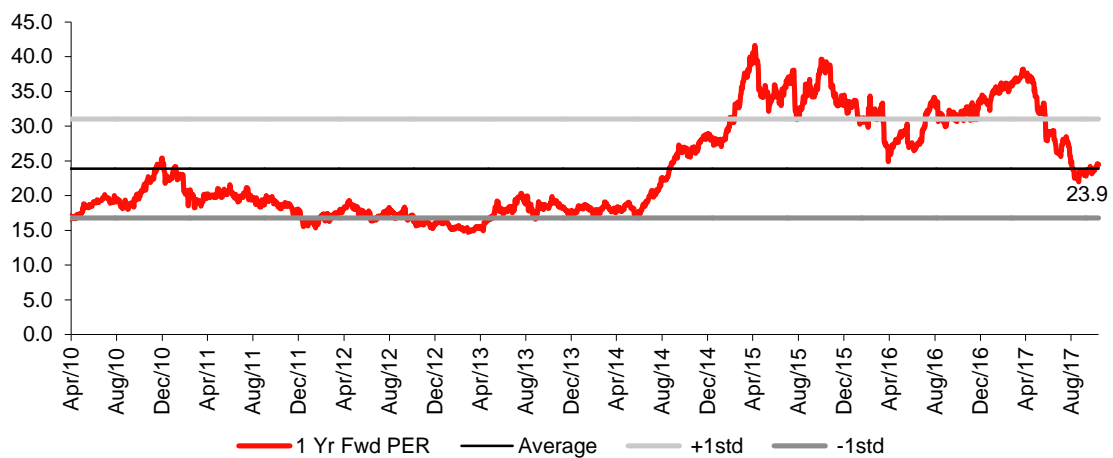
**In the absence of US sales pick-up, high base and R&D spends to dent margins**

In the absence of big launches and continued investments in R&D, we expect margins to remain suppressed. Lupin has guided that absolute FY18 R&D spend would be ~Rs20bn. Even with the company facing challenges in the US business over the next two years, management remains committed to developing complex generics, biosimilars and specialty businesses. Currently, the bulk of R&D spend is happening in oral solids and liquids. Going forward, however, Lupin expects 15% of R&D spend each towards biosimilars, respiratory and complex injectables. We believe that ongoing R&D investments in Topicals, Inhalation, biosimilars & complex injectables provide hope of a sales turnaround over the medium- to long-term.

**We expect the stock to remain range-bound**

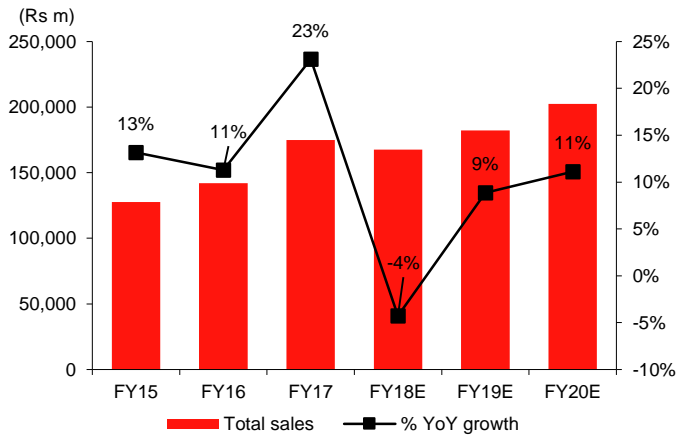
In the last two years, LPC’s stock price has almost halved, primarily reflecting growth concerns in its US business. In the absence of any near- to medium-term triggers, we expect the stock to remain range-bound. We rate the stock Neutral with a TP of Rs1,022 at 19x Sept-19E EPS (a notch lower than large-cap peers like Cipla, Sun Pharma and DRRD due to limited big-ticket opportunities).

**Fig 16 LPC is trading closer to its average multiples**



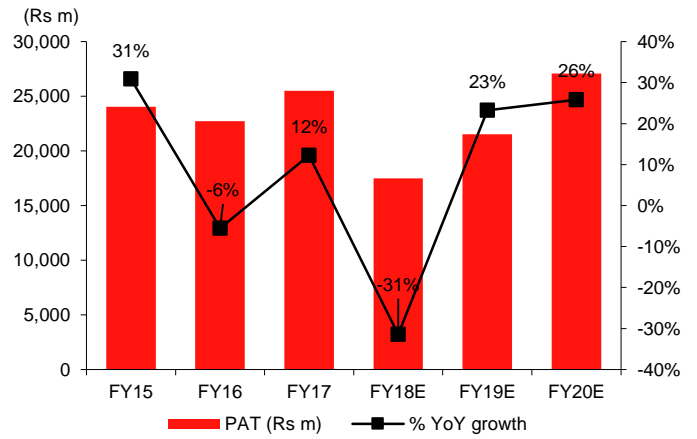
Source: Bloomberg, Macquarie Research, October 2017

**Fig 17 Lupin's annual total sales**



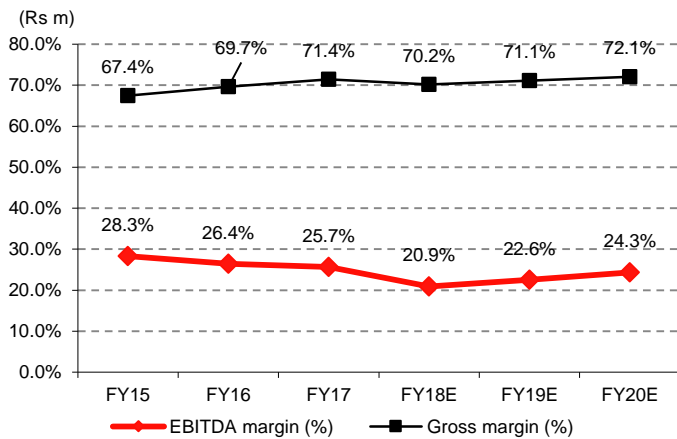
Source: Company data, Macquarie Research, October 2017

**Fig 18 Annual PAT trend**



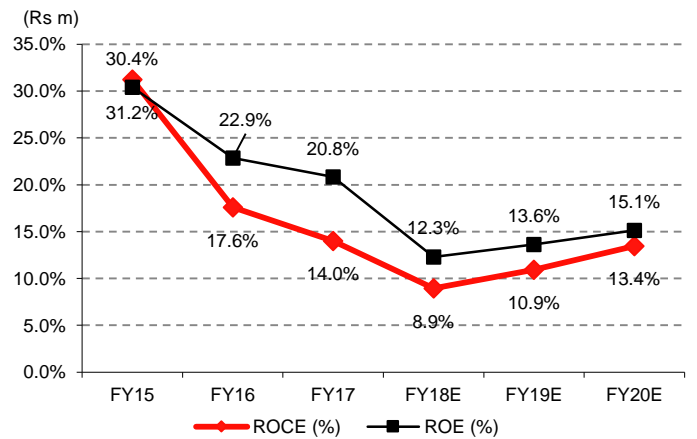
Source: Company data, Macquarie Research, October 2017

**Fig 19 Gross margin and EBITDA margin profile**



Source: Company data, Macquarie Research, October 2017

**Fig 20 Return ratio profile**



Source: Company data, Macquarie Research, October 2017

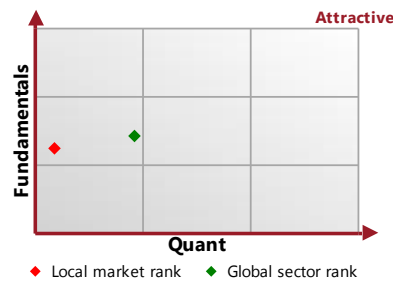
## Macquarie Quant View

The quant model currently holds a strong negative view on Lupin. The strongest style exposure is Profitability, indicating this stock is efficiently converting investments to earnings; proxied by ratios like ROE or ROA. The weakest style exposure is Price Momentum, indicating this stock has had weak medium to long term returns which often persist into the future.

**603/868**

Global rank in  
Pharma, Biotech & Life Sciences

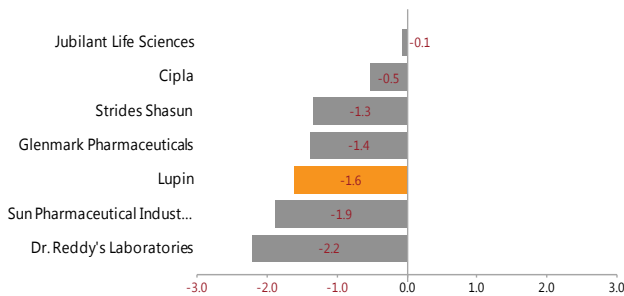
**% of BUY recommendations** 51% (21/41)  
**Number of Price Target downgrades** 1  
**Number of Price Target upgrades** 1



Displays where the company's ranked based on the fundamental consensus Price Target and Macquarie's Quantitative Alpha model.  
Two rankings: Local market (India) and Global sector (Pharma, Biotech & Life Sciences)

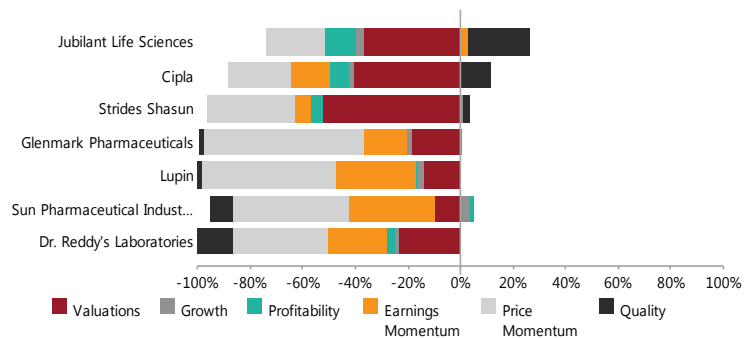
## Macquarie Alpha Model ranking

A list of comparable companies and their Macquarie Alpha model score (higher is better).



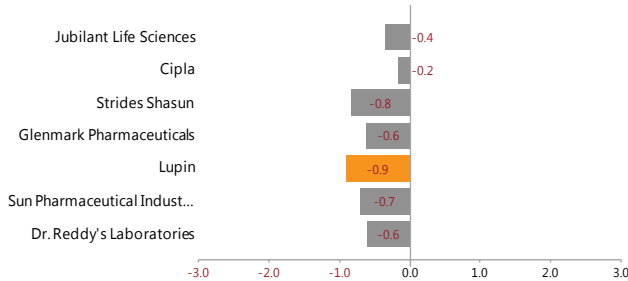
## Factors driving the Alpha Model

For the comparable firms this chart shows the key underlying styles and their contribution to the current overall Alpha score.



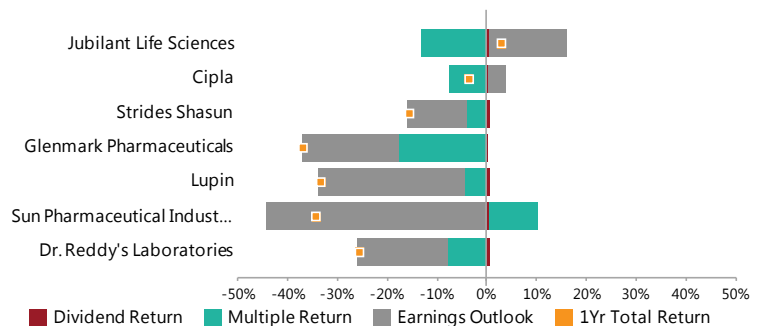
## Macquarie Earnings Sentiment Indicator

The Macquarie Sentiment Indicator is an enhanced earnings revisions signal that favours analysts who have more timely and higher conviction revisions. Current score shown below.



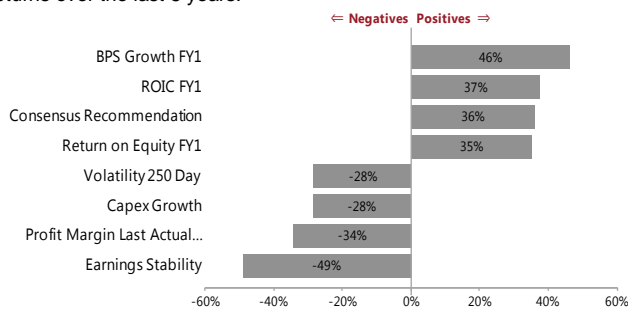
## Drivers of Stock Return

Breakdown of 1 year total return (local currency) into returns from dividends, changes in forward earnings estimates and the resulting change in earnings multiple.



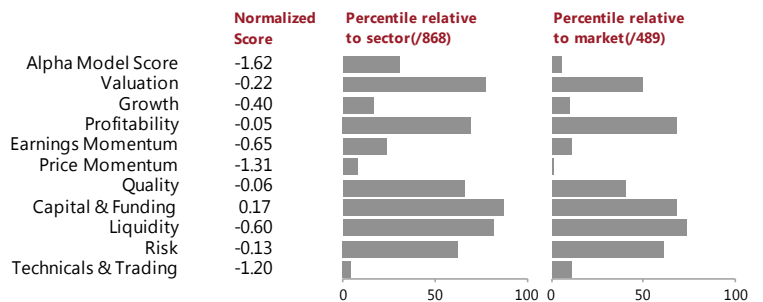
## What drove this Company in the last 5 years

Which factor score has had the greatest correlation with the company's returns over the last 5 years.



## How it looks on the Alpha model

A more granular view of the underlying style scores that drive the alpha (higher is better) and the percentile rank relative to the sector and market.



Source (all charts): FactSet, Thomson Reuters, and Macquarie Research. For more details on the Macquarie Alpha model or for more customised analysis and screens, please contact the Macquarie Global Quantitative/Custom Products Group ([cpg@macquarie.com](mailto:cpg@macquarie.com))

## Lupin (LPC IN)

Quarterly Results					Profit & Loss						
	1Q/18A	2Q/18E	3Q/18E	4Q/18E		2017A	2018E	2019E	2020E		
<b>Revenue</b>	m	40,197	41,872	41,872	43,547	<b>Revenue</b>	m	174,943	167,488	182,321	202,567
<b>Gross Profit</b>	m	28,201	29,376	29,376	30,551	<b>Gross Profit</b>	m	124,929	117,504	129,642	146,023
Cost of Goods Sold	m	11,996	12,496	12,496	12,996	Cost of Goods Sold	m	50,014	49,984	52,678	56,544
<b>EBITDA</b>	m	8,416	8,766	8,766	9,117	<b>EBITDA</b>	m	44,931	35,066	41,150	49,316
Depreciation	m	2,496	2,600	2,600	2,704	Depreciation	m	9,122	10,400	11,100	11,800
Amortisation of Goodwill	m	0	0	0	0	Amortisation of Goodwill	m	0	0	0	0
Other Amortisation	m	0	0	0	0	Other Amortisation	m	0	0	0	0
<b>EBIT</b>	m	5,920	6,166	6,166	6,413	<b>EBIT</b>	m	35,809	24,666	30,050	37,516
Net Interest Income	m	-360	-375	-375	-390	Net Interest Income	m	-1,525	-1,500	-1,350	-1,200
Associates	m	0	0	0	0	Associates	m	0	0	0	0
Exceptionals	m	0	0	0	0	Exceptionals	m	0	0	0	0
Forex Gains / Losses	m	0	0	0	0	Forex Gains / Losses	m	0	0	0	0
Other Pre-Tax Income	m	264	275	275	286	Other Pre-Tax Income	m	1,065	1,100	1,200	1,300
<b>Pre-Tax Profit</b>	m	5,824	6,066	6,066	6,309	<b>Pre-Tax Profit</b>	m	35,349	24,266	29,900	37,616
Tax Expense	m	-1,631	-1,699	-1,699	-1,767	Tax Expense	m	-9,785	-6,794	-8,372	-10,532
<b>Net Profit</b>	m	4,193	4,368	4,368	4,543	<b>Net Profit</b>	m	25,564	17,471	21,528	27,083
Minority Interests	m	0	0	0	0	Minority Interests	m	-72	0	0	0
<b>Reported Earnings</b>	m	4,193	4,368	4,368	4,543	<b>Reported Earnings</b>	m	25,492	17,471	21,528	27,083
<b>Adjusted Earnings</b>	m	4,193	4,368	4,368	4,543	<b>Adjusted Earnings</b>	m	25,492	17,471	21,528	27,083
EPS (rep)		9.28	9.66	9.66	10.05	EPS (rep)		56.40	38.65	47.63	59.92
EPS (adj)		9.28	9.66	9.66	10.05	EPS (adj)		56.40	38.65	47.63	59.92
EPS Growth yoy (adj)	%	-31.5	-31.5	-31.5	-31.5	EPS Growth (adj)	%	12.3	-31.5	23.2	25.8
						PE (rep)	x	18.6	27.1	22.0	17.5
						PE (adj)	x	18.6	27.1	22.0	17.5
EBITDA Margin	%	20.9	20.9	20.9	20.9	Total DPS		7.50	7.50	7.50	7.50
EBIT Margin	%	14.7	14.7	14.7	14.7	Total Div Yield	%	0.7	0.7	0.7	0.7
Earnings Split	%	24.0	25.0	25.0	26.0	Basic Shares Outstanding	m	449	449	449	449
Revenue Growth	%	-4.3	-4.3	-4.3	-4.3	Diluted Shares Outstanding	m	452	452	452	452
EBIT Growth	%	-31.1	-31.1	-31.1	-31.1						
Profit and Loss Ratios					Cashflow Analysis						
	2017A	2018E	2019E	2020E		2017A	2018E	2019E	2020E		
Revenue Growth	%	23.1	-4.3	8.9	11.1	<b>EBITDA</b>	m	44,931	35,066	41,150	49,316
EBITDA Growth	%	19.7	-22.0	17.4	19.8	Tax Paid	m	-11,490	-6,794	-8,372	-10,532
EBIT Growth	%	8.8	-31.1	21.8	24.8	Chgs in Working Cap	m	5,059	2,303	-4,598	-5,264
Gross Profit Margin	%	71.4	70.2	71.1	72.1	Net Interest Paid	m	-1,507	-1,500	-1,350	-1,200
EBITDA Margin	%	25.7	20.9	22.6	24.3	Other	m	-740	-740	-1,294	-1,294
EBIT Margin	%	20.5	14.7	16.5	18.5	<b>Operating Cashflow</b>	m	36,252	28,334	25,536	31,026
Net Profit Margin	%	14.6	10.4	11.8	13.4	Acquisitions	m	0	0	0	0
Payout Ratio	%	13.3	19.4	15.7	12.5	Capex	m	-26,368	-8,374	-9,116	-10,128
EV/EBITDA	x	11.5	14.8	12.6	10.5	Asset Sales	m	0	0	0	0
EV/EBIT	x	14.5	21.0	17.2	13.8	Other	m	380	380	390	390
<b>Balance Sheet Ratios</b>					<b>Investing Cashflow</b>	m	-25,988	-7,994	-8,726	-9,738	
ROE	%	20.8	12.3	13.6	15.1	Dividend (Ordinary)	m	-3,378	-3,370	-3,370	-3,370
ROA	%	14.6	9.0	10.2	11.7	Equity Raised	m	0	0	0	0
ROIC	%	15.0	9.5	11.9	14.6	Debt Movements	m	-9,479	0	0	0
Net Debt/Equity	%	38.0	22.1	10.4	-1.4	Other	m	1,770	0	0	0
Interest Cover	x	23.5	16.4	22.3	31.3	<b>Financing Cashflow</b>	m	-11,087	-3,370	-3,370	-3,370
Price/Book	x	3.5	3.2	2.8	2.5	<b>Net Chg in Cash/Debt</b>	m	-823	16,969	13,439	17,917
Book Value per Share		300.4	331.8	372.2	425.0	<b>Free Cashflow</b>	m	9,884	19,959	16,419	20,897
						<b>Balance Sheet</b>		2017A	2018E	2019E	2020E
						Cash	m	28,135	46,565	62,109	82,230
						Receivables	m	43,073	43,361	47,201	51,597
						Inventories	m	36,423	38,641	42,063	45,980
						Investments	m	0	0	0	0
						Fixed Assets	m	109,250	107,225	105,241	103,569
						Intangibles	m	23,100	23,100	23,100	23,100
						Other Assets	m	26,091	25,528	26,533	27,683
						<b>Total Assets</b>	m	266,073	284,419	306,246	334,159
						Payables	m	25,889	30,594	33,304	36,405
						Short Term Debt	m	23,043	23,043	23,043	23,043
						Long Term Debt	m	56,478	56,478	56,478	56,478
						Provisions	m	0	0	0	0
						Other Liabilities	m	25,342	24,882	25,841	26,939
						<b>Total Liabilities</b>	m	130,752	134,997	138,666	142,866
						Shareholders' Funds	m	134,976	149,077	167,235	190,948
						Minority Interests	m	345	345	345	345
						Other	m	0	0	0	0
						<b>Total S/H Equity</b>	m	135,321	149,422	167,580	191,294
						<b>Total Liab &amp; S/H Funds</b>	m	266,073	284,419	306,246	334,159

All figures in INR unless noted.

Source: Company data, Macquarie Research, October 2017

## INDIA

DRRD IN Neutral

Price (at 13:12, 18 Oct 2017 GMT) Rs2,385.40

Valuation Rs 2,500.00  
- PER

12-month target Rs 2,500.00

Upside/Downside % +4.8

12-month TSR % +5.6

Volatility Index Medium

## GICS sector

Pharmaceuticals, Biotechnology &amp; Life Sciences

Market cap Rsm 395,738

Market cap US\$m 6,103

Free float % 56

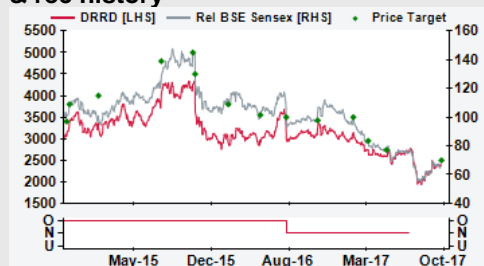
30-day avg turnover US\$m 39.9

Number shares on issue m 165.9

## Investment fundamentals

Year end 31 Mar		2017A	2018E	2019E	2020E
Revenue	bn	140.8	147.9	168.0	186.7
EBIT	bn	13.5	13.7	23.2	33.4
EBIT growth	%	-56.0	1.7	69.3	43.6
Recurring profit	bn	14.7	14.8	24.4	34.6
Reported profit	bn	12.0	11.4	18.5	26.9
Adjusted profit	bn	12.0	11.4	18.5	26.9
EPS rep	Rs	70.43	66.77	108.47	157.58
EPS rep growth	%	-39.8	-5.2	62.5	45.3
EPS adj	Rs	70.43	66.77	108.47	157.58
EPS adj growth	%	-52.0	-5.2	62.5	45.3
PER rep	x	33.9	35.7	22.0	15.1
PER adj	x	33.9	35.7	22.0	15.1
Total DPS	Rs	20.00	20.00	20.00	20.00
Total div yield	%	0.8	0.8	0.8	0.8
ROA	%	6.4	6.4	10.8	14.7
ROE	%	9.6	9.0	13.4	17.2
EV/EBITDA	x	17.0	16.7	12.1	9.4
Net debt/equity	%	25.0	14.5	5.8	-4.3
P/BV	x	3.3	3.1	2.8	2.4

## DRRD IN rel BSE Sensex performance, &amp; rec history



Note: Recommendation timeline - if not a continuous line, then there was no Macquarie coverage at the time or there was an embargo period.

Source: FactSet, Macquarie Research, October 2017

(all figures in INR unless noted)

## Analyst(s)

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23 October 2017

Macquarie Capital Securities India (Pvt) Ltd

# Dr. Reddy's Laboratories

## Headwinds cloud big-ticket opportunities

### Conclusion

- Increased competition for DRRD's key products, in the absence of new approvals, has been a key challenge. Uncertainty over the resolution of the US FDA warning letter and its potential impact on product approval timelines continues to be an overhang. However, the outlook does look promising for 2HFY19 onwards with 3 key medium-term opportunities (Copaxone, NuvaRing and Suboxone – combined peak revenue potential of US\$300-350m), even as uncertainty prevails over the exact timing of the launches. Even as we factor in most of the positives in our FY19/FY20 estimates, delayed timelines and reducing complex arbitrage could play spoilsport. We initiate with a Neutral rating and a TP of Rs2,500 at 20x Sept-19E EPS.

### Impact

- Lack of key approvals remains a challenge in the near term:** Pricing erosion in DRRD's US base business continues to intensify and currently stands at 10-12% YoY. Excluding the big launches, DRRD has guided for 10-12 launches each in FY18/19, in the range of US\$5-30m. We think material approvals are a prerequisite to offset the competitive impact. Copaxone, NuvaRing and Suboxone, along with Aloxi and Gleevec to some extent are key opportunities, the contribution of which is likely to pick up only in FY19 and beyond (Macq FY18-20 EPS CAGR: 47%). With the FDA approval process for complex generics becoming more structured, uncertainty around approval timelines of DRRD's complex products has increased.
- FDA issues have taken a toll as well:** DRRD has also suffered from ongoing US FDA issues, especially in Srikakulam API, Duvvada and Bacchupally. Gleevec, which could have been a USD50-60m revenue opportunity for DRRD, is now just a USD20m opportunity due to Apotex and Teva coming in. Its launch is contingent on the Duvvada facility getting US FDA clearance.
- Good company in a tight spot:** Our dialogs with industry experts and US FDA consultants suggest that DRRD has one of the most robust compliance standards in the industry. Apart from the ongoing remediation at Duvvada and Srikakulam API, we would also keep a close eye on the ongoing cost control program, which could help offset some of the margin concerns.

### Earnings and target price revision

- We rate the stock 'Neutral' with a TP of Rs2,500.

### Price catalyst

- 12-month price target: Rs2,500.00 based on a PER methodology.
- Catalyst: Resolution of US FDA issues, launch of 3 key molecules

### Action and recommendation

- We expect the stock to remain range-bound till we get clarity on the launch timelines of key molecules and resolution of US FDA issues. While any major approvals are likely to lift sentiments, we have factored most of the benefit in our estimates. We rate the stock Neutral with a TP of Rs2,500.



## Analysis of the potential of key opportunities for DRRD

**Fig 1 Key upcoming molecules for DRRD**

Product	Market size (USD m)	Estimated launch timeline	DRRD's revenue potential (USD m)
Aloxi	500	1HFY19	35-40
Suboxone	900	2HFY19	50-60
NuvaRing	650	FY19	100-150
Copaxone 20mg	800	FY19	70-80
Copaxone 40mg	3,000	2HFY20	100-150

Source: IMS data, Company, Macquarie Research, October 2017

### ▪ Copaxone:

- ⇒ Since Copaxone is a Central Nervous System (CNS) injectable drug, we expect generic penetration to be slow in Copaxone. For therapies and immune-suppressants, due to the sensitivity involved, innovator (Teva) can end up having a sizeable market share despite the generic entry.
- ⇒ Copaxone API has been stuck due to US FDA observations at DRRD's Srikakulam facility. The company doesn't intend to do site transfer for the API.
- ⇒ As per IMS data, Copaxone 20mg (daily dosage) has a market size of USD800m. Other key filers include Mylan/Natco and Sandoz/Momenta. Target action date (TAD) for DRRD is in November 2017. With 3 generic players, we expect DRRD to get ~20% market share with annual revenue accretion of USD70-80m.
- ⇒ At 3 times a week, Copaxone 40mg has lower dosage frequency vs daily dosage for Copaxone 20mg. Market size in the US for Copaxone 40mg is USD3bn. With 4-5 generic players, we expect DRRD to have a 10-15% market share post generic entry with annual revenue accretion of USD100-150m.

### ▪ NuvaRing:

- ⇒ Merck's NuvaRing (etonogestrel/ethinyl estradiol vaginal ring) is a small, flexible vaginal ring used to prevent pregnancy.
- ⇒ Overall market size is ~USD650m in the US, with 2 potential generic entrants – DRRD and Teva. The patent is expiring in April 2018. DRRD's TAD is in February-March 2018.
- ⇒ We believe NuvaRing could be a USD100-150m opportunity at peak.
- ⇒ Since NuvaRing is a personal use product, consumer offtake could take time. We expect NuvaRing to reach its peak potential in 3-4 quarters post launch.

### ▪ Suboxone:

- ⇒ Indivior's Suboxone film is a prescription medicine that contains APIs like buprenorphine and naloxone. It is used to treat adults who are addicted to opioids (either prescription or illegal).
- ⇒ DRRD is the first generic player in Suboxone, with TAD in February-March 2018.
- ⇒ The company could potentially benefit from a staggered entry due to ongoing litigations for other generic players.
- ⇒ The US market size for Suboxone is USD900m with 4-5 generic competitors including Actavis, Par and DRRD.
- ⇒ We believe this could be a USD50-60m peak annual revenue opportunity for DRRD

### ▪ Aloxi:

- ⇒ Helsinn's Aloxi injection is used to prevent nausea and vomiting caused by cancer chemotherapy.
- ⇒ With an USD500m US market size, we expect Aloxi to be a USD35-40m opportunity for DRRD.

### ▪ Doxil:

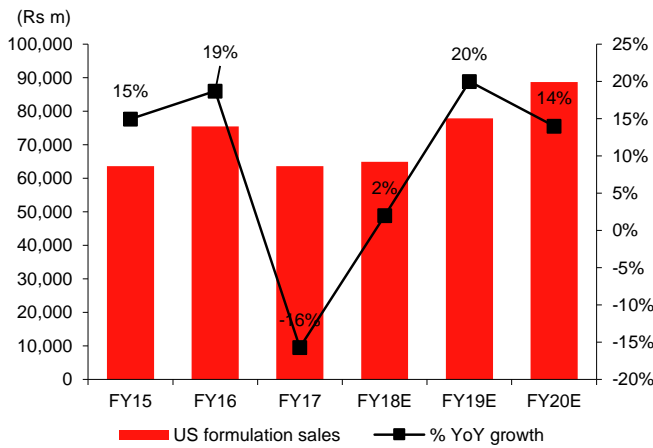
- ⇒ We expect Doxil (chemotherapy medication used to treat certain types of cancer), launched by DRRD in May 2017 to be a USD50m opportunity and as per the company, it will take 2 quarters to reach the contracted market share.

**Base business erosion to restrict DRRD’s US growth**

Increased competition for DRRD’s key products, in the absence of new approvals, continues to play spoilsport. Pricing erosion in DRRD’s base business continues to intensify in the US. In addition, uncertainty over the resolution of the US FDA warning letter and its potential impact on the approval timelines continues to be an overhang. We think material approvals are a prerequisite to offset pricing pressure. Copaxone, NuvaRing and Suboxone, along with Aloxi and Gleevec to some extent are material earnings drivers (Macq FY18-20 EPS CAGR of 47%), contribution of which is likely to pick up only in FY19 and beyond. While we are cognizant of the 3 key medium-term opportunities for DRRD (Copaxone, NuvaRing and Suboxone), uncertainty prevails over the timing of the launches. Also, ramp-up of these products is expected to be gradual. Excluding the 3 big launches, DRRD has guided for 10-12 launches per year, in the range of USD5-30m.

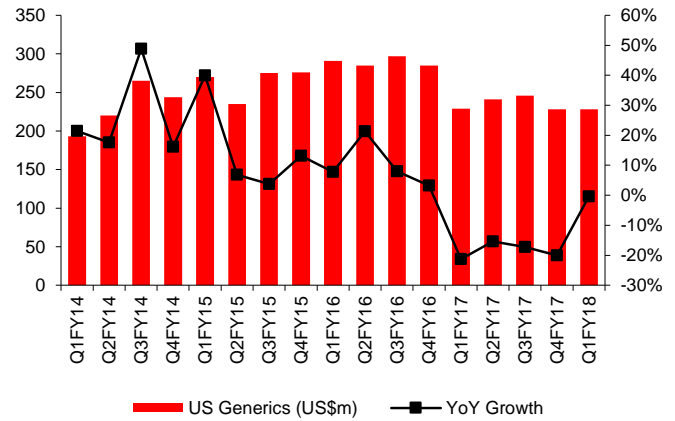
With the FDA approval process for complex generics becoming more structured, uncertainty around approval timelines of DRRD’s complex products has increased. In FY17, DRRD acquired 8 ANDAs from Teva/Allergan for USD350mn. Of these, Vytorin was launched in April 2017. Global biosimilar revenues for DRRD were USD40-45m in FY17. The company expects it to increase to USD70-75m in FY18. As per the company, US launch will happen earliest by FY21.

**Fig 2 US formulation sales - annual**



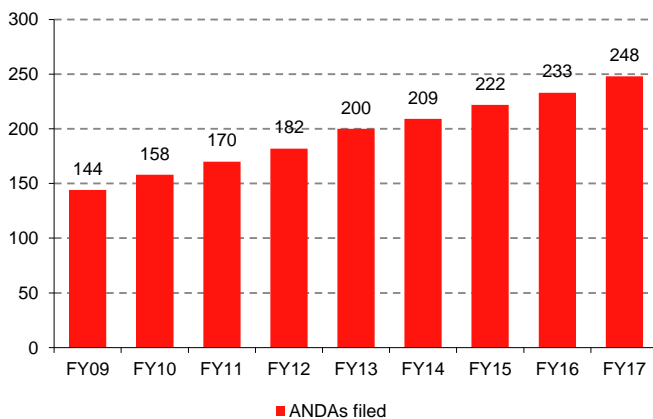
Source: Company data, Macquarie Research, October 2017

**Fig 3 US formulation sales - quarterly**



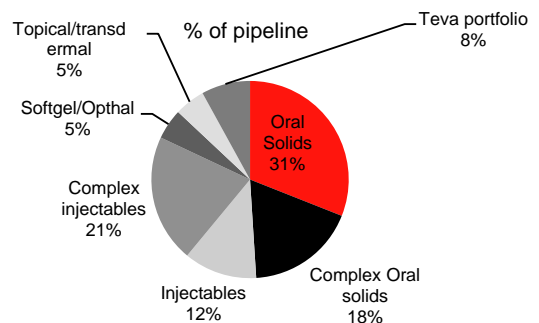
Source: Company data, Macquarie Research, October 2017

**Fig 4 ANDAs filed**



Source: Company data, Macquarie Research, October 2017

**Fig 5 Break-up of filings across dosage forms**

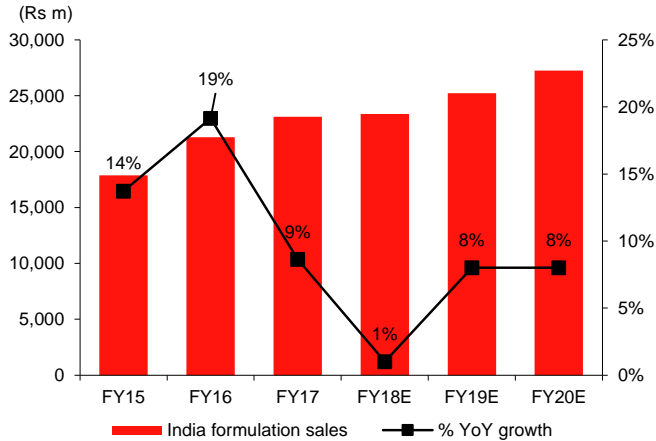


Source: Company data, Macquarie Research, October 2017

**India business**

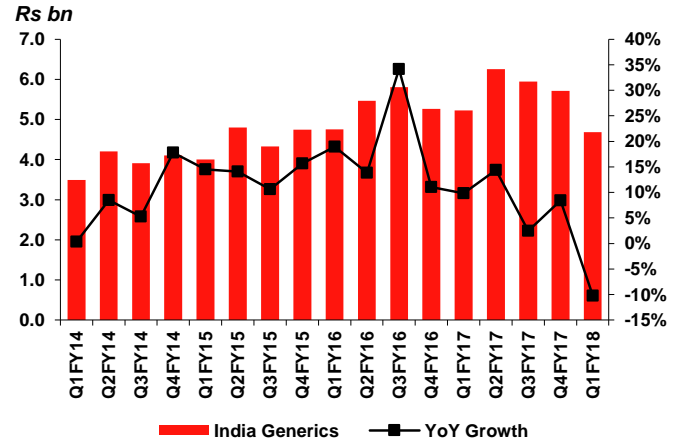
Despite an improvement in growth in the last few years, DRRD's India business has been impacted by NLEM and continues to lag IPM growth. We believe this is unlikely to be corrected soon and are expecting 8% YoY growth in the domestic business each in FY19 and FY20.

**Fig 6 India formulation sales - annual**



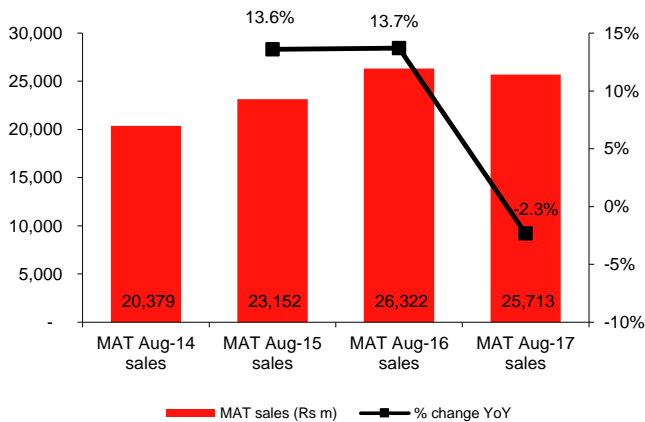
Source: Company data, Macquarie Research, October 2017

**Fig 7 India formulation sales - quarterly**



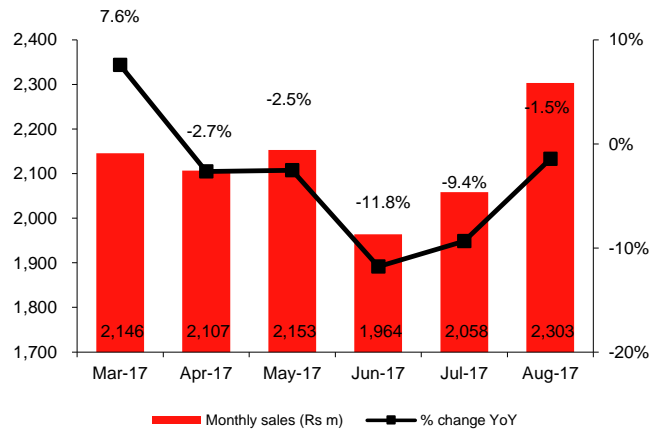
Source: Company data, Macquarie Research, October 2017

**Fig 8 DRRD - India MAT sales (August 2017)**



Source: IMS data, Macquarie Research, October 2017

**Fig 9 DRRD India monthly sales (August 2017)**



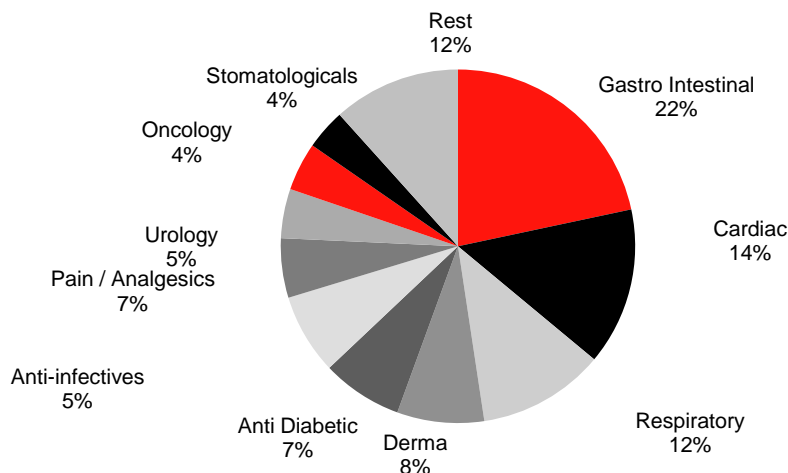
Source: IMS data, Macquarie Research, October 2017

**Fig 10 Key therapeutic drivers in India – Respiratory and derma driving growth**

(Rs m)	MAT sales				MAT sales growth (YoY)		
	MAT Aug-14 sales	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	Aug-15	Aug-16	Aug-17
Gastro Intestinal	4,383	5,122	5,508	5,568	16.9%	7.5%	1.1%
Cardiac	3,182	3,589	3,787	3,700	12.8%	5.5%	-2.3%
Respiratory	2,084	2,317	2,659	2,976	11.2%	14.8%	11.9%
Derma	1,328	1,644	1,881	2,041	23.8%	14.4%	8.6%
Anti Diabetic	1,397	1,686	1,877	1,896	20.7%	11.3%	1.1%
Pain / Analgesics	1,700	1,791	1,914	1,894	5.4%	6.9%	-1.0%
Anti-infectives	1,331	1,497	1,543	1,397	12.4%	3.1%	-9.4%
Urology	724	861	1,029	1,160	18.9%	19.4%	12.8%
Oncology	1,181	1,217	1,712	1,136	3.1%	40.7%	-33.7%
Stomatologicals	770	868	911	950	12.7%	5.1%	4.2%

Source: IMS data, Macquarie Research, October 2017

Fig 11 DRRD therapeutic split in India – GI, Cardiac, Respiratory &amp; derma key focus areas (MAT Aug-17)



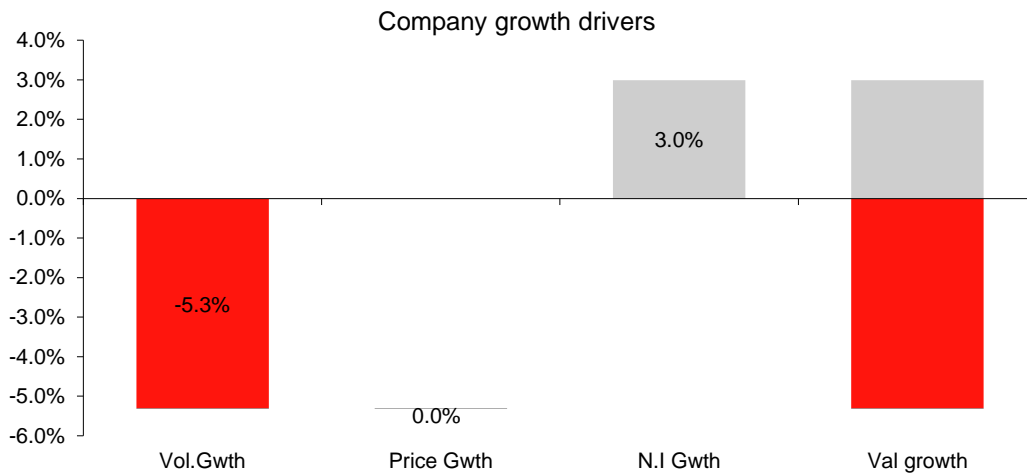
Source: : IMS data, Macquarie Research, October 2017

Fig 12 DRRD top 25 brands - contribute ~50% of total India sales, and grew ~2% YoY (MAT Aug-2017)

	MAT sales (Rs m)				MAT sales growth (YoY)		
	MAT Aug-14 sales	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	Aug-15	Aug-16	Aug-17
OMEZ	1,162	1,391	1,407	1,203	19.8%	1.2%	-14.5%
OMEZ-D	746	879	998	1,022	17.8%	13.6%	2.4%
ATARAX	499	526	677	841	5.5%	28.7%	24.2%
NISE	890	906	881	801	1.8%	-2.7%	-9.1%
ECONORM	541	652	750	780	20.5%	15.0%	3.9%
RAZO-D	452	510	599	707	12.8%	17.4%	17.9%
RAZO	495	537	607	655	8.6%	13.1%	7.9%
STAMLO	696	740	758	637	6.3%	2.4%	-15.9%
STAMLO BETA	476	522	490	533	9.6%	-6.1%	8.9%
CLAMP	411	458	524	506	11.3%	14.6%	-3.5%
KETOROL	310	368	437	496	18.5%	18.8%	13.6%
NOOTROPIL	401	414	467	475	3.3%	13.0%	1.6%
RECLIMET	311	369	438	474	18.7%	18.8%	8.2%
MINTOP	440	514	479	470	16.7%	-6.8%	-1.9%
GLIMY-M	307	354	383	421	15.5%	8.0%	10.1%
ATOCOR	391	441	462	400	12.6%	4.9%	-13.5%
RECLIDE	248	325	346	341	31.0%	6.2%	-1.3%
CRESP	262	320	312	322	22.3%	-2.5%	3.3%
ROZAT	185	241	279	305	30.3%	16.0%	9.3%
XYZAL	178	207	251	293	16.0%	21.1%	17.0%
TELSARTAN	263	294	314	281	11.6%	6.8%	-10.5%
VENUSIA MAX	108	170	214	267	57.5%	25.9%	24.7%
TELSARTAN-H	235	243	249	248	3.6%	2.3%	-0.4%
DOXT-SL	16	214	230	244	1200.9%	7.6%	6.0%
VANTEJ	154	198	214	243	28.6%	8.2%	13.4%
Top 25 products as % of total sales	49.9%	50.9%	48.5%	50.4%			

Source: IMS data, Macquarie Research, October 2017

**Fig 13 DRRD’s domestic sales largely led by new launches**



Source: IMS data, Macquarie Research, October 2017

**Pending US FDA observations remain an overhang**

DRRD has also suffered from ongoing US FDA issues, especially in Srikakulam API, Duvvada and Bacchupally. Duvvada is DRRD’s oncology formulation facility located in Vizag, manufacturing cytotoxic and hormonal injectables. The plant had received a warning letter in November 2015 for batch failures, possible microbial contamination and quality control issues. The company had completed all the remediation efforts and had invited the US FDA for reinspection. The latest observations are post the US FDA reinspection of the Duvvada facility from February 27 to March 8, 2017. Oncology is a key focus area for DRRD and delay in resolution of Duvvada has been a setback for the company.

