Biocon Ltd: Initiating Coverage

Riding a multi-year growth wave… CMP INR: 477 Target Price INR: 590

Biocon Ltd. is the largest biologics company in India and 4th largest insulin player in the world. The company has been able to develop and market some breakthrough products in the domestic as well as emerging markets. It is also one of the largest end-to-end research service providers in India having key relationships with various global players like Bristol Myers Squibb (BMS), Baxter and Abbott. The major growth driver for Biocon is expected to be its biosimilar product portfolio. It is working on eight biosimilar products under the exclusive arrangement with Mylan besides the rh-insulin, which the company is expecting to file in the US and EU once the Malaysian facility comes on stream. Apart from biosimilars, it is also working on its own set of novel products, which could open up out-licensing opportunities over a period of time, especially its ambitious Oral Insulin candidate - IN105. We believe that the impending opening up of the biosimilar market (especially in the US), around USD 71bn market of biologics going off-patent, and high entry barriers for new players places Biocon at the forefront to monetize the lucrative opportunity and support growth over the long run.

Best placed to tap biosimilar opportunity

The core biopharma business of the company includes all its businesses, except the research services business, where small molecules form more than 70% of the business. The growth in this business over the last 3 years has been on the back of traction in immunosuppresants/insulins and its branded formulation business in India. We expect the biosimilar business (insulin exports) to grow at a steady pace, before taking off by FY17E post regulatory approvals for the Malaysian facility. We believe that since growth in the statins business is likely to be muted owing to limited growth opportunity in a crowded market, growth in the core biopharma business would continue to be driven by branded formulations and immunosupprasants/insulins in the near term. Therefore, we expect the core biopharma business to grow at a CAGR of 13.3% over FY14-16E. Going forward, a strong pipeline of biosimilar product launches supported by the exclusive tie-up with Mylan coupled with the company's initiatives to move up the value chain in the Small Molecules business by filing of ANDAs in the US gives us enough visibility on the company's sustainable high growth in the future.

Malaysian facility key to unlock insulin opportunity

The Malaysian facility is an important strategic initiative for the company. Biocon is building it at the cost of ~USD 200 mn in the first phase. The Malaysian facility is expected to be commissioned by the end of FY15, but it will start contributing to the topline from FY17E onwards, as we believe that the regulatory approvals from the relevant geographies would take at least 3-4 quarters to attain. Biocon has received a good deal from the Malaysian Government with various tax breaks and incentives. The company plans to file for all the insulin analogs with Mylan besides rh-insulin from this plant.

Research services a high value franchise

Biocon offers end-to-end contract research services to its strong base of ~150 clients spread across various life science sectors through its subsidiaries - Syngene and Clinigene. The company has three multi-year contracts, with dedicated R&D facilities and scientists exclusively assigned to them, giving us comfort on a steady revenue flow going forward. We believe that research services would continue to remain a key growth driver for the company, with eight products in late stage trials. Along with long-term contracts, the contract research business provides enough visibility to sustain its historical growth rate of 20% plus. Therefore, we expect research services business to grow at a CAGR of 20.9% over FY14-16E.

Valuations

Biocon stock is currently trading at valuations of 16.2x its FY16E core earnings. We value Biocon at its historical average of 20x one-year forward FY16E earnings of INR 29.5/share on account of expected monetization of the biosimilar opportunity, strong balance sheet, steady cash flows and strong growth in the domestic market. We would further like to highlight that major upside in earnings is expected to kick in once the company gets regulatory clearances for the Malaysian facility by FY17E. We initiate coverage on the stock with a "BUY" rating and a target price of INR 590/share.

Financials

Year to March (INR Cr)	FY12	FY13	FY14	FY15E	FY16E
Revenue	**2,087**	**2,485**	**2,877**	**3,304**	**3,816**
Revenue Growth (%)	-24.7%	19.1%	15.8%	14.8%	15.5%
EBITDA	**517**	**570**	**725**	**832**	**953**
Net Profit	323	338	469	529	590
Profit Growth (%)	**-13.9%**	**4.6%**	**38.7%**	**12.9%**	**11.6%**
Shares Outstanding (crs.)	20.0	20.0	20.0	20.0	20.0
Diluted EPS (INR)	**16.2**	**16.9**	**23.4**	**26.5**	**29.5**
EPS Growth (%)	-13.9%	4.6%	38.7%	12.9%	11.6%
Diluted P/E (x)	**29.5**	**28.6**	**21.1**	**18.0**	**16.2**
EV/EBITDA (x)	18.0	16.0	13.2	11.4	9.7
RoE (%)	**15.6%**	**20.2%**	**14.1%**	**15.7%**	**15.1%**

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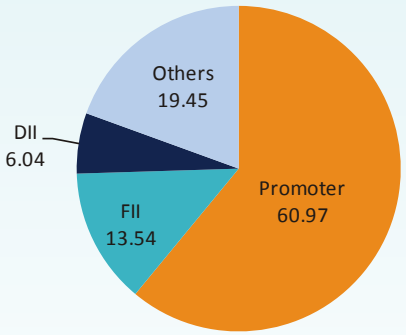
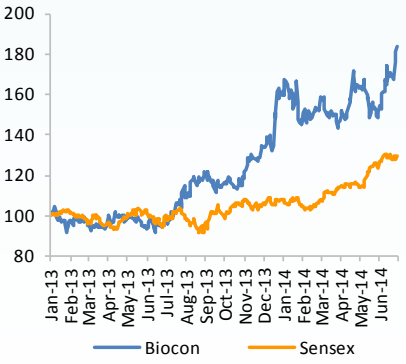
Bloomberg:	BIOS:IN
52-week range (INR):	554 / 286
Share in issue (Crs):	20
M cap (INR crs):	10,465
Avg. Daily Vol. BSE/NSE :('000):	146

SHARE HOLDING PATTERN (%)



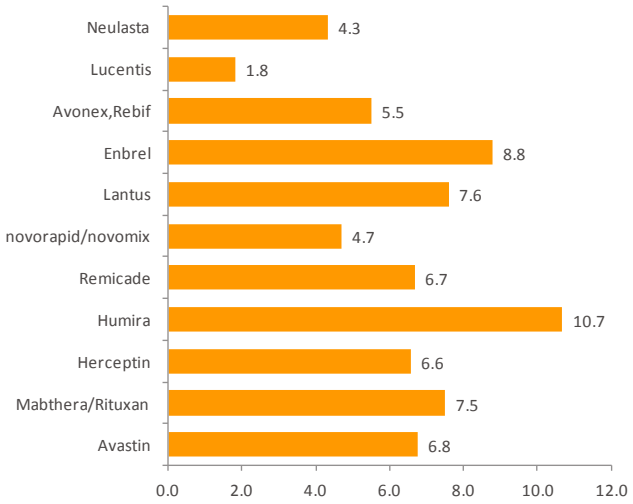


Date: 15th July, 2014

Tapping the biosimilars opportunity

Biosimilars, which are similar versions of biologic drugs, is a field of study which has seen a lot of interest from the innovators and generic players alike. According to IMS, ~USD71 bn worth of biologic drugs are expected to lose patent protection by 2020. Few biosimilars approvals in the regulated markets (Europe: 19 and US:none) and various countries' focus on reducing healthcare costs makes biosimilars a virgin and very attractive space.

Chart 1: List of drugs going off–patent (Sales in USD bn)



EU Expiry date	US Expiry date
2015	2014
2016	2016
Expired	Expired
2015	2028 (extended)
2014	2014
2015	2015
2015	2018
2018	2016
2014	2019
2013	2016
2019	2017

Expiry date may vary country by country in the EU.
Source: IMS, Edel Invest Research.

Biologics are complex structures produced from genetically engineered living cells. There is a high risk of losing the investments made, since even minor changes in the manufacturing process could adversely affect the desired results.

Contrary to their chemical counterparts, these drugs have significant challenges for the developers:

- Biosimilars require extensive non-clinical and clinical tests to prove similarities with the innovator product
- Significant investment is required for the development of biosimilars; ~USD 40-300 mn versus ~USD 1-4 mn for generics
- Time to develop a biosimilar product is around 8-10 years compared to 3-4 years for generics

These factors create entry barriers for non-serious players and thus limit competition in this space.

Why Biocon stands to gain...

The biosimilar business of the company currently contributes a small portion of its overall revenues, with mainly rh-insulin being exported. Biocon plans to increase its geographical reach to further increase revenues from the biosimilar products. The company has a pipeline of nine biosimilar products under various stages of development, which has the potential to further increase revenue contribution from this segment.

