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Pharmaceutical/Biotech

Tailwinds picking up

Overweight (Maintain)

Industry Report
May 15, 2017

Mirae Asset Daewoo Co., Ltd.

[Pharmaceutical/biotech]

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Shares to rise in 2H17 on various pipeline events

We maintain our view that shares will rise gradually in 2H17. However, we think the share rally in 2H will differ from that of 2015 in two respects. First, while Hanmi Pharmaceutical's massive out-licensing deals were the main catalyst in 2015, we think the primary driver this time will be a number of small/mid-sized licensing agreements. Second, unlike in 2015, when stocks—led by Hanmi—rallied across the pharmaceutical/biotech sector, we believe that share performance in 2H17 will be more differentiated, with R&D progress being the key variable. In 2H17, we recommend overweighting small/mid-sized biotech stocks, rather than large pharmas, as we expect major pipeline events to be concentrated in the small/mid-sized biotech space. We also advise buying into a basket of biotech stocks expected to deliver pipeline events.

Korean firms on leading edge of R&D

Korean firms have demonstrated their competitive R&D capabilities by attracting large-scale licensing deals. Since 2015, multinational pharmaceutical companies have inked a total of 10 licensing deals outside the US and Europe valued at more than W300bn, with six of them being with Korean firms (two of the deals were in Japan, one was in China, and one in India). In the chemical drug space, Korean firms have demonstrated strength in developing new "me-too" (generic) drugs, while exhibiting global top-tier capabilities in stem cell therapies and botulinum toxins in the bio space. When it comes to biosimilars, Celltrion and Samsung are taking the lead, while developmental progress is expected in the gene therapy and biobetter segments. Overall, we are optimistic on the outlook for Korean pharmaceutical and biotech firms.

Stocks to watch: Genexine, LegoChem Biosciences, Oscotec, etc.

We think a wide range of R&D achievements could materialize in 2H17, given the growth slowdown facing many global pharmas, the enhanced technologies of domestic pharmas, and dwindling drug pipelines. Key pipelines to watch include: 1) Genexine's long-acting growth hormone, GX-H9; 2) LegoChem Biosciences' antibody-drug conjugates (ADC) platform technology; 3) Oscotec's rheumatoid arthritis treatment, SKI-O-703; 4) Qurient's atopic dermatitis treatment, Q301; 5) Peptron's long-acting platform technology; 6) Kolon Life Science's osteoarthritis drug, Invossa; and 7) SK Biopharm's epilepsy treatment, YKP3089, and sleep disorder drug, SKL-N05.

Table 1. Pipelines to watch in 2H17

Company	Pipeline	Indication	Phase
Genexine	GX-H9	Growth hormone deficiencies	Phase 2 in Europe
	GX-188E	Pre-cancerous cervical disease	Phase 2 in Europe
LegoChem	ADC	Cancer	Development
	LCB10-0200	Antibiotics	Phase 1 in US
Oscotec	SKI-O-703	Rheumatoid arthritis	Phase 1 in US
Qurient	Q301	Atopic dermatitis	Completed Phase 2A in US
Peptron	Long-acting therapeutics	Diabetes/obesity	Non-clinical
Kolon Life Science	Invossa	Osteoarthritis	Completed Phase 3 in Korea; preparing Phase 3 in US
SK Biopharm	YKP3089	Epilepsy	Phase 3 in US
	SKL-N05	Sleep disorder	Phase 3 in US
Chong Kun Dang	CKD-519	Dyslipidemia	Phase 2 in Australia

Source: Mirae Asset Daewoo Research

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I. Hit bottom

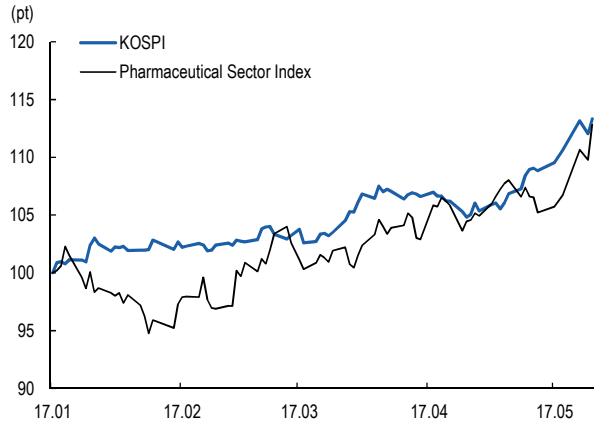
Shares picking up on positive news; sentiment improves

The decline in pharmaceutical/biotech shares arising from the failures of top-tier firms' clinical trials appears to have come to an end. Based on May 12th closing prices, the pharmaceutical index has climbed by 12.2% since the beginning of the year, in line with the KOSPI (+12.8%). Since February, the index has risen 15.3%, outperforming the KOSPI (+9.9%).

The robust performance of pharmaceutical/biotech shares are attributable to: 1) valuation merits stemming from the excessive share price decline; 2) positive news on individual stocks (Kolon Life Science's out-licensing contract over Invossa (degenerative arthritis treatment), Genexine's superior clinical data on continuous growth hormone, and the acquisition of Hugel by Bain Capital; 3) top-tier firms' higher-than-expected 1Q earnings results, and expectations for out-licensing deals in 2H.

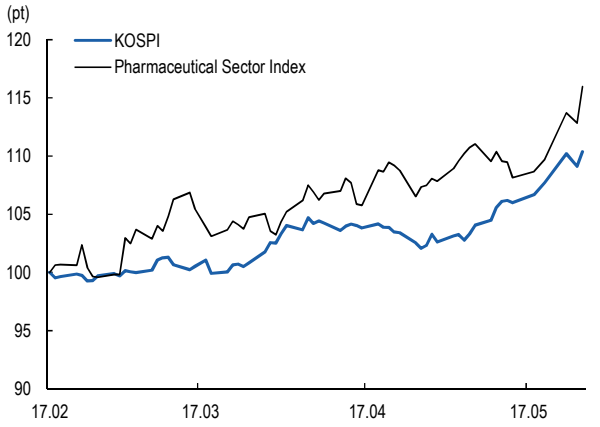
The fact that some shares have been picking up sharply on positive news indicates that the worst is over. In 2H16, pharmaceutical/biotech shares declined, even with the announcement of large-scale out-licensing deals. Recently, however, shares of Sillajen, Genexine, Kolon Life Science, and Hanmi Pharmaceutical have surged on announcements of positive news. We believe investor sentiment has definitely turned for the better.

