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Industry Report
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Biosimilars: Tug of war between price and volume

Korean companies lead the ranks of global biosimilar market

The global biosimilar market is thriving, with antibody biosimilars growing to 40% of the European market in just two years and the US market finally opening up in December 2016. While there have been some initial bumps in the US, we expect biosimilars to slowly gain ground from 2018 onwards. A number of new biosimilars, including those to the global top-selling drug Humira, are awaiting release. What is even more encouraging is that Korean companies are leading the ranks. Now, the key questions for investors are as follows: 1) How much market share can be gained in Europe?; 2) When will market share begin to pick up in the US?; and 3) How far will biosimilar prices fall and will this lead to volume growth?

How long will upturn in Europe last, and when will things in US improve?

In Europe, the sharp market share gains of biosimilars are showing no sign of losing steam. Given that 1) first-generation G-CSF and EPO biosimilars now account for 88% and 62% of their respective markets in the region, and 2) generics comprise 60% of the chemical drug market in major countries, we believe biosimilars will have little problem gaining a 60% market share, especially with many European governments now introducing policies to spur biosimilar prescriptions. In the US, biosimilars are facing tough challenges from original pharmaceutical companies. However, insurance coverage has recently been expanding, and with a string of exclusive deals between original drug companies and private insurers nearing expiration—and biosimilars gaining increasing price competitiveness—we believe biosimilars will slowly begin to seize an increasing slice of the US market in 2018.

How far will prices fall, and how much will volume grow?

Among biosimilars, competition is limited. Because of the substantial costs associated with clinical trials and manufacturing, there are only a handful of biosimilar developers in the market. We believe the biosimilars market will be highly concentrated among a few players, such as Celltrion, Samsung Bioepis, and Amgen. Furthermore, the speed at which new biosimilars are released is crucial to success, putting new entrants at a significant disadvantage. As such, we do not see a high possibility of steep price declines (recall that price discounts of first-generation biosimilars were roughly 35-40%). Rather, evidence suggests lower pricing often leads to increased uptake and overall market growth. Indeed, less than two years into their release, biosimilars of TNF-α inhibitors have seen uptake increase by 19%.

Recommend Buy on Celltrion Healthcare, Celltrion, and Samsung Biologics; our top pick is Celltrion Healthcare

For Celltrion Healthcare, we expect rapid market penetration by Remsima and Truxima in Europe, and market share gains by Inflectra in the US. We think controversies surrounding excessive inventory assets and their expiration dates are no longer of consequence, given that annual revenue has now grown to W1tr. We believe Celltrion Healthcare has the lowest risk among the top three domestic biosimilar firms, while having less valuation pressure.

For Celltrion, we see profit margins improving markedly, driven by higher utilization (due to rising sales) and better process efficiency. Another positive is the stock's potential relocation to the KOSPI and inclusion in the KOSPI 200.

We think Samsung Biologics offers an attractive opportunity from a medium- to long-term perspective. While the absolute size of profits is still small, we see high earnings visibility, given growing demand for bio-CMO. Once the construction of the third plant is complete, total capacity will expand to 360,000 liters, making the company the largest player in the bio-CMO sector. Also compelling is the company's subsidiary, Samsung Bioepis, which remains ahead in the biosimilar development race.

I. Investment recommendation and strategy

Korean companies leading the ranks of biosimilar market

We recommend that investors expand their positions in the biosimilar industry. The global biosimilar market is thriving, with antibody biosimilars growing to 40% of the European market in just two years and the US market finally opening up in December 2016. While there have been some initial bumps in the US, we expect biosimilars to slowly gain ground from 2018 onwards.

The biosimilar market is still in its infancy. Among antibody drugs, only Remicade, Enbrel, and Rituxan have biosimilars. Several new biosimilars - including those to Humira, Herceptin, and Avastin - are awaiting release.

What's even more encouraging is that Korean companies are leading the ranks. Global top-tier biosimilar makers include Celltrion, Samsung Bioepis, Amgen, Pfizer, and Sandoz, of which Celltrion and Samsung Bioepis are leading the market. Celltrion has become the first company to release biosimilars to Remicade and Rituxan. Samsung Bioepis has launched an Enbrel biosimilar for the first time in the world, and is likely to roll out the first Herceptin biosimilar. Of note, Samsung Biologics will likely emerge as the leader in the global bio contract manufacturing organization (CMO) market when its third factory comes online at the end of 2018.

As the global biosimilar market is robust and Korean makers display solid competitiveness, we present Buy on Celltrion Healthcare, Celltrion, and Samsung Biologics. Our top pick is Celltrion Healthcare.

For Celltrion Healthcare (091990 KQ/TP: W71,000/Buy), we expect rapid market penetration by Remsima and Truxima in Europe, and market share gains by Inflectra in the US. We think controversies surrounding excessive inventory assets and their expiration dates are no longer of consequence, given that annual revenue has now grown to W1tr. We believe Celltrion Healthcare has the lowest risk among the top three domestic biosimilar firms, and also has less valuation pressure.

For Celltrion (068270 KQ/TP: W188,000/Buy), we see profit margins improving markedly, driven by higher utilization (due to rising sales) and better process efficiency. Another positive is the stock's potential relocation to the KOSPI and inclusion in the KOSPI 200.

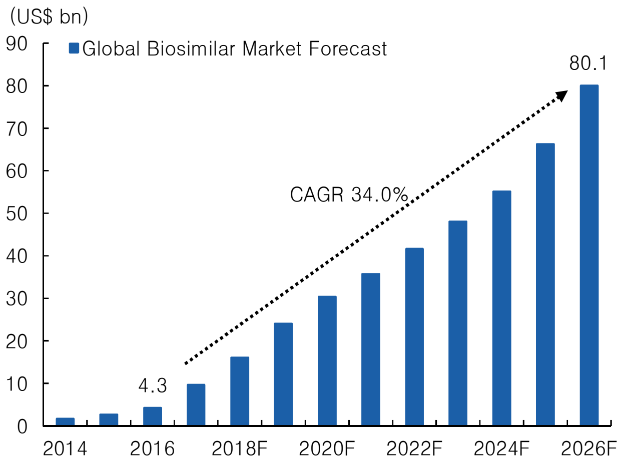
We think Samsung Biologics (207940 KS/TP: W400,000/Buy) offers an attractive opportunity from a medium- to long-term perspective. While the absolute size of profits is still small, due to its second factory's relatively low utilization, we see high earnings visibility, given growing demand for bio-CMO. Once construction of the third plant is complete, total capacity will expand to 360,000 liters, making the company the largest player in the bio-CMO sector. Also compelling is the company's subsidiary, Samsung Bioepis, which remains in the lead in the biosimilar development race.

Figure 1. Global ranking of blockbuster drugs based on 2016 revenue

Ranking	Drug	Company	Revenue(US$bn)	YoY growth (%)
1	Humira	Abbvie	16.1	14.7
2	Harvoni	Gilead Sciences	9.1	-34.5
3	Enbrel	Amgen / Pfizer	8.9	2.0
4	Rituxan	Roche / Biogen	8.6	2.7
5	Remicade	J&J / MSD	7.8	-10.6
6	Revlimid	Celgene	7.0	20.2
7	Avastin	Roche	6.8	1.5
8	Herceptin	Roche	6.8	3.7
9	Lantus	Sanofi	6.1	-10.6
10	Prevenar13	Pfizer	5.7	-8.4

Note: Shaded fields indicate biopharmaceuticals
Source: GEN, Mirae Asset Daewoo Research

Figure 2. Biosimilar market expected to grow at CAGR of 34%



Source: Frost & Sullivan, Mirae Asset Daewoo Research

Table 1. Korean companies ahead of global peers on biosimilar development

Original	Company	Biosimilar	Status	Note
Remicade	Celltrion	Remsima/Inflectra	Approved	Released in Europe and US
	Samsung Bioepis	Flixabi/Renflexis	Approved	Released in Europe and US
	Sandoz	PF-06438179	Phase III completed	Applied for approval in Europe (May 2017); Phase I clinical trial in US
	Pfizer	PF-06438179	Phase III completed	Phase III clinical trial in US
Enbrel	Samsung Bioepis	Brenzys/Benepali	Approved	Released in Europe (Jan. 2016)
	Sandoz	Erelzi	Approved	Approved in Europe (Jun. 2017); approved in US (Aug. 2016)
Rituxan	Celltrion	Truxima	Released	Approved in Europe (Feb. 2017); applied for approval in US (Jun. 2017)
	Sandoz	Rixathon	Released	Approved in Europe (Jun. 2017); applied for approval in US (Sep. 2017)
	Amgen	ABP 798	Phase III	
	Pfizer	PF-05280586	Phase III	Patent dispute with Genentech
Herceptin	Samsung Bioepis	SB3	Applied for approval	Received positive opinion from CHMP in Europe (Sep. 2017)
	Celltrion	Herzuma (CT-P6)	Approved	Applied for approval in Europe (Oct. 2016) and US (Jul. 2017)
	Actavis(Allergan)/Amgen	ABP-980	Approved	Applied for approval in Europe (Mar. 2017) and US (Jul. 2017)
	Biocon/Mylan	Hercules (Myl-1401O)	Phase III	Retracted application for approval in Europe; under review by US FDA
	Pfizer/Hospira	PF-05280014	Phase III	
Lantus	Eli Lilly	Abasaglar/Basaglar	Approved	Released in Europe and US
	Samsung Bioepis/Merck	Lusduna	Approved	Approved in Europe; tentatively approved in US (Jul. 2017)
Humira	Amgen	Amjevita	Approved	Approved in Europe (Mar 2017); approved in US (Sep. 2016)
	Samsung Bioepis	Imraldi	Approved	Approved in Europe (Aug. 2017)
	Boehringer Ingelheim	Cyltezo	Approved	Applied for approval in Europe (Jan. 2017); approved in the US (Aug. 2017)
	Sandoz	GP2017	Approved	Applied for approval in Europe (May 2017); Phase III clinical trial in US
	Pfizer	PF-06410293	Phase III	
Avastin	Amgen/Allergan	ABP 215	Approved	Applied for approval in Europe (Dec. 2016); approved in US (Sep. 2017)
	Boehringer Ingelheim	BI 695502	Phase III completed	
	Pfizer	PF-06439535	Phase III	
	Samsung Bioepis	SB8	Phase III	

Source: Mirae Asset Daewoo Research

Table 2. Investment points and catalysts

Company	Investment points	Catalysts
Celltrion Healthcare	Growth potential of Remsima and Truxima	Growth in US market share
(091990KQ)	Attractive share valuation versus peers	
Celltrion	Profitability improvement on capacity utilization growth and efficient production	Completion of clinical trials for next pipeline drug
(068270KQ)	KOSPI relisting issue	
Samsung Biologics	Likely to emerge as global leader in bio CMO capacity	Disclosure of large order secured by third plant
(207940KS)	Samsung Bioepis' ample pipeline	

Source: Mirae Asset Daewoo Research

Table 3. Ratings and key financials (W, Wbn, %, x)

		Celltrion Healthcare	Celltrion	Samsung Biologics
Rating		Buy	Buy	Buy
TP		71,000	188,000	400,000
CP		54,100	146,900	326,000
Market cap.		7,395	18,015	21,570
Revenue	16	757.7	670.6	294.6
	17F	992.6	938.6	354.6
	18F	1,503.00	1,283.30	551.6
Operating profit	16	178.6	249.7	-30.4
	17F	234.1	449.1	6.2
	18F	384.9	696.1	69.9
EPS	16	1,103	1,456	-3,113.40
	17F	1,820	2,773	-1,664.60
	18F	2,360	4,206	651.5
Revenue growth (YoY)	16	88.3	11.1	222.8
	17F	31	40	20.4
	18F	51.4	36.7	55.5
OP growth (YoY)	16	59.6	-3.6	RR
	17F	31.1	79.8	TTB
	18F	64.5	55	1031.1
EPS growth (YoY)	16	257.5	13.2	TTR
	17F	65.1	90.5	RR
	18F	29.6	51.7	TTB
OP margin	16	23.6	37.2	-10.3
	17F	23.6	47.8	1.7
	18F	25.6	54.2	12.7
ROE	16	21.4	9.5	-5.2
	17F	29.4	15.3	-2.7
	18F	31.2	20.3	1.1
PER	16	N/A	73.8	N/A
	17F	28.2	53	N/A
	18F	21.7	34.9	500.4
PBR	16	0	6.4	2.4
	17F	8	7.5	5.4
	18F	5.9	6.8	5.4

Source: Mirae Asset Daewoo Research

II. Regional analysis: How long will upturn in Europe last and when will things in US improve?

1. By how much will biosimilars expand their market share in Europe?

In Europe, biosimilars have been performing better than initially expected. Biosimilars began to visibly expand their market share in bidding countries following the release of second-generation biosimilars in 2014, and have been rapidly eating into the pharmaceutical market since the early-2015 release in major European countries such as the UK, France, and Germany. In just two years, biosimilars have increased their market share to 40% levels, in terms of volume, in major countries in Europe. Market share gains are showing no sign of losing steam, prompting the question of how far biosimilars will be able to expand their market share in Europe. To find the answer, we reviewed the market share expansion of first-generation biosimilars for EPO, G-CSF, and growth hormone, as well as the market share growth of chemical generic drugs.

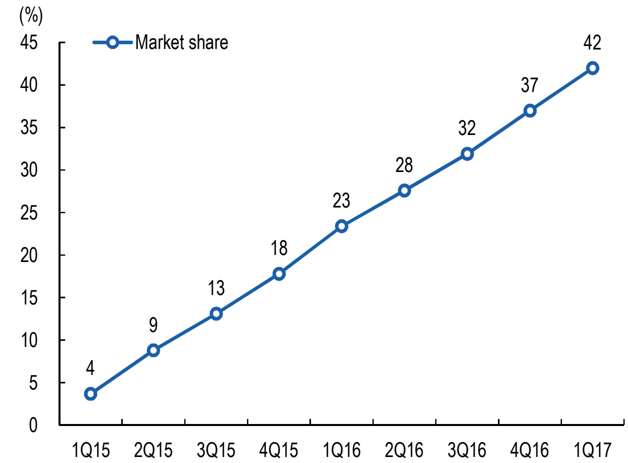
First-generation biosimilars were first introduced in the European market in 2006, starting off with a growth hormone biosimilar and followed by an EPO biosimilar in 2007 and a G-CSF biosimilar in 2008. With 8-10 years having passed since the release of the first biosimilar, the market share of biosimilars in the European market, in terms of volume, now reaches 88% for G-CSF, 62% for EPO, and 39% for growth hormone.

We expect second-generation biosimilars to report market share growth that is similar to first-generation biosimilars for G-CSF or EPO, rather than the growth hormone biosimilar. The first-generation biosimilar for growth hormone recorded relatively lower market share than other biosimilars with better alternatives than the original and biosimilar, such as Norditropin (Novo Nordisk), Saizen (Merck), NutropinAq (Ipsen), and Zomacton (Ferring), readily available in the market.

Among second-generation biosimilars, the biosimilar for anti-TNF-α therapy has been posting rapid market share growth similar to the first-generation G-CSF biosimilar. As seen in Figure 3 and Figure 4, the G-CSF biosimilar recorded a market share of 21% in Europe in its first year and 41% in its second year. The Remicade biosimilar also recorded similar market share levels in its first and second year from release.

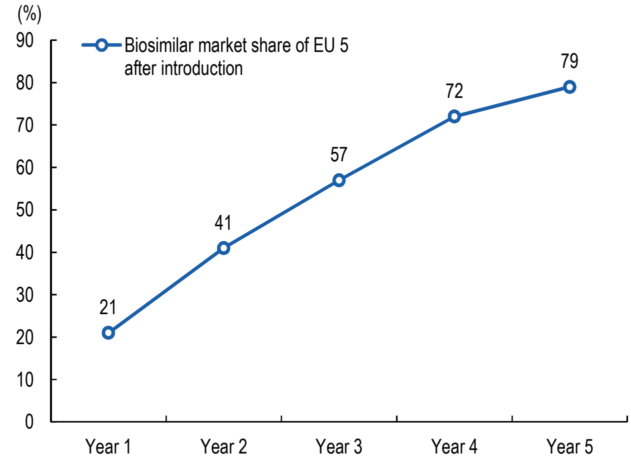
However, we do not expect the TNF-α inhibitor biosimilar to record market share levels near the 88% recorded by the first-generation G-CSF biosimilar. Unlike G-CSF, which is used as a one-time cancer treatment, TNF-α inhibitors are used to treat a chronic condition and doctors are less likely to switch to a new prescription drug during the treatment of the disease.

Figure 3. Second-generation biosimilars swiftly penetrating into the European market



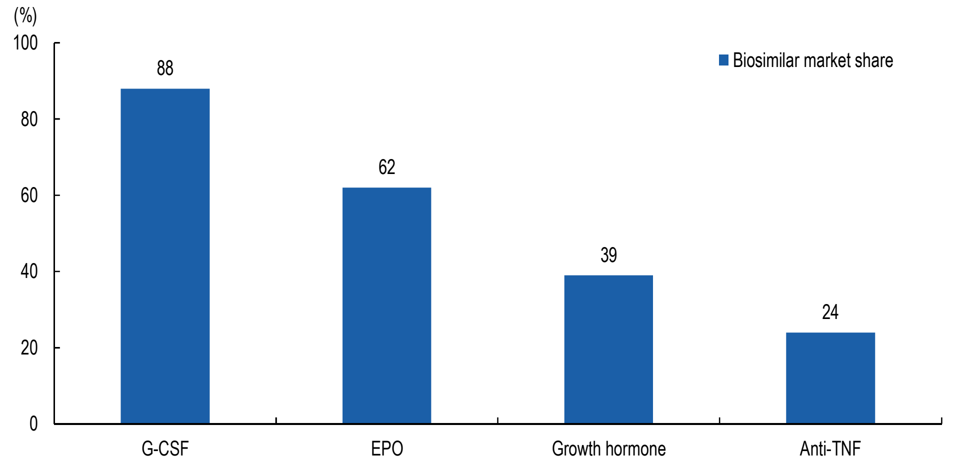
Source: Mirae Asset Daewoo Research

Figure 4. G-CSF biosimilar market share in five major European countries



Source: QuintilesIMS, EvaluatePharma, Mirae Asset Daewoo Research

Figure 5. Biosimilar market share (2016)



Source: QuintilesIMS, EvaluatePharma, Mirae Asset Daewoo Research

We now move on to the review of chemical drugs. According to a 2016 OECD report, generics held a market share of 52%, in terms of volume, in major countries in 2014. In particular, generics recorded notably high market shares in the UK (84%) and Germany (81%).