Table 1: Products under development

	Product	Patent Expiry		Opportunity Size: 2013 Sales in $mn	Stage of development
Sr.No		US	EU		
(a)	Trastuzumab (Herceptin)	2019	2014	6.6	Phase III
(b)	Bevacizumab (Avastin)	2017	2019	6.8	Pre-clinical
(c)	Adalimumab (Humira)	2016	2018	10.7	Pre-clinical
(d)	Pegfligrastim (Neulasta)	2014	2015	4.3	Pre-clinical
(e)	Etanercept (Enbrel)	2028	2015	8.8	Pre-clinical
(f)	Insulin glargine (Lantus)	2014	2014	7.6	Phase 1/II b
(g)	Insulin Lispro (Humalog)	Expired	Expired	2.6	Pre-clinical
(h)	Insulin Aspart (NovoRapid)	2015	2015	3.0	Pre-clinical

Source: Company, Edel Invest Research.

How will Biocon get the reach…

Biocon has a strategic collaboration with Mylan to develop and manufacture eight biosimilars for various markets, with exclusive marketing rights for Mylan in developed markets and co-exclusive rights in other markets. These biosimilars are a mix of MABs (Monoclonal Antibodies)/recombinant proteins/GCSF and Insulin analogs, which together have a market opportunity of ~USD 50 bn globally. They are expected to go off-patent between 2014 and 2020.

Table 2: Snapshot of the deal with Mylan

	Generic Insulin Analogs	Biosimilar Mabs & other Biologics
Global Market Size	**~US$ 13bn**	**~US$ 37bn**
Portfolio Constituents	Glargine, Lispro & Aspart	Trastuzumab, Bevacizumab, Adalimumab, Ethernacept, Peg-filgrastim
Mylan's Exclusive Comemrcialization Regions	US, Canada, Europe, Australia & New Zealand	Developed markets
Upfront Received	$20mn	$18mn

Source: Company, Edel Invest Research.

Biocon's deal with Mylan is a win-win situation for both the players, as it gives the Indian company geographical reach and financial muscle to market its products in the developed markets besides sharing the development cost. As per Mylan, it plans to provide ~USD 50 mn or more annually to fund this collaboration. On the other hand, the deal gives Mylan the capability to make inroads into the lucrative biosimilars market.

Five of the eight products that are part of this deal are among the top ten selling drugs of 2013. These products include:

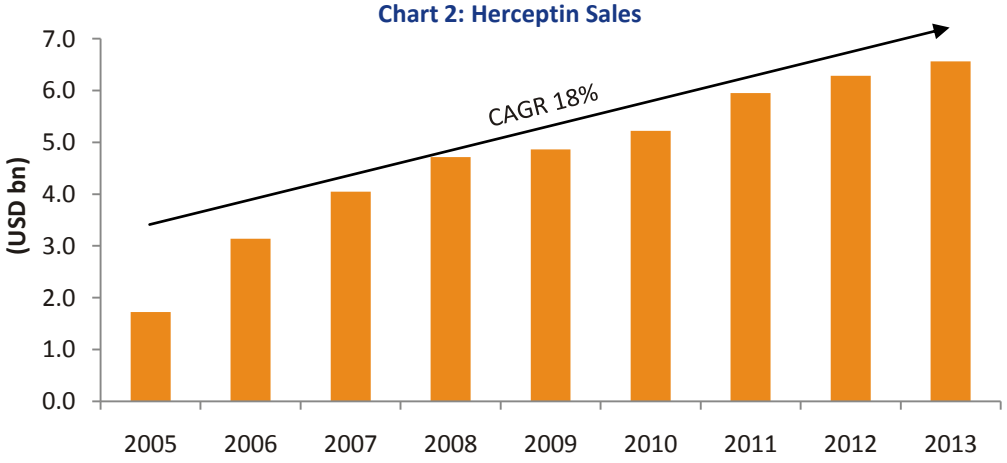
a) Trastuzumab (Breast Cancer)

Marketed as Herceptin by Roche globally, Trastuzumab is primarily used for two major indications, HER2 – Positive breast cancer and HER2 – Positive metastatic gastric cancer. The drug had annual sales of USD 6.6bn in 2013, and was among the top ten selling drugs globally.

As per Decision Resources, HER2 positive disease cases account for <25% of the total breast cancer cases, yet it accounted for ~55% of the US$8.6 billion drug market for the disease in 2011, with majority of the sales dominated by Herceptin.

The patent for this drug is expected to expire in the US in 2019 and the EU in 2014.

Chart 2: Herceptin Sales



Source: Bloomberg, Edel Invest Research.

Biocon was the first company to get an approval for trastuzumab in India followed by Hospira/Celltrion in South Korea. It has already launched the drug in India by the brand name Canmab in a co-exclusive partnership with Mylan. Mylan has launched the same drug with the brand name Hertraz in the Indian market.

The molecule is also in Phase III clinical trials for its global development program where it has already started recruitment. It is one of the most advanced MABs being worked upon under the Mylan deal. Globally, other than Biocon, there are at least five players who are in late stage of development of the biosimilar version of Herceptin.

Table 3: Competitive scenario

Biosimilars under development			
Name	**Company**	**Tie-up**	**Stage of development**
ABP 980	Amgen	Watson(Actavis) & Synthon	Phase III
CT-P6	Hospira	Cellitrion	Phase III
PF-05280014	Pfizer		Phase III
SB3	Samsung Bioepis	Merck	Phase III
BCD-022	Biocad		Phase III (Russia)

Source: Edel Invest Research.

b-e) Other MABs /Recombinant proteins/GCSF under Mylan tie-up

Other than Trastuzumab, the company has a tie up with Mylan for four other molecules, the patent for which would be expiring in both US and EU before 2020. All these opportunities at Biocon are currently under pre-clinical stage of development and would take few years to develop. However, each of these molecules has the potential to generate substantial revenues due to limited competition, which would result in lower price erosion. All these drugs except Etanercept (a similar version of which is already available in China, Columbia and India) are still being tested by various biopharmaceutical companies across the globe.

Table 4: Competitive scenario

Biologic (Brand Name)	Innovator	Competitors (Stage of Development)
Bevacizumab (Avastin)	Roche	Pfizer (Phase I), Amgen/Actavis (Phase III), Boehringer Ingelheim (Phase I completed), Hospira/Cellitrion (Process Development), Biocad (Phase III)
Adalimumab (Humira)	Abbvie	Sandoz (Phase III), Pfizer (Phase I/II completed), Amgen/Actavis (Phase III), Boehringer Ingelheim (Phase I completed), Samsung Bioepic/Merck (Phase I), Hospira/Cellitrion (N/A)
Pegfligrastim (Neulasta)	Amgen	Sandoz (Phase III completed), Hospira/Novoquest (Phase I completed)
Etanercept	Amgen	Sandoz (Phase III), Hospira/Cellitrion (N/A), Hanwha Chemical (Phase III complete in South Korea), Coherus Biosciences/Daichii Sankyo (Phase III- yet to begin recruitment), Samsung Bioepis (Phase III), LG Life Sciences (Phase I completed- South Korea), Daewoong Pharmaceuticals (N/A), Mycenax Biotech (Phase III- South Korea),Bioxpress therapeutics (N/A)

Source: Edel Invest Research.

f) Glargine (Long Acting Insulin)

Glargine, marketed as Lantus by Sanofi globally, is an Insulin analog marketed as a long acting insulin for patients with either Type I or Type II diabetes. This drug is considered to be much more effective than the basic human Insulin. The drug had annual sales of ~USD 8.0bn in 2013, and is among the top ten selling drugs globally. The patent for this drug is expected to expire in the US and EU in 2014.

