April 5, 2016

Biocon Ltd

Asia Insight: Ushering in the Decade of Biosimilars; Upgrade to OW

Industry View	Stock Rating	Price Target
In-Line	**Overweight**	**Rs622.00**

2016 could be a turning point for BIOS. Four potential product filings each in the US and EU would add credibility to its pipeline and bring market recognition. EM monetization is under way, but the US and EU opportunities will take at least two years. Our Rs622 PT is 21x our F18 EPS estimates.

What's Changed?	From	To
Biocon Ltd		
Rating	Underweight	Overweight
Price Target	Rs459.00	Rs622.00

When should markets start paying for its pipeline? Now, in our view – Although the global biosimilar story has more questions than answers at this point, these will be addressed by market forces, regulators and courts in the years to come. In the meantime, we see BIOS as a strong re-rating story given that markets have hardly priced in its biosimilar pipeline (19.8x F17e EPS, which is mostly its non-biosimilar base business). We have a detailed valuation case study in this report – Celltrion (up ten-fold in seven years to a US$10bn market cap on a 40-50x P/E) – and compared it to BIOS, with a current market cap of US$1.4bn. The comparison is relevant to assessing when markets start to discount the bio-similar pipeline.

Value in the pipeline – Our analysis suggests that each of the four lead compounds of BIOS (and its partner Mylan) ranks among a handful of compounds with a good chance of a US and EU launch in the first wave of market formation over the next four to five years (filings in 2016). These are glargine, trastuzumab, pegfilgrastim, and adalimumab. By 2020, we estimate US$244mn (and growing) revenues (BIOS's share), which, at 30% margins, implies a doubling of current profits. Plus, BIOS has a follow-on pipeline of another five products in early stages which together give growth visibility over the longer term.

How about risks? There are several to biosimilar upside, but not much to stock price, we believe, since the growing base business should support the current stock price. Plus, BIOS has several opportunities for success, in our view,with multiple biosimilar products and multiple geographies. Nonetheless, key risks to our thesis include regulatory setbacks (three out of four Phase 3 trials are non-US), legal delays, innovator strategies (for example, shifts to new, improved products), and market challenges.

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Biocon Ltd (BION.NS, BIOS IN)

India Healthcare / India

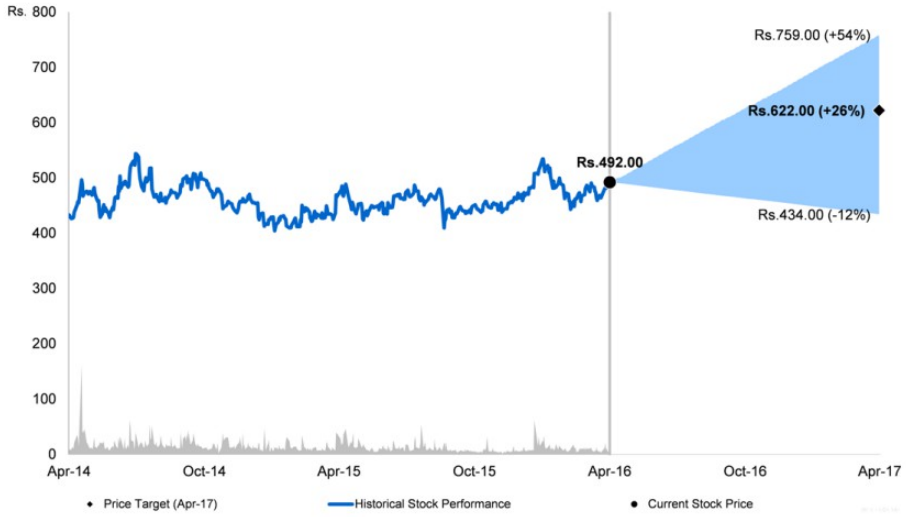
Stock Rating	**Overweight**
Industry View	**In-Line**
Price target	Rs622.00
Up/downside to price target (%)	26
Shr price, close (Apr 4, 2016)	Rs492.00
52-Week Range	Rs544.55-395.30
Sh out, dil, curr (mn)	200
Mkt cap, curr (mn)	Rs98,400
EV, curr (mn)	Rs98,750
Avg daily trading value (mn)	Rs270

Fiscal Year Ending	03/15	03/16e	03/17e	03/18e
ModelWare EPS (Rs)	19.62	22.10	24.79	29.63
Prior ModelWare EPS (Rs)	-	22.10	24.79	29.64
Consensus EPS (Rs)§	19.74	22.42	25.60	30.30
Revenue, net (Rs mn)	30,898	35,054	40,176	46,939
EBITDA (Rs mn)	6,958	7,872	8,799	10,308
ModelWare net inc (Rs mn)	3,923	4,420	4,958	5,926
P/E	23.9	21.9	19.8	16.6
P/BV	2.9	2.7	2.5	2.3
RNOA (%)	13.1	10.4	10.0	10.9
ROE (%)	13.0	13.5	13.8	15.1
EV/EBITDA	13.5	12.6	11.6	9.8
Div yld (%)	1.1	1.0	1.4	1.6
FCF yld ratio (%)	(6.7)	(2.1)	(1.6)	0.2
Leverage (EOP) (%)	(4.2)	1.4	4.2	1.8

Unless otherwise noted, all metrics are based on Morgan Stanley ModelWare framework
§ = Consensus data is provided by Thomson Reuters Estimates
e = Morgan Stanley Research estimates

Risk Reward

US/EM biosimilars filings to be the key re-rating driver



Source: Thomson Reuters, Morgan Stanley Research.

Price Target Rs 622 — Base-case scenario, P/E multiple.

Bull **Rs759**
Sum of the parts

Biosimilars monetization in DM/EM markets: Stronger base business (Rs31/share), clinical progression of five follow-on biosimilars to Phase 3 trials (Rs44/share), monetization of global biosimilars in EU/US (Rs62/share), which could enrich valuations.

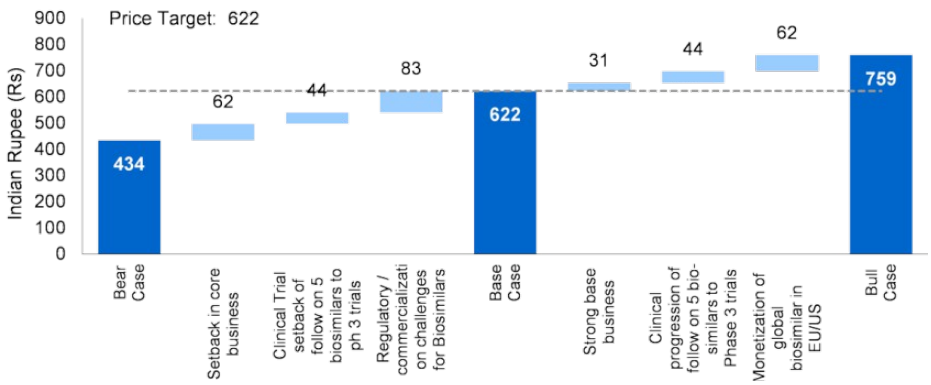
Base **Rs 622**
P/E multiple

US/EU biosimilar filings and gradual base business ramp-up: 15.2% sales growth for the base business and 11.7% earnings growth during F2015-17e. We apply a P/E of 21x to our FY18 EPS estimate of Rs29.6.

Bear **Rs434**
Sum of the parts

Commoditization of base business: Setback in core business (Rs62/share), clinical trials setback (Rs44/share) and regulatory delay/commercialization challenges for biosimilars in the EU/US (Rs83/share).

Exhibit 1: Bear to Bull Case



Source: Thomson Reuters, Morgan Stanley Research scenarios.

Investment Thesis

- Unlocking value in its global biosimilar pipeline and a steadily growing base business should present value in the stock, trading at 19.8x F17e EPS, implying a 15-20% discount to the sector.
- Longer term, Biocon is positioning itself as a key biotech player in both the biosimilar and proprietary segments – human insulin, trastuzumab, glargine, and adalimumab are nearing Phase 3 completion.
- We rate the shares OW relative to our coverage because of Bios's differentiated underlying biosimilars business and no pending FDA issues.

Key Value Drivers

- Acceptance of Bios's BLA filings
- EU/EM approval and launch of glargine, trastusumab and pegGCSF
- Indication extrapolation for adalimumab in EU/EM
- Positive US FDA review/acceptance of trastuzumab filings for early breast cancer

Potential Catalysts

- Global biosimilar filings – glargine, trastuzumab, peg-GCSF, adalimumab
- Favorable court outcome for peg GCSF biosimilars filers – Sandoz and Apotex versus Amgen
- Drug filings, approvals and commercialization – Malaysia facility for EM/DM
- Clinical progress of early stage biosimilar candidates (etanercept, bevacizumab, filgrastim) and insulins (lispro, aspart, Rh) to Phase 3 trials
- US FDA approval (indication extrapolation) for infliximab (Celltrion)
- Base business progress – US ANDA filings, Syngene ramp-up

Risks to Achieving Price Target

- Delay in launch of four key biosimilars in US/EU due to regulatory or legal challenges
- Innovator switching the patients to new brands or alternative therapies
- Higher-than-expected competition in developed and emerging markets
- No indication extrapolation for adalimumab or trastusumab in DM/EM markets
- Low utilization of Malaysian facility

Financials

Exhibit 2: Financials

Financial Summary

Income Statement

(Rs million)	2015	2016E	2017E	2018E
Sales	30,898	35,054	40,176	46,939
Cost of Goods Sold	15,580	17,877	20,490	23,939
Gross Profit	15,318	17,176	19,686	23,000
R&D Expenses	1,683	3,155	3,616	4,224
Personnel Costs	5,334	5,974	6,870	7,763
SG&A	3,026	3,330	4,018	4,929
Operating Profit	6,958	7,872	8,799	10,308
Non-Operating Income	531	1,350	2,067	2,220
EBITDA	7,489	9,222	10,866	12,528
Interest Expenses	89	143	623	672
Depreciation & Amortization	2,210	2,665	3,025	3,265
Pretax Profit	5,190	6,414	7,217	8,591
Income Tax	957	1,411	1,588	1,890
Minority Interest	310	583	672	774
Net Profit	**3,923**	**4,420**	**4,958**	**5,926**
Extraordinary item				
Reported Net profit	**3,923**	**4,420**	**4,958**	**5,926**
Effective Tax Rate	*18%*	*22%*	*22%*	*22%*
EPS (ex-extraordinary)	*24.9*	*22.1*	*24.8*	*29.6*
DPS	*5.0*	*5.0*	*7.0*	*8.0*

Cash Flow Statement

(Rs million)	2015	2016E	2017E	2018E
Profit after tax	4,974	4,420	4,958	5,926
Add : Depreciation	2,210	2,665	3,025	3,265
Add : Inc in Def Tax Liability	(33.0)	-	-	-
Extraordinary Items	-	-	-	-
Net change in Wrk capital	(3,372)	1,337	(1,977)	(2,747)
Net cash from operations	3,779	8,422	6,006	6,445
Capital Expenditure	(7,967)	(9,136)	(5,500)	(4,000)
Dec/(Inc) in Investments	645	-	-	-
Net cash from Investing	(7,322)	(9,136)	(5,500)	(4,000)
Issue of equity shares	-	-	-	-
Dividends paid including divdend tax	(1,170)	(1,170)	(1,638)	(1,600)
Net cash from financing	(1,170)	(1,170)	(1,638)	(1,600)
Net Inc/(Dec) in Net Debt	4,713	1,884	1,132	(845)
Opening Net Debt	(6,420)	(1,241)	649	1,781
Closing Net Debt	(1,241)	649	1,781	936
	-	-	-	-

Balance Sheet

(Rs million)	2015	2016E	2017E	2018E
SOURCES OF FUNDS				
Equity Capital	1,000	1,000	1,000	1,000
Reserves & Surplus	31,706	34,956	38,276	42,602
Networth	32,706	35,956	39,276	43,602
Minority Interest	1,722	1,722	1,722	1,722
Debt	10,306	11,550	12,527	13,502
Deferred tax	417	417	417	417
Total	**45,151**	**49,645**	**53,942**	**59,243**
APPLICATION OF FUNDS				
Net Block	15,807	21,285	22,759	22,494
Capital WIP	14,938	15,938	16,938	17,938
Intangible assets	2,320	2,320	2,320	2,320
Net Fixed Assets	33,065	39,543	42,017	42,752
Investments	131	131	131	131
Cash & Cash Equivalents	11,547	10,901	10,746	12,566
Inventories	4,527	7,203	8,255	9,645
Receivables	7,705	8,163	9,356	10,931
Loans & Advances	6,779	2,454	2,812	3,286
Current Assets	19,011	17,820	20,424	23,862
Less: Current Liabilities & Provisions	18,603	18,749	19,376	20,067
Net Current Assets	408	(929)	1,048	3,795
Total	**45,151**	**49,645**	**53,942**	**59,243**

Ratio Analysis

	2015	2016E	2017E	2018E
Profitability Ratios				
Gross Margin	49.6%	49.0%	49.0%	49.0%
Operating Margin	22.5%	22.5%	21.9%	22.0%
Pre-tax Margin	16.8%	18.3%	18.0%	18.3%
Net Margin	16.1%	12.6%	12.3%	12.6%
Sales Growth	7.4%	13.4%	14.6%	16.8%
Net Profit growth	-5.2%	12.7%	12.2%	19.5%
Valuation Ratios				
P/E	23.9	21.9	19.8	16.6
P/BV	3.0	2.7	2.5	2.3
ROE	13.0%	13.5%	13.8%	15.1%
ROCE	12.4%	13.8%	15.1%	16.4%
EV/EBITDA	13.4	11.1	9.5	8.2
Leverage Ratios				
Net Debt/Equity	0.0	0.0	0.0	0.0
Total Debt/Equity	0.3	0.3	0.3	0.3
Turnover Ratios				
Inventory (days of net sales)	60	60	60	60
Receivables (days of net sales)	41	41	41	41
Cash cycle (days of net sales)	101	101	101	101
Net working capital (x net sales)	-15	-3	1	19

Source: Company data, Morgan Stanley Research estimates

Investment Thesis

- **Double-upgrade to OW** in view of potential milestones (i.e., regulatory filings) for its four lead biosimilar compounds in the US and EU in 2016/F17. Plus, the base business should continue to grow at an early/mid teens rate. Valuation appears inexpensive, in our view.
- **Central thesis** – We have presented one Asian biosimilar case study in this report – Celltrion. It suggests that markets could be willing to pay for the pipeline as the company hits major milestones and US/EU markets continue to embrace new biosimilar launches.
- **Deep dive into the pipeline** – Based on our extensive proprietary work, we have presented nuances in BIOS's clinical trials, compared with competitors, assessed market potential by product/indication and derived revenue estimates till 2020 ($244mn, BIOS's share which we think should double its current profits at 30% margins).
- **Our new PT of Rs622** (21x F18e EPS) implies 26% upside potential. Assuming BIOS delivers on its pipeline over the next 5-10 years, **we expect this to be a multi-year growth and re-rating story**. BIOS is our favoured midcap in our coverage universe.