Figure 1. Since January, pharmaceutical index has moved in line with KOSPI



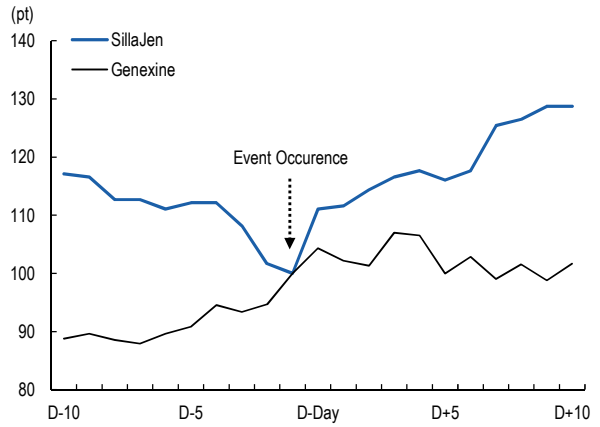
Source: FnGuide, Mirae Asset Daewoo Research

Figure 2. Since February, pharmaceutical index has outperformed KOSPI by 5.4%



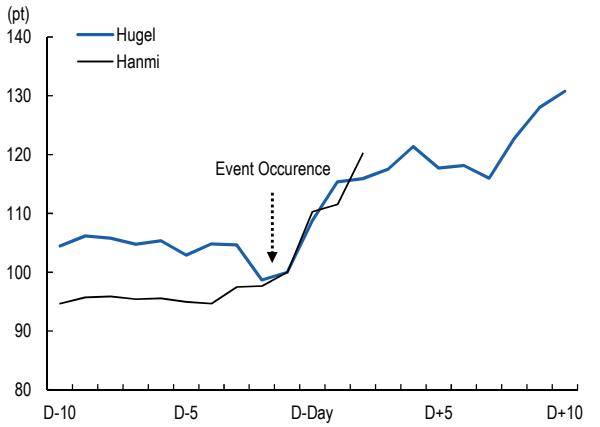
Source: FnGuide, Mirae Asset Daewoo Research

Figure 3. Shares have recently picked up on positive news (1)



Source: FnGuide, Mirae Asset Daewoo Research

Figure 4. Shares have recently picked up positive news (2)



Source: FnGuide, Mirae Asset Daewoo Research

II. Shares to rise gradually in 2H

Share performance in 2H17 to be differentiated

We maintain our view that shares will see a gradual rise in 2H17. However, we think the share rally in 2H will differ from that of 2015 in two respects. First, while Hanmi Pharmaceutical's massive out-licensing deals were the main catalyst in 2015, we think the primary driver this time will be a number of small/mid-sized licensing agreements. Second, unlike in 2015, when stocks—led by Hanmi—rallied across the pharmaceutical/biotech sector, we believe that share performance in 2H17 will be more differentiated, with R&D progress being the key variable.

We expect a gradual rise in share price, as a large-scale out-licensing deal that could boost investor sentiment sharply is unlikely to occur soon. Although the resumption of Phase 3 clinical trials for efpeglenatide could provide a catalyst, both Sanofi and Hanmi Pharmaceutical have recently announced that they would not resume clinical trials until the end of the year at the earliest.

The results of clinical trials deserve keen attention, given that shares of Genexine climbed before and after the April 1st announcement of clinical trial data on its continuous growth hormone.

Pipelines to watch in 2H17 include Genexine's continuous growth hormone (GX-H9), LegoChem Biosciences' ADC platform, Qurient's atopic dermatitis treatment (Q301), Peptron's long-acting therapeutics, Kolon Life Science's osteoarthritis drug (Invossa), SK Biopharm's epilepsy (YKP3089) and Sleep disorder (SKL-N05) treatments, Oscotec's rheumatoid arthritis treatment (SKI-O-703), and Chong Kun Dang's CETP inhibitor (CKD-519).

In 2H17, we recommend overweighting small/mid-sized biotech stocks rather than large pharmas, as we expect major pipeline events to be concentrated in the small/mid-sized biotech space. We also advise buying into a basket of biotech stocks that are expected to deliver pipeline events.

Table 2. Pipelines to watch in 2H17

Company	Pipeline	Indication	Phase	Notes
Genexine	GX-H9	Growth hormone deficiencies	Phase 2 in Europe	Continuous growth hormone
	GX-188E	Precancerous cervical disease	Phase 2 in Europe	DNA vaccine; combination trial with Merck's KEYTRUDA
LegoChem	ADC	Cancer	Development	Potential contract with Takeda in 2H
	LCB10-0200	Antibiotics	Phase 1 in US	Developed by Therapeutics
Oscotec	SKI-O-703	Rheumatoid arthritis	Phase 1 in US	Outstanding Phase 1 clinical data likely
Qurient	Q301	Atopic dermatitis	Completed Phase 2A in US	Drug repositioning
Peptron	Long-acting therapeutics	Diabetes/obesity	Non-clinical	Contract with global pharmas
Kolon Life Science	Invossa	Osteoarthritis	Completed Phase 3 in Korea /preparing Phase 3 in US	Signed contracts with Korean and Japanese partners
SK Biopharm	YKP3089	Epilepsy	Phase 3 in US	Likely to submit NDA by year-end
	SKL-N05	Sleep disorder	Phase 3 in US	Likely to submit NDA by year-end
Chong Kun Dang	CKD-519	Dyslipidemia	Phase 2 in Australia	CETP inhibitor

Source: Mirae Asset Daewoo Research

III. Expect outstanding R&D achievements again

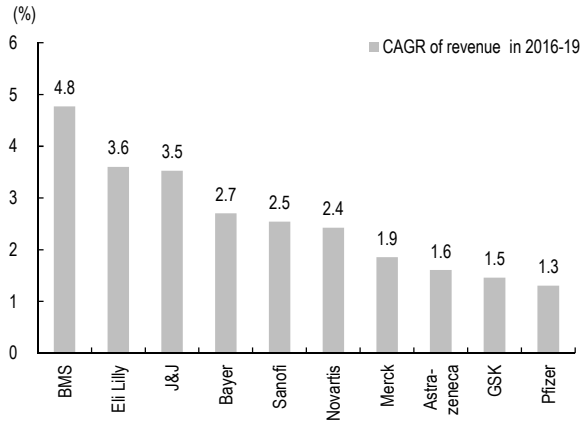
Multinational pharmas endeavor to sign in-licensing and M&A deals

From February 2015 to 1H16, the domestic pharmaceutical/biotech sector was re-rated, backed by high expectations for multiple, large-scale out-licensing deals. Actually, Hanmi Pharmaceutical was the only firm that clinched out-licensing deals, and some of the deals were reduced or cancelled, denting confidence in domestic firms' R&D capability.

We still believe Korean pharmaceutical/biotech firms have robust technological competitiveness. In particular, small- and medium-sized biotech firms have high potential for out-licensing deals.

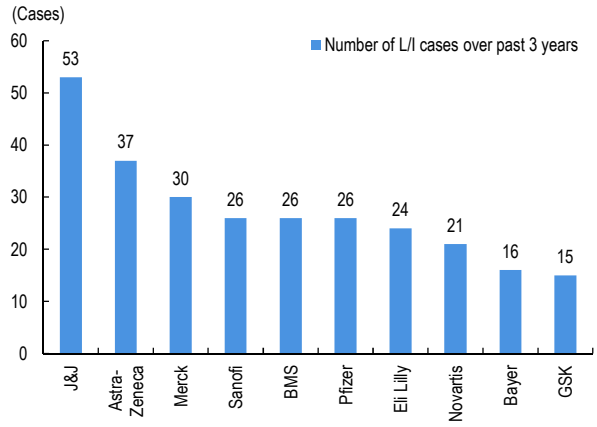
In our March 29th pharmaceutical/biotech report ("Overweight gradually"), we examined multinational pharmas' current positions. Multinational pharmas are currently endeavoring to expand their pipelines via in-licensing and M&A deals, as they face the risk of low growth due to the expiration of patents for their major products. Major multinational pharmas hold more than W7tr in cash, on average, and their annual EBITDA is estimated at more than the amount of their cash holdings. As such, the current market environment is favorable for domestic firms with competitive pipelines to win out-licensing contracts.