Chart 3: Lantus Sales

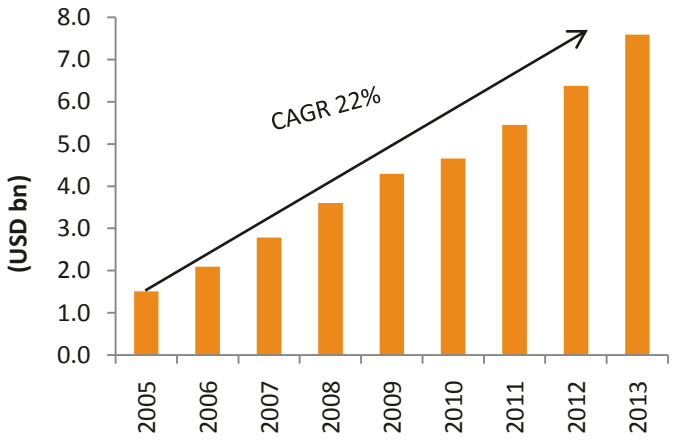
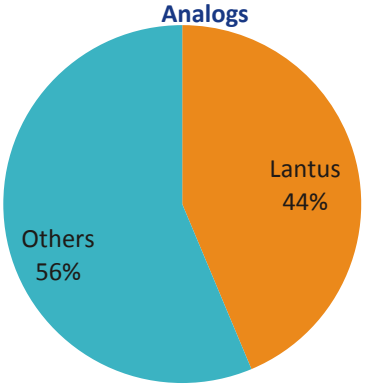


Chart 4: Lantus 44% of ~USD 17bn Insulin Analogs



Source: Bloomberg, Edel Invest Research.

Besides Sanofi, Biocon and Wockhardt are the only players in India to market glargine. Biocon markets the drug under the brand name Basalog. The company already has approvals from 10 emerging markets for the marketing of the product.

The company has already completed Phase I/II clinical trials for its global development program, and is expected to start recruitment for Phase III soon. Among the insulin analogs being worked upon under the Mylan deal, Glargine is in the most advanced stage of development. Globally, other than Biocon, there are at least two other players who are in the late stage development of the biosimilar version of Lantus.

Table 5: Competitive scenario

Name	Company	Tie-up	Stage of development
LY2963016	Eli Lilly	Boehringer Ingelheim	NDA(US) & Received positive opinion from CHMP
MK-1293	Merck	Samsung Bioepis	Phase III

Source: Edel Invest Research.

g-h) Other Analogs under the tie-up

Other than Glargine, the company has two other analogs in tie-up with Mylan. The patent for these two drugs would be expiring in both US and EU before 2015. Both these opportunities are currently under pre-clinical stage of development at Biocon, and would take few years to develop. But each has the potential to generate substantial revenue contribution given the limited competition, thus resulting in lower price erosion. All these drugs are still being tested by various biopharmaceutical companies across the globe.

Table 6: Competitive Scenario

Biologic (Brand Name)	Innovator	Competitors (Stage of Development)
Insulin Lispro (Humalog)	Eli Lilly	Sanofi (Phase I)
Insulin Aspart (NovoRapid)	NovoRapid	Sanofi (Phase I)

Source: Edel Invest Research.

It doesn't stop here...

Aside from the eight biosimilar products under the Mylan deal, the company has the recombinant human insulin (rh-insulin) in its portfolio. Biocon markets this product in the Indian market since 2004 by the brand name Insugen. The company has got this product registered for launch in 55 other countries. However, due to capacity constraints it is currently marketing the product only in ~20 countries.

The company has been able to increase penetration substantially and has taken market share from other players mainly on the back of the high quality of the product at a very competitive price in the emerging markets (EM's).

rh-Insulin Volume market Share (in select EM's): Evolution

Chart 5: Mar-09

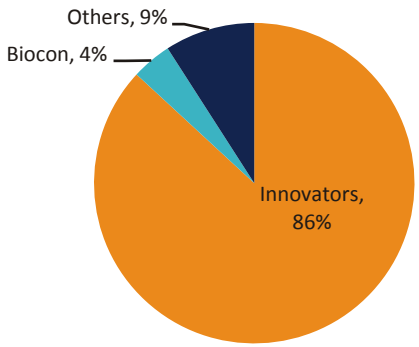
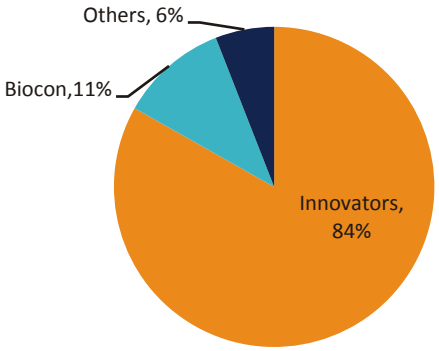


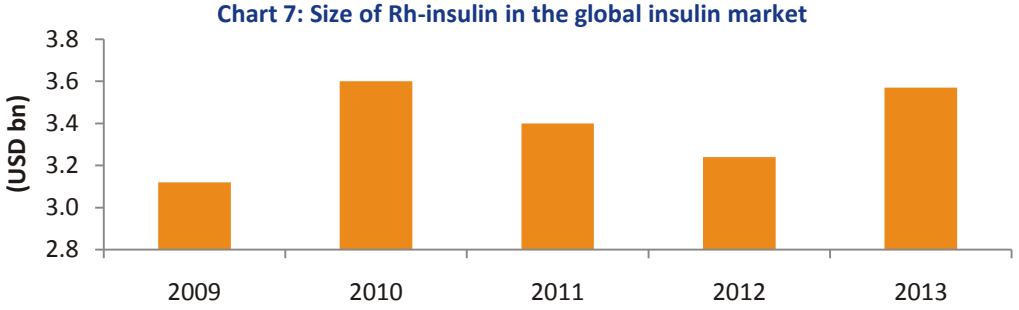
Chart 6: Mar-13



Source: Company, Edel Invest Research.

Though the consensus opinion is that the rh-insulin as a percentage of market is losing ground to the modern insulins, it is interesting to note that the size of the drug in absolute terms has remained stable and continues to be a sizable opportunity for Biocon.

Chart 7: Size of Rh-insulin in the global insulin market



Source: Edel Invest Research.

In the EU, Biocon has already completed phase III trials for the biosimilar rh-insulin, though the company has guided that it would has delayed the process of filing the drug with regulator until the Malaysian facility comes on stream.

Malaysia key to insulin opportunity

The Malaysian facility is an important strategic initiative that the company is building at the cost of ~USD 200 mn in the first phase; it is Asia's largest integrated Insulin manufacturing facility. The facility is expected to be commissioned by the end of FY15, but it will start contributing to company's topline from FY17E onwards, as the regulatory approvals from the relevant geographies would take at least 3-4 quarters to attain. The company plans to file for all the insulin analogs with Mylan besides the rh-insulin from this plant.

Though the Malaysian facility would put pressure on Biocon's profitability in the initial years on the back of increased overheads, the company has enough tax incentives from the Malaysian government to mitigate the hit on the bottomline.

- 10-year tax holiday
- Grant for training Malaysian employees
- Research & Development grants

All of these would help the company to improve its profitability going forward.

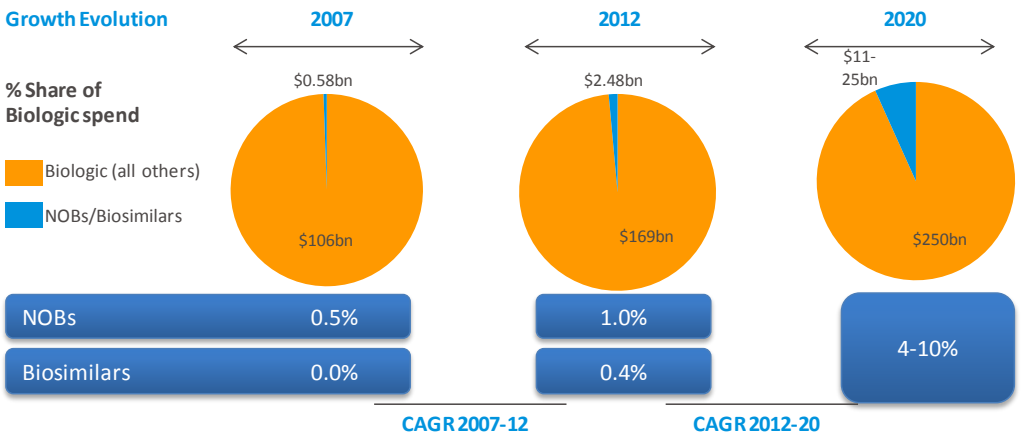
There are some uncertainties though...

Biosimilars regulations still evolving

Considering the complexity and differentiation in the structure of a Biosimilar product, the pathway to getting regulatory approval for the same is also different. The regulations for biosimilars are still evolving across various markets.

In the US, which is the largest market for biologics, the guidelines are still being framed, whereas in the EU and other global markets the final guidelines are in place but are still evolving. Lack of clarity on regulatory guidelines is the primary reason for low penetration (less than 2% or USD 2.48 bn) of biosimilars and non-original biologics (NOBs) in the total biopharmaceutical market. Once the guidelines are in place, especially in the US market, we may see higher penetration of 4% to 10% going forward.

