

Biocon

10 June 2016

Reuters: BION.BO; Bloomberg: BIOS IN

Lantus Biosimilar Opportunity To Be Significantly Smaller

Biocon, India's premium biopharmaceutical company, has demonstrated industry-leading capabilities in developing the most complex biosimilar products. The company is a front-runner in the race to introduce biosimilar products for developed markets. In recent weeks, Biocon's stock price has run up notably in anticipation of growth presented by the launch of biosimilars in regulated markets. We do not entirely agree with the enthusiasm of investors and believe this is an overreaction. We initiate coverage on Biocon with Sell rating and a target price of Rs630 based on 21x price earning multiple on FY18E earnings. Biocon's quick progress in the biosimilar domain is noteworthy and holds tremendous long-term potential, but in the near to mid-term (upto FY-20) the potential returns from the launch of biosimilars may not be commensurate with investments that have to be made as the path to approval, commercialisation, and growth has tangible risks and hurdles. We forecast Biocon generating US\$40mn in peak sales (including Mylan share) from Lantus biosimilar (insulin glargine) by FY-2020. We expect Lantus brand sales to erode by more than 50% by the time Biocon biosimilar hits the market. The Lantus pie over the next three years will be split among [seven competing molecules](#) that offer a notably better value proposition than Lantus.

We currently do not have any estimates on adalimumab (biosimilar Humira) as there are patents on the drug, which expire as late as 2022, and thus we are not sure if biosimilar companies may be able to launch copies prior to that. As regards trastuzumab (biosimilar Herceptin), biosimilar companies will have to offer a steep discount in order to carve a share from Roche's Herceptin.

Competition to erode more than 50% of Lantus sales by FY19: Seven molecules ([LixilAn](#), [Toujeo](#), [Ryzodeg](#), [Tresiba](#), [Abasaglar](#), [Merck's biosimilar Lantus](#), [Xultophy](#)) that offer a better value proposition will erode the Lantus pie. We forecast biosimilar Lantus from Biocon to garner US\$40mn in peak sales by 2020 (including Mylan's contribution).

Interchangeability for Lantus biosimilar is unlikely: We do not believe regulators will grant interchangeability to biosimilars of Lantus. UK and Australian diabetes federations have taken positions that insulins should not be substituted by biosimilars at the pharmacist level. Lantus vial market, which we believe is more vulnerable to substitution by biosimilar candidates, will be largely cannibalized by Sanofi's Toujeo and to some extent Eli Lilly's Abasaglar.

Litigation by Sanofi: Lantus launch can be notably delayed, as Sanofi may choose to litigate with Biocon for infringement of its underlying patents on Lantus.

Commercialization risks: Limited marketing strength and manufacturing scale will limit Biocon's ability to compete with veterans like Eli Lilly and Merck. Patients and physicians are expected to have more familiarity with the Eli Lilly pen than the Biocon pen version.

We are skeptical on the quality of clinical data on biosimilar Neulasta (pegfilgrastim): In case of Pegfilgrastim, we are skeptical on the quality of data as the company remains silent about demonstrating bioequivalence and meeting the secondary end-points in the study.

Commercialization risk for Neulasta biosimilar: In a very short span, Amgen has shifted about one-third of Neulasta sales on to Neulasta onpro (an on-body injector).

Capex: Significant capex towards biosimilar manufacturing and foray of Syngene into contract manufacturing will limit free cash flow generation.

Depreciation and amortisation expenses to limit EPS growth: Amortization of capitalized research and development or R&D expenses on biosimilar portfolio development and pre-operative expenses for insulin manufacturing facility at Malaysia will limit EPS growth.

Y/E March (Rsmn)	FY15	FY16	FY17E	FY18E	FY19E
Net sales	31,960	35,355	40,174	45,909	52,278
EBITDA	7,489	9,496	10,819	12,046	14,474
Net profit	4,974	9,412	5,537	6,055	7,043
EPS (Rs)	25	47	28	30	35
EPS growth (%)	19.5	89.2	(41.2)	9.4	16.3
EBITDA margin (%)	23.4	26.9	26.9	26.2	27.7
PER (x)	29.0	15.3	26.0	23.8	20.5
P/BV (x)	4.4	3.6	3.2	2.9	2.6
EV/EBITDA (x)	18.7	14.9	13.2	11.8	9.4
RoCE (%)	14.2	10.2	11.6	12.0	12.7
RoE (%)	16.2	25.0	14.2	14.2	14.9

Source: Company, Nirmal Bang Institutional Equities Research

SELL

Sector: Pharmaceuticals

CMP: Rs721

Target Price: Rs630

Downside: 13%

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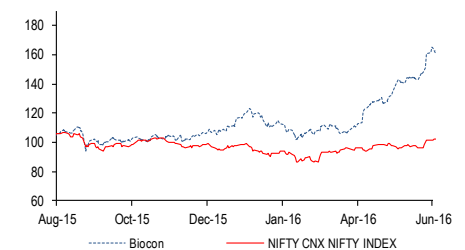
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Key Data