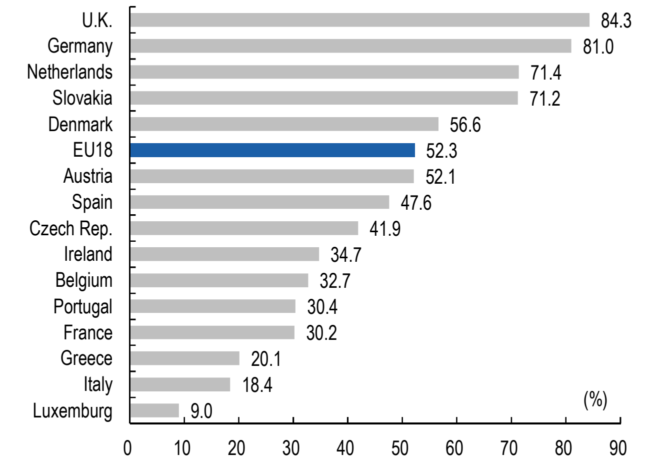
We point out that generics have been posting faster market share growth recently, with the average market share of generics in the UK, Germany, Spain, and France rising from 49.8% in 2010 to 52.1% in 2011, 56.2% in 2012, and 59.9% in 2013, as governments encouraged the prescription of generics to reduce healthcare costs.

Biosimilars are likely to follow a similar path as generics, with European governments expected to implement favorable policies and show preference toward biosimilars, as with chemical generic drugs. The UK, which records the highest market penetration of generics, at 84%, also records the highest penetration of biosimilars, at 74%. On the other hand, France has maintained the most conservative stance toward the adoption of generics (market penetration 30%) and also records low market penetration of biosimilars, at 27%.

Meanwhile, we expect the market penetration rates of biosimilars to exceed that of generics. While generics needed over 10 years to expand their market share to 40% levels, second-generation biosimilars have secured a 40%-level market share in just two years from release. With the price tag of biopharmaceuticals set significantly higher than that of chemical drugs, applying the same discount rates led to larger discounts in amount and likely helped to accelerate the market penetration of biosimilars.

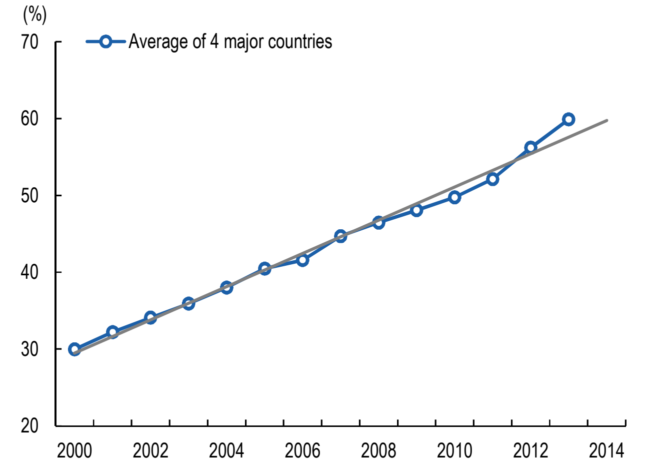
In all, reviewing the market penetration of first-generation biosimilars and chemical generic drugs, we expect second-generation biosimilars to expand their market share, in terms of volume, to 60% levels in the European market.

Figure 6. Chemical generic drug market share (in terms of volume)



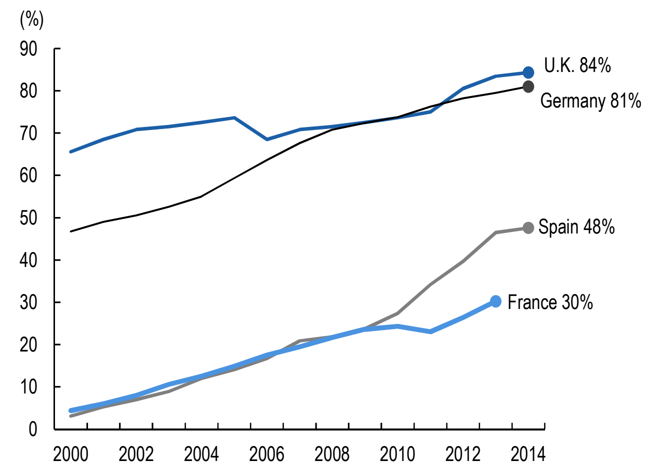
Source: OECD Health Statistics 2016, Mirae Asset Daewoo Research

Figure 7. Average market share of generics in four major countries in Europe (in terms of volume)



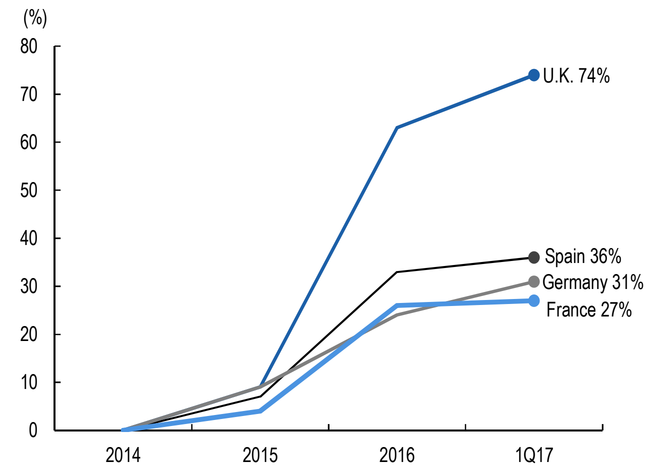
Source: OECD Health Statistics 2016, Mirae Asset Daewoo Research

Figure 8. Chemical drug market share in four major countries in Europe (in terms of volume)



Source: OECD Health Statistics 2016, Mirae Asset Daewoo Research

Figure 9. Biosimilar market share in four major countries in Europe (in terms of volume)



Source: Mirae Asset Daewoo Research

2. Why is it taking longer for biosimilars to penetrate the US market?

The market that seemingly held the most growth potential for biosimilars was the US, which is the largest market for biopharmaceuticals, with consumption reaching 50% of global supply. Following the rapid market penetration of second-generation biosimilars in Europe and the solid performance of first-generation biosimilar Zarxio in the US market, expectations remained high for second-generation biosimilars in the US market. Moreover, the private insurance and PBM-focused market structure was seen as favorable for the effective sales of biosimilars. As such, Johnson & Johnson (J&J), which sells the original drug Remicade, expected to lose 10-15% of its market share after the release of biosimilars.

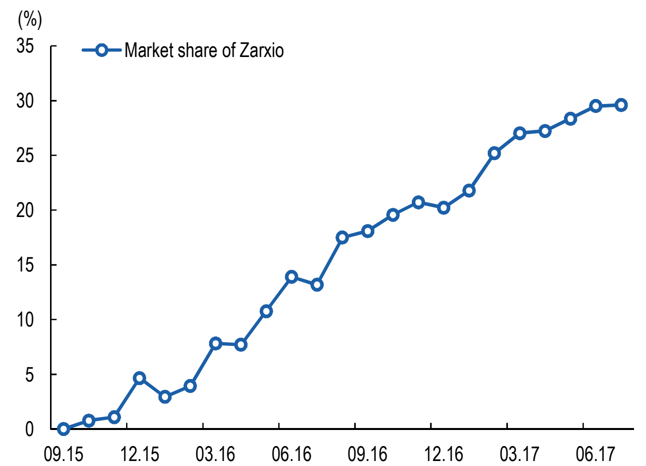
However, contrary to upbeat forecasts, second-generation biosimilars have been struggling in the US market. Pfizer, which sells a Remicade biosimilar in the US, stated at its 2Q17 earnings conference that Inflectra's US market share stood at just 2.3%, as of end-June. Considering the large success of biosimilars in the European market and the strong performance of Zarxio (offered at the same 15% discount rate as Inflectra), what could be the cause of the weaker-than-expected performance of Inflectra?

Original drug makers aggressively defending their market share

One of the largest obstacles for biosimilars in the US market is the aggressive defense tactics employed by original drug makers. Neupogen, the original drug of Zarxio, accounted for just 5.7% of Amgen's total revenue in 2014 (before the release of a biosimilar) at $1.16bn. One-week dosage Neulasta had already replaced most of the demand, with revenue of the newer drug reaching $4.6bn, or 22.7% of the company's total revenue.

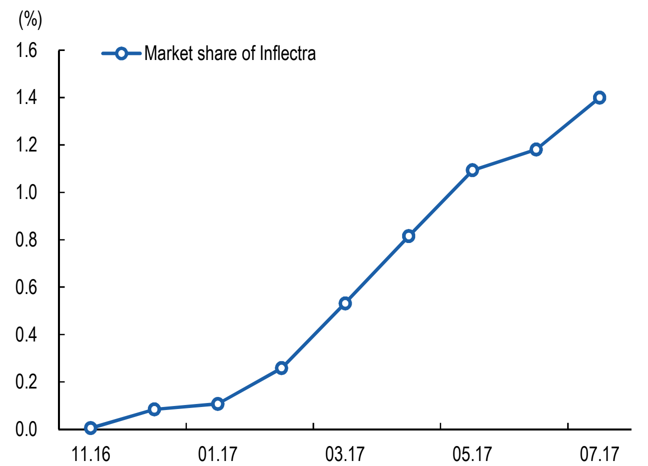
However, before the release of a biosimilar, Remicade was the world's fourth-best-selling drug and J&J's largest pharmaceutical revenue generator, with revenue reaching $6.87bn in 2014. With the US market accounting for $4.84bn in revenue, as of 2016, J&J will not go down without a fight.

Figure 10. First-generation biosimilars posted sharp growth in the US market



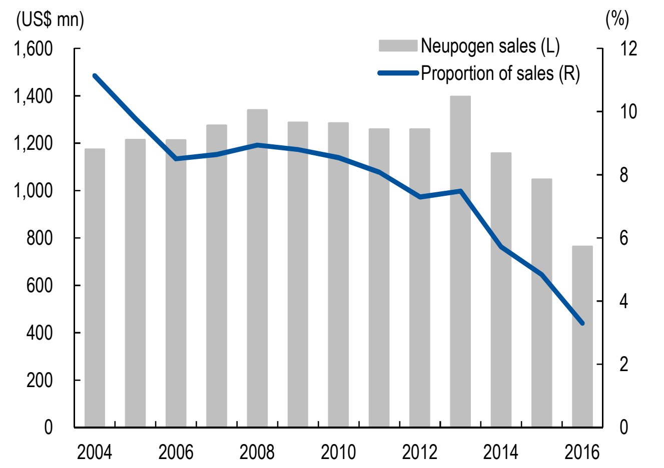
Source: Bloomberg, Mirae Asset Daewoo Research

Figure 11. Second-generation biosimilars struggling in the US market



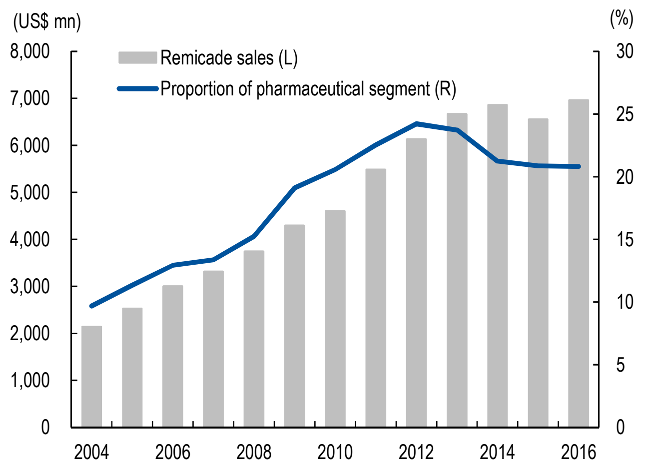
Source: Bloomberg, Mirae Asset Daewoo Research

Figure 12. Neupogen revenue and weight in Amgen's total revenue



Source: Amgen, Mirae Asset Daewoo Research

Figure 13. Remicade revenue and weight in J&J's pharma revenue



Source: J&J, Mirae Asset Daewoo Research

Accordingly, J&J's strategies to defend its market share in the US can be summarized as follows.

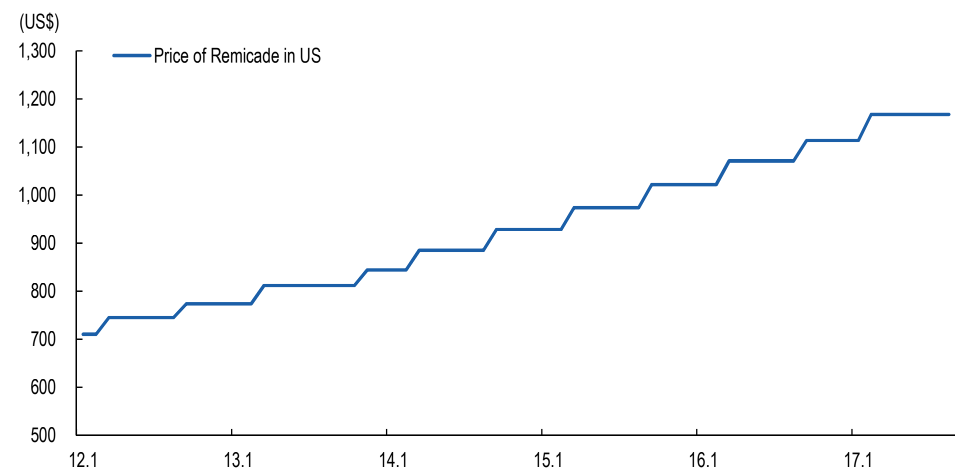
1) Deep discount: J&J raised Remicade's list price from US$1,113 to US$1,168 following the release of Inflectra (Pfizer), offerings deeper discounts on the price of Remicade to insurers. Remicade is today 64% more expensive than in 2011.

2) Exclusive deals: J&J has entered into exclusive deals with private insurers, which account for around 50% of the US market. The contractual periods vary from six months up to a maximum of two years. Hospitals are under pressure from insurers to prescribe Remicade, despite the higher price.

3) Bundling sales: J&J has bundling contracts with major hospitals, supplying medical equipment, as well as medicine.

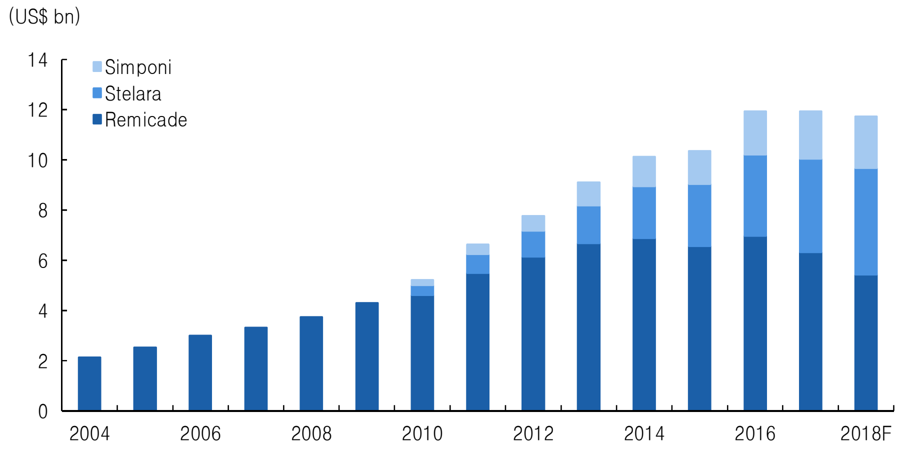
4) Switch to biobetters: J&J has released biobetter versions, such as Simponi (rheumatoid arthritis drug) and Stelara (Crohn's disease and psoriasis drug) to meet the competition from biosimiliars. Growing sales of Simponi and Stelara are offsetting the decline in Remicade's sales, keeping their combined sales steady over the past few years.

Figure 14. Remicade's list price on steady increase, even after release of biosimilar version



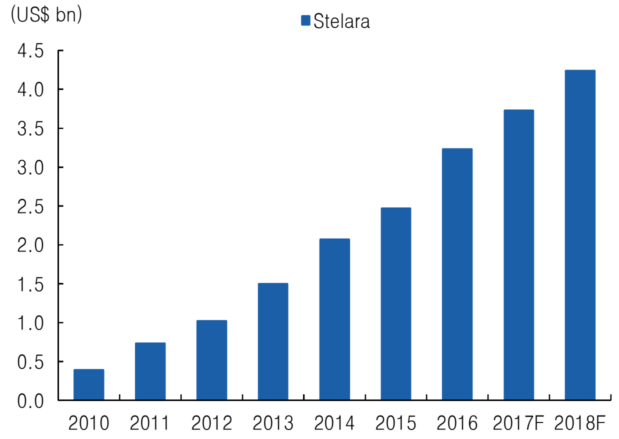
Source: Bloomberg, Mirae Asset Daewoo Research

Figure 15. Biobetters to meet competition from biosimilars



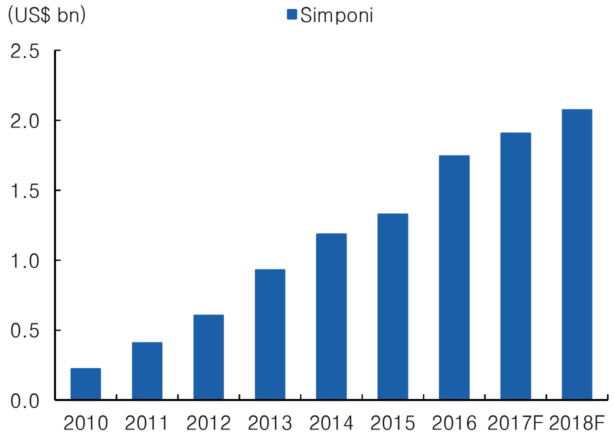
Source: JNJ, Mirae Asset Daewoo Research

Figure 16. JNJ's Crohn's disease and psoriasis drug Stelara: Revenue trend



Source: JNJ, Mirae Asset Daewoo Research

Figure 17. JNJ's rheumatoid arthritis drug Simponi: Revenue trend



Source: JNJ, Mirae Asset Daewoo Research

We attribute the slow growth of the US biosimilars market to the lack of policy support. In contrast to their US counterpart, many European governments are introducing policies to encourage biosimilar prescriptions to reduce pressure on healthcare budgets. Most European countries provide financial incentives for doctors and pharmacists to move over to biosimilars, allow switching patients to biosimilar medications under doctor's supervision and have offered government guidelines for prescribing biosimilars, related information, and education. Notably, Germany, Spain, and Italia have introduced a quota for biosimilar use.