Figure 5. Multinational pharmas face risk of low growth



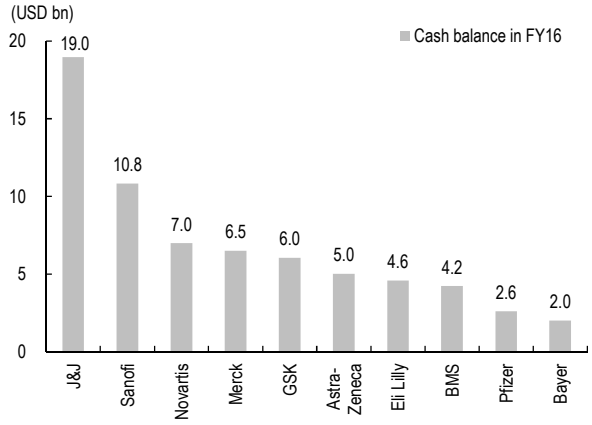
Source: Bloomberg, Mirae Asset Daewoo Research

Figure 6. Multinational pharmas pursuing growth via in-licensing deals



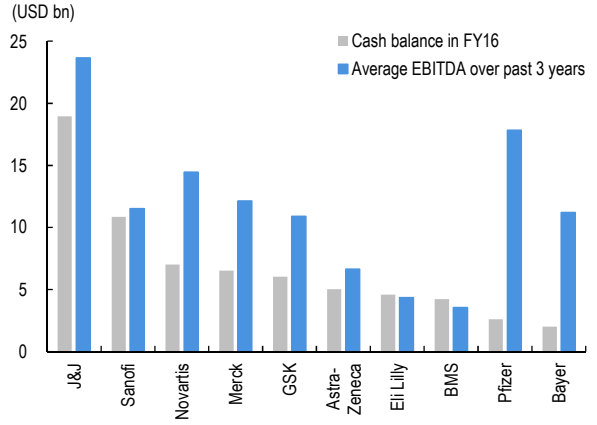
Source: Bloomberg, Mirae Asset Daewoo Research

Figure 7. Major multinational pharmas hold around US$6.8bn in cash on average



Source: Bloomberg, Mirae Asset Daewoo Research

Figure 8. Multinational pharmas' annual EBITDA estimated at more than cash holdings



Source: Bloomberg, Mirae Asset Daewoo Research

Domestic pharmas' out-licensing deals to increase on strong technological capabilities

Domestic pharmaceutical firms have signed a number of out-licensing agreements since 2H13, with top-tier multinational players - namely Gilead Sciences, Sanofi, Eli Lilly, and Genentech - on fairly favorable terms. Domestic players that have not landed meaningful licensing-out deals since LG Life Sciences' agreement with Gilead in 2007 are now enjoying the rebound of deals on the back of improved R&D capabilities. In addition, the cases of Medytox's agreement with Allergan and Kolon Life Science's deal with Mitsubishi Tanabe illustrate that the technologies of small-/medium-sized biotech firms have advanced significantly.

Indeed, Korean pharmaceutical firms boast strong R&D capabilities, following closely on the heels of US and European players. Table 3 and 4 below show multinational pharmaceutical firms' licensing deals worth W300bn or over, with deals with non-US/European firms highlighted; among the 10 such cases, six were with Korean firms (versus two with Japanese firms, and one each with a Chinese and Indian firm). Including the deal between Kolon Life Science and Mitsubishi Tanabe, Korean firms landed seven contracts out of 11 licensing deals with non -US/European players.

Table2. Korean pharmaceutical/biotech firms' out-licensing deals with multinational pharmas

Company	Partner	Indication	Development stage	Milestone	Upfront	Date of signing
LG Life Sciences	Gilead	Liver disease	Phase 2a clinical trials	US$200mn	US$20mn	11/07/07
Medytox	Allergan	BOTOX	Australian Phase 2 trials completed	US$362mn	US$65mn	9/26/13
SK Chemicals	Sanofi Pasteur MSD	Pneumococcal vaccine conjugate	Joint development and marketing	W50bn	W25bn	3/19/14
Hanmi Pharmaceutical	Eli Lilly	Rheumatoid arthritis	Phase 1 clinical trials completed	US$690mn	US$50mn	3/19/15
Hanmi Pharmaceutical	Boehringer Ingelheim	Lung cancer	Phase 2 clinical trials in Korea	US$730mn	Us$50mn	7/28/15
Hanmi Pharmaceutical	Sanofi	Diabetes	Preclinical/Phase 1/Phase 2 clinical trials	EUR3.9bn	EUR0.4bn	11/5/15
Hanmi Pharmaceutical	Janssen	Diabetes/obesity	Phase 1 clinical trials completed	US$915mn	US$105mn	11/9/15
Hanmi Pharmaceutical	Genentech	Anti-cancer	Phase 1 clinical trials in Korea	US$910mn	US$80mn	16.09.29
Kolon Life Science	Mitsubishi Tanabe	Degenerative arthritis	Approval application submitted in Korea/preparing for Phase 3 trails in the US	W498.9bn	W27.3	11/1/16
Dong-A ST	AbbVie	Cancer immunotherapy	Search for candidate materials	US$525mn	US$40mn	12/28/16

Source: Mirae Asset Daewoo Research

Table 3. Big pharmas' major M&As and licensing deals in 2015

Date	Acquirer/licensee	M&A target/licensor	Size of deal (USDmn)
1/6/15	Gilead Sciences	Phenex Pharmaceuticals AG	470.0
1/12/15	Roche	Foundation Medicine Inc	1,030.0
1/12/15	Janssen	AC Immune SA	509.0
1/16/15	Roche	Trophos SA	386.1
2/5/15	AstraZeneca Plc	Allergan Plc	700.0
2/5/15	Pfizer Inc	Hospira Inc	17,000.0
2/23/15	BMS	Rigel Pharmaceuticals Inc	339.0
2/23/15	Merck & Co Inc	NGM Biopharmaceuticals Inc	450.0
2/23/15	BMS	Flexus Biosciences Inc	1,250.0
3/4/15	AbbVie Inc	Pharmacyclics Inc	21,000.0
3/19/15	AstraZeneca Plc	Daiichi Sankyo (Japan)	825.0
3/19/15	Eli Lilly	Hanmi Pharmaceuticals (Korea)	690.0
3/19/15	AbbVie Inc	C2N Diagnostics LLC	785.0
3/20/15	Eli Lilly	Innovent Biologics (China)	1,056.0
4/6/15	BMS	UniQure NV	2,307.0
4/7/15	Merck & Co Inc	Arvinas Inc	434.0
4/20/15	Roche	Curadev Pharma (India)	555.0
4/24/15	AstraZeneca Plc	Innate Pharma SA	1,275.0
5/11/15	Pfizer Inc	Am-Pharma BV	600.0
5/11/15	Eli Lilly	BioNTech AG;	360.0
5/13/15	Sanofi	Selecta Biosciences Inc	300.0
5/19/15	Janssen	Achillion Pharmaceuticals Inc	1,100.0
6/1/15	Janssen Biotech Inc	Poseida Therapeutics Inc	584.0
6/3/15	AbbVie Inc	Halozyme Therapeutics Inc	1,193.0
6/15/15	Genentech Inc	Almac Discovery Ltd	363.9
6/29/15	Novartis AG	Spinifex Pharmaceuticals Pty Ltd	312.0
7/28/15	Boehringer Ingelheim	Hanmi Pharmaceuticals (Korea)	730.0
7/28/15	Merck & Co Inc	cCAM Biotherapeutics Ltd	605.0
7/31/15	AstraZeneca Plc	Ionis Pharmaceuticals Inc	4,090.0
8/6/15	AstraZeneca Plc	Heptares Therapeutics Ltd	510.0
8/12/15	Janssen Biotech Inc	Alligator Bioscience AB	700.0
8/14/15	Novo Nordisk	Genmab A/S	502.0
8/17/15	Novartis AG	AVEO Pharmaceuticals Inc	326.0
8/21/15	Novartis Pharma AG	GlaxoSmithKline Plc	1,034.0
8/31/15	BMS	Promedior Inc	1,250.0
9/15/15	Amgen Inc	Xencor Inc	1,745.0
9/16/15	Amgen Inc	Dezima Pharma BV	1,550.0
9/30/15	Novartis	XOMA Corp	517.0
10/1/15	Genentech Inc	Arvinas Inc	300.0
10/9/15	Roche	Adheron Therapeutics Inc	580.0
10/14/15	Janssen Biotech Inc	Novera Therapeutics	345.4
10/14/15	BMS	Five Prime Therapeutics Inc	1,737.5
11/2/15	BMS	Cardioxyl Pharmaceuticals Inc	2,075.0
11/3/15	Sanofi	BioNTech AG	1,560.0
11/5/15	Sanofi	Hanmi Pharmaceuticals (Korea)	3,192.8
11/6/15	Sanofi	Lexicon Pharmaceuticals Inc	1,700.0
11/6/15	AstraZeneca Plc	ZS Pharma Inc	2,700.0
11/9/15	Janssen	Hanmi Pharmaceuticals (Korea)	915.0
12/1/15	GlaxoSmithKline Plc	Zymeworks Inc	440.0
12/7/15	Pfizer Inc	BioAtla LLC	1,000.0
12/7/15	Roche	SQZ Biotech	500.0
12/8/15	Roche	Pieris Pharmaceuticals Inc	415.4
12/9/15	BMS	Kyorin Pharmaceutical (Japan)	405.0
12/17/15	AstraZeneca Plc	Acerta Pharma BV	4,000.0
12/21/15	Eli Lilly	Halozyme Therapeutics Inc	825.0
12/30/15	Roche	Tensha Therapeutics Inc	535.0