Current Shares O/S (mn)	200.0
Mkt Cap (Rsbn/US\$bn)	146.2/2.2
52 Wk H / L (Rs)	739/395
Daily Vol. (3M NSE Avg.)	1,020,528

Share holding (%)	4QFY16	3QFY16	2QFY16
Promoter	60.7	60.7	61.0
Public	37.4	37.4	39.0
Others	1.9	-	-

One Year Indexed Stock Performance



Price Performance (%)

	1 M	6 M	1 Yr
Biocon	19.5	59.5	68.3
Nifty Index	7.0	7.4	2.8

Source: Bloomberg

Investment Arguments

Exhibit 1: Pros and cons of investing In Biocon

Pros	Cons
Attractively poised to take advantage of a growing diabetes market.	Insulin business requires significant upfront capital investment, which will affect free cash flow in the near term.
Diabetes product portfolio should help build a decent market share in the long run.	R&D expenses to remain high in the near term because of development of biologics portfolio.
The research services business of Syngene should support near-term growth.	Next generation insulin and combination products will significantly erode the potential market for Lantus.
The company is building an abbreviated new drug application or ANDA portfolio for US market, which could potentially shape up to be an important growth driver.	Competitors in the Lantus biosimilar space are better positioned in terms of overall cost structure
Biosimilar capabilities should allow the company to chase long-term growth	Growth of SGLT2 and GLP-1 class within diabetes space is affecting insulin market's volume growth.
Japanese approval certifies the quality of insulin Glargine file and should help prospects in emerging markets.	Regulators are currently averse to automatic substitution in biosimilar space and this led to limited market share for biosimilar players. Unlike the small molecule generic market, biosimilar space is also witnessing interest of innovators and large pharmaceutical companies.
Positive Phase 3 data on Trastuzumab improves investor's confidence in Biocon's capability of developing biosimilar version of monoclonal antibodies, which is supposedly a significantly higher hurdle than simple peptides like insulin.	Pending patents on Lantus may delay Biocon's entry in US and European markets.
	Lantus in vial represents a declining market and by the time Biocon enters the market, Sanofi would be aggressively looking to cannibalize this space.
	Valuation seems to more than discount the potential growth opportunity presented by Syngene and biosimilars in emerging markets.
	Neulasta sales are being cannibalized by Neulasta Onpro kit, reducing the potential market opportunity for biosimilar players.
	Commercialization hurdles in Trastuzumab (biosimilar Herceptin) as the innovator has several defenses ready to encounter biosimilars. We are not sure if the regulators would permit indication extrapolation while approving biosimilars
	In view of commercial hurdles, Biocon may have to offer significant discounts to earn market share. We remain concerned about the financial viability of biosimilars at such low prices and low market share.

Source: Nirmal Bang Institutional Equities Research

Biosimilar Lantus – What to expect

Potential opportunity size for Biocon

Timing of entry: We expect Biocon to reach the market in second-half of 2018 (FY-2019). As there are unexpired patents protecting Lantus, Biocon may enter the market only after a settlement with Sanofi. We expect double-digit royalty payment from Biocon/Mylan to Sanofi. Biocon should be the third entrant after Eli Lilly and Merck.

Probability of substitution: We see a very low probability that pharmacists may be allowed to substitute Lantus with biosimilars. In a best-case scenario, pharmacy substitution for Lantus may be allowed for vials. However, the vial market is reducing every year and with the launch of Toujeo the cannibalisation of vial market (most of which is in US) will accelerate significantly.

Exhibit 2: Pros and cons – Chances that pharmacy level substitution may be allowed

Pros	Cons
Biocon has successfully conducted bioequivalence studies in Type 1 diabetes patients which prove its Glargine is bioequivalent to Lantus. We understand that Eli Lilly's Abasaglar has proven bioequivalence in healthy patients.	Eli Lilly's Abasaglar, which is a biosimilar /follow-on to Lantus, cannot be substituted for Lantus. It can only be substituted under medical supervision.
Biocon will be launching insulin Glargine in vial format too, where we believe the risk associated with substitution is lower than it is with pens.	In Australia, the law allows automatic substitution of biosimilars, but does not allow substitution of Lantus by Abasaglar.
	Insulin is supposed to have a narrow therapeutic window and hence, according to some experts, even batch-to-batch variations of insulin can cause differences in glycemic control.
	Diabetics form a very large population and the risks posed by substitution at pharmacy level may not be manageable. It may be difficult to trace any hypersensitivity or immunogenicity-related adverse effect. Repeated switching between biosimilar and brand may pose immunogenicity problem.
	We are not aware of any switching studies that Biocon/ Mylan conducted, as required for interchange ability. Biocon refused to comment when probed.
	Characterization remains a major hurdle. Biocon may have worked on it extensively, but regulatory bar could be even higher, as witnessed in the case of Copaxone.
	UK and Australian diabetes federations have stated that they do not recommend patients adequately controlled on a particular brand to be shifted to biosimilar copies.