Biocon's current business profile – BIOS's current business includes bio-pharmaceuticals (statins, immuno-suppressants, etcetera), branded formulations in India, contract research (73% owned listed subsidiary, Syngene – US$1.2bn market cap), and some biosimilar business in emerging markets (insulin, glargine, etcetera). The company's nine-month annualized sales for F16 are Rs35bn with a net profit of Rs4.3bn. We estimate low- to mid-teens growth for Biocon's base business over the next couple of years. In addition, it is developing a global biosimilar pipeline in partnership with Mylan (covered by David Risinger).

Exhibit 3: Biocon: Biosimilar development pipeline and competitive landscape

			Stage of Development						
Orginiator Drug Profile		**Biosimilars**	**PreClinical**	**Phase 1**	**Phase 2**	**Phase 3**	**Filed**	**Approved**	**Comments**
Drug	**Lantus**	**Biocon**							Ph 3 completion in Jun 16/ Nov 16; US/EU filings in FY17
Global Sales	USD 7.1bn	Lilly							FDA approval in Dec 15; already launched in EU
Innovator	Sanofi								
US Patent	Feb-15								
EU Patent	May-15								
Indication	Type 1 and 2 Diabetes Mellitus								
Drug	**Herceptin**	**Biocon**							Ph 3 completion - Jan 16 (MBC); US/EU filings in FY17
Global Sales	USD 6.5bn								
Innovator	Roche	Amgen							Ph 3 completion - Jun 16 (EBC)
US Patent	Jun-19	Pfizer							Ph 3 completion - Oct 16 (MBC) / Apr 16 (EBC)
EU Patent	Jul-14	Celltrion							Ph 3 completion - Dec 16 (EBC)
Indication	mBreast Cancer	DRL							
Drug	**Neulasta**	**Biocon**							Ph 3 completion in Sep 15; US/EU filings in FY17
Global Sales	USD 4.7bn	Apotex							US filing in Dec 2014
Innovator	Amgen	Sandoz							US filing in Nov 2015
US Patent	Oct-15	Coherus							Ph 3 completion in Dec 15/ May 16; US Filing expetced in Mid 2016
EU Patent	Aug-17	Pfizer							
Indication	Chemo-induced Neutropenia								
Drug	**Humira**	**Biocon**							US/EU filings in FY17
Global Sales	USD 14bn	Amgen							US filing in Nov 15; EU filing in Dec 15
Innovator	Abbvie	Sandoz							Ph 3 completion in Jul-15
US Patent	Dec-16	Coherus							Ph 3 completion in May-16; US Filing expected in Early 2017
EU Patent	Oct-18	Baxalta							Ph 3 completion in Sep-16
Indication	Chronic Plaque Psoriasis	Boehringer							Ph 3 completion in Mar-17

Source: Company data, Morgan Stanley Research

Biocon's advanced biosimilar pipeline includes four products – glargine (brandname Lantus), trastuzumab (Herceptin), pegfilgrastim (Neulasta), and adalimumab (Humira). All four are in Phase 3 clinical studies, and BIOS/Mylan aim to file all four in the US and EU in 2016/F17. Details of clinical study designs are given inside.

We note that they have done Phase 3 in the US only for glargine, while the others are being done in the EU and emerging markets (though Phase 1 for a few have been done in the US). We also note that a couple of competitors are also following the same trials strategy. The tie-up with Mylan is on a cost- and sales- (royalty) sharing basis. We have assumed a one-third share for Biocon in the US/EU markets, while it retains full upside from EM launches.

Competitive positioning of pipeline – Please see **Exhibit3**We have compared Biocon's Phase 3 progress with other competing players. Overall, we believe that BIOS/Mylan should be among the first wave of launches in the US and EU markets for these products, implying reasonable economics. Also, the competitive intensity doesn't appear too high, with three competing products for glargine (including BIOS), five for trastuzumab, four for pegfilgrastim, and seven for adalimumab. EU launches can start in 2018 (subject to patent/SPC expiries) given limited legal barriers. We expect US launches will get delayed in view of potential patent court cases, 180-day patent dance, 30 months NDA (new drug application) stay, etc. We assume US launches from 2019 onwards.

What's the bottom line? We detail our product and market assumptions and estimates later in the report. In general, we assume 65-70% price erosion and up to 10% market share in the two or three years after launch for each of these products in the US/EU markets. This is based on a few recent instances of biosimilar launches in EU/EMs with 20-60% erosion (such as infliximab, glargine, filgrastim). Plus, this takes into account that BIOS/Mylan would likely be the third to fifth launch in most of these products (trastu could be earlier).

Exhibit 4: Mylan/Biocon sales, US$ millions

Biosimilars	Patent Expiration		Brand Sales	CY2017	CY2018	CY2019	CY2020
Mylan / Biocon Sales (US, EU, RoW)	**USA**	**EU**	**USD mn**				
Glargine	Feb-15	May-15	8.4	10	30	90	164
Trastuzumab	Jun-19	Jul-14	6.8	-	60	71	137
Pegfilgrastim	Oct-15	Aug-17	4.7	-	17	68	89
Adalimumab	Dec-16	Oct-18	14.0	-	10	39	72
Total Sales				**10**	**116**	**268**	**461**
Biocon Sales							
Glargine			-	10	24	54	90
Trastuzumab			-	-	37	44	75
Pegfilgrastim			-	-	9	30	41
Adalimumab			-	-	10	23	38
Total Sales			-	**10**	**79**	**152**	**244**

Source: Morgan Stanley Research estimates

We also note that follow-on competition beyond these competitors is not high, and is almost entirely absent in a few products, such as glargine, implying sustainable upside. Plus, emerging markets should provide a nice tailwind to BIOS's upside from its portfolio. Overall, we estimate US$244mn sales by 2020 for Biocon from these four products in the US, EU and EM markets. See **Exhibit 4**. Since these products would have been launched just one or two years previously, we expect sales to continue to grow after 2020. These should be high-margin sales and at 30% net margins would imply a doubling of BIOS's current net profit.

Underappreciated value – We benchmark BIOS's valuation versus prominent Asian biosimilar player Celltrion, later in this report. We believe that Celltrion's last seven years of drug development, a period over which its market cap grew ten-fold, to US$10bn now, could be a good comparison for Biocon ($1.4bn market cap) in terms of how the market values and discounts bio-similar pipelines as such pipelines make regulatory/monetization progress. The market discounted Celltrion as its lead compound, infliximab, made clinical and regulatory progress in the US and EU markets all the way until monetization. The milestones around which the stock appreciated most were filings of biosimilar applications in the US and EU, and its approval and market launch in the EU. In our view, such comparison is instructive in view of the similarity of underlying bio-similar business of the two companies, although the companies differ in terms of specific product profile and development stage.

Why should markets pay attention to BIOS now? We believe that as BIOS/Mylan get closer to four regulatory submissions in two major regions – the US and EU – in 2016/F17, the market will start to discount their pipeline even though monetization is two or three years away for each product (as was the case with Celltrion). Plus, BIOS is likely to accelerate its EM registrations using its Phase 3 data. In addition, its greenfield Malaysian facility will turn productive from F18 onwards. Finally, in the next 12-24 months, we believe markets will start to look favorably at BIOS's next product lineup (presently in the early stages of development, Phase 1)

– aspart, lispro, filgrastim, bevacumab, and etanercept.

Price target – We have raised our price target to Rs622 (21x F18e EPS) by rolling forward our target multiple by one year and raising it from 18.5x earlier. Our new target multiple is 15% higher than the shares' five-year average and is still at a 5-10% discount to industry multiples. We argue for a higher target multiple in view of the potential improvement in business fundamentals driven by the regulatory progress of its biosimilar pipeline. Our new price target implies 26% upside from the current share price, and we expect this to be a multiyear story as the global biosimilar market opens up and as BIOS/Mylan demonstrate success in commercialization.

What's in the price? The stock is trading at 19.8x F17e EPS, which primarily reflects its 'non-biosimilar' base business earnings. This is a 15-20% discount to the India pharmaceutical industry and in line with the stock's past five-year average valuations. We therefore believe that the market has not given much attention to BIOS's global biosimilar pipeline in view of uncertainty and a lack of major milestones. This should be addressed in the next few quarters as the company starts to file in the regulated markets and as the US and EU markets open up to biosimilars (such as Lilly's glargine launch in December 2016 or progress on Apotex's court case for pegfilgrastim in US).

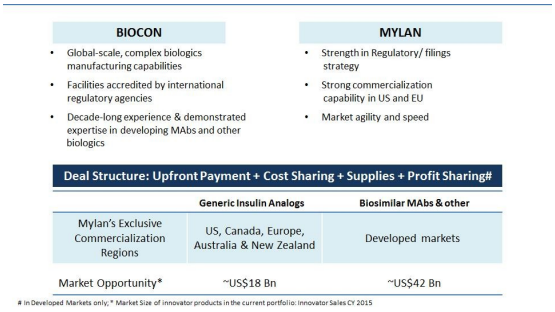
Key stock catalysts include:

- Filing of dossiers for the US/EU – glargine, trastuzumab, peg-GCSF, adalimumab
- Clinical progression of five follow-on biosimilars to Phase 3 trials
- Registration and monetization in EM for its biosimilar pipeline
- Malaysian facility – drug filings, approvals and monetization
- US court case progression for competition for biosimilars (such as pegfilgrastim for Apotex, infliximab for Celltrion) providing visibility for follow-on players like BIOS
- Base business progress – US ANDA filings, Syngene ramp-up

Morgan Stanley versus consensus – The Street has a split opinion on BIOS shares, with 9 Buy, 5 Hold and 9 Sell recommendations, as per Bloomberg. Our double upgrade to OW will mean 10 Buy recommendations versus 13 'non Buys', making our views a bit on the anti-consensus side. We note that the average price target on Bloomberg for BIOS is Rs512/share, while our new price target is 22% higher, at Rs622 (it is among the top two in a group of 23 analysts covering the stock).

Industry positioning – BIOS is our favourite mid-cap idea in our coverage universe due to its multi-year growth and re-rating story. In addition, we like Glenmark (OW) among the mid caps. In the large caps, we like Lupin (OW) due to impending earnings momentum driven by gFortamet and gGlumetza. We are EW on Sun (high dependence on gGleevec for F17e EPS, Halol can delay US base business recovery) and DRL (FDA and earnings risks). We are UW on GSK (slow growth and rich valuations) and Cipla (limited US pipeline).

Exhibit 5: Mylan/Biocon partnership



Source: Biocon

Central Debate – When Will the Market Start Paying for Biocon's Global Biosimilar Pipeline?

Case study

Biocon has been investing in its global biosimilar pipeline for the past few years. However, so far the market has valued the company for its base business comprising APIs (statins, insulin, immuno-suppressants), contract research (73.5% owned listed subsidiary, Syngene), and domestic branded formulations. The stock currently trades at 19.8x F17e EPS (a 15% discount to the industry), which primarily reflects base business earnings.

Why have the markets not paid attention to BIOS's global biosimilar pipeline? We believe it is for the following reasons:

1) So far, BIOS has been in the investing phase in terms of research spend on global trials and capex for its glargine facility in Malaysia. No major milestone has been announced by the company

2) It has had limited success in commercialization of its biosimilar assets, predominantly in less lucrative EMs. Developed-market monetization is still at least two to three years away

3) Major milestones, such as dossier submissions, approvals, patent challenge court cases, and launches, have not been achieved for any of its four leading biosimilar assets

4) The US/EU biosimilar ecosystem has been uncertain up until recently in terms of regulatory approvals, patent estate and intellectual property court cases, substitutability, indication extrapolation, etcetera.

What is different now? We believe that BIOS will transition from the development stage (2008-15) for its lead compounds to the advanced regulatory and monetization stage over the next five years (2016-20). This is an important transition and is the one, we believe, that will be valued by investors as BIOS hits major milestones. We expect 2016 to be the transformational year for BIOS, if it succeeds in filing four dossiers in the US and EU markets each. We cite the following key developments which should change perceptions about BIOS and spur the market to start paying for its pipeline.

1) Both BIOS and Mylan have highlighted potential US and EU filings for all four lead compounds in F17/2016. This will also be accompanied by filings in several EMs.