Source: GlobalData, Mirae Asset Daewoo Research

Table 4. Big pharmas' major M&As and licensing deals in 2016 and 2017

Date	Acquirer/licensee	M&A target/licensor	Size of deal (USDmn)
1/6/16	Merck & Co Inc	Quartet Medicine Inc	595.0
1/10/16	Sanofi	Innate Pharma SA	436.9
1/27/16	Merck & Co Inc	Cancer Research Technology Ltd	515.0
1/30/16	Abbott Laboratories	Alere Inc	5,300.0
3/7/16	AbbVie Inc	Boehringer Ingelheim GmbH	595.0
3/15/16	Roche	Blueprint Medicines Corp	1,010.0
3/23/16	BMS	Padlock Therapeutics Inc	600.0
4/4/16	Gilead Sciences	Nimbus Apollo Inc	1,200.0
4/6/16	Janssen Biotech Inc	Tesaro Inc	450.0
4/20/16	AbbVie Inc	arGEN-X BV	685.0
4/21/16	AbbVie Inc	CytomX Therapeutics Inc	490.0
4/21/16	GlaxoSmithKline Plc	Zymeworks Inc	908.0
4/28/16	AbbVie Inc	Stemcentrx Inc	9,800.0
5/5/16	Pfizer Inc	WAVE Life Sciences Ltd	911.0
5/10/16	Bayer AG	Monsanto Company	66,000.0
5/14/16	Pfizer Inc	Anacor Pharmaceuticals Inc	5,200.0
5/18/16	Janssen Biotech Inc	MacroGenics Inc	740.0
6/9/16	Merck & Co Inc	Afferent Pharmaceuticals Inc	1,250.0
6/27/16	Sanofi	Boehringer Ingelheim GmbH	5,216.3
6/28/16	Novartis AG	Xencor Inc	2,560.0
7/5/16	BMS	Cormorant Pharmaceuticals AB	520.0
7/19/16	Janssen Biotech Inc	Ionis Pharmaceuticals Inc	810.0
8/1/16	Pfizer Inc	Bamboo Therapeutics Inc	645.0
8/20/16	Pfizer Inc	Medivation Inc	14,000.0
9/16/16	Johnson & Johnson	Abbott Medical Optics Inc	4,325.0
9/28/16	Amgen Inc	Arrowhead Pharmaceuticals Inc	673.5
9/29/16	Genentech Inc	Hanmi Pharmaceuticals (Korea)	910.0
10/4/16	Amgen Inc	Nuevolution AB	410.0
12/16/16	Novartis AG	Ziarco Pharma Ltd	1,000.0
12/20/16	BMS	PsiOxus Therapeutics Ltd	936.0
12/20/16	Roche	ImmuNext Inc	400.0
12/21/16	Pfizer Inc	BioInvent International AB	516.0
12/28/16	AbbVie Inc	Dong-A ST (Korea)	525.0
1/9/17	Sanofi	ImmuNext Inc	500.0
1/9/17	GlaxoSmithKline Plc	Adaptimmune Therapeutics Plc	300.0
1/9/17	Amgen Inc	Immatics Biotechnologies GmbH	530.0
1/17/17	Biogen Inc	Forward Pharma A/S; Undisclosed	1,250.0
1/17/17	Eli Lilly	CoLucid Pharmaceuticals Inc	960.0
1/20/17	Merck & Co Inc	BMS; Ono Pharmaceutical Co Ltd	625.0
1/26/17	Johnson & Johnson	Actelion Ltd	30,000.0
4/6/17	Novartis AG	Tribos LLC	1,000.0
4/13/17	Roche	BMS	375.0
5/3/17	AstraZeneca	Pieris Pharmaceutical	2,100.0

Source: GlobalData, Mirae Asset Daewoo Research

Domestic pharmas' technology capabilities by drug type

1) Chemical drugs: Competitiveness in me- too drugs

As latecomers to the sector, Korean pharmaceutical firms largely lag behind companies in the US, Europe, and Japan in the research and development of chemical drugs. However, Korean players have recently displayed strength in the development of me-too drugs.

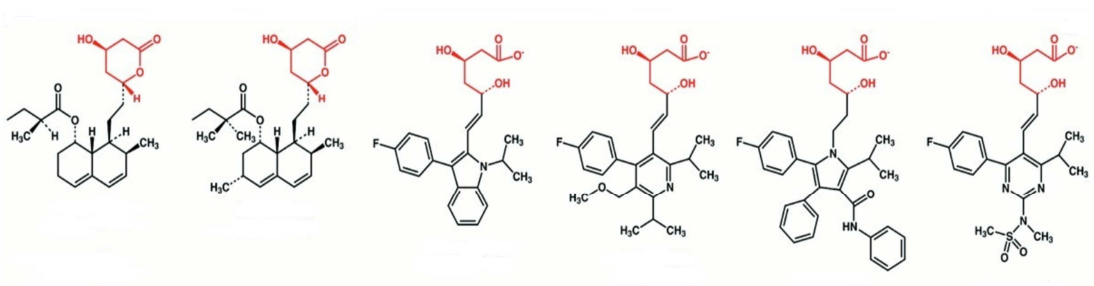
A me-too drug is a new drug that has only minor differences in chemical structure from a first-in-class drug. The drug typically has similar efficacy with the first-in-class drug, but requires smaller investment, involves lower risks, and takes less time to develop. In addition, the development of me-too drugs could give rise to a best-in-class drug with stronger efficacy, higher levels of safety, and reduced side effects, compared with first-in-class drugs.