Table 4. Biosimilar policies in Europe

Policy type	Belgium	France	Germany	Greece	Hungary	Italy	Poland	Spain	Sweden	UK
Prescription budget schemes	X	X	O	O	X	O	X	O	O	O
Biosimilar quota	O	X	O	–	O	O	X	O	O	X
Prescription pattern monitoring	O	X	O	O	–	O	X	O	O	O
Prescription conditions/guidelines	O	O	O	O	O	O	X	X	O	O
Switching1)	O	O	O	–	O	O	O	O	O	O
INN prescription	X	X	X	X	X	X	O	X	X	X
Biosimilar substitution	X	O	O	X	X	X	–	X	O	X
Incentives/penalties (Prescription issuers)	O	X	O	O	X	O	X	O	O	O
Incentives/penalties (Pharmacists)	O	O	O	O	O	O	O	O	O	O
Information & education	O	O	O	–	O	O	O	O	O	O

Note: 1) Switching patients to biosimilar medications is permissible only under doctor's supervision; Germany and Sweden allow biosimilars produced by original drug manufacturers
Source: Mirae Asset Daewoo Research

3. Future outlook: Biosimilars will slowly begin to grab increasing slice of the US market in 2018

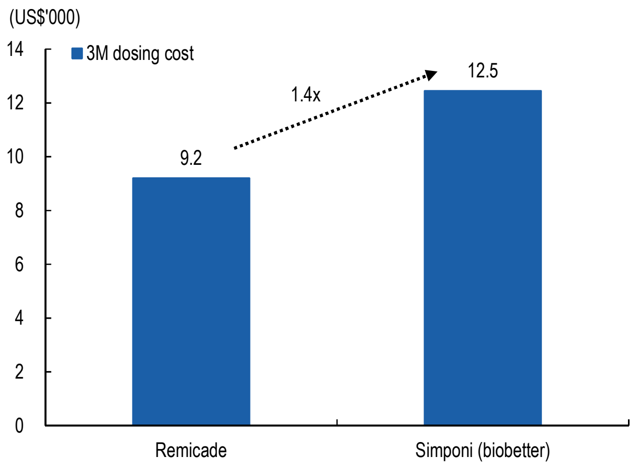
While there have been some initial bumps in the US, we expect biosimilars to slowly gain ground from 2018 onwards, for the following reasons:

First, during 2Q17 earnings call, Pfizer announced that Inflectra is fully covered by Medicare, a federally-funded social insurance program. Inflectra's market share has been steadily increasing in the public segment (based on the US Department of Veterans Affairs' purchases), after reaching 20%, and nearing 50% in the private insurance segment. Given that J&J's exclusive contracts with private insurers range from six months to a maximum of two years, we expect a string of contracts to expire starting from mid-2017, creating opportunities for Pfizer to expand its market presence.

Second, biosimilar manufacturers will likely adopt more aggressive pricing policies. According to Pfizer, Inflectra's average selling price (ASP) stands at US$753.4 in 3Q17, which represents a 35% discount versus Remicade's wholesale acquisition cost (WAC). However, due to J&J's price discount policy, Remicade's ASP stands at US$808.9, narrowing the real price gap to 6.9%. According to the Centers for Medicare and Medicaid Services (CMS), Remicade's ASP will increase QoQ to US$822.2 in 4Q17, while Inflectra's ASP will decline QoQ to US$742.7. We expect Inflectra to sharpen its price competitiveness against the original drug, with Inflectra's price cuts spreading beyond the public insurance segment since early 3Q17.

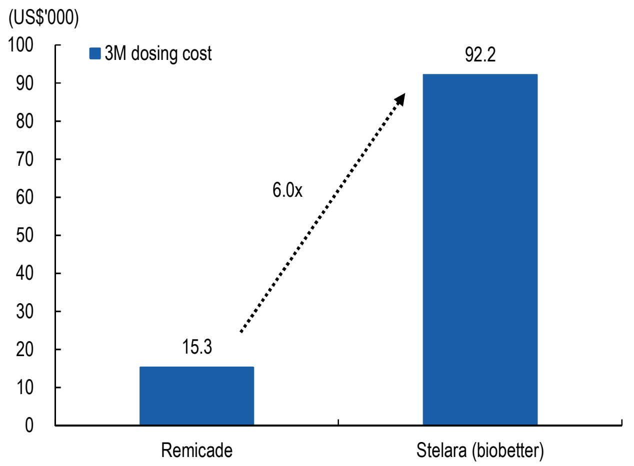
Third, we expect switching to biobetters to be limited, as biobetters, which are new drugs, are priced relatively high. A three-month treatment with Stelara costs six times as much as one with Remicade. Thus, biobetters are unlikely to constitute a serious threat, with biosimilars showing increasing price competitiveness. J&J's Stelara and Simponi entered the market in 2010, following FDA approval in 2009. Sales of Remicade had increased as steadily as those of Stelara and Simponi before 2015, when major European countries adopted a biosimilar version of Remicade.

Figure 18. Biobetters' high price tag (Remicade vs. Simponi)



Source: Bloomberg, Mirae Asset Daewoo Research

Figure 19. Biobetters' high price tag (Remicade vs. Simponi)

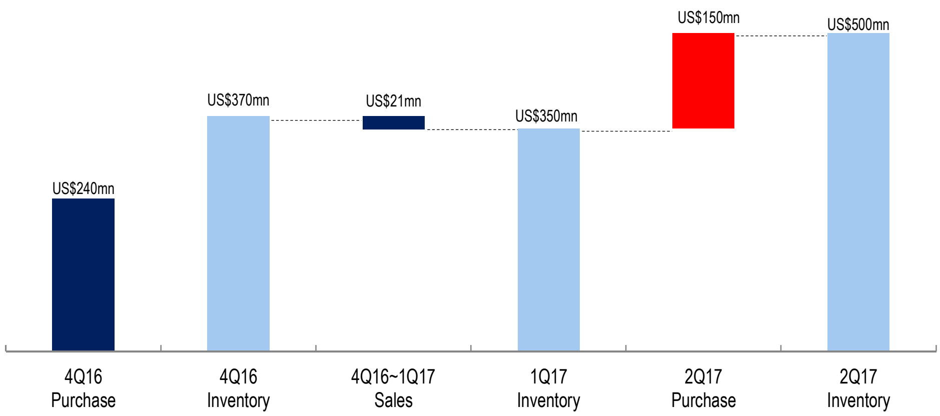


Source: Bloomberg, Mirae Asset Daewoo Research

4. Pfizer's inventory building reflects rosy outlook for Inflectra

In 4Q16, Pfizer entered into a W265.4bn-worth contract with Celltrion Healthcare. Assuming Pfizer's acquisition cost at 65% of market price, the contract could translate into US$370m in revenue. Given that revenue from Inflectra amounted to US$4m in 4Q16 and US$17mn in 1Q17, we estimate Pfizer still has an inventory of Inflectra equivalent to US$350mn in revenue at end-1Q17. Nevertheless, Pfizer made another purchase, worth W110.5bn, in 2Q17, which would translate into W170bn in revenue. Pfizer's inventory building shows that the outlook for Inflectra is bright, as the company pursues more aggressive marketing and pricing strategies.

Figure 20. Pfizer's inventory building in 2Q17 confirms its strong commitment to biosimilar market



Source: Pfizer, Celltrion Healthcare, Mirae Asset Daewoo Research

III. Analysis of price and quantity factors: How far will prices fall and how much will volume grow?

1. Biosimilar market to become oligopoly with limited number of players

We first took a look at the competitive landscape of the biosimilar industry. Competition in the biosimilar market is not as extreme as feared. It was a few years ago that companies around the world, particularly in Korea and India, rushed into the biosimilars market to seize a rising opportunity. However, only a handful of companies – Celltrion, Samsung Bioepis, Pfizer, Amgen and Sandoz – are developing and conducting clinical trials on a global scale, whereas small-to-medium-sized biotech companies have suspended R&D programs or limited the scope of clinical trials to domestic markets. The development and production of biosimilars is challenging and costly, requiring large-scale Phase III clinical trials of 500-800 patients.

There are various examples which testify to the difficulty in developing biosimilars. Earlier this year, the EMA and the FDA rejected applications by Sandoz and Pfizer, respectively, due to GMP violations at production sites. Meanwhile, Coherus and Daiichi Sankyo discontinued the joint development of Coherus' Enbrel biosimilar in Japan. Outpacing Samsung Bioepis and Celltrion, Biocon and Mylan became the first to seek EMA approval for a Herceptin biosimilar, but issues at Biocon's Bengaluru plant resulted in a year’s delay.

Table 5. Failed biosimilar development since 2017

Date	Company	Pipeline	Original drug	Related authorities	Note
17.01.27	Sandoz	Zioxtenzo	Neulasta	EMA	Failed bioequivalence; GMP violation
17.06.03	Biocon / Mylan	MYL–1401O	Herceptin	EMA	Issues at Biocon's Bengaluru plant
17.06.12	Coherus / Daiichi Sankyo	CHS-1701	Neulasta	FDA	FDA requests for additional information on clinical studies and manufacturing process
17.06.22	Pfizer	Epoetin Hospira	Epogen	FDA	GMP violations at Hospira’s Kansas plant
17.07.05	Coherus / Daiichi Sankyo	CHS-0214	Enbrel	Voluntary decision	Failure to establish production-ready formula

Source: Mirae Asset Daewoo Research

We expect the emergence of new entrants to be limited. Remicade’s case shows how difficult it is to penetrate the biosimilar market without first-mover advantage. Given the 32 month-gap between Celltrion’s first biosimilar and Samsung Bioepis’ second biosimilar, it is difficult to apply Remicade’s case to others. However, new entrants are at a significant disadvantage, given the speed at which new biosimilars penetrate the market and the marginal differences with reference drugs, in terms of efficacy.

Although the timing of market release is a key variable, we expect only the second and third runners-up to be able to carve out meaningful market shares. Unless they have significant cost competitiveness, the fourth and fifth runners-up stand little chance against frontrunners. As such, we do not expect the number of competitors to increase further.

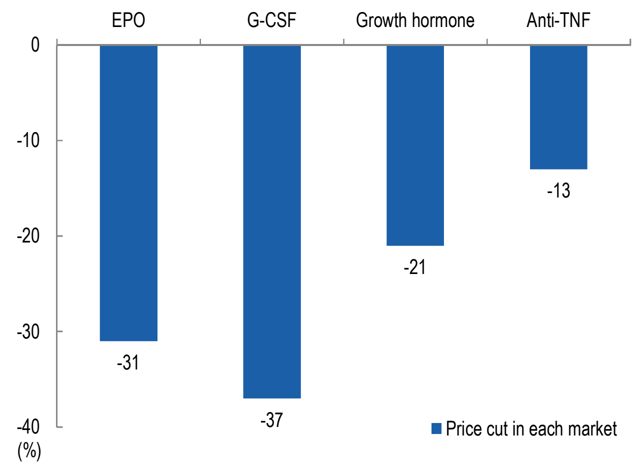
We believe the biosimilars market will be highly concentrated among a few players, such as Celltrion, Samsung Bioepis, Pfizer, Amgen, and Sandoz, which are globally conducting Phase III clinical trials. As such, we do not see a high possibility of steep price declines.

2. P-1: Price discounts of biosimilars stand at 40-45% in Europe

In Europe, the price discounts for first-generation biosimilars were 37% for G-CSF가, 31% for EPO, and 21% for growth hormone (versus 13% for TNF-α inhibitors, a second-generation biosimilar). The wide discrepancy in discounts appears attributable to differences in the degree of competition. In 2016, eight biosimilars to G-CSF, five biosimilars to EPO, and four biosimilars to growth hormone were released in Europe. Price discounts for biosimilars hinge on the number of competitive products released, and second- generation biosimilars will likely be dominated by only a handful of companies. As such, biosimilar prices are unlikely to drop sharply, going forward. Currently, price discounts for second-generation biosimilars stand at 35-40%. Even if more biosimilars are launched, price discounts will likely expand only modestly, to 40-45%.

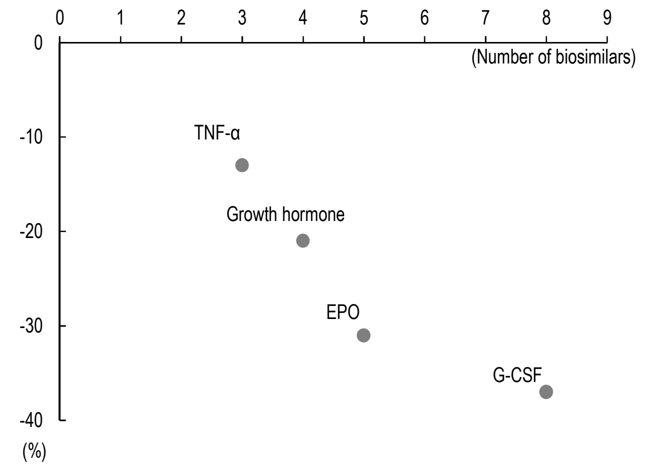
There were concerns that the launch of second-generation biosimilars would prompt drug makers to cut their original drug prices, thus denting the price competitiveness of biosimilars. In fact, the price cuts on original drugs were only modest, given that Remicade price changes ranged from -15% to +5% in the second and third years of the launch of its biosimilars (according to IMS Health). Rather, Remicade prices were raised by 10-30% in Denmark, Finland, and Norway.

Figure 21. Price discounts of biosimilars



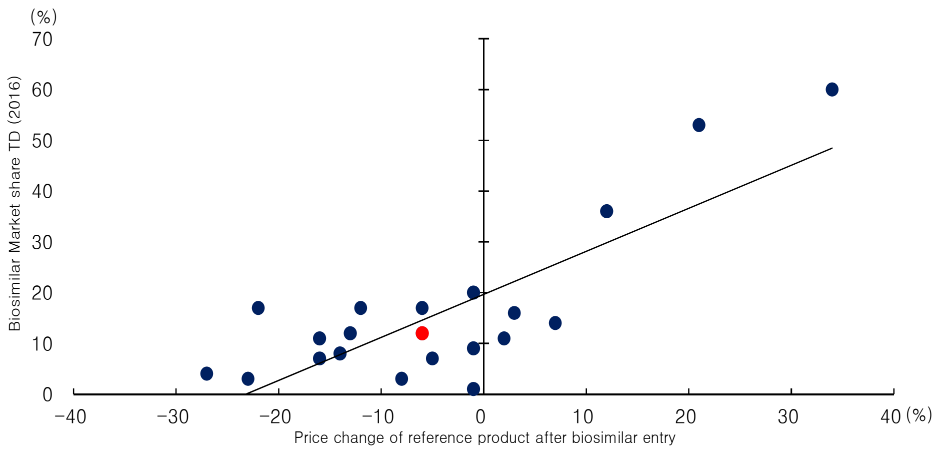
Source: QuintilesIMS, Mirae Asset Daewoo Research

Figure 22. Price discounts by the number of biosimilars available



Source: QuintilesIMS, Mirae Asset Daewoo Research

Figure 23. Only modest price cuts on original drugs after launch of biosimilars



Note: Red dot is median value.
Source: QuintilesIMS, Mirae Asset Daewoo Research

3. P-2: Price discount could widen to 50% in the US market

In the US, the price discount of Inflectra, Celltrion's biosimilar to Remicade, stands at 19% (versus 15% at the time of release) based on the wholesale acquisition cost (WAC), but only 6.9% in terms of ASP. Biosimilars are facing tough challenges from original pharmaceutical companies. Of note, Samsung Bioepis has applied a 35% discount to its Remicade biosimilar (based on the WAC), indicating that discounts for biosimilars will increase further amid intense competition.

However, low prices are the greatest advantage of biosimilars, and biosimilar makers initially expected fierce price competition. As such, there is no reason to be concerned about price discounts. We believe that the price discount could widen to 50% in the US market.

We expect a high price discount in the US market relative to the European market, as: 1) the US market is more fiercely competitive; 2) latecomers will also likely see opportunities in the US market, given that it will take some time for major original drugs' patents to expire in the US; and 3) prices of biologics are higher in the US. Of note, the market share of biosimilars climbs in line with price discounts, as evidenced by first-generation biosimilars.

However, we do not expect excessive price competition, in light of: 1) the limited number of biosimilar makers; 2) massive development costs; and 3) significant production costs. Recall that the price discounts of first-generation biosimilars did not exceed 40%, despite intense competition and relatively low development/production costs.