2) Clinicaltrials.gov indicate completion of Phase 3 studies for glargine, trastuzumab, peg GCSF, and adalimumab in June/November 2016, January 2016 , Sep 2015 and 2016/17 – all of which are consistent with management expectations of C16/F17 filing timelines. Though we note that it is doing US-based studies only for glargine, the rest all are global (ex US) Phase 3 trials.

3) Several precedents will be set by other companies in their run-up to biosimilar monetization, providing clarity for the evolution of BIOS's pipeline. In particular, we cite the potential glargine launch in the US by Lilly in December 2016 (settled with Sanofi), pending US approval for Celltrion's infliximab, and the progression of the Apotex court case for peg-GCSF in the US (see following sections with details on each assets).

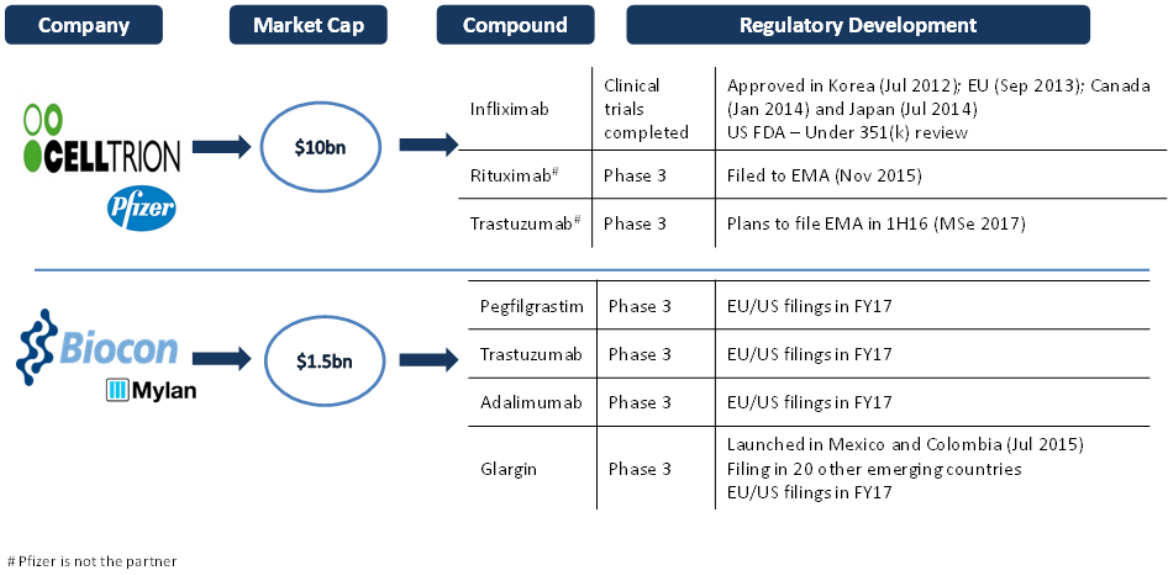
4) BIOS commissioning of its US$200m greenfield glargine facility in Malaysia and its qualification by several global regulatory agencies in F2016-17.

5) Validation of BIOS's pipeline in view of its partnership with Mylan and their matching guidance on regulatory progress.

Celltrion Case Study – We detail below a case study on Celltrion, Korea– to illustrate how markets have valued

this company as its global biosimilar pipeline made regulatory progress over the past few years. We note that there are several differences between the two – Celltrion and Biocon – in terms of products under development, regulatory progress achieved, competitive dynamics, business plan, commercial upside, et cetera. However, in our view, the broader comparison between the two is relevant and apt for the purpose of identifying inflection points and benchmarking BIOS.

Exhibit 6: Biocon valuation and pipeline comparison with Celltrion



Pfizer is not the partner

Source: Company data, Morgan Stanley Research

Valuations – Biocon's current market capitalization is US$1.4bn versus US$10bn for Korea-listed Celltrion. These market capitalizations imply P/Es of 19.8x and 38.7x for Biocon and Celltrion, respectively.

What do they have? The late-stage biosimilar pipeline for the two companies is summarized in **Exhibit6** above Both of these companies have three to five assets in late stage - ie, either Phase 3, the filing or the approval stage. Celltrion is ahead of the others in commercialization, with infliximab already launched in the EU and US approval expected in the near term. In addition, it has already filed rituximab in EU in November 2015 and plans to file trastuzumab application in EU in 2016. Similarly, Biocon has common asset trastuzumab and three other assets, all expected to get filed in the EU/US in FY17.

Partnerships to lend credibility and imply shared economics – Both of these Asian players have partnered with different US companies for commercialization. Celltrion is partnered with Pfizer (select products/select markets) while Biocon is partnered with Mylan. This implies that both of these players will enjoy shared economics (35-50% of overall sales, on our estimates), and hence, our comparison is like-for-like. Also, the partnership-driven model lends credibility to the underlying research and development work done by these two Asian players and a brings higher probability of success.

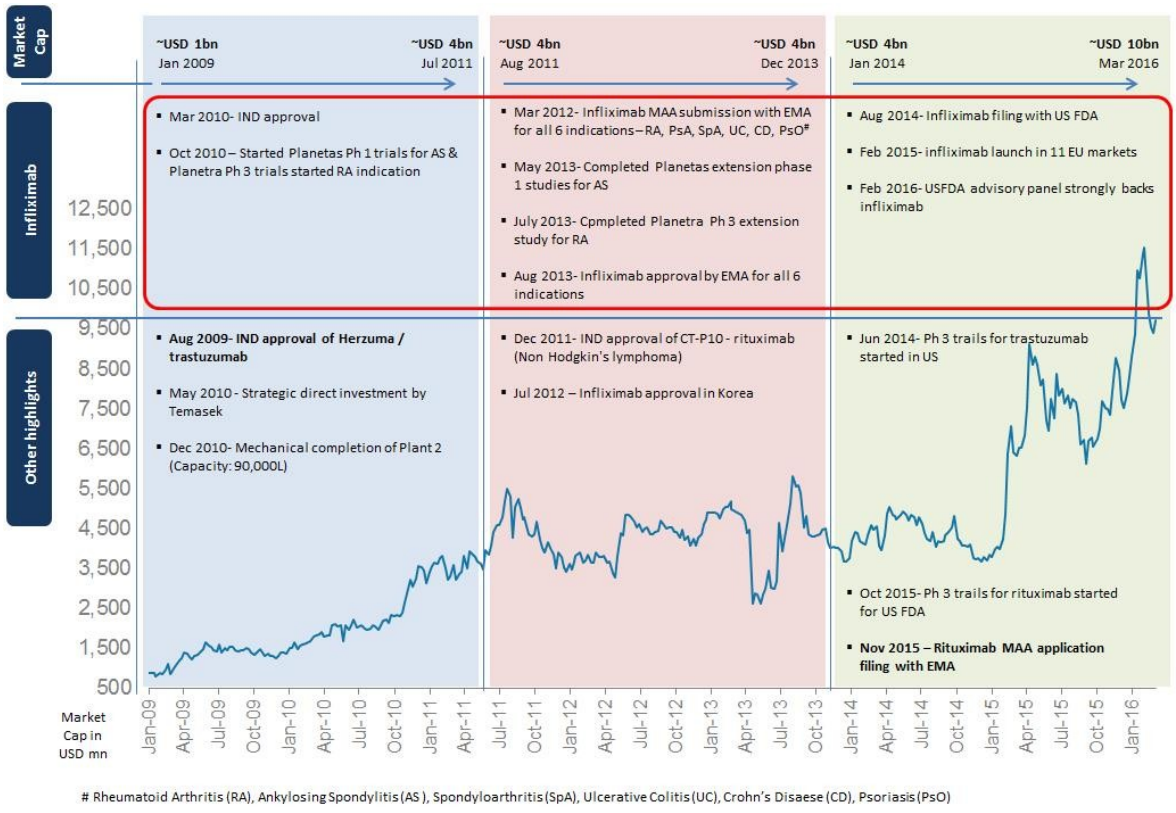
Morgan Stanley is acting as financial advisor to Allergan plc ("Allergan") in relation to its definitive merger agreement under which Pfizer Inc. ("Pfizer") will combine with Allergan, as announced on November 23, 2015. The transaction is subject to certain conditions, including receipt of regulatory approval in certain jurisdictions, including the United States and European Union, the receipt of necessary approvals from both Pfizer and Allergan shareholders and the completion of Allergan's pending divestiture of its generics business to Teva Pharmaceutics Ltd.. Allergan has agreed to pay fees to Morgan Stanley for its financial services, including transaction fees that are contingent upon the closing of the transaction. Please refer to the notes at the end of the report.

Case Study #1 – Celltrion's Journey Thus Far

Celltrion's market capitalization has risen ten-fold over the past seven years, from US$1bn in early 2009 to US$10bn now. We summarize the key developments that coincided with the evolution of its market cap in

Exhibit 7. A simple assessment shows that markets have priced in or rewarded valuations as the company demonstrated its regulatory and commercial success with its lead compound, infliximab (Remsima, Johnson & Johnson's Remicade). Progress or completion of clinical trials, regulatory filings, and approval and commercialization in the US and EU appear to be the most dominant factors in stock price evolution, according to Jennifer Kim, Morgan Stanley's Korean Pharma analyst covering Celltrion. Her rating on Celltrion is UW, while the price target of KRW71,000 implies a US$6.7bn market cap.

Exhibit 7: Celltrion's market cap re-rating



Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS), Spondyloarthritis (SpA), Ulcerative Colitis (UC), Crohn's Disaese (CD), Psoriasis (PsO)

Source: Thomson Reuters, company data

Phase 1: 2009-11 – During this phase, Celltrion was conducting Phase 3 clinical studies for its lead compound, infliximab, in the EU and US. Plus, it had received IND (Investigational New Drug Application) approval for its second biosimilar asset – trastuzumab. While the drug was making regulatory progress during this three-year period, the market cap of the company grew 4x, to USD4bn from USD1bn in 2009.

Phase 2: 2011-13 – This was a volatile phase for the stock, in which it rose by 100% from its lows to hit a US$5bn market cap (mid-2013), but point to point, the stock was flat over this three-year period. Notably, the stock peaked in August 2013 (up 100% in four months) on account of EU approval for infliximab for all six indications.

Phase 3: 2014-16 – During the most recent phase, the stock has more than doubled, from a US$4bn market cap in early 2014 to US$10bn now. This period has been the most successful for Celltrion in terms of monetization of infliximab (in 11 EU markets in February 2015) and regulatory progress in the US (strong FDA advisory panel backing in February 2016).

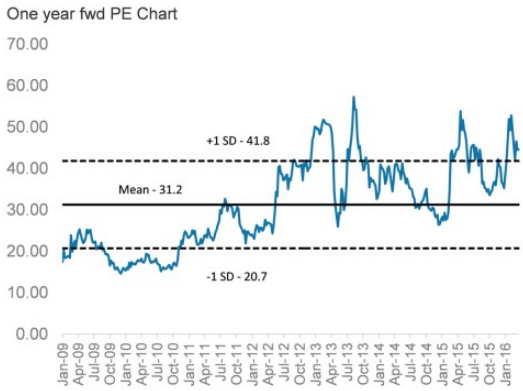
Re-rating story – Over the past 7-8 years, Celltrion's stock has re-rated as it demonstrated success with its global biosimilar pipeline. In Phase 1 (2009-11), the stock traded at roughly 20x one-year forward earnings. This has now re-rated to 40-50x forward earnings over the last couple of years.

Implications for Biocon – It appears to us that Biocon is in the Phase 1 equivalent of the Celltrion story above, in view of it potentially filing four products in the US and EU markets (each) over the next few months. However, markets have yet to recognize the progress for BIOS, in our view. Approvals and launches should happen over

the next 2-4 years, we estimate. Biocon is presently valued at a US$1.4bn market capitalization versus roughly US$4bn for Celltrion during Phase 2 above.

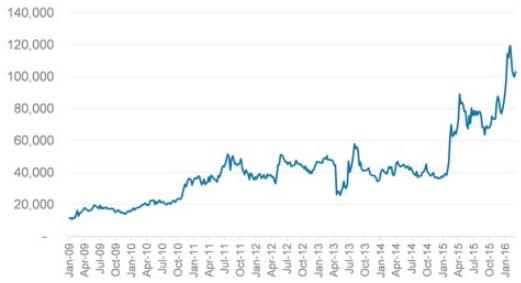
Notably, Celltrion was trading around 20x one-year forward earnings before regulatory approvals, and subsequently re-rated to 40-50x. Biocon is presently trading at 19.8x F17e EPS, implying a material re-rating possibility if its biosimilar pipeline delivers.

Exhibit 8: Celltrion: One-year forward P/E (x)



Source: Thomson Reuters, Morgan Stanley Research

Exhibit 9: Celltrion: Share price (KRW)



Source: Thomson Reuters, Morgan Stanley Research

We note that Celltrion's earnings also included an inventory buildup of infliximab at a sister company (Celltrion Healthcare, 53.8% owned by the chairman, Jung-Jin Suh). In contrast, BIOS's current sales are largely derived from its base business, including some contribution from EM biosimilars (and no contribution from DM biosimilars). This would give multi-year growth visibility if and when its biosimilars get launched in the US/EU markets over the next five years.