Source: Nirmal Bang Institutional Equities Research

While the physician can make a supervised switch, switching at the pharmacist level will be difficult. It will make evaluation of adverse events, in particular casualty (e.g. hypersensitivity or other immune-mediated reactions) difficult. To prevent this situation, prescribers may have an opportunity to prohibit pharmacy switching, by indicating 'Dispense as Written' on prescriptions.

Market share battle

It will be difficult for Biocon to garner market share for three reasons:

- 1) Direct competition with veterans
- 2) Indirect competition with next generation insulin's.
- 3) Target market is fragmented and hence marketing costs may take a toll.

Direct competition with veterans in the space

Several issues pose major hurdles for Biocon to compete effectively in basal insulin market. They are as follows:

- 1) **Eli Lilly has the advantage of early entry into biosimilar insulin glargine market.**
- 2) **Global manufacturing scale allows better pricing capability for Eli Lilly.**
- 3) **Lower marketing costs for competitors:** Biocon will be competing with Eli Lilly and Merck that have a ready field force across geographies to promote their brands. Their incremental marketing costs will be substantially lower or almost nil.
- 4) **Patient familiarity with device:** Eli Lilly uses Kwikpen for all its insulin products and it is using the same pen for Abasaglar too. Patients and physicians will be more willing to shift to Abasaglar rather than any other biosimilar product
- 5) **Global reputation:** Merck and Eli Lilly have global reputation.
- 6) **Large and fragmented target audience:** The target audience, being physicians, will be fragmented and therefore requires an extensive sales force and significant marketing efforts.

It will be a tough battle for Biocon in Lantus follow-on/biosimilar market. Competing in terms of pricing with players having a global marketing presence and global manufacturing scale in diabetes/insulin space is not easy. This will limit Biocon's ability to discount its product at levels attractive enough to encourage patient shifts. In case Biocon needs to settle with Sanofi for an early launch prior to expiry of its pending patents, the company may also need to commit royalty payment on potential sales, further denting its pricing power.

Lantus vials, which have a significant sales volume in US, potentially represent an attractive market for Biocon to build its share, but it all depends on how much of this pie is available when Biocon launches its biosimilar Lantus and whether or not it can launch as there are patents that protect Lantus vials in the US. The vial market is shrinking every year and probably the rate of decline should accelerate as Sanofi is looking to cannibalize this segment with its newly launched product, Toujeo. Even Ryzodeg, Lixilan and Xultophy will also cannibalize this segment.

Indirect competition from next generation insulins and combination products to exert more pressure on Biocon

The share of Lantus in basal insulin market is expected to decline by more than 50% over the next three to four years. The primary forces that will eat away Lantus share include:

- 1) **Toujeo** - Sanofi's own follow-on of Lantus
- 2) **Tresiba** – Next generation basal insulin from Novo Nordisk (recently approved in US)
- 3) **Ryzodeg** – Next generation premix insulin from Novo Nordisk (recently approved in US)
- 4) **LixiLan** – A fixed dose combination of Lantus and Lixisenatide (GLP-1)
- 5) **Xultophy** – A fixed-dose combination of Tresiba and Liraglutide
- 6) **Eli Lilly's Abasaglar** – Follow-on to Lantus
- 7) **MK-1293 in Europe** – Follow-on to Lantus.

Over the next three years (by 2019), Lantus is expected to lose >50% of its volume market share to direct and indirect competitors that include:

Exhibit:3 – Brand Sales Projection for Lantus

Lantus Brand Sales Projection	CY15	CY16	CY17	CY18	CY19	CY20	CY21	CY22
LANTUS	7,300	6,451	5,321	3,564	2,088	1,587	1,093	595
US	4,500	3,915	3,067	1891	923	646	369	92
Growth (Volume)	-	3%	3%	3%	3%	3%	3%	3%
Share Erosion	-	13%	34%	59%	80%	86%	92%	98%
EU	1,100	935	753	470	227	170	102	34
Growth (Volume)	-	3%	3%	3%	3%	3%	3%	3%
Share Erosion	-	15%	34%	59%	80%	85%	91%	97%
Emerging Market	1,350	1276	1225	1021	846	700	569	437
Growth (Volume)	-	8%	8%	8%	8%	8%	8%	8%
Share Erosion	-	6%	16%	30%	42%	52%	61%	70%
Rest of World	350	326	276	182	94	72	53	31
Growth (Volume)	-	5%	5%	5%	5%	5%	5%	5%
Share Erosion	-	7%	25%	51%	75%	81%	86%	92%

Source: Nirmal Bang Institutional Equities Research

Abasaglar – It is a follow-on version to Lantus launched by Eli Lilly and Boehringer Ingelheim. It was recently launched in Europe and other geographies. As per the settlement of ongoing litigation with Sanofi, Eli Lilly will launch Abasaglar in US in December 2016 and will pay royalty to Sanofi on worldwide sales. Eli Lilly is already well entrenched in insulin space and hence it should be easier for it to garner incremental sales from Abasaglar. We expect Abasaglar to capture 20% of Lantus market.