For example, Gleevec, which could have been a USD50-60m revenue opportunity for DRRD, is now just a USD20m opportunity and is contingent on the Duvvada facility getting a clearance from the US FDA. Out of the 13 observations received in March 2017 for DRRD’s Duvvada plant post US FDA reinspection, 4 are repeat observations. Given the nature of observations, our assessment suggests resolution could happen only in 2HFY19.

Duvvada, Miryalaguda and Srikakulam API together contribute 10-12% of total revenues. Bacchupally used to contribute 80% of US revenue and now its contribution is down to 40% of US revenue. DRRD has derisked its Bacchupally site by Srikakulam Unit 1 (SEZ) – which is an important plant for the future. This is a formulation unit and could be an alternative to Bacchupally. There is another formulation unit at Srikakulam along with an API unit.

**Duvvada:** Key molecules from Duvvada are Azacitidine, Decitabine, Sirolimus. However, manufacturing is well distributed. DRRD will invite FDA for inspection in 3QFY18.

- ⇒ **Miryalaguda:** All clear. EIR has been received
- ⇒ **Srikakulam API:** All clear expected anytime soon
- ⇒ **Bacchupally:** DRRD has responded to follow-on query and expects a clearance in 1-2 quarters.

**Fig 14 Recent FDA inspection track record has been patchy**

Facility	Formulations/API	Inspection date	Type	Pending observations
Bachupally	Formulations	May-17	Form 483	11
Duvvada	Formulations	Mar-17	Warning letter	13
Miryalaguda	API	Feb-17	NA	EIR
Srikakulam API	API	Apr-17	Warning letter	2
Mirfield, UK	API	Sep-17	Form 483	3

Source: Company data, Macquarie Research, October 2017

**Fig 15 Nature of the 13 observations at DRRD's Duvvada facility**

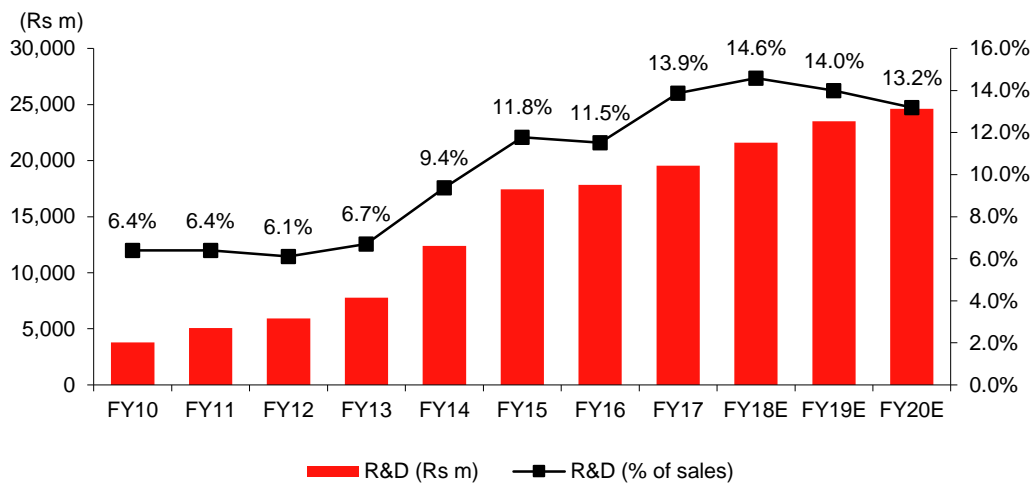
Sr. No.	Nature of observation	Repeat observation
1	Failure to thoroughly review any unexplained discrepancy whether or not the batch has already been distributed	Yes
2	Written procedures for production and process controls have not been established and followed	Yes
3	Failure to maintain complete data to ensure compliance with established specifications and standards	No
4	Production records do not contain complete and accurate information	No
5	Written procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed, including validation of all aseptic processes	No
6	Aseptic processing areas are deficient regarding the system for monitoring environmental conditions	No
7	Procedures for the preparation of master production and control records are not followed.	No
8	Appropriate controls are not exercised over computer or related systems to assure that changes to master production records and control records or other records are instituted only by authorized personnel	No
9	Data is not documented contemporaneously	Yes
10	Thorough review of documents is not performed	No
11	Procedures for maintenance of equipment had not been established and followed	No
12	No evidence to support when and how the samples were collected throughout the batch manufacturing	Yes
13	Samples collected to evaluate conformance of a batch are not representative	No

Source: US FDA, Macquarie Research, October 2017

**Accelerating R&D spends to build its pipeline**

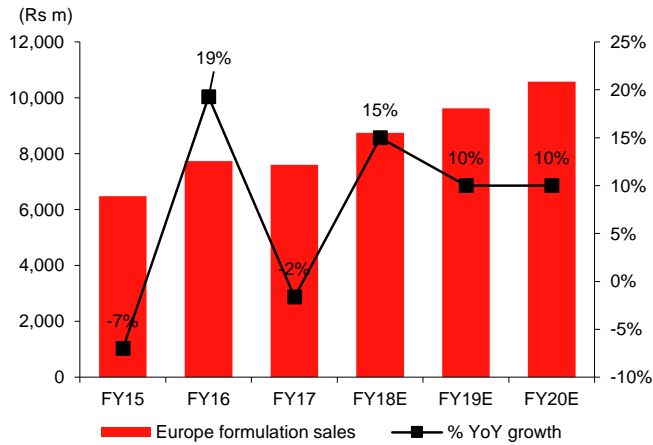
In the absence of key launches in the last two years, DRRD stepped up its investments in biologics, proprietary and complex generics. There has been a lot of investment in capacity creation as well. 60-65% of DRRD's R&D is focused on generics, while 25% is on proprietary products (high due to clinical trials) and 15% on biologics.

**Fig 16 We expect R&D as % of sales to taper down FY19 onwards**



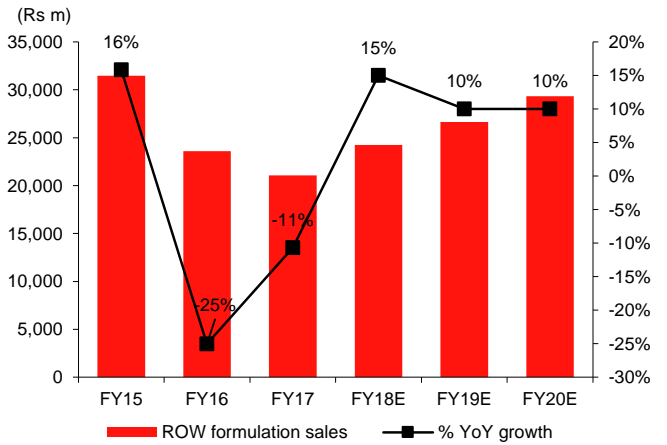
Source: Company data, Macquarie Research, October 2017

**Fig 17 Europe formulation sales**



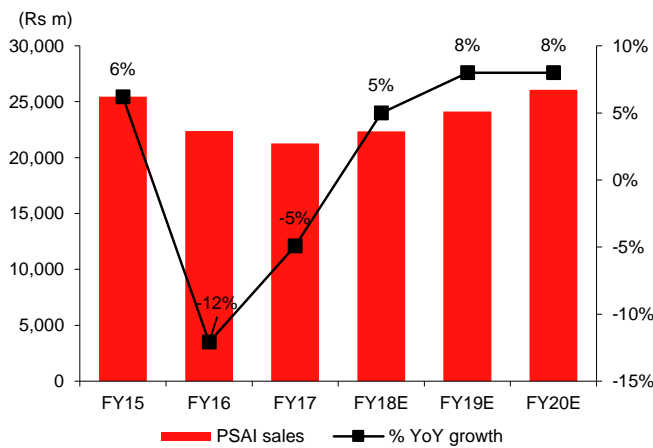
Source: Company data, Macquarie Research, October 2017

**Fig 18 ROW – up from low base post Venezuela issue**



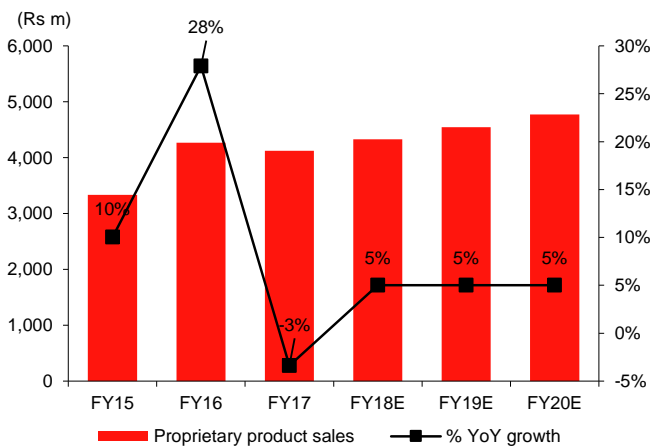
Source: Company data, Macquarie Research, October 2017

**Fig 19 PSAI sales**



Source: Company data, Macquarie Research, October 2017

**Fig 20 Proprietary sales**

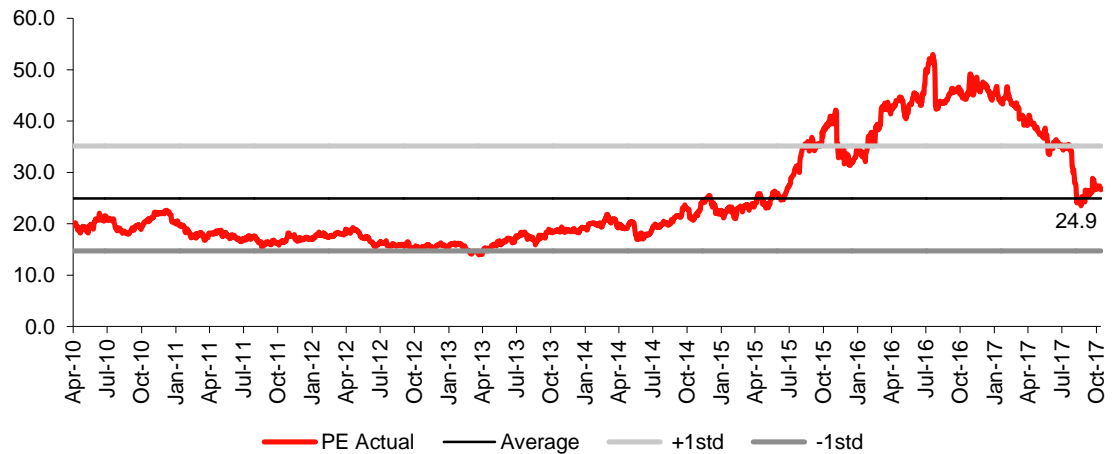


Source: Company data, Macquarie Research, October 2017

**Currently in a tight spot**

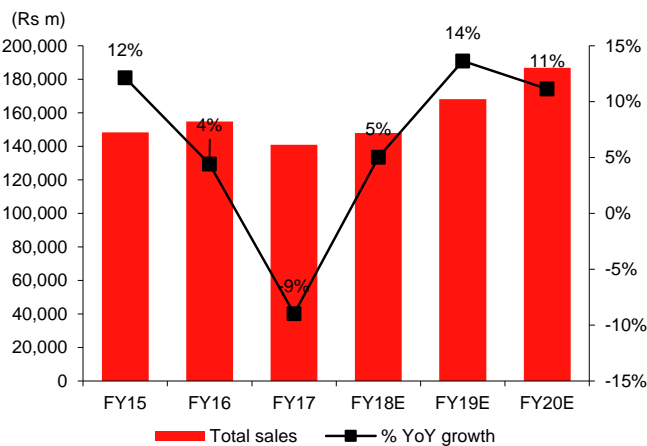
We expect the stock to remain range bound till we get clarity on the launch timelines of key molecules and resolution of US FDA issues. While any major approvals are likely to lift sentiments, we have factored most of the benefit in our estimates. We rate the stock Neutral with a TP of Rs2,500 at 20x Sept-19 EPS.

**Fig 21 DRRD's 1-year forward PER chart**



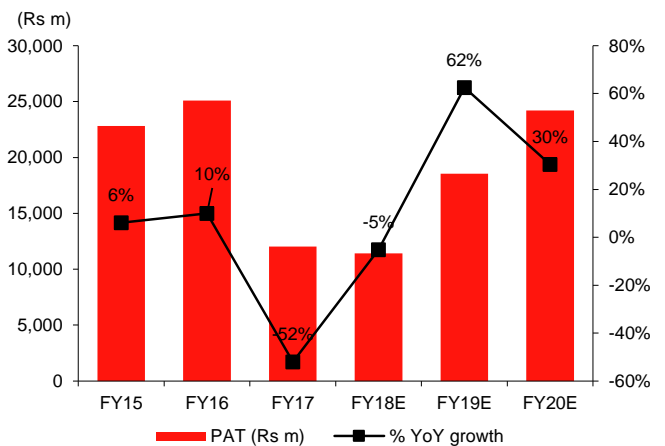
Source: Bloomberg, Macquarie Research, October 2017

**Fig 22 Total annual sales**



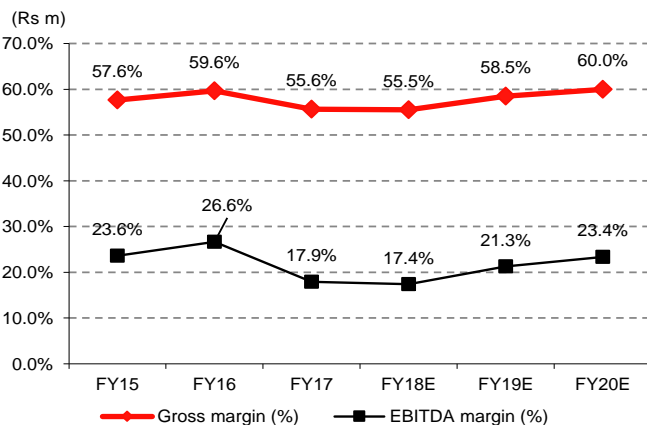
Source: Company data, Macquarie Research, October 2017

**Fig 23 Annual PAT trend**



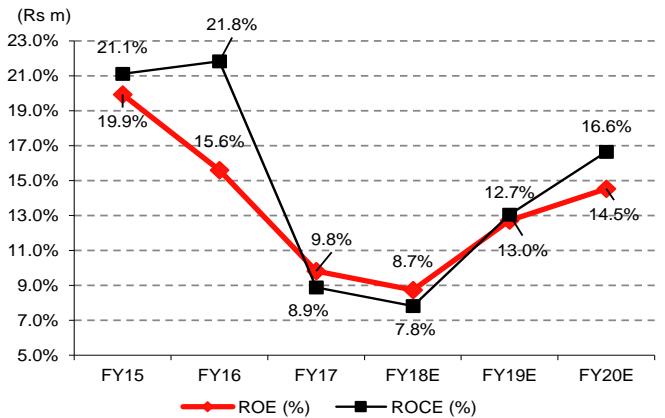
Source: Company data, Macquarie Research, October 2017

**Fig 24 Gross and EBITDA margin trend**



Source: Company data, Macquarie Research, October 2017

**Fig 25 Return ratios trend**



Source: Company data, Macquarie Research, October 2017



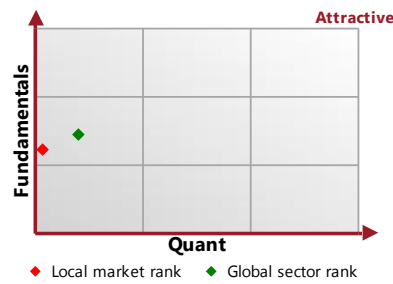
## Macquarie Quant View

The quant model currently holds a strong negative view on Dr. Reddy's Laboratories. The strongest style exposure is Growth, indicating this stock has good historic and/or forecast growth. Growth metrics focus on both top and bottom line items. The weakest style exposure is Price Momentum, indicating this stock has had weak medium to long term returns which often persist into the future.

**754/868**

Global rank in  
Pharma, Biotech & Life Sciences

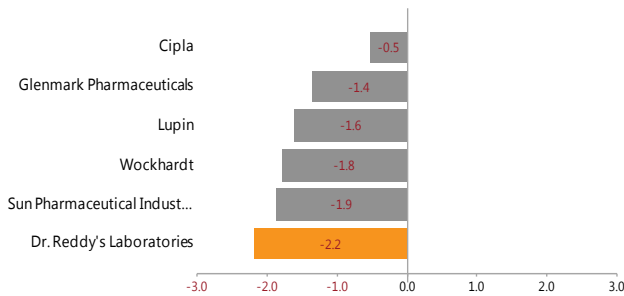
**% of BUY recommendations** 21% (8/38)  
**Number of Price Target downgrades** 4  
**Number of Price Target upgrades** 6



Displays where the company's ranked based on the fundamental consensus Price Target and Macquarie's Quantitative Alpha model.  
Two rankings: Local market (India) and Global sector (Pharma, Biotech & Life Sciences)

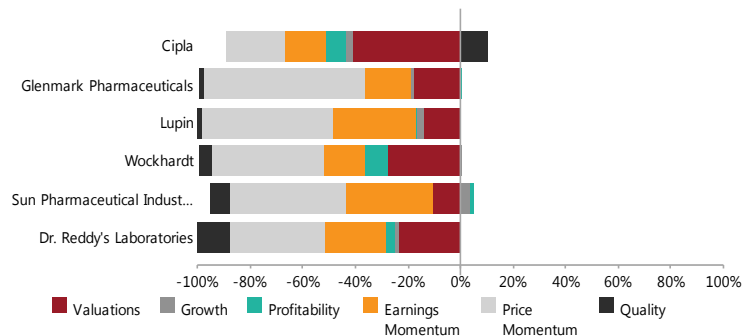
## Macquarie Alpha Model ranking

A list of comparable companies and their Macquarie Alpha model score (higher is better).



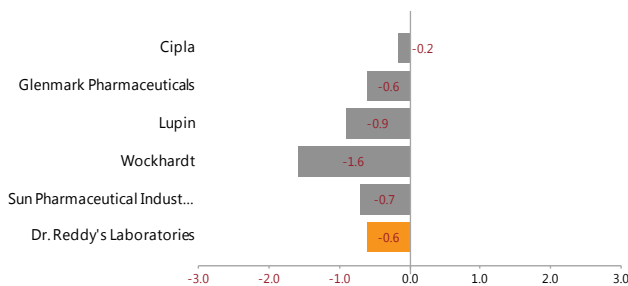
## Factors driving the Alpha Model

For the comparable firms this chart shows the key underlying styles and their contribution to the current overall Alpha score.



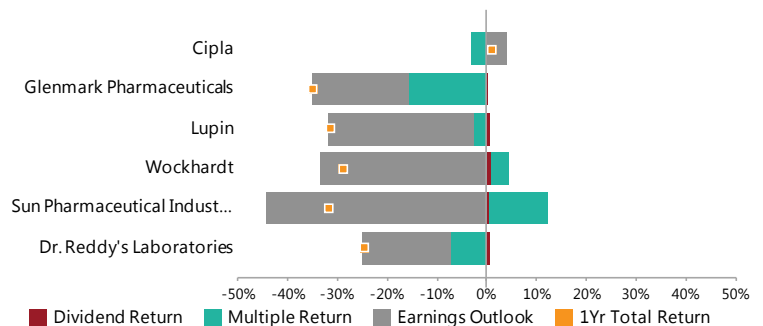
## Macquarie Earnings Sentiment Indicator

The Macquarie Sentiment Indicator is an enhanced earnings revisions signal that favours analysts who have more timely and higher conviction revisions. Current score shown below.



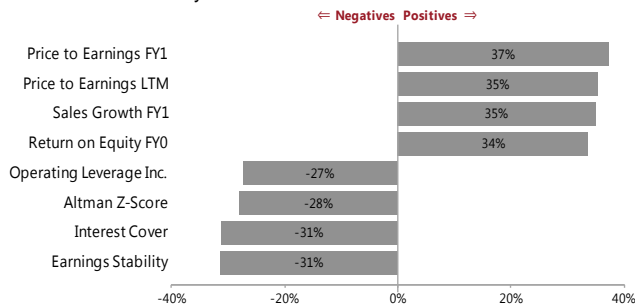
## Drivers of Stock Return

Breakdown of 1 year total return (local currency) into returns from dividends, changes in forward earnings estimates and the resulting change in earnings multiple.



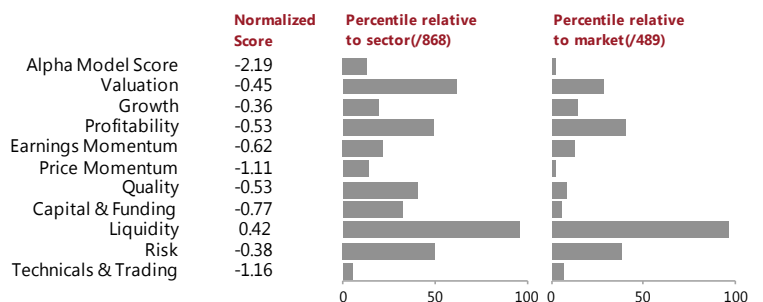
## What drove this Company in the last 5 years

Which factor score has had the greatest correlation with the company's returns over the last 5 years.



## How it looks on the Alpha model

A more granular view of the underlying style scores that drive the alpha (higher is better) and the percentile rank relative to the sector and market.



Source (all charts): FactSet, Thomson Reuters, and Macquarie Research. For more details on the Macquarie Alpha model or for more customised analysis and screens, please contact the Macquarie Global Quantitative/Custom Products Group ([cpq@macquarie.com](mailto:cpq@macquarie.com))

## Dr. Reddy's Laboratories (DRRD IN)

Quarterly Results					Profit & Loss						
	1Q/18A	2Q/18E	3Q/18E	4Q/18E		2017A	2018E	2019E	2020E		
<b>Revenue</b>	m	36,971	36,971	36,971	36,971	<b>Revenue</b>	m	140,809	147,884	168,029	186,731
<b>Gross Profit</b>	m	21,177	17,228	20,519	23,151	<b>Gross Profit</b>	m	78,356	82,076	98,297	123,990
Cost of Goods Sold	m	15,794	19,742	16,452	13,820	Cost of Goods Sold	m	62,453	65,808	69,732	62,742
<b>EBITDA</b>	m	8,666	3,717	6,189	7,049	<b>EBITDA</b>	m	25,220	25,621	35,433	45,908
Depreciation	m	2,025	2,025	2,025	2,025	Depreciation	m	7,931	8,100	8,200	8,350
Amortisation of Goodwill	m	0	0	0	0	Amortisation of Goodwill	m	0	0	0	0
Other Amortisation	m	950	950	950	950	Other Amortisation	m	3,791	3,800	4,000	4,200
<b>EBIT</b>	m	5,691	742	3,214	4,074	<b>EBIT</b>	m	13,498	13,721	23,233	33,358
Net Interest Income	m	200	200	200	200	Net Interest Income	m	806	800	800	800
Associates	m	75	75	75	75	Associates	m	349	300	350	400
Exceptionals	m	0	0	0	0	Exceptionals	m	0	0	0	0
Forex Gains / Losses	m	0	0	0	0	Forex Gains / Losses	m	0	0	0	0
Other Pre-Tax Income	m	0	0	0	0	Other Pre-Tax Income	m	0	0	0	0
<b>Pre-Tax Profit</b>	m	5,966	1,017	3,489	4,349	<b>Pre-Tax Profit</b>	m	14,653	14,821	24,383	34,558
Tax Expense	m	-852	-852	-852	-852	Tax Expense	m	-2,614	-3,409	-5,842	-7,623
<b>Net Profit</b>	m	5,114	165	2,637	3,496	<b>Net Profit</b>	m	12,039	11,412	18,541	26,935
Minority Interests	m	0	0	0	0	Minority Interests	m	0	0	0	0
<b>Reported Earnings</b>	m	5,114	165	2,637	3,496	<b>Reported Earnings</b>	m	12,039	11,412	18,541	26,935
<b>Adjusted Earnings</b>	m	5,114	165	2,637	3,496	<b>Adjusted Earnings</b>	m	12,039	11,412	18,541	26,935
EPS (rep)		29.92	0.96	15.43	20.45	EPS (rep)		70.43	66.77	108.47	157.58
EPS (adj)		29.92	0.96	15.43	20.45	EPS (adj)		70.43	66.77	108.47	157.58
EPS Growth yoy (adj)	%	-0.7	-58.9	-6.3	-4.9	EPS Growth (adj)	%	-52.0	-5.2	62.5	45.3
						PE (rep)	x	33.9	35.7	22.0	15.1
						PE (adj)	x	33.9	35.7	22.0	15.1
EBITDA Margin	%	23.4	10.1	16.7	19.1	Total DPS		20.00	20.00	20.00	20.00
EBIT Margin	%	15.4	2.0	8.7	11.0	Total Div Yield	%	0.8	0.8	0.8	0.8
Earnings Split	%	44.8	1.4	23.1	30.6	Basic Shares Outstanding	m	171	171	171	171
Revenue Growth	%	5.0	5.0	5.0	5.0	Diluted Shares Outstanding	m	171	171	171	171
EBIT Growth	%	3.2	-3.1	1.1	0.8						
Profit and Loss Ratios					Cashflow Analysis						
	2017A	2018E	2019E	2020E		2017A	2018E	2019E	2020E		
Revenue Growth	%	-9.0	5.0	13.6	11.1	<b>EBITDA</b>	m	25,220	25,721	35,733	43,616
EBITDA Growth	%	-38.8	1.6	38.3	29.6	Tax Paid	m	-5,770	-3,409	-5,842	-7,623
EBIT Growth	%	-56.0	1.7	69.3	43.6	Chgs in Working Cap	m	-5,250	2,375	-5,036	-4,676
Gross Profit Margin	%	55.6	55.5	58.5	66.4	Net Interest Paid	m	923	0	0	0
EBITDA Margin	%	17.9	17.3	21.1	24.6	Other	m	806	800	800	800
EBIT Margin	%	9.6	9.3	13.8	17.9	<b>Operating Cashflow</b>	m	15,929	25,487	25,655	32,117
Net Profit Margin	%	8.5	7.7	11.0	14.4	Acquisitions	m	0	0	0	0
Payout Ratio	%	28.4	30.0	18.4	12.7	Capex	m	-40,931	-10,352	-11,762	-13,071
EV/EBITDA	x	17.0	16.7	12.1	9.4	Asset Sales	m	0	0	0	0
EV/EBIT	x	31.3	31.0	18.4	12.9	Other	m	59,335	0	0	0
<b>Balance Sheet Ratios</b>					<b>Investing Cashflow</b>	m	18,404	-10,352	-11,762	-13,071	
ROE	%	9.6	9.0	13.4	17.2	Dividend (Ordinary)	m	-3,390	-3,406	-3,406	-3,406
ROA	%	6.4	6.4	10.8	14.7	Equity Raised	m	-15,694	0	0	0
ROIC	%	9.1	6.9	11.8	16.9	Debt Movements	m	16,314	0	0	0
Net Debt/Equity	%	25.0	14.5	5.8	-4.3	Other	m	-922	0	0	0
Interest Cover	x	nmf	nmf	nmf	nmf	<b>Financing Cashflow</b>	m	-3,692	-3,406	-3,406	-3,406
Price/Book	x	3.3	3.1	2.8	2.4	<b>Net Chg in Cash/Debt</b>	m	31,133	11,729	10,487	15,639
Book Value per Share		717.4	764.2	852.7	974.3	<b>Free Cashflow</b>	m	-25,002	15,136	13,893	19,046
					Balance Sheet						
	2017A	2018E	2019E	2020E		2017A	2018E	2019E	2020E		
Cash	m	18,400	22,054	16,541	22,180	Cash	m	18,400	22,054	16,541	22,180
Receivables	m	37,986	35,603	44,150	49,243	Receivables	m	37,986	35,603	44,150	49,243
Inventories	m	28,528	26,739	27,339	30,493	Inventories	m	28,528	26,739	27,339	30,493
Investments	m	0	0	0	0	Investments	m	0	0	0	0
Fixed Assets	m	57,979	56,331	55,593	55,664	Fixed Assets	m	57,979	56,331	55,593	55,664
Intangibles	m	46,176	46,176	46,176	46,176	Intangibles	m	46,176	46,176	46,176	46,176
Other Assets	m	25,994	25,546	28,455	30,439	Other Assets	m	25,994	25,546	28,455	30,439
<b>Total Assets</b>	m	215,063	212,449	218,253	234,196	<b>Total Assets</b>	m	215,063	212,449	218,253	234,196
Payables	m	10,569	9,906	13,147	14,664	Payables	m	10,569	9,906	13,147	14,664
Short Term Debt	m	43,626	35,000	20,000	10,000	Short Term Debt	m	43,626	35,000	20,000	10,000
Long Term Debt	m	5,449	6,000	5,000	5,000	Long Term Debt	m	5,449	6,000	5,000	5,000
Provisions	m	0	0	0	0	Provisions	m	0	0	0	0
Other Liabilities	m	32,798	30,916	34,344	37,984	Other Liabilities	m	32,798	30,916	34,344	37,984
<b>Total Liabilities</b>	m	92,442	81,822	72,491	67,648	<b>Total Liabilities</b>	m	92,442	81,822	72,491	67,648
Shareholders' Funds	m	122,621	130,627	145,762	166,548	Shareholders' Funds	m	122,621	130,627	145,762	166,548
Minority Interests	m	0	0	0	0	Minority Interests	m	0	0	0	0
Other	m	0	0	0	0	Other	m	0	0	0	0
<b>Total S/H Equity</b>	m	122,621	130,627	145,762	166,548	<b>Total S/H Equity</b>	m	122,621	130,627	145,762	166,548
<b>Total Liab &amp; S/H Funds</b>	m	215,063	212,449	218,253	234,196	<b>Total Liab &amp; S/H Funds</b>	m	215,063	212,449	218,253	234,196

All figures in INR unless noted.

Source: Company data, Macquarie Research, October 2017

## INDIA

CIPLA IN Neutral

Price (at 03:24, 18 Oct 2017 GMT) Rs611.00

<b>Valuation</b>	<b>Rs</b>	<b>632.00</b>
- PER		
<b>12-month target</b>	<b>Rs</b>	<b>632.00</b>
<b>Upside/Downside</b>	<b>%</b>	<b>+3.4</b>
<b>12-month TSR</b>	<b>%</b>	<b>+3.8</b>
<b>Volatility Index</b>		<b>Low</b>

## GICS sector

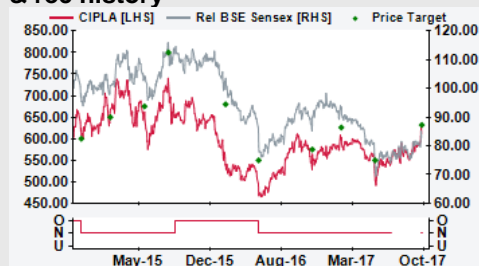
Pharmaceuticals, Biotechnology &amp; Life Sciences

<b>Market cap</b>	<b>Rsm</b>	<b>491,672</b>
<b>Market cap</b>	<b>US\$m</b>	<b>7,547</b>
<b>Free float</b>	<b>%</b>	<b>63</b>
<b>30-day avg turnover</b>	<b>US\$m</b>	<b>12.7</b>
<b>Number shares on issue</b>	<b>m</b>	<b>804.7</b>

## Investment fundamentals

Year end 31 Mar		2017A	2018E	2019E	2020E
Revenue	bn	146.3	156.2	176.9	197.4
EBIT	bn	11.5	19.6	25.6	30.5
EBIT growth	%	-33.2	69.7	31.1	19.2
Recurring profit	bn	12.2	20.7	27.1	32.0
Reported profit	bn	10.1	16.3	21.4	24.9
Adjusted profit	bn	10.1	16.3	21.4	24.9
EPS rep	Rs	12.49	20.26	26.53	30.95
EPS rep growth	%	-26.0	62.2	31.0	16.7
EPS adj	Rs	12.49	20.26	26.53	30.95
EPS adj growth	%	-26.0	62.2	31.0	16.7
PER rep	x	48.9	30.2	23.0	19.7
PER adj	x	48.9	30.2	23.0	19.7
Total DPS	Rs	2.00	2.00	2.00	2.00
Total div yield	%	0.3	0.3	0.3	0.3
ROA	%	5.5	9.3	11.6	12.7
ROE	%	8.3	12.3	14.3	14.5
EV/EBITDA	x	20.8	17.9	14.4	12.7
Net debt/equity	%	20.6	9.2	-1.2	-11.0
P/BV	x	3.9	3.5	3.1	2.7

## CIPLA IN rel BSE Sensex performance, &amp; rec history



Note: Recommendation timeline - if not a continuous line, then there was no Macquarie coverage at the time or there was an embargo period.

Source: FactSet, Macquarie Research, October 2017  
(all figures in INR unless noted)

## Analyst(s)

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23 October 2017

Macquarie Capital Securities India (Pvt) Ltd

## Cipla

## Improving US momentum factored in

## Conclusion

- We expect Cipla's relatively smaller US base (USD392m in FY17) to deliver decent 12% revenue CAGR over FY17-20E. Cipla's key strengths remain its strong branded franchises in India and South Africa. Realizing that it has under-invested in innovation vs peers, Cipla is now focusing on providing greater impetus to Specialty and Respiratory. Even as R&D spends remain elevated at 8-9% of sales, Cipla has guided for EBITDA margin expansion in FY18 (16.9% in FY17). With 39% revenues from India and improving US growth, Cipla would be an attractive play, were valuations not so rich—PE of 23x on FY19E vis-à-vis an earnings CAGR of ~16% over FY16-20E. While we are positive on the long-term potential of Cipla (driven by US and resultant operating leverage), we expect the stock to remain closer to current levels given the limited valuation buffer at ~23x FY19E PER. We initiate coverage with a Neutral rating and a TP of Rs632, based on 22x Sep-2019E EPS.

## Impact

- **Guiding to improved US sales growth:** Cipla has lined up one limited competition launch almost every quarter starting early 3QFY18. The company is targeting at least 10-11 launches and 20-25 filings in the US in FY18, with higher focus on Specialty. Within Specialty, the company is focusing on Respiratory and CNS. Limited competition products filed in FY17 include Albuterol MDI, Nanopaclitaxel, Fenofibrate Capsules and Esomeprazole DR. While we note that lack of major pricing pressure is a positive, further delay in launch of key limited competition products could be a setback.
- **India business remains strong:** Cipla has a robust domestic business with 39% of its FY17 sales coming from India. While Cipla has a strong acute portfolio, which leads to seasonality, it is gradually building its chronic range.
- **Weakness in EMs and API persists:** EM business has been impacted due to forex fluctuation, rationalisation and tender-phasing. Partner-specific issues and increasing competition have been affecting the API segment. Ex-India and US, we expect South Africa (12% of FY17 sales) to do well.
- **Europe recovery on the right track:** Savings in employee costs are on track courtesy the business model change in Europe from direct-to-market to B2B in FY16. This move came after the front-end strategy had been pursued in Europe since CY12. Cipla is also now focusing on higher margin products, with a much leaner structure. After the transformation in Europe (4% of FY17 sales), the company is back to profitability in the market.

## Earnings and target price revision

- We rate the stock Neutral with TP of Rs632.

## Price catalyst

- 12-month price target: Rs632.00 based on a PER methodology.
- Catalyst: 1) Niche US approvals 2) Sustained margin improvement.

## Action and recommendation

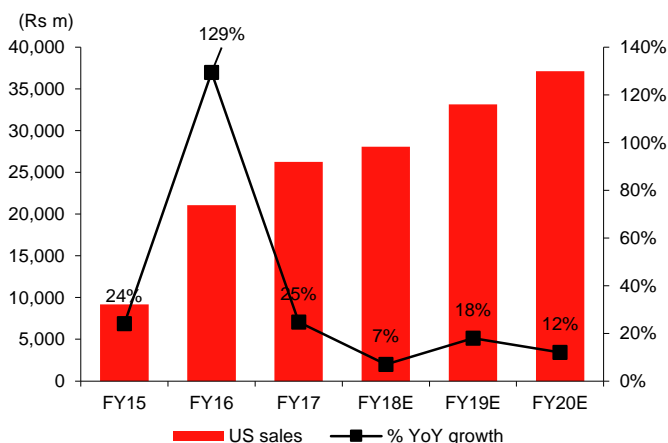
- Cipla trades at ~23x FY19E EPS despite low-teens ROIC. We believe any meaningful upside from Inhalers for US given regulatory complexity is still 2-3 years away. Rate Neutral.

## US business poised to grow on a smaller base

Amongst the large caps, Cipla has the least exposure to the US with just US\$392m revenues in FY17, much lower than US\$1bn+ for other large-cap Indian pharma companies such as Sun Pharma, Lupin, DRRD and Aurobindo Pharma. Cipla’s US business is witnessing improved momentum with the company filing 32 products, its highest number in a single year, in FY17, exceeding its guidance of 20-25. These included Albuterol (first MDI filing, no pending patents), Nanopaclitaxel, Fenofibrate Capsules and Esomeprazole DR. During FY17, Cipla launched few limited competition products such as Bupropion XL, Feno and Fenofibrate Tablets Trichol. Cipla is targeting at least 10-11 launches and 20-25 filings in the US in FY18, with focus on the Specialty portfolio. Cipla has lined up one significant limited competition launch almost every quarter starting in early 3QFY18. As per Cipla, each of the new launches in the US will be significantly higher than the current average product revenue size of US\$6-7m (though less than US\$30m).

We believe Renvela, Nanopaclitaxel, Albuterol, Cialis, Reyataz, Latuda and Fosrenol are interesting opportunities for Cipla over 2HFY18/FY19. The company has also planned few low-competition launches in 2HFY18/FY19, especially in its HIV portfolio (Viread and Atripla). Prezista is another key molecule within its HIV portfolio, with launch expected in FY21. Dymista (azelastine hydrochloride and fluticasone propionate) nasal spray used for the treatment of seasonal allergic rhinitis (pediatric exclusivity till August 2018) is an additional important product for Cipla. In our view, Dymista can add ~US\$25-30m to Cipla’s top line.

**Fig 1 Cipla’s annual US sales**



Source: Company data, Macquarie Research, October 2017

**Fig 2 Key Para IV launches in FY18/FY19**

Brand	Generic name	Launch details
Tamiflu	Oseltamivir Phosphate	Through InvaGen
Renvela	Sevelamer Carbonate	Through InvaGen
Renagel	Sevelamer HCl	Through InvaGen
Fosrenol	Lanthanum Carbonate	Through InvaGen
Viread	Tenofovir disoproxil fumarate	Partnership with Teva

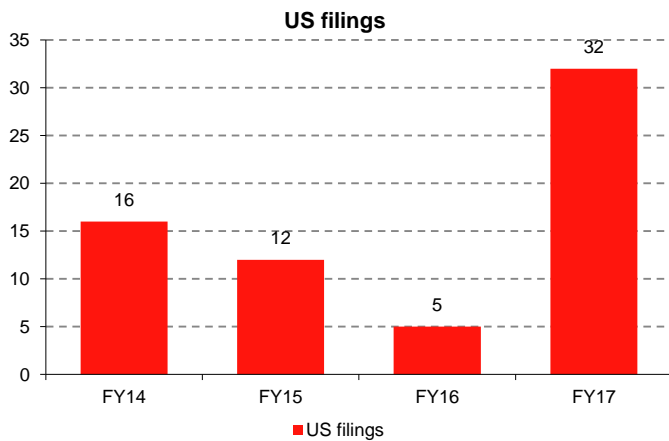
Source: Company data, Macquarie Research, October 2017

While we note that lack of major pricing pressure is a positive, further delay in launch of key limited competition products could be a setback. For example, delay in Sevelamer approval has been a setback for the company. Within Specialty, the company is focusing on Respiratory and CNS. Within the inhaler space, European regulations do not require extensive Pharmacokinetic (PK) study whereas in the US, the FDA requires an extensive PK study. This could potentially lead to few limited competition opportunities in the respiratory space in the US for Cipla. Most inhaler patents in the US expire between CY19-CY23. During FY17, Cipla received EIRs for its Indore, Goa and InvaGen facilities. Since the observations are not critical in nature, we do not anticipate any delay in approvals from these facilities.