Figure 24. Market share climbs in line with price discounts (EPO)

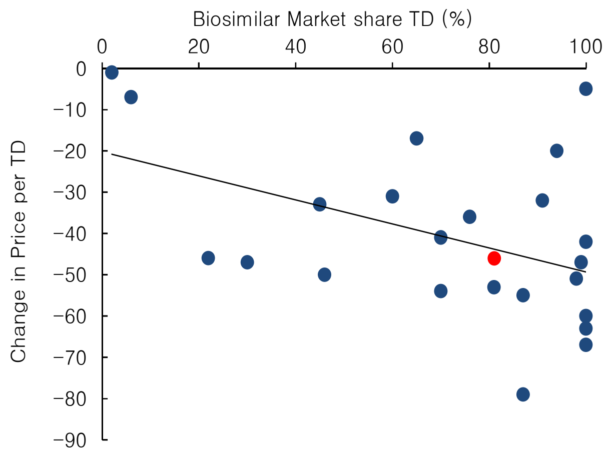


Figure 25. Market share climbs in line with price discounts (G-CSF)

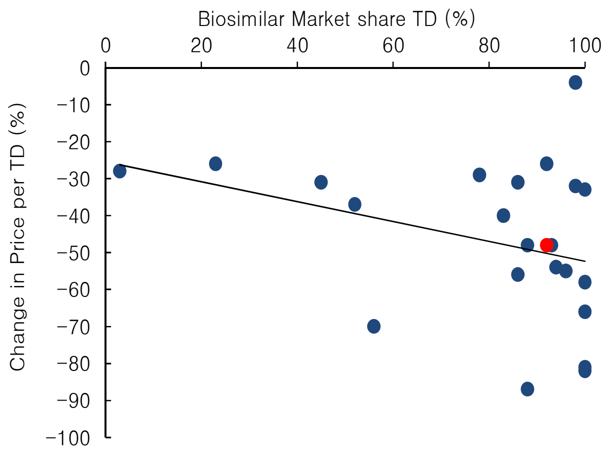


Figure 26. Market share climbs in line with price discounts (growth hormone)

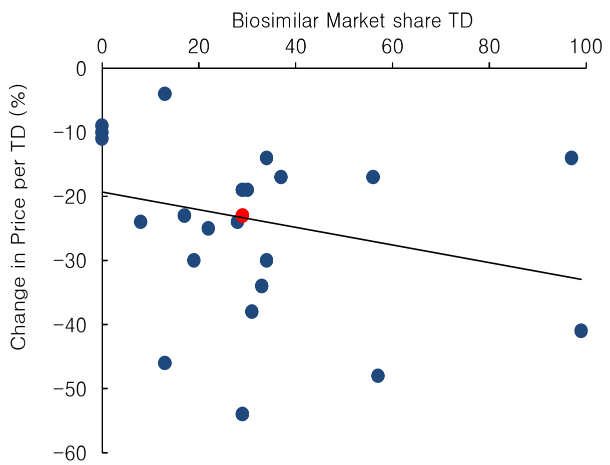
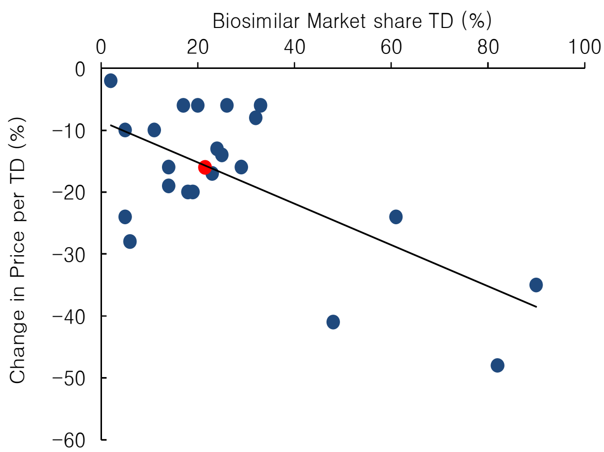


Figure 27. Market share climbs in line with price discounts (TNF-α inhibitor)



Note: The red dot is the median value.
Source: QuintilesIMS, Mirae Asset Daewoo Research

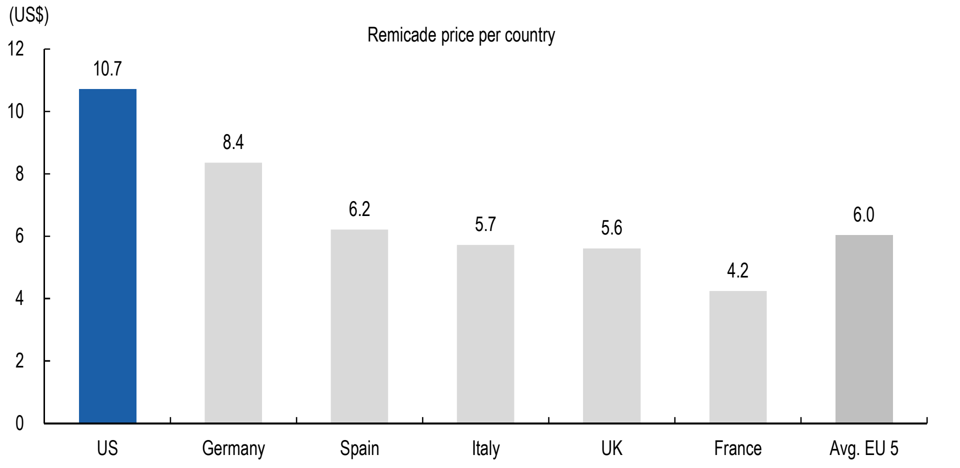
Note: The red dot is the median value.
Source: QuintilesIMS, Mirae Asset Daewoo Research

Even 50% discount would keep biosimilar makers' margins intact in US

In mid-2016, the US price of Remicade (100mg) stood at US$1,071, 78% higher than the ASP (US$603) for the five major European countries—the UK, Spain, Italy, France, Germany, and Italy. In Europe, if assuming a price discount of 40%, the price of Remicade biosimilars would stand at around US$362. In the US, even based on a price discount of 60%, the price would reach US$428. Therefore, all other things being equal, even a 50% discount would keep biosimilar makers' margins intact in the US.

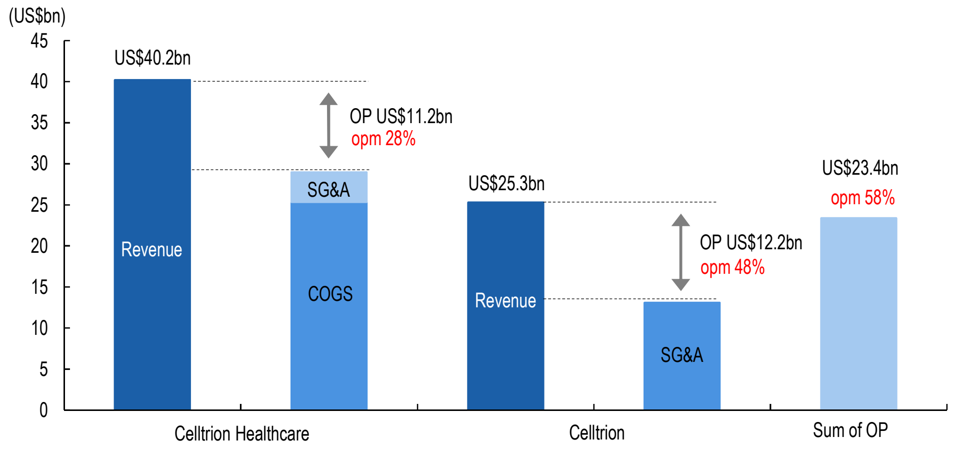
Celltrion's Remicade biosimilar generated revenue mainly in Europe until it posted US revenue for the first time in 4Q16. Of note, even when price discount was as much as 70% in some European countries in 2015, Celltrion's margins remained high.

Figure 28. US price of Remicade (100mg) 78% higher than the ASP (US$603) for five major European countries



Source: Mirae Asset Daewoo Research

Figure 29. Profit structures of Celltrion and Celltrion Healthcare in 2015



Source: Celltrion and Celltrion Healthcare, Mirae Asset Daewoo Research

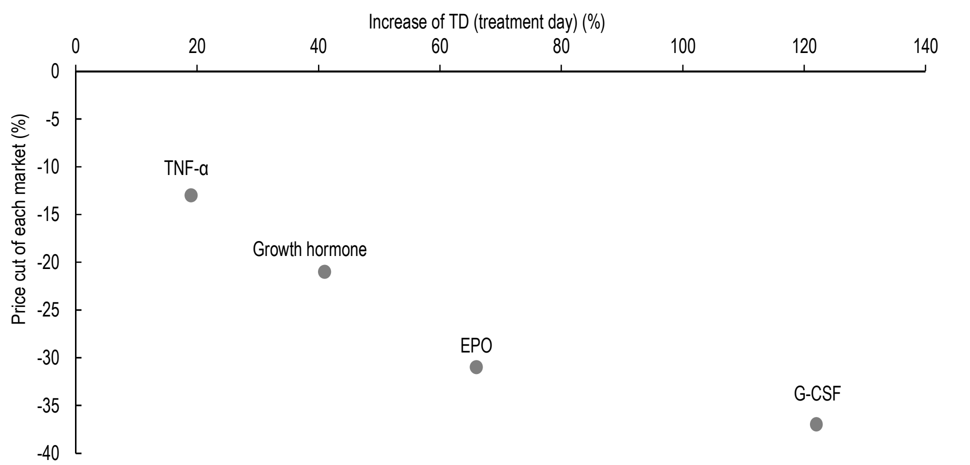
4. Q: Overall market to expand on price cuts

Market watchers are concerned that the overall market will shrink markedly, due to price discounts for biosimilars and price cuts for original drugs. However, evidence suggests that lower pricing often leads to increased uptake and overall market growth.

Since the launch of biosimilars, overall prices of EPO, G-CSF, and growth hormone have dropped 31%, 37%, and 21%, respectively. Meanwhile, the combined number of prescription days for original drugs and their biosimilars has increased by 66% for EPO, 122% for G-CSF, and 41% for growth hormone. As such, the overall market has expanded.

We expect this pattern to repeat for second-generation biosimilars. As of end-2016, the combined number of prescription days for Remicade (and its biosimilars) and Herceptin (and its biosimilars) has increased by 19% since the launch of their biosimilars. We see this as significant volume growth in less than two years, given that the biosimilars to Remicade and Herceptin were both released in Europe in February 2015.

Figure 30. First-generation biosimilars: Lower pricing leads to increased uptake



Source: QuintilesIMS, Mirae Asset Daewoo Research

Figure 31. EPO: Lower pricing leads to increased uptake

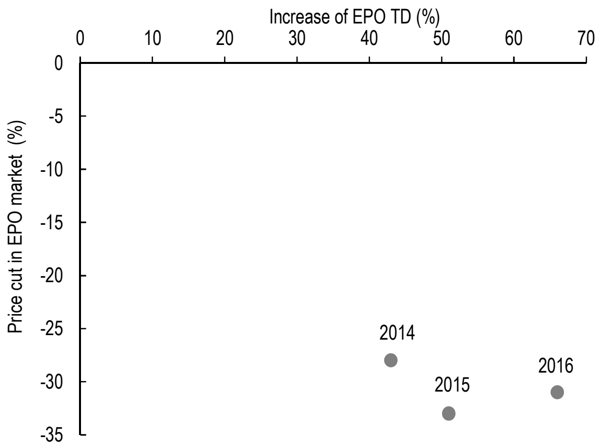


Figure 32. G-CSF: Lower pricing leads to increased uptake

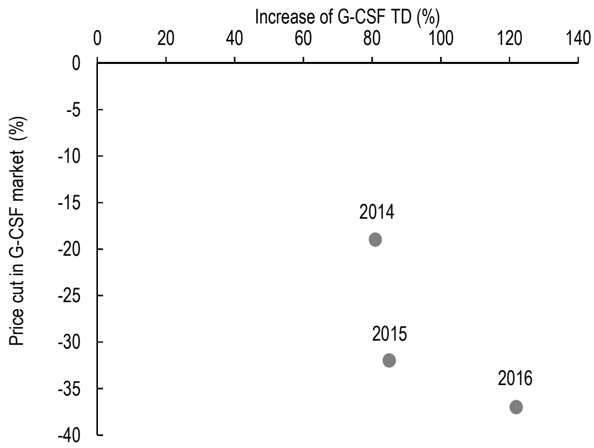


Figure 33. Growth hormone: Lower pricing leads to increased uptake

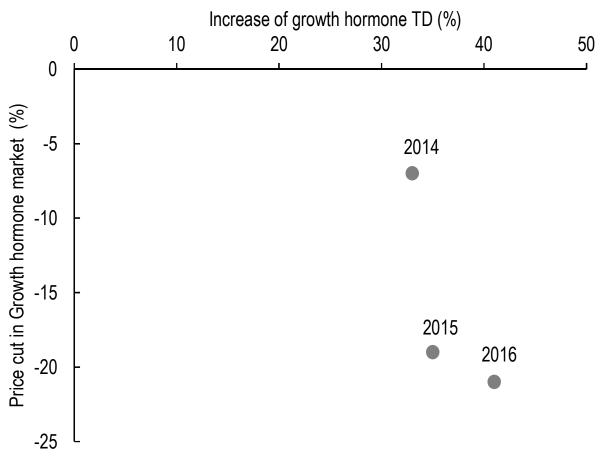
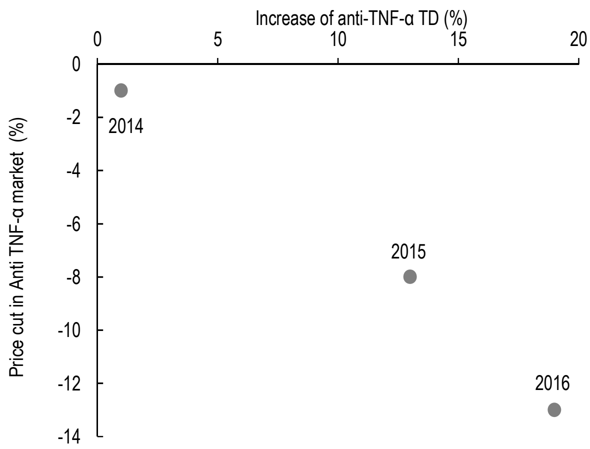


Figure 34. TNF-α inhibitor: Lower pricing leads to increased uptake

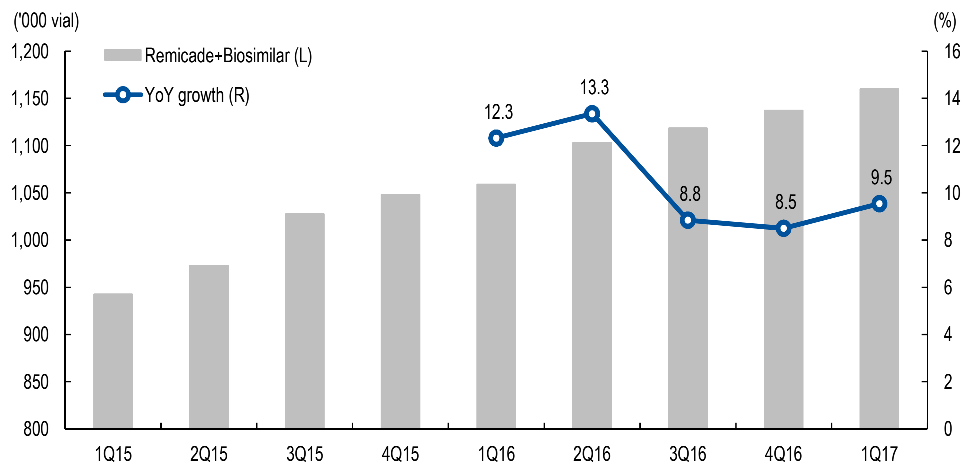


Source: QuintilesIMS, Mirae Asset Daewoo Research

Source: QuintilesIMS, Mirae Asset Daewoo Research

A similar trend is also found in terms of vials. The combined number of vials prescribed for Remicade and its biosimilars increased 10.7% from 3.99mn in 2015 to 4.42mn in 2016. As second-generation biosimilars are priced much higher than first-generation biosimilars, the effect of lower pricing on demand will likely be far greater for second-generation biosimilars.

Figure 35. Number of vials prescribed for Remicade and its biosimilars is on the increase



Source: Mirae Asset Daewoo Research

IV. Outlook by biosimilar: Speed is key to success

1. Speed of releasing new biosimilars and marketing capability

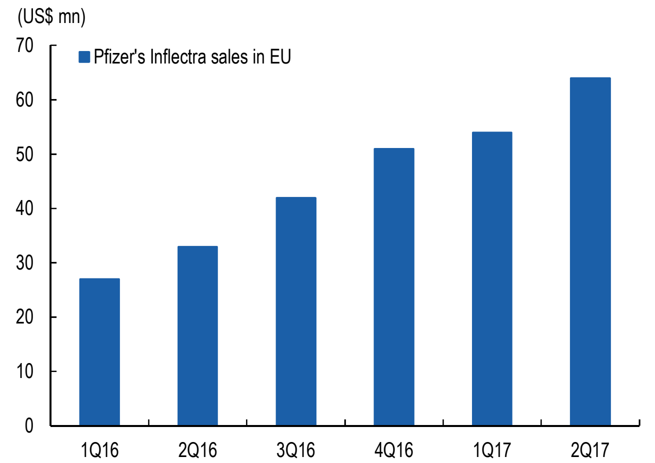
The speed at which new biosimilars are released is crucial to their success. A case in point is the release of biosimilars to Remicade in Europe. Remsima, the first biosimilar to Remicade, has gained dominance in the Remicade biosimilar market. However, the market share of Flixabi, the second Remicade biosimilar, has been stagnant. As of 1Q17, Remsima accounted for 42% of the market, while the share of Flixabi stood at only 1.5%.

For biosimilars to Enbrel, Samsung Bioepis' Benepali, the first biosimilar released in Europe, is steadily expanding its market share. As of 2Q17, Benepali controlled 99% of the Danish Enbrel market and 30% of the German market. Currently, no company is developing an additional Enbrel biosimilar, with the exception of Sandoz, as the US patent for Enbrel has been extended to 2028. As such, we expect Benepali's market dominance to persist.

Overall, the companies that are first and second to release biosimilars will likely control most of the market, giving first-mover advantage to existing players and leaving new entrants at a significant disadvantage.