MK-1293 – Merck has filed for biosimilar Lantus in EU and a filing in US is round the corner. Merck too has a global presence in diabetes space by virtue of its diabetes franchise. Merck should capture about 15% of Lantus market.

Tresiba – This long-acting basal insulin from Novo Nordisk was recently approved in US. It has some very relevant and important advantages over Lantus, the main being that Tresiba can be dosed any time during the day (no fixed schedule as in case of Lantus or Levemir). Tresiba is also associated with lower rates of night-time hypoglycemia, which is an important benefit from a patient, payor and physician perspective. **Tresiba, which has been launched in as many as 43 countries across the world, has been able to garner a market share exceeding 25% in select geographies.** Tresiba garnered 34% market share in value terms in Japanese market. In US, where the drug was launched recently, the new -to-brand market share is already 8%.

Toujeo – Toujeo is an improved version of Lantus and carries higher insulin dose per unit volume. We believe Toujeo is well poised to cannibalize Lantus vial market in the US. Lantus vial market comprises 40% of Lantus sales and is more vulnerable than Lantus pen to cannibalization by biosimilars.

Toujeo can offer patients on vial the same benefit at no extra cost. The key benefit of using vial with syringe is that the injection time is shorter compared to a pen and its costs less than a pen. As Toujeo packs three times more insulin than Lantus in a single milliliter of insulin, the injection time is proportionately reduced. This benefit is particularly meaningful for patients who are on a heavy insulin dose. Patients who take a heavy insulin dose than those who are on a low dose are expected to use a vial over a pen. This is because the economics of using a vial over a pen are better justified in such patients and the injection time is lower.

The price differential is almost 20% between a vial and a pen. Sanofi is offering a co-pay discount for using Toujeo, which leaves almost no reason for a patient to stick to a vial and a syringe.

Over and above, Toujeo is associated with lower rates of hypoglycemia than Lantus. The US regulator has not granted this claim in the label, but EU authorities have accepted the claim.

Ryzodeg – Ryzodeg is a fixed dose combination of Insulin degludec or Tresiba (basal insulin) and Insulin aspart or Novorapid (meal time insulin). It has been approved by the US Food and Drug Administration or USFDA recently (September 2015) and has important benefits. **The key benefit of Ryzodeg is that it minimizes the number of injections for a diabetic patient** (a potential benefit that a vial has over a pen). While a basal bolus regimen typically requires up to four injections a day, Ryzodeg need only be injected once or twice a day.

The other important and meaningful benefits being lower hypoglycemia events and even lower weight gain. Mixed insulin is not a new concept. Earlier mixed insulin involved a mixture of a short or rapid acting form of insulin that is mixed with an intermediate acting insulin. However, because intermediate-acting insulin lacks the flat profile that long-acting analogue insulin has, this increases the risk of nighttime hypos occurring. Ryzodeg, however, uses an ultra-long acting analogue insulin (Tresiba) which has a flat profile and therefore results in a more stable sugar level through the night, reducing the risk of hypos.

Xultophy – It is a fixed-dose combination of Victoza (GLP-1) and Tresiba (Basal insulin). The advantage of such a combination is significant and we expect a good share of basal insulin market to shift to this combination. We expect the combination of GLP-1 to become therapy of choice in patients who are inadequately controlled on basal insulin in combination with oral anti diabetes drugs.

Traditional practice in diabetes is that after titration of basal insulin to achieve morning glucose control, adding a bolus, or prandial, rapid-acting insulin analog has been recommended either in a stepwise approach or as a full basal-bolus insulin regimen. **However, clinical evidence from studies on GLP-1 drug candidates suggest that adding a GLP-1 receptor agonist to basal insulin may be as effective as adding prandial insulin therapy. These results have given providers and patients a potentially easier option when glycemic control is not achieved with basal insulin in combination with oral anti diabetes drugs (OAD's)**

The key benefits of this combination are:

1. Lowers the number of injections required
2. Delivers **weight loss** as against weight gain with insulin therapy.
3. Helps significantly higher number of patients achieve their HbA1C goal when compared to Lantus alone.
4. Lower rates of confirmed hypoglycemia.

We anticipate physicians to be more aggressive in adopting this combination of GLP-1 and basal insulin as Victoza has recently demonstrated superiority over existing treatment option in reducing the risk of CV events in type 2 diabetes patients. Even Novo Nordisk has indicated that they expect the share of GLP-1 class in type 2 diabetes segment to significantly go up from current levels.