Exhibit 10: Follow-on – Biosimilar and insulin pipeline

Other Biosimilars Program			Stage of Development						
Orginiator Drug Profile		Biosimilars	PreClinical	Phase 1	Phase 2	Phase 3	Filed	Approved	Comments
Enbrel (etanercept)		**Biocon**							
Global Sales	USD 8.7bn	Sandoz							FDA filing in Oct15
Innovator	Amgen								
US Patent	Apr-29	Coherus							EU filings in End 2016 / Early 2017
EU Patent	Aug-15	Celltrion							
Indication	Auto-immune						Enbrel etanercept		
Neupogen (filgrastim)		**Biocon**							
Global Sales	USD 1bn	Sandoz							FDA approval in Mar 15; US launch in Sep 15
Innovator	Amgen	Apotex							US FDA filing in Feb 2015
US Patent	Dec-13	Several filgrastim biosimilars approved in EU - Sandoz, Ratiopharma, Hexal, Hospira, Accord, AbZ Pharma, Apotex							
EU Patent	Expired								
Indication	Chemo-induced Neutropenia						NEUPOGEN (FILGRASTIM)		
Avastin (bevacizumab)		**Biocon**							EU Phase 1; RoW Phase 3 trials
Global Sales	USD 6.9bn	Amgen/Allergan							Ph 3 studies completed in Sep 15; Filing in 2016
Innovator	Roche	Pfizer							Ph 3 studies started in July 2015
US Patent	Jul-19	Boehringer							Ph 3 recuritement
EU Patent	Jan-22								
Indication	mColorectal Cancer	Sandoz							
		Oncobiologics							
		Momenta							
		Coherus					AVASTIN bevacizumab		
Humalog (lispro)		**Biocon**							
Global Sales	USD 2.8bn	Sanofi							Ph completion in Dec 15 and Feb 16
Innovator	Eli Lilly								
US Patent	Expired								
EU Patent	Expired								
Indication	Diabetes						Humalog insulin lispro		
Novolog (aspart)		**Biocon**							
Global Sales	USD 4.7bn	Sanofi							
Innovator	Novo Nordisk								
US Patent	Expired								
EU Patent	Expired								
Indication	Diabetes						NovoLog insulin aspart (rDNA origin) injection		

Source: Biocon, Morgan Stanley Research

Deep Dive into the Pipeline #1 – Glargine

Introduction – We believe that BIOS's global biosimilar pipeline is not well contextualized by the Street, and is therefore not well understood by investors. Economics for each product are nuanced by launch timing, competitive dynamics, sales by indication, patent expiration/estate, etcetera for each of the two key markets – the US and EU. In this section, we have detailed each of the four leading assets of BIOS and assessed the commercial upside over next five years till 2020.

Asset #1 – Glargine

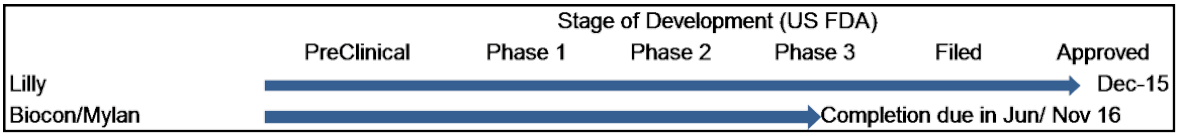
Drug profile – Lantus (insulin glargine) is a long-acting basal insulin analogue (human insulin), given once daily to help control blood sugar levels of those with type 1 and 2 diabetes. The product was developed by Sanofi. It comes in two forms: Solostar pen and vial.

Patent expiry – Lantus's compound patent expired in August 2014 and pediatric exclusivity expired in February 2015 in the US, whereas the compound patent expired in November 2009 in the EU and Japan. A patent term extension in Japan expired in November 2014. The supplementary protection certificate (SPC) for Lantus including pediatric extension in major EU countries expired in May 2015. Sanofi also has patents protecting the Lantus formulations and devices that are currently under litigation and which expire on varying dates between 2023 and 2028.

Market potential – Lantus generated estimated global sales of US$7.1 bn ($ 4.5 bn in US) in net sales globally for Sanofi in 2015. The leading countries which contributed to Lantus sales were the US, France, China, and Germany. The total market for basal insulin is around US$13.2bn in the US, of which Lantus has a 50-60% share by volume. As per Sanofi's 20 F filings, the Lantus market in the US is assumed to be flat to slightly growing till 2019.

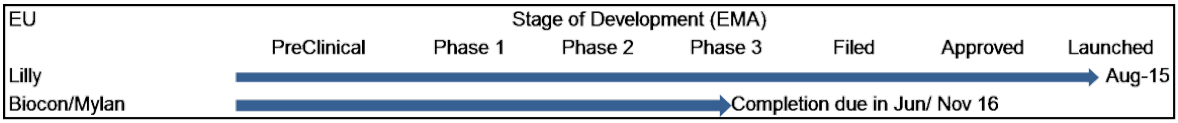
Competitive landscape – Lilly is among those ahead of Biocon/Mylan in the biosimilar glargine queue, as far as development stage, with Biocon's completion due in June/November 2016.

Exhibit 11: Biosimilars of glargine – Stages of development (US FDA)



Source: Clinical trials, company data, Morgan Stanley Research

Exhibit 12: Biosimilars – Stages of development (EMA)



Source: 10K filings, company data, Morgan Stanley Research

Lilly and Boehringer Ingelheim (BI) have co-developed Lantus biosimilars for both the US and EU markets as Basaglar and Abasria, respectively. Their launch plan in US / EU markets is as following:

US market – Lantus biosimilar Basaglar from Eli Lilly got US FDA approval through 505(b)(2) route in Dec 2015 (tentative approval in Aug 2014, filed in Oct 2013). However, in Sep 2015, Sanofi and Lilly reached an agreement according to which Lilly would not launch Lantus biosimilar in US till Dec 2016. The settlement is restricted to Lantus Solostar (inj pen version) and doesn't cover the drug packaged in vials or any Lantus combination products. Solostar accounts for 62% Lantus sales in US.

EU markets – Lilly / BI got approval for Lantus biosimilar Abasaglar from the EU in Sep 2014 (filed with EMA in July 2013). Beginning in 2015, Lilly introduced Abasaglar in some of the key markets such as Czech Republic, Slovakia, and Estonia, followed by the UK in August 2015, at around a 15-20% price discount to the innovator.

Exhibit 13: Abasaglar pen from Lilly

Source: Company Presentation

Exhibit 14: Lilly / BI LY2963016 Studies

Lilly / BI LY2963016 Studies		
	Insulin Glargine	Insulin Glargine
Phase	Phase 3	Phase 3
Health Authority	Global (inc. US FDA)	Global (inc. US FDA)
Clinicalreadouts.gov Identifier	NCT01421459	NCT01421147
Indications	**Diabetes Mellitus, Type 2**	**Diabetes Mellitus, Type 1**
Estimated Enrollment	759	536
Study Start Date	September 2011	August 2011
Primary Completion Date	September 2012	August 2012
Study Completion Date	September 2012	April 2013
Status	Completed	Completed
Sponsor / Collaborator	Lilly / BI	Lilly / BI

Source: Clinicaltrials, Morgan Stanley Research

Exhibit 15: Biocon/Mylan Phase 3 Trials

Biocon /Mylan Phase 3 Trials			
	Insulin Glargine	Insulin Glargine	Insulin Glargine
Phase	Phase 3	Phase 3	Phase 3
Health Authority	Global (inc. US FDA, EMA)	Global (inc. US FDA, EMA)	Global (inc. US FDA, EMA)
Clinicalreadouts.gov Identifier	NCT02227862	NCT02227875	NCT02666430
Indications	**Type 1 Diabetes**	**Type 2 Diabetes**	**Type 1 Diabetes Mellitus**
Estimated Enrollment	500	600	110
Study Start Date	August 2014	August 2014	December 2015
Primary Completion Date	June 2016	June 2016	November 2016
Study Completion Date	June 2016	June 2016	November 2016
Status	Ongoing(enroll, completed)	Ongoing(enroll, completed)	Enrolling
Sponsor / Collaborator	Mylan/Biocon	Mylan/Biocon	Mylan/Biocon

Source: Clinicaltrials, Morgan Stanley Research

Biocon and Mylan insulin glargine biosimilar development plan – Mylan/Biocon started two Phase 3 non-inferiority studies for insulin glargine in August 2014 and one Phase 3 extension study in December 2015 in the US. Each of these trials are listed in Europe as well with similar start dates. The non-inferiority studies are expected to be completed by June 2016 and an extension study by November 2016.

EM/RoW insulin biosimilar progress – LILY/BI received Japanese regulatory approval for their insulin glargine product in January 2015. Subsequently, in May 2015, Australia's Pharmaceutical Benefits Advisory Committee (PBAC) gave positive recommendations to Lilly's biosimilar glargine, Basaglar. In addition, PBAC said that it will consider marking the biosimilar as equivalent (i.e. flagging). Biocon launched insulin glargine in the Colombian and Mexican markets in July 2015. Before that, in 2009, it launched Basalog – long-lasting basal insulin glargine in India. In addition Biocon has registered glargine in 20 emerging markets. Recently, BIOS announced the approval of its glargine in Japan. Indian generic drugmaker Lupin has entered into a strategic distribution agreement with LG Life Sciences (South Korea) to launch insulin glargine (Basugine).

Key challenges that Mylan/Biocon may face:

- **Patent litigation barrier** – 30 months stay post litigation (delayed launch) may arise if Biocon/Mylan go through the 505(b)(2) route (like the Lilly case). If they plan to file the under 351(k), they may need to give 180 days notice to innovator after product approval.
- **Market conversion from Lantus to Toujeo** – Sanofi launched Toujeo (a new formulation of insulin glargine) in the US at the end of March 2015 at a price level similar to Lantus. The aim is to shift Lantus market to Toujeo before entry of biosimilars
- **Marketing challenges** – Lilly is among innovators with strong marketing teams versus Mylan which is a specialty company with limited marketing experience (especially in diabetes). The impact can be meaningful if the FDA doesn't give interchangeability status.
- **Third in the queue** – Biocon/Mylan are tracking to be the third players in the insulin

biosimilar market both in the US and EU. Lilly is among those that would have first-mover advantage over Mylan/Biocon, which could limit Mylan/Biocon market-share gains.

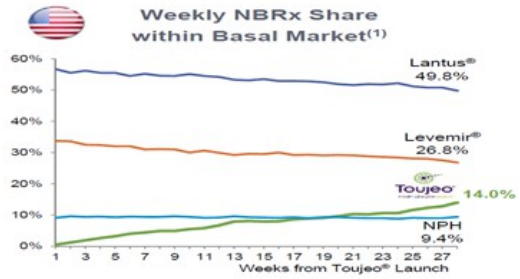
Economics – Overall, we estimate worldwide sales of US$24mn/$54mn/$90mn in 2018/19/20 (FY19/20/21) for Biocon assuming 65-70% price erosion and 5-10% market share in the regulated markets.

Exhibit 16: Glargine economics

Glargine	CY2017	CY2018	CY2019	CY2020
US Sales to Mylan/Biocon	-	-	40	94
US Sales to Biocon	-	-	14	33
US Price Discount	*40%*	*65%*	*70%*	*70%*
US Market Share			*3%*	*7%*
EU / RoW Sales to Biocon	10	24	40	57
Total Sales to Biocon	**10**	**24**	**54**	**90**

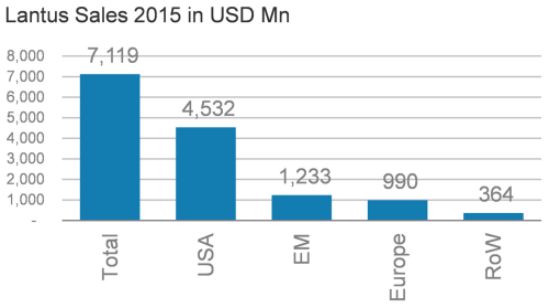
Source: Morgan Stanley Research estimates

Exhibit 17: Weekly NBRx share within basal in US



Source: Company data

Exhibit 18: Lantus reported sales



Source: Company data

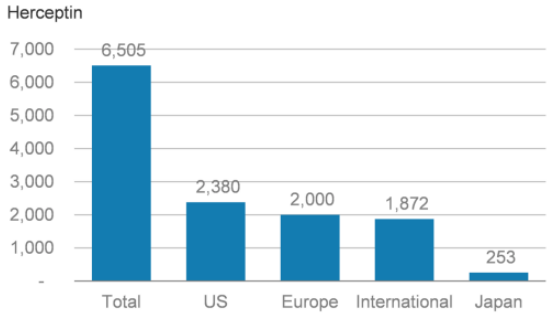
Deep Dive into the Pipeline #2 – Trastuzumab

Drug profile – Trastuzumab (brandname Herceptin) is a monoclonal antibody that interferes with the human epidermal growth factor receptor (HER2)/neu receptor. In some cancers, notably certain types of breast cancer, HER2 is overexpressed, and causes cancer cells to reproduce uncontrollably. Trastuzumab is therefore used to treat certain breast cancers. Roche is the innovator of Herceptin. The product was approved by the US FDA in September 1998 and by EMA in August 2000.

Patent expiration – The compound patent for Herceptin expires in the US in June 2019 and expired in Europe in July 2014. Previously, Hospira UK won a court case overturing two patents (115 and 455) related to dosages and the composition of the drug. The basic underlying compound patent held by Roche on its medicine was not challenged by Hospira.

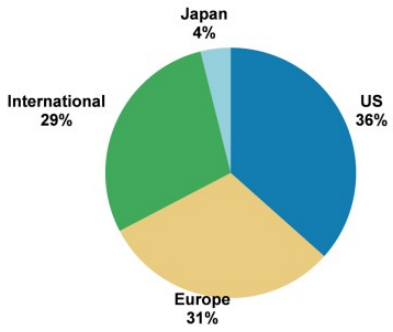
Market – Total sales for Herceptin in 2015 were US$6.5bn. The US accounts for roughly 35% of the market (US$2.4bn) while Europe is the second-largest market with a 30% share. Herceptin is used for adjuvant (early stage) and metastatic (late stage) breast cancer. A cancer's stage refers to how much the cancer has grown and where it has spread. Early-stage cancer treatment accounts for roughly 60% of Herceptin's global sales.