Accordingly, multinational pharmaceutical firms place a great deal of focus on the development of me-too drugs. Indeed, a significant portion of major blockbuster drugs are best-in-class me-too drugs.

A case in point illustrating how me-too drugs can lead to the development of blockbuster drugs is statin-based hyperlipidemia drugs. Merck first introduced a new statin-based hyperlipidemia drug lovastatin (brand name: Lovastatin). Following lovastatin, Merck and Novartis launched simbastatin (Zocor) and fluvastatin (Lescol), respectively, with improved half-life and bioavailability. In 1996, Pfizer launched atorvastatin (Lipitor), which had been the top-selling drug in the world in 2001-2011, before it was overtaken by AstraZeneca's rosuvastatin (Crestor) in 2012. Figure 9 shows that major statin-class drugs are all based on the chemical structure of Mevacor.

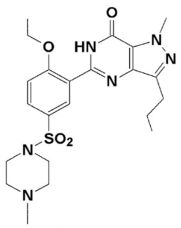
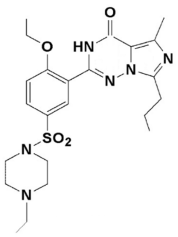
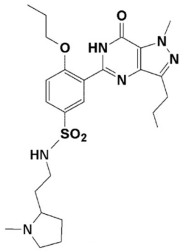
Figure 10 shows ED treatments based on PDE5 inhibitors. After Pfizer first developed sildenafil (brand name: Viagra) in 1998, Bayer introduced vardenafil (Levitra) in 2003 and Dong-A ST udenafil (Zydena) in 2005. The two drugs also share a similar chemical structure with sildenafil.

Figure 9. Case of me-too drug development: Statin-based hyperlipidemia drugs

Chemical structure						
Medical name	Lovastatin	Simvastatin	Fluvastatin	Cerivastatin	Atorvastatin	Rosuvastatin
Brand name	Mevacor	Zocor	Lescol	Baycol	Lipitor	Crestor
Developer	Merck	Merck	Novartis	Bayer	Pfizer	AstraZeneca
FDA approval	8/31/1987	12/23/1991	12/31/1993	6/26/1997	12/17/1996	8/12/2003
Half-life (hour)	1.1~1.7	2~3	<3	2~3	14	20.8
Administration time	Night	Night	Night	Night	Anytime	Anytime
Bioavailability (%)	5	5	6	60	12	20

Source: Respective companies, Mirae Asset Daewoo Research

Figure 10. Case of me-too drug development: PDE5 inhibitor-based ED drugs

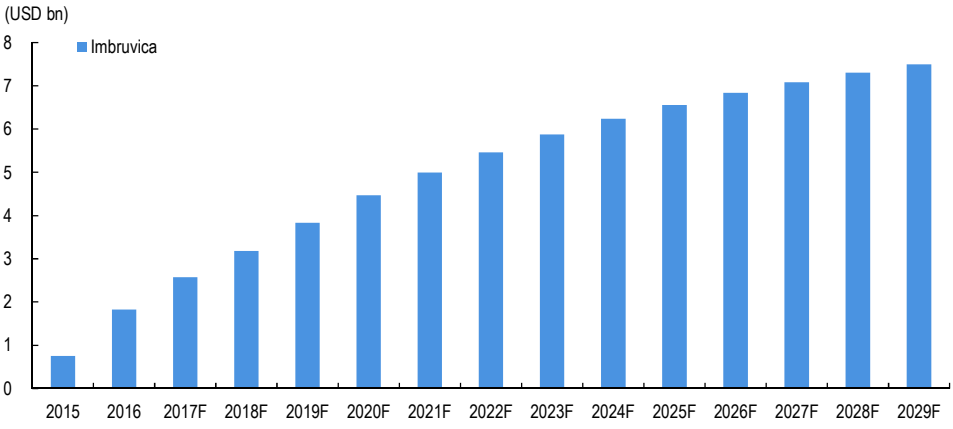
Chemical structure			
Medical name	Sildenafil	Vardenafil	Udenafil
Brand name	Viagra	Levitra	Zydena
Developer	Pfizer	Bayer	Dong-A ST
FDA approval	3/27/1998	8/19/2003	-
Onset time	1 hour	15 minutes	15 minutes
Duration	4 hours	4.5 hours	24 hours

Source: Respective companies, Mirae Asset Daewoo Research

Boryung Pharmaceutical's Kanarb is also a me-too drug based on ARB targeting hypertension. LG Life Sciences' Zemiglo and Dong-A ST's Suganon are both me-too diabetes drugs based on DDP-4.

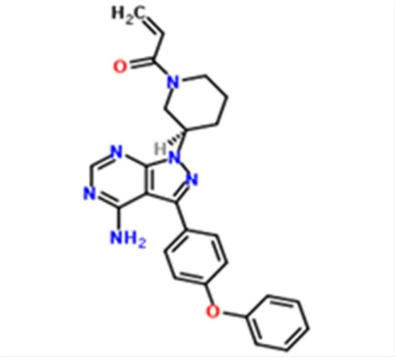
Hanmi Pharmaceutical's out-licensing of a BTK inhibitor to Eli Lilly in March 2015 well illustrates Korean pharmaceutical firms' capabilities for developing me-too drugs. Multinational pharmaceutical firms had been keen on developing BTK inhibitors or licensing in the drugs, with AbbVie acquiring Pharmacyclics, the original developer of Imbruvica (first-in-class BTK inhibitor) for US$21bn. However, as only a small number of companies were developing the drug, Hanmi Pharmaceutical's me-too drug, which was in the Phase 1 clinical trial stage, was put in the spotlight. Based on positive results in the pre-clinical trials, the company was able to land a US$690mn deal.

Figure 11. Forecast for sales of Imbruvica, a BTK inhibitor-based first-in-class drug



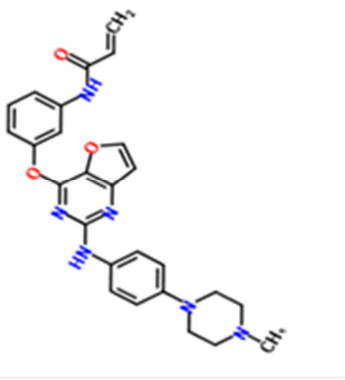
Source: GlobalData, Mirae Asset Daewoo Research

Figure 12. AbbVie's Ibrutinib structure (first in class)



Source: ChemSpider, Mirae Asset Daewoo Research

Figure 13. Hanmi Pharm's Poseltinib (Me too)



Source: ChemSpider, Mirae Asset Daewoo Research

2) Biologic drugs have stronger competitiveness than chemical drugs

We think Korean pharmaceutical companies have stronger competitiveness in the development of biologics, compared with chemical drugs. They began their research on biologics as early as their developed market counterparts. Indeed, US consulting firm Pugatch Consilium, in its BCI Survey 2016, rated Korea as the second most competitive country (after Singapore) among 18 emerging market economies, in terms of biopharmaceutical innovation.