### Acquiring scale in the US

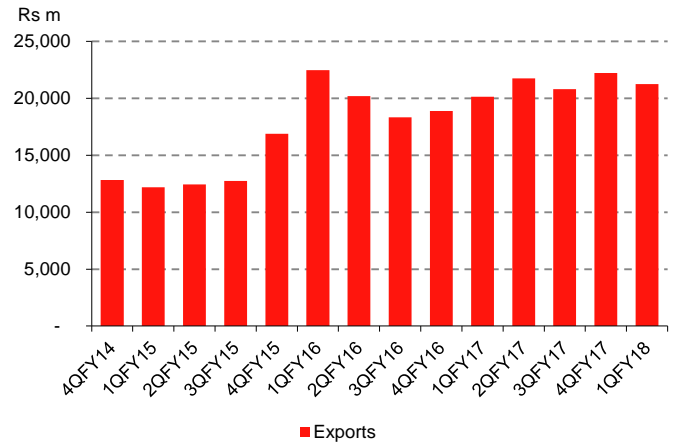
In FY16, Cipla acquired two companies, InvaGen and Exelan, for US\$550m, to meaningfully boost its US portfolio. The company has successfully integrated all the major operational aspects of InvaGen with Cipla Global. There was full contribution from InvaGen in Cipla’s FY17 US sales of US\$392m in FY17 (21% YoY growth over US\$324m in FY16). InvaGen has ~50 products, with many products in the US\$4-5m revenue range. We note that Cipla has already taken a one-time net of tax impairment charge of US\$32m (6% of acquisition value) on its InvaGen acquisition. The InvaGen acquisition became EBITDA accretive from 1QFY17. In FY17, Cipla also acquired three products from Teva’s US portfolio, gaining from the regulatory necessity to divest post the Teva-Allergan deal.

**Fig 3 Cipla's US filings**



Source: Company data, Macquarie Research, October 2017

**Fig 4 Cipla's quarterly export sales**

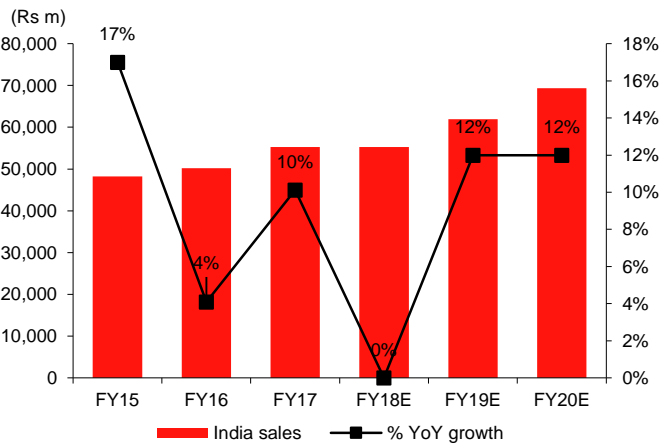


Source: Company data, Macquarie Research, October 2017

**India business remains strong**

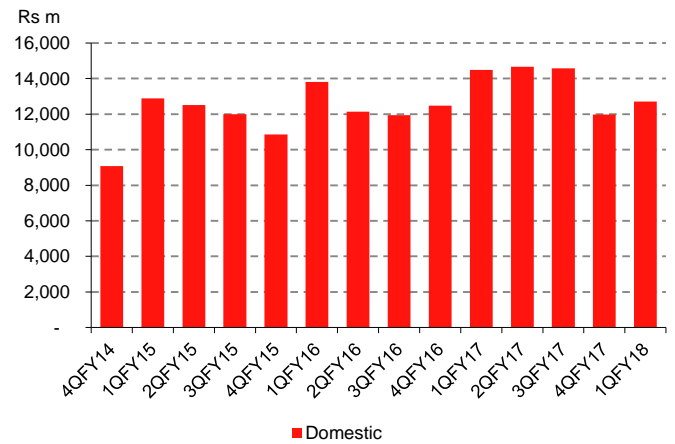
Cipla has a strong domestic business with ~39% of its total sales coming from India. In India, Cipla has a strong sales force of ~7,500. While Cipla has a robust acute portfolio, which leads to seasonality, it is gradually building its chronic range as well. As per Cipla, the net margin of its trade generic business in India is not significantly lower than the branded generics business. Cipla entered into an important in-licensing agreement and recently launched three products in India, Azmarda, Histamine and Bolstran, which are under patent cover. Post a slowdown in FY18 due to the GST destocking impact (~12% YoY decline of Cipla's domestic sales in 1QFY18), we expect growth to bounce back to 12% YoY each in FY19 and FY20.

**Fig 5 Annual domestic sales**



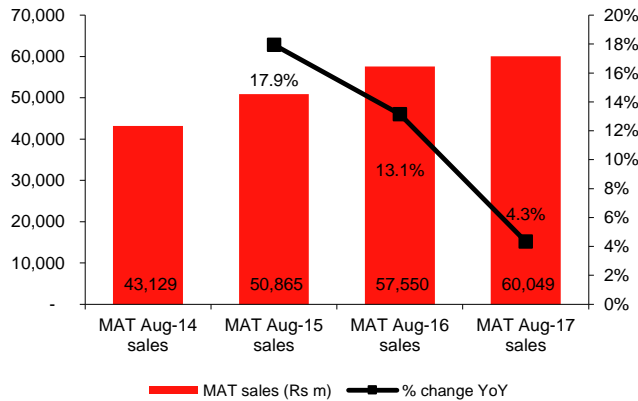
Source: Company data, Macquarie Research, October 2017

**Fig 6 Quarterly domestic sales**



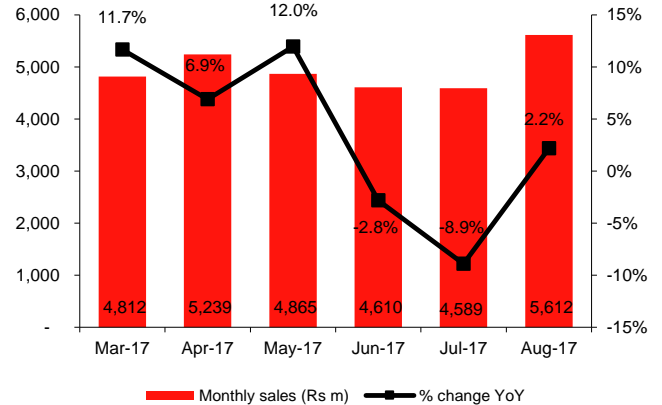
Source: Company data, Macquarie Research, October 2017

**Fig 7 Cipla domestic MAT sales (August 2017)**



Source: IMS data, Macquarie Research, October 2017

**Fig 8 Cipla domestic monthly sales (August 2017)**



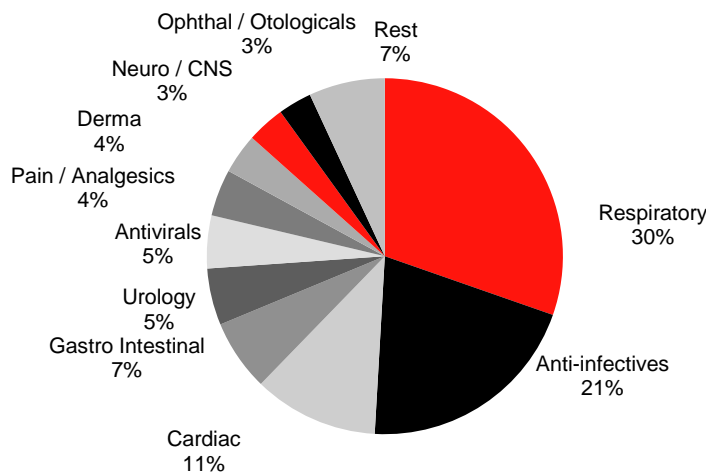
Source: IMS data, Macquarie Research, October 2017

**Fig 9 Key therapeutic drivers – Respiratory and Cardiac driving growth**

(Rs m)	MAT sales				MAT sales growth (YoY)		
	MAT Aug-14 sales	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	Aug-15	Aug-16	Aug-17
Respiratory	13,271	15,060	16,915	18,225	13.5%	12.3%	7.7%
Anti-infectives	9,840	11,403	13,246	12,344	15.9%	16.2%	-6.8%
Cardiac	5,138	6,111	6,377	6,818	19.0%	4.3%	6.9%
Gastro Intestinal	2,663	3,206	3,865	3,890	20.4%	20.5%	0.7%
Urology	1,844	2,270	2,661	3,095	23.1%	17.2%	16.3%
Antivirals	1,581	2,095	2,406	2,885	32.5%	14.8%	19.9%
Pain / Analgesics	1,506	1,866	2,331	2,550	23.9%	24.9%	9.4%
Derma	1,481	1,809	2,032	2,190	22.1%	12.3%	7.8%
Neuro / CNS	1,276	1,617	1,823	2,070	26.8%	12.7%	13.6%
Ophthal / Otologicals	1,318	1,622	1,740	1,828	23.0%	7.3%	5.0%

Source: IMS data, Macquarie Research, October 2017

**Fig 10 Cipla's domestic therapeutic split – Cardiac, Neuro, Anti-infectives and GI key focus areas**



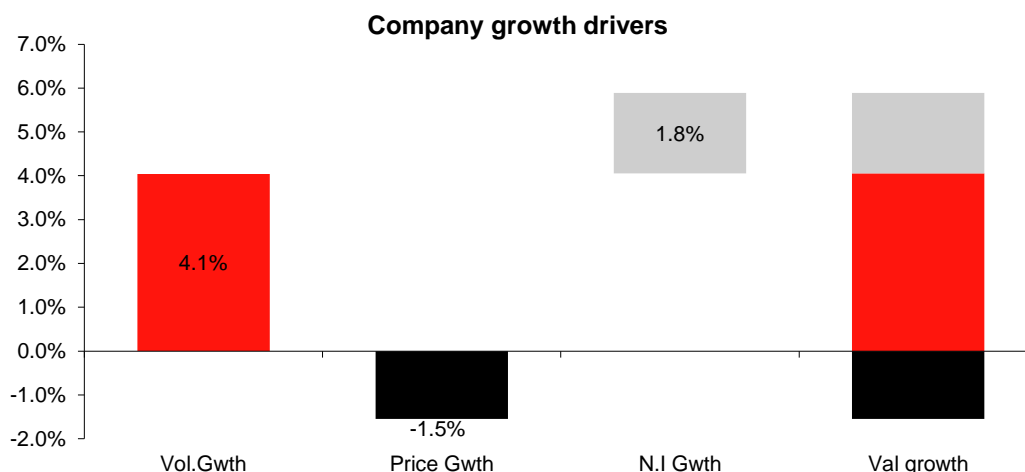
Source: IMS data, Macquarie Research, October 2017

Fig 11 Cipla's top 25 brands contribute ~42% of domestic sales and grew 3.9% YoY (MAT Aug-2017)

	MAT sales				MAT sales growth (YoY)		
	MAT Aug-14 sales	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	Aug-15	Aug-16	Aug-17
FORACORT	1,654	2,053	2,373	2,612	24.1%	15.6%	10.1%
SEROFLO	1,443	1,647	1,724	1,847	14.1%	4.7%	7.1%
DUOLIN	1,028	1,235	1,464	1,699	20.1%	18.6%	16.1%
ASTHALIN	1,569	1,410	1,532	1,660	-10.1%	8.6%	8.4%
BUDECORT	1,252	1,689	1,920	1,549	34.9%	13.7%	-19.4%
AEROCORT	1,081	1,119	1,155	1,169	3.5%	3.2%	1.2%
MONTAIR-LC	630	758	925	1,105	20.3%	22.1%	19.5%
AZEE	737	888	1,110	1,004	20.4%	25.0%	-9.5%
MEROCRIT	484	632	714	988	30.6%	13.1%	38.3%
DYTOR	573	788	850	973	37.6%	7.8%	14.4%
URIMAX-D	520	647	781	944	24.4%	20.7%	20.8%
XYLISTIN	696	840	922	917	20.6%	9.8%	-0.6%
URIMAX	495	640	743	821	29.3%	16.1%	10.6%
IBUGESIC PLUS	456	571	688	808	25.1%	20.6%	17.5%
EMESET	582	719	882	782	23.5%	22.8%	-11.4%
NOVAMOX	883	830	870	777	-6.0%	4.8%	-10.7%
ADVENT	608	633	798	769	4.1%	26.0%	-3.6%
ACIVIR	471	553	647	714	17.5%	17.0%	10.4%
CIPLOX	822	715	732	702	-13.1%	2.5%	-4.1%
METOLAR	546	671	637	659	23.1%	-5.2%	3.5%
AMLOPRES-AT	515	548	598	629	6.3%	9.1%	5.2%
TAZACT	506	806	1,059	613	59.3%	31.3%	-42.1%
OMNIKACIN	245	351	440	591	43.4%	25.4%	34.3%
NICOTEX	295	446	465	576	51.0%	4.4%	23.6%
LEVOLIN	330	371	442	510	12.5%	19.0%	15.4%
Top 25 products as % of total sales	42.7%	42.4%	42.5%	42.3%			

Source: IMS data, Macquarie Research, October 2017; MAT = Moving Annual Turnover.

Fig 12 Domestic business – Largely volume-led growth for Cipla

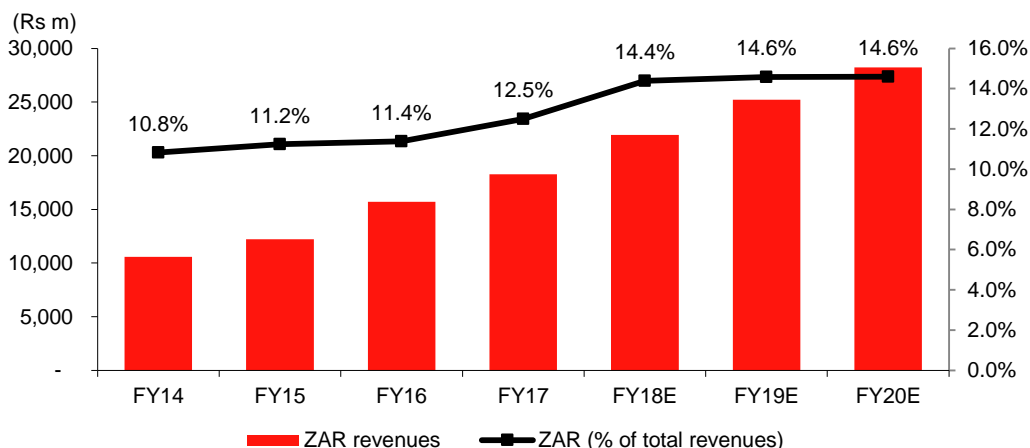


Source: IMS data, Macquarie Research, October 2017

### Apart from India and US, South Africa to be an important growth driver

Cipla is the fourth-largest pharma company in South Africa. Including the tender business, Cipla is the third-largest pharma company in South Africa. The tender business, constituting ~30-35% of Cipla's revenues in South Africa, is a high-margin business for the company. The exclusive agreement with Serum Institute aids Cipla to launch low-cost vaccines under its exclusive agreement. In FY17, Cipla launched its first innovator Breath Actuated Inhaler Device SynchroBreathe in South Africa and it has done remarkably well. Cipla has a partnership with the South African Government to set up the country's first biotech manufacturing facility.

**Fig 13 Cipla's South Africa sales**



Source: Company data, Macquarie Research, October 2017

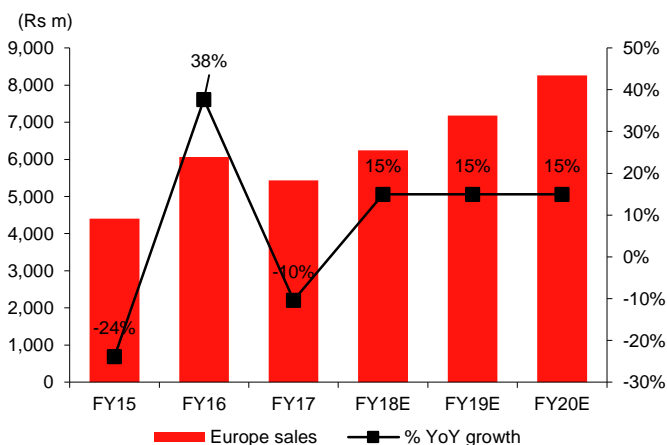
**Weakness in EMs and API persists**

Growth in emerging markets (all markets other than US, India, South Africa and Europe) has been a challenge for Cipla (9% YoY decline in FY17) due to a combination of currency volatility, impact of rationalization and tender-phasing. The company continues its efforts to improve profitability driven by greater share of high margin SKUs and country rationalization. Partner-specific issues and increasing competition have been impacting the API segment.

**Europe turnaround on the right track**

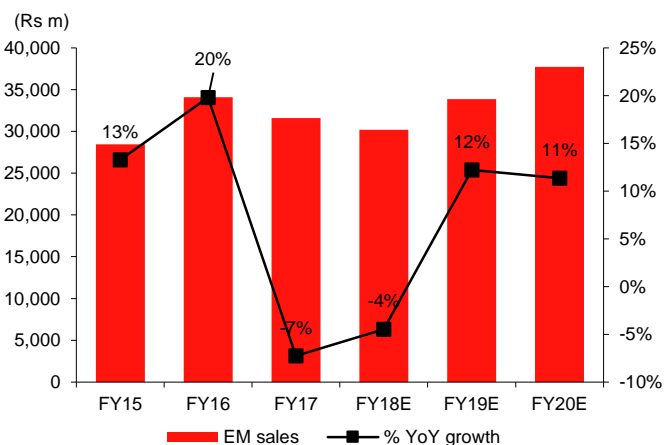
Turnaround in Cipla's Europe business is happening on the back of restructuring exercise and focus on higher margin products. Owing to significant consolidation and improved profitability in Europe, the working capital situation improved significantly in FY17. Savings in employee costs are happening due to business model change in Europe from direct to market to B2B in FY16. This move came after the front-end strategy had been pursued in Europe since CY12. Cipla is also now focusing on higher margin products, with a much leaner structure. After the transformation in Europe, the company is back to profitability in the market. The company has a strong respiratory product base in Europe including Ipratropium MDI, Mometasone, Salmeterol/Fluticasone, Fluticasone, Seroflo and Ipratropium Salbutamol. Seroflo was launched in the UK through its partner, Kent, and the product is reporting a gradual uptick.

**Fig 14 Europe sales**



Source: Company data, Macquarie Research, October 2017

**Fig 15 EM sales**



Source: Company data, Macquarie Research, October 2017



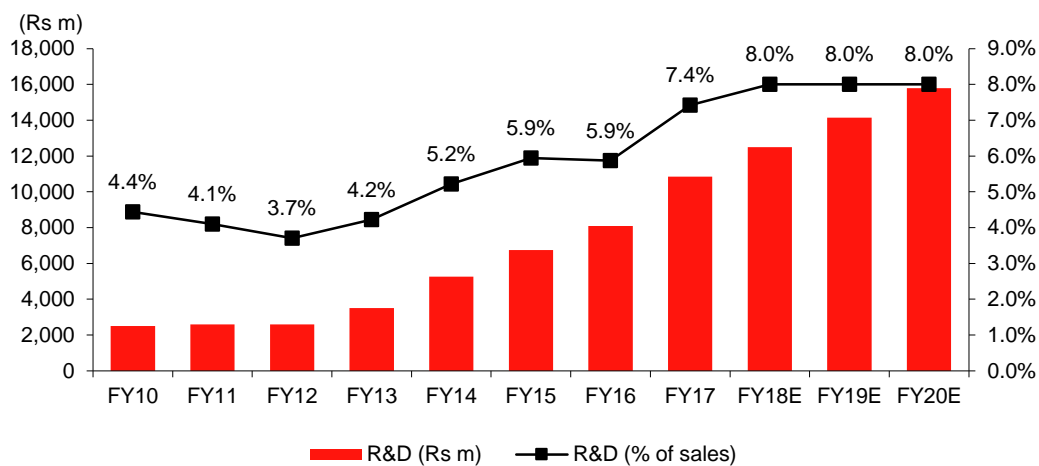
### More focussed approach in the biosimilar business

Cipla Biotech, which had been working on developing biosimilars, is repositioning its business to explore new business development opportunities including in-licensing to derisk its future investment in this segment without solely relying on its in-house development. Cipla will be employing the in-licensing model for Biotech, and the organic development route for Specialty and Respiratory will be given higher priority.

### Guiding to improved margins in FY18 despite higher R&D spends

The management has guided for improved EBITDA margin YoY in FY17 (16.9% in FY17) as US sales ramp up and profitability of Europe improves. The company expects R&D (as percentage of sales) in FY18 to be in the 8-9% range (7.6% in FY17). Cipla is investing towards building a specialty franchise through a mix of in-house development and in-licensing opportunities.

**Fig 16 R&D spend (% of sales) has been continuously increasing for Cipla**

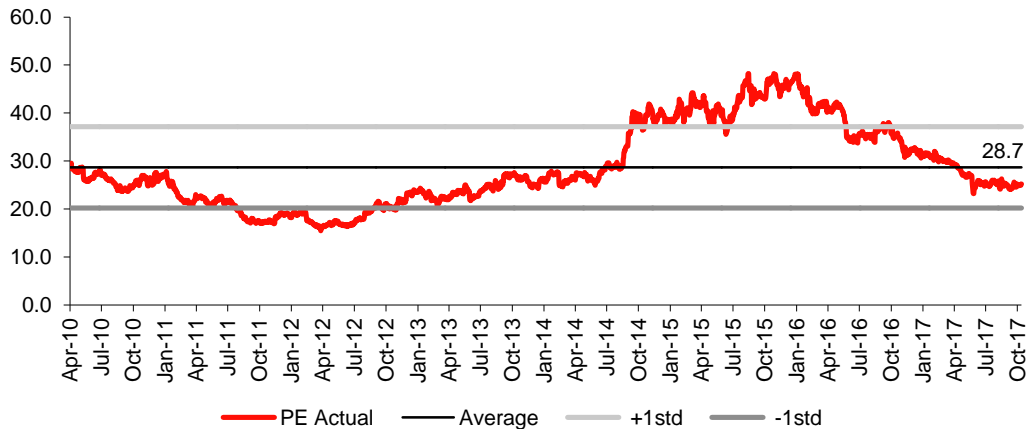


Source: Company data, Macquarie Research, October 2017

### Improving US momentum largely factored in current stock price

With 39% revenues from India and improving US growth, Cipla would be an attractive play, were valuations not so rich—PE of 23x on 2019E vis-à-vis an earnings CAGR of ~16% over FY16-20E. While we are positive on the long-term potential of Cipla (driven by US and resultant operating leverage), we expect the stock to remain closer to current levels given the limited valuation buffer at ~23x FY19E PER. We rate the stock Neutral with a TP of Rs632, based on 22x Sept-19E EPS. We are assigning a higher multiple to Cipla vs peers due to higher contribution from the relatively stable India business and improving US sales growth.

**Fig 17 Cipla's valuations have come off significantly from highs**

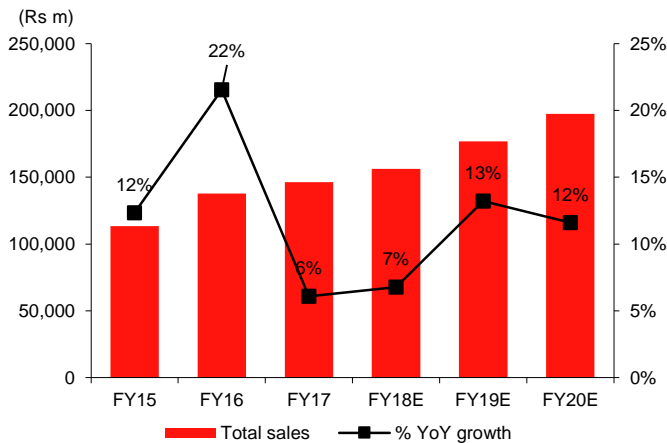


Source: Bloomberg, Macquarie Research, October 2017

**Financial highlights**

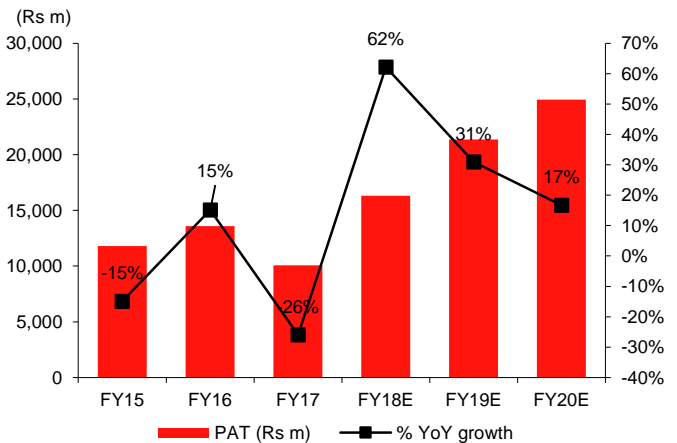
From a capital allocation standpoint, Cipla is investing in complex generics and specialty investments. FY17 capex was at 6% of sales (Rs8.5bn). FY18 annual capex is likely to be in the range of Rs7-9bn. Heavy capital investments over the last 2-3 years are likely to taper down for Cipla starting FY18. Net debt to equity as of end-FY17 stood at 0.21x. As at FY17 end, long-term debt stands at US\$550m, which is the debt used to fund the InvaGen acquisition. In addition, Cipla also has working capital debt of US\$85bn.

**Fig 17 Cipla's annual sales outlook**



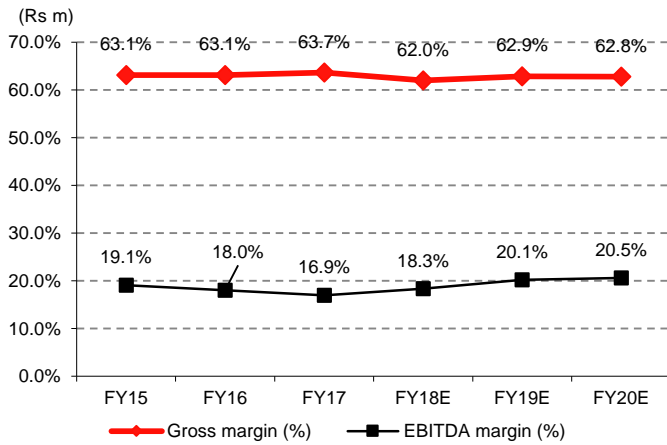
Source: Company data, Macquarie Research, October 2017

**Fig 18 Cipla's annual PAT**



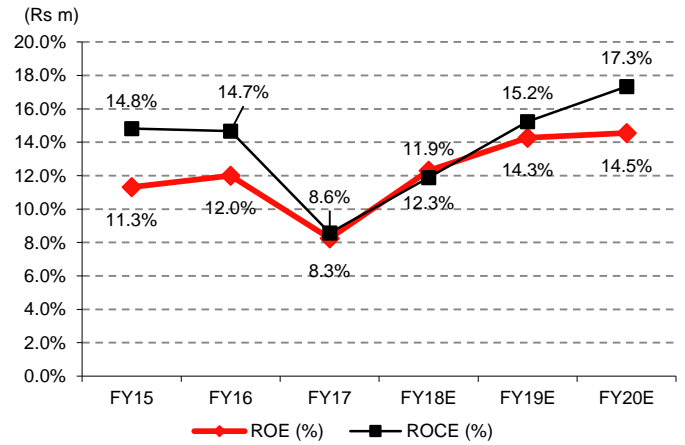
Source: Company data, Macquarie Research, October 2017

**Fig 19 Gross and EBITDA margin outlook**



Source: Company data, Macquarie Research, October 2017

**Fig 20 Return ratio profile**



Source: Company data, Macquarie Research, October 2017

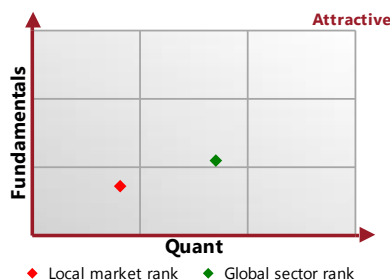
### Macquarie Quant View

The quant model currently holds a reasonably negative view on Cipla. The strongest style exposure is Quality, indicating this stock is likely to have a superior and more stable underlying earnings stream. The weakest style exposure is Profitability, indicating this stock is not efficiently converting investments to earnings; proxied by ratios like ROE or ROA.

**376/868**

Global rank in  
Pharma, Biotech & Life Sciences

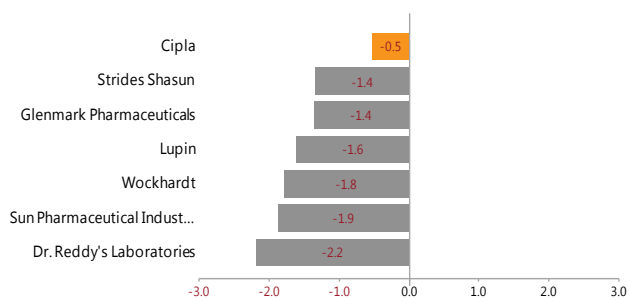
- % of BUY recommendations: 50% (20/40)
- Number of Price Target downgrades: 0
- Number of Price Target upgrades: 4



Displays where the company's ranked based on the fundamental consensus Price Target and Macquarie's Quantitative Alpha model.  
Two rankings: Local market (India) and Global sector (Pharma, Biotech & Life Sciences)

### Macquarie Alpha Model ranking

A list of comparable companies and their Macquarie Alpha model score (higher is better).



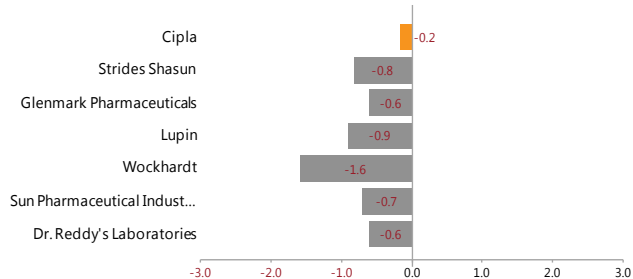
### Factors driving the Alpha Model

For the comparable firms this chart shows the key underlying styles and their contribution to the current overall Alpha score.



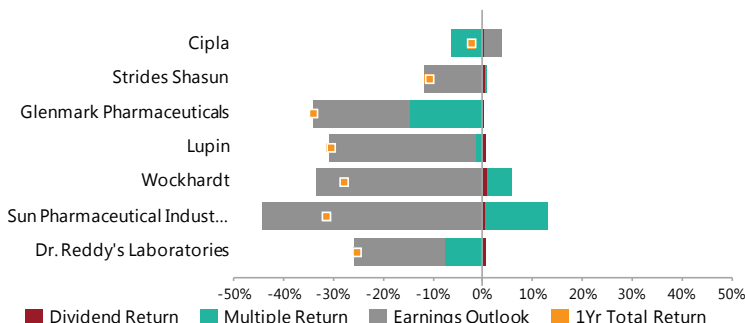
### Macquarie Earnings Sentiment Indicator

The Macquarie Sentiment Indicator is an enhanced earnings revisions signal that favours analysts who have more timely and higher conviction revisions. Current score shown below.



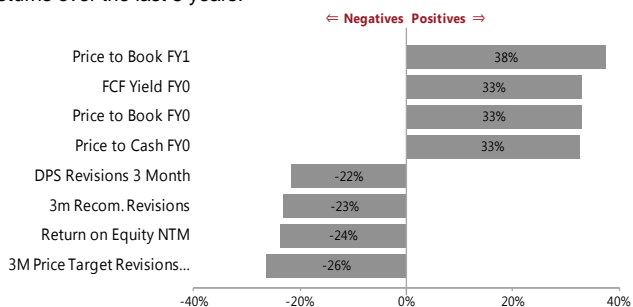
### Drivers of Stock Return

Breakdown of 1 year total return (local currency) into returns from dividends, changes in forward earnings estimates and the resulting change in earnings multiple.



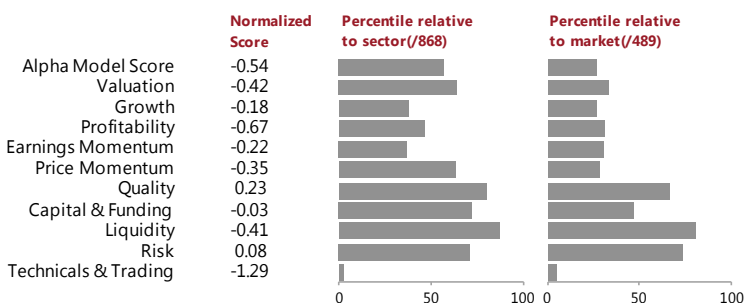
### What drove this Company in the last 5 years

Which factor score has had the greatest correlation with the company's returns over the last 5 years.



### How it looks on the Alpha model

A more granular view of the underlying style scores that drive the alpha (higher is better) and the percentile rank relative to the sector and market.



Source (all charts): FactSet, Thomson Reuters, and Macquarie Research. For more details on the Macquarie Alpha model or for more customised analysis and screens, please contact the Macquarie Global Quantitative/Custom Products Group ([cpg@macquarie.com](mailto:cpg@macquarie.com))

## Cipla (CIPLA IN)

Quarterly Results					Profit & Loss						
	1Q/18A	2Q/18E	3Q/18E	4Q/18E		2017A	2018E	2019E	2020E		
<b>Revenue</b>	m	35,531	40,577	39,695	40,417	<b>Revenue</b>	m	146,302	156,220	176,867	197,378
<b>Gross Profit</b>	m	22,470	25,736	24,854	23,795	<b>Gross Profit</b>	m	93,131	96,854	111,177	123,894
Cost of Goods Sold	m	13,061	14,841	14,841	16,622	Cost of Goods Sold	m	53,171	59,366	65,689	73,484
<b>EBITDA</b>	m	6,204	9,016	8,234	5,206	<b>EBITDA</b>	m	24,758	28,660	35,635	40,548
Depreciation	m	2,184	2,184	2,366	2,366	Depreciation	m	13,229	9,100	10,000	10,000
Amortisation of Goodwill	m	0	0	0	0	Amortisation of Goodwill	m	0	0	0	0
Other Amortisation	m	0	0	0	0	Other Amortisation	m	0	0	0	0
<b>EBIT</b>	m	4,020	6,832	5,868	2,840	<b>EBIT</b>	m	11,529	19,560	25,635	30,548
Net Interest Income	m	-325	-325	-325	-325	Net Interest Income	m	-1,594	-1,300	-1,200	-1,200
Associates	m	0	0	0	0	Associates	m	0	0	0	0
Exceptionals	m	0	0	0	0	Exceptionals	m	0	0	0	0
Forex Gains / Losses	m	0	0	0	0	Forex Gains / Losses	m	0	0	0	0
Other Pre-Tax Income	m	600	600	600	600	Other Pre-Tax Income	m	2,287	2,400	2,620	2,620
<b>Pre-Tax Profit</b>	m	4,295	7,107	6,143	3,115	<b>Pre-Tax Profit</b>	m	12,222	20,660	27,055	31,968
Tax Expense	m	-1,085	-1,085	-1,085	-1,085	Tax Expense	m	-1,798	-4,339	-5,681	-7,033
<b>Net Profit</b>	m	3,210	6,022	5,059	2,030	<b>Net Profit</b>	m	10,424	16,321	21,373	24,935
Minority Interests	m	0	0	0	0	Minority Interests	m	-360	0	0	0
<b>Reported Earnings</b>	m	3,210	6,022	5,059	2,030	<b>Reported Earnings</b>	m	10,064	16,321	21,373	24,935
<b>Adjusted Earnings</b>	m	3,210	6,022	5,059	2,030	<b>Adjusted Earnings</b>	m	10,064	16,321	21,373	24,935
EPS (rep)		3.99	7.48	6.28	2.52	EPS (rep)		12.49	20.26	26.53	30.95
EPS (adj)		3.99	7.48	6.28	2.52	EPS (adj)		12.49	20.26	26.53	30.95
EPS Growth yoy (adj)	%	88.6	35.4	50.4	267.5	EPS Growth (adj)	%	-26.0	62.2	31.0	16.7
						PE (rep)	x	48.9	30.2	23.0	19.7
						PE (adj)	x	48.9	30.2	23.0	19.7
EBITDA Margin	%	17.5	22.2	20.7	12.9	Total DPS		2.00	2.00	2.00	2.00
EBIT Margin	%	11.3	16.8	14.8	7.0	Total Div Yield	%	0.3	0.3	0.3	0.3
Earnings Split	%	19.7	36.9	31.0	12.4	Basic Shares Outstanding	m	806	806	806	806
Revenue Growth	%	6.7	6.8	6.9	6.7	Diluted Shares Outstanding	m	806	806	806	806
EBIT Growth	%	94.3	42.0	57.4	209.1						
Profit and Loss Ratios					Cashflow Analysis						
	2017A	2018E	2019E	2020E		2017A	2018E	2019E	2020E		
Revenue Growth	%	6.1	6.8	13.2	11.6	<b>EBITDA</b>	m	24,758	28,660	35,635	40,548
EBITDA Growth	%	-0.2	15.8	24.3	13.8	Tax Paid	m	-4,503	-4,339	-5,681	-7,033
EBIT Growth	%	-33.2	69.7	31.1	19.2	Chgs in Working Cap	m	2,307	-2,382	-6,194	-6,153
Gross Profit Margin	%	63.7	62.0	62.9	62.8	Net Interest Paid	m	-1,469	-1,300	-1,200	-1,200
EBITDA Margin	%	16.9	18.3	20.1	20.5	Other	m	2,730	0	0	0
EBIT Margin	%	7.9	12.5	14.5	15.5	<b>Operating Cashflow</b>	m	23,824	20,639	22,559	26,162
Net Profit Margin	%	6.9	10.4	12.1	12.6	Acquisitions	m	-1,879	0	0	0
Payout Ratio	%	16.0	9.9	7.5	6.5	Capex	m	-10,982	-8,123	-8,313	-8,487
EV/EBITDA	x	20.8	17.9	14.4	12.7	Asset Sales	m	0	0	0	0
EV/EBIT	x	44.6	26.3	20.1	16.8	Other	m	-265	2,400	2,620	2,620
						<b>Investing Cashflow</b>	m	-13,127	-5,723	-5,693	-5,867
<b>Balance Sheet Ratios</b>					Dividend (Ordinary)	m	-2,269	-1,607	-1,607	-1,607	
ROE	%	8.3	12.3	14.3	14.5	Equity Raised	m	0	0	0	0
ROA	%	5.5	9.3	11.6	12.7	Debt Movements	m	-10,803	0	0	0
ROIC	%	6.2	9.9	12.8	14.7	Other	m	-167	0	0	0
Net Debt/Equity	%	20.6	9.2	-1.2	-11.0	<b>Financing Cashflow</b>	m	-13,239	-1,607	-1,607	-1,607
Interest Cover	x	7.2	15.0	21.4	25.5						
Price/Book	x	3.9	3.5	3.1	2.7	<b>Net Chg in Cash/Debt</b>	m	-2,541	13,309	15,260	18,688
Book Value per Share		155.5	173.7	198.3	227.2	<b>Free Cashflow</b>	m	12,841	12,516	14,246	17,675
						Balance Sheet					
							2017A	2018E	2019E	2020E	
						Cash	m	14,477	16,333	26,593	37,281
						Receivables	m	33,522	31,258	34,260	37,242
						Inventories	m	34,853	42,839	48,501	54,125
						Investments	m	0	0	0	0
						Fixed Assets	m	57,297	56,320	54,633	53,120
						Intangibles	m	54,271	54,271	54,271	54,271
						Other Assets	m	14,422	11,014	12,290	13,558
						<b>Total Assets</b>	m	208,841	212,035	230,546	249,596
						Payables	m	15,711	17,872	20,234	22,581
						Short Term Debt	m	4,672	4,672	4,672	4,672
						Long Term Debt	m	36,454	25,000	20,000	12,000
						Provisions	m	7,569	7,569	7,569	7,569
						Other Liabilities	m	14,799	12,570	13,954	15,329
						<b>Total Liabilities</b>	m	79,205	67,684	66,429	62,150
						Shareholders' Funds	m	125,254	139,969	159,735	183,064
						Minority Interests	m	4,382	4,382	4,382	4,382
						Other	m	0	0	0	0
						<b>Total S/H Equity</b>	m	129,637	144,351	164,117	187,446
						<b>Total Liab &amp; S/H Funds</b>	m	208,841	212,035	230,546	249,596

All figures in INR unless noted.

Source: Company data, Macquarie Research, October 2017

## INDIA

CDH IN Underperform

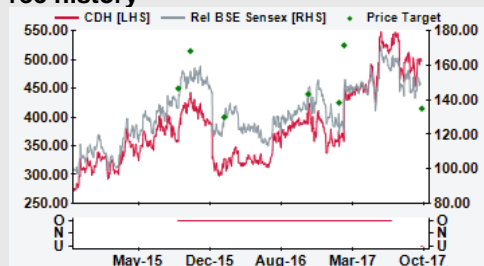
Price (at 13:38, 18 Oct 2017 GMT) Rs491.50

<b>Valuation</b>	<b>Rs</b>	<b>415.00</b>
- PER		
<b>12-month target</b>	<b>Rs</b>	<b>415.00</b>
<b>Upside/Downside</b>	<b>%</b>	<b>-15.6</b>
<b>12-month TSR</b>	<b>%</b>	<b>-14.8</b>
<b>Volatility Index</b>		<b>Medium</b>
<b>GICS sector</b>		
<b>Pharmaceuticals, Biotechnology &amp; Life Sciences</b>		
<b>Market cap</b>	<b>Rsm</b>	<b>503,296</b>
<b>Market cap</b>	<b>US\$m</b>	<b>7,857</b>
<b>Free float</b>	<b>%</b>	<b>25</b>
<b>30-day avg turnover</b>	<b>US\$m</b>	<b>7.7</b>
<b>Number shares on issue</b>	<b>m</b>	<b>1,024</b>

## Investment fundamentals

Year end 31 Mar		2017A	2018E	2019E	2020E
Revenue	bn	94.3	101.6	116.6	127.0
EBIT	bn	15.3	17.8	25.1	28.6
EBIT growth	%	-26.5	16.7	40.9	13.7
Recurring profit	bn	16.5	19.0	26.5	30.1
Reported profit	bn	14.9	15.5	20.9	23.8
Adjusted profit	bn	14.9	15.5	20.9	23.8
EPS rep	Rs	14.53	15.11	20.44	23.21
EPS rep growth	%	-2.3	3.9	35.3	13.6
EPS adj	Rs	14.53	15.11	20.44	23.21
EPS adj growth	%	-2.4	3.9	35.3	13.6
PER rep	x	33.8	32.5	24.0	21.2
PER adj	x	33.8	32.5	24.0	21.2
Total DPS	Rs	3.20	3.14	4.25	4.83
Total div yield	%	0.7	0.6	0.9	1.0
ROA	%	12.1	11.5	15.0	15.2
ROE	%	24.2	20.4	23.2	22.0
EV/EBITDA	x	27.5	22.8	17.3	15.5
Net debt/equity	%	42.6	31.4	17.9	6.2
P/BV	x	7.2	6.1	5.1	4.3

## CDH IN rel BSE Sensex performance, &amp; rec history



Note: Recommendation timeline - if not a continuous line, then there was no Macquarie coverage at the time or there was an embargo period.