Chart 8: Global penetration of biosimilars



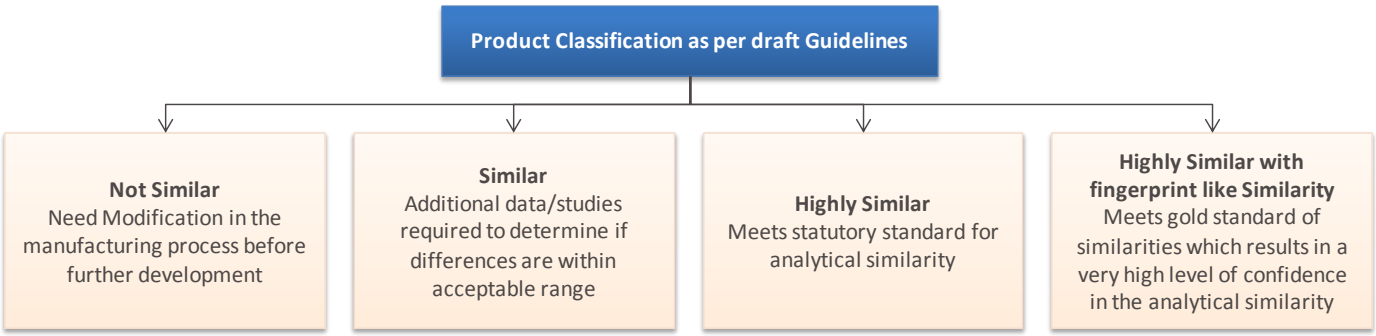
Source: IMS health, MIDAS, MAT Dec 2012. IMS analysis & estimates. NOBs are recombinant and synthesized only.

US key to higher biosimilar penetration

The US is the largest biologics market in the world with ~50% share of the USD 169 bn market. Yet, it is far behind in terms of framing up regulations for approvals of biosimilars. Things have started moving gradually though, with the signing of the Patient Protection & Affordable Care Act (PPACA) by President Barack Obama in 2010 and amendment of section 351, which led to the inclusion of section 351(k) (which defines regulatory pathway for biosimilar approvals). Since then, the USFDA has issued certain draft guidelines for biosimilars, but these guidelines have been modeled on the European regulations. Some of the major features are:

Comparability

The guidelines require following a "totality of evidence" approach to establish similarity in quality, safety and efficacy for a biosimilar versus the reference product with the help of analytical, non-clinical and clinical studies. The approach and scope of the studies required to prove the same would however vary from case to case.



Extrapolation of indication

The USFDA has proposed that a biosimilar applicant may use clinical data of one condition for support to obtain approvals in other conditions for which the reference product is indicated; this is again in line with the guidelines of EMA.

Interchangeability

The USFDA has been vague regarding the safety and quality considerations for interchangeability. Currently, no country allows for automatic substitution of biologics with biosimilars.

Nomenclature

The USFDA has not yet specifically outlined whether the biosimilar needs to be sold by the generic name or whether it would have to be branded separately. On the other hand, the EMA requires a biosimilar to be marketed as a different brand.

The silver lining...

As far as insulins are concerned, biosimilar developers may not have to use the abbreviated biosimilars pathway 351(k) to file for the approval of such products. The reference products for all the products that Biocon has been working on were all approved by the USFDA as NDA's. Thus, the company could file for a 505(b)(2) to get approval for these products, as was seen in the recent Eli Lilly filing for Glargine.

We believe that since most of the Biocon products (except rh-insulin) are under pre-clinical/clinical trials, it would take at least three years for the company to get few of its late-stage products in the market. We thus believe that the major traction in the company's biosimilar business would come once the regulatory approvals for the Malaysian facility are in place. We have factored in a CAGR of only 11.1% over FY14-16E in the biosimilar business considering capacity constraints in the insulin facility at Bangalore. Going forward, the commencement of production in the Malaysian facility would help Biocon improve its growth visibility substantially.

Domestic business to continue strong growth momentum

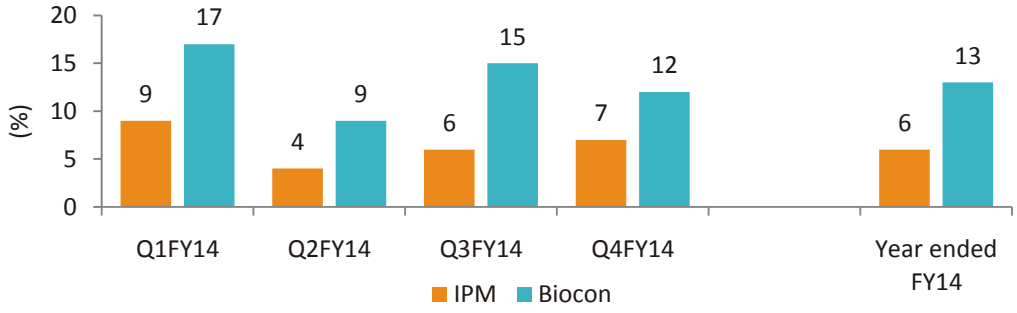
Biocon made a foray into the Indian branded formulations segment in 2004 with Insugen. Over the years, the company has expanded its product bouquet to 80 products - covering seven therapeutic segments. Diabetology, Oncology and Nephrology are the key therapeutic segments, contributing most of the growth. Biocon has been one of the fastest growing companies in the domestic market, with some innovative biologic drugs giving it an extra edge. It is the only branded formulations company to derive more than 50% of its revenues from biologics.

The company has always been focusing on affordable innovation, and has been able to deliver some critical therapies at a discount of as high as 50% to the existing products.

Biocon has delivered many firsts in the Indian branded market, like Streptokinase which is the only 'methionine free' brand in India, and Nufil & Erypro, which were launched as a safety device in the form of pre-filled syringes for the first time in India. The company has been able to create brands like Insugen & Basalog, which are India's largest selling generic insulins and analogs. Its flagship brands like BioMab EGFR (oncology), Evertor(oncology), Picon (auto-immune) and Calpsor C (auto-immune) have a market share of 50%, 46%, 33% and 34%, respectively.

On the back of its sustained focus on diabetology and affordable innovation, Biocon has become the fastest growing Insulin company in India; it boasts of a growth rate of 41% compared to 19% for Sanofi and 20% for Novo Nordisk. Even though last year the company faced some industry-related problems, it was still able to deliver a growth rate higher than the Industry.

Chart 9: Biocon branded formulations growth vs. IPM FY14



Source: Company, Edel Invest Research.

Of late, Biocon has started to focus on consolidating its therapeutic segments on the basis of related therapeutic class. This would help reduce the fieldforce strength from the present ~1400 medical representatives, improve productivity and cut costs.

The company is expected to get back to its earlier high growth trajectory going forward on the back of stability in the domestic pharma market, launch of new products like disposable pens, low cost re-usable pens among others and the growing incidence of diabetes & cancer in India. We thus factor in a CAGR of 25% over FY14-16E in the domestic branded business.

Moving into value added products

Small molecules is currently the largest segment for Biocon, accounting for ~50% of the company's revenues. It comprises mainly API's for statins and immunosuppressants, besides certain specialty API's such as Fidaxomicn and Orlistat.

Reduced focus on statins

Statins had been a key growth driver for Biocon, as it benefited largely with the patent expiry of fermentation-based statins such as Lovastatin, simvastatin and Pravastatin. However, with the patent expiry of Atorvastatin, which is a chemically synthesized statin, Biocon sales growth from this segment has reduced substantially. Therefore, the company has been gradually reducing its focus on this segment. We haven't factored in any growth from this segment going forward.

Immunosuppressant and specialty API's to drive near term growth

Immunosuppressants have been like an annuity business for Biocon, as it is a niche therapy area involving a complex manufacturing process and requiring dedicated facilities, thus limiting competition. With a portfolio of seven products, including Mycophenolate Mofetil, Sirolimus and Tacrolimus, the company has supply arrangements with manufacturers in the key markets of US and EU, enabling them to grow at a steady pace and gain a good market share. Going forward, we see increased traction coming in from immunosuppressants especially Sirolimus and Everolimus, as Biocon's clients gain approvals in the regulated markets for these products.