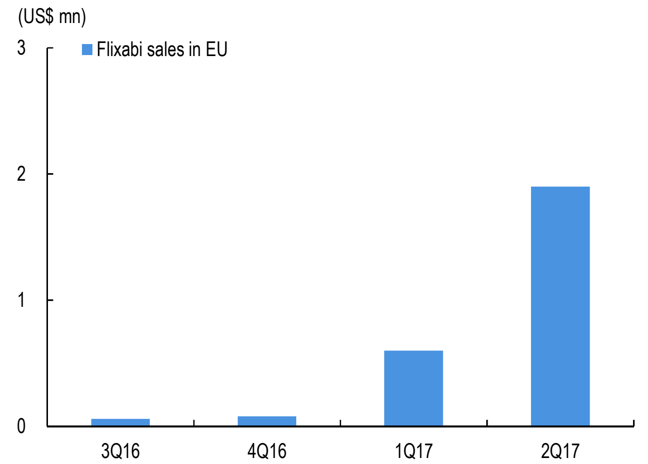
With regard to Remicade biosimilar, Celltrion was far ahead of rivals in the development race; the firm's Remicade biosimilar was approved roughly 32 months earlier than that of Samsung Bioepis. This has allowed Celltrion's biosimilar to markedly outperform competing biosimilars, in terms of market share. Meanwhile, for Rituxan, Herceptin, and Humira biosimilars awaiting release, we expect differences in market share between developers to remain minimal, in light of the likely marginal differences in release dates.

Figure 36. First movers gain upper hand: Inflectra sales in Europe



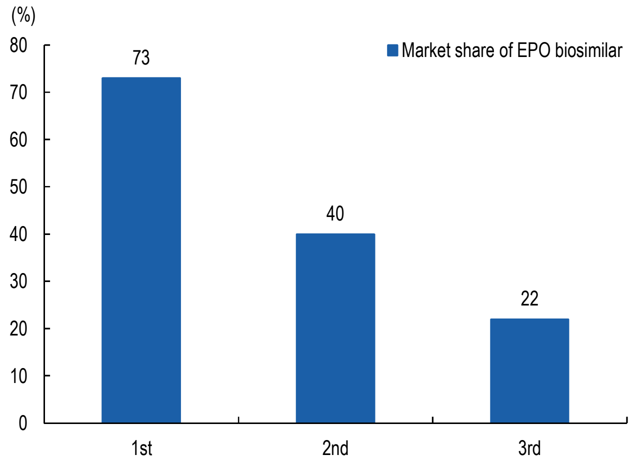
Source: Pfizer, Mirae Asset Daewoo Research

Figure 37. First movers gain upper hand: Flixabi sales in Europe



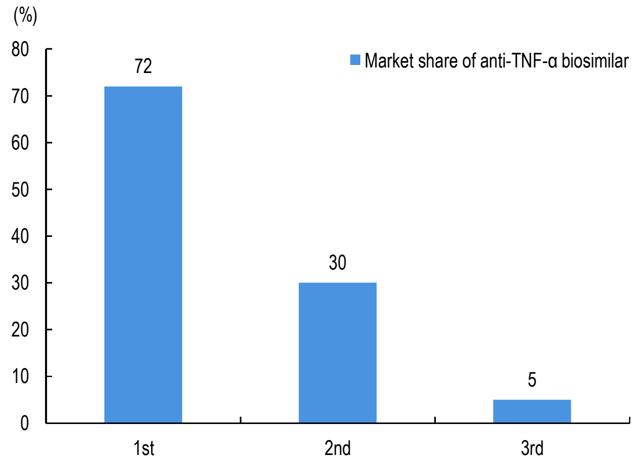
Source: Biogen, Mirae Asset Daewoo Research

Figure 38. EPO biosimilar M/S breakdown



Source: Mirae Asset Daewoo Research

Figure 39. TNF- inhibitor biosimilar M/S breakdown



Source: Mirae Asset Daewoo Research

An effective marketing strategy is also an important variable for biosimilar companies. As biosimilars have no clinically significant differences, in terms of efficacy, the most aggressive and efficient marketers should gain the upper hand in the market. The acquisition of massive clinical data is also important. For biosimilar drugs, Phase II trials alone often enroll up to 500-800 patients to prove that they are bioequivalent to original drugs.

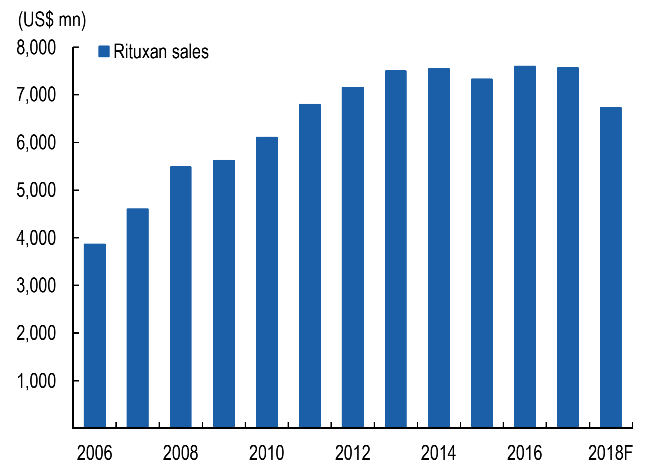
We believe that Celltrion is somewhat ahead of rivals, in terms of marketing strategy. In Norway, the firm carried out a clinical study involving roughly 500 patients, which showed that a switch to its biosimilar from the original drug was not inferior to continued treatment with the original drug. Another clinical study in Denmark (involving 802 patients) also proved the bioequivalence of the firm's biosimilar with the original drug. Results from these clinical studies have helped convince doctors of the efficacy of biosimilars.

The prospects for the future performance of biosimilars for Rituxan, Herceptin, and Humira, in Europe are as follows:

2. Rituxan biosimilar: Celltrion's launch followed by that of Sandoz

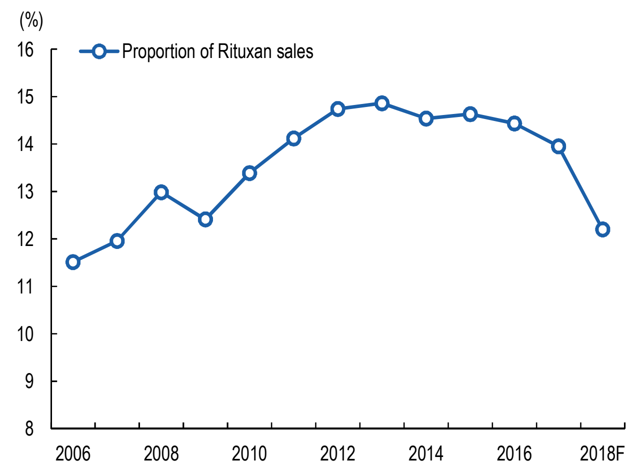
After gaining an approval from the European Medicines Agency (EMA) in February, Celltrion launched the world's first-ever Rituxan biosimilar (Truxima) in April, which has been rapidly gaining ground ever since. Sandoz's Rituxan biosimilar has subsequently been granted approval, with a four-month lag. With no additional competition expected for quite some time, we think Truxima will easily be able to seize more than 60% of the market.

Figure 40. Rituxan sales trend



Source: Roche, Mirae Asset Daewoo Research

Figure 41. Rituxan as % of Roche's total sales

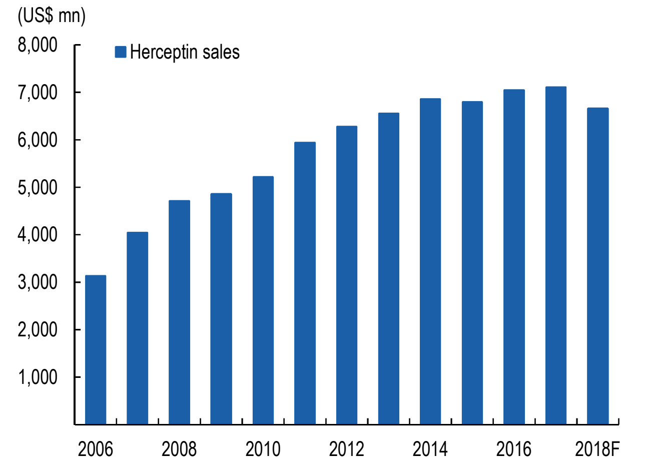


Source: Roche, Mirae Asset Daewoo Research

3. Herceptin biosimilar: 1) Samsung Bioepis; 2) Celltrion; 3) Amgen

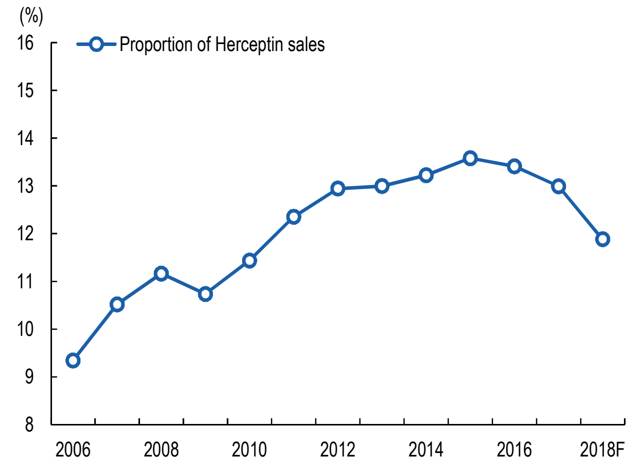
There are five Herceptin biosimilar drugs competing in Europe. Notably, Samsung Bioepis and Celltrion are expected to launch their Herceptin biosimilars ahead of rivals, as approval of Biocon/Mylan's version (first to file for approval) was recently hit with setbacks, due to manufacturing issues. Amgen's version is likely to be the third to be authorized after Celltrion's biosimilar (with a five-month lag). We expect Samsung Bioepis and Celltrion to markedly outperform latecomers in the market, given their successful track record in Europe with the Enbrel and Remicade biosimilars, respectively.

Figure 42. Herceptin sales trend



Source: Roche, Mirae Asset Daewoo Research

Figure 43. Herceptin as % of Roche's total sales



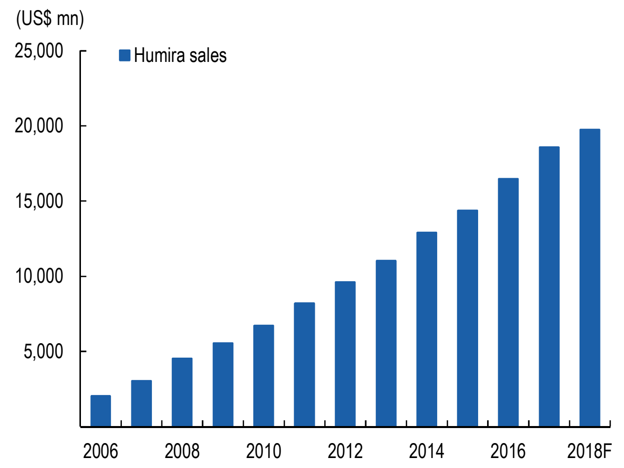
Source: Roche, Mirae Asset Daewoo Research

4. Humira biosimilar: Fierce competition expected

Although competition will likely remain muted in the biosimilar market as a whole, fierce competition is expected among biosimilars for Humira (the world's best-selling drug, with 2016 full-year sales of US$16.1bn) going forward. In Europe, the expiration of the patent for Humira is slated for October 2018, which should buy some time for some latecomers to develop biosimilars, leading to additional releases of Humira biosimilars in the market.

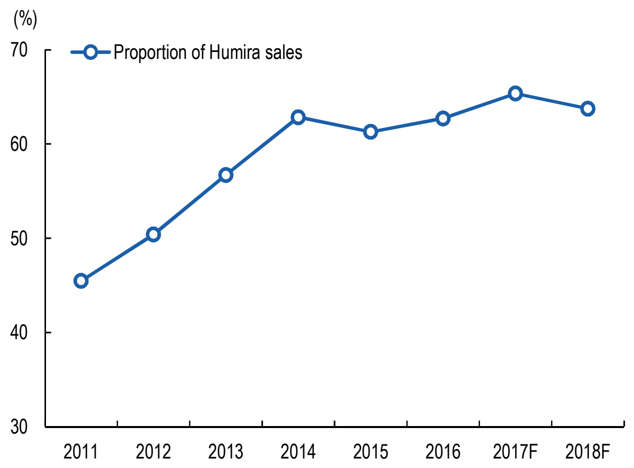
In Europe, Amgen was the first company to gain approval for its Humira biosimilar (March 2017), followed by Samsung Bioepis (August 2017). Boehringer Ingelheim and Sandoz filed for approval of their biosimilars in January and June, respectively. Given the review period of roughly 14 months, both the biosimilars are likely to gain approval, prior to the patent expiration for the original drug. With the four aforementioned companies likely to launch their respective Humira biosimilars simultaneously upon patent expiration, intensified competition is expected in the market going forward.

Figure 44. Humira sales trend



Source: AbbVie, Mirae Asset Daewoo Research

Figure 45. Humira as % of AbbVie's total sales



Source: AbbVie, Mirae Asset Daewoo Research

Celltrion Healthcare (091990 KQ)

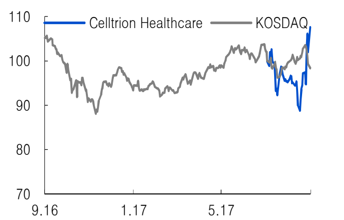
Exceptional performance in Europe; gradual improvement in US

Healthcare

(Initiate)	Buy
Target Price(12M, W)	**71,000**
Share Price (09/25/17, W)	54,100
Expected Return	31%

OP (17F, Wbn)	234
Consensus OP (17F, Wbn)	243
EPS Growth (17F, %)	65.1
Market EPS Growth (17F, %)	44.6
P/E (17F, x)	29.7
Market P/E (17F, x)	9.9
KOSDAQ	642.04
Market Cap (Wbn)	7,395
Shares Outstanding (mn)	137
Free Float (%)	31.2
Foreign Ownership (%)	38.0
Beta (12M)	1.02
52-Week Low	44,650
52-Week High	54,100

(%)	1M	6M	12M
Absolute	12.9	-	-
Relative	14.4	-	-



Initiate coverage with Buy and TP of W71,000; our top biosimilar pick

We initiate our coverage on Celltrion Healthcare with a Buy rating and target price of W71,000, and present the stock as our top pick among biosimilar names. Our target price is based on a P/E of 30x our 2018F EPS. While Celltrion Healthcare is a biosimilar distributor, the company is seeing fast revenue growth in developed markets (US and Europe), engages in marketing jointly with its partners, and has exclusive rights to Celltrion's pipeline. We view our target multiple of 30x as reasonable, given that the top Korean drugmakers skewed towards the distribution business are trading at mid/high-20x levels. The company's high inventory assets and their expiration dates have been a source of concern, but we believe such controversies are no longer of consequence, now that annual revenue has grown to roughly W1tr. We believe that Celltrion Healthcare has the lowest risk among the top three Korean biosimilar firms, with the least valuation pressure.

Exceptional in Europe; watch for gradual improvements in US

Celltrion Healthcare has been making great strides in Europe, with Remsima taking over 40% of the region's market in just two years since its release. We believe that Remsima will continue to dominate the market, given that the competing biosimilar was released with a significant time lag (more than two and a half years). After gaining approval from the European Medicines Agency (EMA) in February, the company's second biosimilar, Truxima, went on sale in April and has been rapidly gaining ground ever since. Sandoz's Rituxan biosimilar has subsequently been granted approval, but with a four-month delay, and no further competition is expected for some time. Herzuma, a biosimilar to Herceptin, is also expected to gain EMA authorization.

In the US, the company has struggled, due to unexpected countermoves by original pharma companies. However, we believe the company will slowly begin to gain share in 2018, given that: 1) expanding insurance coverage; 2) the looming expiration of exclusive deals between original drug companies and private insurers; and 3) marketing partner Pfizer's strong commitment towards Inflectra.

Rapid growth to continue with launch of Herzuma in 2018 and SC-type Remsima in 2019

For 2017, we forecast revenue and operating profit to grow to W992.6bn (+31% YoY) and W234.1bn (+31.1% YoY), respectively, driven by Remsima's ongoing market share expansion in Europe, as well as Truxima's rapid penetration in the region. Looking further ahead, we expect revenue and operating profit to expand 41.9% and 47.6% CAGR, respectively, through 2020, on the back of the European launch of Herzuma and Inflectra's US share gain in 2018 and the release of a subcutaneous (SC)-version of Remsima in 2019.