Source: FactSet, Macquarie Research, October 2017

(all figures in INR unless noted)

## Analyst(s)

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23 October 2017

Macquarie Capital Securities India (Pvt) Ltd

# Cadila Healthcare

## AG launch to limit Lialda upside

### Conclusion

- We expect US, India and Emerging markets (including Brazil and Mexico) to be the key growth drivers for Cadila (CDH) going forward. However, recent launch of Lialda authorized generic (AG) by Shire will restrict the Lialda upside for CDH. Although we like CDH's strong near-term US sales momentum, we believe the high US run rate is not sustainable beyond FY19. We believe Street estimates build in the earnings momentum in FY18/1HFY19 percolating beyond FY19 as well. With limited visibility from FY20 due to absence of big opportunities, current valuations at ~24x FY19 EPS are stretched. We initiate with Underperform and a TP of Rs415.

### Impact

- US growth momentum to slow down starting late FY19:** CDH expects 30 ANDA approvals from Moraiya and 10 more from other facilities in FY18. Out of these, excluding Lialda, six are decent opportunities (USD30-35m). Prevacid, Sirolimus, Toprol XL and generic version of Asacol HD are a few interesting opportunities that will likely play out in FY18/FY19. Once these play out, in the absence of big-ticket molecules, we expect US growth momentum to slow down starting 2HFY19/FY20.
- Launch of AG to restrict Lialda opportunity:** As per Symphony data, Lialda reported robust secondary sales of USD82m in August. However, in the first week of September, Shire launched the AG version of Lialda possibly because it was rapidly losing market share to CDH. For example, CDH had ~55% market share in Lialda in August. However, post the launch of authorized generic by Shire, we expect CDH's volumes and pricing to be impacted. Currently, pricing of AG is between Shire's and CDH's price points. We would also keep an eye on Teva and Mylan's approval status for Lialda.
- India and EMs to drive non-US growth:** CDH remains well positioned to leverage the volume-driven growth in the domestic pharma market given its new product launches, penetration into tier II towns and increasing sales force productivity. The consumer wellness subsidiary, Zydus Wellness, has a few well-established mature brands that act as a cash cow. CDH's biosimilars/vaccines business are making gradual inroads in the emerging markets.

### Earnings and target price revision

- In spite of strong near-term US sales momentum, we believe the current run-rate is not sustainable. At 24x FY19 PER, the valuations are expensive. We rate the stock Underperform with TP of Rs415 at 19x Sept-19 EPS.

### Price catalyst

- 12-month price target: Rs415.00 based on a PER methodology.
- Catalyst: Pick-up in US approvals.

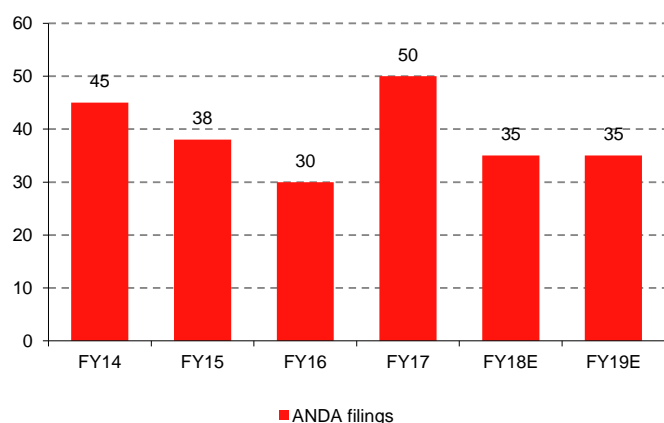
### Action and recommendation

- CDH is trading at a PER of ~24x FY19E earnings, which we believe, factors in the healthy US launch pipeline. We do not see innovative business making any meaningful impact in developed markets in the medium term as it would require substantial upfront investment to build brands. Rate Underperform.

## US business momentum to be strong in FY18/1HFY19

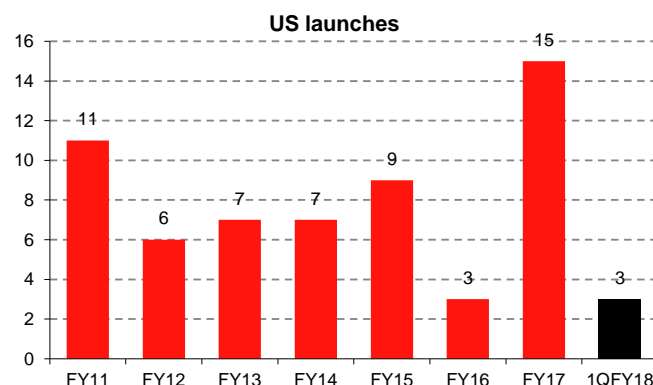
In FY17, CDH's US business was held hostage to the pending regulatory issues at its key Moraiya facility. Moraiya plant receiving an EIR from US FDA in June 2017 has opened approval floodgates for CDH. The company has 179 ANDAs pending approval, out of which more than 80 are Para IV filings (including few FTFs). The company expects to file 30-35 ANDAs each in FY18 and FY19 and is targeting ~40 product launches till December 2018. Amongst existing molecules, we note that pricing pressure has recently increased in Tamsulosin HCL (Flomax) due to higher competition. Key upcoming product launches for CDH will be in the oral solids (traditionally strong area for CDH), transdermal as well as differentiated 505(b)(2)s. Key upcoming products in 2HFY18 are Supracin OTT, Toprol XL (likely launch in 4QFY18) and Lensoprasol. These could be USD30-35m opportunities each. CDH is also expecting approval of 1-2 transdermal products from Moraiya and another one from SEZ facility. Even as CDH has not disclosed the launch timelines of the generic version of Asacol HD, we expect the company to launch it in the next 1-2 quarters. Once these play out, in the absence of big-ticket molecules, we expect US growth momentum to slow down starting 2HFY19/FY20.

**Fig 1 CDH's ANDA filings**



Source: Company, Macquarie Research, October 2017

**Fig 2 Launches in US have picked up**



Source: Company, Macquarie Research, October 2017

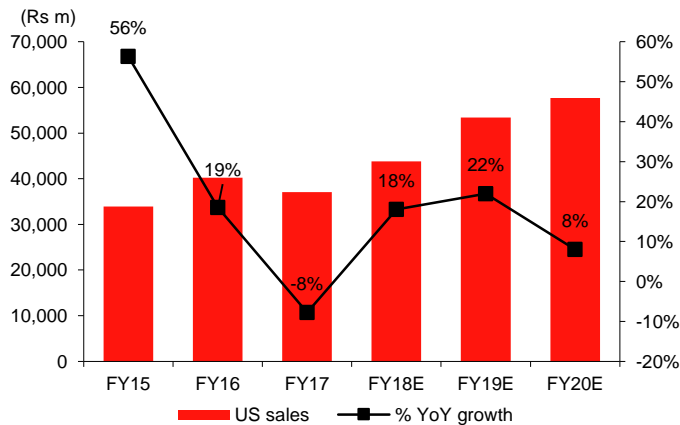
### Competition from AG to Lialda is a dampener

CDH received the approval for generic Lialda in June 2017. CDH is the first generic company to get an approval for Lialda. Shire had reported USD714m revenues from Lialda in the US. CDH continues to have exclusivity on Lialda until a new player gets approval. As per Symphony data, Lialda reported robust secondary sales of USD82m in August. In the first week of September, Shire launched the authorized generic version of Lialda since it was rapidly losing market share to CDH. For example, CDH had ~55% market share in Lialda in the month of August. However, post the launch of authorized generic by Shire, we expect CDH's volumes and pricing to be impacted. Currently, pricing of AG is between Shire and CDH's pricing. Early launch of AG by Shire is clearly a dampener for CDH. We would also keep an eye on Teva and Mylan's approval status for Lialda.

### Gradually entering into niche therapies

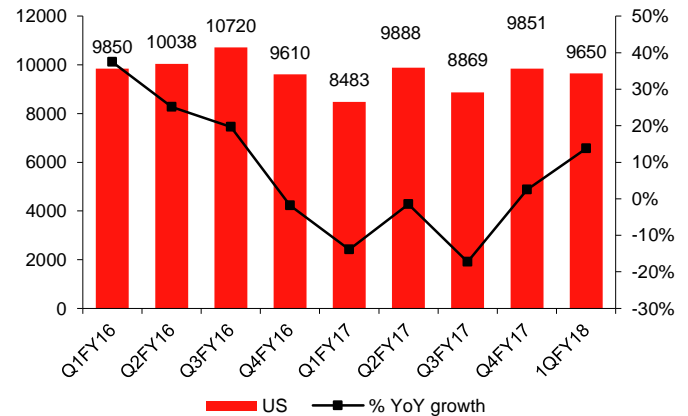
In the last two years, CDH's product portfolio has seen a structural shift with more Para IVs in the pipeline now. Earlier, the company used to pre-dominantly focus on Para III opportunities. Over the next 2-3 years, the company expects to build a pipeline of specialty and complex molecules – the upside of which will be much beyond FY20. CDH continues to explore specialty opportunities in the US, along with companies having a complex ANDA pipeline. CDH's foray into the specialty segment was through the FY17 acquisition of Sentyln Therapeutics, a US-based company specializing in pain management. As per IMS data, combined annual sales of Sentyln's two products is ~USD60m. As per the management, performance of Sentyln has been above CDH's expectations.

**Fig 3 Annual US sales**



Source: Company, Macquarie Research, October 2017

**Fig 4 Quarterly US sales**

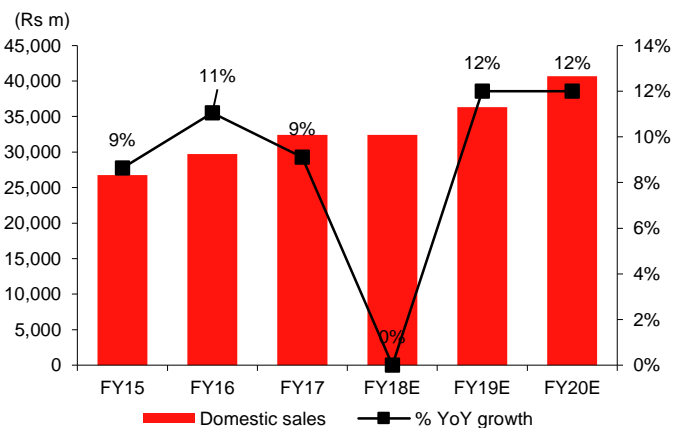


Source: Company, Macquarie Research, October 2017

**We are building improvement in India sales in FY19 and FY20**

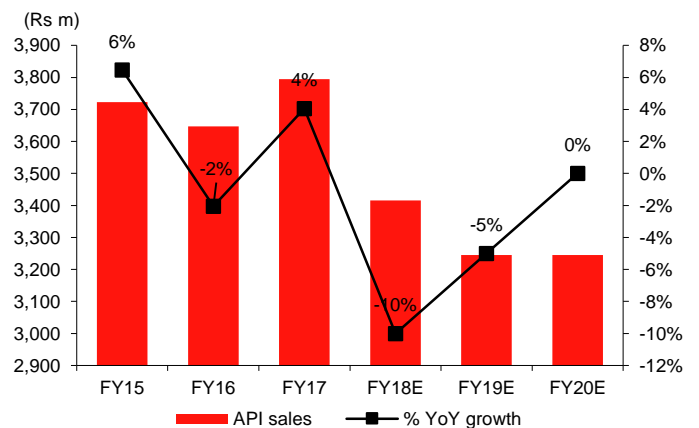
India business contributed 34% to CDH's total sales in FY17. Presently, as per IMS data, CDH's India sales growth is largely volume led. Since July, YoY sales growth in India has improved after the GST disruption, though not normalized. Inventory levels are still down vs pre-GST. There are also issues in availing GST credit, which has increased working capital requirements for pharma manufacturers. We expect low to mid-single digit growth in 2QFY17, with gradual normalization over 2HFY18. The company is open to acquiring brands in India and niche acquisitions in the health and wellness space. CDH is looking to launch its vaccines business in India starting FY18 and has already received approvals for 3 vaccines with more approvals expected in the coming quarters. Few of these vaccines could be Rs1bn opportunity each. The company expects vaccines and biosimilars to drive growth in India and emerging markets.

**Fig 5 Domestic annual sales**



Source: Company, Macquarie Research, October 2017

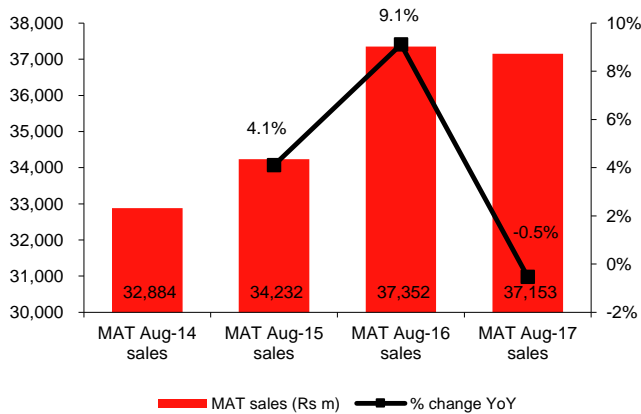
**Fig 6 API annual sales**



Source: Company, Macquarie Research, October 2017

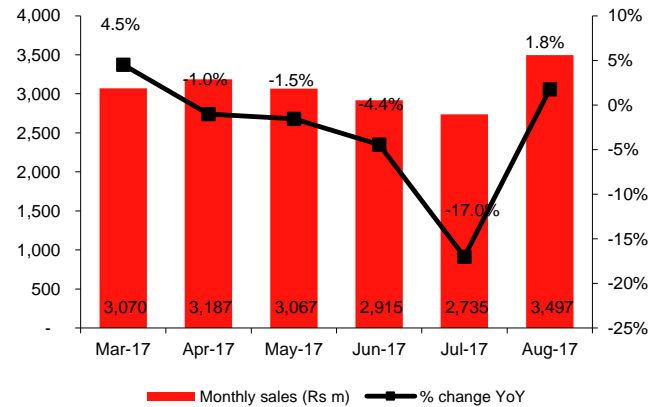


**Fig 7 Cadila - India MAT sales (August 2017)**



Source: IMS data, Macquarie Research, October 2017

**Fig 8 Cadila India monthly sales (August 2017)**



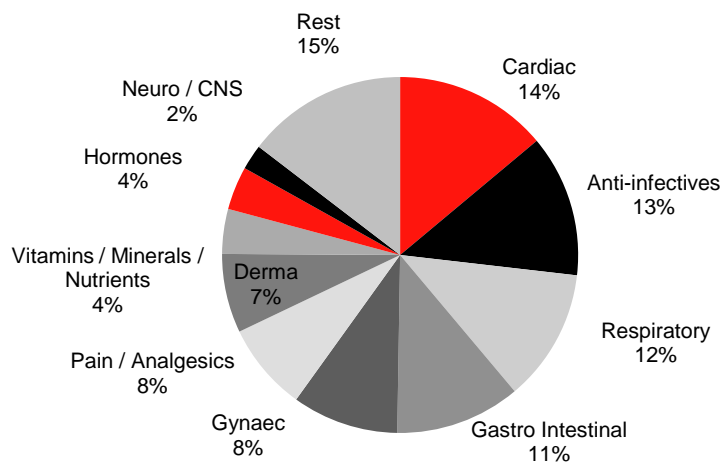
Source: IMS data, Macquarie Research, October 2017

**Fig 9 Key therapeutic drivers in India – Respiratory driving growth**

(Rs m)	MAT sales				MAT sales growth (YoY)		
	MAT Aug-14 sales	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	Aug-15	Aug-16	Aug-17
Cardiac	4,836	5,021	5,457	5,170	3.8%	8.7%	-5.2%
Anti-infectives	4,558	4,566	4,936	4,797	0.2%	8.1%	-2.8%
Respiratory	3,314	3,450	4,163	4,477	4.1%	20.7%	7.5%
Gastro Intestinal	3,967	3,967	4,388	4,229	0.0%	10.6%	-3.6%
Gynaec.	3,765	3,792	3,971	3,590	0.7%	4.7%	-9.6%
Pain / Analgesics	2,345	2,591	2,775	2,971	10.5%	7.1%	7.1%
Derma	2,737	2,786	2,619	2,667	1.8%	-6.0%	1.8%
Vitamins / Minerals / Nutrients	1,273	1,355	1,482	1,514	6.4%	9.4%	2.1%
Hormones	1,463	1,501	1,559	1,465	2.6%	3.9%	-6.0%
Neuro / CNS	780	725	817	852	-7.0%	12.6%	4.3%

Source: IMS data, Macquarie Research, October 2017

**Fig 10 Cadila therapeutic split in India – Cardiac, Anti-Infectives, Respiratory, GI & Gynae key focus areas**



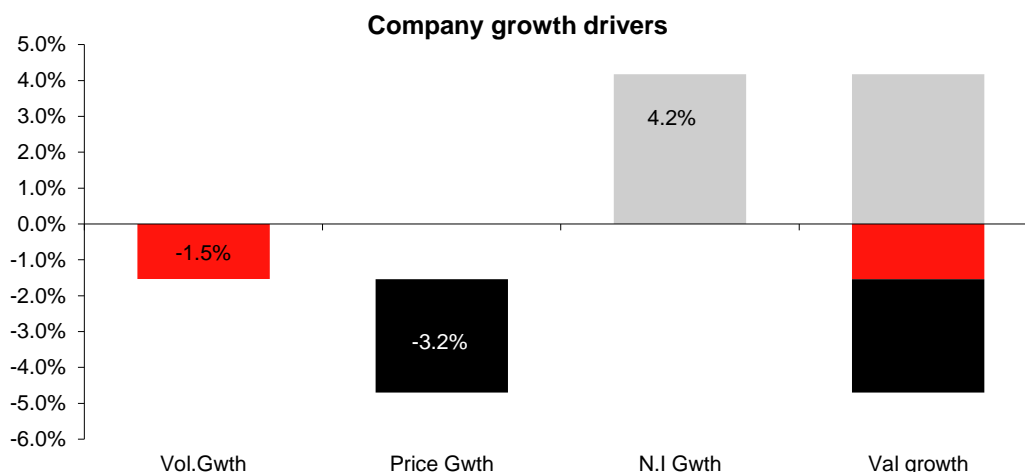
Source: : IMS data, Macquarie Research, October 2017

Fig 11 Cadila's top 25 brands - contribute ~41% of total India sales, and declined 6% YoY (MAT Aug-2017)

	MAT sales				MAT sales growth (YoY)		
	MAT Aug-14 sales	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	Aug-15	Aug-16	Aug-17
SKINLITE	1,578	1,583	1,422	1,407	0.4%	-10.2%	-1.1%
DERIPHYLLIN	888	959	1,203	1,183	8.0%	25.4%	-1.6%
ATORVA	904	1,080	1,130	911	19.5%	4.7%	-19.4%
MIFEGEST-KIT	1,109	1,119	1,219	881	0.9%	8.9%	-27.7%
PANTODAC	780	796	938	872	2.1%	17.9%	-7.1%
DECA DURABOLIN	790	840	907	867	6.3%	7.9%	-4.4%
FALCIGO	680	664	855	672	-2.3%	28.8%	-21.4%
AMICIN	451	505	608	670	12.0%	20.4%	10.2%
FORMONIDE	443	495	616	637	11.6%	24.5%	3.4%
ATEN	791	743	746	611	-6.0%	0.4%	-18.2%
AMLODAC	842	655	664	588	-22.2%	1.3%	-11.4%
THROMBOPHOB	417	441	521	547	5.6%	18.3%	5.0%
AMPILOX	485	517	550	520	6.6%	6.4%	-5.5%
NUCOXIA	355	404	452	517	13.7%	12.1%	14.4%
PRIMOLUT-N	549	519	557	516	-5.6%	7.4%	-7.5%
DEXONA	529	520	497	450	-1.5%	-4.5%	-9.4%
CLOPITORVA	269	344	420	428	27.9%	22.2%	1.9%
MONOTAX	282	337	404	419	19.3%	19.9%	3.7%
NATUROGEST	328	348	320	398	6.0%	-7.9%	24.4%
ZYROP	282	400	348	397	42.1%	-13.1%	14.2%
OCID	478	483	493	370	1.0%	2.1%	-24.9%
PENEGRA	262	305	353	357	16.3%	15.9%	0.9%
PANTODAC-DSR	308	328	331	355	6.5%	0.9%	7.5%
GRD	354	364	365	346	2.7%	0.4%	-5.1%
PROLUTON	239	283	323	346	18.4%	14.1%	7.3%
Top 25 products as % of total sales	43.8%	43.9%	43.5%	41.1%			

Source: IMS data, Macquarie Research, October 2017

Fig 12 CDH's domestic growth largely led by new launches

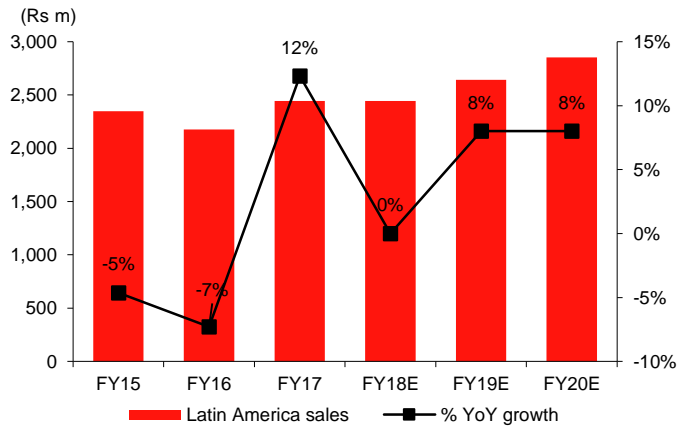


Source: IMS data, Macquarie Research, October 2017

### Other revenue segments

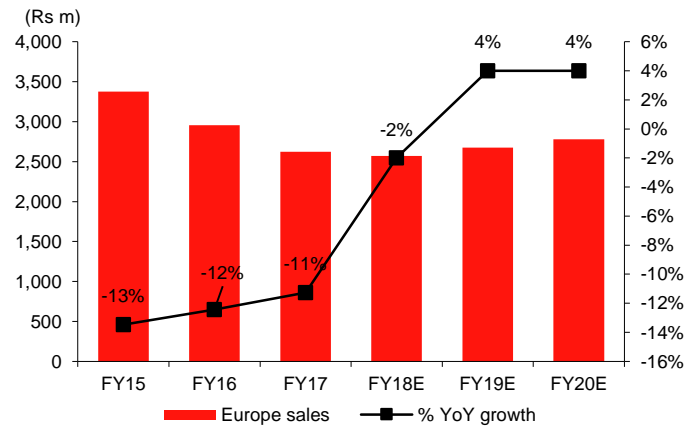
Within emerging markets, Cadila is focussing on the branded and generic business in Asia and Africa. CDH is looking to participate in WHO tenders for vaccines to drive growth in emerging markets. The company's topline growth in the consumer wellness segment (Zydus Wellness) is being driven by volumes, particularly in Sugarfree and Nutralite. Even though CDH is the market leader, penetration in each of these categories remains quite low. Looking ahead, we expect steady mid-single-digit growth in both consumer wellness and animal health business for CDH.

**Fig 13 LatAm annual sales**



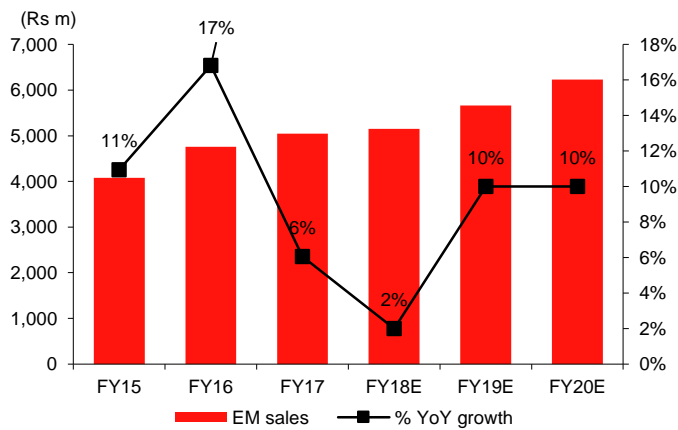
Source: Company, Macquarie Research, October 2017

**Fig 14 Europe annual sales**



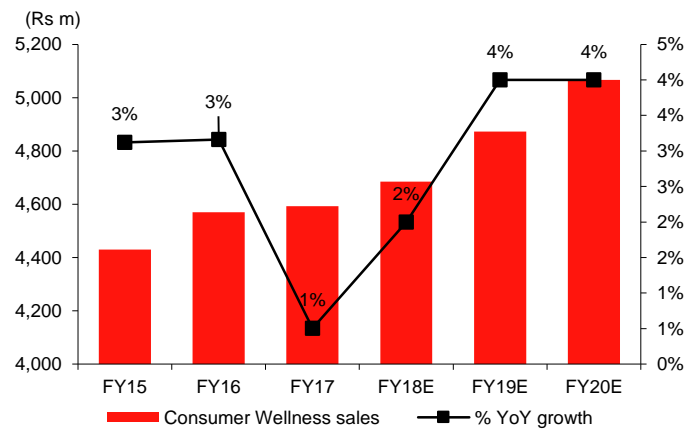
Source: Company, Macquarie Research, October 2017

**Fig 15 EM annual sales**



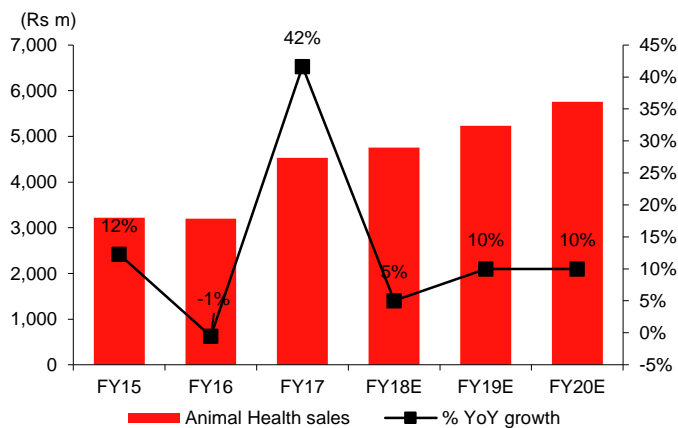
Source: Company, Macquarie Research, October 2017

**Fig 16 Consumer wellness annual sales**



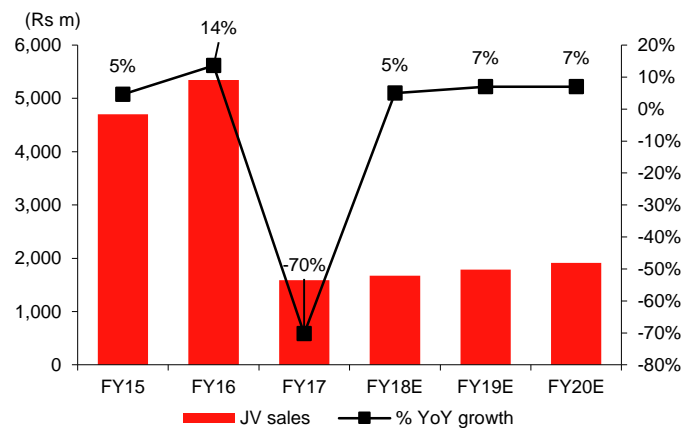
Source: Company, Macquarie Research, October 2017

**Fig 17 Animal health annual sales**



Source: Company, Macquarie Research, October 2017

**Fig 18 Annual JV sales**

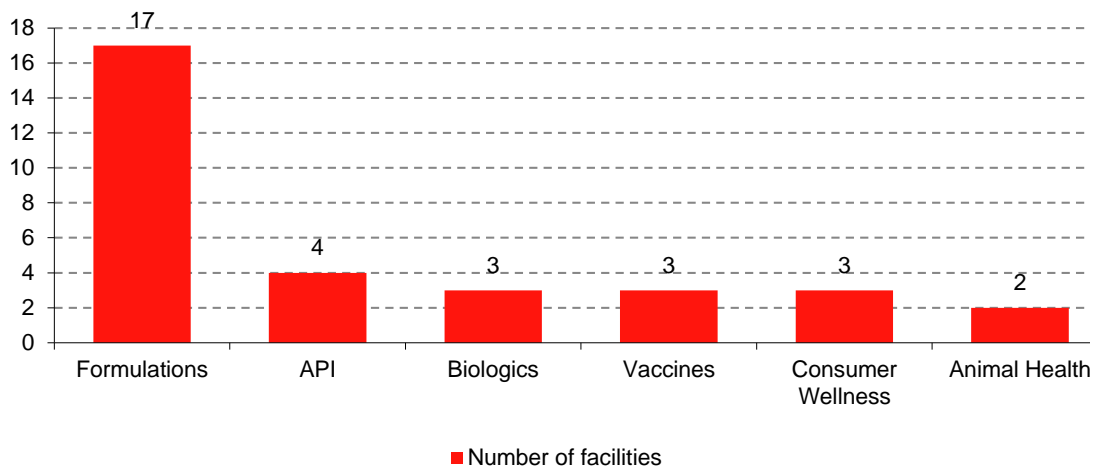


Source: Company, Macquarie Research, October 2017

### Investing in upgrading infrastructure post Moraiya warning letter

CDH has 11 US FDA approved facilities, of which nine are currently supplying to the US. There are no pending US FDA issues at any of these facilities. Moraiya is the most important facility for the company as ~40% of CDH’s current US products come from this facility, including some high value fillings. US FDA issued a form 483 following inspection of the Moraiya facility in Sep-14 highlighting inadequate review of consumer complaints and not identifying the root cause of recurring problems. Subsequently in Dec-15, US FDA issued a warning letter largely detailing issues raised earlier in the form 483. The warning letter also highlighted that (1) CDH did not adequately investigate out-of-specification (OOS) laboratory test results and (2) CDH failed to establish and follow adequate written procedures describing the handling of all written & oral complaints for a drug product. Post Moraiya warning letter, CDH invested USD100m in capex to upgrade its infrastructure and quality controls. The company has also invested in creating quality awareness, especially on the behavioural aspects of plant employees. Apart from Moraiya, Baddi (10-15% contribution), Ahmedabad SEZ (Oral solid dosage plant), topical plant in Ahmedabad are key facilities. The company expects Ahmedabad SEZ to ramp up and be a key contributor to US sales (as big as Moraiya) in the near future. There are ~70 products pending approval from this facility.

**Fig 19 CDH’s manufacturing facility split**

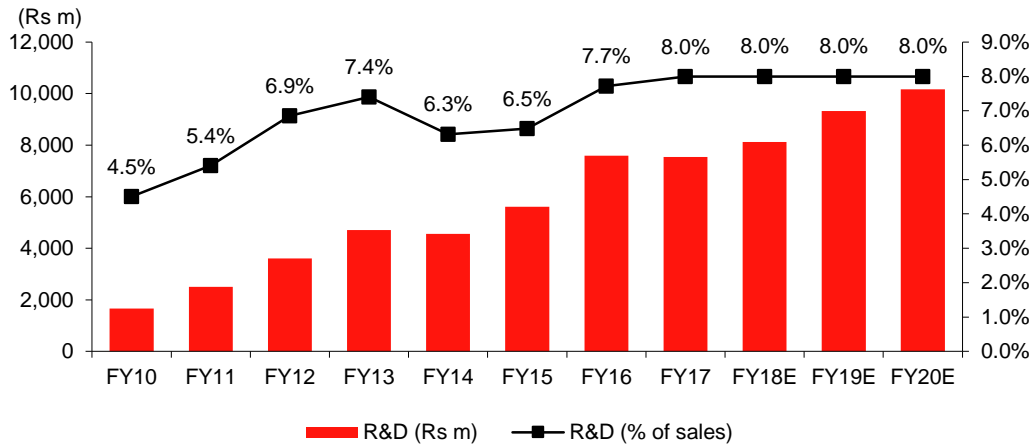


Source: : Company, Macquarie Research, October 2017

### Upside risk to our R&D estimates at 8% of sales

CDH has guided for R&D spends in the range of 7-8% in FY18. CDH intends to become a research driven company by 2020. CDH has a mix of NCE pipeline coupled with Biosimilar & Biologics and Vaccines portfolio. We see this as a positive move as a branded franchise would provide a stable, high margin revenue stream. However we do not see innovative business making any meaningful impact in developed markets in near term as it would require substantial upfront investment to build brands. Currently, CDH invests ~25% of its total R&D spend on its innovation portfolio. With increasing shift towards niche opportunities, there is an upside risk to our FY19 and FY20 R&D estimates.

**Fig 20 CDH's R&D spends have increased significantly over the past few years**

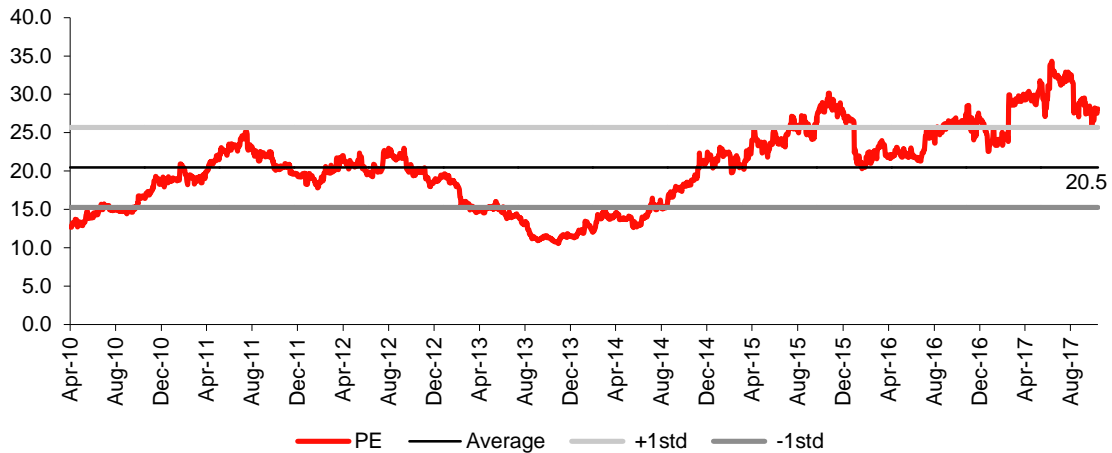


Source: Company, Macquarie Research, October 2017

**Strong near-term US growth priced in**

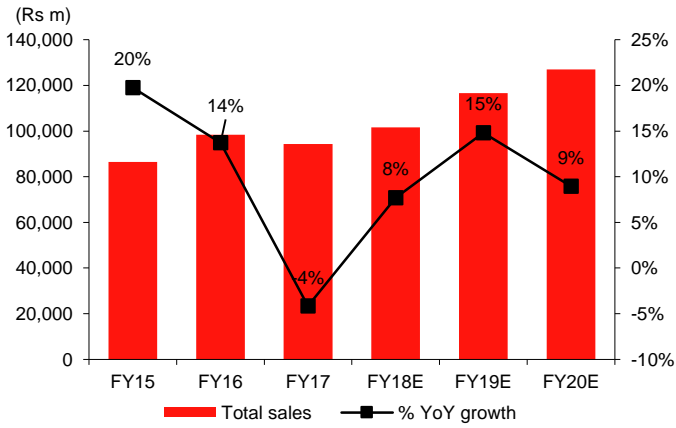
CDH is trading at a PER of ~24x FY19E earnings, which we believe, factors in the healthy US launch pipeline. In spite of strong near-term US sales momentum, we believe the current run-rate is not sustainable. We do not see innovative business making any meaningful impact in developed markets in the medium term as it would require substantial upfront investment to build brands. Currently, CDH has net debt of ~Rs35bn and cash of Rs8-9bn. We rate the stock Underperform with TP of Rs415 at 19x Sept-19 EPS.

**Fig 21 CDH is trading one standard deviation above its long-term mean**



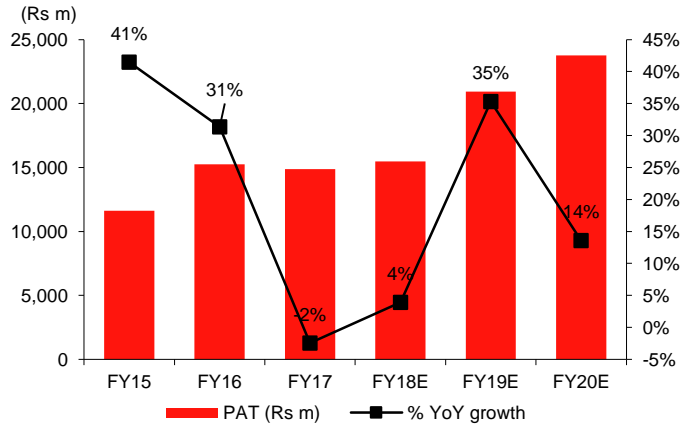
Source: Bloomberg, Macquarie Research, October 2017

**Fig 22 Annual total sales**



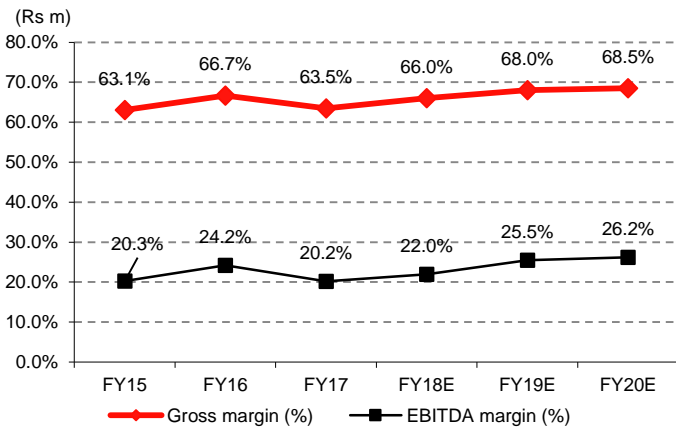
Source: Company, Macquarie Research, October 2017

**Fig 23 Annual PAT trend**



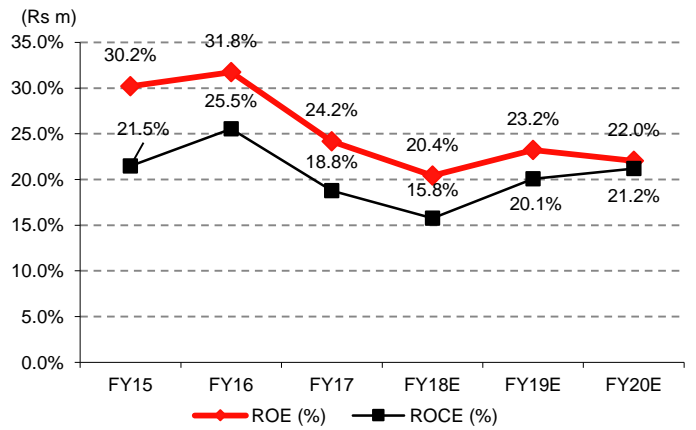
Source: Company, Macquarie Research, October 2017

**Fig 24 Gross and EBITDA margin profile**



Source: Company, Macquarie Research, October 2017

**Fig 25 Return ratio profile**



Source: Company, Macquarie Research, October 2017

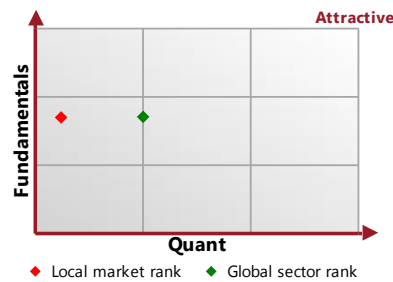
## Macquarie Quant View

The quant model currently holds a strong negative view on Cadila Healthcare. The strongest style exposure is Earnings Momentum, indicating this stock has received earnings upgrades and is well liked by sell side analysts. The weakest style exposure is Quality, indicating this stock is likely to have a weaker and less stable underlying earnings stream.

**580/868**

Global rank in  
Pharma, Biotech & Life Sciences

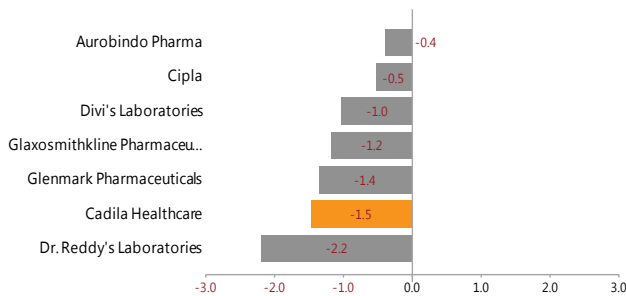
**% of BUY recommendations** 62% (21/34)  
**Number of Price Target downgrades** 2  
**Number of Price Target upgrades** 1



Displays where the company's ranked based on the fundamental consensus Price Target and Macquarie's Quantitative Alpha model.  
Two rankings: Local market (India) and Global sector (Pharma, Biotech & Life Sciences)

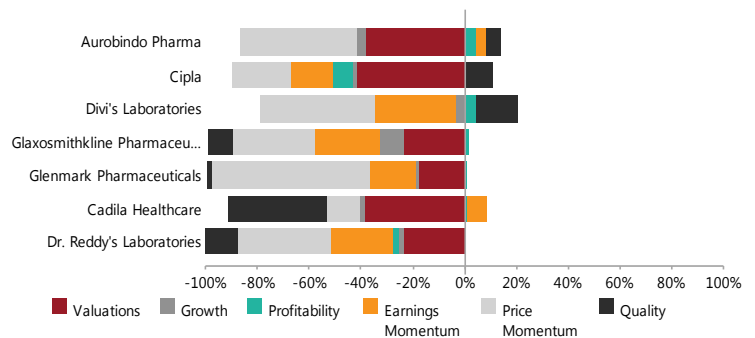
## Macquarie Alpha Model ranking

A list of comparable companies and their Macquarie Alpha model score (higher is better).



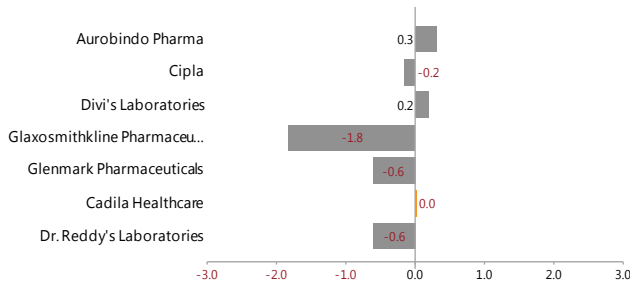
## Factors driving the Alpha Model

For the comparable firms this chart shows the key underlying styles and their contribution to the current overall Alpha score.