Forward integration by leveraging current API portfolio to unlock further value

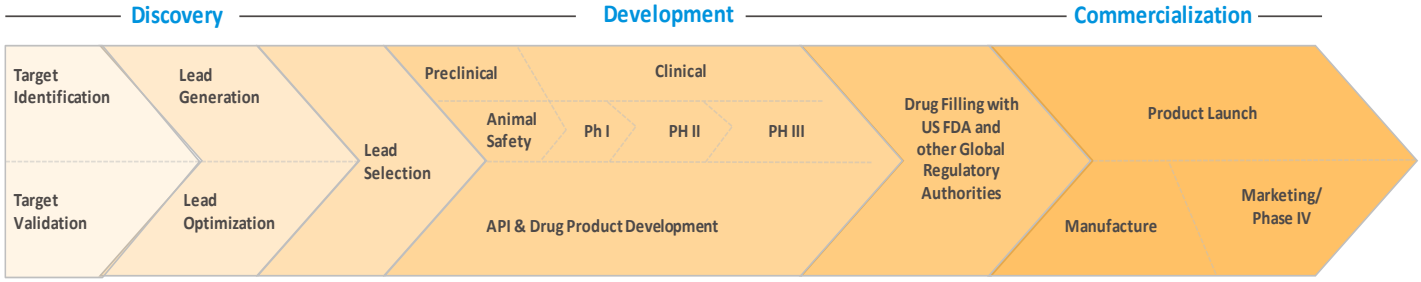
Biocon is moving up the value chain and has identified a portfolio of 15-20 products, ANDA filing for which are expected to begin in FY15. The company has indicated that the focus would be on vertically integrated products that would complement its core therapeutic strength of Oncology, Diabetology, Cardiology, Dermatology and auto-immune diseases.

With filings expected to begin only in FY15, revenue flows are not expected until FY17-18 due to a 2-3 year USFDA approval timelines. However, this will be a key driver for long-term growth of this segment.

Research services a high value franchise

Biocon offers end-to-end research services through its subsidiaries Syngene and Clinigene to its strong base of ~150 clients spread across various lifescience segments. The company has made a conscious effort to evolve this business from a "fee for service" based model to providing integrated and value-added services, leading to improvement in its margins.

Integrated Discovery & Development Platforms – Syngene & Clinigene



Source: Company, Edel Invest Research.

Biocon caters to 16 of the top 20 pharmaceutical companies. The company has three multi-year contracts, with dedicated R&D facilities and scientists exclusively assigned to them, giving us comfort on a steady revenue flow going forward.

- **Bristol Myers Squibb** has been in collaboration with Syngene since 2007. It has a dedicated research facility at Biocon Bristol-Myers Squibb Research Center (BBRC) in Bangalore. Till date, they have identified six drug candidates for further study. With a team of over 400 scientists working exclusively on this partnership, BMS is one of the biggest clients for Syngene. In June 2014, this contract was further extended for 5 years, indicating Biocon's strength in custom research services.

- **Abbott** set up a dedicated Nutrition R&D Centre in 2012. It is a 13000 sq ft facility with over 50 research scientists working on the development of nutrition products for maternal & child nutrition and diabetes care for the Indian consumers.

- In February 2014, Baxter **International** entered into a partnership to set up The Baxter Global Research Centre (BGRC). The centre will focus on R&D activities centered on product and analytical development, besides pre-clinical evaluation in parenteral nutrition and renal therapy, with a team of over 100 Syngene scientists.

In addition, Syngene currently has eight molecules under late stage development, five of which are under Phase III, which can potentially lead to supply contracts from the innovator on commercialization. Syngene has enough capacity to manufacture initial batches, but would require capex in order to meet the future requirements. No such plans have been firmed up as yet.

The strength and quality of Biocon's research capabilities were validated when GE Capital invested INR 125 cr for a 7.69% stake in Syngene, valuing the company at ~INR 1625 cr. The company has guided for a listing of Syngene by the end of FY15, though we are yet to get clarity on how these funds would be deployed.

We believe research services would continue to remain a key growth driver for the company, with eight products in late stage trials. Also, with three important long-term contracts, the business provides enough visibility to sustain its historical growth rate of 20% plus. We thus expect research services business to grow at a CAGR of 20.9% over FY14-16E.

Novel pipeline provides for out-licensing option

Biocon is working on an exciting pipeline of ~5 novel molecules, which are currently under various stage of development. The company has already launched Itolizumab in India, while its ambitious product "oral insulin" is in an advanced stage of development. We expect this segment to surprise in the long run in case Biocon is able to strike an out-licensing deal for any of these products.

IN-105

IN-105 (Oral Insulin) is the one of the most talked about projects for Biocon. The company started the project with a tie-up with Nobex, North Carolina, in 2004. Later, since Nobex went bankrupt, Biocon bought out the IP for oral insulin from them.

The drug progressed well till the phase III trials in India, but failed to clear the primary endpoint, where the change in Hb1Ac (Hemoglobin A1c test) was not statistically significant due to higher than anticipated placebo effect. Hb1Ac is an important blood test used to determine how well your diabetes is being controlled. However, the drug passed all the secondary endpoints, which indicated that it works in terms of reduction of glucose levels. This then led Biocon to believe that the failure was not on account of a faulty drug design but probably on account of some other external factors (like inappropriate trial subjects).

The company found a partner in BMS (Bristol Myers Squibb), which entered into an option agreement with Biocon, where BMS would provide financial and development assistance to establish efficacy through a number of Phase I & II studies. On completion of the studies, BMS would have an exclusive option to develop and commercialize the asset worldwide (excluding India). Biocon will receive licensing fee in addition to potential regulatory and commercialization milestones if BMS exercises its option. The company expects the read-outs for the first set studies in the US to be available by the end of FY15.

Table 7: Competitive Scenario

Name	Company	Stage of Developement	Remarks
ORMD-0801	Oramed	Phase II a completed	US FDA- Completed Phase II(a) in Nov 2013 for type 2 diabetes mellitus patients, expected to initiate Phase II(b) trials by Q4 FY14. Phase 2(a) for Type 1 diabetes mellitus patients has been initiated in March 2014. Has also completed Phase 1 and 2 trials in Isreal and South Africa for T1 & T2 patients.
Capsulin	Diabetology	Phase II a completed	Diabetology signed a license agreement with USV to develop and commercialize oral insulin for the Indian Market.
OI338GT/NN1953	NovoNordisk/Merrion	Phase 1 completed	Oral basal insulin analogue intended as a tablet treatment. Phase II (a) to commence in H1 2015
Oshadi ICP	Oshadi Pharmaceutials	Phase 1 completed	Phase I trials competed in Isreal (for T1).Currently recruiting for Phase 2.
TBL1002OI	Transgene Biotek	Pre-clinical	Pre clinical results announed in 2012
Nodlin	Nod pharmaeuticals	Phase I	Currently undegoing Phase I in China

Source: Edel Invest Research.

We would like to highlight that BMS's entry into Biocon's oral insulin program is a big positive. But the company seems to be lagging in the race to launch the first oral insulin in the world on account of the failure of its phase III studies. It may yet be the first to launch oral insulin considering the uncertain nature of the novel pipeline results.

Alzumab (Itolizumab)

It is the second novel biologic developed by Biocon after Nimotuzumab (Biomab EGFR). The drug was launched in India for the treatment of Psoriasis. According to Biocon, nearly 2-3% of the world population suffers from psoriasis.

Biocon partnered with The Center of Molecular Immunology (CIM), Havana in 2004 for the development of Itolizumab.

Itolizumab is a MAB that selectively targets CD6, an antigen found to play a significant role in T-cell stimulation, triggering an autoimmune response. This is the first anti-CD6 monoclonal antibody in the world to be commercialised. Currently, the area of T-cell co-stimulation is a hotbed of clinical research activity worldwide with applications ranging from melanoma, multiple sclerosis (MS) and rheumatoid arthritis (RA).

Biocon is currently working on other indications for the product like rheumatoid arthritis and multiple sclerosis. The company has already completed a Phase II trial in rheumatoid arthritis. It is currently under active discussion to outlicense this drug to a global player, which could help the company to monetize this asset effectively.

Valuation

Biocon Ltd. is the largest biologics company in India, with major focus on insulins and MAbs. Approximately 65% of its domestic branded formulations business comes from Diabetelogy, Oncology & Nephrology. With the ever expanding cases of diabeties and cancer globally, the company has huge potential to grow its business on a sustainable basis over a long period of time.

The biosimilar space is currently a virgin space. It is estimated that ~USD 72 bn of biologic drugs are scheduled to go off-patent by 2020, which opens up a big opportunity for biosimilar producers like Biocon. The company's tie-up with Mylan is a step in the right direction and would help them to tap this opportunity effectively. With biosimilars expected to invite few competitors it would result in a steady cash flow for Biocon at a high margin.