Exhibit 19: Herceptin sales (US$ millions), 2015



Source: Roche

Exhibit 20: Herceptin sales by region, 2015



Source: Roche

Innovator defence – Roche is focusing on combination therapies HER2 plus franchise in order to defend its Herceptin market. Its HER2 franchise (Herceptin plus new additions, Perjeta and Kadcyla) has been able to generate significant demand owing to longer treatment duration for patients taking the new standard combination (Herceptin + Perjeta +docetaxel) as a first-line therapy in HER2 positive MBC, accounting for 40% of Herceptin's global sales. Roche is also carrying out the APHINITY trial for the Herceptin + Perjeta combination to expand into adjuvant therapy (~60% of Herceptin sales).

In addition, Roche has already improved formulations (greater patient convenience) for trastuzumab (from intravenous – 150mg/440mg to subcutaneous injection – 600mg) in ex-US markets.

Herceptin – Intravenous versus subcutaneous

"The subcutaneous formulation of Herceptin provides an alternative to intravenous Herceptin and is an important treatment option for patients with HER2 positive breast cancer. Because it is less invasive and takes five rather than 30-90 minutes to administer, subcutaneous Herceptin is more convenient for patients and may reduce healthcare costs relative to the standard intravenous formulation."

– Hal Barron, M.D., Roche's Chief Medical Officer and Head, Global Product Development

Competitive landscape – The USFDA has yet to approve any cancer-related indications for any of the monoclonal antibody biosimilars. Response rate – not survival or progression-free survival – is an acceptable primary end point in clinical trials of biosimilars versus the originator drug. Currently, five trastuzumab biosimilars are under Phase 3 clinical development, including Mylan/Biocon's entry.

Based on primary completion dates for Phase 3 trials, it appears that the leading five players will complete primary Phase 3 trials in 2016. And given that the US patent expiration is in June 2019, all of them can potentially be in the US in the first wave of launches, subject to innovator patent defence including patent challenge court cases.

Clinical design – We note differences in the clinical trial settings for these five players in terms of indication (early breast cancer, EBC, or metastatic breast cancer, MBC), geography of trials (US and/or non-US), and number of patients recruited. We believe that EBC trials may be more important than MBC since late-stage patients are already exposed to certain treatments and therefore the impact of trastuzumab may be difficult to establish in these patients. PFE and Celltrion are the only players that are doing Phase 3 trials for both EBC and MBC. The FDA may not allow indication extrapolation in the case of oncology products such as Herceptin.

Amgen – As per Amgen's biosimilar pipeline disclosures, it is conducting trials for ABP 980 in both breast and gastric cancer. As per clinicaltrials.gov, it appears Amgen is conducting trials in non-US countries such as Germany, the UK, Italy, Canada, Russia, Brazil, Mexico, and South Africa.

Exhibit 21: Amgen's trastuzumab biosimilar readouts

Amgen's trastuzumab biosimilar readouts	
	trastuzumab (ABP 980)
Phase	Phase 3
Health Authority	EU
Identifier	NCT01901146
Indications	**Early Breast Cancer**
Estimated Enrollment	827
Study Start Date	April 2013
Primary Completion	June 2016
Study Completion	February 2017
Primary Outcome Measures	pCR (invasive tumour adsence within 3-7 wks after the last dose in the neoadjuvant ph
Secondary Outcome	Event-free survival/Overall survival (16 months)
Status	Ongoing (enroll. Completed)

Source: clinicaltrials.gov, Morgan Stanley Research

Pfizer – Pfizer has only enrolled 220 patients versus, for example, Amgen's 806, in Phase 3 trials for early breast cancer Phase 3 studies. The US FDA is the health authority for its two Phase 3 clinical trials.

Exhibit 22: Pfizer's trastuzumab biosimilar readouts

Pfizer's trastuzumab biosimilar readouts		
	trastuzumab (PF-05280014)	
Phase	Phase 3	Phase 3
Health Authority	US FDA	US FDA
Identifier	NCT01989676	NCT02187744
Indications	**Metastatic Breast Cancer**	**Early Breast Cancer**
Estimated Enrollment	690	220
Study Start Date	February 2014	September 2014
Primary Completion	October 2016	April 2016
Study Completion	February 2018 (Co. guides October 2017)	December 2016
Primary Outcome Measures	ORR (Week 25)	% of patients with steady state drug concentration Cycle 5
Secondary Outcome	Duration of Response (DOR) upto 12 months (1-yr PFS, 1-yr Survival Rate)	pCR/incidence of anti-trastuzumab antibodies (ADAs)
Status	Recruiting	Ongoing (enroll. Completed)

Source: clinicaltrials.gov, Morgan Stanley Research

Exhibit 23: Mylan trastuzumab biosimilar readouts

Mylan trastuzumab biosimilar readouts		
	trastuzumab (PF-05280014)	
Phase	Phase 3	Phase 1
Health Authority	Global (Ex US FDA)	US FDA
Identifier	NCT02472964	NCT02594761
Indications	**Metastatic Breast Cancer**	**Early Breast Cancer**
Estimated Enrollment	600	132
Study Start Date	July 2012	Aug 2013
Primary Completion	Jan 2016	Feb 2014
Study Completion	Dec 2018	Feb 2014
Primary Outcome Measures	Best Overall Response rate	Pharmacokinetic similarity
Secondary Outcome	Time to tumor progession Overall Survival Duration of Response	Local Infusion Tolerance Immunogenicity Measurement of C-reactive Protein
Status	Ongoing (enroll. Completed)	Completed

Source: clinicaltrials.gov, Morgan Stanley Research

Biocon/Mylan– Mylan started Phase 3 trials Hercules Myl1401O (biosimilar trastuzumab) in July 2012 (in non-US markets) for metastatic breast cancer indications which are expected to get completed by December 2018 (primary completion by January 2016). Previously Mylan/Biocon completed Phase 1 trials in February 2014 for EBC with the US FDA as the key health authority.

Celltrion – Hospira used to be the marketing partner for trastuzumab. Following the Pfizer-Hospira deal in

2015, Pfizer decided to return the rights to Celltrion. During an analyst day on December 7, 2015, management commented that it might seek a new marketing partner in Europe, but potentially pursue a direct sales model in the US. Though Celltrion had a headstart on others for its trastuzumab Phase 3 trials (commenced in June 2010), it has to start new trials since earlier trials were done for MBC (and not EBC). The US FDA is the key health authority for both of these Phase 3 clinical trials.

Exhibit 24: Celltrion's trastuzumab biosimilar readouts

	trastuzumab (CT-P6)			
Phase	Phase 3	Phase 3	Phase1/ Phase 2	Phase1 (New)
Health Authority	Hungary, US FDA	Singapore, US FDA	Korea, US FDA	USFDA
Identifier	NCT02162667	NCT01084876	NCT01084863	NCT02665637
Indications	**Early Breast Cancer**	**Metastatic Breast Cancer**	**Metastatic Breast Cancer**	**Healthy Volunteers**
Estimated Enrollment	532	383	174	70
Study Start Date	June 2014	June 2010	January 2010	December 2015
Primary Completion	December 2016	December 2011	December 2011	July 2016
Study Completion	June 2019	December 2017	December 2017	July 2016
Primary Outcome Measures	Pathological Complete Response(pCR) after Neo-adjuvant therapy/Surgery (up tp 30wk)	Efficacy; Designated as safety issue:No	PK; Designated as safety issue:No	PK (up to 10wk); Designated as safety issue:N
Status	Recruiting	Ongoing(enroll, completed)	Ongoing(enroll, completed)	Recruiting
	Korea FDA approved in January 2014; Brazil ANVISA rejected in March 2016			

Source: clinicaltrials.gov, Morgan Stanley Research

Demonstrating immunogenicity is challenging in immunosuppressed oncology patients – Clinical trials must be carried out in a sufficiently sensitive and homogenous population. For trastuzumab biosimilars, EBC represents a more sensitive and homogeneous population, while MBC is a highly heterogeneous setting that can vary based on prior treatment, the location of metastasis, and the molecular phenotype of the metastatic cell. Since common breast cancer treatments (chemotherapy and radiotherapy) are associated with an immunosuppressive effect, MBC patients are more likely to have greater risks of immune impairment and secondary cancers.

Indication extrapolation – It is unclear whether the FDA will allow indication extrapolation (from MBC to EBC).

Clinical trials design for trastuzumab

In the United States, the first approval of trastuzumab biosimilars will probably be in the neoadjuvant setting. "This is the ideal platform for testing trastuzumab biosimilars, because it is the most homogenous population not confounded by prior use of chemotherapy and other factors, and it is the most sensitive population to trastuzumab-based chemotherapy."

– Dr. E. Francisco J Esteva, M.D., PhD, Medical Oncology, NYU Medical Oncology Associates

Early/pre-clinical stage developments – A few other players who are working on this opportunity for various EM/DM markets include Dr. Reddy Lab (India), Hanwha Chemical (South Korea), PlantForm (Canada), Stada/Gedeon Richter (Germany/Hungary), BioXpress (Switzerland), and Oncobiologics/Viropro (USA).

Emerging markets – There have been a few EM approvals of trastuzumab, including Canmab by Biocon in India (2014), Herzuma by Celltrion in South Korea (2014), and by Biocad in Russia (2016).

Risks to trasuzumab opportunity

- **Innovator defence** – Innovator Roche is aggressively defending the Herceptin market against biosimilars through improved formulations (from intravenous to subcutaneous injection) in ex-US markets, new standard combination (Herceptin + Perjeta + docetaxel) as a first-line therapy in HER2 positive MBC and APHINITY trial for the Herceptin + Perjeta combination to expand into adjuvant therapy.
- **Physician acceptance** – Building up physician acceptance of biosimilars will not happen

quickly, as oncologists are likely to demand more clinical and long-term post-approval data before they are convinced that biosimilars have comparable efficacy and safety profiles compared with reference drugs. In addition, oncologists may be more conservative in switching their patients to biosimilars during the relatively short period of treatment course compared with chronic diseases such as RA and diabetes. From a patient's perspective, efficacy is naturally more important than price.

- **IP challenge** – There could be patent defence by the innovator in the court, which could delay the generic launches.

Economics – We expect 4-5 players to launch biosimilar trastuzumab in the US in the first wave, including Amgen, Pfizer, Celltrion, and Mylan/Biocon. Most of these players are expected to enter the European market first since the EU patent expired in 2014. We estimate Biocon's share of sales at roughly US$37mn, US$44mn and US$75mn in 2018/19/20, with 5-7% market share and 65-70% price erosion.

Exhibit 25: Trastuzumab economics

Trastuzumab	CY2017	CY2018	CY2019	CY2020
US Sales to Mylan/Biocon	-	-	-	35
US Sales to Biocon	-	-	-	12
US Price Discount	*0%*	*0%*	*0%*	*65%*
US Market Share	*0%*	*0%*	*0%*	*5%*
EU / RoW Sales to Biocon	-	37	44	63
Total Sales to Biocon	**-**	**37**	**44**	**75**

Source: Company data, Morgan Stanley Research estimates

Deep Dive into the Pipeline #3 – Neulasta

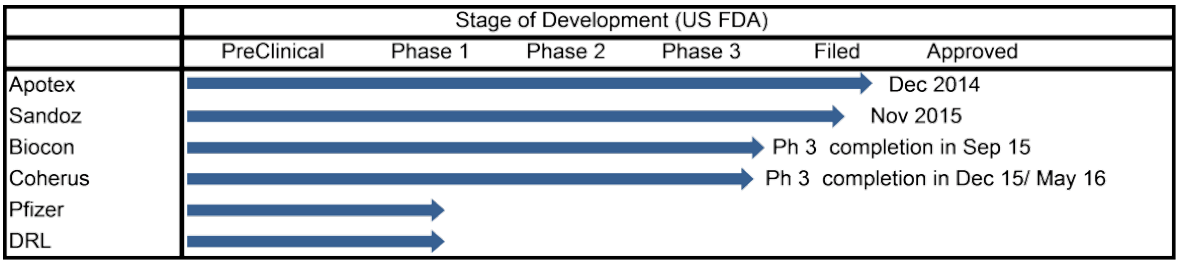
Drug profile – Amgen is the innovator of the Neulasta (pegfilgrastim) biologic. It is a long-acting granulocyte colony stimulating factor (G-CSF) that is used to bolster white cells in patients undergoing chemotherapy for cancer (to prevent inspection in patients undergoing chemotherapy). Pegfilgrastim has a human half-life of 15-80 hours, much longer than the parent filgrastim (3-4 hours).

Patent expiry – US patents expired in October 2015, but remain in force in Europe until August 2017. Supplementary protection certificates (SPCs) have been issued related to the indicated products for patents in at least the following countries – France, Germany, Italy, Spain, and the United Kingdom, expiring in August 2017.

Market size – Neulasta grossed sales of US$4.7bn in 2015, of which, US accounted for US$3.9bn of sales. Therefore, US commercialization holds the key to generating returns on this opportunity.

Competitive landscape – Apotex, Sandoz, Biocon and Coherus are the key late stage (Phase 3) players in pegfilgrastim for regulated market.

Exhibit 26: Neulasta – Stages of development (US FDA)



Source: Company data, Morgan Stanley Research; # largely includes only late-stage clinical development assets

Apotex/Intas – The FDA accepted Apotex's pegfilgrastim biosimilar application (351(k)) in December 2014. As per the requirements of the BPCIA (Biologics Price Competition and Innovation Action) act, Apotex has exchanged the information under patent dance with Amgen.