LixiLan – It is a fixed-dose combination of Lixisenatide (once daily GLP-1) and Lantus from the stable of Sanofi Aventis. The combination delivers similar advantages as Xultophy. In addition, it has also shown significant reduction in postprandial glucose as compared to basal insulin alone. Hence, it can lower or eliminate the need of meal-time insulin for patients.

The US PDUFA date for the drug is in August 2016. Sanofi has used the priority voucher for getting an accelerated approval. This probably indicates Sanofi's intent to cannibalize as much of Lantus sales as early as possible.

Forecast for Pegfilgrastim (Neulasta biosimilar – brand sales US\$5bn in CY15)

We remain skeptical on approval prospects of biosimilar Neulasta (Pegfilgrastim) for Biocon. Biocon states it has successfully demonstrated clinical equivalence, but it remains silent about whether or not it has demonstrated bioequivalence and met other secondary end-points in Phase 3 clinical study. Any potential delay in approval could substantially reduce the opportunity size for Biocon. We currently forecast \$50m in risk adjusted peak sales for Biocon's biosimilar pegfilgrastim (including Mylan share).

Coherus Bioscience, which is competing neck-to-neck with Biocon for US/EU launch, has announced that its biosimilar is the only one to have demonstrated no immunogenicity in healthy patients with an intact immune system. However, Coherus Bioscience has also declared that it has missed demonstrating bioequivalence in the pharmacokinetic study, AUC end-point. Hence, the company is conducting another study to see whether it can show bioequivalence on AUC end-point. We are not sure if Biocon's biosimilar version has demonstrated bioequivalence.

Pegfilgrastim biosimilar may be easy to market but cannibalization by Neulasta Onpro (an onbody injector) will cut the potential opportunity by half

In case of Pegfilgrastim, it is easier for biosimilars to capture market share as the purchase decision is largely made by Group purchasing Organizations (GPOs) and this significantly helps as you need not maintain a big sales force. **Amgen which launched Neulasta Onpro (on body injector) just one year back has already cannibalized 33% of Neulasta sales in the US.**

Litigation Hurdles

Sandoz and Apotex which have already received approval from the USFDA for their biosimilar copies of Neulasta have not been able to launch their copies yet. Amgen has sued Sandoz for patent infringement. We forecast risk adjusted peak sales of \$50m for Biocon's pegfilgrastim. We believe even Amgen would compete with biosimilars by lowering its prices for Neulasta brand.

Other biosimilars – Adalimumab (Humira) and Trastuzumab (Herceptin)

Adalimumab

We currently do not have estimates for adalimumab as patents, which expire as late as 2022, cover it and hence we are not sure if biosimilar companies may be able to launch copies prior to that. Recently the Patent Trial and Appeal Board (PTAB) ruled against one of the Humira patents. There are other two patents that still protect Humira until 2022. Coherus Bioscience has also challenged these patents.

Trastuzumab

At the American Society of Clinical Oncology's (ASCO) 2016 meeting, Biocon and Mylan announced Phase-3 data on their biosimilar Herceptin (MYL 14010). MYL 14010 successfully demonstrated equivalence on safety and efficacy to Roche's Herceptin. As per our understanding, Biocon/Mylan is the first company to have successfully demonstrated clinical equivalence in a Phase-3 study of their biosimilar copy to Roche's Herceptin. Positive data from Phase-3 study clears the air around Biocon's capability to develop biosimilar copies of the more difficult to copy biologics – so-called monoclonal antibodies. **We are looking at US\$125mn in peak sales of Trastuzumab for Biocon/Mylan.**

Brand sales opportunity – Geography-wise

Roche's Herceptin generated US\$6.6bn in annual global sales, which is divided as under among various geographies:

Exhibit 4: Herceptin Sales – Geography wise

Market	Sales (US\$mn)	Patent protection
United States	2,600	2019
Europe	2,100	Expired
Japan	260	Expired
Other international markets	2,000	Unknown*

*Would vary from country to country

Source: Roche

Competition

Other companies, which are likely to emerge close to Biocon in the market, include Amgen, Celltrion, Samsung and Pfizer. Ongoing Phase-3 clinical trials for these potential competing biosimilars should also report data by YE 2016.. As far as emerging markets are concerned, there might be additional competitors. Biocad has already gained approval for its biosimilar Herceptin in Russia.

Potential opportunity for Trastuzumab

We can look at the Trastuzumab opportunity in two parts – Cannibalisation of existing sales and expansion of access. While there is not much scope to expand access in developed markets, there is enough in international markets.

Cannibalization of existing sales

From a cannibalisation perspective, the trend will vary across geographies. For US market, the patent expires in 2019 and hence any potential competition is far off and we do not give any value to the US opportunity now.

As far as European markets are concerned, Roche has several defenses ready to counter competition from biosimilar candidates. Herceptin registers around US\$2.1bn in annual sales in Europe. We believe biosimilars, at best, should be able to cannibalize 40% of Herceptin's sales and the same is possible only if the discount is steep. We are assuming a price discount of 60%.