Biocon had reported earnings growth of 13.1% over FY07-14 in its core business, with steady margins at ~25%. Going forward, we expect the company to grow at a CAGR of 14.3% over FY14-16E due to the continued thrust on the research services, domestic market and improved product mix with reduction in the Small Molecules segment. The expected commissioning of Malaysian facility by the end of FY15 and regulatory approvals from emerging markets in the next 9-12 months post commissioning and developed markets by FY17E could open up significant opportunities in biosimilar insulins.

Biocon's stock is currently trading at valuations of 16.2x its FY16E core earnings. We value the company at it historical average of 20x one-year forward FY16E earnings of INR 29.5/share on account of expected monetization of the biosimilar opportunity, steady cash flows and respectable growth in the domestic market. . We would further like to highlight that major upside in earnings is expected to kick in once the company gets regulatory clearances for the Malaysian facility by FY17E. We initiate coverage on the stock with a "BUY" rating and a target price of INR 590/share.

Chart 10: 1 Yr. Forward PE

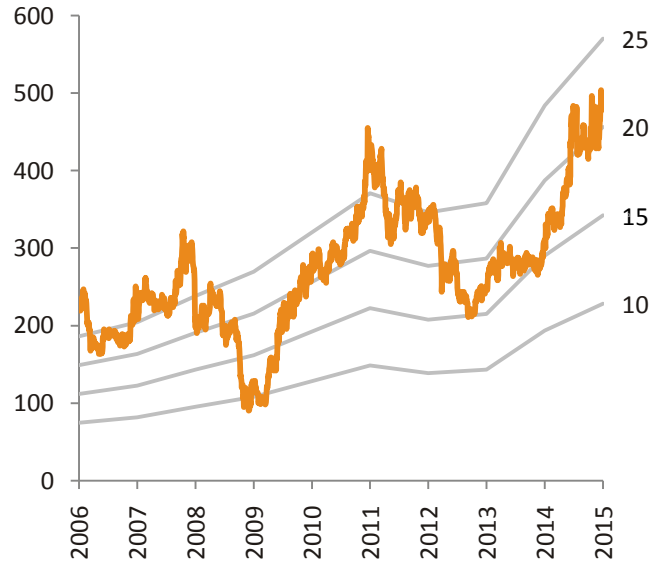
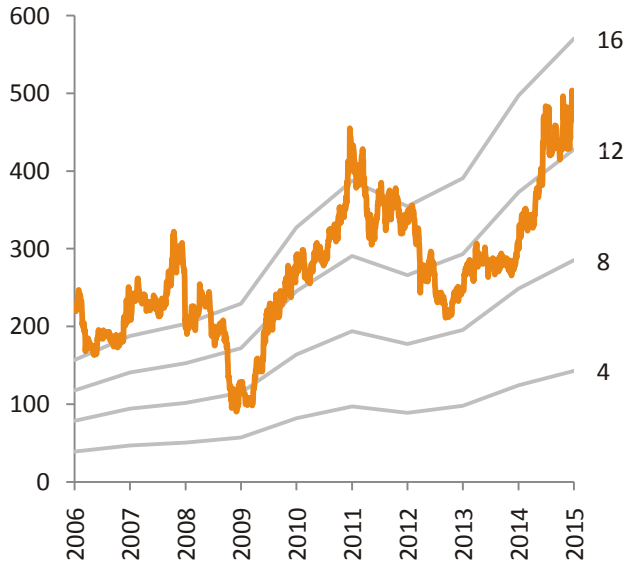


Chart 11: 1 Yr. Forward EV/EBITDA



Source: Edel Invest Research.

Investment Risk

Delay in commissioning/regulatory clearance for Malaysian facility

Much of Biocon's future growth is expected to be driven by the commericalization of the the Malaysian facility and regulatory approvals for the same, as currently in the insulin business it is facing capacity constraints. So, any delay in getting the facility on-stream would impact future growth estimates.

Failure of clinical trials

Like in novel products, the biosimilars also need to go through clinical studies, and any failure on that front would lead to change in estimates.

Increased competition

Insulins and MAbs that are currently under development as per the Mylan contract are also being developed by many other players. Considering that biosimilars products are currently not interchangeable, it is in the best interest of the players to be one of the first to tap the market.

Currency risk

Approximately 67% of revenues for the company are from the export markets, and this contribution is expected to rise further. Any adverse movements in currency could impact our earnings estimates.

Regulatory risks/delays

Given the various changes in the domestic pharma industry price regulations, any restriction on prices for Biocon's products would lead to a change in our estimates.

Immunosuppressants/Insulins are assumed to be biocon's driver for growth in its small molecule business driven by regulatory approvals of its products, any delay in approval would impact our estimates.

Company Overview

Established in 1978 by Kiran Mazumdar Shaw, Biocon Ltd. started out as a manufacturer of industrial enzymes using fermentation based technology. In 1995, the company made a foray into biopharmaceuticals by leveraging its fermentation capabilities to produce statins and immunosuppresants. Today, Biocon is a fully integrated biopharmaceutical company with in-house research services through its two fully-owned subsidiaries, Syngene and Clinigene.

The company operates through five business verticals, covering everything from small molecules API's and biosimilars to novel biologics. Biocon is a leader in the insulins space, where it is the fourth largest insulin manufacturer in the world and contributes ~10% to its total sales. In the emerging markets, Biocon commands ~12% market share (in select EM's) in the insulin segment, led by recombinant human insulin. Small molecules account for 50% of the company's revenues and comprise API's for statins, immunosuppressant as well as specialty API's. The company is also present in the domestic branded formulations market, where it is the largest domestic branded biologics company. The future growth driver would be its biosimilars division, which includes the portfolio of insulins that the company is currently exporting to emerging markets and also future revenues from exports of MAbs & insulins as part of the tie-up with Mylan.

The company has always focused on providing affordable innovation. It has launched various novel molecules over the years at competitive prices, including Canmab, the world's most affordable trastuzumab for treatment of breast cancer and Alzumab, the world's first anti CD6 Mab commercialized for psoriasis.

Biocon provides end-to-end research services through its subsidiaries Syngene and Clinigene. The company has a distinction of working with 16 of the top 20 global pharmaceutical companies as their clients.

Biocon operates through two manufacturing sites in Bangalore which have approvals from various regulatory authorities, including USFDA and EDQM. Additionally, the company is in the process of setting up an insulin manufacturing facility in Malaysia, which is expected to be Asia's largest integrated insulins plant.