FY (12)	12/14	12/15	12/16	12/17F	12/18F	12/19F
Revenue (Wbn)	165	402	758	993	1,503	2,094
OP (Wbn)	37	112	179	234	385	555
OP margin (%)	22.4	27.9	23.6	23.6	25.6	26.5
NP (Wbn)	-370	21	123	224	323	506
EPS (W)	-5,711	308	1,103	1,820	2,360	3,702
ROE (%)	174.1	-22.3	21.4	29.4	31.2	34.9
P/E (x)	-	-	-	29.7	22.9	14.6
P/B (x)	-	-	-	8.5	6.2	4.3
FY (12)	12/14	12/15	12/16	12/17F	12/18F	12/19F

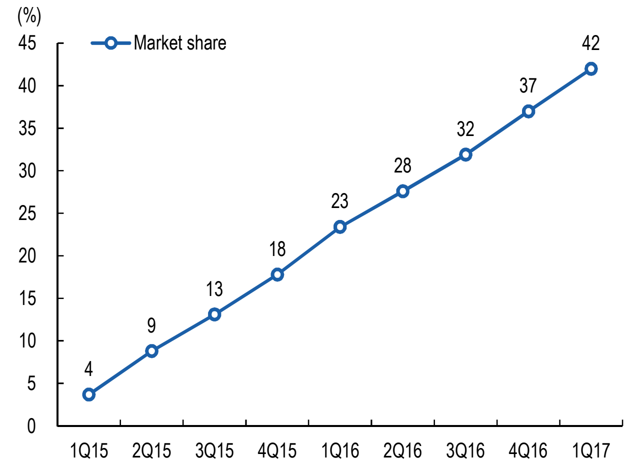
Note: All figures are based on consolidated K-IFRS; NP refers to net profit attributable to controlling interests
Source: Company data, Mirae Asset Daewoo Research estimates

Table 6. Sales forecast of Celltrion Healthcare (US$mn, %)

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Remicade													
Global market (US$mn)	8,829	8,486	8,897	9,261	9,326	9,280	8,816	8,375	7,957	7,559	7,181	6,822	6,481
Growth (%)	-2	-4	5	4	1	0	-5	-5	-5	-5	-5	-5	-5
Outside US	3,987	4,230	4,505	4,280	4,066	3,863	3,669	3,486	3,312	3,146	2,989	2,839	2,697
Growth (%)	-12	6	7	-5	-5	-5	-5	-5	-5	-5	-5	-5	-5
Biosimilar market share	30	41	51	51	51	51	51	51	51	51	51	51	51
Biosimilar sales	1,196	1,751	2,316	2,200	2,090	1,985	1,886	1,792	1,702	1,617	1,536	1,459	1,386
Celltrion partners' share	99	99	96	92	90	88	85	82	79	76	73	70	67
Celltrion partners' sales	1,184	1,734	2,223	2,024	1,881	1,747	1,603	1,469	1,345	1,229	1,121	1,022	929
US	4,842	4,256	4,392	4,981	5,260	5,418	5,147	4,889	4,645	4,413	4,192	3,982	3,783
Growth (%)	9	-12	3	13	6	3	-5	-5	-5	-5	-5	-5	-5
Biosimilar market share		3	4	7	28	41	51	51	51	51	51	51	51
Biosimilar sales		106	158	364	1,446	2,243	2,645	2,513	2,387	2,268	2,155	2,047	1,945
Celltrion partners' share		97	90	75	65	60	60	60	58	56	54	52	50
Celltrion partners' sales		103	142	273	940	1,346	1,587	1,508	1,385	1,270	1,164	1,064	972
Rituxan													
Global market (US$mn)	7,591	7,651	8,006	7,609	7,957	8,759	8,819	8,774	8,335	7,919	7,523	7,147	6,789
Growth (%)	4	1	5	-5	5	10	1	-1	-5	-5	-5	-5	-5
Outside US	3,524	3,344	3,445	3,600	3,819	4,067	3,864	3,671	3,487	3,313	3,147	2,990	2,840
Growth (%)	3	-5	3	5	6	7	-5	-5	-5	-5	-5	-5	-5
Biosimilar market share		4	7	28	41	51	51	51	51	51	51	51	51
Biosimilar sales		117	251	991	1,580	2,092	1,987	1,888	1,793	1,704	1,619	1,538	1,461
Celltrion partners' share		70	70	70	68	66	64	62	60	58	56	54	52
Celltrion partners' sales		82	175	694	1,075	1,381	1,272	1,170	1,076	988	906	830	760
US	4,067	4,307	4,561	4,009	4,137	4,692	4,955	5,103	4,848	4,606	4,375	4,157	3,949
Growth (%)	4	6	6	-12	3	13	6	3	-5	-5	-5	-5	-5
Biosimilar market share				4	7	28	41	51	51	51	51	51	51
Biosimilar sales				144	301	1,292	2,050	2,625	2,493	2,369	2,250	2,138	2,031
Celltrion partners' share				60	60	60	58	56	54	52	50	48	46
Celltrion partners' sales				86	181	775	1,189	1,470	1,346	1,232	1,125	1,026	934
Herceptin													
Global market (US$mn)	7,052	7,242	7,220	7,047	7,400	8,069	7,993	7,854	7,462	7,088	6,734	6,397	6,077
Growth (%)	4	3	0	-2	5	9	-1	-2	-5	-5	-5	-5	-5
Outside US	4,443	4,443	4,216	4,406	4,675	4,979	4,730	4,493	4,269	4,055	3,852	3,660	3,477
Growth (%)	3	0	-5	5	6	7	-5	-5	-5	-5	-5	-5	-5
Biosimilar market share			7	28	41	51	51	51	51	51	51	51	51
Biosimilar sales			307	1,213	1,934	2,561	2,432	2,311	2,195	2,086	1,981	1,882	1,788
Celltrion partners' share			20	25	30	35	33	31	29	27	25	23	21
Celltrion partners' sales			61	303	580	896	803	716	637	563	495	433	376
US	2,609	2,799	3,004	2,640	2,725	3,090	3,263	3,361	3,193	3,033	2,882	2,737	2,601
Growth (%)	5	7	7	-12	3	13	6	3	-5	-5	-5	-5	-5
Biosimilar market share				2	7	28	41	51	51	51	51	51	51
Biosimilar sales				53	198	851	1,350	1,728	1,642	1,560	1,482	1,408	1,337
Celltrion partners' share				25	25	25	24	23	22	21	20	19	18
Celltrion partners' sales				13	50	213	324	398	361	328	296	267	241

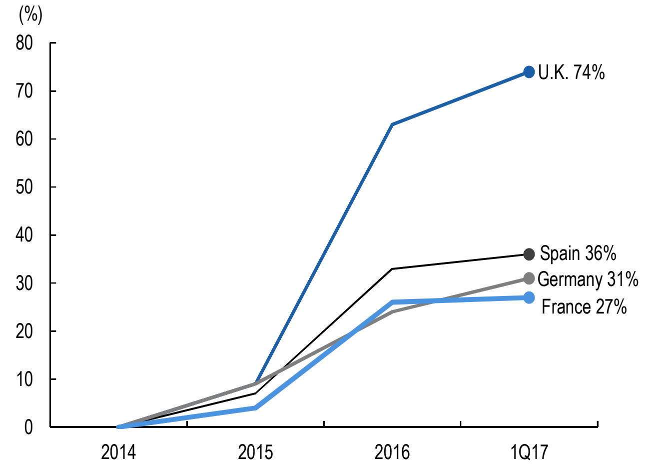
Source: Mirae Asset Daewoo Research

Figure 46. Remsima's market share trends in Europe



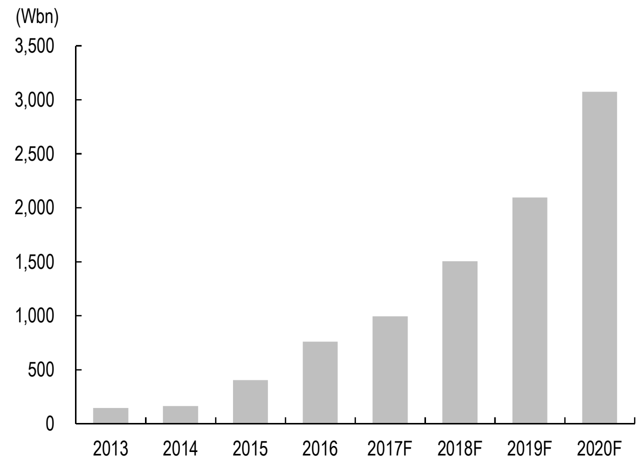
Source: Mirae Asset Daewoo Research

Figure 47. Remsima's market share trends in major European countries



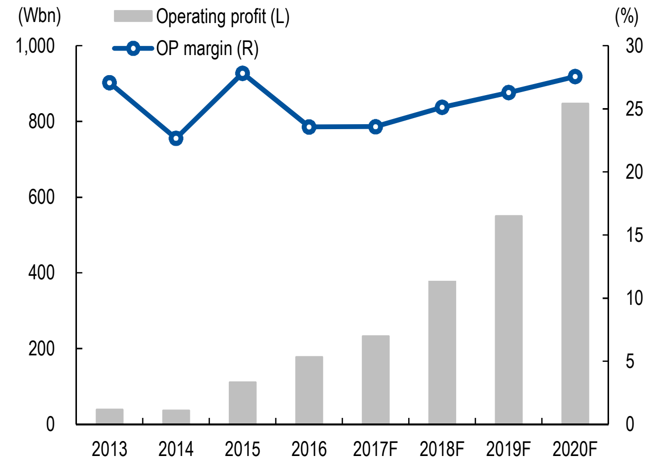
Source: Mirae Asset Daewoo Research

Figure 48. Revenue trends



Source: Company data, Mirae Asset Daewoo Research

Figure 49. OP and OP margin trends



Source: Company data, Mirae Asset Daewoo Research

Celltrion Healthcare (091990 KQ/Buy/TP: W71,000)

Comprehensive Income Statement (Summarized)

(Wbn)	12/16	12/17F	12/18F	12/19F
Revenue	**758**	**993**	**1,503**	**2,094**
Cost of Sales	**538**	**700**	**1,045**	**1,451**
Gross Profit	**220**	**293**	**458**	**643**
SG&A Expenses	**41**	**59**	**73**	**88**
Operating Profit (Adj)	**179**	**234**	**385**	**555**
Operating Profit	**179**	**234**	**385**	**555**
Non-Operating Profit	**-16**	**61**	**39**	**113**
Net Financial Income	-27	-12	25	97
Net Gain from Inv in Associates	0	0	0	0
Pretax Profit	163	295	424	668
Income Tax	40	71	102	162
Profit from Continuing Operations	123	224	323	506
Profit from Discontinued Operations	0	0	0	0
Net Profit	123	224	323	506
Controlling Interests	123	224	323	506
Non-Controlling Interests	0	0	0	0
Total Comprehensive Profit	**123**	**224**	**323**	**506**
Controlling Interests	123	224	323	506
Non-Controlling Interests	0	0	0	0
EBITDA	179	234	385	555
FCF (Free Cash Flow)	30	121	766	870
EBITDA Margin (%)	23.6	23.6	25.6	26.5
Operating Profit Margin (%)	23.6	23.6	25.6	26.5
Net Profit Margin (%)	16.2	22.6	21.5	24.2

Statement of Financial Condition (Summarized)

(Wbn)	12/16	12/17F	12/18F	12/19F
Current Assets	**1,949**	**2,085**	**2,739**	**3,660**
Cash and Cash Equivalents	96	23	737	1,575
AR & Other Receivables	364	273	414	576
Inventories	1,472	1,767	1,555	1,461
Other Current Assets	17	22	33	48
Non-Current Assets	**38**	**46**	**62**	**80**
Investments in Associates	0	0	0	0
Property, Plant and Equipment	0	0	0	0
Intangible Assets	1	1	2	2
Total Assets	**1,987**	**2,131**	**2,801**	**3,740**
Current Liabilities	**1,143**	**1,072**	**1,430**	**1,874**
AP & Other Payables	683	785	1,189	1,656
Short-Term Financial Liabilities	322	145	108	92
Other Current Liabilities	138	142	133	126
Non-Current Liabilities	**195**	**187**	**176**	**165**
Long-Term Financial Liabilities	33	0	0	0
Other Non-Current Liabilities	162	187	176	165
Total Liabilities	**1,339**	**1,259**	**1,606**	**2,039**
Controlling Interests	**649**	**872**	**1,195**	**1,701**
Capital Stock	112	112	112	112
Capital Surplus	381	381	381	381
Retained Earnings	206	429	752	1,258
Non-Controlling Interests	**0**	**0**	**0**	**0**
Stockholders' Equity	**649**	**872**	**1,195**	**1,701**

Cash Flows (Summarized)

(Wbn)	12/16	12/17F	12/18F	12/19F
Cash Flows from Op Activities	30	122	766	871
Net Profit	123	224	323	506
Non-Cash Income and Expense	63	60	76	64
Depreciation	0	0	0	0
Amortization	0	0	0	0
Others	63	60	76	64
Chg in Working Capital	-120	-78	444	366
Chg in AR & Other Receivables	-314	91	-140	-163
Chg in Inventories	-73	-294	212	93
Chg in AP & Other Payables	118	77	369	428
Income Tax Paid	**-23**	**-71**	**-102**	**-162**
Cash Flows from Inv Activities	0	-8	-16	-19
Chg in PP&E	0	0	0	0
Chg in Intangible Assets	0	-1	-1	-1
Chg in Financial Assets	-4	-7	-16	-18
Others	**4**	**0**	**1**	**0**
Cash Flows from Fin Activities	22	-211	-36	-16
Chg in Financial Liabilities	87	-211	-36	-16
Chg in Equity	-834	0	0	0
Dividends Paid	0	0	0	0
Others	**769**	**0**	**0**	**0**
Increase (Decrease) in Cash	59	-73	714	838
Beginning Balance	37	96	23	737
Ending Balance	**96**	**23**	**737**	**1,575**

Forecasts/Valuations (Summarized)

	12/16	12/17F	12/18F	12/19F
P/E (x)	-	29.7	22.9	14.6
P/CF (x)	-	23.5	18.5	13.0
P/B (x)	-	8.5	6.2	4.3
EV/EBITDA (x)	-	32.1	17.6	10.6
EPS (W)	1,103	1,820	2,360	3,702
CFPS (W)	1,671	2,306	2,918	4,168
BPS (W)	5,787	6,383	8,742	12,444
DPS (W)	0	0	0	0
Payout ratio (%)	0.0	0.0	0.0	0.0
Dividend Yield (%)	-	0.0	0.0	0.0
Revenue Growth (%)	88.6	31.0	51.4	39.3
EBITDA Growth (%)	59.8	30.7	64.5	44.2
Operating Profit Growth (%)	59.8	30.7	64.5	44.2
EPS Growth (%)	258.1	65.0	29.7	56.9
Accounts Receivable Turnover (x)	3.6	3.1	4.4	4.2
Inventory Turnover (x)	0.5	0.6	0.9	1.4
Accounts Payable Turnover (x)	0.9	1.0	1.2	1.1
ROA (%)	6.9	10.9	13.1	15.5
ROE (%)	21.4	29.4	31.2	34.9
ROIC (%)	14.4	16.3	32.1	84.7
Liability to Equity Ratio (%)	206.4	144.3	134.4	119.9
Current Ratio (%)	170.5	194.6	191.5	195.3
Net Debt to Equity Ratio (%)	40.0	13.9	-52.7	-87.2
Interest Coverage Ratio (x)	5.5	13.4	43.5	79.2

Source: Company data, Mirae Asset Daewoo Research estimates

Celltrion, Inc. (068270 KQ)

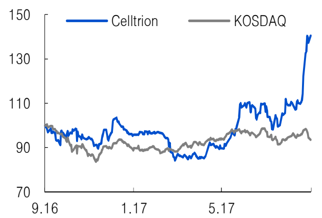
Reaping the benefits of first-mover advantage

Healthcare

(Initiate)	Buy
Target Price(12M, W)	188,000
Share Price (09/25/17, W)	146,900
Expected Return	28%

OP (17F, Wbn)	449
Consensus OP (17F, Wbn)	471
EPS Growth (17F, %)	90.5
Market EPS Growth (17F, %)	44.6
P/E (17F, x)	53.0
Market P/E (17F, x)	9.9
KOSDAQ	642.04
Market Cap (Wbn)	18,015
Shares Outstanding (mn)	123
Free Float (%)	61.5
Foreign Ownership (%)	25.9
Beta (12M)	0.65
52-Week Low	88,100
52-Week High	146,900

(%)	1M	6M	12M
Absolute	28.9	63.6	39.8
Relative	30.5	55.0	49.9



Initiate coverage with Buy and TP of W188,000

We initiate our coverage on Celltrion with a Buy rating and target price of W188,000. We derived our target price by applying a P/E of 42.5x – the median of the stock's historical band – to our 2018F EPS. We modeled our revenue estimates on Celltrion Healthcare's COGS and took into account the timing of revenue generation and inventory assets of both companies. Celltrion developed the world's first antibody biosimilar to be approved in Europe and the US. With it quick release and abundant clinical data, the company is reaping the benefits of being a first mover in the industry. A shareholders' meeting is scheduled on September 29th to vote on the company's relocation to the KOSPI. If approved, the subsequent inclusion into the KOSPI 200 will likely have a positive impact on the stock's supply and demand.

Truxima and Herzuma to support sustainable growth

We believe Celltrion is well-positioned to continue strong growth, driven by the rollout of highly competitive biosimilars. Truxima, which went on sale in Europe last April, following EMA approval in February, has been gaining rapid share in the region. Sandoz's Rituxan biosimilar has been subsequently granted approval, but with a four-month time lag. With no additional competition expected for quite some time, we think Truxima will easily be able to seize more than 60% of the market.

Things are also looking up for Herzuma. While Herzuma is the third Herceptin biosimilar to file for EMA approval, it looks likely to become the second to be authorized after Samsung Bioepis' biosimilar, as approval of Biocon/Milan's version (first to file for approval) was recently hit with setbacks, due to manufacturing issues. We are optimistic on Herzuma's approval, given Celltrion's successful track record with Remsima and Truxima.

Revenue to expand 37% CAGR through 2020

For 2017, we project revenue and operating profit to expand to W938.6bn (+40% YoY) and W449.1bn (+79.8% YoY), respectively. We expect 2018 OP margin to exceed 50%, boosted by higher utilization due to the full-fledged production of Truxima, coupled with efficiency gains in the production process. Driven by the release of Truxima and Herzuma, we see revenue and operating profit growing 37% and 53.9% CAGR, respectively, through 2020.