Subcutaneous avatar of Herceptin in Europe should limit adoption of biosimilars

Roche has a subcutaneous version of its Herceptin already approved in European market. The key advantage of a subcutaneous version is that it can be administered in significantly less time (5 minutes versus 30 minutes or 90 minutes for the loading dose). Apart from patient convenience, there are also tangible savings for the healthcare system (approximately 10% of total costs of a full course of Herceptin). In two Phase-3 clinical trials in EU, it has been found that 92% of patients prefer subcutaneous administration over the IV version. **To further promote subcutaneous Herceptin sales, Roche is also conducting trials to see if Herceptin can be administered at home.**

Besides the subcutaneous defense, Roche can also adopt bundled pricing approach / Discounting Herceptin and pricing Perjeta at a premium

Currently, Herceptin is used for four different indications:

- 1) Neo adjuvant HER2+ve breast cancer
- 2) Adjuvant HER2 +ve breast cancer
- 3) First and second- line metastatic breast cancer
- 4) Gastric cancer

About 10% of sales of Herceptin in breast cancer come from neoadjuvant breast cancer indication, 70% from adjuvant indication and 30% from metastatic indication. Roche has already received approval for its add-on drug candidate Perjeta in neo-adjuvant and first-line metastatic indication.

Approval for Perjeta in adjuvant breast cancer - the largest indication is contingent on positive Phase -3 data from the ongoing APHINITY study. The data is expected any time this year. We see more than a good chance of a successful outcome in Phase -3 APHINITY trials as Perjeta has already demonstrated the benefits of use in neo-adjuvant and first-line metastatic indication.

Currently, we assume that biosimilars players in Europe will have to offer a 50%-60% discount to grab market share and this should translate into a 40% share of overall Herceptin's current sales pie. Assuming a 6% share for Biocon in the biosimilar pie, the opportunity should mean US\$50mn in incremental sales from trastuzumab biosimilar in Europe.

Potential in emerging markets/ international markets

Herceptin derives about US\$2bn in sales from Herceptin in international markets. We believe that not all of Herceptin sales in international markets will be immediately accessible for biosimilar players because of different intellectual property or IP situations and regulatory bars across geographies. To cite an example, China is believed to have a notoriously high bar for getting an approval. We assume that only 50% of international markets will be accessible.

There are two ways that biosimilars can look to play the emerging market potential. One is, as we discussed earlier, is to cannibalise the existing market pie and the other is to expand access by discounting the prices to a level where affordability is significantly enhanced.

We believe a 80% discount should be enough to breed volume growth, but we are not sure if the cost dynamics will work at such a price discount. For now, we assume that Biocon will discount its biosimilar by 60% and get an 8% share of the available pie (i.e. 50% of international markets' sales) and also expand the market by 20% from the current level. This translates into incremental sales of US\$75mn in international markets.

Syngene poised for solid growth

Syngene has ventured into the contract manufacturing space and the idea is to provide more scale to the business. There are inherent limitations in the pure research outsourcing model and providing contract manufacturing is the next logical step. The intention is to build a presence across the value chain of pharmaceutical outsourcing business and thus capture client relationships for garnering a larger share of their outsourcing pie.

The company has demonstrated good capability in not only retaining clients, but also adding to the list ever year. This bodes well for growth prospects of the business.

We expect Syngene to post a 23% CAGR over the next couple of years, and as the base grows, the growth rate should decline.

Recommendation –The recent run up in the stock price has discounted a greater proportion of the potential opportunity, but the risks are underappreciated. Direct competition from other biosimilar players and next generation molecules from innovators casts major uncertainty over realization of potential benefits in the near to mid-term. The investments that have been made so far are significant and the business would require further investments. This would limit free cash flow generation.

Unfortunately, the biosimilar space appears crowded with multiple players expected to reach the market around the same time. The potential return on investment is significantly diluted in such a scenario.. With innovators prepared with their life cycle management strategies, we expect biosimilars to offer a steeper discount than the traditional 20-30% price discounts to gain acceptance. The market share gains in the regulated market are expected to be limited in the near to mid term and we are cautious whether such high investments required in the business are justified at such steep price discounts and low market shares.

Over the next 3-4 years, the larger part of the opportunity for Biocon will be driven by emerging markets, while regulated markets will have limited contribution. A better way to play the potential opportunity presented by the biosimilar space would be a large cap pharma company that is poised well in the biosimilar space, but is yet to make a mark as far as newsflow is concerned.