Patent court case – Amgen filed suit alleging that the Apotex biosimilar will infringe two of its patents and asked for a preliminary injunction to prevent Apotex from its product launch until 180 days after it gets FDA approval. Court in its Dec 2015 ruling granted Amgen a preliminary injunction against the launch by Apotex. Now Apotex has to give 180 days' notice after the FDA approval before launching the product. The next case trial is scheduled for July 11, 2016.

Exhibit 27: Sandoz LA-EP2006 – Phase 3 trials

Sandoz LA-EP2006- Phase 3 Trials		
	LA-EP2006	LA-EP2006
Phase	Phase 3	Phase 3
Health Authority	Russia	US FDA
Clinicalreadouts.gov Identifier	NCT01516736	NCT01735175
Indications	**Chemotherapy-induced Neutropenia; Breast Cancer**	**Neutropenic Complications**
Estimated Enrollment	308	318
Study Start Date	March 2012	June 2012
Primary Completion Date	December 2013	May 2013
Study Completion Date	December 2013	September 2013
Status	Completed	Completed
Sponsor / Collaborator	Sandoz	Sandoz

Source: clinicaltrials.gov

Exhibit 28: Apotex – Phase 3 trials

Apotex- Phase 3 Trials	
	APO-Peg-03
Phase	Phase 3
Health Authority	Hungary
Cinicaltrialsregister.eu Identifier	2011-002678-21
Indications	**Breast cancer receiving tac**
Estimated Enrollment	600
Study Start Date	Nov 2011
Primary Completion Date	NA
Study Completion Date	May 2014
Status	Completed
Sponsor / Collaborator	Apotex

Source: EU Clinical Trials, clinicaltrials.gov

Sandoz filed its biosimilar application with the FDA in November 2015 and EMA in February 2016. The FDA has

accepted its application, triggering a 10-month review period under the agency's 351(k) regulatory pathway for biosimilars. Similarly, EMA started reviewing the MAA application in February 2016.

Coherus announced in February 2016 that its proposed biosimilar CHS 1701 has met both primary endpoints in Phase 3 studies. It expects to complete a follow-on PK/PD study for this product late in the first half of 2016 and move forward with BLA filing thereafter. It expects EU MAA filings in 2017.

Exhibit 29: CHS-1701 – Phase 3 trials

Coherus Biosciences - CHS-1701- Phase 3 Trials			
	CHS-1701	CHS-1701	CHS-1701
Phase	1	1	1
Health Authority	US FDA	US FDA	US FDA
Clinicalreadouts.gov Identifier	NCT02418104	NCT02650973	NCT02385851
Indications	Immunogenicity	Pharmacokinetic and	Bioequivalence
Estimated Enrollment	303	256	116
Study Start Date	May 2015	Feb 2016	Feb 2015
Primary Completion Date	Dec 2015	May 2016	July 2015
Study Completion Date	Dec 2015	May 2016	July 2015
Status	Completed	Ongoing	Completed
Sponsor / Collaborator	Coherus	Coherus	Coherus

Source: clinicaltrials.gov, Morgan Stanley Researc

Exhibit 30: Mylan/Biocon MYL-1401H – Phase 3 trials

Mylan / Biocon MYL-1401H- Phase 3 Trials		
	MYL-1401H	MYL-1401H
Phase	Phase 3	Phase 1
Health Authority	EU	US FDA
Clinicalreadouts.gov Identifier	NCT02467868	NCT01516736
Indications	Chemotherapy-Induced Febrile Neutropenia	Chemotherapy-Induced Febrile Neutropenia
Estimated Enrollment	193	218
Study Start Date	March 2015	Sep 2014
Primary Completion Date	September 2015	Jun 2015
Study Completion Date	March 2016	Jun 2015
Status	Ongoing(enroll, completed)	Completed
Sponsor / Collaborator	Mylan	Mylan

Source: clinicaltrials.gov, Morgan Stanley Research

Mylan/Biocon plans to file its peg GCSG application in both the US and EU in 2016. The FDA was the health authority for Phase 1 trials while Europe (German, Russia, Poland, Hungary, etcetera) and Latin America (Mexico) are the health authorities in Phase 3 trials.

Gedeon Richter – EMA started evaluation of the MAA application for peg-GCSF from Richter in Dec 2015. The company aims to launch its biosimilar in EU (excluding Russia) after the patent expiration. Richter started Phase 3 trials in October 2013 (240 patients) and completed them in April 2015.

Early stage/Other competitors include DRL, Pfizer/Hospira (HSP-130) assets in Phase 1. Teva withdrew its application for Balugrastim in November 2013, citing ongoing consultation with the FDA.

Amgen – Innovator response – Amgen has been trying to defend Neulasta from competition with the launch of the Neulasta Onpro kit, which includes a single dose of the drug and a disposable injector system worn like a patch on the arm. It avoids the need for a return visit to the doctor the day after chemotherapy is administered. As many patients elect to have chemotherapy treatment on a Friday, which gives them the weekend to recover, they need to attend a clinic on Saturday for their last Neulasta injection (a patient should not receive Neulasta any sooner than 24 hours after finishing chemotherapy). Launched last year, the new formulation as of December 2015 accounted for almost a quarter of all Neulasta prescriptions in the US in the fourth quarter, according to Amgen. It does not expect a biosimilar launch in the US until the end of 2016 at the earliest.

Emerging markets – Four companies – Intas, Emcure, DRL, and Lupin – have launched Neulasta biosimilars in India. Intas launched Neupeg in August 200, Emcure launched Pegex in January 2010, DRL launched Peg-grafeel in May 2010 while most recently Lupin launched Lupifil-P in September 2013.

Economics – We expect this to be a 3-4 player market. Assuming 55% price erosion and 2.5-3% market share, we estimate Biocon can generate sales of US$9mn/$30mn/$41mn in 2018-20 from global markets.

Exhibit 31: Pegfilgrastim biosimilar

Pegfligrastim	CY2017	CY2018	CY2019	CY2020
US Sales to Mylan/Biocon	-	-	42	57
US Sales to Biocon	-	-	15	20
US Price Discount	*0%*	*50%*	*55%*	*60%*
US Market Share			*3%*	*4%*
EU / RoW Sales to Biocon	-	9	16	21
Total Sales to Biocon	**-**	**9**	**30**	**41**

Source: Company data, Morgan Stanley Research estimates

Deep Dive into the Pipeline #4 – Humira: Patent Complexity

Drug profile – Humira (adalimumab) was originally developed by AbbVie. Adalimumab is a human monoclonal antibody that treats autoimmune diseases by inhibiting tumour necrosis factor (TNF); a soluble inflammatory cytokine. Adalimumab binds to TNF-alpha (TNFα), preventing it from activating TNF receptors, which cause the inflammatory reactions associated with autoimmune diseases

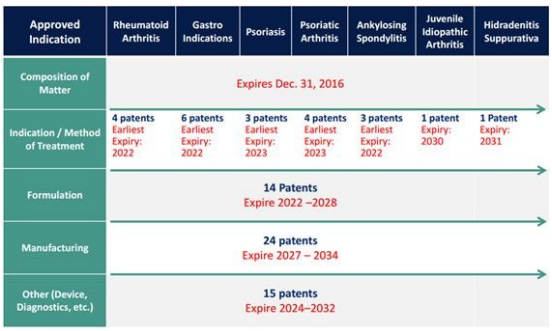
Patent information – The US composition of matter patent covering adalimumab is expected to expire in December 2016, and the equivalent EU patent is expected to expire in the majority of EU countries in October 2018. In addition, in the US, non-composition of matter patents covering adalimumab expire no earlier than 2022. Humira, as per its investor presentation, has assumed biosimilar entry in the US in 2022 and in the EU in 2019 (4Q 2018).

Humira has over 70 formulation, manufacturing, and method of treatment patents that could make entry for biosimilars in the US extremely difficult

"Any company seeking to market biosimilar versions of Humira will have to contend with this extensive patent estate, which AbbVie intends to defend vigorously. We believe the litigation process and our intellectual property estate will protect Humira from biosimilar entry until 2022."

– AbbVie CEO Richard Gonzalez

Exhibit 32: Humira patent expiration in the US by indication



Source: AbbVie

Exhibit 33: Humira – Key indications

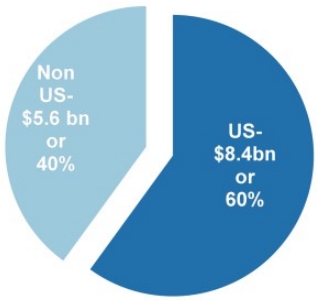
Condition	Principal Markets
Rheumatoid arthritis	North America, European Union
Psoriatic arthritis	North America, European Union
Ankylosing spondylitis	North America, European Union
Crohn's disease (moderate to severe)	North America, European Union
Plaque psoriasis (moderate to severe)	North America, European Union
Juvenile idiopathic arthritis	North America, European Union
Ulcerative colitis (moderate to severe)	United States, European Union
Axial spondyloarthropathy	United States, European Union
Pediatric Crohn's disease (severe)	United States, European Union
Pediatric enthesitis-related arthritis	European Union

Source: AbbVie

Market size – Humira, launched in January 2003, is approved in over 60 markets, including the US, EU markets, Japan, China, Brazil, and Australia. Its worldwide sales were US$14bn in 2015, of which US$8.4bn were from the US. Three core indications – rheumatology, gastroenterology and dermatology – account for 40%, 45% and 15% of Humira's global sales, respectively.

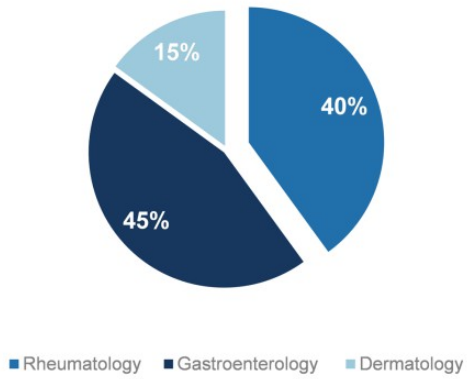
AbbVie continues to work on Humira formulation and delivery enhancements to improve convenience and the overall patient experience. It aims to generate US$18bn of sales globally from Humira by 2020. Higher biologic penetration, increasing market share, and expansion to new indications (HS, Uveitis) are expected to drive this growth.

Exhibit 34: Total market of US$14bn -Humira, 2015



Source: AbbVie

Exhibit 35: Sales split by indication- Humira, 2015



Source: AbbVie

Competitive landscape – We identify 6-7 players presently in Phase 3 clinical trials for DM registration. Amgen and Sandoz appear to be the frontrunners in the race to biosimilar adalimumab in Europe/US.

Exhibit 36: Stages of development (US FDA)- Plaque psoriasis

Stage of Development- Plaque Psoriasis

Humira	PreClinical	Phase 1	Phase 2	Phase 3	Filed
Amgen	→	→	→	→	US- Nov 15; EU-Dec 15
Sandoz	→	→	→	→	Ph 3 completion in Jul-15
Biocon	→	→	→	→	Filing in FY17
Coherus	→	→	→	→	Ph 3 completion in May-16
Baxalta	→	→	→	→	Ph 3 completion in Sep-16
Boehringer Ingelheim	→	→	→	→	Ph 3 completion in Mar-17

Source: Morgan Stanley Research, clinicaltrials.gov, Clincialtrials register.eu

Exhibit 37: Phase 3 details - Humira

Phase 3 trials	Plaque Psoriasis	Rheumatoid Arthritis
Amgen	Y	Y
Pfizer		Y
Coherus	Y	
Sandoz	Y	
Mylan / Biocon	Y	
Boehringer Ingelheim	Y	Y
Momenta/ Baxalta	Y	

Source: Clinical trials, company data, Morgan Stanley Research

Amgen – Amgen started Phase 3 clinical trials for its biosimilar adalimumab ABP 501 for psoriasis indication in October 2013 for the US and EU markets. It announced positive results from two Phase 3 studies in November 2015 and October 2014, respectively, that its biosimilar ABP 501 meets safety and efficacy criteria with Humira.

Amgen filed ABP 501 for approval in the US in November 2015 and the EU in December 2015. The FDA accepted the application for ABP 501 in January 2016, with a final decision expected by September 2016. However, the launch in the US may get delayed due to patent issues. The US Patent and Trademark Office (PTO) has declined to review a pair of AbbVie patents that Amgen contends are invalid. This could delay Amgen's plans to bring its biosimilar to the market by 2017. Amgen can challenge those patents in court, but AbbVie believes its legal protection will keep Humira safe from competition until 2022.

Exhibit 38: Amgen's TNF inhibitor biosimilar readouts

Amgen's TNF inhibitor biosimilars readouts						
	adalimumab (ABP 501)					
Phase	Phase 4	Phase 4	Phase 4	Phase 3	Phase 4	Phase 3
Health Authority	Canada Health	US FDA	Canada Health	EMA, Canada Health	US FDA	Global (inc. US FDA)
Clinicalreadouts.gov Identifier	NCT00833729	NCT01543204	NCT00967538	NCT01970488	NCT01927757	NCT01970475
Indications	**Plaque Psoriasis**	**Psoriasis**	**Psoriasis**	**Psoriasis**	**Rheumatoid Arthritis**	**Rheumatoid Arthritis**
Estimated Enrollment	10	64	89	350	90	526
Study Start Date	February 2009	October 2011	September 2009	October 2013	May 2013	October 2013
Primary Completion Date	February 2010	May 2015	July 2014	July 2014	June 2015	November 2014
Study Completion Date	February 2010	May 2015	July 2014	March 2015	April 2016	November 2014
Status	Completed	Completed	Completed	Completed	Ongoing(enrollment completed)	Completed
	FDA filed on November 25, 2015 / EMA filed on December 4, 2015					
Sponsor / Collaborator	Amgen	Amgen	Amgen	Amgen	Amgen	Amgen

Source: Clinicalreadouts.gov, Morgan Stanley Research

Sandoz – Sandoz started Phase 3 clinical trials for adalimumab for psoriasis indication in December 2013 for the US and EU markets. The trials mainly focus on moderate to severe plaque-type psoriasis. These are global trials that span 12 countries across Europe, the US, and Asia including Japan. As per the latest update, Sandoz expects to complete Phase 3 studies by April 2016. According to management, adalimumab will be a key building block in Sandoz's immunology portfolio, which includes other biosimilar candidates currently such as etanercept (Amgen's Enbrel) and rituximab (Roche's Rituxan/MabThera).