FY (12)	12/14	12/15	12/16	12/17F	12/18F	12/19F
Revenue (Wbn)	471	603	671	939	1,283	1,690
OP (Wbn)	201	259	250	449	696	957
OP margin (%)	42.7	43.0	37.3	47.8	54.2	56.6
NP (Wbn)	113	154	178	340	542	745
EPS (W)	960	1,286	1,456	2,773	4,206	5,511
ROE (%)	9.7	10.5	9.5	15.3	20.3	22.5
P/E (x)	37.5	62.6	73.8	53.0	34.9	26.7
P/B (x)	3.2	5.5	6.4	7.5	6.8	5.7
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0

Note: All figures are based on consolidated K-IFRS; NP refers to net profit attributable to controlling interests
Source: Company data, Mirae Asset Daewoo Research estimates

Table 7. Pipeline status

Pipeline	Original	Indication	Status	Notes
Remsima	Remicade	Autoimmune disease	Launched in Europe/US	First antibody biosimilar
Truxima	Rituxan	Oncology	Launched in Europe/ Filed for approval in the US	First oncology biosimilar
Herzuma	Herceptin	Oncology	Filed for approval in Europe/US	
CT-P13SC	Remicade	Autoimmune disease	Phase 1/3 trials	Biobetter
CT-P27	Monoclonal antibody	Infectious disease	Phase 2b trials	New Drug
CT-P16	Avastin	Oncology	Phase 1 trials	
CT-P5	Enbrel	Autoimmune disease	Preparing for pre-clinical trials	
CT-P15	Erbitux	Oncology	Preparing for pre-clinical trials	
CT-P17	Humira	Autoimmune disease	Non-clinical	
CT-P26	Antibody drug conjugation	Oncology	Non-clinical	Biobetter
CT-P25	Cell culture vaccine	Infectious disease	Under development	New Drug
CT-P24	Monoclonal antibody	Infectious disease	Under development	New Drug
CT-P19	Monoclonal antibody	Infectious disease	Under development	New Drug
CT-P14	Synagis	Infectious disease	Under development	

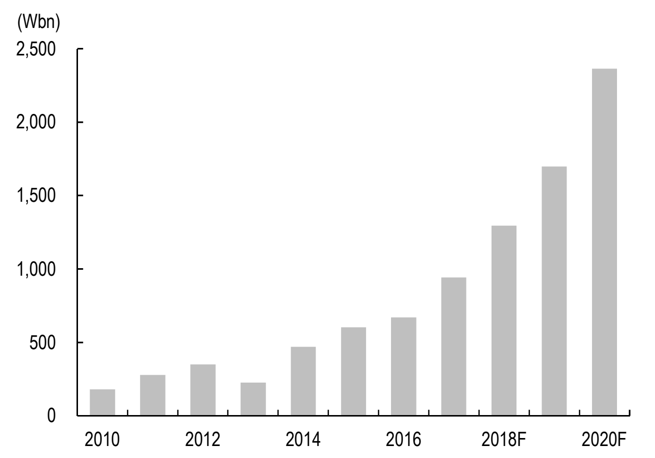
Source: Company data, Mirae Asset Daewoo Research

Table 8. Pipeline development status

Original	Drug maker	Product name	Clinical phase	Notes
Remicade	Celltrion	Remsima/Inflectra	Approved	Released in US, Europe, & Korea
	Samsung Bioepis	Flixabi/Renflexis	Approved	Released in Europe in Sep. 2016/ Approved in US in Apr. 2017
	Sandoz	PF-06438179	Phase 3 trials completed	Filed for EMA approval in May 2017/ US Phase 1 trials
	Pfizer	PF-06438179	Phase 3 trials completed	US Phase 3 trials
	Ranbaxy/Epirus	BOW015	Phase 3 trials	
Rituxan	Celltrion	Truxima	Released	Approved in Europe in Feb 2017/Filed for US approval in Jun 2017
	Sandoz	Rixathon	Released	Approved in Europe in Jun. 2017/Filed for US approval in Sep. 2017
	Amgen	ABP 798	Phase 3 trials	
	Pfizer	PF-05280586	Phase 3 trials	Patent litigation with Genentech
	Boehringer Ingelheim	BI 695500	Phase 3 trials	Development suspended in Oct. 2015
Herceptin	Samsung Bioepis	SB3	Filed for approval	Received positive CHMP opinion from EMA in Sep. 2017
	Celltrion	Herzuma (CT-P6)	Approved	Filed for EMA approval in Oct 2016/Filed for US approval in Jul 2017
	Actavis(Allergan)/Amgen	ABP-980	Approved	Filed for EMA approval in Mar. 2017/Filed for US approval in Jul. 2017
	Biocon/Mylan	Hercules (Myl-1401O)	Phase 3 trials	Europe application withdrawn/US FDA under review
	Pfizer/Hospira	PF-05280014	Phase 3 trials	

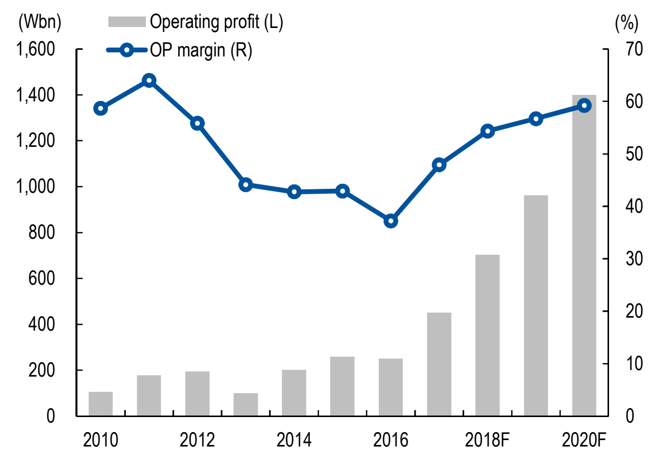
Source: Mirae Asset Daewoo Research

Figure 50. Revenue trend



Source: Company data, Mirae Asset Daewoo Research

Figure 51. OP and OP margin trends



Source: Company data, Mirae Asset Daewoo Research

Celltrion, Inc. (068270 KQ/Buy/TP: W188,000)

Comprehensive Income Statement (Summarized)

(Wbn)	12/16	12/17F	12/18F	12/19F
Revenue	**671**	**939**	**1,283**	**1,690**
Cost of Sales	**274**	**328**	**411**	**539**
Gross Profit	**397**	**611**	**872**	**1,151**
SG&A Expenses	**147**	**161**	**177**	**194**
Operating Profit (Adj)	**250**	**449**	**696**	**957**
Operating Profit	**250**	**449**	**696**	**957**
Non-Operating Profit	**-21**	**-13**	**-1**	**0**
Net Financial Income	-11	-8	-6	-3
Net Gain from Inv in Associates	1	0	0	0
Pretax Profit	229	436	695	957
Income Tax	49	92	146	202
Profit from Continuing Operations	180	345	549	755
Profit from Discontinued Operations	0	0	0	0
Net Profit	180	345	549	755
Controlling Interests	178	340	542	745
Non-Controlling Interests	2	5	7	10
Total Comprehensive Profit	**178**	**345**	**549**	**755**
Controlling Interests	176	340	542	745
Non-Controlling Interests	2	5	8	10
EBITDA	338	538	786	1,048
FCF (Free Cash Flow)	237	200	179	306
EBITDA Margin (%)	50.4	57.3	61.3	62.0
Operating Profit Margin (%)	37.3	47.8	54.2	56.6
Net Profit Margin (%)	26.5	36.2	42.2	44.1

Statement of Financial Condition (Summarized)

(Wbn)	12/16	12/17F	12/18F	12/19F
Current Assets	**1,254**	**1,621**	**2,137**	**2,855**
Cash and Cash Equivalents	268	336	401	586
AR & Other Receivables	758	948	1,296	1,707
Inventories	185	200	273	359
Other Current Assets	43	137	167	203
Non-Current Assets	**1,768**	**1,780**	**1,802**	**1,831**
Investments in Associates	6	10	13	18
Property, Plant and Equipment	868	870	876	884
Intangible Assets	848	851	857	866
Total Assets	**3,022**	**3,401**	**3,939**	**4,685**
Current Liabilities	**610**	**592**	**583**	**576**
AP & Other Payables	35	51	70	92
Short-Term Financial Liabilities	471	431	400	368
Other Current Liabilities	104	110	113	116
Non-Current Liabilities	**213**	**265**	**263**	**261**
Long-Term Financial Liabilities	208	256	254	252
Other Non-Current Liabilities	5	9	9	9
Total Liabilities	**823**	**857**	**846**	**837**
Controlling Interests	**2,054**	**2,394**	**2,936**	**3,680**
Capital Stock	117	122	129	136
Capital Surplus	748	748	748	748
Retained Earnings	1,169	1,503	2,038	2,776
Non-Controlling Interests	**145**	**150**	**157**	**168**
Stockholders' Equity	**2,199**	**2,544**	**3,093**	**3,848**

Cash Flows (Summarized)

(Wbn)	12/16	12/17F	12/18F	12/19F
Cash Flows from Op Activities	251	243	225	354
Net Profit	180	345	549	755
Non-Cash Income and Expense	189	188	241	296
Depreciation	40	40	40	41
Amortization	49	49	49	50
Others	100	99	152	205
Chg in Working Capital	-74	-198	-419	-495
Chg in AR & Other Receivables	-96	-190	-348	-411
Chg in Inventories	5	-15	-73	-86
Chg in AP & Other Payables	16	14	13	15
Income Tax Paid	**-45**	**-92**	**-146**	**-202**
Cash Flows from Inv Activities	-162	-167	-111	-118
Chg in PP&E	-14	-43	-46	-49
Chg in Intangible Assets	-164	-52	-55	-58
Chg in Financial Assets	10	-79	-17	-19
Others	**6**	**7**	**7**	**8**
Cash Flows from Fin Activities	29	-5	-46	-47
Chg in Financial Liabilities	-132	8	-33	-35
Chg in Equity	100	0	0	0
Dividends Paid	0	0	0	0
Others	**61**	**-13**	**-13**	**-12**
Increase (Decrease) in Cash	118	67	65	186
Beginning Balance	150	268	336	401
Ending Balance	**268**	**336**	**401**	**586**

Forecasts/Valuations (Summarized)

	12/16	12/17F	12/18F	12/19F
P/E (x)	73.8	53.0	34.9	26.7
P/CF (x)	35.5	33.8	23.9	18.9
P/B (x)	6.4	7.5	6.8	5.7
EV/EBITDA (x)	38.6	34.3	23.3	17.3
EPS (W)	1,456	2,773	4,206	5,511
CFPS (W)	3,023	4,346	6,137	7,777
BPS (W)	16,794	19,537	21,726	25,940
DPS (W)	0	0	0	0
Payout ratio (%)	0.0	0.0	0.0	0.0
Dividend Yield (%)	0.0	0.0	0.0	0.0
Revenue Growth (%)	11.3	39.9	36.6	31.7
EBITDA Growth (%)	-0.9	59.2	46.1	33.3
Operating Profit Growth (%)	-3.5	79.6	55.0	37.5
EPS Growth (%)	13.2	90.5	51.7	31.0
Accounts Receivable Turnover (x)	0.9	1.1	1.1	1.1
Inventory Turnover (x)	3.2	4.9	5.4	5.3
Accounts Payable Turnover (x)	20.8	11.7	9.9	9.7
ROA (%)	6.3	10.7	15.0	17.5
ROE (%)	9.5	15.3	20.3	22.5
ROIC (%)	7.9	13.3	18.4	21.8
Liability to Equity Ratio (%)	37.4	33.7	27.4	21.8
Current Ratio (%)	205.5	273.8	366.4	495.3
Net Debt to Equity Ratio (%)	18.3	10.5	5.2	-1.9
Interest Coverage Ratio (x)	17.7	34.8	54.9	79.5

Source: Company data, Mirae Asset Daewoo Research estimates

Samsung Biologics (207940 KS)

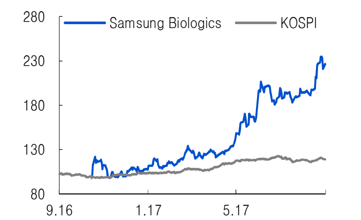
Biotech giant still growing

Healthcare

(Initiate)	Buy
Target Price(12M, W)	400,000
Share Price (09/25/17, W)	326,000
Expected Return	23%

OP (17F, Wbn)	6
Consensus OP (17F, Wbn)	9
EPS Growth (17F, %)	-
Market EPS Growth (17F, %)	44.6
P/E (17F, x)	-
Market P/E (17F, x)	9.9
KOSPI	2,380.40
Market Cap (Wbn)	21,570
Shares Outstanding (mn)	66
Free Float (%)	21.8
Foreign Ownership (%)	9.7
Beta (12M)	1.24
52-Week Low	142,000
52-Week High	338,000

(%)	1M	6M	12M
Absolute	16.4	73.9	-
Relative	16.3	58.4	-



Initiate coverage with Buy and TP of W390,000

We initiate our coverage on Samsung Biologics with a Buy rating and target price of W390,000. We derived our target price by summing up the values of the firm's operations (W224,000) and subsidiary Samsung Bioepis (W166,000). The operating value was calculated based on a P/E of 30x (20% premium to our target P/E for coverage top-tier pharmas) and the present value of 2023F (a year when the third plant is expected to operate at full capacity) net profit. For the value of Samsung Bioepis, we applied a P/E of 36x (12-month forward P/E of Celltrion over the past year) to the present value of its six pipeline drugs. To derive the operating value, we used our net profit forecast for 2023, in light of a likely increase in the firm's earnings visibility by that year. After having already secured enough orders to fully utilize its second plant (with a CMO capacity of 180,000 liters), we believe that the firm should be able to gain sufficient orders for its soon-to-be completed third plant (150,000 liters) driven by strong demand for biologics CMO.

Scale advantage

Samsung Biologics, which ranks first in capacity (180,000 liters) in the global biologics CMO market, is currently building its third production plant. Once the plant comes online, Samsung Biologics' production capacity will rise to 360,000 liters, the largest in the world for a biologics CMO. We thus believe that the firm will benefit greatly from: 1) the ongoing expansion of the biologics CMO market, fueled by releases of new biologics; 2) the take-off of the biosimilar market; and 3) pharmas' growing dependence on production through CMOs. Regarding concerns over potential capacity ramp-up by rivals Boehringer Ingelheim and Lonza, we note that their plants are 20 to 30 years old (with low production yields) and scattered across different regions (e.g., Europe, the US, Asia), putting the firm at a disadvantage in terms of mass production. We believe that Samsung Biologics holds the upper hand over the aforementioned peers, thanks to its advanced 360,000-liter-capacity plant located in Songdo. Notably, after the acquisition of big pharmas BMS and Roche as key customers, the company signed a CMO contract with Janssen subsidiary Cilag at end-2016, which we believe also confirmed its competitive edge in production capability and quality control.

Subsidiary Samsung Bioepis deserves attention

Samsung Biologics' subsidiary, Samsung Bioepis (a biosimilar developer), also deserves attention. Samsung Bioepis developed the world's first Enbrel biosimilar, which has garnered over 30% market share in some countries since its release in Europe. The firm is also expected to launch the world's first Herceptin biosimilar, as approval of Biocon/Mylan's version (first to file for approval) has been delayed, due to manufacturing issues. In addition, the company has released the world's second Remicade biosimilar following Celltrion. The company is also moving rapidly to launch Lantus, Humira, and Avastin biosimilars. Given that its marketing partners are Merck and Biogen, we expect the company's biosimilar products to fare well.

FY (12)	12/14	12/15	12/16	12/17F	12/18F	12/19F
Revenue (Wbn)	29	91	295	355	552	787
OP (Wbn)	-81	-204	-30	6	70	239
OP Margin (%)	-279.3	-224.2	-10.2	1.7	12.7	30.4
NP (Wbn)	-28	1,905	-177	-110	43	210
EPS (W)	-818	38,489	-3,113	-1,665	651	3,171
ROE (%)	-4.5	107.4	-5.2	-2.7	1.1	5.1
P/E (x)	-	-	-	-	500.4	102.8
P/B (x)	-	-	2.4	5.4	5.4	5.1
Dividend Yield (%)	-	-	0.0	0.0	0.0	0.0

Note: All figures are based on consolidated K-IFRS; NP refers to net profit attributable to controlling interests
Source: Company data, Mirae Asset Daewoo Research estimates

Table 9. Valuation (Wbn, x, 1,000 shares, W)

	Fair value	Details
Samsung Biologics	15,329.6	
Present value of 2023F net profit	511.0	Third plant expected to operate at full capacity in 2013 (equity method gains excluded)
Target P/E	30.0	20% premium to our target P/E of 25x for top-tier companies in our coverage
Samsung Bioepis	11,033.7	
Present value of 2023F net profit	306.5	
Target P/E	36.0	12-month forward P/E of Celltrion over the past year
Fair market capitalizations	26,363.3	
No. of shares	66,165.0	1,000 shares
Fair price	398,448	W
Target price	400,000	W

Source: Mirae Asset Daewoo Research

Table 10. Pipelines of Samsung Bioepis

Project	Reference drug	Indication	Phase
SB4 (Benepali)	Enbrel	Rheumatoid arthritis	Launched in EU
SB2 (Flixabi)	Remicade	Rheumatoid arthritis	Launched in EU/US
SB9 (Lusduna)	Lantus	Diabetes Mellitus	Approved in EU/US (tentative)
SB3	Herceptin	Breast cancer	BLA submitted in EU
SB5 (Imraldi)	Humira	Rheumatoid arthritis	BLA submitted in EU
SB8	Avastin	Colorectal cancer	Phase3
SB11	Lucentis	Macular degeneration	Phase3
SAIT101	Rituxan	Anti-cancer	Phase1/3

Source: Samsung Biologics, Mirae Asset Daewoo Research

Table 11. Sales forecast of Samsung Bioepis (US$mn, %)