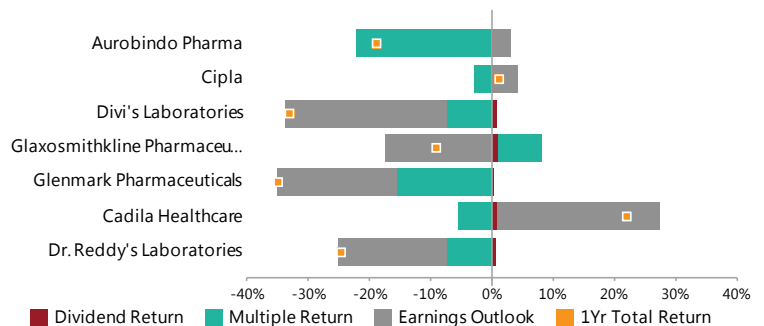
## Macquarie Earnings Sentiment Indicator

The Macquarie Sentiment Indicator is an enhanced earnings revisions signal that favours analysts who have more timely and higher conviction revisions. Current score shown below.



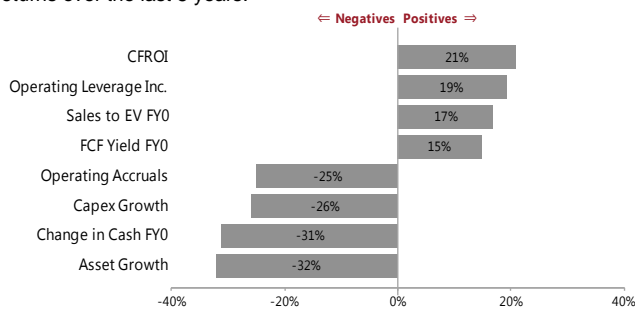
## Drivers of Stock Return

Breakdown of 1 year total return (local currency) into returns from dividends, changes in forward earnings estimates and the resulting change in earnings multiple.



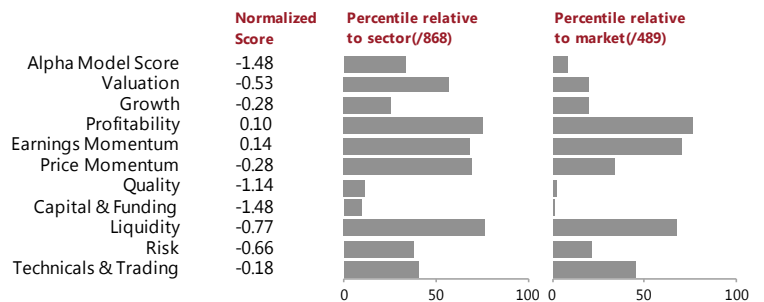
## What drove this Company in the last 5 years

Which factor score has had the greatest correlation with the company's returns over the last 5 years.



## How it looks on the Alpha model

A more granular view of the underlying style scores that drive the alpha (higher is better) and the percentile rank relative to the sector and market.



Source (all charts): FactSet, Thomson Reuters, and Macquarie Research. For more details on the Macquarie Alpha model or for more customised analysis and screens, please contact the Macquarie Global Quantitative/Custom Products Group ([cpg@macquarie.com](mailto:cpg@macquarie.com))

## Cadila Healthcare (CDH IN)

Quarterly Results					Profit & Loss						
	1Q/18A	2Q/18E	3Q/18E	4Q/18E		2017A	2018E	2019E	2020E		
<b>Revenue</b>	m	25,390	25,390	25,390	25,390	<b>Revenue</b>	m	94,295	101,560	116,602	127,029
<b>Gross Profit</b>	m	16,757	16,757	16,757	16,757	<b>Gross Profit</b>	m	59,844	67,030	79,289	87,015
Cost of Goods Sold	m	8,633	8,633	8,633	8,633	Cost of Goods Sold	m	34,451	34,530	37,313	40,014
<b>EBITDA</b>	m	5,586	5,586	5,586	5,586	<b>EBITDA</b>	m	19,036	22,343	29,733	33,282
Depreciation	m	1,125	1,125	1,125	1,125	Depreciation	m	3,750	4,500	4,600	4,700
Amortisation of Goodwill	m	0	0	0	0	Amortisation of Goodwill	m	0	0	0	0
Other Amortisation	m	0	0	0	0	Other Amortisation	m	0	0	0	0
<b>EBIT</b>	m	4,461	4,461	4,461	4,461	<b>EBIT</b>	m	15,286	17,843	25,133	28,582
Net Interest Income	m	-200	-200	-200	-200	Net Interest Income	m	-450	-800	-600	-500
Associates	m	250	250	250	250	Associates	m	338	1,000	1,000	1,000
Exceptionals	m	0	0	0	0	Exceptionals	m	0	0	0	0
Forex Gains / Losses	m	0	0	0	0	Forex Gains / Losses	m	0	0	0	0
Other Pre-Tax Income	m	250	250	250	250	Other Pre-Tax Income	m	1,286	1,000	1,000	1,000
<b>Pre-Tax Profit</b>	m	4,761	4,761	4,761	4,761	<b>Pre-Tax Profit</b>	m	16,460	19,043	26,533	30,082
Tax Expense	m	-857	-857	-857	-857	Tax Expense	m	-1,289	-3,428	-5,307	-6,016
<b>Net Profit</b>	m	3,904	3,904	3,904	3,904	<b>Net Profit</b>	m	15,171	15,615	21,227	24,065
Minority Interests	m	-38	-38	-38	-38	Minority Interests	m	-291	-150	-300	-300
<b>Reported Earnings</b>	m	3,866	3,866	3,866	3,866	<b>Reported Earnings</b>	m	14,880	15,465	20,927	23,765
<b>Adjusted Earnings</b>	m	3,866	3,866	3,866	3,866	<b>Adjusted Earnings</b>	m	14,880	15,465	20,927	23,765
EPS (rep)		3.78	3.78	3.78	3.78	EPS (rep)		14.53	15.11	20.44	23.21
EPS (adj)		3.78	3.78	3.78	3.78	EPS (adj)		14.53	15.11	20.44	23.21
EPS Growth yoy (adj)	%	3.9	3.9	3.9	3.9	EPS Growth (adj)	%	-2.4	3.9	35.3	13.6
						PE (rep)	x	33.8	32.5	24.0	21.2
						PE (adj)	x	33.8	32.5	24.0	21.2
EBITDA Margin	%	22.0	22.0	22.0	22.0	Total DPS		3.20	3.14	4.25	4.83
EBIT Margin	%	17.6	17.6	17.6	17.6	Total Div Yield	%	0.7	0.6	0.9	1.0
Earnings Split	%	25.0	25.0	25.0	25.0	Basic Shares Outstanding	m	1,024	1,024	1,024	1,024
Revenue Growth	%	7.7	7.7	7.7	7.7	Diluted Shares Outstanding	m	1,024	1,024	1,024	1,024
EBIT Growth	%	16.7	16.7	16.7	16.7						
Profit and Loss Ratios					Cashflow Analysis						
	2017A	2018E	2019E	2020E		2017A	2018E	2019E	2020E		
Revenue Growth	%	-4.1	7.7	14.8	8.9	<b>EBITDA</b>	m	19,036	22,343	29,733	33,282
EBITDA Growth	%	-20.1	17.4	33.1	11.9	Tax Paid	m	-2,376	-3,428	-5,307	-6,016
EBIT Growth	%	-26.5	16.7	40.9	13.7	Chgs in Working Cap	m	-3,728	-3,680	-2,933	-2,033
Gross Profit Margin	%	63.5	66.0	68.0	68.5	Net Interest Paid	m	-5	-800	-600	-500
EBITDA Margin	%	20.2	22.0	25.5	26.2	Other	m	568	0	0	0
EBIT Margin	%	16.2	17.6	21.6	22.5	<b>Operating Cashflow</b>	m	13,495	14,435	20,894	24,732
Net Profit Margin	%	15.8	15.2	17.9	18.7	Acquisitions	m	0	0	0	0
Payout Ratio	%	22.0	20.8	20.8	20.8	Capex	m	-29,734	-8,125	-9,328	-10,162
EV/EBITDA	x	27.5	22.8	17.3	15.5	Asset Sales	m	0	0	0	0
EV/EBIT	x	34.1	28.3	20.4	18.0	Other	m	631	1,000	1,000	1,000
<b>Balance Sheet Ratios</b>					<b>Investing Cashflow</b>	m	-29,103	-7,125	-8,328	-9,162	
ROE	%	24.2	20.4	23.2	22.0	Dividend (Ordinary)	m	-3,271	-3,217	-4,353	-4,943
ROA	%	12.1	11.5	15.0	15.2	Equity Raised	m	0	0	0	0
ROIC	%	21.1	14.4	18.3	19.3	Debt Movements	m	14,992	0	0	0
Net Debt/Equity	%	42.6	31.4	17.9	6.2	Other	m	11,437	0	0	0
Interest Cover	x	34.0	22.3	41.9	57.2	<b>Financing Cashflow</b>	m	23,158	-3,217	-4,353	-4,943
Price/Book	x	7.2	6.1	5.1	4.3	<b>Net Chg in Cash/Debt</b>	m	7,544	4,094	8,213	10,626
Book Value per Share		68.0	80.0	96.1	114.5	<b>Free Cashflow</b>	m	-16,239	6,310	11,565	14,570
					<b>Balance Sheet</b>		2017A	2018E	2019E	2020E	
					Cash	m	19,140	23,234	31,446	42,073	
					Receivables	m	22,775	18,818	21,606	23,538	
					Inventories	m	18,037	18,194	20,889	22,757	
					Investments	m	643	1,643	2,643	3,643	
					Fixed Assets	m	48,337	51,962	56,690	62,152	
					Intangibles	m	11,494	11,494	11,494	11,494	
					Other Assets	m	31,781	31,986	32,533	32,912	
					<b>Total Assets</b>	m	152,207	157,332	177,301	198,569	
					Payables	m	16,736	12,924	14,839	16,166	
					Short Term Debt	m	24,769	24,769	24,769	24,769	
					Long Term Debt	m	24,684	24,684	24,684	24,684	
					Provisions	m	0	0	0	0	
					Other Liabilities	m	14,857	11,395	12,576	13,394	
					<b>Total Liabilities</b>	m	81,046	73,772	76,867	79,013	
					Shareholders' Funds	m	69,600	81,849	98,423	117,245	
					Minority Interests	m	1,561	1,711	2,011	2,311	
					Other	m	0	0	0	0	
					<b>Total S/H Equity</b>	m	71,161	83,560	100,434	119,556	
					<b>Total Liab &amp; S/H Funds</b>	m	152,207	157,332	177,301	198,569	

All figures in INR unless noted.

Source: Company data, Macquarie Research, October 2017



## INDIA

GNP IN Outperform

Price (at 06:14, 18 Oct 2017 GMT) Rs606.70

<b>Valuation</b>	<b>Rs</b>	<b>728.00</b>
- PER		
<b>12-month target</b>	<b>Rs</b>	<b>728.00</b>
<b>Upside/Downside</b>	<b>%</b>	<b>+20.0</b>
<b>12-month TSR</b>	<b>%</b>	<b>+20.3</b>
<b>Volatility Index</b>		<b>Low/Medium</b>

## GICS sector

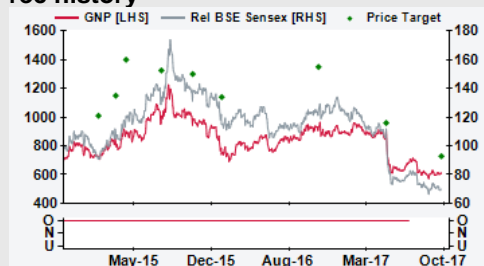
Pharmaceuticals, Biotechnology &amp; Life Sciences

<b>Market cap</b>	<b>Rsm</b>	<b>171,089</b>
<b>Market cap</b>	<b>US\$m</b>	<b>2,633</b>
<b>Free float</b>	<b>%</b>	<b>48</b>
<b>30-day avg turnover</b>	<b>US\$m</b>	<b>9.9</b>
<b>Number shares on issue</b>	<b>m</b>	<b>282.0</b>

## Investment fundamentals

Year end 31 Mar		2017A	2018E	2019E	2020E
Revenue	bn	91.9	95.3	101.0	107.9
EBIT	bn	17.7	17.1	19.0	20.2
EBIT growth	%	52.3	-3.4	10.8	6.6
Recurring profit	bn	15.7	15.3	17.2	18.5
Reported profit	bn	11.9	11.0	12.3	13.3
Adjusted profit	bn	11.9	11.0	12.3	13.3
EPS rep	Rs	42.16	39.07	43.77	47.22
EPS rep growth	%	195.9	-7.3	12.0	7.9
EPS adj	Rs	42.16	39.07	43.77	47.22
EPS adj growth	%	69.4	-7.3	12.0	7.9
PER rep	x	14.4	15.5	13.9	12.8
PER adj	x	14.4	15.5	13.9	12.8
Total DPS	Rs	2.00	2.00	2.00	2.00
Total div yield	%	0.3	0.3	0.3	0.3
ROA	%	16.9	14.0	13.7	13.5
ROE	%	31.5	22.0	20.2	18.2
EV/EBITDA	x	10.2	10.3	9.3	8.6
Net debt/equity	%	81.6	61.2	41.3	27.4
P/BV	x	3.8	3.1	2.5	2.2

## GNP IN rel BSE Sensex performance, &amp; rec history



Note: Recommendation timeline - if not a continuous line, then there was no Macquarie coverage at the time or there was an embargo period.

Source: FactSet, Macquarie Research, October 2017  
(all figures in INR unless noted)

## Analyst(s)

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23 October 2017

Macquarie Capital Securities India (Pvt) Ltd

# Glenmark Pharmaceuticals

## Banking on out-licensing deals

### Conclusion

- Glenmark (GNP) continues to bear the brunt of the slower pace of FDA approvals and a lack of meaningful free cash generation. We believe out-licensing deals from its innovative portfolio are crucial to tackle both these issues. Given positive Phase 2 data for GBR 830 and Phase 3 data for GBR 310, out-licensing deals for these molecules are likely in FY18 and FY19, respectively (not factored into our estimates). Resultant free cash generation and lowering of debt remain key monitorables. Notwithstanding the challenges, we note that the company has limited product concentration risk (ex-Zetia and Mupirocin). Also, at CMP, we believe there is significant valuation comfort. In addition, GNP's relatively better US FDA inspection track record holds it in good stead. We initiate coverage on the stock with an Outperform rating and a TP of Rs728.

### Impact

- Several key US molecules awaiting approval:** Apart from setbacks like a lower-than-expected benefit from Zetia, meaningful approvals have eluded GNP in the US. The expected Mupirocin launch of Taro in 2HFY18 could shave off US\$30m in annualised US revenues for GNP. Over the near to medium term, there are several key impending launches with revenue potential of US\$20m-30m each like Nitroglycerin, Aprepitant, Diclofenac Sodium Gel 1% and Welchol, which have been delayed. In addition, we expect the company to launch Suboxone, Sevelamer, Concerta, Abrexin, Vagifem and Nuvaring in FY19-20, which could be meaningful opportunities.
- Fairly steady performance expected in India, Europe and ROW:** Barring the near-term GST issue in 2QFY18 (strong 15.2% YoY growth in 1QFY18 was largely due to channel filling) and any regulatory action, we expect GNP's India growth to be at 12% YoY each in FY18 and FY19. Growth is likely to remain in the range of 10-12% in both Europe and ROW. After a disappointing couple of years in the LatAm market, GNP is looking to break even in this market (ex-Venezuela) in FY18.
- Balance sheet concerns to weigh on valuations:** Lack of meaningful free cash generation due to high cash tax payout and elevated working capital remain investor concerns. R&D spends in FY18 and FY19 are likely to be high at ~11% of sales. High cash balance at meagre 1-1.5% yields remain a drag. In the absence of out-licensing deals, we expect free cash generation will continue to be suppressed. We assign a 16x FY19E PER multiple to GNP (in line with its average PER multiple during FY11-14) to reflect these concerns.

### Earnings and target price revision

- We rate the stock 'Outperform' with a TP of Rs728 at 16x Sept-19E EPS.

### Price catalyst

- 12-month price target: Rs728.00 based on a PER methodology.
- Catalyst: 1) Incremental US approvals, 2) BEAT platform monetization

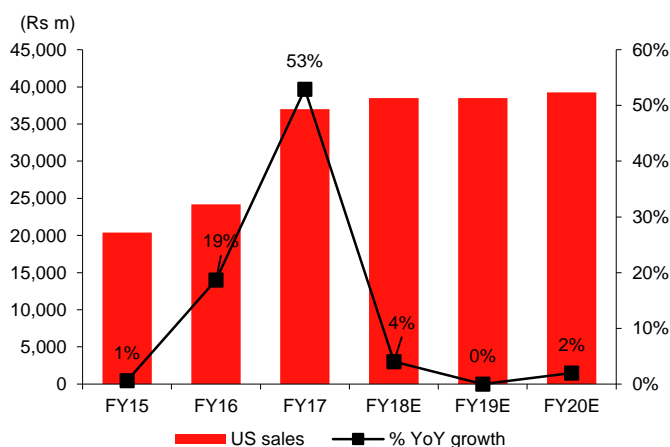
### Action and recommendation

- GNP is trading at attractive valuations of ~14x FY19E EPS. Reduction in net-debt and US sales acceleration remain key.

## Timely approvals and monetising innovation pipeline key to drive US growth

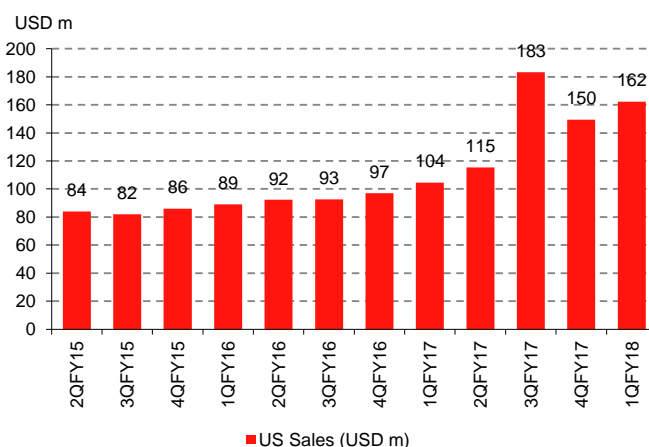
The absence of meaningful approvals has pulled back near-term US growth (ex-Zetia). New approvals remain quintessential and GNP is guiding to 15 launches in the US for FY18. GNP will be primarily focussing on 3 key therapies – oncology, respiratory and dermatology. Out of its potential pipeline, approvals for the oncology products have the highest potential to be fast-tracked by the FDA given significant unmet medical needs. GNP plans to enter new dosage forms with lower competitive intensity like inhalers. In the next 5 years, the company expects the contribution of ANDAs filed for oral solids to reduce from 46% currently to 22% of total filings. We expect quality of the product pipeline to improve with much higher contribution from derma, controlled substances and drug device combinations. GNP also expects to file 7-8 US DMFs annually. We expect an increasing US contribution (including any out-licensing deals) to total sales to support margins. Over the next decade, GNP expects the following catalysts to play out: (i) innovative new molecular entities (NME), (ii) 9 new drug application (NDA)/ biologic license application (BLA) and (iii) 30% of revenues coming from specialty and innovation segments.

**Fig 1 Annual US sales**



Source: Company data, Macquarie Research, October 2017

**Fig 2 Quarterly US sales**



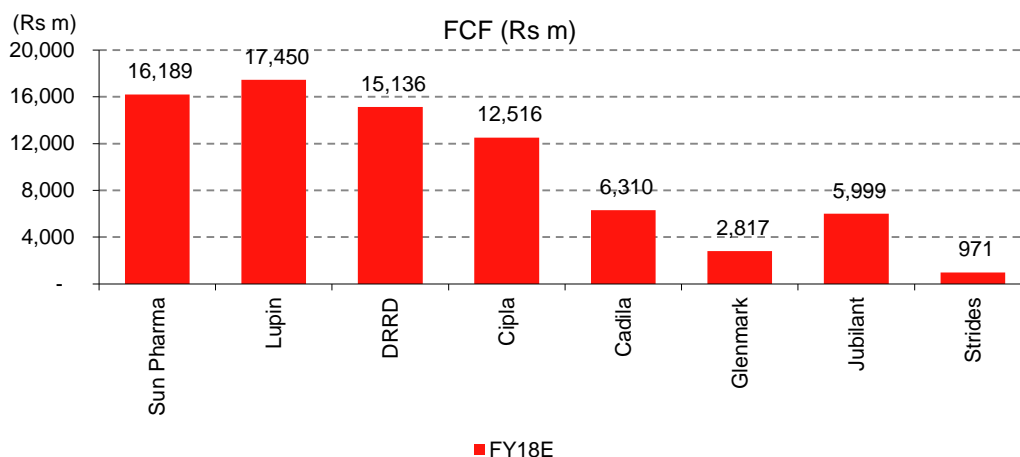
Source: Company data, Macquarie Research, October 2017

Apart from setbacks like a lower-than-expected benefit from Zetia, meaningful approvals have eluded GNP in the US. The expected Mupirocin launch of Taro in 2HFY18 could shave off US\$30m in annualised US revenues for GNP. Over the near to medium term, there are several key impending launches with revenue potential of US\$20-30m each like Nitroglycerin, Aprepitant, Diclofenac Sodium Gel 1%, and Welchol, which have been delayed. In addition, we expect the company to launch Suboxone, Sevelamer, Concerta, Abrexin, Vagifem and Nuvaring in FY19-20, which could be meaningful opportunities.

### Pick-up in the US business vital to balance sheet improvement

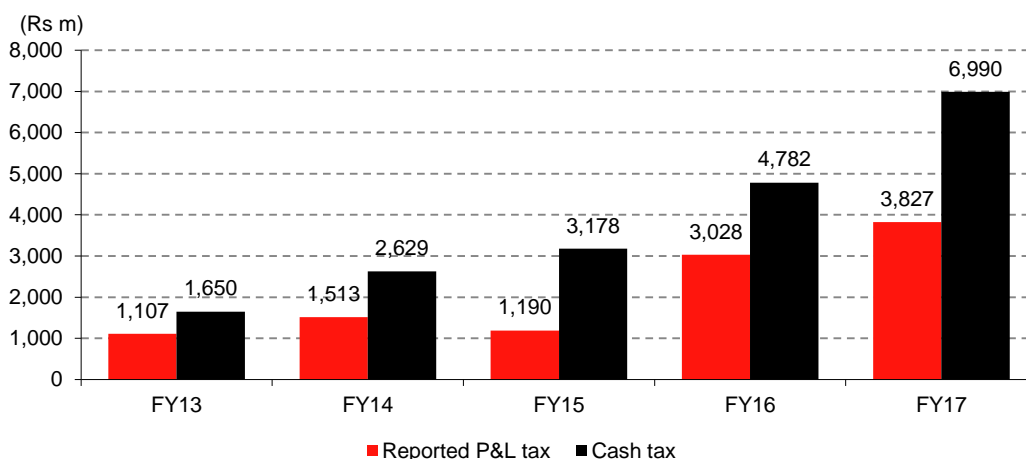
GNP expects to generate Rs3bn in FCF in FY18, which would lower net debt to Rs33bn in FY18. This remains an important data point to monitor as financial discipline at GNP has been a key investor grievance. Historically, GNP’s free cash generation has been weaker than peers due to ongoing investments in building its innovation/specialty pipeline, elevated receivables especially in the India business and high cash tax payout. If there is a pick-up in meaningful approvals in the US and GNP signs out-licensing deals for GSP 310 and GBR 830, we expect free cash generation to improve. Apart from better profitability, cash tax payout for the out-licensing revenue is minimal. Hence, pick-up in the US business (including out-licensing income) is key to improved free cash generation for GNP. The company has guided for a 22% EBITDA margin from FY18 onwards, which we believe looks difficult in the absence of any out-licensing deal. GNP expects ROCE to be 18-20% over the next 4-5 years. Annual capex on fixed assets would be Rs6-7bn. Annual spend on intangible assets to be Rs2bn due to in-licensing of complex generics.

**Fig 3 GNP's free cash generation pales compared to peers**



Source: Company data, Macquarie Research, October 2017

**Fig 4 Big gap between reported P&L and cash tax**



Source: Company data, Macquarie Research, October 2017

**Key facilities have recently received US FDA clearance**

GNP's relatively better US FDA inspection track record holds it in good stead. GNP's important facilities like Goa, Baddi and Indore have been cleared in the last six months. In our view, sales from these 3 facilities would constitute ~80% of US formulation sales.

**Fig 5 Key US-FDA approved facilities of GNP with last inspection status**

Facility	Last inspection	Status
Argentina	May-14	EIR received
Dahej SEZ API	Apr-15	EIR received
Pithampur (Indore SEZ)	Feb-16	Approvals received post inspection
Aurangabad	Jun-16	Form 483 issues
Ankleshwar API	Dec-16	EIR received
Baddi	Dec-16	No observations
Goa	Dec-16	Approvals received post inspection

Source: Company data, Macquarie Research, October 2017

### Specialty/innovation pipeline shaping up well

GNP has readied a strong NME and specialty pipeline and expects to launch its specialty business in the US with its first NDA approval in respiratory within 3-5 years. The most advanced asset under development in Phase 3 (GSP 301) is a respiratory inhaler product, which is a combination of an anti-histamine and steroid for allergic rhinitis. Over the next 5-10 years, GNP believes ~30% of its revenues will come from specialty and innovation segments. We believe out-licensing deals from its innovative portfolio are crucial to tackle FCF issues and meet its 22% FY18 margin guidance. Given positive Phase 2 data for GBR 830 and Phase 3 data for GBR 310, out-licensing deals for these molecules in FY18 and FY19, respectively, are likely. **We are not building any out-licensing income in our estimates.**

**Fig 6 GNP’s specialty/innovation pipeline**

Therapy	Molecule	MoA/Class	Indication	Pre Clinical	Phase 1	Phase 2	Phase 3	Approval
Oncology	GBR 1302	HER2 X CD3	Breast Cancer Gastric Cancer	██████████	██████████	██████████	██████████	██████████
Oncology	GBR 1342	CD38 X CD3	Multiple Myeloma	██████████	██████████	██████████	██████████	██████████
Oncology	GBR 1372	EGFR X CD3	Colorectal Cancer	██████████	██████████	██████████	██████████	██████████
Oncology	GBR 8383	OX40R Agonist	Multiple Cancers	██████████	██████████	██████████	██████████	██████████
Dermatology	GBR 830	OX40 Antagonist	Atopic Dermatitis	██████████	██████████	██████████	██████████	██████████
Respiratory	GRC 388XX	Undisclosed	COPD, IPF	██████████	██████████	██████████	██████████	██████████
Respiratory	GSP 301	Steroid + AH	Allergic Rhinitis	██████████	██████████	██████████	██████████	██████████
Respiratory	GSP 304	LAMA	COPD	██████████	██████████	██████████	██████████	██████████
Respiratory	GBR 310	Biosimilar	Asthma, CIU	██████████	██████████	██████████	██████████	██████████
Pain	GRC 27864	mPGES-1	Chronic Pain	██████████	██████████	██████████	██████████	██████████

Source: Company, Macquarie Research, October 2017

**Fig 7 Filing timelines of the pipeline**

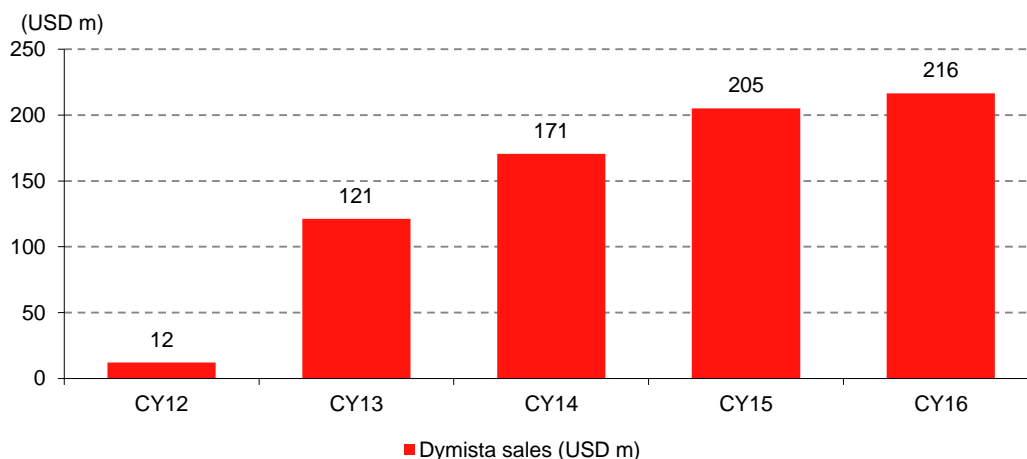
Therapy Area	Molecule	Status	Filing Timelines (NDA/BLA)				
			2019	2020	2021	2022	2023 and Beyond
Respiratory	GSP 301	Phase 3	✓				
	GSP 304	Phase 2	✓				
	GBR 310	Pre Clinical		✓			
	GRC 388XX	Pre Clinical					✓
Dermatology	GBR 830	Phase 2				✓	
Oncology	GBR 1302	Phase 1				✓	
	GBR 1342	Pre Clinical					✓
	GBR 1372	Pre Clinical					✓
	GBR 8383	Pre Clinical					✓

Source: Company, Macquarie Research, October 2017

### GSP 301: Could be a US\$70-80m peak revenue opportunity

In March 2017, GNP announced positive results from a Phase 3 trial of Mometasone/Olopatadine fixed-dose combination (GSP 301), a nasal spray used for the treatment of Seasonal Allergic Rhinitis. Glenmark plans to submit a 505(b)(2) NDA in early CY18, with launch likely in FY19. Dymista (a combination of azelastine and fluticasone) launched in 2012, had annual US sales of ~US\$180m in CY16.

- Could be a US\$70-80m opportunity at peak:** Currently, there are limited FDA-approved combination treatments for seasonal allergic rhinitis. In addition, the number of people affected is steadily growing. As per latest data, over 17m adults and 6m children in the US are affected by seasonal allergic rhinitis every year. As of Jan-17, as per IMS data, annual value of the US nasal spray market was US\$1.3bn. We expect GNP to launch the product in FY19 with a contract sales force. In our view, GNP will also be looking to launch this product in other geographies, which would bring in additional revenues.
- Phase 3 data:** The GSP 301 trial, consisting of a large sample size of 1,176 adults and adolescents, demonstrated statistically significant and clinically meaningful improvement from baseline, compared to placebo (p<0.001), olopatadine (p=0.028), and mometasone (p=0.019). All investigational treatments administered in the trial were well-tolerated, and showed no meaningful differences in reported adverse events (AEs) across study arms. The most common AE occurring in at least 2% of patients was dysgeusia (distortion of sense of taste).

**Fig 8 Annual global secondary sales of Dymista**

Source: Symphony data, Macquarie Research, October 2017

### GBR 310: First biosimilar in clinical trials

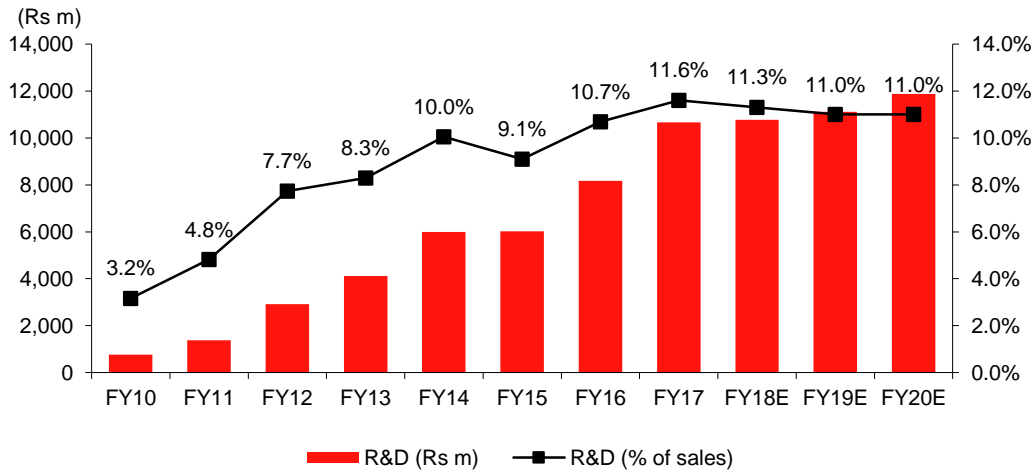
GNP initiated clinical investigation for GBR 310, its biosimilar candidate for XOLAIR (Omalizumab) in April 2017. This is the first biosimilar coming from GNP's stable and lies within the company's expertise domain of respiratory and derma. As per GNP, GBR 310 has the potential to be amongst the first biosimilar candidates to be submitted for approval for a respiratory or allergic disease. According to IMS sales data for MAT February 2017, annual sales of the XOLAIR 150 mg injection was ~US\$1.7bn in the US. At present, there is no other competition to XOLAIR in the market or in the filing process. **We believe this product could be a US\$200-250m product for GNP at peak.**

- **Biosimilar candidate for XOLAIR:** The US FDA has cleared GNP's Investigational New Drug (IND) application to initiate a first-in-human study of GBR 310, a proposed biosimilar. GBR 310 will assess its pharmacokinetics in healthy adult volunteers between 18 – 65 years of age. GBR 310 is a recombinant DNA-derived humanized immunoglobulin G1 kappa monoclonal antibody. Roche's XOLAIR US sales in CY16 reported a strong 15% YoY growth to reach US\$1.5bn. We believe GNP will need to invest ~US\$80-100m over the next 3 years. GNP has indicated that it proposes to file this molecule by CY20. The product is being developed at GNP's in-house biologics centre.
- **What will GBR310 treat?** GBR310's current proposed indication is for the treatment of allergic asthma and chronic idiopathic urticaria. XOLAIR is an injectable prescription medicine used to treat: (i) moderate to severe persistent asthma in patients 6 years of age or older whose asthma symptoms are not controlled by inhaled corticosteroids and (ii) chronic idiopathic urticaria (chronic hives without a known cause) in patients 12 years of age and older who continue to have hives that are not controlled by antihistamine treatment.

### GBR 830: Out-licensing deal likely in FY18

The molecular target of GBR 830 is to inhibit pathologically activated T cells and effector memory T cells, which are involved in a variety of autoimmune and chronic inflammatory disorders. The lead indication being evaluated for GBR 830 is moderate-to-severe atopic dermatitis. Glenmark is targeting a BLA filing for GBR 830 in 2022. Atopic dermatitis is the most common inflammatory skin disease, affecting up to 3% of the adult population and its prevalence has increased 2-3 fold over the last 100 years. In August 2017, GNP reported positive data from a Phase 2a study of GBR 830. In this Phase 2a study, a total of 31 patients were evaluated following the last study visit. Patients were assessed on multiple endpoints after receiving two doses with two viable biopsies. In the GBR 830 cohort, 17 out of 23 patients experienced at least a 50% reduction in their Eczema Area and Severity Index (EASI) score at day 57 compared to baseline, a key secondary endpoint of the study. The most common treatment-related adverse event was headache, with no clinically meaningful differences between GBR 830 and placebo.

**Fig 9 R&D spends have increased substantially for GNP**

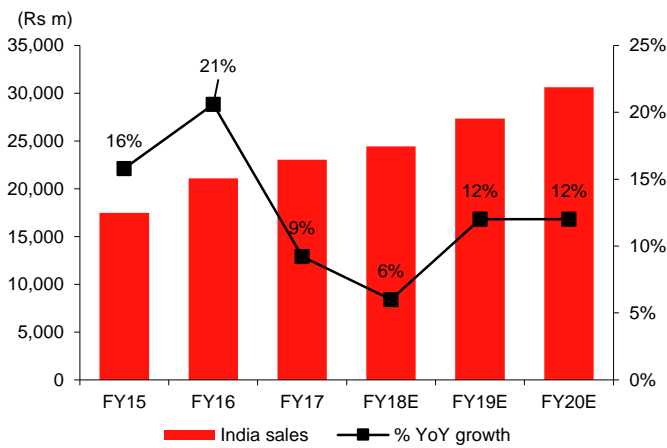


Source: Company data, Macquarie Research, October 2017

**Fairly steady in non-US geographies**

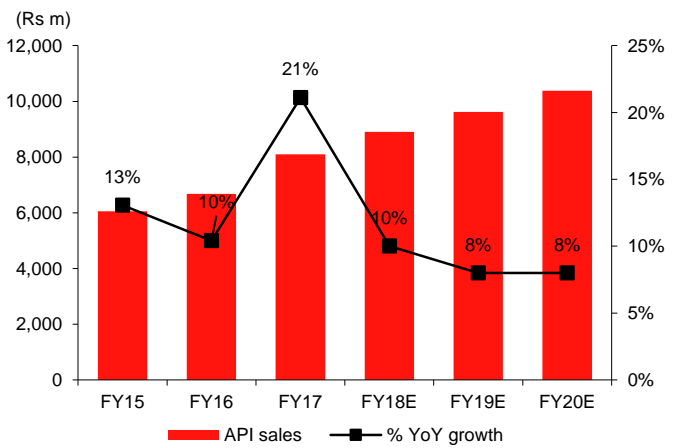
Barring the near-term disruption due to GST implementation in 2QFY18 (strong 15.2% YoY growth in 1QFY18 was largely due to channel filling) and any regulatory action, we expect GNP's India growth to be at 12% YoY each in FY19 and FY20. Growth is likely to remain in the range of 10-12% in both Europe and ROW. After a disappointing couple of years in the LatAm market, GNP is looking to break even in this market (ex-Venezuela) in FY18.