Business Model

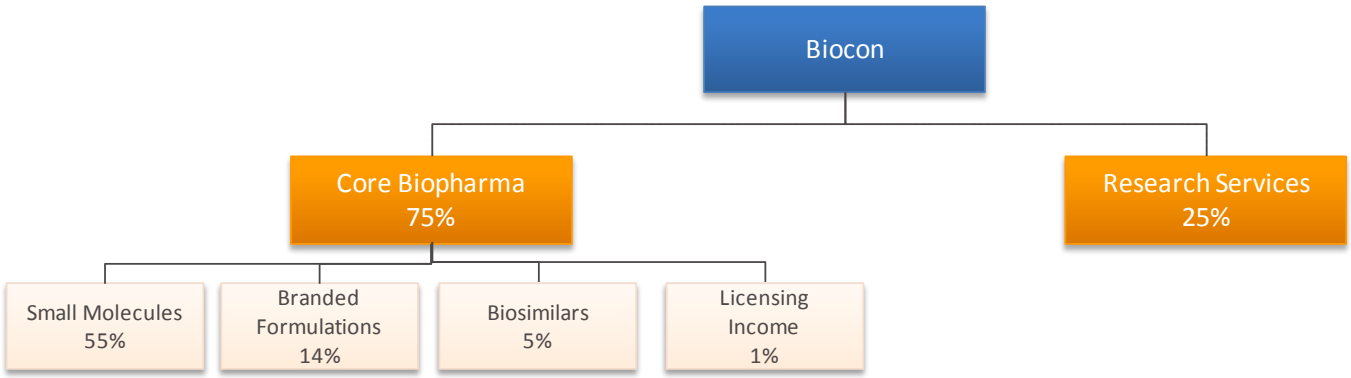


Table 8: Management Profile

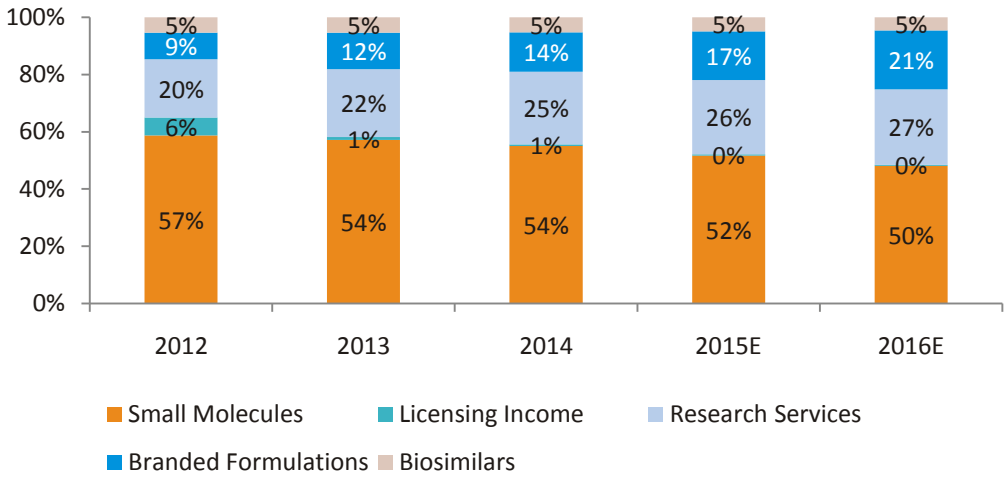
Name	Designation	Description
Mrs Kiran Mazumdar Shaw	*Chairperson & Managing Director*	First generation entrepreneur with more than 38 years' experience in biotechnology and industrial enzymes. She is a Master Brewer from Ballarat University, Australia and has been awarded the Padma Bhushan for her pioneering efforts in Biotechnology in 2005.
Dr. Arun Chandavarkar	*Chief Executive Officer and Joint Managing Director*	Dr Chandavarkar is a core member of Biocon's leadership team as CEO and Joint MD. He has played a pivotal role in the evolution of Biocon over the last 24 years. His qualifications include B.Tech from IIT Bombay and PhD from MIT, Cambridge, USA.
Mr Murali Krishnan	*President, Group Finance*	He completed his Bachelor's degree in Commerce from Bangalore University with a top rank in 1975. He began his career with Biocon in 1981 and has over 22 years of experience in planning, finance, cost accounting, MIS and tax related issues.

Financial Analysis

Growth to be driven by Research Services

Biocon revenues have grown at a CAGR of 16.5% over FY07-FY14 mainly on account of steady growth in the Research Services buiness (up at a CAGR of 23.5% over the same period). We expect that going forward the Research Services business would grow at CAGR of 20.9% over FY14-16E. The growth in the Biosimilars business is expected to be more back-ended, as it is majorly contingent upon getting the Malaysian facility on stream and securing the regulatory clearances, which we believe would not happen before FY17E.

Chart 13: Revenue Mix

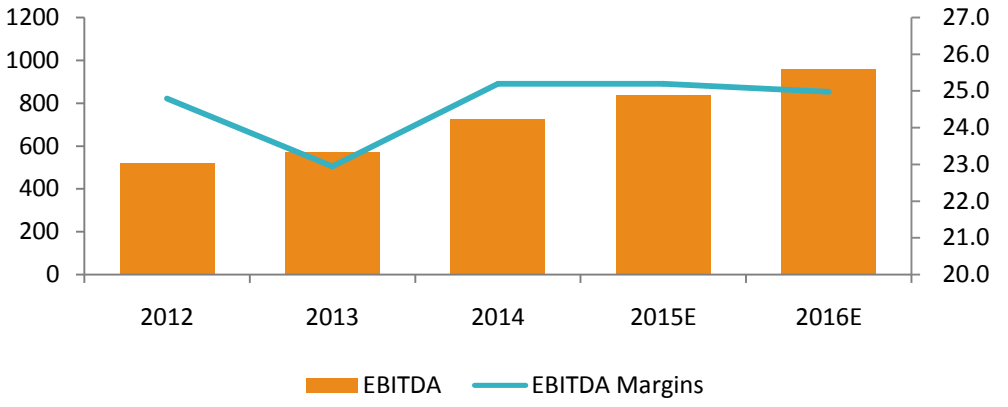


Source: Edel Invest Research.

Malaysian facility to put pressure on margins in short term

Biocon EBITDA margins post the divestment of Axicorp have remained stable at ~25%, but we believe that in FY15 it would be sustained at the same level. Going forward, with the Malaysian facility coming on-stream there would be an increase in overheads as the company would not be generating any revenues until all the regulatory approvals are in place. Though over a longer run, the margins are expected to move up considering the fact that the contribution of high-margin biosimilars is expected to rise.

Chart 14: EBITDA & EBITDA Margin



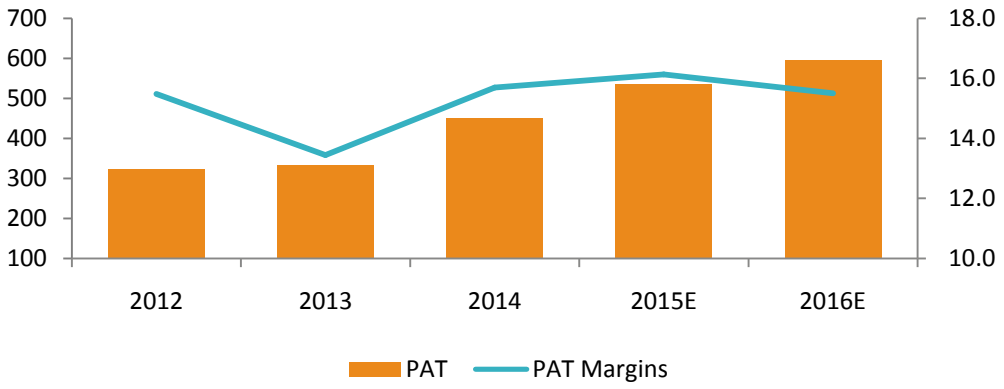
Source: Company, Edel Invest Research.

Financial Analysis

Expect steady growth in profit

Biocon grew its profits by 13% over FY07-FY14, lower than the revenue growth, mainly on the back of higher investments made on R&D. With R&D expenses expected to remain in the range of 8-10% as a percentage of sales we believe that growth in the bottomline would also be steady for the initial 2-3 years before expanding substantially post FY17E.

Chart 15: Adj. PAT & PAT margins



Source: Company, Edel Invest Research.

Continue to remain FCF positive

Over the last five years, Biocon has invested ~INR 2200 cr in creating capacities for research besides investments in the Malaysian facility. The company has been able to fund much of this expediture from its internal accruals, as it generated operating cash flow of ~INR 2850 cr over the same period. Going forward, we believe that Biocon would generate enough cash flows to fund its capex requirement since much of its R&D is funded by the Mylan deal and retained income from the Pfizer deal.

Chart 16: Operating cash flows & Capex

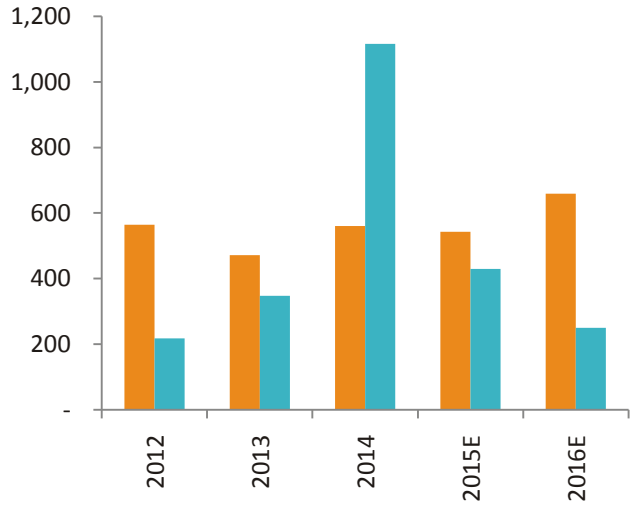
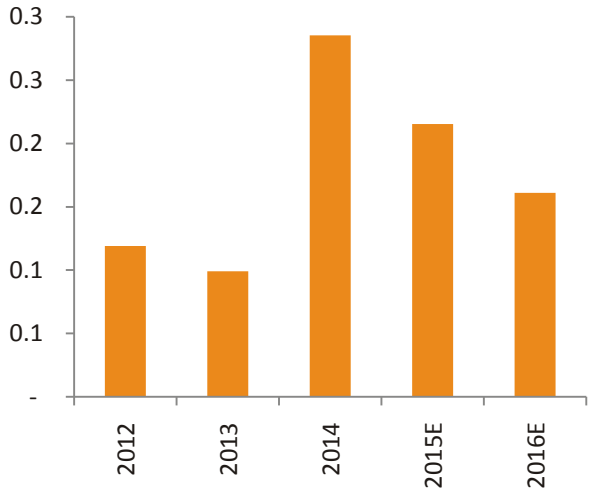