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Herceptin													
Global market (US$mn)	7,052	7,242	7,220	7,047	7,400	8,069	7,993	7,854	7,462	7,088	6,734	6,397	6,077
Growth (%)	4	3	0	-2	5	9	-1	-2	-5	-5	-5	-5	-5
Outside US	4,443	4,443	4,216	4,406	4,675	4,979	4,730	4,493	4,269	4,055	3,852	3,660	3,477
Growth (%)	3	0	-5	5	6	7	-5	-5	-5	-5	-5	-5	-5
Biosimilar market share			7	28	41	51	51	51	51	51	51	51	51
Biosimilar sales			307	1,213	1,934	2,561	2,432	2,311	2,195	2,086	1,981	1,882	1,788
Bioepis' partners' share			80	60	40	35	33	31	29	27	25	23	21
Bioepis' partners' sales			245	728	774	896	803	716	637	563	495	433	376
US	2,609	2,799	3,004	2,640	2,725	3,090	3,263	3,361	3,193	3,033	2,882	2,737	2,601
Growth (%)	5	7	7	-12	3	13	6	3	-5	-5	-5	-5	-5
Biosimilar market share				2	7	28	41	51	51	51	51	51	51
Biosimilar sales				53	198	851	1,350	1,728	1,642	1,560	1,482	1,408	1,337
Bioepis' partners' share				25	25	25	24	23	22	21	20	19	18
Bioepis' partners' sales				13	50	213	324	398	361	328	296	267	241
Humira													
Global market (US$mn)	16,078	18,422	19,676	20,366	21,090	21,850	21,371	19,203	19,359	20,977	21,617	21,882	20,788
Growth (%)	15	15	7	4	4	4	-2	-10	1	8	3	1	-5
Outside US	5,646	5,883	5,883	5,883	5,883	5,883	5,883	5,589	5,310	5,044	4,792	4,552	4,325
Growth (%)	1	4	0	0	0	0	0	-5	-5	-5	-5	-5	-5
Biosimilar market share			2	7	28	41	51	51	51	51	51	51	51
Biosimilar sales			118	428	1,620	2,434	3,026	2,874	2,731	2,594	2,464	2,341	2,224
Bioepis' partners' share			25	25	25	25	24	24	23	23	22	22	21
Bioepis' partners' sales			29	107	405	596	726	675	628	584	542	503	467
US	10,432	12,539	13,793	14,483	15,207	15,967	15,488	13,614	14,050	15,933	16,825	17,330	16,463
Growth (%)	24	20	10	5	5	5	-3	-12	3	13	6	3	-5
Biosimilar market share							2	4	7	28	41	51	51
Biosimilar sales							310	488	1,022	4,388	6,962	8,912	8,467
Bioepis' partners' share							25	25	25	25	24	24	23
Bioepis' partners' sales							77	122	255	1,075	1,671	2,094	1,947
Lantus													
Global market (US$mn)	6,343	5,117	5,308	5,782	6,057	6,248	6,134	6,032	5,943	5,865	5,798	5,743	5,698
Growth (%)	-11	-19	4	9	5	3	-2	-2	-1	-1	-1	-1	-1
Outside US	2,427	2,063	2,156	2,208	2,283	2,360	2,440	2,523	2,609	2,698	2,790	2,884	2,983
Growth (%)	-8	-15	5	2	3	3	3	3	3	3	3	3	3
Biosimilar market share	3	7	28	41	51	51	51	51	51	51	51	51	51
Biosimilar sales	70	150	594	913	1,174	1,214	1,255	1,298	1,342	1,387	1,435	1,483	1,534
Bioepis' partners' share			5	10	15	20	20	20	19	18	17	16	15
Bioepis' partners' sales			30	91	176	243	251	260	255	250	244	237	230
US	3,916	3,054	3,152	3,575	3,775	3,888	3,694	3,509	3,334	3,167	3,008	2,858	2,715
Growth (%)	-12	-22	3	13	6	3	-5	-5	-5	-5	-5	-5	-5
Biosimilar market share	0	4	7	28	41	51	51	51	51	51	51	51	51
Biosimilar sales	16	109	229	984	1,562	2,000	1,900	1,805	1,714	1,629	1,547	1,470	1,396
Bioepis' partners' share					5	10	15	20	20	20	19	18	17
Bioepis' partners' sales					78	200	285	361	343	326	294	265	237

Source: Mirae Asset Daewoo Research

Table 12. Sales forecast of Samsung Bioepis (US$mn, %)

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Avastin													
Global market (US$mn)	7,053	6,815	6,703	6,687	6,197	6,184	6,402	6,726	7,029	7,077	6,723	6,387	6,068
Growth (%)	1	-3	-2	0	-7	0	4	5	5	1	-5	-5	-5
Outside US	3,971	3,733	3,621	3,512	3,407	3,305	3,136	3,277	3,477	3,703	3,518	3,342	3,175
Growth (%)	5	-6	-3	-3	-3	-3	-5	5	6	7	-5	-5	-5
Biosimilar market share							7	28	41	51	51	51	51
Biosimilar sales							228	903	1,439	1,904	1,809	1,719	1,633
Bioepis' partners' share							25	25	25	24	23	22	21
Bioepis' partners' sales							57	226	360	457	416	378	343
US	3,082	3,082	3,082	3,174	2,790	2,880	3,266	3,448	3,552	3,374	3,206	3,045	2,893
Growth (%)	-3	0	0	3	-12	3	13	6	3	-5	-5	-5	-5
Biosimilar market share				2	4	7	28	41	51	51	51	51	51
Biosimilar sales				63	100	209	899	1,427	1,827	1,735	1,649	1,566	1,488
Bioepis' partners' share				0	3	5	8	10	15	15	15	14	13
Bioepis' partners' sales				0	3	10	72	143	274	260	247	219	193
Enbrel													
Global market (US$mn)	9,234	9,168	9,164	9,234	9,338	8,972	8,622	8,286	7,964	7,656	7,360	7,076	6,804
Growth (%)	2	-1	0	1	1	-4	-4	-4	-4	-4	-4	-4	-4
Outside US	3,515	3,620	3,783	4,014	4,275	4,061	3,858	3,665	3,482	3,308	3,143	2,985	2,836
Growth (%)	-11	3	5	6	7	-5	-5	-5	-5	-5	-5	-5	-5
Biosimilar market share	3	7	28	41	51	51	51	51	51	51	51	51	51
Biosimilar sales	100	264	1,040	1,662	2,197	2,088	1,983	1,884	1,790	1,700	1,615	1,535	1,458
Bioepis' partners' share	100	100	70	70	70	68	66	64	62	60	58	56	54
Bioepis' partners' sales	100	264	728	1,163	1,538	1,420	1,309	1,206	1,110	1,020	937	859	787
Remicade													
Global market (US$mn)	8,829	8,486	8,897	9,261	9,326	9,280	8,816	8,375	7,957	7,559	7,181	6,822	6,481
Growth (%)	-2	-4	5	4	1	0	-5	-5	-5	-5	-5	-5	-5
Outside US	3,987	4,230	4,505	4,280	4,066	3,863	3,669	3,486	3,312	3,146	2,989	2,839	2,697
Growth (%)	-12	6	7	-5	-5	-5	-5	-5	-5	-5	-5	-5	-5
Biosimilar market share	30	41	51	51	51	51	51	51	51	51	51	51	51
Biosimilar sales	1,196	1,751	2,316	2,200	2,090	1,985	1,886	1,792	1,702	1,617	1,536	1,459	1,386
Bioepis' partners' share		1	3	5	7	9	10	10	10	10	10	10	10
Bioepis' partners' sales		17	67	101	132	157	160	147	134	123	112	102	93
US	4,842	4,256	4,392	4,981	5,260	5,418	5,147	4,889	4,645	4,413	4,192	3,982	3,783
Growth (%)	9	-12	3	13	6	3	-5	-5	-5	-5	-5	-5	-5
Biosimilar market share		3	4	7	28	41	51	51	51	51	51	51	51
Biosimilar sales		106	158	364	1,446	2,243	2,645	2,513	2,387	2,268	2,155	2,047	1,945
Bioepis' partners' share		3	10	15	20	25	25	25	24	23	22	21	20
Bioepis' partners' sales		3	14	41	188	336	397	377	332	292	256	224	194

Source: Mirae Asset Daewoo Research

Table 13. Pipelines of peer companies

Reference drug	Company	Name	Phase	Notes
Enbrel	Samsung Bioepis	Brenzys/Benepali	Approved	EU launch (01/16)
	Sandoz	Erelzi	Approved	EU approval (06/17), US approval (08/16)
	Coherus BioSciences	CHS-0214	Phase3	Patent litigation with Amgen
Remicade	Celltrion	Remsima/Inflectra	Approved	EU/US/KOR Launch
	Samsung Bioepis	Flixabi/Renflexis	Approved	EU launch (09/16), US approval (04/17)
	Sandoz	PF-06438179	Phase3 completed	Applied for approval in EU (05/17), Phase 1 in US
	Pfizer	PF-06438179	Phase3 completed	Phase 3 in US
	Ranbaxy/Epirus	BOW015	Phase3	
Herceptin	Samsung Bioepis	SB3	Applied for approval	CHMP recommendation (09/17)
	Celltrion	Herzuma (CT-P6)	Approved	Applied for approval in EU (10/16), applied for approval in US (07/17)
	Actavis(Allergan)/Amgen	ABP-980	Approved	Applied for approval in EU (03/17), applied for approval in US (07/17)
	Biocon/Mylan	Hercules (Myl-1401O)	Phase3	Approval withdrawal in EU, FDA in review
	Pfizer/Hospira	PF-05280014	Phase3	
Lantus	Eli Lilly	Abasaglar/ Basaglar	Approved	EU/US launch
	Samsung Bioepis/Merck	Lusduna	Approved	EU approval, US tentative approval (07/17)
Humira	Amgen	Amjevita	Approved	EU approval (03/17), US approval (09/16)
	Samsung Bioepis	Imraldi	Approved	EU approval (08/17)
	Boehringer Ingelheim	Cyltezo	Approved	Applied for approval in EU (01/17), US approval (08/17)
	Sandoz	GP2017	Approved	Applied for approval in EU (05/17), Phase 3 in US
	Pfizer	PF-06410293	Phase3	
	Momenta	M923	Phase3 completed	
	Baxalta (Shire)	M923	Phase3	
	Coherus	CHS-1420	Phase3	
	Merck KGaA	MSB11022	Phase3	
Avastin	Amgen/Allergan	ABP 215	Approved	Applied for approval in EU (12/16), US approval (09/17)
	Boehringer Ingelheim	BI 695502	Phase3 completed	
	Pfizer	PF-06439535	Phase3	
	Samsung Bioepis	SB8	Phase3	

Source: Mirae Asset Daewoo Research

Samsung Biologics (207940 KS/Buy/TP: W400,000)

Comprehensive Income Statement (Summarized)

(Wbn)	12/16	12/17F	12/18F	12/19F
Revenue	**295**	**355**	**552**	**787**
Cost of Sales	**268**	**287**	**414**	**472**
Gross Profit	**27**	**68**	**138**	**315**
SG&A Expenses	**57**	**61**	**68**	**76**
Operating Profit (Adj)	**-30**	**6**	**70**	**239**
Operating Profit	**-30**	**6**	**70**	**239**
Non-Operating Profit	**-201**	**-144**	**-15**	**30**
Net Financial Income	-16	-9	-14	-17
Net Gain from Inv in Associates	-129	-140	0	47
Pretax Profit	-231	-138	55	269
Income Tax	-54	-28	12	59
Profit from Continuing Operations	-177	-110	43	210
Profit from Discontinued Operations	0	0	0	0
Net Profit	-177	-110	43	210
Controlling Interests	-177	-110	43	210
Non-Controlling Interests	0	0	0	0
Total Comprehensive Profit	**-177**	**-110**	**43**	**210**
Controlling Interests	-177	-110	43	210
Non-Controlling Interests	0	0	0	0
EBITDA	30	67	131	301
FCF (Free Cash Flow)	-226	-234	-26	165
EBITDA Margin (%)	10.2	18.9	23.7	38.2
Operating Profit Margin (%)	-10.2	1.7	12.7	30.4
Net Profit Margin (%)	-60.0	-31.0	7.8	26.7

Statement of Financial Condition (Summarized)

(Wbn)	12/16	12/17F	12/18F	12/19F
Current Assets	**1,461**	**980**	**615**	**632**
Cash and Cash Equivalents	230	664	222	156
AR & Other Receivables	72	82	94	109
Inventories	164	205	257	321
Other Current Assets	995	29	42	46
Non-Current Assets	**6,072**	**6,443**	**6,838**	**7,184**
Investments in Associates	4,944	5,093	5,398	5,722
Property, Plant and Equipment	1,091	1,313	1,398	1,417
Intangible Assets	14	15	17	18
Total Assets	**7,533**	**7,423**	**7,452**	**7,817**
Current Liabilities	**2,477**	**2,537**	**2,533**	**2,545**
AP & Other Payables	115	156	243	349
Short-Term Financial Liabilities	2,278	2,301	2,211	2,120
Other Current Liabilities	84	80	79	76
Non-Current Liabilities	**974**	**913**	**904**	**1,046**
Long-Term Financial Liabilities	439	389	389	539
Other Non-Current Liabilities	535	524	515	507
Total Liabilities	**3,451**	**3,451**	**3,437**	**3,592**
Controlling Interests	**4,082**	**3,972**	**4,015**	**4,225**
Capital Stock	165	165	165	165
Capital Surplus	2,487	2,487	2,487	2,487
Retained Earnings	1,425	1,315	1,358	1,567
Non-Controlling Interests	**0**	**0**	**0**	**0**
Stockholders' Equity	**4,082**	**3,972**	**4,015**	**4,225**

Cash Flows (Summarized)

(Wbn)	12/16	12/17F	12/18F	12/19F
Cash Flows from Op Activities	-63	44	115	241
Net Profit	-177	-110	43	210
Non-Cash Income and Expense	211	178	90	94
Depreciation	56	56	56	57
Amortization	4	5	5	6
Others	151	117	29	31
Chg in Working Capital	-74	-43	9	13
Chg in AR & Other Receivables	-29	-8	-11	-13
Chg in Inventories	-44	-41	-51	-64
Chg in AP & Other Payables	1	1	2	4
Income Tax Paid	**0**	**28**	**-12**	**-59**
Cash Flows from Inv Activities	-1,373	706	-163	-88
Chg in PP&E	-163	-278	-141	-75
Chg in Intangible Assets	-5	-6	-6	-7
Chg in Financial Assets	-1,008	1,003	-11	-2
Others	**-197**	**-13**	**-5**	**-4**
Cash Flows from Fin Activities	1,631	-28	-90	59
Chg in Financial Liabilities	205	-28	-90	59
Chg in Equity	1,484	0	0	0
Dividends Paid	0	0	0	0
Others	**-58**	**0**	**0**	**0**
Increase (Decrease) in Cash	196	434	-442	-66
Beginning Balance	35	230	664	222
Ending Balance	**230**	**664**	**222**	**156**

Forecasts/Valuations (Summarized)

	12/16	12/17F	12/18F	12/19F
P/E (x)	-	-	500.4	102.8
P/CF (x)	247.4	315.6	162.0	71.0
P/B (x)	2.4	5.4	5.4	5.1
EV/EBITDA (x)	386.6	352.9	182.3	79.8
EPS (W)	-3,113	-1,665	651	3,171
CFPS (W)	610	1,033	2,012	4,589
BPS (W)	61,700	60,035	60,687	63,858
DPS (W)	0	0	0	0
Payout ratio (%)	0.0	0.0	0.0	0.0
Dividend Yield (%)	0.0	0.0	0.0	0.0
Revenue Growth (%)	224.2	20.3	55.5	42.6
EBITDA Growth (%)	-	123.3	95.5	129.8
Operating Profit Growth (%)	-	-	1,066.7	241.4
EPS Growth (%)	-	-	-	387.1
Accounts Receivable Turnover (x)	5.8	5.0	6.9	8.6
Inventory Turnover (x)	2.1	1.9	2.4	2.7
Accounts Payable Turnover (x)	285.3	134.9	107.9	68.4
ROA (%)	-2.6	-1.5	0.6	2.7
ROE (%)	-5.2	-2.7	1.1	5.1
ROIC (%)	-2.2	0.4	2.7	11.5
Liability to Equity Ratio (%)	84.5	86.9	85.6	85.0
Current Ratio (%)	59.0	38.6	24.3	24.9
Net Debt to Equity Ratio (%)	36.8	51.0	59.0	59.0
Interest Coverage Ratio (x)	-1.6	0.3	3.6	12.4

Source: Company data, Mirae Asset Daewoo Research estimates

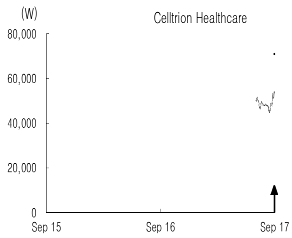
APPENDIX 1

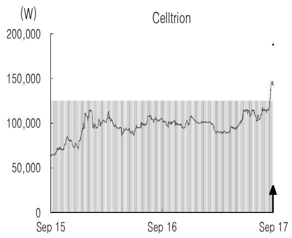
Important Disclosures & Disclaimers

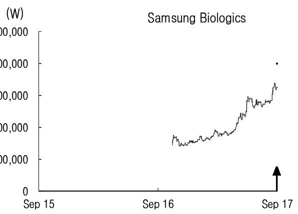
2-Year Rating and Target Price History

Company (Code)	Date	Rating	Target Price
Celltrion Healthcare (091990)	09/25/2017	Buy	71,000
Celltrion (068270)	09/25/2017	Buy	188,000
	08/06/2013	No Coverage	

Company (Code)	Date	Rating	Target Price
Samsung Biologics(207940)	09/25/2017	Buy	400,000







Stock Ratings	
Buy	: Relative performance of 20% or greater
Trading Buy	: Relative performance of 10% or greater, but with volatility
Hold	: Relative performance of -10% and 10%
Sell	: Relative performance of -10%

Industry Ratings	
Overweight	: Fundamentals are favorable or improving
Neutral	: Fundamentals are steady without any material changes
Underweight	: Fundamentals are unfavorable or worsening

Ratings and Target Price History (Share price (—), Target price (▬), Not covered (■), Buy (▲), Trading Buy (■), Hold (●), Sell (◆))
* Our investment rating is a guide to the relative return of the stock versus the market over the next 12 months.
* Although it is not part of the official ratings at Mirae Asset Daewoo Co., Ltd., we may call a trading opportunity in case there is a technical or short-term material development.
* The target price was determined by the research analyst through valuation methods discussed in this report, in part based on the analyst's estimate of future earnings.
* The achievement of the target price may be impeded by risks related to the subject securities and companies, as well as general market and economic conditions.

Equity Ratings Distribution & Investment Banking Services

	Buy	Trading Buy	Hold	Sell
Equity Ratings Distribution	69.67%	17.06%	13.27%	0.00%
Investment Banking Services	70.73%	17.07%	12.20%	0.00%

* Based on recommendations in the last 12-months (as of June 30, 2017)

Disclosures
We managed the IPO of Celltrion Healthcare with one year.

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