**Fig 10 Annual India sales**



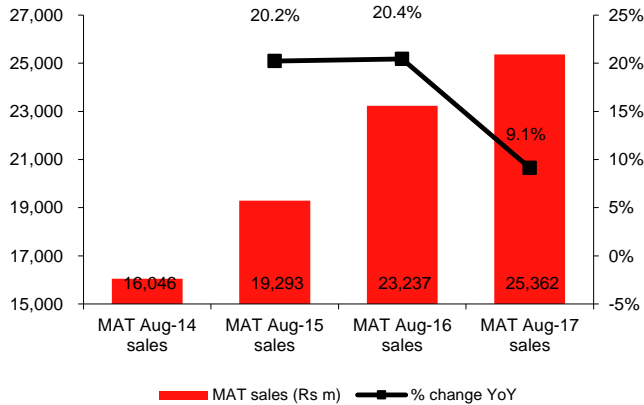
Source: Company data, Macquarie Research, October 2017

**Fig 11 Annual API sales**



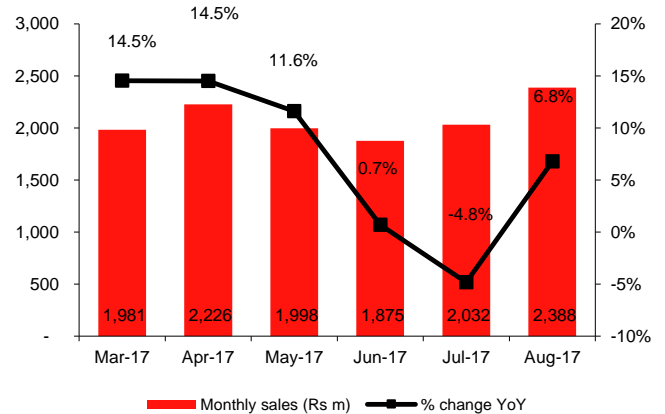
Source: Company data, Macquarie Research, October 2017

**Fig 12 GNP - India MAT sales (August 2017)**



Source: IMS data, Macquarie Research, October 2017

**Fig 13 GNP India monthly sales (August 2017)**



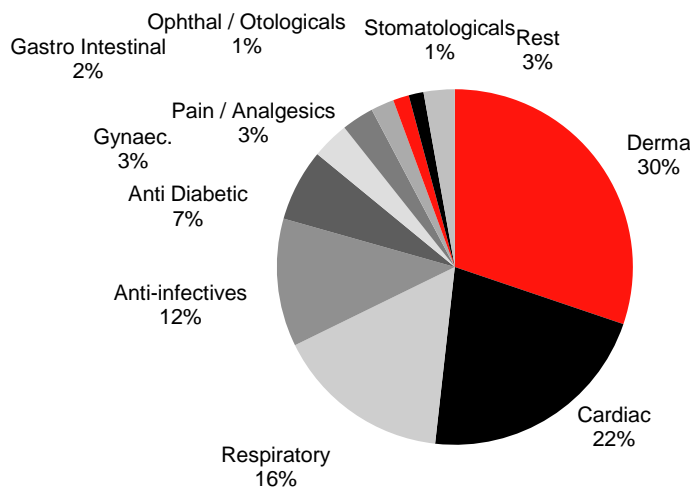
Source: IMS data, Macquarie Research, October 2017

**Fig 14 Key therapeutic drivers in India – Derma, Respiratory & Cardiac driving growth**

(Rs m)	MAT sales				MAT sales growth (YoY)		
	MAT Aug-14 sales	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	Aug-15	Aug-16	Aug-17
Derma	4,056	5,012	6,418	7,661	23.6%	28.0%	19.4%
Cardiac	3,592	4,136	4,962	5,468	15.1%	20.0%	10.2%
Respiratory	2,347	2,871	3,607	4,054	22.4%	25.6%	12.4%
Anti-infectives	2,333	2,740	3,166	2,952	17.5%	15.5%	-6.8%
Anti Diabetic	1,128	1,629	1,750	1,663	44.4%	7.4%	-5.0%
Gynaec.	664	683	754	861	2.8%	10.5%	14.1%
Pain / Analgesics	609	677	801	742	11.3%	18.2%	-7.3%
Gastro Intestinal	332	421	490	535	26.8%	16.4%	9.2%
Ophthal / Otologicals	276	326	346	367	18.0%	6.0%	6.1%
Stomatologicals	269	288	325	343	7.1%	13.0%	5.5%

Source: IMS data, Macquarie Research, October 2017

**Fig 15 GNP therapeutic split in India – Derma, Cardiac & Respiratory are key focus areas (August 2017)**



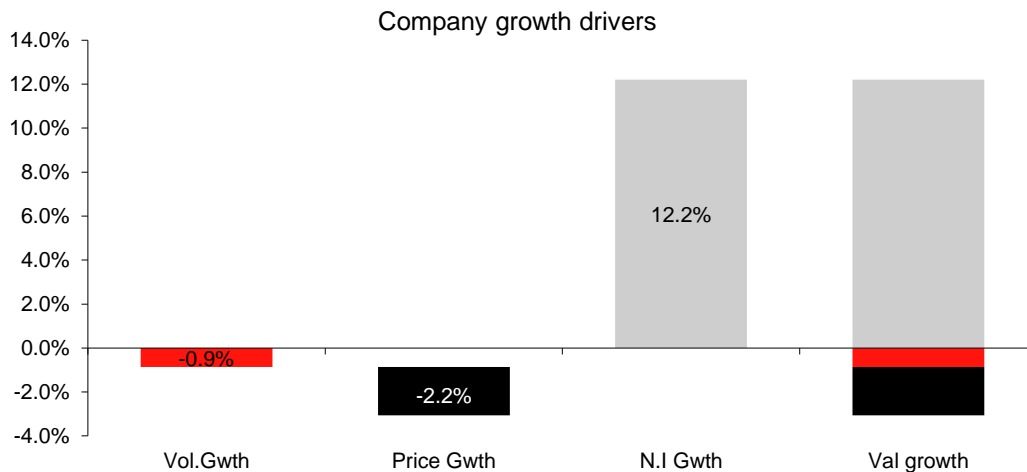
Source: : IMS data, Macquarie Research, October 2017

**Fig 16 GNP top 25 brands - contribute ~55% of total India sales, and increased ~17% YoY (MAT Aug-2017)**

	MAT sales				MAT sales growth (YoY)		
	MAT Aug-14 sales	MAT Aug-15 sales	MAT Aug-16 sales	MAT Aug-17 sales	Aug-15	Aug-16	Aug-17
TELMA	1,290	1,457	1,845	1,731	13.0%	26.6%	-6.2%
TELMA-H	950	1,070	1,235	1,476	12.5%	15.5%	19.5%
CANDID	551	671	880	980	21.8%	31.1%	11.3%
CANDID-B	690	749	892	949	8.4%	19.2%	6.3%
ASCORIL +	773	812	941	931	5.0%	15.9%	-1.0%
TELMA-AM	442	537	650	819	21.4%	21.1%	26.0%
ASCORIL-LS	274	419	602	752	53.0%	43.7%	24.9%
ONABET	143	261	424	493	82.8%	62.4%	16.2%
ZITA-MET PLUS	-	-	242	479	NA	NA	97.9%
ASCORIL-D	-	71	329	470	NA	360.6%	42.7%
CANDITRAL	139	201	277	415	44.7%	37.5%	49.9%
ALEX	-	4	14	407	NA	224.3%	2908.2%
SYNTRAN	0	69	170	359	50575.2%	146.8%	111.6%
BON-K2	213	275	351	338	28.6%	27.7%	-3.5%
MOMATE	219	262	295	338	19.5%	12.8%	14.5%
CANDID MOUTH	250	267	303	321	6.6%	13.5%	5.9%
LIZOLID	311	335	333	313	7.9%	-0.7%	-5.9%
ZITA PLUS	-	33	303	312	NA	816.8%	2.9%
ALTACEF	233	300	338	304	28.5%	12.5%	-9.9%
COLY-MONAS	108	176	196	296	63.2%	11.5%	50.7%
MILIXIM	244	277	309	290	13.3%	11.7%	-6.2%
CANDIBIOTIC	223	269	276	278	20.7%	2.7%	0.6%
ZITEN-M	-	-	130	271	NA	NA	109.2%
TACROZ	177	197	237	260	11.6%	20.4%	9.5%
MILIBACT	135	202	278	254	49.8%	37.9%	-8.5%
Top 25 products as % of total sales	45.9%	46.2%	51.0%	54.6%			

Source: IMS data, Macquarie Research, October 2017

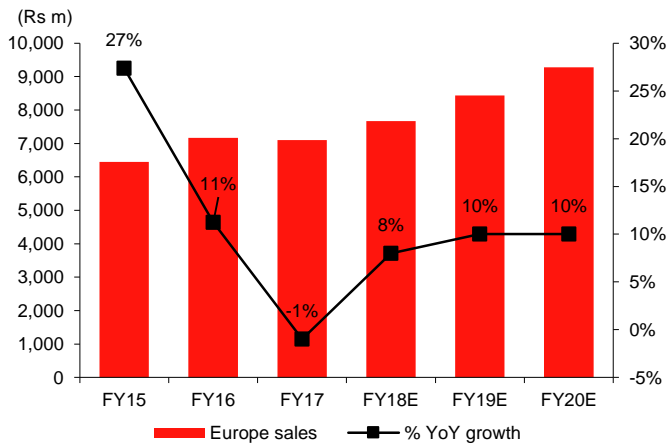
**Fig 17 GNP's domestic growth driven by new launches (MAT Aug-17)**



Source: IMS data, Macquarie Research, October 2017

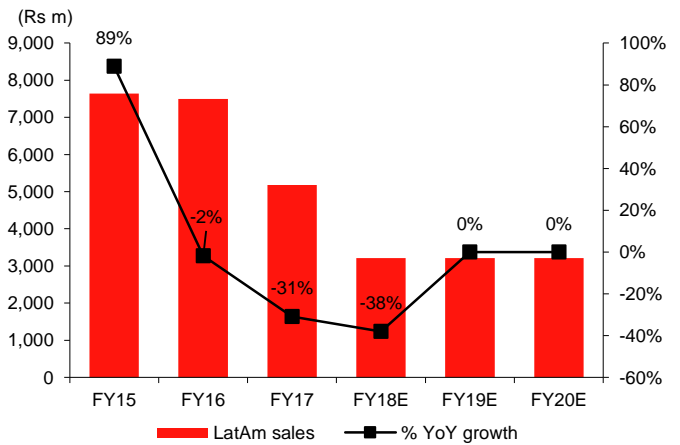


**Fig 18 Annual Europe sales**



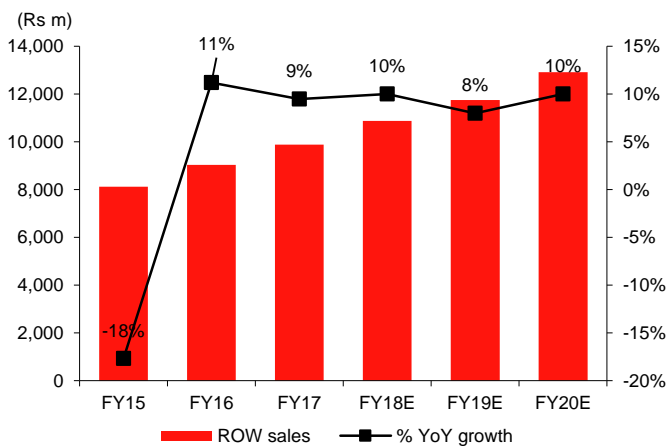
Source: Company data, Macquarie Research, October 2017

**Fig 19 Annual LatAm sales**



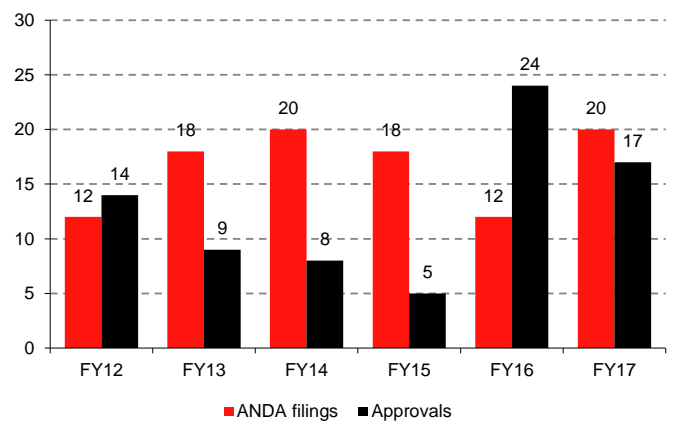
Source: Company data, Macquarie Research, October 2017

**Fig 20 Annual ROW sales**



Source: Company data, Macquarie Research, October 2017

**Fig 21 New launches are expected to pick up**

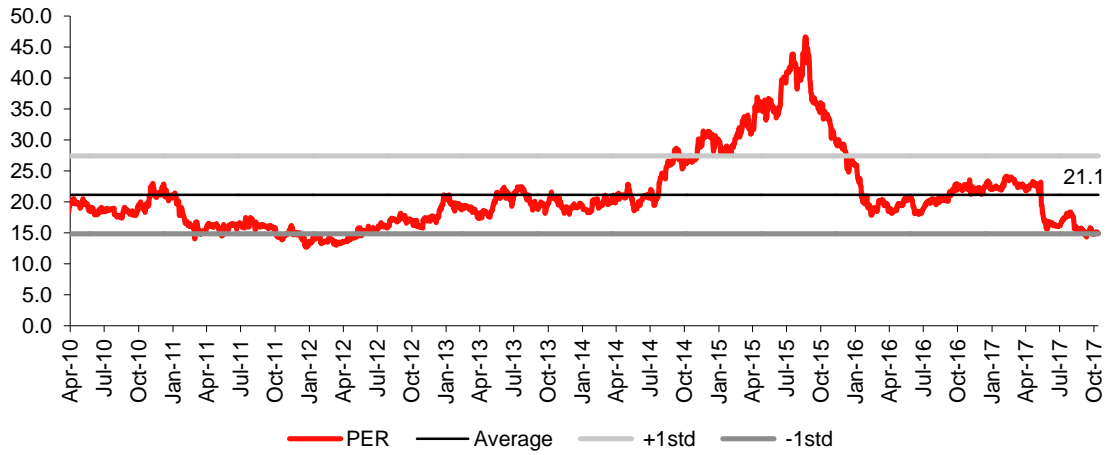


Source: Company data, Macquarie Research, October 2017

**We assign GNP a lower multiple vs peers**

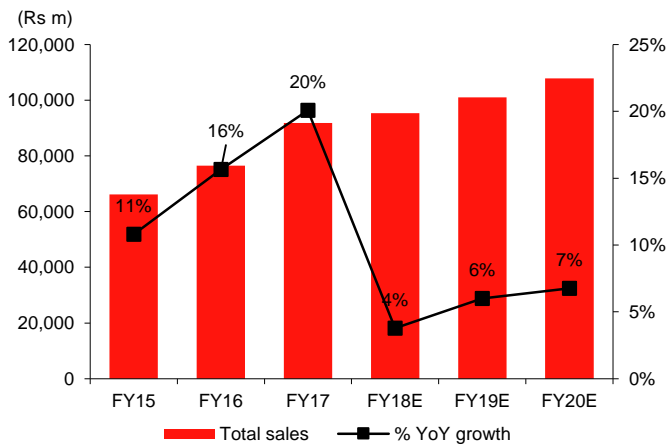
The lack of meaningful free cash generation due to a high cash tax payout and elevated working capital remain investor concerns. FY18 and FY19 R&D is likely to remain high at ~11% of sales. A high cash balance at meagre 1-1.5% yields remain a drag. In the absence of out-licensing deals, we expect free cash generation will continue to be suppressed. We assign a 16x FY19E PER multiple to GNP (in line with its average PER multiple during FY11-14) to reflect these concerns. At CMP, we believe there is significant valuation comfort. We rate the stock 'Outperform' with a TP of Rs728.

**Fig 22 GNP trading at 1 standard deviation below mean**



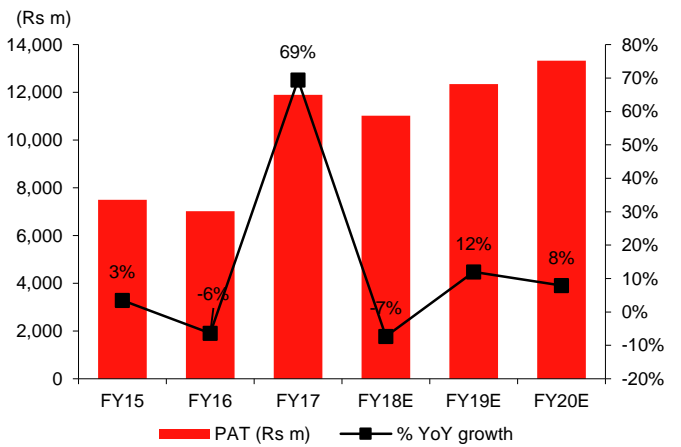
Source: Bloomberg, Macquarie Research, October 2017

**Fig 23 GNP's annual total sales**



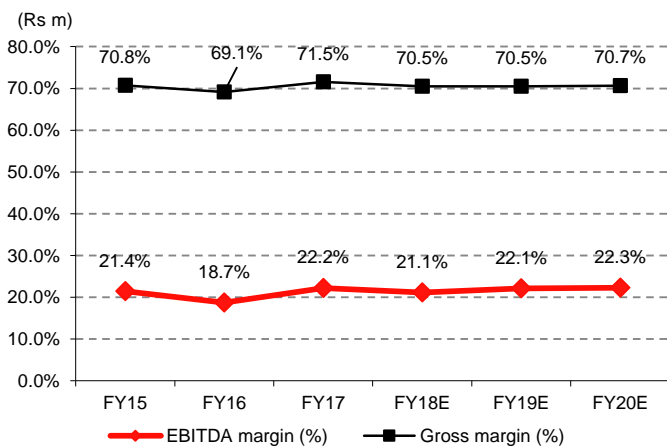
Source: Company data, Macquarie Research, October 2017

**Fig 24 GNP's annual PAT trend**



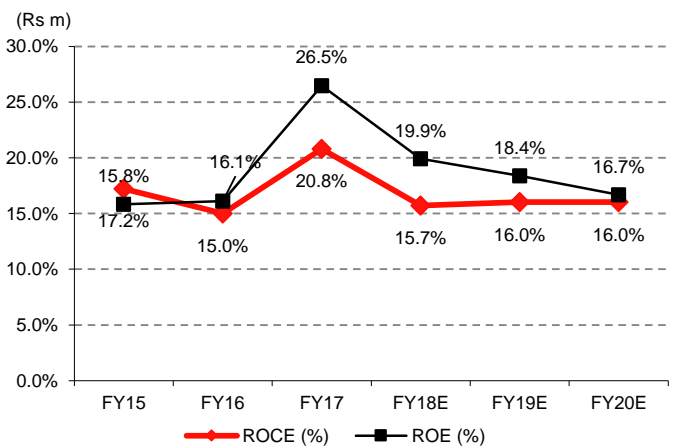
Source: Company data, Macquarie Research, October 2017

**Fig 25 Gross and EBITDA margin trend**



Source: Company data, Macquarie Research, October 2017

**Fig 26 Return ratio profile**



Source: Company data, Macquarie Research, October 2017

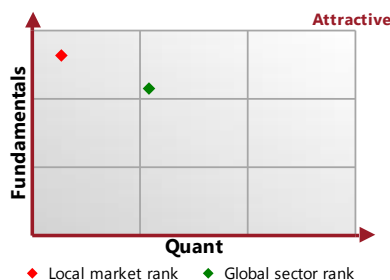
## Macquarie Quant View

The quant model currently holds a strong negative view on Glenmark Pharmaceuticals. The strongest style exposure is Profitability, indicating this stock is efficiently converting investments to earnings; proxied by ratios like ROE or ROA. The weakest style exposure is Price Momentum, indicating this stock has had weak medium to long term returns which often persist into the future.

**556/868**

Global rank in  
Pharma, Biotech & Life Sciences

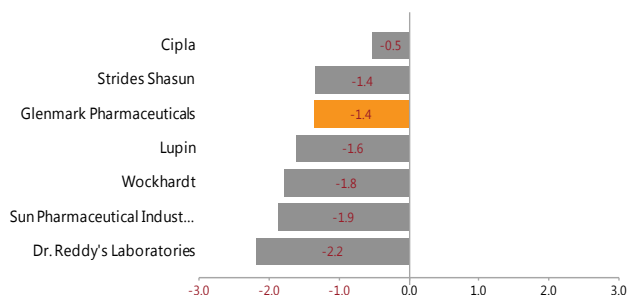
**% of BUY recommendations** 46% (13/28)  
**Number of Price Target downgrades** 4  
**Number of Price Target upgrades** 1



Displays where the company's ranked based on the fundamental consensus Price Target and Macquarie's Quantitative Alpha model.  
Two rankings: Local market (India) and Global sector (Pharma, Biotech & Life Sciences)

## Macquarie Alpha Model ranking

A list of comparable companies and their Macquarie Alpha model score (higher is better).



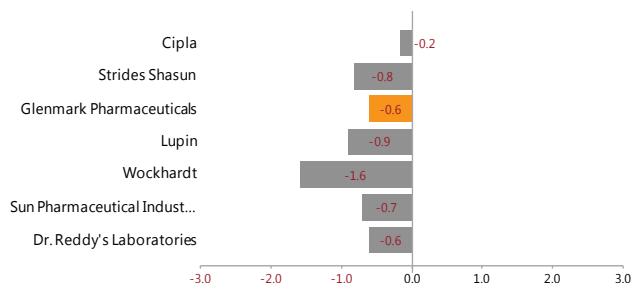
## Factors driving the Alpha Model

For the comparable firms this chart shows the key underlying styles and their contribution to the current overall Alpha score.



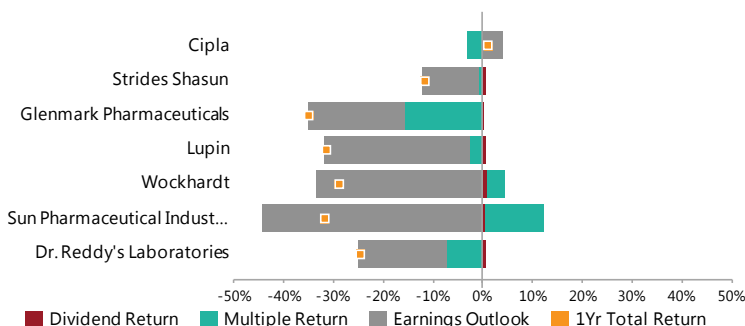
## Macquarie Earnings Sentiment Indicator

The Macquarie Sentiment Indicator is an enhanced earnings revisions signal that favours analysts who have more timely and higher conviction revisions. Current score shown below.



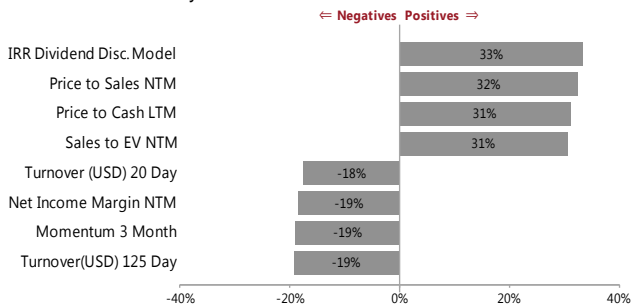
## Drivers of Stock Return

Breakdown of 1 year total return (local currency) into returns from dividends, changes in forward earnings estimates and the resulting change in earnings multiple.



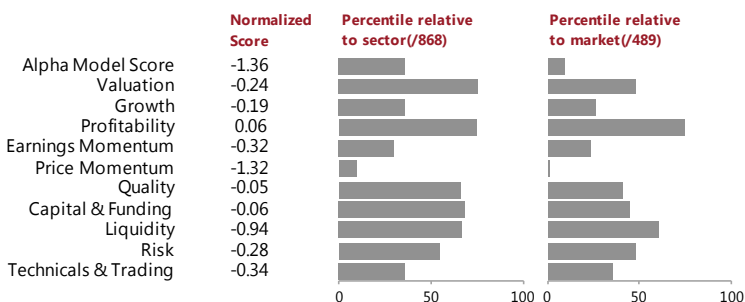
## What drove this Company in the last 5 years

Which factor score has had the greatest correlation with the company's returns over the last 5 years.



## How it looks on the Alpha model

A more granular view of the underlying style scores that drive the alpha (higher is better) and the percentile rank relative to the sector and market.



Source (all charts): FactSet, Thomson Reuters, and Macquarie Research. For more details on the Macquarie Alpha model or for more customised analysis and screens, please contact the Macquarie Global Quantitative/Custom Products Group ([cpq@macquarie.com](mailto:cpq@macquarie.com))

## Glenmark Pharmaceuticals (GNP IN)

Quarterly Results					Profit & Loss						
	1Q/18A	2Q/18E	3Q/18E	4Q/18E		2017A	2018E	2019E	2020E		
<b>Revenue</b>	m	22,877	23,830	23,830	24,783	<b>Revenue</b>	m	91,857	95,319	101,049	107,888
<b>Gross Profit</b>	m	16,128	16,800	16,800	17,472	<b>Gross Profit</b>	m	65,714	67,200	71,239	76,223
Cost of Goods Sold	m	6,749	7,030	7,030	7,311	Cost of Goods Sold	m	26,143	28,119	29,809	31,665
<b>EBITDA</b>	m	4,827	5,028	5,028	5,229	<b>EBITDA</b>	m	20,367	20,112	22,352	24,005
Depreciation	m	720	750	750	780	Depreciation	m	2,644	3,000	3,400	3,800
Amortisation of Goodwill	m	0	0	0	0	Amortisation of Goodwill	m	0	0	0	0
Other Amortisation	m	0	0	0	0	Other Amortisation	m	0	0	0	0
<b>EBIT</b>	m	4,107	4,278	4,278	4,449	<b>EBIT</b>	m	17,723	17,112	18,952	20,205
Net Interest Income	m	-552	-575	-575	-598	Net Interest Income	m	-2,373	-2,300	-2,300	-2,200
Associates	m	0	0	0	0	Associates	m	0	0	0	0
Exceptionals	m	0	0	0	0	Exceptionals	m	0	0	0	0
Forex Gains / Losses	m	0	0	0	0	Forex Gains / Losses	m	0	0	0	0
Other Pre-Tax Income	m	120	125	125	130	Other Pre-Tax Income	m	374	500	500	500
<b>Pre-Tax Profit</b>	m	3,675	3,828	3,828	3,981	<b>Pre-Tax Profit</b>	m	15,724	15,312	17,152	18,505
Tax Expense	m	-1,029	-1,072	-1,072	-1,115	Tax Expense	m	-3,827	-4,287	-4,803	-5,181
<b>Net Profit</b>	m	2,646	2,756	2,756	2,866	<b>Net Profit</b>	m	11,897	11,025	12,349	13,324
Minority Interests	m	0	0	0	0	Minority Interests	m	0	0	0	0
<b>Reported Earnings</b>	m	2,646	2,756	2,756	2,866	<b>Reported Earnings</b>	m	11,897	11,025	12,349	13,324
<b>Adjusted Earnings</b>	m	2,646	2,756	2,756	2,866	<b>Adjusted Earnings</b>	m	11,897	11,025	12,349	13,324
EPS (rep)		9.38	9.77	9.77	10.16	EPS (rep)		42.16	39.07	43.77	47.22
EPS (adj)		9.38	9.77	9.77	10.16	EPS (adj)		42.16	39.07	43.77	47.22
EPS Growth yoy (adj)	%	-7.3	-7.3	-7.3	-7.3	EPS Growth (adj)	%	69.4	-7.3	12.0	7.9
						PE (rep)	x	14.4	15.5	13.9	12.8
						PE (adj)	x	14.4	15.5	13.9	12.8
EBITDA Margin	%	21.1	21.1	21.1	21.1	Total DPS		2.00	2.00	2.00	2.00
EBIT Margin	%	18.0	18.0	18.0	18.0	Total Div Yield	%	0.3	0.3	0.3	0.3
Earnings Split	%	24.0	25.0	25.0	26.0	Basic Shares Outstanding	m	282	282	282	282
Revenue Growth	%	3.8	3.8	3.8	3.8	Diluted Shares Outstanding	m	282	282	282	282
EBIT Growth	%	-3.4	-3.4	-3.4	-3.4						
Profit and Loss Ratios					Cashflow Analysis						
	2017A	2018E	2019E	2020E		2017A	2018E	2019E	2020E		
Revenue Growth	%	20.1	3.8	6.0	6.8	<b>EBITDA</b>	m	20,367	20,112	22,352	24,005
EBITDA Growth	%	42.2	-1.3	11.1	7.4	Tax Paid	m	6,990	4,287	4,803	5,181
EBIT Growth	%	52.3	-3.4	10.8	6.6	Chgs in Working Cap	m	-8,615	-1,176	568	177
Gross Profit Margin	%	71.5	70.5	70.5	70.7	Net Interest Paid	m	-2,192	-2,300	-2,300	-2,200
EBITDA Margin	%	22.2	21.1	22.1	22.3	Other	m	4,005	0	0	0
EBIT Margin	%	19.3	18.0	18.8	18.7	<b>Operating Cashflow</b>	m	20,555	20,924	25,422	27,164
Net Profit Margin	%	13.0	11.6	12.2	12.3	Acquisitions	m	0	0	0	0
Payout Ratio	%	4.7	5.1	4.6	4.2	Capex	m	-7,334	-9,532	-9,600	-9,710
EV/EBITDA	x	10.2	10.3	9.3	8.6	Asset Sales	m	0	0	0	0
EV/EBIT	x	11.7	12.1	10.9	10.3	Other	m	211	500	500	500
						<b>Investing Cashflow</b>	m	-7,123	-9,032	-9,100	-9,210
<b>Balance Sheet Ratios</b>					Dividend (Ordinary)	m	-678	-564	-564	-564	
ROE	%	31.5	22.0	20.2	18.2	Equity Raised	m	3	0	0	0
ROA	%	16.9	14.0	13.7	13.5	Debt Movements	m	7,943	0	0	0
ROIC	%	21.7	15.1	15.3	15.3	Other	m	1,836	0	0	0
Net Debt/Equity	%	81.6	61.2	41.3	27.4	<b>Financing Cashflow</b>	m	9,103	-564	-564	-564
Interest Cover	x	7.5	7.4	8.2	9.2						
Price/Book	x	3.8	3.1	2.5	2.2	<b>Net Chg in Cash/Debt</b>	m	22,535	11,328	15,758	17,389
Book Value per Share		159.2	196.3	238.1	279.8	<b>Free Cashflow</b>	m	13,221	11,392	15,823	17,454
						Balance Sheet					
							2017A	2018E	2019E	2020E	
						Cash	m	10,564	13,317	19,470	25,623
						Receivables	m	24,043	36,943	36,428	35,913
						Inventories	m	21,391	19,001	18,736	18,472
						Investments	m	157	157	157	157
						Fixed Assets	m	24,495	31,027	37,227	43,426
						Intangibles	m	479	479	479	479
						Other Assets	m	30,647	31,785	31,578	31,370
						<b>Total Assets</b>	m	111,776	132,709	144,075	155,440
						Payables	m	19,035	23,552	23,224	22,895
						Short Term Debt	m	1,872	1,872	1,872	1,872
						Long Term Debt	m	45,363	45,363	45,363	45,363
						Provisions	m	0	0	0	0
						Other Liabilities	m	584	6,541	6,449	6,358
						<b>Total Liabilities</b>	m	66,855	77,328	76,908	76,489
						Shareholders' Funds	m	44,925	55,386	67,171	78,956
						Minority Interests	m	-4	-4	-4	-4
						Other	m	0	0	0	0
						<b>Total S/H Equity</b>	m	44,921	55,381	67,167	78,952
						<b>Total Liab &amp; S/H Funds</b>	m	111,776	132,709	144,075	155,440

All figures in INR unless noted.

Source: Company data, Macquarie Research, October 2017

## INDIA

JUBILANT IN Outperform

Price (at 06:53, 18 Oct 2017 GMT) Rs635.80

<b>Valuation</b>	<b>Rs</b>	<b>900.00</b>
- PER		
<b>12-month target</b>	<b>Rs</b>	<b>900.00</b>
<b>Upside/Downside</b>	<b>%</b>	<b>+41.6</b>
<b>12-month TSR</b>	<b>%</b>	<b>+42.0</b>
<b>Volatility Index</b>		<b>High</b>

## GICS sector

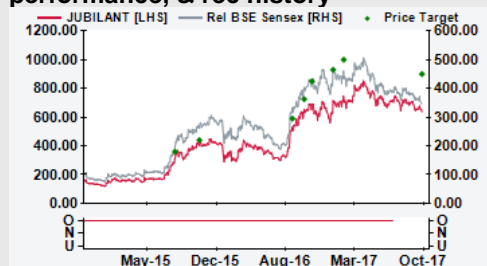
Pharmaceuticals, Biotechnology &amp; Life Sciences

<b>Market cap</b>	<b>Rsm</b>	<b>101,283</b>
<b>Market cap</b>	<b>US\$m</b>	<b>1,560</b>
<b>Free float</b>	<b>%</b>	<b>42</b>
<b>30-day avg turnover</b>	<b>US\$m</b>	<b>2.1</b>
<b>Number shares on issue</b>	<b>m</b>	<b>159.3</b>

## Investment fundamentals

Year end 31 Mar		2017A	2018E	2019E	2020E
Revenue	m	58,614	71,984	86,764	93,616
EBIT	m	10,539	12,044	14,256	15,827
EBIT growth	%	17.1	14.3	18.4	11.0
Recurring profit	m	7,376	9,332	11,993	14,002
Reported profit	m	5,757	6,719	8,635	10,081
Adjusted profit	m	5,757	6,719	8,635	10,081
EPS rep	Rs	36.91	43.08	55.37	64.64
EPS rep growth	%	64.6	16.7	28.5	16.8
EPS adj	Rs	36.91	43.08	55.37	64.64
EPS adj growth	%	47.2	16.7	28.5	16.8
PER rep	x	17.2	14.8	11.5	9.8
PER adj	x	17.2	14.8	11.5	9.8
Total DPS	Rs	3.00	3.00	3.00	3.00
Total div yield	%	0.5	0.5	0.5	0.5
ROA	%	11.8	13.7	16.0	16.1
ROE	%	18.0	17.9	19.4	18.9
EV/EBITDA	x	9.4	8.4	7.2	6.6
Net debt/equity	%	83.9	57.3	31.5	9.4
P/BV	x	2.9	2.4	2.0	1.7

## JUBILANT IN rel BSE Sensex performance, &amp; rec history



Note: Recommendation timeline - if not a continuous line, then there was no Macquarie coverage at the time or there was an embargo period.

Source: FactSet, Macquarie Research, October 2017

(all figures in INR unless noted)

## Analyst(s)

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+91 22 6720 4134 alankar.garude@macquarie.com

23 October 2017

Macquarie Capital Securities India (Pvt) Ltd

# Jubilant Life Sciences

## Specialty biz to lend predictability

### Conclusion

- Jubilant Life Sciences' (Jubilant) differentiated US business model makes it relatively better placed to tackle pricing erosion vs other Indian pharma peers. With a focus on specialty (radiopharma, CMO and allergy), tailwinds from its Life Science Ingredients (LSI) business, and lower interest costs, we believe Jubilant is well poised to deliver a strong ~21% EPS CAGR over FY17-20. Jubilant's free cash generation has seen an uptick, which has led to Rs9bn debt reduction over the last two years. As specialty's EBITDA contribution increases, we expect EBITDA margins and free cash generation to continue to ramp up. Financial discipline with expanding pharma contribution is a key positive. We initiate coverage of Jubilant as one of our top picks, with an Outperform rating and Rs900 target price.

### Impact

- Unfolding specialty business to drive EBITDA:** We expect radiopharma to be a key driver, led by ramp-up of the current portfolio and launch of niche high-value generics. We expect the Triad acquisition to strengthen Jubilant's radiopharma franchise, given it is the second-largest network in the US, with a 20-25% market share. We believe Ruby-fill (commercially launched in 1Q) has the potential to be Jubilant's first US\$100m product by FY21, a key lever for medium-term growth. Also, there is visibility for the launch of new products (Exametazime and I-131 MIBG), which provides comfort for long-term growth. The CMO order-book stands at ~US\$630m, providing sales visibility over 4-5 years, which should further drive EBITDA growth momentum.
- Upturn in the LSI business a positive:** We expect the cyclical LSI business, which is currently witnessing strong tailwinds, to report 13% YoY growth in FY18 and 12% growth in FY19, led by price hikes in vitamins (led by short supply of Beta) and new product launches from the retrofitted Symtet facility. Debt in the LSI business at ~Rs12.5bn (including Rs5-6bn of working capital debt) remains high. Over the next five years, Jubilant aims to reduce LSI debt and lower the contribution of LSI to less than 20% of EBITDA.
- Pressure in the generics business is the only blemish:** Jubilant's solid dosage sales were US\$130m in FY17. Out of this, US\$85-90m sales were from the US. While Jubilant has maintained volumes, US pricing is under pressure. However, we note that Jubilant's US formulations business is much smaller than peers'. We expect Jubilant's non-US dosage business to grow at ~10%, while the US dosage business is expected to be flattish in FY18.

### Earnings and target price revision

- We initiate coverage at Outperform with a TP of Rs900 at 15x Sept-19 EPS.

### Price catalyst

- 12-month price target: Rs900.00 based on a PER methodology.
- Catalyst: 1) Rubi-fill ramp-up 2) FCF generation 3) new approvals

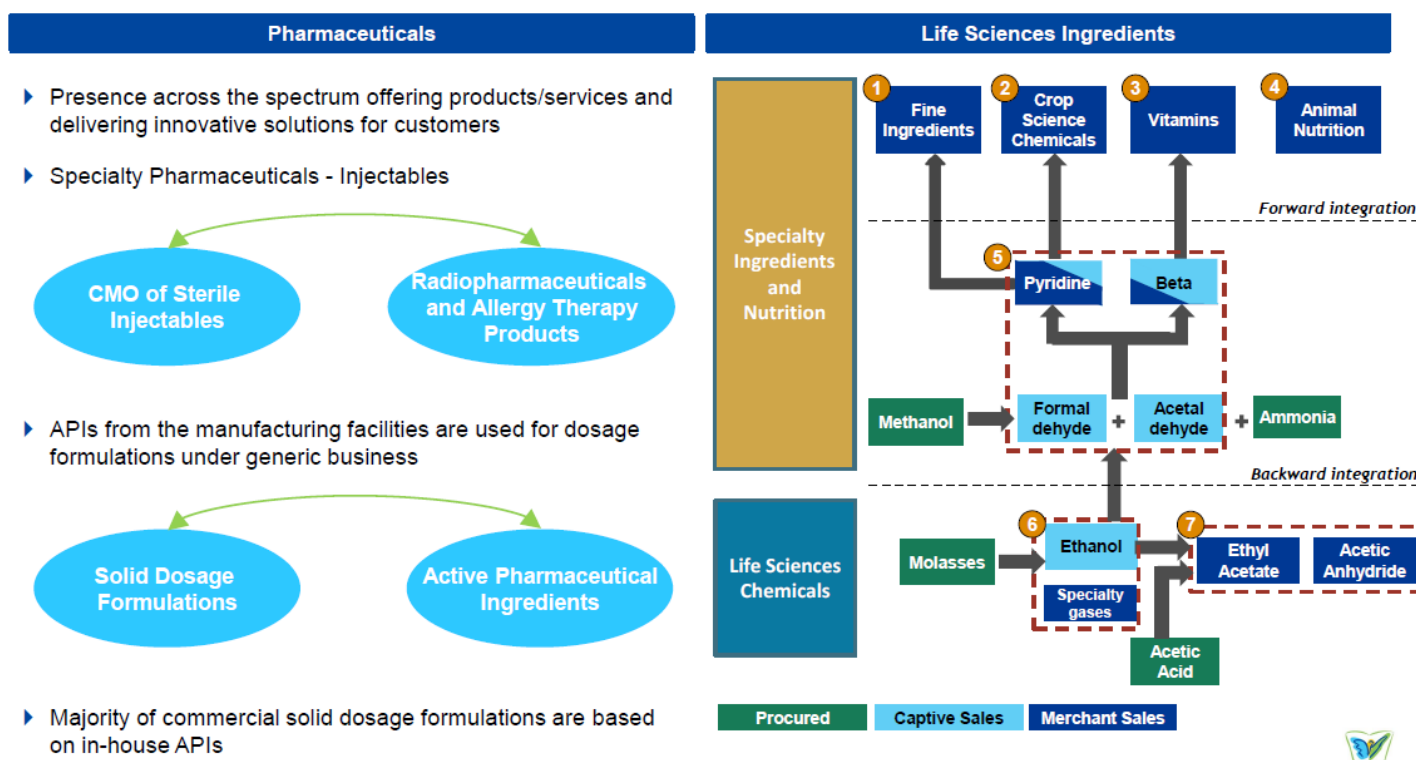
### Action and recommendation

- In our view, improving free cash generation is an encouraging sign. The company also has a strong US FDA compliance record. We expect re-rating to continue and believe current weakness provides an attractive entry point.

### Jubilant's business structure has evolved considerably

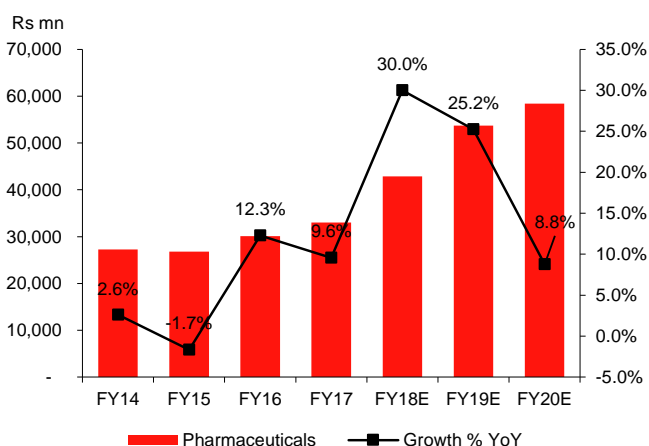
From a company which started out having presence only in the life sciences segment, Jubilant has evolved its pharma business successfully, especially in the last 5-6 years. We note that the company has taken conscious steps to increase the contribution of the high-margin pharma business in the overall mix. The contribution of pharma to overall profitability has risen almost 2.5x in the past six years. Thus, compared to the 26% contribution to overall EBITDA in FY11, the pharma segment contributed ~68% to overall EBITDA in FY17.

Fig 1 Jubilant's business structure



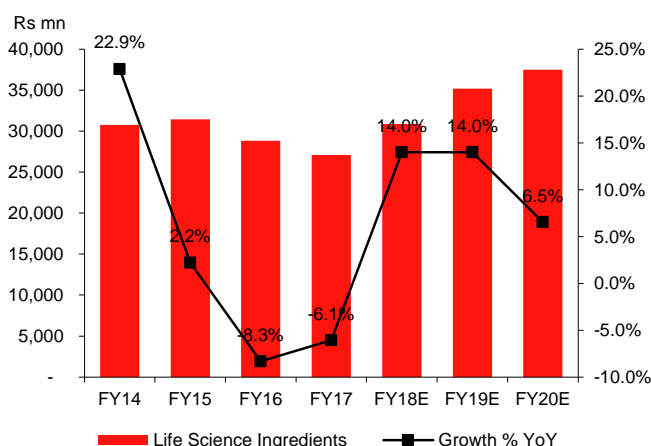
Source: Company data, Macquarie Research, October 2017

Fig 2 Pharma annual revenues



Source: Company data, Macquarie Research, October 2017

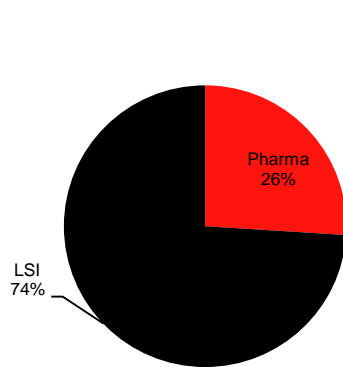
Fig 3 LSI annual revenues



Source: Company data, Macquarie Research, October 2017

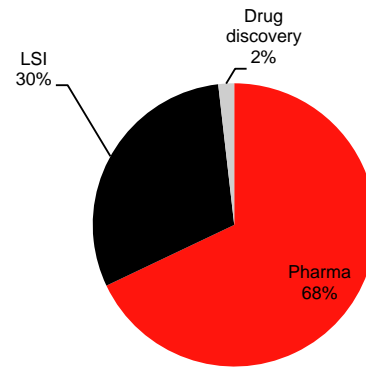
Going forward, we expect the EBITDA contribution of the pharma business to increase further as the specialty business (CMO/radiopharma) gains momentum.

**Fig 4 Contribution of Pharma to EBITDA in FY11**



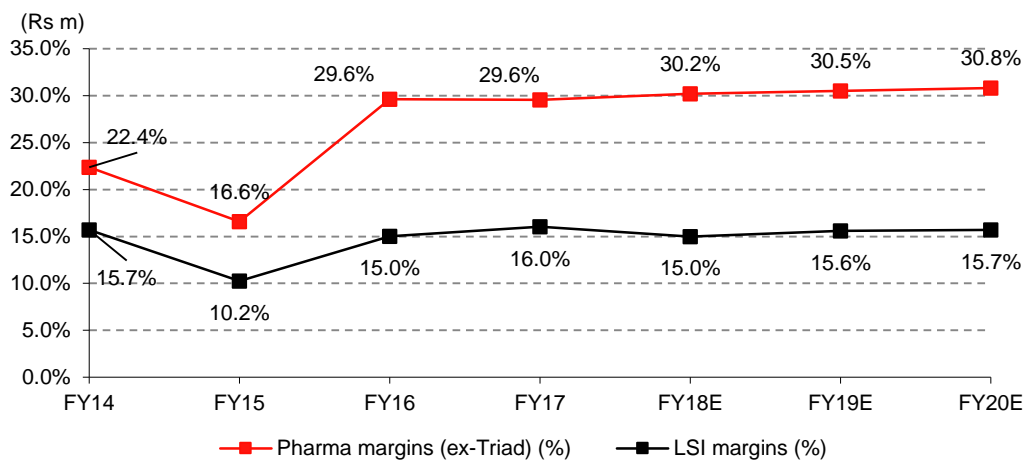
Source: Company data, Macquarie Research, October 2017

**Fig 5 Contribution of Pharma to EBITDA in FY17**



Source: Company data, Macquarie Research, October 2017

**Fig 6 Margin profile: Pharma (ex-Triad) and LSI segments**

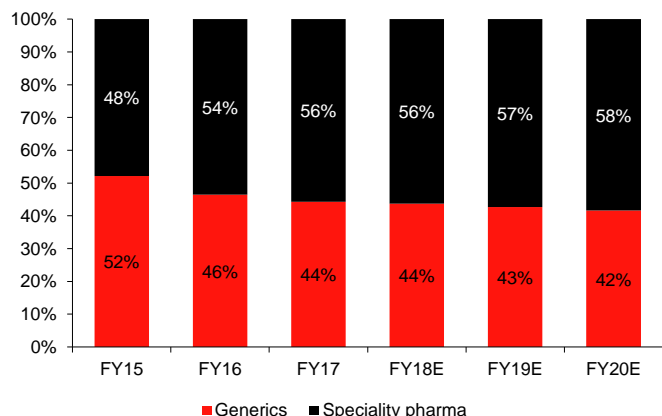


Source: Company data, Macquarie Research, October 2017

**Unfolding specialty pharma business to drive EBITDA (ex-Triad)**

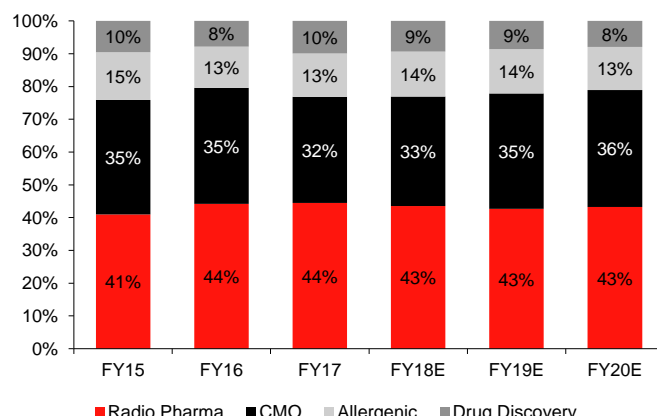
Jubilant’s specialty business is entirely based in North America in the sterile injectables space. The three key components of Jubilant’s specialty business are radiopharma, allergy and CMO. The allergy business achieved revenues of US\$35-40m in FY17. This is a B2C business with only three players in the US. Jubilant’s radiopharma business reported ~US\$120m revenues in FY17. The overall size of the US radiopharma industry is US\$1-1.2bn and it is growing at 3-5% YoY. It is a niche business segment, with a different value chain. There are two parts of the radiopharma industry in the US: (i) Single-Photon Emission Computed Tomography (SPECT) – higher volume, flattish growth; and (ii) Positron Emission Tomography (PET) – small volumes, growing market. We expect Jubilant’s radiopharma business to be a key growth driver, led by the ramp-up of the current portfolio and launch of niche high-value products every year from FY17.