Chart 17: Debt to Equity

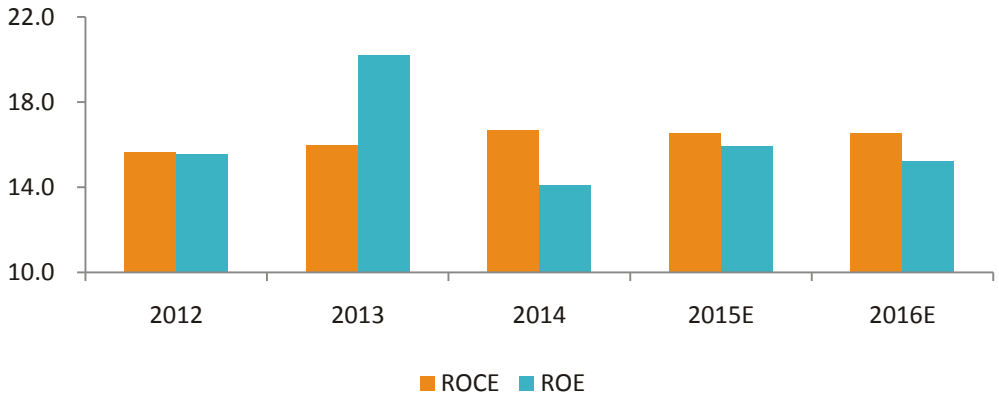


Source: Company, Edel Invest Research.

Return ratios expected to sustain

We expect Biocon's RoCE to remain at the current range of 16-17%. The monetization of the biosimilar opportunities and utilization of its investment in Malaysia would help the company to improve its return ratios to much above 20%.

Chart 18: RoCE & RoE



Source: Company, Edel Invest Research.

Financial Analysis

Income Statement (INR Cr)

Year to March	FY12	FY13	FY14	FY15E	FY16E
Net revenue	2,087	2,485	2,877	3,304	3,816
Materials costs	852	1,045	1,186	1,348	1,542
Gross profit	1,235	1,441	1,691	1,955	2,274
Employee costs	279	353	421	462	534
R & D Expenses	146	171	131	248	286
SG & A Expenses	293	347	414	413	501
EBITDA	517	570	725	832	953
Depreciation & Amortization	174	179	204	208	263
EBIT	343	391	521	625	690
Other income	47	53	56	61	69
EBIT incl. other income	389	443	577	686	759
Interest expenses	12	8	2	24	21
Exceptional Items	(15)	27	38	-	-
Profit before tax	377	435	576	661	738
Provision for tax	54	98	107	132	148
Net profit	323	338	469	529	590
Adj. Net Profit	323	334	452	529	590
Basic shares outstanding (crs)	20.00	20.00	20.00	20.00	20.00
EPS (Rs.)	16.2	16.9	23.4	26.5	29.5
Dividend per share (Rs.)	5.8	8.8	5.9	5.9	5.9
Dividend payout (%)	36.0%	51.9%	25.0%	22.1%	19.8%

Common Size

Year to March	FY12	FY13	FY14	FY15E	FY16E
Materials costs	40.8%	42.0%	41.2%	40.8%	40.4%
Employee expenses	13.4%	14.2%	14.6%	14.0%	14.0%
Manufacturing & Other Expenses	14.0%	13.9%	14.4%	12.5%	13.1%
Research & Development Expenses	7.0%	6.9%	4.6%	7.5%	7.5%
Depreciation	8.4%	7.2%	7.1%	6.3%	6.9%
EBITDA margins	24.8%	22.9%	25.2%	25.2%	25.0%
EBIT margins	16.4%	15.7%	18.1%	18.9%	18.1%
Net profit margins	15.5%	13.6%	16.3%	16.0%	15.5%

Growth Ratios

Year to March	FY12	FY13	FY14	FY15E	FY16E
Revenues	-24.7%	19.1%	15.8%	14.8%	15.5%
EBITDA	-8.5%	10.2%	27.2%	14.8%	14.5%
PBT	-15.6%	15.4%	32.2%	14.9%	11.6%
Net profit	-13.9%	4.6%	38.7%	12.9%	11.6%

Financial Analysis

Balance Sheet

As on 31st March	FY12	FY13	FY14	FY15E	FY16E
Equity capital	100	100	100	100	100
Reserves & surplus	2,177	2,660	3,009	3,521	4,094
Borrowings	271	267	864	764	664
Deferred Tax Liabilities (Net)	(8)	41	45	45	45
Sources of funds	**2,540**	**3,068**	**4,018**	**4,430**	**4,903**
Net Fixed Assets	1,660	1,823	2,731	2,953	2,940
Investments	556	587	765	765	965
Inventories	378	398	377	443	512
Sundry debtors	492	510	600	634	732
Cash & Bank Balances	524	673	804	840	977
Loans and advances	328	426	474	516	596
Total current assets	1,722	2,007	2,255	2,433	2,817
Sundry creditors and others	1,187	1,097	1,549	1,537	1,636
Provisions	212	251	184	184	184
Total current liabilities & provisions	1,398	1,348	1,733	1,721	1,819
Net current assets	324	659	522	712	998
Uses of funds	**2,540**	**3,068**	**4,018**	**4,430**	**4,903**
Book value per share (Rs.)	114	135	151	177	206

Free cash flow

Year to March	FY12	FY13	FY14	FY15E	FY16E
Net profit	338	311	431	529	590
Add : Depreciation	174	179	204	208	263
Others	(111)	168	(342)	(37)	(48)
Gross cash flow	402	658	292	700	805
Less: Changes in WC	162	(187)	269	(154)	(149)
Operating cash flow	564	471	561	546	657
Less: Capex	218	348	1,116	430	250
Free cash flow	347	123	(555)	116	407

CasH Flow Statement

Year to March	FY12	FY13	FY14	FY15E	FY16E
Cash flow from operations	564	471	561	546	657
Cash Flow from investing activities	(359)	(376)	(938)	(369)	(381)
Cash Flow from financing activities	(265)	(122)	53	509	(141)
Capex	(218)	(348)	(1,116)	(430)	(250)
Dividends	(16)	(26)	(17)	(17)	(17)

Financial Analysis

Profitability & Efficiency Ratios

Year to March	FY12	FY13	FY14	FY15E	FY16E
ROAE (%)	15.6%	20.2%	14.1%	15.7%	15.1%
ROACE (%)	15.6%	16.0%	16.7%	16.4%	16.4%
ROIC (%)	15.6%	15.8%	16.3%	16.2%	16.3%
Inventory day	69	57	49	49	49
Debtors days	88	74	70	70	70
Payable days	68	69	70	70	70
Cash conversion cycle (days)	89	62	49	49	49
Current ratio	1.2	1.5	1.3	1.4	1.5
Debt/Equity	0.1	0.1	0.3	0.2	0.2

Turnover Ratios

Year to March	FY12	FY13	FY14	FY15E	FY16E
Total asset turnover	0.6	0.6	0.6	0.6	0.6
Fixed asset turnover	1.3	1.4	1.3	1.2	1.3
Equity turnover	1.0	1.0	1.0	1.0	1.0

Du Pont Analysis

Year to March	FY12	FY13	FY14	FY15E	FY16E
NP margin (%)	16.2%	20.5%	14.4%	16.0%	15.5%
Total assets turnover	0.6	0.6	0.6	0.6	0.6
Leverage multiplier	1.7	1.7	1.7	1.8	1.6
ROAE (%)	15.6%	20.2%	14.1%	15.7%	15.1%

Valuation Parameters

Year to March	FY12	FY13	FY14	FY15E	FY16E
Diluted EPS (Rs.)	16.2	16.9	23.4	26.5	29.5
Y-o-Y growth (%)	-13.9%	4.6%	38.7%	12.9%	11.6%
Diluted PE (x)	29.5	28.6	21.1	18.0	16.2
Price/BV (x)	4.2	3.5	3.2	2.7	2.3
EV/Sales (x)	5.8	4.7	4.4	3.8	3.3
EV/EBITDA (x)	18.0	16.0	13.2	11.4	9.7
Dividend yield (%)	1.2%	1.8%	1.2%	1.2%	1.2%

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