Exhibit 39: Sandoz/Novartis' TNF-alpha inhibitor biosimilar readouts

Sandoz/Novartis' TNF-alpha inhibitor biosimilars readouts	
	adalimumab (GP2017)
Phase	Phase 3
Health Authority	EMA
Clinicalreadouts.gov Identifier	NCT02016105
Indications	**Plaque Type Psoriasis**
Estimated Enrollment	448
Study Start Date	December 2013
Primary Completion Date	July 2015
Study Completion Date	April 2016
Status	Ongoing(enroll, completed)
Sponsor / Collaborator	Sandoz

Exhibit 40: Pfizer's TNF inhibitor biosimilar readouts

Pfizer's TNF inhibitor biosimilar readouts	
	adalimumab (PF-06410293)
Phase	Phase 3
Health Authority	US FDA
Clinicalreadouts.gov Identifier	NCT02480153
Indications	**Rheumatoid Arthritis**
Estimated Enrollment	560
Study Start Date	June 2015
Primary Completion Date	March 2017
Study Completion Date	June 2018
Status	Recruiting
Sponsor / Collaborator	Pfizer

Source: Clinicalreadouts.gov, Morgan Stanley Research

Source: Clinical trials, company data, Morgan Stanley Research

Mylan/Biocon – Mylan/Biocon started Phase 3 trials in April 2015 in the EU (trials not registered on US clinicaltrials.gov). Management has guided to file its biosimilar candidate in the US/EU in 2016. It completed Phase 1 studies in June 2015 as per clinicaltrials.gov.

Exhibit 41: Mylan/Biocon TNF inhibitor biosimilar readouts

Mylan/Biocon TNF inhibitor biosimilar readouts		
	adalimumab (BMO-2)	**adalimumab (BMO-2)**
Phase	Phase 3	Phase 1
Health Authority	EU (Germany)	Belgium FAMHP
Clinicalreadouts Identifier	2014-003420-46	NCT02472912
Indications	**Chronic Plaque Psoriasis**	**Chronic Plaque Psoriasis**
Estimated Enrollment	294	270
Study Start Date	Apr 2015	Dec 2014
Primary Completion Date	NA	May 2015
Study Completion Date	NA	Jun 2015
Status	Ongoing(enroll, completed)	Completed
Sponsor / Collaborator	Mylan/Biocon	Mylan/Biocon

Source: Clinicalreadouts.gov, Morgan Stanley Research

Coherus BioSciences started Phase 3 clinical trials for its biosimilar candidate CHS 1420 in August 2015. The

study is expected to be completed by March 2017. However, management anticipates initiating the PK bioequivalence bridging study by the end of the first half of 2016 with Phase 3 drug material and file a BLA in the US in the second half of 2016 and MAA with EMA in 2017.

Exhibit 42: Coherus' TNF-alpha inhibitor biosimilar readouts

Coherus' TNF-alpha inhibitor biosimilars readouts	
	adalimumab (CHS-1420)
Phase	Phase 3
Health Authority	US FDA
Clinicalreadouts.gov Identifier	NCT02489227
Indications	**Plaque Psoriasis**
Estimated Enrollment	500
Study Start Date	August 2015
Primary Completion Date	May 2016
Study Completion Date	March 2017
Status	Ongoing(enroll, completed)
Sponsor / Collaborator	Coherus Biosciences

Source: Clinicalreadouts.gov, Morgan Stanley Research

Exhibit 43: Baxalta TNF-alpha inhibitor biosimilar readouts

Baxalta TNF-alpha inhibitor biosimilars readouts	
	adalimumab (M923)
Phase	Phase 3
Health Authority	USFDA, Canada
Clinicalreadouts.gov Identifier	NCT02581345
Indications	**Chronic Plaque-type Psoriasis**
Estimated Enrollment	516
Study Start Date	Sep 2015
Primary Completion Date	Sep 2016
Study Completion Date	May 2017
Status	Recruiting
Sponsor / Collaborator	Baxalta

Source: Clinicalreadouts.gov, Morgan Stanley Research

Baxalta/Momenta started Phase 3 clinical trials for its biosimilar candidate M923 in September 2015 for chronic plaque psoriasis indications. These Phase 3 studies are expected to be completed by May 2017. Management targets first regulatory submission in 2017 and first commercial launch in 2018. Baxalta is responsible for clinical development and manufacturing while Momenta would take care of high resolution analytics, characterization, and clinical/regulatory strategy.

Morgan Stanley & Co. International plc ("Morgan Stanley") is acting as financial advisor to Shire Plc ("Shire") in relation to Shire's proposed combination with Baxalta Incorporated ("Baxalta") as announced on January 11, 2016. The proposed transaction is subject to approval by Baxalta and Shire shareholders, regulatory approval and other customary closing conditions. This report and the information provided herein is not intended to (i) provide voting advice, (ii) serve as an endorsement of the proposed transaction, or (iii) result in the procurement, withholding or revocation of a proxy or any other action by a security holder. Shire has agreed to pay fees to Morgan Stanley for its financial services. Please refer to the notes at the end of the report.

Boehringer Ingelheim started Phase 3 clinical trials for its biosimilar candidate BI 695501 in March 2016 for chronic plaque psoriasis indications. These Phase 3 studies are expected to get completed by October 2017 (recruitment not yet started).

Exhibit 44: Boehringer Ingelheim's TNF inhibitor biosimilar readouts

Boehringer Ingelheim's TNF inhibitor biosimilar readouts		
	adalimumab (BI 695501)	**adalimumab (BI 695501)**
Phase	Phase 3	Phase 3
Health Authority	Global (inc. US FDA)	Global (inc. US FDA)
Clinicalreadouts.gov Identifier	NCT02137226	NCT02694523
Indications	**Rheumatoid Arthritis**	**Chronic Plaque Psoriasis**
Estimated Enrollment	650	600
Study Start Date	January 2015	Mar 2016
Primary Completion Date	March 2016	March 2017
Study Completion Date	October 2016	October 2017
Status	Ongoing(enroll, completed)	Recruitment not yet started
Sponsor / Collaborator	Boehringer Ingelheim	Boehringer Ingelheim

Source: Clinicalreadouts.gov, Morgan Stanley Research

Emerging Markets – Cadila launched its adalimumab in India in December 2014 under the brand name

Exemptia.

Exhibit 45: Biosimilars and non-originator biologicals of adalimumab approved or in development

Company name, Country	Product name	Stage of development
AET /BioXpress, Germany/Switzerland	-	Biosimilar in pipeline. Development partnership announced in November 2012
Amgen, USA	ABP 501	Phase 3 trials ongoing in the EU / US. Positive results from Phase 3 trial in arthritis announced in February 2015
Boehringer Ingelheim, Germany	BI695501	Phase 1 studies in Belgium /New Zealand completed in 2012 /2015. Phase 3 study to be completed in Dec 2016
Coherus Biosciences, USA	CHS-1420	Pharmacokinetic study completed in August 2014
Fujifilm/Kyowa, Japan	FKB327	50:50 joint venture announced in March 2012. Phase 3 clinical trial ongoing
LG Life Sciences	LBAL	Phase 1 trial expected to be completed in March 2015
Momenta/Baxalta, USA	M923	Phase 3 clinical trial started in October 2015 [10]. Collaborating with Baxter on six biosimilars
Oncobiologics/Viropro, USA	ONS-3010	Phase 1 PK study completed in Feb 2015. One of six mabs biosimilars for which the companies are collaborating
Pfizer, USA	PF-06410293	Phase 1 study expected to be completed in January 2014
Sandoz, Switzerland	GP2017	Started Phase 3 clinical trial in December 2013, expected to be completed in April 2016
Zydus Cadila, India	Exemptia	'Similar biologic' launched in India in December 2014

Source: Gabi Online, company data

Innovator defence – In July 2015, AbbVie received approval from the EMA for a new formulation for Humira. As per management, this is specifically designed to reduce injection pain (by 50-80%), injection volume, and, potentially, the number of injections required. The formulation is currently under review by the FDA. We believe AbbVie will try to transition its franchise to improved formulations before biosimilar launches in 2022.

Economics – We expect this to be around a 6-7 player market. Innovator AbbVie has already blocked the US market until 2022 (multiple patents estate) but expects biosimilars to enter the EU by 4Q18. Assuming Mylan/Biocon enter the EU/RoW markets in FY19/20, we estimate Biocon's share of sales at US$10mn/$23mn/38mn in 2018/19/20, respectively.

Exhibit 46: Adalimumab economics

Adalimumab	CY2017	CY2018	CY2019	CY2020
US Sales to Mylan/Biocon	-	-	-	-
US Sales to Biocon	-	-	-	-
US Price Discount		*65%*	*70%*	*70%*
US Market Share				
EU / RoW Sales to Biocon	-	10	23	38
Total Sales to Biocon	**-**	**10**	**23**	**38**

Source: Company data, Morgan Stanley Research estimates

Valuation and PT Discussion

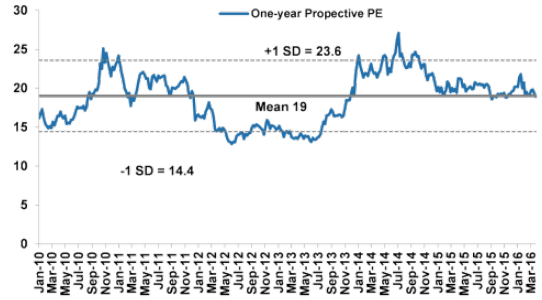
Valuation and Price Target Methodology: We arrive at our new price target of Rs622 (up 35% from Rs459) by applying a target P/E multiple of 21x (up from 18.5x) to FY18 EPS estimate of Rs29.6. Our price target change is primarily on account rolling forward our target EPS to FY18e from FY17e and a higher target P/E multiple (15% higher than its five-year average valuations and still 5-10% discount to India pharmaceutical industry multiples) to account for upcoming US/EU filings for key biosimilars in DMs and EMs. Our 21x target P/E multiple for Biocon reflects:

- **Improving visibility of second wave of BIOS's 5 biosimilar assets** (including Aspart and Lispro) for global markets
- **Steady base business fundamentals:** Scale up visibility in domestic formulations and contract research businesses
- **Prospects of global biosimilar opportunities** coming to fruition in ensuing years (2017-20)- glargine, trastuzumab, peg-GCSF, adalimumab
- Commercialization of green field Malaysian facility ($200mln capex)

Challenges that lie ahead include:

- **Challenges in monetizing biosimilar assets:** These include regulatory setbacks, litigation delays, manufacturing scale-up, and market acceptance (substitutability and pricing)
- **Near-term growth challenges** due to capacity constraints and rising research spending
- **Base business is in large part API sales to institutional customers** (i.e., limited retail branding), which carries the risk of a sudden loss of sales and/or margins.

Exhibit 47: Biocon: One-year forward PE



Source: Thomson Reuters, Morgan Stanley Research

Bull and Bear Cases

Bull Case (Rs759, up from Rs551) – Value unlocking in novel biological pipeline - a) Stronger base business: US ANDA filings, Syngene ramp-up – (Rs31 from Rs46/share); b) Clinical progression of five follow-on biosimilars to Phase 3 trials – etanercept; bevacizumab; filgrastim; and three insulins – (Rs44 from Rs24/share) and c) Re-rating driven by global biosimilars launch – earlier than anticipated launch (court cases, FDA advisory committee), indication extrapolation (trastuzumab, adalimumab) – (Rs62 from Rs23/share).

Bear Case (Rs434, up from Rs307) – Commoditization of base business - a) Setback in core business (Rs 81 from Rs55/share); b) Clinical progression of five follow-on biosimilars to Phase 3 trials – etanercept; bevacizumab; filgrastim; and three insulins – (Rs44 from Rs37/share) and c) Regulatory and commercialization challenges (no indication extrapolation, higher competition, innovator fightback, incomplete filings, etcetera

(Rs83 from Rs55/share).

Celltrion - Valuation Methodology and Risks

Price Target Methodology:

We derive our price target of W71,000 from a residual income model. We use a cost of equity of 7.6% (4.0% risk-free rate, equity risk premium of 5.5%, and beta of 0.7) and 3.5% terminal growth. Our price target implies 2016/2017 P/Es of 55.2 x/38.7x and EV/EBITDAs of 32.8x/24.3x

Key Risks to Our Price Target:

1) Upside risks: early successful trials/launch at risk and strong enough demand to offset price discounts; 2) Downside risks: unsuccessful trials/launch and slower uptake/higher margin pressure.