**Fig 7 Contribution of specialty to rise**



Source: Company data, Macquarie Research, October 2017

**Fig 8 Within specialty pharma, radio pharma is a key growth driver**



Source: Company data, Macquarie Research, October 2017

**Rubyfill can reach US\$100m revenues at peak in FY21**

In FY17, Jubilant announced US FDA approval of Rubyfill for its New Drug Application (NDA) pursuant to section 505 (b) (2) filing. This approved NDA provides for the use of Rubyfill for PET imaging of the myocardium. The US market for the drug was US\$75m in 2016, and there is at present only one company, Bracco, which is unable to fully meet demand and arguably has an inferior profile than Jubilant’s product. Jubilant is forecasting the market to reach US\$250m in five years. We note that in the absence of relationships with hospitals, Rubyfill has been slow off the block. Also, Rubyfill can mainly get an entry once Bracco’s existing contracts expire. With the Triad acquisition, we expect an improved ramp-up of Rubyfill starting 2HFY19. We believe Rubyfill has the potential to be Jubilant’s first US\$100m product at peak in FY21, a key lever for medium-term growth for radiopharma. We expect Rubyfill to achieve US\$5m sales in FY18, with a ramp-up to US\$25m in FY19. As of now, there are no other filers for Rubyfill.

**Triad will be important to drive radiopharma sales in US, including Rubyfill**

In FY17, Jubilant announced the acquisition of the radiopharmacy business of Triad Isotopes. Triad operates the second-largest radiopharmacy network in the US, with more than 50 pharmacies distributing nuclear medicine products nationwide. In our view, this acquisition fits well with Jubilant’s existing niche nuclear medicine business and facilitates forward integration with direct access to hospital networks. Following the acquisition, Jubilant will have the ability to deliver more than 3m patient doses annually through ~1,700 clients. We believe Triad will help provide requisite marketing push to Jubilant’s 505(b)(2) pipeline. Triad has ~US\$200m annual revenues with ~5% estimated EBITDA margins (consolidated in financials from 1<sup>st</sup> September, 2017). Currently ~30-40% of Jubilant’s radiopharma sales in the US are through the network of Triad. Given Triad was a stressed asset in our view, Jubilant has been able to negotiate a sweet deal for themselves from the lenders. Jubilant expects to fund the acquisition through internal accruals, with miniscule impact on net debt levels; hence we believe overall outlay for the acquisition will be <US\$30-35m. Jubilant is guiding that the acquisition will be earnings-accretive in the first full year of operations.

Additionally, there is visibility on the launch of new specialty products in the pipeline (Exametazime and I-131 MIBG), which could provide comfort on the long-term growth of the business. Jubilant currently has six products in the market, with the top three contributing a large part of the revenue: (i) MAA (lung ventilation scan); (ii) I131 (thyroid diagnosis & treatment); and (iii) DTPA (renal & lung imaging). Jubilant has a strong pipeline of such drugs, with current market size ~US\$800m. These include:

- **Exametazime (generic Ceretec):** 505 (b) (2) filing with the USFDA, with launch expected in 2HFY18. Product used for brain imaging and Jubilant claims superior scan quality. We estimate >US\$25m sales at peak.
- **I-131 MIBG:** US FDA has granted orphan drug status with eligibility for accelerated approval for this NDA. Indicated for paediatric Neuroblastoma treatment. Enrolment for a 65-patient pivotal phase II trial is expected in H2 FY17, with fast-track approval post this trial likely in FY19. Market size for I-131 MIBG is pegged at US\$100m as off-label use already prevalent.



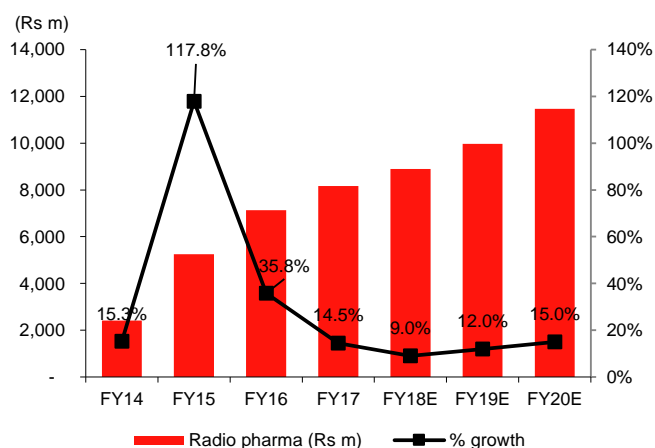
**Long term specialty business contracts lend visibility**

Jubilant has signed long-term contracts with all key distribution networks in the US for its specialty pharma business effective for 39 months from January 2017. We believe this provides growth visibility to the current specialty base business in the US. More importantly, this sets the near to medium-term base for this business. We note that Rubyfill is not part of these contracts, as distributors bring in limited expertise for this product.

**CMO business ramp-up largely on track to reach pre-warning letter peak**

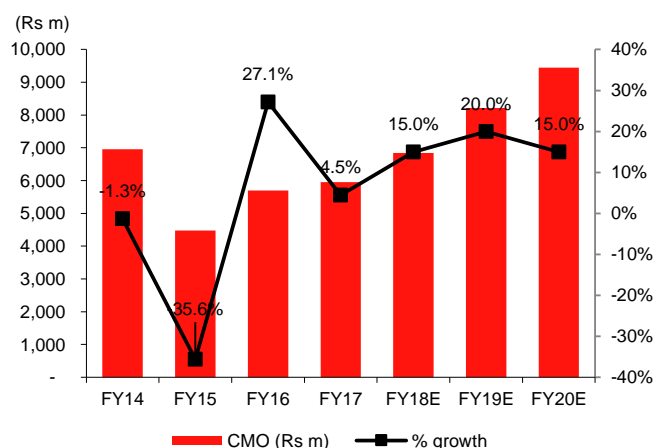
Jubilant's CMO revenues had fallen from a peak of ~US\$130m to ~US\$70m, with margins falling from ~22% to sub 10% in FY15 driven by warning letter (WL) at its facility. Post resolution of the WL at the facilities, Jubilant has started seeing steady ramp-up of its sterile CMO sales (~US\$95m in FY17). As sales revert to the earlier peak, we expect operating leverage in CMO business to help drive EBITDA growth momentum. Since Jubilant's CMO facilities are located in North America, Jubilant gains on faster transportation and higher trust. A shortage of CMO injectable sites has led to Jubilant signing new contracts at higher prices. The CMO orderbook stands at ~US\$630m, providing sales visibility over 4-5 years, which should further drive EBITDA growth momentum.

**Fig 9 Radiopharma revenue forecasts**



Source: Company data, Macquarie Research, October 2017

**Fig 10 CMO revenue forecasts**



Source: Company data, Macquarie Research, October 2017








**Pressure in the generics business is a worry**

Jubilant's solid dosage sales are US\$130m. Out of this, ~US\$85-90m sales are from the US. While Jubilant has maintained volumes, pricing in the US is under pressure. However, we note that Jubilant's US formulations business is much smaller than peers. We expect Jubilant's non-US dosage business to grow at ~10%, while the US dosage business is expected to be flattish in FY18. The company has 30 pending ANDAs. On the API side, growth was restricted in FY17, largely due to capacity constraints. The top eight products contribute ~60% to API business, with margins at ~35% due to economics of scale. Jubilant is looking to file ten ANDAs in FY18. FY18 R&D is expected to remain steady at 8.5% of pharma sales.

### Upturn in the LSI business a positive

We expect the cyclical LSI business, which is currently seeing strong tailwinds, to report 14% YoY growth each in FY18 and FY19, led by price hikes in vitamins (led by short supply of Beta) and new product launches from the retrofitted Symtet facility. Debt in the LSI business at ~Rs12.5bn (including Rs5-6bn of working capital debt) is high. Over the next five years, Jubilant aims to lower the contribution of LSI to less than 20% of EBITDA. Jubilant expects capacity utilisation to improve in the LSI business as they convert the failed Symtet plant into a multi-purpose unit, from which a new product is likely to be launched in the next 1-2 months. ~40% of the LSI business (life science chemicals) is purely commoditized, while ~60% (specialty ingredients and nutrients) is built around the Pyridine architecture. Life Science Chemicals is a high volume business, operating at high single-digit to low double-digit margins. Jubilant is amongst the top 4 manufacturers globally for acetic anhydride. For ethyl acetate, Jubilant is amongst the top 7 global manufacturers. We note that owing to lower working capital requirements, the business has high ROCEs. Despite volatility in revenues and margins, Jubilant aims to keep absolute EBITDA of this business stable. With capacity expansion due to retrofitting and launch of at least seven new products, we expect an improved performance in FY18 and FY19 for the LSI business.

Fig 11 Most of Jubilant's pharma assets are in US and Canada

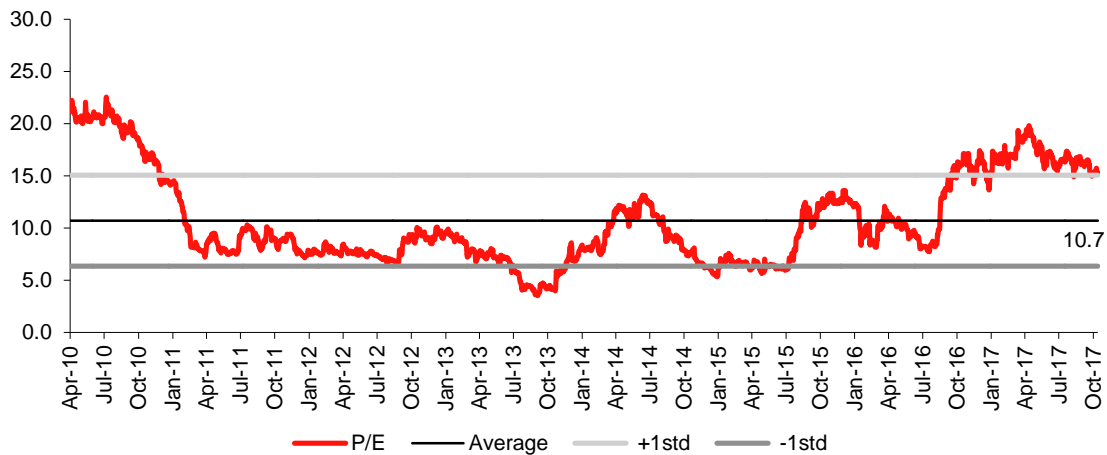
Regulatory Agency	Cadista USA	Roorkee India	CMO / Allergy Spokane	CMO Montreal	JDI Montreal Canada	Nanjangud India
 (USA)	Mar 2017	Mar 2017	Nov 2016	Dec 2016	Dec 2016	Oct 2015
 (Canada)				Sep 2015	Apr 2016	
 (Japan)		Dec 2015	Feb 2017			May 2016
 (India SLA / CDSCO)		Sep 2015				Sep 2016
 (Brazil)				May – June 2016		Mar 2015
 (Turkey)			Mar 2015			
 (Mexico)						Aug 2015

Source: Company data, Macquarie Research, October 2017

**High focus on free cash generation, increasing pharma contribution to drive re-rating**

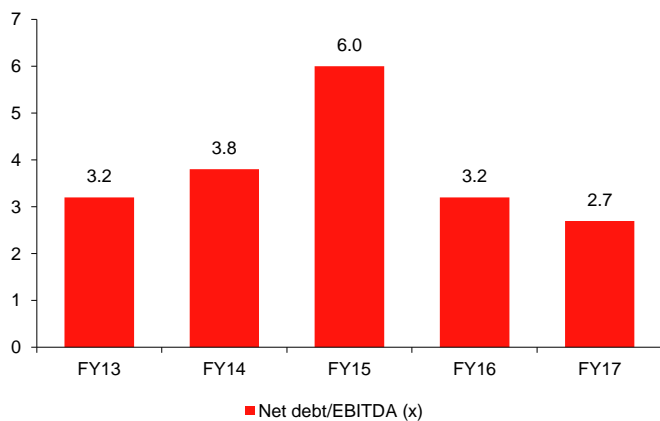
Jubilant expects annual capex of ~Rs3bn, out of which ~Rs2.2bn would be for the pharma business. Jubilant’s free cash generation has seen a sharp uptick in the last six quarters, which has led to Rs9bn debt reduction over the last two years. Jubilant is targeting another Rs15bn reduction in the next three years (excluding any reduction in debt from Jubilant Pharma IPO). The company aims to reduce its Debt/EBITDA from the current ~3x to ~2x over the medium term. In our view, improving free cash generation is an encouraging sign. The company also has a strong US FDA compliance record. We believe the current weakness provides an attractive entry opportunity. We rate the stock Outperform with a TP of Rs900 at 15x Sept-19 EPS. Our 15x target multiple for Jubilant is the lowest across our coverage due to its high presence in the commodity LSI business.

**Fig 12 We expect increasing pharma contribution to drive Jubilant’s re-rating**



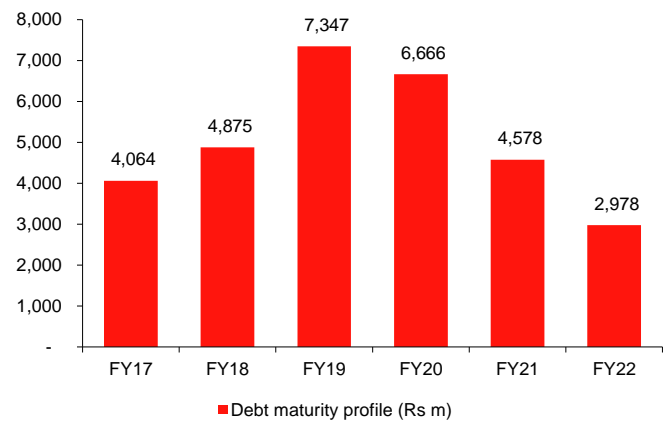
Source: Bloomberg, Macquarie Research, October 2017

**Fig 13 Net debt to EBITDA has been coming down**



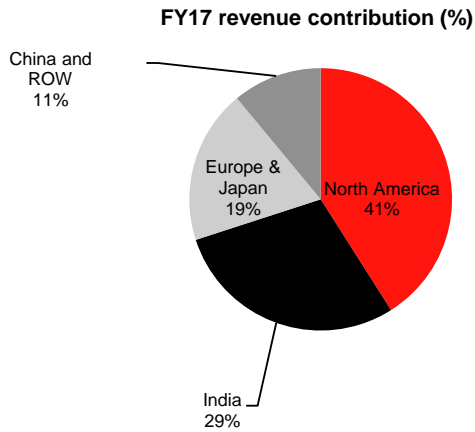
Source: Company data, Macquarie Research, October 2017

**Fig 14 Debt maturity profile**



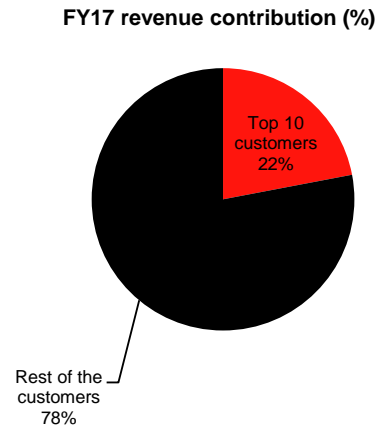
Source: Company data, Macquarie Research, October 2017

**Fig 15 FY17 geography-wise revenue contribution (%)**



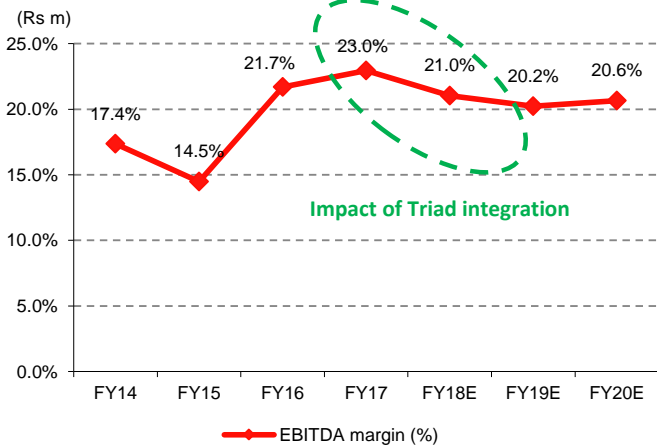
Source: Company data, Macquarie Research, October 2017

**Fig 16 Well-diversified client mix**



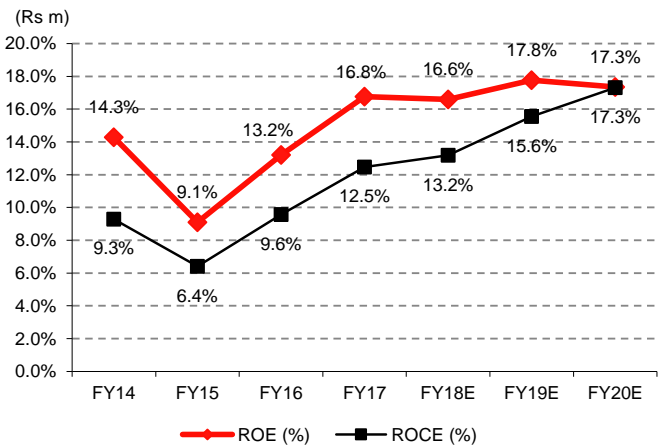
Source: Company data, Macquarie Research, October 2017

**Fig 17 EBITDA margin to be impacted by Triad**



Source: Company data, Macquarie Research, October 2017

**Fig 18 Return ratio profile**



Source: Company data, Macquarie Research, October 2017

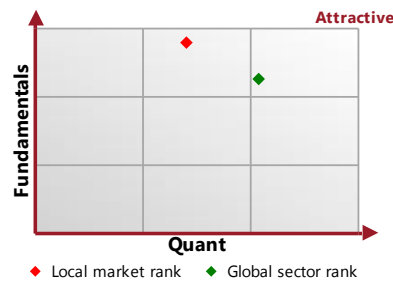
## Macquarie Quant View

The quant model currently holds a neutral view on Jubilant Life Sciences. The strongest style exposure is Quality, indicating this stock is likely to have a superior and more stable underlying earnings stream. The weakest style exposure is Profitability, indicating this stock is not efficiently converting investments to earnings; proxied by ratios like ROE or ROA.

**269/868**

Global rank in  
Pharma, Biotech & Life Sciences

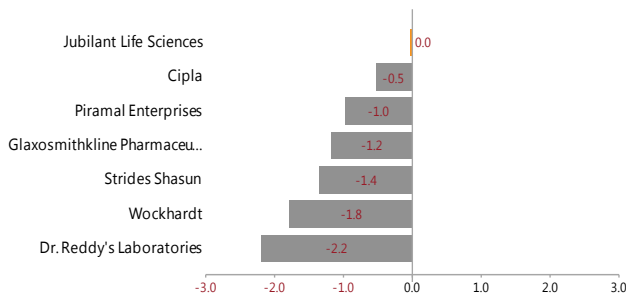
**% of BUY recommendations** 100% (7/7)  
**Number of Price Target downgrades** 0  
**Number of Price Target upgrades** 1



Displays where the company's ranked based on the fundamental consensus Price Target and Macquarie's Quantitative Alpha model.  
Two rankings: Local market (India) and Global sector (Pharma, Biotech & Life Sciences)

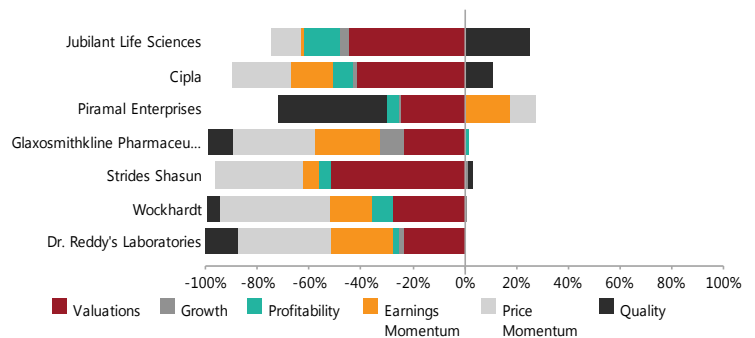
## Macquarie Alpha Model ranking

A list of comparable companies and their Macquarie Alpha model score (higher is better).



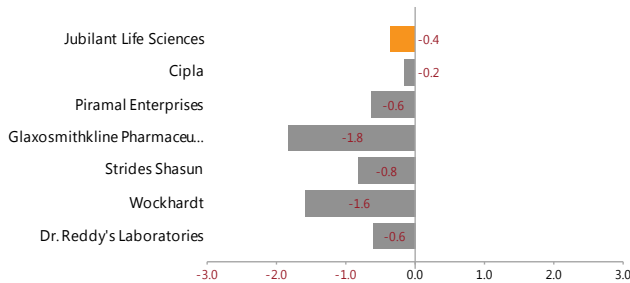
## Factors driving the Alpha Model

For the comparable firms this chart shows the key underlying styles and their contribution to the current overall Alpha score.



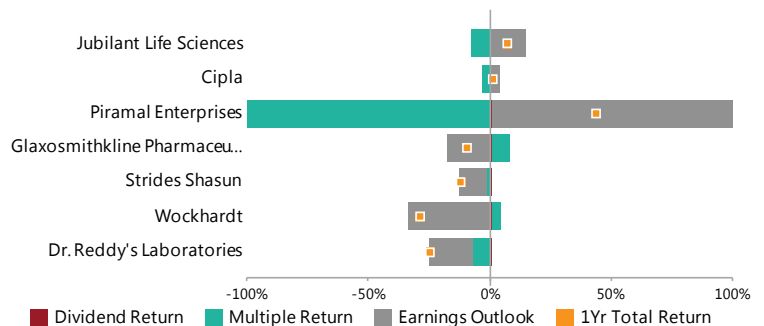
## Macquarie Earnings Sentiment Indicator

The Macquarie Sentiment Indicator is an enhanced earnings revisions signal that favours analysts who have more timely and higher conviction revisions. Current score shown below.



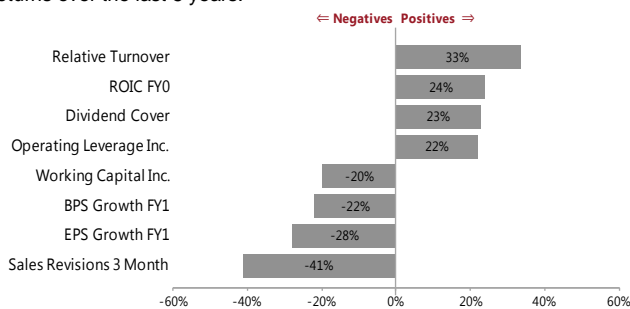
## Drivers of Stock Return

Breakdown of 1 year total return (local currency) into returns from dividends, changes in forward earnings estimates and the resulting change in earnings multiple.



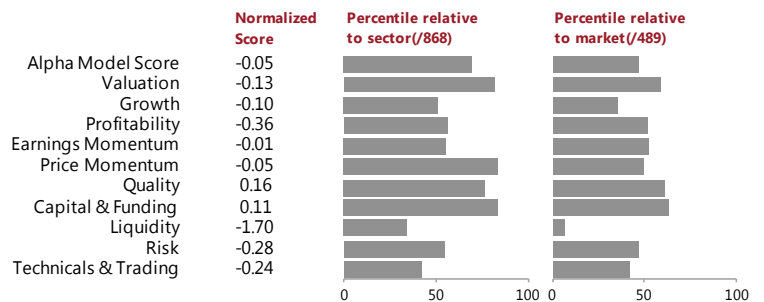
## What drove this Company in the last 5 years

Which factor score has had the greatest correlation with the company's returns over the last 5 years.



## How it looks on the Alpha model

A more granular view of the underlying style scores that drive the alpha (higher is better) and the percentile rank relative to the sector and market.



Source (all charts): FactSet, Thomson Reuters, and Macquarie Research. For more details on the Macquarie Alpha model or for more customised analysis and screens, please contact the Macquarie Global Quantitative/Custom Products Group ([cpg@macquarie.com](mailto:cpg@macquarie.com))

## Jubilant Life Sciences (JUBILANT IN)

Quarterly Results					Profit & Loss						
	1Q/18A	2Q/18E	3Q/18E	4Q/18E		2017A	2018E	2019E	2020E		
Revenue	m	17,996	17,996	17,996	17,996	Revenue	m	58,614	71,984	86,764	93,616
Gross Profit	m	9,883	9,883	9,883	9,883	Gross Profit	m	38,619	39,532	47,649	51,891
Cost of Goods Sold	m	8,113	8,113	8,113	8,113	Cost of Goods Sold	m	19,995	32,452	39,115	41,724
EBITDA	m	3,786	3,786	3,786	3,786	EBITDA	m	13,453	15,144	17,556	19,327
Depreciation	m	775	775	775	775	Depreciation	m	2,914	3,100	3,300	3,500
Amortisation of Goodwill	m	0	0	0	0	Amortisation of Goodwill	m	0	0	0	0
Other Amortisation	m	0	0	0	0	Other Amortisation	m	0	0	0	0
EBIT	m	3,011	3,011	3,011	3,011	EBIT	m	10,539	12,044	14,256	15,827
Net Interest Income	m	-750	-750	-750	-750	Net Interest Income	m	-3,411	-3,000	-2,610	-2,200
Associates	m	0	0	0	0	Associates	m	0	0	0	0
Exceptionals	m	0	0	0	0	Exceptionals	m	0	0	0	0
Forex Gains / Losses	m	0	0	0	0	Forex Gains / Losses	m	0	0	0	0
Other Pre-Tax Income	m	72	72	72	72	Other Pre-Tax Income	m	249	288	347	374
Pre-Tax Profit	m	2,333	2,333	2,333	2,333	Pre-Tax Profit	m	7,376	9,332	11,993	14,002
Tax Expense	m	-653	-653	-653	-653	Tax Expense	m	-1,630	-2,613	-3,358	-3,920
Net Profit	m	1,680	1,680	1,680	1,680	Net Profit	m	5,746	6,719	8,635	10,081
Minority Interests	m	0	0	0	0	Minority Interests	m	10	0	0	0
Reported Earnings	m	1,680	1,680	1,680	1,680	Reported Earnings	m	5,757	6,719	8,635	10,081
Adjusted Earnings	m	1,680	1,680	1,680	1,680	Adjusted Earnings	m	5,757	6,719	8,635	10,081
EPS (rep)		10.77	10.77	10.77	10.77	EPS (rep)		36.91	43.08	55.37	64.64
EPS (adj)		10.77	10.77	10.77	10.77	EPS (adj)		36.91	43.08	55.37	64.64
EPS Growth yoy (adj)	%	16.7	16.7	16.7	16.7	EPS Growth (adj)	%	47.2	16.7	28.5	16.8
						PE (rep)	x	17.2	14.8	11.5	9.8
						PE (adj)	x	17.2	14.8	11.5	9.8
EBITDA Margin	%	21.0	21.0	21.0	21.0	Total DPS		3.00	3.00	3.00	3.00
EBIT Margin	%	16.7	16.7	16.7	16.7	Total Div Yield	%	0.5	0.5	0.5	0.5
Earnings Split	%	25.0	25.0	25.0	25.0	Basic Shares Outstanding	m	156	156	156	156
Revenue Growth	%	22.8	22.8	22.8	22.8	Diluted Shares Outstanding	m	156	156	156	156
EBIT Growth	%	14.3	14.3	14.3	14.3						
Profit and Loss Ratios					Cashflow Analysis						
	2017A	2018E	2019E	2020E		2017A	2018E	2019E	2020E		
Revenue Growth	%	2.0	22.8	20.5	7.9	EBITDA	m	13,453	15,144	17,556	19,327
EBITDA Growth	%	7.9	12.6	15.9	10.1	Tax Paid	m	-1,439	-2,613	-3,358	-3,920
EBIT Growth	%	17.1	14.3	18.4	11.0	Chgs in Working Cap	m	369	67	97	160
Gross Profit Margin	%	65.9	54.9	54.9	55.4	Net Interest Paid	m	-3,323	-3,000	-2,610	-2,200
EBITDA Margin	%	23.0	21.0	20.2	20.6	Other	m	3,626	0	0	0
EBIT Margin	%	18.0	16.7	16.4	16.9	Operating Cashflow	m	12,685	9,598	11,684	13,366
Net Profit Margin	%	9.8	9.3	10.0	10.8	Acquisitions	m	0	0	0	0
Payout Ratio	%	8.1	7.0	5.4	4.6	Capex	m	-4,623	-3,599	-3,471	-3,230
EV/EBITDA	x	9.4	8.4	7.2	6.6	Asset Sales	m	0	0	0	0
EV/EBIT	x	12.0	10.5	8.9	8.0	Other	m	119	288	347	374
Balance Sheet Ratios					Investing Cashflow	m	-4,504	-3,311	-3,124	-2,855	
ROE	%	18.0	17.9	19.4	18.9	Dividend (Ordinary)	m	-559	-561	-561	-561
ROA	%	11.8	13.7	16.0	16.1	Equity Raised	m	0	0	0	0
ROIC	%	12.8	13.6	15.9	17.7	Debt Movements	m	-4,088	0	0	0
Net Debt/Equity	%	83.9	57.3	31.5	9.4	Other	m	-2,212	0	0	0
Interest Cover	x	3.1	4.0	5.5	7.2	Financing Cashflow	m	-6,859	-561	-561	-561
Price/Book	x	2.9	2.4	2.0	1.7	Net Chg in Cash/Debt	m	1,473	5,726	8,000	9,950
Book Value per Share		220.4	260.0	311.7	372.8	Free Cashflow	m	8,062	5,999	8,214	10,137
					Balance Sheet		2017A	2018E	2019E	2020E	
					Cash	m	4,564	10,290	18,290	28,240	
					Receivables	m	10,053	4,777	4,716	4,615	
					Inventories	m	12,204	7,229	7,137	6,984	
					Investments	m	0	0	0	0	
					Fixed Assets	m	33,147	33,646	33,817	33,546	
					Intangibles	m	17,622	17,622	17,622	17,622	
					Other Assets	m	12,816	11,806	11,784	11,750	
					Total Assets	m	90,406	85,371	93,366	102,757	
					Payables	m	7,495	4,091	4,039	3,953	
					Short Term Debt	m	2,556	2,556	2,556	2,556	
					Long Term Debt	m	31,176	31,176	31,176	31,176	
					Provisions	m	0	0	0	0	
					Other Liabilities	m	14,426	6,635	6,610	6,567	
					Total Liabilities	m	55,653	44,459	44,381	44,252	
					Shareholders' Funds	m	34,360	40,518	48,592	58,112	
					Minority Interests	m	393	393	393	393	
					Other	m	0	0	0	0	
					Total S/H Equity	m	34,753	40,911	48,985	58,505	
					Total Liab & S/H Funds	m	90,406	85,371	93,366	102,757	

All figures in INR unless noted.

Source: Company data, Macquarie Research, October 2017

## INDIA

STR IN Outperform

Price (at 13:56, 18 Oct 2017 GMT) Rs874.60

Valuation Rs 1,100.00

- Sum of Parts

12-month target Rs 1,100.00

Upside/Downside % +25.8

12-month TSR % +26.2

Volatility Index Medium

## GICS sector

Pharmaceuticals, Biotechnology &amp; Life Sciences

Market cap Rsm 78,076

Market cap US\$m 1,215

Free float % 66

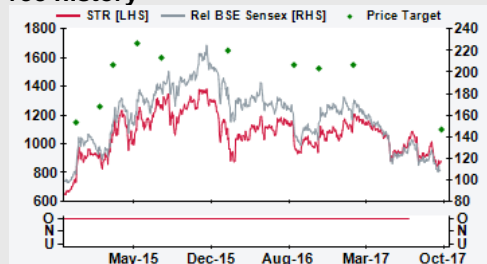
30-day avg turnover US\$m 11.8

Number shares on issue m 89.27

## Investment fundamentals

Year end 31 Mar		2017A	2018E	2019E	2020E
Revenue	m	35,105	34,113	35,939	40,301
EBIT	m	5,359	4,186	6,307	7,529
EBIT growth	%	26.4	-21.9	50.7	19.4
Recurring profit	m	3,953	3,386	5,207	6,629
Reported profit	m	3,486	2,562	4,078	5,301
Adjusted profit	m	3,486	2,562	4,078	5,301
EPS rep	Rs	39.05	28.69	45.68	59.38
EPS rep growth	%	38.7	-26.5	59.2	30.0
EPS adj	Rs	39.05	28.69	45.68	59.38
EPS adj growth	%	19.3	-26.5	59.2	30.0
PER rep	x	22.4	30.5	19.1	14.7
PER adj	x	22.4	30.5	19.1	14.7
Total DPS	Rs	4.00	4.00	4.00	4.00
Total div yield	%	0.5	0.5	0.5	0.5
ROA	%	6.9	4.8	6.5	7.2
ROE	%	12.5	9.1	13.1	15.0
EV/EBITDA	x	12.7	15.5	11.6	10.0
Net debt/equity	%	49.7	40.8	29.6	19.3
P/BV	x	2.9	2.7	2.4	2.1

## STR IN rel BSE Sensex performance, &amp; rec history



Note: Recommendation timeline - if not a continuous line, then there was no Macquarie coverage at the time or there was an embargo period.

Source: FactSet, Macquarie Research, October 2017

(all figures in INR unless noted)

## Analyst(s)

Alankar Garude, CFA

+91 22 6720 4134 alankar.garude@macquarie.com

23 October 2017

Macquarie Capital Securities India (Pvt) Ltd

## Strides Shasun

## Regulated markets to drive growth

## Conclusion

- With sharpened focus on the B2C business, market share gains in the regulated markets and a robust compliance track record, Strides is one of our top picks in the mid-cap space. We expect Strides' US business to double until FY20 from its current modest base of US\$100m. We expect recent key approvals like Lovaza and Potassium Citrate ER tablets to alone generate US\$50m combined peak sales. Strides has gained a strong foothold in Australia, which along with the US, we expect will be a key margin driver. We expect earnings momentum to pick up in FY19 as the rate of product approvals picks up further. We initiate coverage with an Outperform recommendation and a SOTP-based target price of Rs1,100.

## Impact

- US revenues to double over FY17-20E:** We expect the US business to be driven by upcoming launches (15-20 launches guided for the next 12 months). We note that unlike large-cap peers which are focussing on blockbuster molecules to drive growth, Strides is more focussed on building a portfolio of limited competition opportunities in the range of US\$10-50m. Lovaza, Potassium Citrate ER and Gilenya (2HFY19) are known limited-competition opportunities that provide growth visibility. We expect Lovaza and Potassium Citrate ER to hit a US\$50m combined annualized revenue run-rate by 4QFY18. In addition, market share of its first fully integrated product, Ranitidine, continues to grow (currently at ~30% vs 18% in 4QFY17).
- Strong foothold in Australia – a key differentiator:** STR has a 21% share in the Australian generics market and aims to be the no. 2 player in the next 2 years from no.3 currently. We believe there are 3 levers of growth in Australia: (i) Strides aims to grow from 1,000 to 2,000 pharmacies in the next 2-3 years (ii) currently, Strides markets 150 products in Australia, which it plans to increase to 300 products and (iii) expansion of its consumer healthcare franchise in Australia – there is no price control in this segment.
- Robust US FDA track record:** Strides has managed to be relatively much-better off in terms of US FDA issues vs peers due to its long-standing focus on process, people and equipment. The company has adopted best-in-class technology, which leads to superior control on final products. It was amongst one of the early adopters of automation to ensure quality compliance.

## Earnings and target price revision

- We rate the stock Outperform with a SOTP-based TP of Rs1,100.

## Price catalyst

- 12-month price target: Rs1,100.00 based on a PER methodology.
- Catalyst: 1) New approvals in the US 2) Margin ramp-up driven by synergies

## Action and recommendation

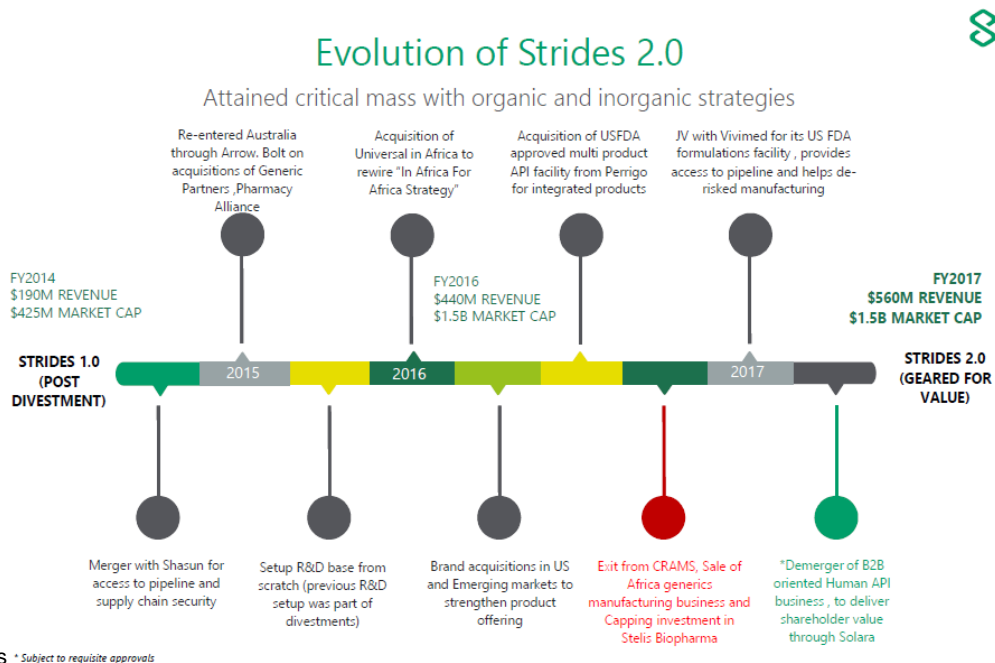
- In our view, the key drivers for Strides are (i) gaining scale in the US, (ii) attaining the numero uno position in Australia in the next 3-5 years, (iii) R&D capped at US\$30m annually, (iv) capex cycle largely over and (v) leveraging its global portfolio. We believe recent correction due to muted 1HFY18 performance is an attractive entry point.

### Focussing squarely on its B2C business

Strides has created a bespoke strategy, specific to itself. Recently, Strides demerged its commodity API business into a new entity. The API business demerger will be effective from October 1, 2017 and Strides Shasun will be renamed as Strides Pharma. Hereon, external API sales for Strides Pharma are ~Rs500m. The human API business of Sequent Scientific will also be carved out into this new listed entity to form one of the largest standalone Indian API companies. As per the management, the current structure of Strides Pharma is fully aligned and focus is now solely on execution. Post the restructuring, Strides Pharma will operate in two markets – Regulated and Emerging.

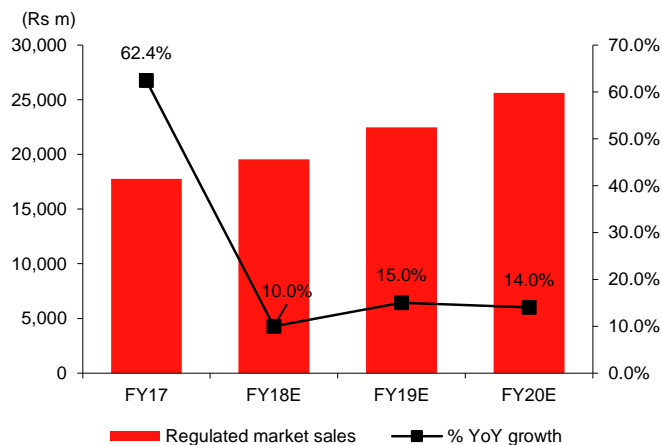
- **Regulated:** The regulated markets for Strides are the US, Australia and UK. The business will be complemented by 4 USFDA approved facilities in India, Europe and Singapore (under construction) and 3 R&D centres with ~400 scientists.
- **Emerging:** The emerging markets business will be comprised of Africa, India and the donor funded programs under the institutional franchise. The company is working on improving the margin profile of this business, with a better asset turnover.