① Stem cell therapy

Out of all biologic drug categories, Korean players are particularly competitive in stem cell therapy treatments. Of the total of six stem cell treatments that have so far been launched globally, four have been developed by Korean companies, with the other two by US and Italian companies. Although those four Korea-developed treatments have yet to obtain approvals from the US FDA and European Medicines Agency (EMA), they have been approved by Korea's Ministry of Food and Drug Safety (MFDS). Moreover, the accumulation of prescription data following their commercial launches will be conducive to future marketing and R&D for such treatments.

Table 5. Approval status for key stem cell treatments

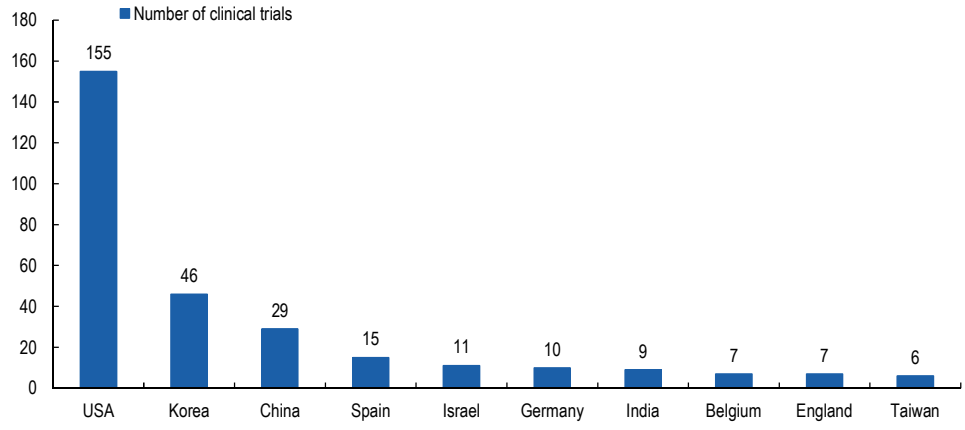
Company	Drug	Indication	Based on	Approval	Remarks
Pharmicell	Hearticellgram-AMI	Myocardial infarction	Bone marrow adult stem cells	Sept. 2011	World's first
Medipost	Cartistem	Regenerative treatment for knee cartilage	Umbilical cord blood adult stem cells	Jan. 2012	World's second
Anterogen	Cupstem	Treatment of anal fistula in Crohn's disease	Fat adult stem cells	Jan. 2012	World's third
Osiris (US)	Prochymal	Treatment of acute graft versus host disease (GvHD)	Bone marrow adult stem cells	May 2012	Approved in Canada
Corestem	Neuronata-R	treatment of Lou Gehrig's disease	Bone marrow adult stem cells	July 2014	World's fifth
Chiesi (Italy)	Holoclar	Treatment of moderate-to-severe forms of limbal stem cell deficiency (LSCD)	Corneal epithelium	Feb. 2015	Approved in Europe

Source: Mirae Asset Daewoo Research

In terms of the number of clinical trials conducted from 1999 through 2016, Korea (46) ranked second after the US (155). In terms of the number of stem cell therapy-related thesis, Korea jumped from ninth place in 2009 to fourth place in 2015, while in terms of the number of related patents, it has remained in fourth place since 2007.

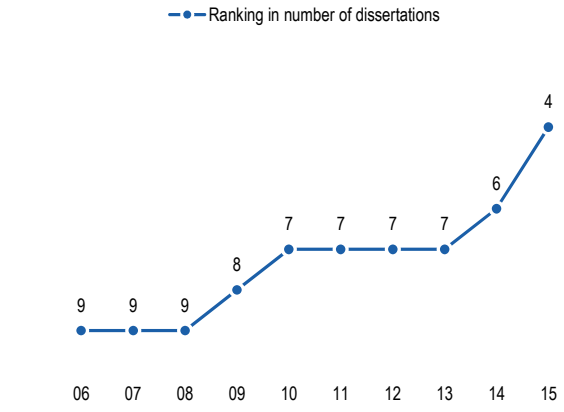
According to the Korea Institute of S&T Evaluation and Planning, Korea's stem cell therapy technology levels are now 85% of those of the top countries in that field, while Korea's stem cell differentiation and cultivation technologies are about 84.8% of those of the top countries.

Figure 14. No. of clinical trials conducted in 1999-2016 by country



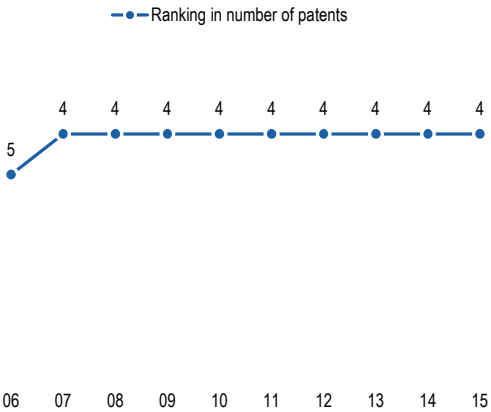
Source: MFDS, Mirae Asset Daewoo Research

Figure 15. Changes in rankings in No. of stem cell-related thesis (2006-15)



Source: GSTEP, Mirae Asset Daewoo Research

Figure 16. Changes in rankings in No. of stem cell-related patents (2006-15)



Source: GSTEP, Mirae Asset Daewoo Research

② Gene therapy

Development of gene therapies (which typically target rare/incurable diseases) usually progresses slowly, due to difficulties in recruiting patients for clinical trials and proving their efficacy through such trials. As a result, only a handful of gene therapy treatments have so far entered late-phase clinical trials, with UniQure's Glybera and GSK's Strimvelis being the only gene therapy treatments that have been approved by the EMA.

Meanwhile, Korean pharmaceutical firms' gene therapy developments have been progressing at a relatively fast pace. For example, ViroMed is carrying out Phase 3a clinical trials in the US for its in-house developed VM202-PAD (critical limb ischemia treatment) and VM202-DPN (diabetic peripheral neuropathy treatment). Kolon Group's TissueGene is also poised to conduct global clinical trials for Invossa, a cell therapy drug to treat degenerative arthritis. We expect Phase 3 clinical trials for these treatments to yield positive results going forward, considering the upbeat results of their respective Phase 2 clinical trials.

Table 6. Gene therapies: Current status of clinical trials

Product	Company	Indication	Phase
Glybera	UniQure	Lipoprotein lipase deficiency	Approved by EMA in 2012
Strimvelis	GSK	Adenosine deaminase deficiency	Approved by EMA in 2016
SPK-RPE65	Spark Therapeutics	Inherited retinal disease (IRD) caused by mutations in the RPE65 gene	Phase 3
Lenti-D	Bluebird Bio	Cerebral adrenoleukodystrophy	Phase 3
Ad-RTS-hIL-12	Ziopharm Oncology	Breast cancer, melanoma	Phase 2
GSK2696275	GSK	Wiskott-Aldrich syndrome	Phase 2
LentiGlobin BB305	Bluebird Bio	Transfusion-dependent β-thalassemia	Phase 2
SPK-CHM	Spark Therapeutics	Choroideremia (CHM), an inherited retinal dystrophy	Phase 2
BAX 335	Baxalta	Hemophilia B	Phase 2
SPK-FIX/ SPK-9001	Spark Therapeutics/ Pfizer	Hemophilia B	Phase 2
AMT-060/ AAV5-hFIX	Uniqure/Chiesi	Hemophilia B	Phase 2
DTX101	Dimension Therapeutics	Hemophilia B	Phase 2
BMN 270	BioMarin	Hemophilia A	Phase 2
AMT-110	Uniqure	Sanfilippo type B syndrome,	Phase 2
CGF166	Novartis	Hearing loss	Phase 2