Risks to Recommendation

- 1) The biosimilar business of Biocon is a valuable asset and it makes strategic sense for the larger pharma companies looking to get quick access to this high barrier space. In case of a potential sale of its biosimilar portfolio we believe there is notable upside in the stock price
- 2) Lower than anticipated competition for its biosimilar products and faster than anticipated approval timelines
- 3) Regulatory changes that allow automatic substitution of biosimilars including follow-on Lantus

Biocon - Company background

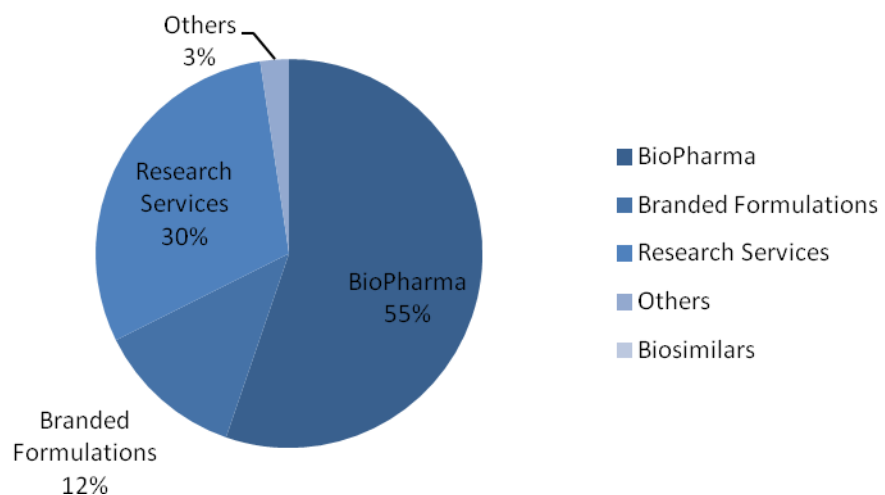
Biocon started as a niche player with its unique expertise in fermentation technology to build global leadership in manufacturing and supply of statins. Over time, the statin business was commoditised, but the company leveraged its expertise in fermentation to build its presence in high-entry barrier biosimilar space. The company has accelerated its biosimilar development efforts to emerge as a front-runner in the race to launch biosimilar products in regulated and developed markets. The company has four biosimilar products (Insulin Glargine, Trastuzumab, Pegfilgrastim, and Adalimumab) in late stage clinical trials intended for approval in developed markets (US and EU).

Besides having a front-end product business, Biocon also successfully nurtured and developed contract research and manufacturing business, which was recently listed on the bourses as Syngene International. By virtue of its strong client relationship and full service offering in the contract research and manufacturing space, Syngene continues to grow at a notably fast pace (>20%).

The characterisation capabilities that the company has developed by virtue of its developmental efforts on the biosimilar front is being leveraged for filing of ANDA application on complex chemical drugs products like Copaxone. The company so far has made 7-8 ANDA applications and is looking for 5-6 filings each year. Apart from Copaxone, we are not aware which products these ANDAs are targeting, but in most probability these have to be out of its existing product portfolio and we guess the products are potentially tacrolimus (generic Prograf), cyclosporine (generic Sandimmune) and potentially statin brands in US market. The company potentially runs a cost advantage on these products by virtue of global scale in APIs of these products.

Biocon is aspiring to reach US\$1bn in annual revenues by FY19 and believes that a large part of the potential growth will emanate from sale of biosimilars, growth in branded formulations business and research services business.

Exhibit 5: Biocon’s revenue model – FY16



Source: Company, Nirmal Bang Institutional Equities Research

Financials

Exhibit 6: Income statement

Y/E March (Rsmn)	FY15	FY16	FY17	FY18E	FY19E
Net sales	31,960	35,355	40,174	45,909	52,278
% growth	7	11	14	14	14
Raw material costs	11,819	13,301	15,150	17,072	19,073
Staff costs	5,334	6,363	7,406	9,111	10,675
Other expenditure	2,000	2,100	2,205	2,315	2,431
R&D Costs	7,086	7,313	7,891	9,139	10,773
Total expenditure	26,239	29,077	32,652	37,637	42,952
EBITDA	7,489	9,496	10,819	12,046	14,474
% growth	1	27	14	11	20
EBITDA margin (%)	23	27	27	26	28
Other income	531	0	0	0	0
Interest costs	89	102	422	372	323
Gross profit	20,141	22,054	25,025	28,837	33,204
% growth	12	9	13	15	15
Depreciation	2,210	2,423	2,447	2,911	4,024
Profit before tax	6,241	12,725	7,950	8,763	10,127
% growth	16	104	-38	10	16
Tax	957	2,569	1,590	1,709	1,924
Effective tax rate (%)	18	20	20	20	19
Net profit	5,284	10,156	6,360	7,054	8,203
% growth	23	92	(37)	11	16
EPS (Rs)	25	47	28	30	35
% growth	19	89	(41)	9	16
DPS (Rs)	5.0	5.0	5.0	5.0	7.5
Payout (%)	20	11	18	17	21
Dividend on equity shares	5.0	5.0	5.0	5.0	7.5
Tax on dividend	(200)	200	200	200	300