Fig 1 Evolution of Strides' B2C strategy



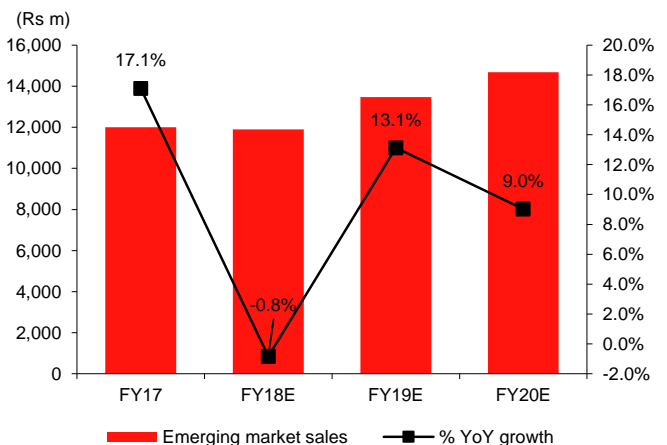
Source: Company data, Macquarie Research, October 2017

Fig 2 Regulated market sales



Source: Company data, Macquarie Research, October 2017

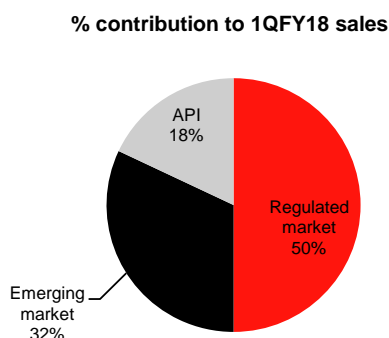
Fig 3 Emerging market sales (incl institutional)



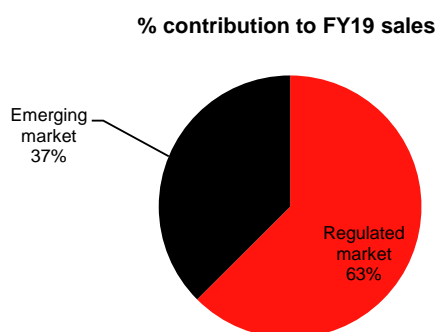
Source: Company data, Macquarie Research, October 2017



**Fig 4 Revenue split as of 1QFY18**



**Fig 5 Expected revenue split in FY19**



Source: Company data, Macquarie Research, October 2017

Source: Company data, Macquarie Research, October 2017

**US business primed for growth**

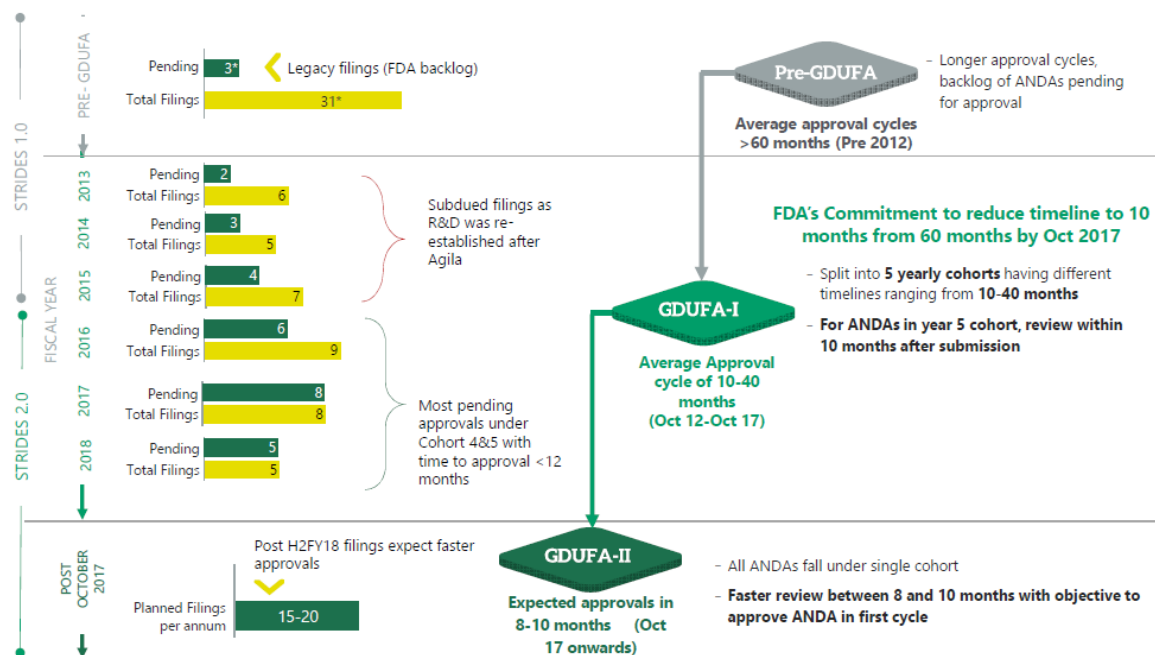
We expect Strides’ US business to be driven by upcoming launches (15-20 launches guided for the next 12 months). Strides’ US business has 3 components: (i) Consumer healthcare business, (ii) Partnered business and (iii) Direct pharma business. Recently, its US business has been impacted due to deferral in product approvals, which was in turn due to a delay in US FDA inspections. These inspections have since been completed with no major observations. Strides is witnessing mid-single-digit pricing erosion in the US, which is likely to continue. We note that unlike large-cap peers, which are focussing on blockbuster molecules to drive growth, Strides is more focussed on building a portfolio of limited competition opportunities in the range of US\$10-50m. Lovaza, Potassium Citrate ER (both recently approved) and Gilenya (2HFY19) are known limited-competition opportunities that provide growth visibility. We expect Lovaza and Potassium Citrate ER to hit a US\$50m combined annualized revenue run-rate by 4QFY18. In addition, market share of its first fully integrated product, Ranitidine, continues to grow (currently at ~30% vs 18% in 4QFY17). On an absolute basis, we expect the partnered business in the US to stabilise from hereon. Strides has now fixed a floor price in its agreements with its partners in the US.

**Fig 6 Key products in the US for Strides with its competitive positioning as of Jun-17**

Molecule	Strides' position	Strides' market share(%)	Number of competitors
Carisoprodol		96%	3
Ergocalciferol	Number 1	45%	3
Vancomycin		55%	5
Methoxylin		30%	4
Acarbose		20%	7
Benzonatate	Number 2	19%	8
Dutasteride		26%	11
Lamivudine / Zidovudine		19%	7
Buspiron 7.5mg		11%	3
Calcitriol		14%	6
Ranitidine	Number 3	21%	5
Abcavir		10%	6
Mycophenolate Mofetil Tab		7%	8

Source: IMS, Bloomberg, Macquarie Research, October 2017

**Fig 7 Increased pace of US FDA approvals could benefit Strides**



Source: Company data, Macquarie Research, October 2017

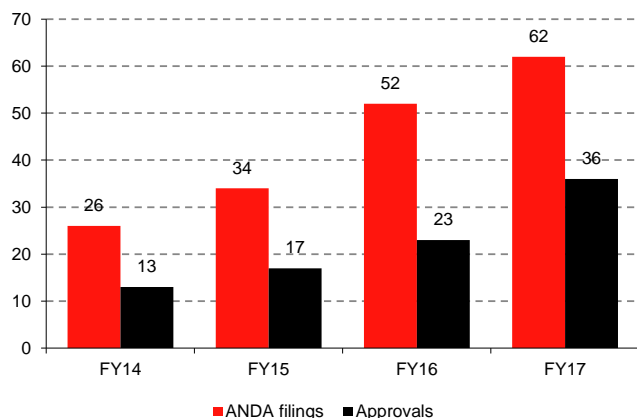
There are a couple of Para IVs in the pipeline, which could be of revenue potential more than US\$50m. Other key products in the pipeline include Renvela/Renagel, Celebrex, Lyrica, Noxafil, Viread and Welchol. With an increase in the approval rate, we expect seasonality in the US business to gradually be corrected.

**Fig 8 Settled Para IV opportunities for Strides**

Brand	Generic	Settled date of launch	Market size (USD m)	Annual revenue potential for Strides (USD m)
Gilenya	Fingolimod	Feb-19	2,000	20
Daliresp	Roflumilast	Jan-20	200	20

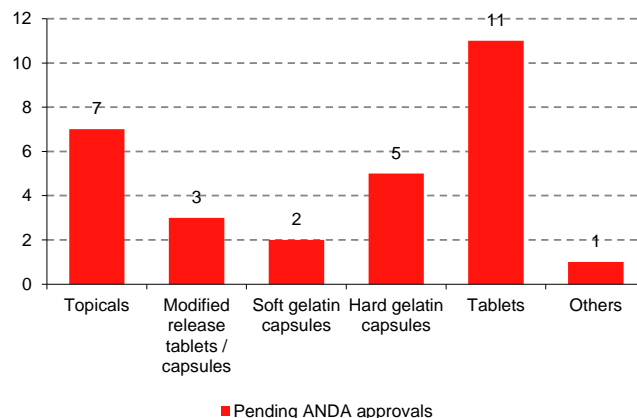
Source: Company data, Macquarie Research, October 2017

**Fig 9 ANDA filings and approvals**



Source: Company data, Macquarie Research, October 2017

**Fig 10 ANDAs pending approval (as of 1QFY18 end)**



Source: Company data, Macquarie Research, October 2017

**Near-spotless US FDA track record provides comfort**

Strides has managed to be relatively much-better off in terms of US FDA issues vs peers due to its long-standing focus on process, people and equipment. Strides has adopted best-in-class technology, which leads to superior control on final products. Strides was amongst one of the early adopters of automation to ensure quality compliance.

**Fig 11 US FDA inspection status**

Facility	Type	Last inspection	Number of observations	Status
Bengaluru	Formulations	May-17	3	Product approvals received post inspection
Puducherry	Formulations	May-17	0	No Form 483 issued
Chennai	Formulations	Nov-16	0	No Form 483 issued
Milan	Formulations	May-15	0	No Form 483 issued
Perigo	API	Nov-13	0	No Form 483 issued

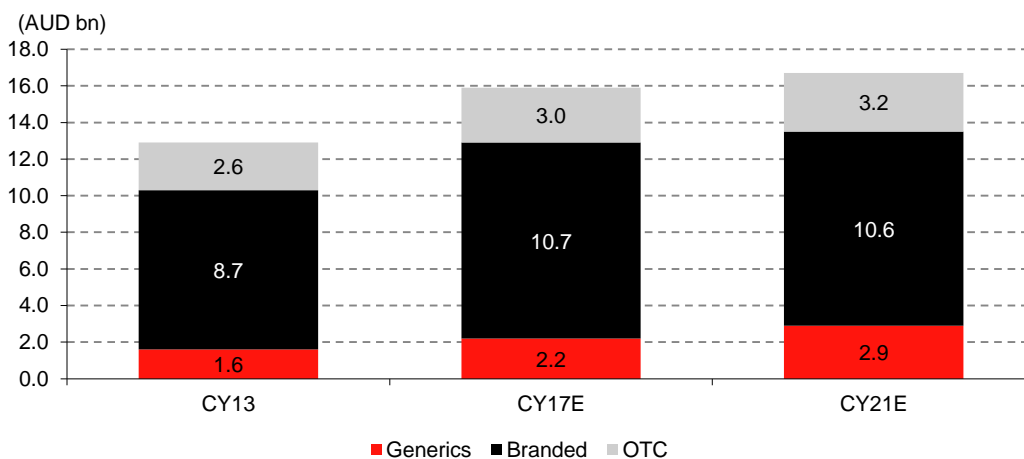
Source: Company data, Macquarie Research, October 2017

**Strong foothold in Australia – A key differentiator**

**Unique nature of the Australian generic pharma industry**

The current size of the generic pharma industry in Australia is ~AU\$2bn, with the addressable market for Strides being AU\$1.5bn. Generic penetration is relatively low at 60%, largely due to the innovator’s drug being reimbursed by the PBS program of the government, which has changed now. The generic pharma industry is extremely consolidated in Australia, with the top 3 companies (Apotex, Mylan and Strides, through Arrow acquisition) having ~70% market share. These leading pharma companies have tie-ups with wholesalers like Symbian, API and Sigma – which control 90% of the market. There are ~5,250 pharmacies in Australia, which cannot be consolidated since a pharmacist can own a maximum of 5 pharmacies. The structure of the Australian generic pharma market has been quite stable over the last many years.

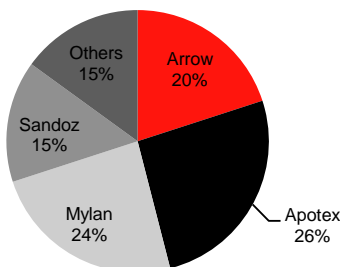
**Fig 12 Pharma market size in Australia**



Source: Industry data, Macquarie Research, October 2017

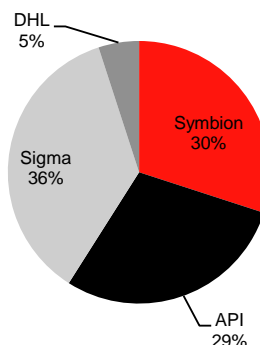
**Fig 13 Generic manufacturer market share in Australia (FY17)**

**Generic manufacturer market share in Australia**



**Fig 14 Generic wholesaler market share in Australia (FY17)**

**Generic wholesaler market share in Australia**



Source: Industry data, Macquarie Research, October 2017

Source: Industry data, Macquarie Research, October 2017

In addition, 4 banner groups like Pharmacy Alliance control most of the market. Making an organic entry in Australia is challenging. Hence, through the acquisition of Arrow Pharma and strategic tie-up with Pharmacy Alliance, Strides has managed to get a meaningful entry in Australia. Another strength of Strides is its preferred supplier relationship with Sigma, which has the largest retail pharmacy footprint in the country. STR has 21% share in the Australian generics market with revenues of ~US\$150m in FY17 and aims to be the no. 2 player in Australia in the next 2 years from no.3 currently. The Australia business is seasonally softer in 4Q and strong in 2Q and 3Q. PBS had led to low- to mid-single-digit pricing erosion in Australia in the last 2 years. Most of this impact has already been reflected in reported financials. We believe there are 3 levers of growth in Australia (i) Strides aims to grow from 1,000 to 2,000 pharmacies in the next 2-3 years (ii) currently, Strides markets 150 products in Australia, which it plans to increase to 300 products in the next few years. Going ahead, STR will look to add 25-30 products annually in Australia. (iii) expansion of its consumer healthcare franchise in Australia – there is no price control here.

We note that EM markets (Africa, India and Institutional) have a big leverage on margins for the overall company.

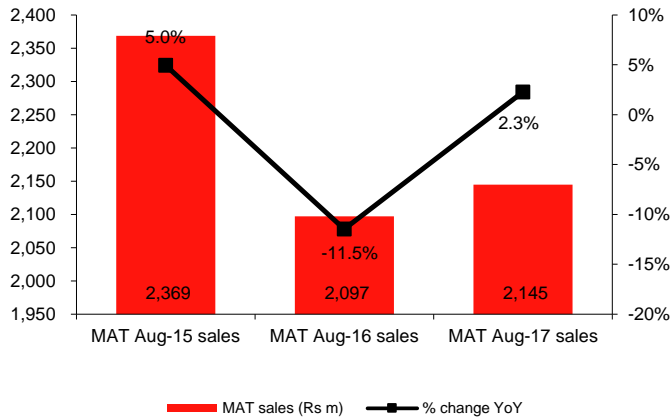
**Strong distribution presence in Africa is an advantage**

The Africa business contributed ~13% to overall topline in FY17. Restructuring in Strides’ Africa business to reduce the gap b/w secondary and primary sales is now done; sequential growth should play out. The Africa business is being billed largely in Euros and USD, with very little exposure to local currency. While STR’s market share in the anti-malarial business remains intact, overall funding of the donor programs has dropped by ~40-50%. On the other hand, the ARV business continues to witness healthy traction.

**India slowly getting back to growth**

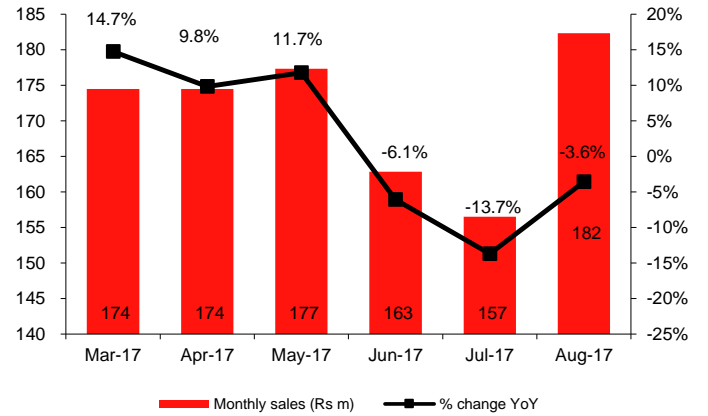
In the India business, all supply chain issues are resolved and sales force productivity should now drive growth. STR aims to develop 4-5 brands in the US\$1-10m range in India. The company is also focussing on introducing brands in the Indian market that are fungible with international markets.

**Fig 15 Strides India MAT sales (Aug-17)**



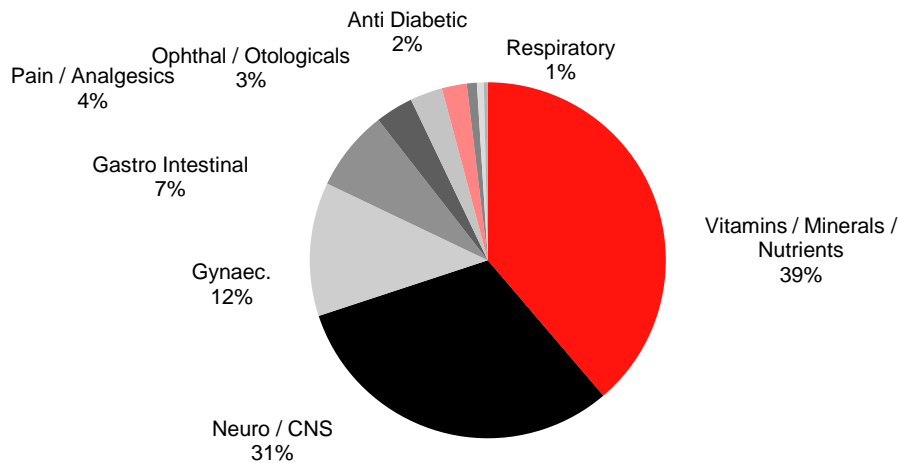
Source: IMS data, Macquarie Research, October 2017

**Fig 16 Strides India monthly sales**



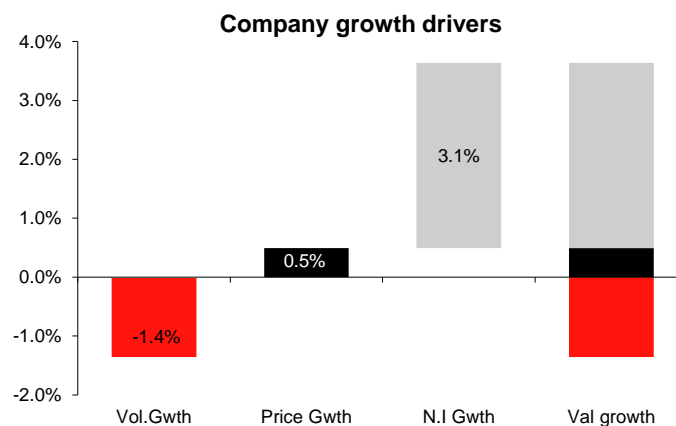
Source: IMS data, Macquarie Research, October 2017

**Fig 17 Therapeutic split of Strides in India**



Source: IMS data, Macquarie Research, October 2017

**Fig 18 Domestic growth drivers for Strides**



Source: IMS data, Macquarie Research, October 2017

### No major capex plans in the near future

Since FY11, Strides has been investing heavily in setting up its infrastructure and ensuring quality compliance. The company has invested US\$45m in setting up its IT infrastructure (to lower manual intervention) over the last 3 years. The Singapore facility will be ready for manufacturing in 2HFY18. Post JV with Vivimed for the US FDA approved facility in Alathur and Singapore expansion, STR will not be needing further capacity expansion at least for the next 3-4 years. The company expects to incur annual maintenance capex of US\$10-15m for the next few years. After the API demerger, Strides Pharma will have net debt of Rs18bn.

### Other restructuring announcements in the last 6 months

#### 1. Exit from the Africa generics manufacturing business

The 6 generic facilities in Africa will be divested to the existing management team led by Mr. Sinhue Noronha. In CY16, the generic business in Africa reported revenues of US\$21m with EBITDA of US\$1.4m. Strides expects to receive a cash consideration of US\$16m for these divested generic facilities.

#### 2. Sale of Probiotic business

In December 2015, Strides had acquired a 51% stake in the probiotic business of Shriram Group promoted Medispan for Rs102m. The business had Rs76m revenues at the time of acquisition. Revenues have declined since then to Rs58m. The promoters of Strides will acquire a 51% stake in this business from Strides and the business will be managed by its erstwhile promoters (Medispan). This divestment of the probiotic portfolio will not result in any capital gain or loss for Strides Shasun.

#### 3. No further investments by Strides into Stelis Biopharma

Strides had made a total capital commitment of US\$57m in Stelis, of which Strides has already invested US\$22m. Going forward, Strides will not be making any further investment in this business and will continue to own a significant minority stake. The remainder of the capital commitment will be funded by the promoters of Strides Shasun and GMS Holdings (which owns 25.1% in Stelis). Stelis will continue to pursue a B2B business model. As per the management, Stelis is not ready for a separate listing yet as the commercial revenue generation is only expected to kick in significantly later and the current growth phase will require significant upfront investments.

### We value Strides Shasun at Rs1,100/share

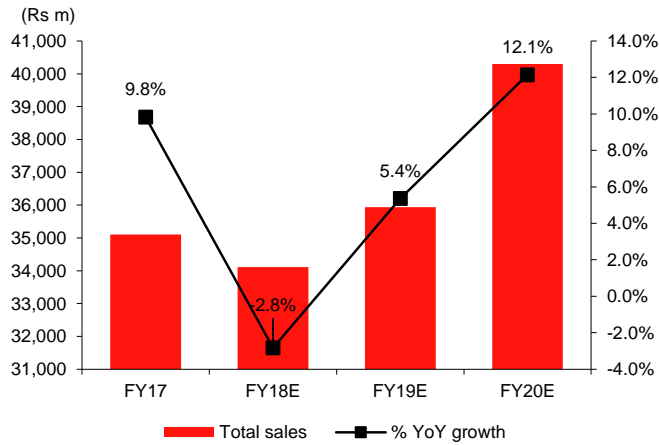
We have demerged Strides API numbers starting 2HFY18 and value it separately. On a SOTP basis, we derive a value of Rs1,100 for Strides Shasun. This includes a value of Rs946 (18x Sept-19E EPS) for the pharma business, Rs136 (15x TTM EBITDA) for the demerged API business and Rs18 for its investments in Stellis and Oncobiologics (valued at book value and market value, respectively).

Fig 19 Strides SOTP calculation

<b>Strides Pharma (core business)</b>	
Sept-19 earnings	52.5
Target PER multiple	18.0 x
<b>Strides Pharma value (a)</b>	<b>946</b>
<b>Strides API (Demerged business)</b>	
Trailing 12 months EBITDA	1,112
Target EV (@15x TTM EBITDA)	16,680
Debt	4,500
<b>Strides API value (b)</b>	<b>136</b>
<b>Investments in Stellis and Oncobiologics</b>	
<b>At BV and market value respectively (c)</b>	<b>18</b>
<b>SOTP Target Price (a + b + c)</b>	<b>1,100</b>

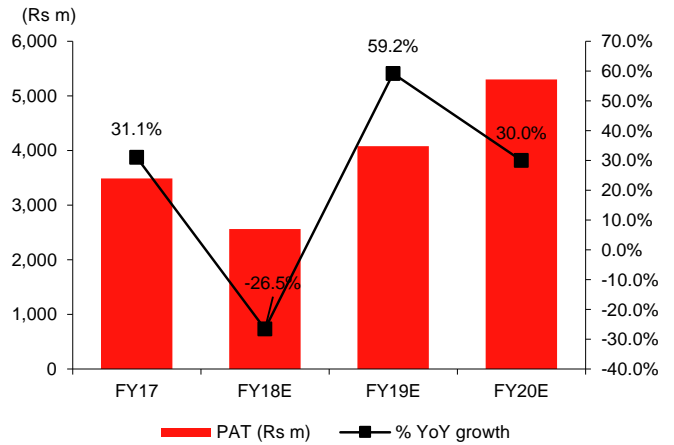
Source: Macquarie Research, October 2017

**Fig 20 Annual total sales**



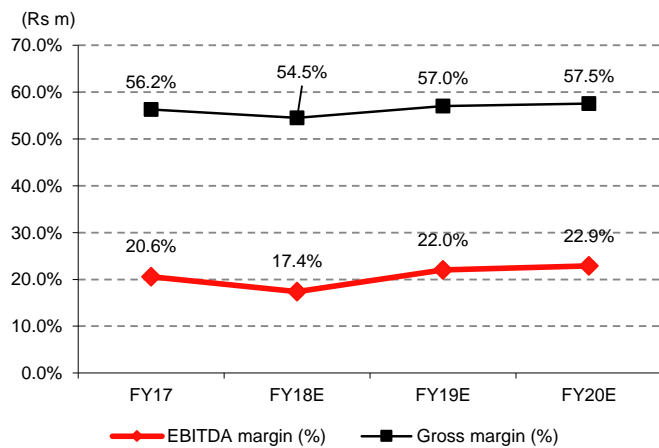
Source: Company data, Macquarie Research, October 2017

**Fig 21 Annual PAT trend**



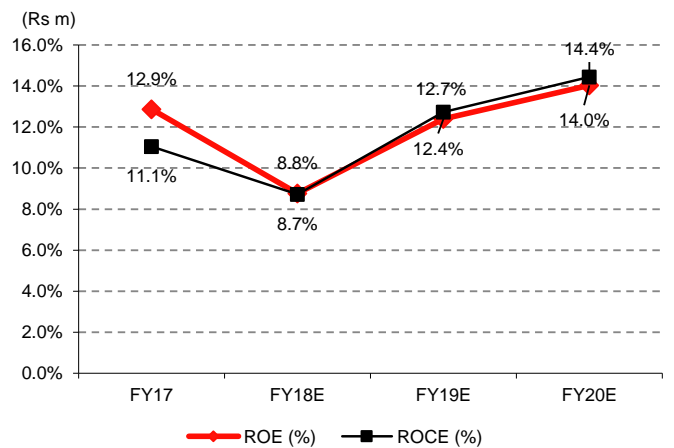
Source: Company data, Macquarie Research, October 2017

**Fig 22 Gross margin and EBITDA margins**



Source: Company data, Macquarie Research, October 2017

**Fig 23 Return ratios to improve in FY19 and FY20**



Source: Company data, Macquarie Research, October 2017

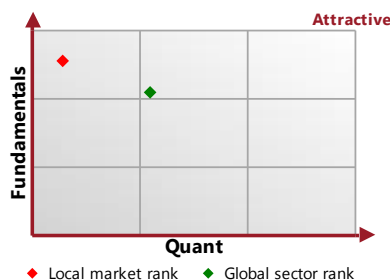
### Macquarie Quant View

The quant model currently holds a strong negative view on Strides Shasun. The strongest style exposure is Growth, indicating this stock has good historic and/or forecast growth. Growth metrics focus on both top and bottom line items. The weakest style exposure is Price Momentum, indicating this stock has had weak medium to long term returns which often persist into the future.

**553/868**

Global rank in Pharma, Biotech & Life Sciences

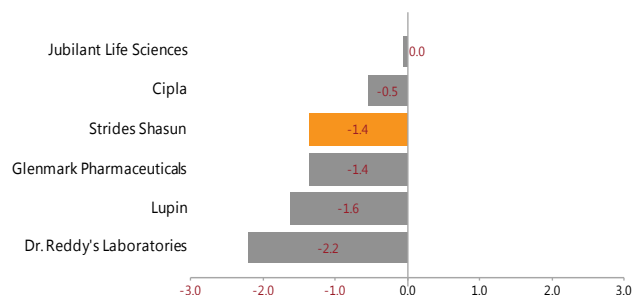
**% of BUY recommendations** 100% (7/7)  
**Number of Price Target downgrades** 0  
**Number of Price Target upgrades** 1



Displays where the company's ranked based on the fundamental consensus Price Target and Macquarie's Quantitative Alpha model. Two rankings: Local market (India) and Global sector (Pharma, Biotech & Life Sciences)

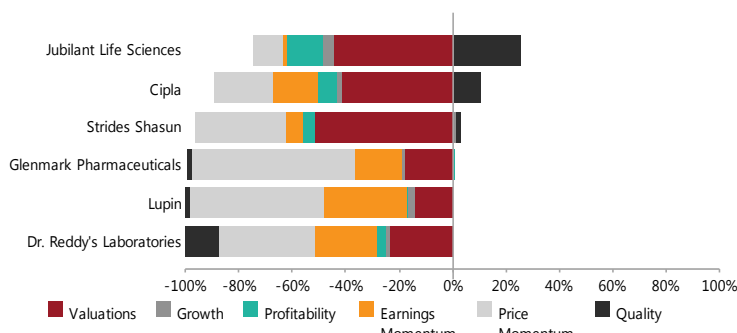
### Macquarie Alpha Model ranking

A list of comparable companies and their Macquarie Alpha model score (higher is better).



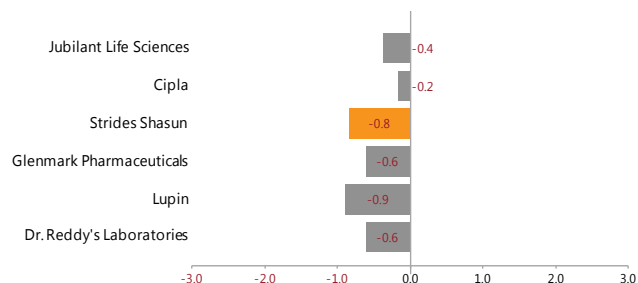
### Factors driving the Alpha Model

For the comparable firms this chart shows the key underlying styles and their contribution to the current overall Alpha score.



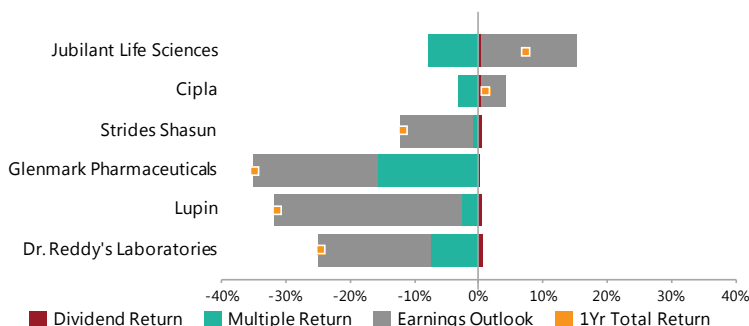
### Macquarie Earnings Sentiment Indicator

The Macquarie Sentiment Indicator is an enhanced earnings revisions signal that favours analysts who have more timely and higher conviction revisions. Current score shown below.



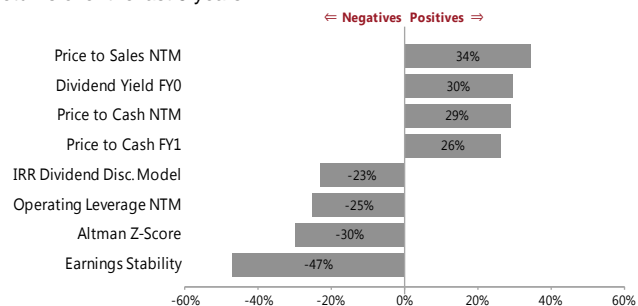
### Drivers of Stock Return

Breakdown of 1 year total return (local currency) into returns from dividends, changes in forward earnings estimates and the resulting change in earnings multiple.



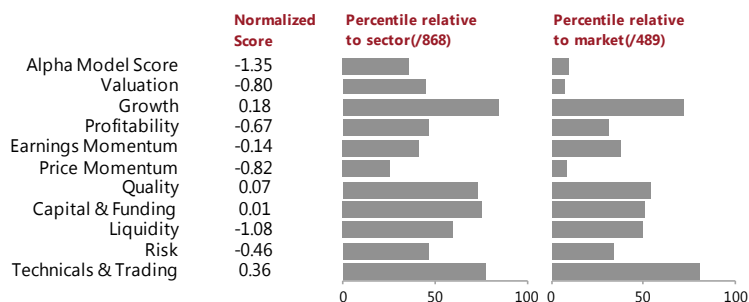
### What drove this Company in the last 5 years

Which factor score has had the greatest correlation with the company's returns over the last 5 years.



### How it looks on the Alpha model

A more granular view of the underlying style scores that drive the alpha (higher is better) and the percentile rank relative to the sector and market.



Source (all charts): FactSet, Thomson Reuters, and Macquarie Research. For more details on the Macquarie Alpha model or for more customised analysis and screens, please contact the Macquarie Global Quantitative/Custom Products Group ([cpq@macquarie.com](mailto:cpq@macquarie.com))



## Strides Shasun (STR IN)

Quarterly Results					Profit & Loss						
	1Q/18A	2Q/18E	3Q/18E	4Q/18E		2017A	2018E	2019E	2020E		
<b>Revenue</b>	m	8,528	8,528	8,528	8,528	<b>Revenue</b>	m	35,105	34,113	35,939	40,301
<b>Gross Profit</b>	m	4,648	4,648	4,648	4,648	<b>Gross Profit</b>	m	19,743	18,591	20,485	23,173
Cost of Goods Sold	m	3,880	3,880	3,880	3,880	Cost of Goods Sold	m	15,362	15,521	15,454	17,128
<b>EBITDA</b>	m	1,484	1,484	1,484	1,484	<b>EBITDA</b>	m	7,230	5,936	7,907	9,229
Depreciation	m	438	438	438	438	Depreciation	m	1,872	1,750	1,600	1,700
Amortisation of Goodwill	m	0	0	0	0	Amortisation of Goodwill	m	0	0	0	0
Other Amortisation	m	0	0	0	0	Other Amortisation	m	0	0	0	0
<b>EBIT</b>	m	1,046	1,046	1,046	1,046	<b>EBIT</b>	m	5,359	4,186	6,307	7,529
Net Interest Income	m	-450	-450	-450	-450	Net Interest Income	m	-2,269	-1,800	-1,500	-1,400
Associates	m	0	0	0	0	Associates	m	0	0	0	0
Exceptionals	m	0	0	0	0	Exceptionals	m	0	0	0	0
Forex Gains / Losses	m	0	0	0	0	Forex Gains / Losses	m	0	0	0	0
Other Pre-Tax Income	m	250	250	250	250	Other Pre-Tax Income	m	863	1,000	400	500
<b>Pre-Tax Profit</b>	m	846	846	846	846	<b>Pre-Tax Profit</b>	m	3,953	3,386	5,207	6,629
Tax Expense	m	-118	-118	-118	-118	Tax Expense	m	-470	-474	-729	-928
<b>Net Profit</b>	m	728	728	728	728	<b>Net Profit</b>	m	3,483	2,912	4,478	5,701
Minority Interests	m	-88	-88	-88	-88	Minority Interests	m	4	-350	-400	-400
<b>Reported Earnings</b>	m	640	640	640	640	<b>Reported Earnings</b>	m	3,486	2,562	4,078	5,301
<b>Adjusted Earnings</b>	m	640	640	640	640	<b>Adjusted Earnings</b>	m	3,486	2,562	4,078	5,301
EPS (rep)		7.17	7.17	7.17	7.17	EPS (rep)		39.05	28.69	45.68	59.38
EPS (adj)		7.17	7.17	7.17	7.17	EPS (adj)		39.05	28.69	45.68	59.38
EPS Growth yoy (adj)	%	-26.5	-26.5	-26.5	-26.5	EPS Growth (adj)	%	19.3	-26.5	59.2	30.0
						PE (rep)	x	22.4	30.5	19.1	14.7
						PE (adj)	x	22.4	30.5	19.1	14.7
EBITDA Margin	%	17.4	17.4	17.4	17.4	Total DPS		4.00	4.00	4.00	4.00
EBIT Margin	%	12.3	12.3	12.3	12.3	Total Div Yield	%	0.5	0.5	0.5	0.5
Earnings Split	%	25.0	25.0	25.0	25.0	Basic Shares Outstanding	m	89	89	89	89
Revenue Growth	%	-2.8	-2.8	-2.8	-2.8	Diluted Shares Outstanding	m	89	89	89	89
EBIT Growth	%	-21.9	-21.9	-21.9	-21.9						
Profit and Loss Ratios					Cashflow Analysis						
	2017A	2018E	2019E	2020E		2017A	2018E	2019E	2020E		
Revenue Growth	%	9.8	-2.8	5.4	12.1	<b>EBITDA</b>	m	7,230	5,936	7,907	9,229
EBITDA Growth	%	24.4	-17.9	33.2	16.7	Tax Paid	m	-586	-474	-729	-928
EBIT Growth	%	26.4	-21.9	50.7	19.4	Chgs in Working Cap	m	-3,413	38	-475	-1,134
Gross Profit Margin	%	56.2	54.5	57.0	57.5	Net Interest Paid	m	-1,521	-1,800	-1,500	-1,400
EBITDA Margin	%	20.6	17.4	22.0	22.9	Other	m	1,172	0	0	0
EBIT Margin	%	15.3	12.3	17.5	18.7	<b>Operating Cashflow</b>	m	2,881	3,700	5,203	5,767
Net Profit Margin	%	9.9	7.5	11.3	13.2	Acquisitions	m	-1,742	0	0	0
Payout Ratio	%	10.2	13.9	8.8	6.7	Capex	m	-6,731	-2,729	-2,875	-3,224
EV/EBITDA	x	12.7	15.5	11.6	10.0	Asset Sales	m	0	0	0	0
EV/EBIT	x	17.2	22.0	14.6	12.2	Other	m	1,422	1,000	400	500
<b>Balance Sheet Ratios</b>					<b>Investing Cashflow</b>	m	-7,051	-1,729	-2,475	-2,724	
ROE	%	12.5	9.1	13.1	15.0	Dividend (Ordinary)	m	-432	-429	-429	-429
ROA	%	6.9	4.8	6.5	7.2	Equity Raised	m	34	0	0	0
ROIC	%	9.8	8.4	12.3	14.2	Debt Movements	m	6,037	0	0	0
Net Debt/Equity	%	49.7	40.8	29.6	19.3	Other	m	-2,257	0	0	0
Interest Cover	x	2.4	2.3	4.2	5.4	<b>Financing Cashflow</b>	m	3,382	-429	-429	-429
Price/Book	x	2.9	2.7	2.4	2.1	<b>Net Chg in Cash/Debt</b>	m	-788	1,542	2,299	2,614
Book Value per Share		303.6	327.5	368.4	423.0	<b>Free Cashflow</b>	m	-3,849	971	2,328	2,543
					Balance Sheet						
		2017A	2018E	2019E	2020E		2017A	2018E	2019E	2020E	
Cash	m	16,019	17,561	19,860	22,474	Cash	m	16,019	17,561	19,860	22,474
Receivables	m	9,971	14,769	15,560	17,448	Receivables	m	9,971	14,769	15,560	17,448
Inventories	m	7,380	13,519	14,243	15,971	Inventories	m	7,380	13,519	14,243	15,971
Investments	m	2,451	2,451	2,451	2,451	Investments	m	2,451	2,451	2,451	2,451
Fixed Assets	m	12,534	13,513	14,788	16,312	Fixed Assets	m	12,534	13,513	14,788	16,312
Intangibles	m	19,348	19,348	19,348	19,348	Intangibles	m	19,348	19,348	19,348	19,348
Other Assets	m	10,932	13,115	13,661	14,965	Other Assets	m	10,932	13,115	13,661	14,965
<b>Total Assets</b>	m	<b>78,634</b>	<b>94,275</b>	<b>99,911</b>	<b>108,970</b>	<b>Total Assets</b>	m	<b>78,634</b>	<b>94,275</b>	<b>99,911</b>	<b>108,970</b>
Payables	m	7,457	14,153	14,911	16,720	Payables	m	7,457	14,153	14,911	16,720
Short Term Debt	m	13,940	13,940	13,940	13,940	Short Term Debt	m	13,940	13,940	13,940	13,940
Long Term Debt	m	16,377	16,377	16,377	16,377	Long Term Debt	m	16,377	16,377	16,377	16,377
Provisions	m	0	0	0	0	Provisions	m	0	0	0	0
Other Liabilities	m	12,117	18,578	19,406	21,384	Other Liabilities	m	12,117	18,578	19,406	21,384
<b>Total Liabilities</b>	m	<b>49,890</b>	<b>63,048</b>	<b>64,634</b>	<b>68,421</b>	<b>Total Liabilities</b>	m	<b>49,890</b>	<b>63,048</b>	<b>64,634</b>	<b>68,421</b>
Shareholders' Funds	m	27,104	29,238	32,887	37,759	Shareholders' Funds	m	27,104	29,238	32,887	37,759
Minority Interests	m	1,640	1,990	2,390	2,790	Minority Interests	m	1,640	1,990	2,390	2,790
Other	m	0	0	0	0	Other	m	0	0	0	0
<b>Total S/H Equity</b>	m	<b>28,744</b>	<b>31,227</b>	<b>35,277</b>	<b>40,549</b>	<b>Total S/H Equity</b>	m	<b>28,744</b>	<b>31,227</b>	<b>35,277</b>	<b>40,549</b>
<b>Total Liab &amp; S/H Funds</b>	m	<b>78,634</b>	<b>94,275</b>	<b>99,911</b>	<b>108,970</b>	<b>Total Liab &amp; S/H Funds</b>	m	<b>78,634</b>	<b>94,275</b>	<b>99,911</b>	<b>108,970</b>

All figures in INR unless noted.

Source: Company data, Macquarie Research, October 2017

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## Recommendation definitions

**Macquarie - Australia/New Zealand**

Outperform – return >3% in excess of benchmark return  
Neutral – return within 3% of benchmark return  
Underperform – return >3% below benchmark return

Benchmark return is determined by long term nominal GDP growth plus 12 month forward market dividend yield

**Macquarie – Asia/Europe**

Outperform – expected return >+10%  
Neutral – expected return from -10% to +10%  
Underperform – expected return <-10%

**Macquarie – South Africa**

Outperform – expected return >+10%  
Neutral – expected return from -10% to +10%  
Underperform – expected return <-10%

**Macquarie - Canada**

Outperform – return >5% in excess of benchmark return  
Neutral – return within 5% of benchmark return  
Underperform – return >5% below benchmark return

**Macquarie - USA**

Outperform (Buy) – return >5% in excess of Russell 3000 index return  
Neutral (Hold) – return within 5% of Russell 3000 index return  
Underperform (Sell) – return >5% below Russell 3000 index return

## Volatility index definition\*

This is calculated from the volatility of historical price movements.

**Very high-highest risk** – Stock should be expected to move up or down 60–100% in a year – investors should be aware this stock is highly speculative.

**High** – stock should be expected to move up or down at least 40–60% in a year – investors should be aware this stock could be speculative.

**Medium** – stock should be expected to move up or down at least 30–40% in a year.

**Low-medium** – stock should be expected to move up or down at least 25–30% in a year.

**Low** – stock should be expected to move up or down at least 15–25% in a year.

\* Applicable to Asia/Australian/NZ/Canada stocks only

**Recommendations** – 12 months

**Note:** Quant recommendations may differ from Fundamental Analyst recommendations

## Financial definitions

All "Adjusted" data items have had the following adjustments made:

Added back: goodwill amortisation, provision for catastrophe reserves, IFRS derivatives & hedging, IFRS impairments & IFRS interest expense  
Excluded: non recurring items, asset revals, property revals, appraisal value uplift, preference dividends & minority interests

**EPS** = adjusted net profit / epowa\*

**ROA** = adjusted ebit / average total assets

**ROA Banks/Insurance** = adjusted net profit / average total assets

**ROE** = adjusted net profit / average shareholders funds

**Gross cashflow** = adjusted net profit + depreciation

\*equivalent fully paid ordinary weighted average number of shares

All Reported numbers for Australian/NZ listed stocks are modelled under IFRS (International Financial Reporting Standards).

## Recommendation proportions – For quarter ending 30 September 2017

	AU/NZ	Asia	RSA	USA	CA	EUR	
Outperform	50.38%	56.22%	40.70%	46.21%	63.85%	41.61%	(for global coverage by Macquarie, 4.18% of stocks followed are investment banking clients)
Neutral	37.50%	28.16%	43.02%	47.52%	30.00%	39.51%	(for global coverage by Macquarie, 2.68% of stocks followed are investment banking clients)
Underperform	12.12%	15.62%	16.28%	6.27%	6.15%	18.88%	(for global coverage by Macquarie, 1.08% of stocks followed are investment banking clients)

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