Source: Mirae Asset Daewoo Research

Table 7. Development status of Korean biologics companies' gene therapies

Product	Company	Indication	Phase
Invossa	TissueGene	Regenerative arthritis	Phase 3
VM202-PAD	ViroMed	Critical limb ischemia	Phase 3
VM202-DPN	ViroMed	Diabetic Peripheral Neuropathy	Phase 3
VM202-ALS	ViroMed	Amyotrophic Lateral Sclerosis	Phase 2
GX-188E	Genexine	Cervical Intraepithelial Neoplasia (CIN caused by persistent HPV infection	Phase 2

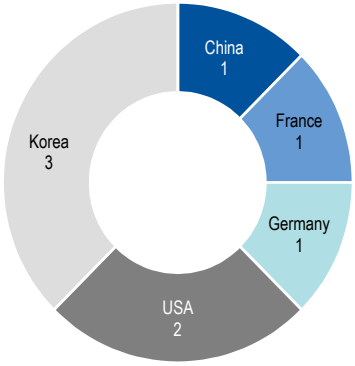
Source: Mirae Asset Daewoo Research

③ Botulinum toxins

Korean pharmaceutical companies also have a competitive edge in botulinum toxins (which are often marketed under the brand name Botox). Out of the total of eight botulinum toxin products that have so far been released globally, three have been developed by Korean companies (Medytox, Hugel, Daewoong Pharmaceutical), two by US companies, and the remaining three by German, French, and Chinese companies. Medytox, in particular, has signed an out-licensing deal with Allergan over its botulinum toxin product, an upgraded version of Allergan's original Botox.

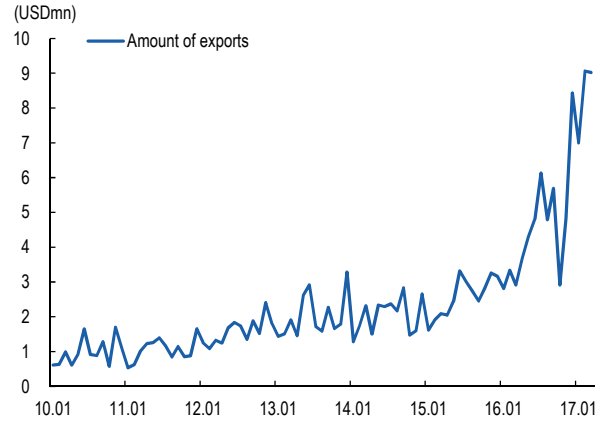
Korean botulinum toxin makers (e.g. Medytox) are now enjoying solid benefits from the rapid growth of the global botulinum toxin market, which is well protected by high entry barriers. Korean botulinum toxin makers have recently seen rapid growth in their exports (Figure 18). Medytox represents over 60% of Korea's total botulinum exports, with the number of its export markets nearing 60.

Figure 17. Three out of eight botulinum toxins were developed by Korean companies



Source: Mirae Asset Daewoo Research

Figure 18. Rapidly growing botulinum toxin exports



Source: Mirae Asset Daewoo Research

3) Biosimilars: Celltrion and Samsung Bioepis are global leaders

Korean players are leading the global biosimilars market. In the global market, Celltrion, Samsung Bioepis, Pfizer, and Amgen are considered the top four players, with Celltrion and Samsung Bioepis having taken the lead in the market.

Celltrion has developed Remicade and the world's first-ever biosimilar for Rituxan, while Samsung Bioepis has developed the world's first-ever Enbrel biosimilar and the world's second Remicade biosimilar. In addition, Samsung Bioepis and Celltrion were the world's second and third applicants for European approval of Herceptin biosimilars, respectively. Samsung Bioepis also appears to be ahead of rivals in the development of biosimilars for Humira and Lantus.

As biosimilars have no clinically significant differences, in terms of efficacy, the first movers and most aggressive marketers should gain the upper hand in the market. Celltrion and Samsung Bioepis are both moving rapidly in developing and launching products, and both have secured prominent marketing partners (Pfizer and Teva for Celltrion; Merck and Biogen for Samsung Bioepis). Thus, the two companies will likely enjoy great advantages as first movers going forward.

We are also upbeat about Samsung Biologics' bio contract manufacturing organization (CMO) businesses, in light of: 1) the steady expansion of the global biopharmaceutical market; 2) the take-off of the biosimilars market; and 3) drug developers' growing dependence on production through CMOs.

Table 8. Development status of Remicade biosimilar

Company	Product	Indication	Phase	Notes
Celltrion	**Remsima/Inflectra**	**Rheumarthritis**	**Approved**	**Launch in US/Europe/Korea/etc.**
Samsung Bioepis	**Flixabi/Renflexis**	**Rheumarthritis**	**Approved**	**Launch in Europe, patent application in US**
Nichiiko	NI-071	Rheumarthritis	Phase 3 clinical trials	
Sandoz	PF-06438179	Rheumarthritis	Phase 3 clinical trials	Purchased license from Pfizer
Ranbaxy/Epirus	BOW015	Rheumarthritis	Phase 3 clinical trials	
Amgen	ABP 710	Rheumarthritis	Phase 3 clinical trials	

Source: Mirae Asset Daewoo Research

Table 9. Development status of Rituxan biosimilar

Company	Product	Indication	Phase	Notes
Celltrion	**Truxima**	**Non-Hodgkin lymphomas**	**Approved**	**Approved in Europe**
Sandoz	GP2013	Non-Hodgkin lymphomas	Phase 3 clinical trials, completed	Patent application in Europe
Amgen	ABP 798	Autoimmunity	Phase 3 clinical trials	
Pfizer	PF-05280586	Autoimmunity	Phase 3 clinical trials	
Boehringer Ingelheim	BI 695500	Autoimmunity	Phase 3 clinical trials	Ended development in October, 2015

Source: Mirae Asset Daewoo Research

Table 10. Development status of Enbrel biosimilar

Company	Product	Indication	Phase	Notes
Samsung Bioepis	**Brenzys/Benepali**	**Rheumarthritis**	**Approved**	**Launch in Europe**
Sandoz	Erelzi	Rheumarthritis	Phase 3 clinical trials completed	Approved in US
Coherus BioSciences	CHS-0214	Rheumarthritis	Phase 3 clinical trials completed	

Source: Mirae Asset Daewoo Research

Table 11. Development status of Herceptin biosimilar

Company	Product	Indication	Phase	Notes
Biocon/Mylan	Hercules (Myl-1401O)	Breast cancer	Phase 3 clinical trials, completed	Patent application in Europe
Samsung Bioepis	SB3	Breast cancer	Phase 3 clinical trials, completed	Patent application in Europe
Celltrion	Herzuma (CT-P6)	Breast cancer	Phase 3 clinical trials	Patent application in Europe
Actavis/Amgen	ABP-980	Breast cancer	Phase 3 clinical trials	
Pfizer/Hospira	PF-05280014	Breast cancer	Phase 3 clinical trials	

Source: Mirae Asset Daewoo Research

Table 12. Development status of Lantus biosimilar

Company	Product	Indication	Phase	Notes
Eli Lilly	Abasaglar/ Basaglar	Diabetes	Approved	Launched in US/Europe
Samsung Bioepis/Merck	MK-1293/SB9	Diabetes	Phase 3 clinical trials, completed	Approved in Europe, patent application in US
Biocon/Mylan	Basalog	Diabetes	Phase 3 clinical trials, completed	Patent application in Europe