Biocon: Key risks to price target; key investment concerns

1) Regulatory risks include delay in product approvals, indication extrapolation, clinical trial design

- **Higher product complexities** - The FDA, as of now. has approved only one biosimilar product filgrastim(Zarxio) in the US through the 351(K) route and several through the 505(b) (2) route including glargine. However, the subsequent filings are more complex in nature, which the FDA may take longer to approve (or not approve if data is insufficient).
- **Indication extrapolation** - Europe most recently gave approval to Celltrion's biosimilar infliximab for all six indications though it submitted clinical data for only two indications. Canada, however, has not followed a similar approach in extrapolating the data across other indications. This is untested for the USFDA, which may use a stringent approach for indication extrapolation.
- **Clinical trials design-** Biocon is conducting three out of four Phase 3 trials at non- US locations, even though these are meant for US filings. However, BIOS maintains that these trials are consistent with FDA requirements. We note that a few other competitors are also doing non US studies for US filing for a few bio-similar products.

2) Legal risks include at risk launches, delay in market entry (180 days, patent dance), 30m NDA stay

- **Uncertainty about 180 days notice of commercialization** to innovators if a biosimilar maker has chosen to participate in the patent **-** This has been litigated by Apotex and the matter is in Appeal. In addition, Sandoz has currently filed a petition in the Supreme Court against a Federal circuit court ruling that 180 days notice can be given earlier than product approval date.
- **Implications of not participating in Patent Dance (launch at risk)**- If the company chooses not to participate in the patent dance and launch the Biosimilar then (a) it cannot file any relevant declaratory judgment suits, e.g. for non-infringement or invalidity, and (b) it is subject to the filing of immediate lawsuits by the reference product sponsor, e.g. for declaratory judgment of infringement and validity. Therefore, Biosimilar applicants as of now have a choice to either participate in the patent dance (delay the start of litigation by at least by 8 months) or forego disclosure and risk immediate lawsuits by the innovator.

3) Asset monetization risks include innovator defence (flexible pricing, reformulation, patents) marketing challenges, slower biosimilar update from physicians

Exhibit 48: Commercial risks / challenges

	Lantus	Herceptin	Neulasta	Humira
Innovator Defense	Sanofi introduced Lantus Pens in order to ease dosage adminstration (portable, accurate, less time consuming and less painful). In the process it has also garnered additional patents protecting devices which expire on varying dates between 2023 and 2028. In additon innovator has also launched Taujeo (to switch patients from Lantus)	Improved formulation from intravenous to subcutaneous injection. Plus Innovator has also launched HER2 franchise combination therapies as well	Amgen launched Onpro Kit which aims to improve patients convenience by eliminating the need to return visit to the doctor the day after chemotherapy is administered	AbbVie in July 2015 received approval from the EMA for a new formulation. This new formulation can reduce injection pain (by 50 to 80%), injection volume, and potentially the number of injections required

Source: Company data, Morgan Stanley Research

4) Other risks include a slowdown in base business due to factors such as capacity constraints or a sluggish domestic market; risk pertaining to Syngene business - late-stage client molecules may not culminate in business; and delays in scale-up or regulatory filings from Malaysia facility.

Industry Valuation Tables

Exhibit 49: Industry valuations

Valuation and Summary												
Company	Price (Rs)	Market	EPS				2-yr EPS	P/E				F2016 P/E
	04-Apr-16	Cap (US$m)	F2015	F2016E	F2017E	F2018E	Grth (16-18)	F2015	F2016E	F2017E	F2018E	to growth
BSE Sensex	25,270	615,112	1,413	1,558	1,857	2,136	17.1%	17.9	16.2	13.6	11.8	0.9
large Cap												
Cipla	515	6,356	14.7	24.6	27.4	33.9	17.4%	35.0	20.9	18.8	15.2	1.2
Cadila Healthcare	321	5,055	11.2	14.2	14.5	19.9	18.4%	28.5	22.5	22.1	16.1	1.2
Divi's Laboratories*	1,009	4,119	32.1	40.1	47.9	56.7	18.9%	31.4	25.1	21.0	17.8	1.3
Dr Reddy's Labs	2,980	7,786	130.2	157.4	158.7	181.7	7.4%	22.9	18.9	18.8	16.4	2.6
Glenmark	792	3,425	24.5	29.0	46.3	54.6	37.1%	32.4	27.3	17.1	14.5	0.7
Lupin Ltd	1,465	10,105	53.5	49.8	79.4	91.2	35.4%	27.4	29.4	18.4	16.1	0.8
Sun Pharmaceuticals	815	30,221	18.9	21.5	34.7	38.4	33.7%	43.1	37.9	23.5	21.2	1.1
Mid cap												
Aurobindo Pharma*	730	6,557	27.0	34.4	42.5	50.4	21.0%	27.0	21.2	17.2	14.5	1.0
Biocon	491	1,510	24.9	22.1	24.8	29.6	15.8%	19.7	22.2	19.8	16.6	1.4
Dishman*	329	407	14.9	20.0	25.3	32.7	28.1%	22.1	16.5	13.0	10.0	0.6
IPCA	572	1,089	20.1	7.6	29.6	41.0	132.2%	28.4	75.2	19.3	13.9	0.6
Jubilant Lifesciences*	410	1,005	(1)	30.4	39.1	49.3	27.4%	NM	13.5	10.5	8.3	0.5
Piramal Enterprise*	1,048	3,371	8.9	23.7	39.2	47.9	42.2%	117.5	44.2	26.7	21.9	1.0
Strides Arcolabs*	1,063	1,434	1.5	33.9	63.3	76.3	50.0%	713.5	31.3	16.8	13.9	0.6
Torrent Pharma*	1,362	3,546	44.4	102.8	76.9	83.7	-9.7%	30.7	13.3	17.7	16.3	(1.4)
Natco*	418	921	9.0	9.1	19.1	21.9	55.0%	46.2	45.9	21.9	19.1	0.8
MNCs												
Aventis Pharma*	4,127	1,462	85.6	139.6	144.5	174.7	11.9%	48.2	29.6	28.6	23.6	2.5
GlaxoSmithKline Pharma	3,811	4,966	56.2	67.9	84.4	95.8	18.8%	67.8	56.1	45.2	39.8	3.0
Indian Companies- Large cap		**72,667**					**22.6%**	**32.8**	**29.2**	**21.7**	**19.4**	**1.3**
Indian Companies- mid cap		**19,841**					**20.3%**	**33.0**	**20.5**	**16.8**	**14.2**	**1.0**
MNCs		**6,757**					**16.4%**	**62.0**	**46.6**	**39.9**	**34.4**	**2.8**
ALL		**99,265**					**21.2%**	**34.0**	**27.9**	**21.3**	**18.8**	**1.3**

Source: Thomson Reuters estimates for Not Covered (*) companies, Morgan Stanley Research estimates for others.

Exhibit 50: Industry valuations

Company Name	P/ Book value			P/Sales			ROE		
	F2014	F2015	F2016E	F2014	F2015	F2016E	F2014	F2015	F2016E
Indian companies									
large Cap									
Cipla	4.1	3.8	3.6	4.1	3.6	3.0	14.9%	11.2%	17.4%
Cadila Healthcare	9.6	7.7	6.1	3.8	3.3	3.0	23.9%	27.1%	27.1%
Divi's Laboratories*	8.8	7.8	6.4	8.6	7.4	6.2	25.3%	24.9%	25.4%
Dr Reddy's Labs	5.6	4.5	3.8	3.8	3.4	3.1	23.7%	19.9%	19.9%
Glenmark	7.2	7.1	4.9	3.2	3.0	2.5	25.5%	22.1%	18.0%
Lupin Ltd	9.5	7.4	6.1	5.8	5.1	4.7	26.5%	27.1%	20.7%
Ranbaxy Laboratories*	11.1	8.2	7.3	2.7	2.8	2.8	8.3%	34.9%	15.6%
Sun Pharmaceuticals	9.1	6.6	6.6	10.5	6.2	7.0	17.0%	17.7%	17.3%
Mid cap									
Aurobindo Pharma*	11.9	8.1	6.1	5.3	3.5	3.0	32.6%	30.1%	27.3%
Biocon	3.2	3.0	2.7	3.4	3.2	2.8	13.7%	12.0%	12.3%
Dishman*	2.3	2.1	1.9	1.9	1.7	1.6	9.7%	9.4%	11.7%
IPCA	3.7	3.3	3.0	2.2	2.3	2.5	24.4%	11.5%	4.0%
Jubilant Lifesciences*	2.5	2.5	2.3	1.1	1.1	1.1	12.3%	-0.4%	17.0%
Piramal Enterprise*	1.7	2.0	2.1	4.1	3.4	2.8	0.4%	1.7%	5.6%
Strides Arcolabs*	NA	5.2	3.0	NA	5.5	1.9	NA	0.7%	13.8%
Torrent Pharma*	12.5	9.3	5.9	5.7	5.0	3.4	36.1%	30.3%	43.1%
Natco*	8.9	7.3	5.1	8.7	7.7	5.6	15.3%	18.3%	13.5%
MNCs									
Aventis Pharma*	6.3	5.5	5.3	5.1	4.6	3.9	17.4%	11.4%	17.8%
GlaxoSmithKline Pharma	16.2	17.6	18.9	12.7	9.8	10.4	24.2%	26.0%	33.6%
Indian Companies- Large cap	**8.2**	**6.6**	**5.6**	**5.9**	**4.8**	**4.5**	**20.8%**	**22.3%**	**20.7%**
Indian Companies- mid cap	**5.6**	**5.2**	**4.6**	**4.2**	**3.5**	**3.0**	**9.3%**	**9.1%**	**12.7%**
MNCs	**11.3**	**11.8**	**12.5**	**9.9**	**8.2**	**8.0**	**19.1%**	**25.0%**	**32.5%**
ALL	**7.4**	**6.2**	**5.4**	**5.4**	**4.4**	**4.0**	**17.0%**	**18.5%**	**18.7%**

Source: Thomson Reuters estimates for Not Covered (*) companies, Morgan Stanley Research estimates for others.

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Not-Rated/Hold	**81**	**2%**	**5**	**1%**	**6%**
Underweight/Sell	**691**	**20%**	**95**	**13%**	**14%**
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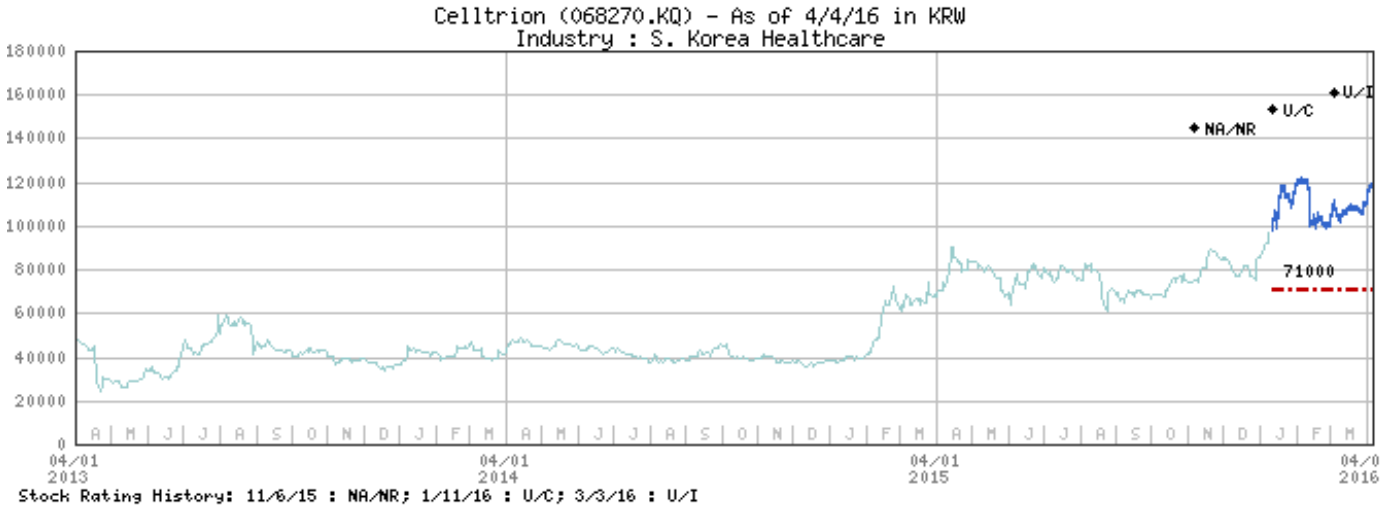
Stock Price, Price Target and Rating History (See Rating Definitions)



Stock Rating History: 11/6/15 : NA/NR; 1/11/16 : U/C; 3/3/16 : U/I

Price Target History: 1/11/16 : 71000

Source: Morgan Stanley Research Date Format : MM/DD/YY Price Target No Price Target Assigned (NA)
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Stock and Industry Ratings (abbreviations below) appear as ◆ Stock Rating/Industry View
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INDUSTRY COVERAGE: India Healthcare

COMPANY (TICKER)	RATING (AS OF)	PRICE* (04/04/2016)
Sameer Baisiwala, CFA		
Biocon Ltd (BION.NS)	O (04/05/2016)	Rs492.00
Cadila Healthcare Ltd. (CADI.NS)	O (01/29/2016)	Rs315.15
Cipla Ltd. (CIPL.NS)	U (08/13/2013)	Rs514.30
Dr. Reddy's Lab (REDY.NS)	E (11/26/2015)	Rs3,011.75
GlaxoSmithKline Pharma (GLAX.NS)	U (02/28/2013)	Rs3,758.05
Glenmark Pharmaceuticals (GLEN.NS)	O (12/13/2012)	Rs800.20
IPCA Laboratories (IPCA.NS)	E (07/25/2014)	Rs569.90
Lupin Ltd. (LUPN.NS)	O (10/03/2006)	Rs1,461.15
Sun Pharmaceutical Industries (SUN.NS)	E (12/21/2015)	Rs815.05

Stock Ratings are subject to change. Please see latest research for each company.
* Historical prices are not split adjusted.