Source: Company, Nirmal Bang Institutional Equities Research

Exhibit 8: Balance sheet

Y/E March (Rs mn)	FY15	FY16	FY17	FY18E	FY19E
Equity	1,000	1,000	1,000	1,000	1,000
Reserves	31,706	39,556	43,893	48,748	53,991
Net worth	32,706	40,556	44,893	49,748	54,991
Net deferred tax liabilities	417	346	346	346	346
Short-term loans	2,610	3,949	3,894	4,378	4,830
Long-term loans	7,696	20,724	19,879	19,034	18,189
Total loans	10,306	24,673	23,773	23,412	23,019
Liabilities	63,754	84,816	89,794	96,056	1,02,786
Gross block	29,750	33,134	39,147	50,625	58,997
Depreciation	2,210	2,423	2,447	2,911	4,024
Net block	15,807	16,768	20,334	28,901	33,249
Capital work-in-progress	14,938	20,013	21,529	17,216	12,559
Long-term investments	-	-	-	-	-
Inventories	4,527	5,114	5,785	6,504	7,177
Debtors	7,705	8,229	9,999	11,242	12,404
Cash	11,678	23,498	20,952	20,998	26,203
Loans and advances	4,506	5,976	5,976	5,976	5,976
Other current assets	4,915	5,344	7,114	8,357	9,519
Total current assets	25,626	39,932	39,827	41,835	48,875
Creditors	4,293	5,471	6,189	6,958	7,678
Other current liabilities	11,254	10,805	10,750	11,234	11,686
Total current liabilities	15,547	16,276	16,939	18,192	19,365
Net current assets	10,079	23,656	22,888	23,643	29,511
Misc. expenses	-	-	-	-	-
Total assets	63,754	84,816	89,794	96,056	1,02,786

Source: Company, Nirmal Bang Institutional Equities Research

Exhibit 7: Cash flow

Y/E March (Rs mn)	FY15	FY16	FY17	FY18E	FY19E
EBIT	5,721	6,278	7,522	8,272	9,325
(Inc.)/dec. in working capital	(3,540)	(2,602)	(1,779)	(708)	(663)
Cash flow from operations	3,441	13,000	9,463	11,811	14,333
Other income	531	-	-	-	-
Depreciation	2,210	2,423	2,447	2,911	4,024
Interest paid (-)	(5)	(454)	(845)	(845)	(845)
Tax paid (-)	(1,334)	(1,470)	(1,590)	(1,709)	(1,924)
Dividends paid (-)	(1,000)	(1,000)	(1,000)	(1,000)	(1,500)
Net cash from operations	2,107	11,530	7,873	10,102	12,409
Capital expenditure (-)	(9,169)	(8,459)	(7,529)	(7,165)	(3,715)
Net cash after capex	(7,062)	3,071	344	2,937	8,694
Inc./(dec.) in short-term borrowing	171	-	-	-	-
Inc./(dec.) in long-term borrowing	3,247	-	-	-	-
Inc./(dec.) in preference capital	-	-	-	-	-
Inc./(dec.) in borrowings	3,418	-	-	-	-
(Inc.)/dec. in investments	2,079	(1,982)	-	-	-
Equity issue/(buyback)	-	-	-	-	-
Cash from financial activities	1,862	9,173	(2,890)	(2,890)	(3,490)
Others	-	-	-	-	-
Opening cash balance	5,570	4,626	14,464	11,918	11,964
Closing cash balance	4,626	14,464	11,918	11,964	17,169
Change in cash balance	(944)	9,838	(2,546)	47	5,204

Source: Company, Nirmal Bang Institutional Equities Research

Exhibit 9: Key ratios

Y/E March	FY15	FY16	FY17	FY18E	FY19E
Profitability & return ratios					
EBITDA margin (%)	23.4%	26.9%	26.9%	26.2%	27.7%
EBIT margin (%)	17.9%	17.8%	18.7%	18.0%	17.8%
Net profit margin (%)	16.5%	28.7%	15.8%	15.4%	15.7%
RoE (%)	16.2%	25.0%	14.2%	14.2%	14.9%
RoCE (%)	14.2%	10.2%	11.6%	12.0%	12.7%
Working capital & liquidity ratios					
Receivables (days)	102.4	116.1	116.1	112.7	107.9
Inventory (days)	157.9	158.8	156.7	153.4	150.2
Payables (days)	169.0	169.8	167.6	164.2	160.7
Current ratio (x)	2.5	2.4	2.3	2.5	2.8
Quick ratio (x)	2.1	2.0	1.9	2.2	2.4
Valuation ratios					
EV/sales (x)	4.4	4.0	3.6	3.1	2.6
EV/EBITDA (x)	18.7	14.9	13.2	11.8	9.4
P/E (x)	29.0	15.3	26.0	23.8	20.5
P/BV (x)	4.4	3.6	3.2	2.9	2.6

Source: Company, Nirmal Bang Institutional Equities Research

Disclaimer

Stock Ratings Absolute Returns

BUY > 15%

ACCUMULATE -5% to 15%

SELL < -5%

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