Source: Mirae Asset Daewoo Research

Table 13. Development status of Humira biosimilar

Company	Product	Indication	Phase	Notes
Amgen	ABP 501	Rheumarthritis	Phase 3 clinical trials, completed	Approved in US
Samsung Bioepis	SB5	Rheumarthritis	Phase 3 clinical trials, completed	Patent application in Europe
Sandoz	GP2017	Rheumarthritis	Phase 3 clinical trials	
Boehringer Ingelheim	BI695501	Rheumarthritis	Phase 3 clinical trials	
Fujifilm/Kyowa Hakko	FKB327	Rheumarthritis	Phase 3 clinical trials	
Momenta/Baxalta	M923	Rheumarthritis	Phase 3 clinical trials	
Pfizer	PF-06410293	Rheumarthritis	Phase 3 clinical trials	
Merck KGaA	MSB11022	Rheumarthritis	Phase 3 clinical trials	

Source: Mirae Asset Daewoo Research

Table 14. Development status of Avastin biosimilar

Company	Product	Indication	Phase	Notes
Amgen/Allergan	ABP 215	Non-small cell lung cancer	Phase 3 clinical trials, completed	Patent application in US and Europe
Boehringer Ingelheim	BI 695502	Non-small cell lung cancer	Phase 3 clinical trials	
Pfizer	PF-06439535	Cancer	Phase 3 clinical trials	
Samsung Bioepis	SB8	Colorectal cancer, Non-small cell lung cancer	Phase 3 clinical trials	
AstraZeneca/Fujifilm	FKB238	Solid cancer	Phase 1 clinical trials	

Source: Mirae Asset Daewoo Research

4) Biobetters: Hanmi Pharmaceutical, Genexine, and Peptron deserve attention

The development of biobetters is currently one of the major R&D trends. Biobetters are new biologic entities that are improved versions of an original biologic. The differentiation from the original biologic may be in the form of not only improved efficacy/potency and safety, but also improvements in dosing convenience, including reduced dosing frequency.

Although it takes higher costs and longer periods to develop biobetters than biosimilars, biobetters have the potential to receive patents and charge higher prices than their original drugs. Once released, biobetters typically increase their markets shares rapidly, based on their differentiated competitiveness.

Korean firms have strength in biobetter development, as evidenced by Hanmi Pharmaceutical's biobetter out-licensing deals (a W5tr contract with Sanofi and W1tr contract with Janssen) in 2015. Both drugs reduced the pain of injection and the number of hospital visits by lowering dosing frequency

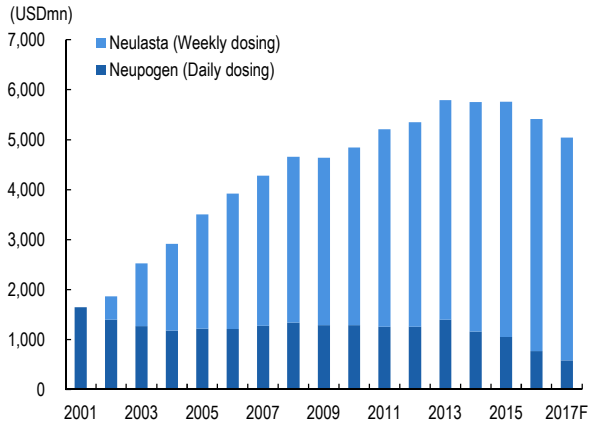
We believe that biologic firms, including Genexine and Peptron, deserve attention in 2H, as they are currently conducting clinical trials for biobetters.

Table 15. Comparison of biologics, biosimilars, and biobetters

	Biologics	biosimilars	biobetters
Characteristics	Manufactured from biologic materials via advanced biotechnology	Bioequivalent to and as safe as original drugs	Higher efficacy and safety than original drugs
Development period	15 years or longer	8-10 years	10 years or longer
Development costs	US$12mn	US$1-2mn	US$5mn
Patent	Recognized	Not recognized	Recognized
Pricing	Reflect R&D costs	Lower than prices of original drugs	Higher than prices of original drugs

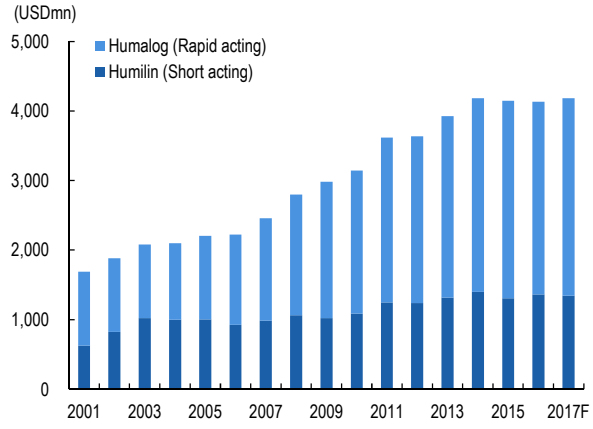
Source: IMS Health, Mirae Asset Daewoo Research

Figure 19. Successful cases of biobetters: 1) Long-acting G-CSF



Source: Amgen, Mirae Asset Daewoo Research

Figure 20. Successful cases of biobetters: 2) Rapid-acting insulin



Source: Eli Lilly, Mirae Asset Daewoo Research

IV. Notable biotech firms and pipelines

We think a wide range of R&D achievements could materialize in 2H17, given the growth slowdown facing many global pharmas, the enhanced technologies of domestic pharmas, and dwindling drug pipelines. Key pipelines to watch include: 1) Genexine's long-acting growth hormone, GX-H9; 2) LegoChem Biosciences' antibody-drug conjugates (ADC) platform technology; 3) Oscotec's rheumatoid arthritis treatment, SKI-O-703; 4) Qurient's atopic dermatitis treatment, Q301; 5) Peptron's long-acting platform technology; 6) Kolon Life Science's osteoarthritis drug, Invossa; and 7) SK Biopharm's epilepsy treatment, YKP3089, and sleep disorder drug, SKL-N05.

Table 16. Notable biotech firms and pipelines

Genexine		
	Notable pipeline	Long-acting growth hormone GX-H9
	Development status	Phase 2 in Europe
	Differentiation	Improved dosing convenience (once biweekly)
	Event expected in 2H17	To announce six-month Phase 2 clinical data
LegoChem		
	Notable pipeline	ADC platform technology
	Development status	Undergoing pre-clinical testing
	Differentiation	Confirmed high efficacy and safety in pre-clinical trial
	Event expected in 2H17	Potential contract with Takeda in 2H
Oscotec		
	Notable pipeline	Rheumatoid arthritis treatment SKI-O-703
	Development status	Phase 1 in the US
	Differentiation	Addressed SYK inhibitor's side effects
	Event expected in 2H17	To announce Phase1 clinical data
Qurient		
	Notable pipeline	Atopic dermatitis treatment Q301
	Development status	Completed Phase 2A in the US
	Differentiation	Confirmed positive Phase 2A clinical data
	Event expected in 2H17	Likely to sign an out-licensing deal
Peptron		
	Notable pipeline	Once-weekly diabetics/obesity treatment
	Development status	Non-clinical
	Differentiation	Improved dosing convenience
	Event expected in 2H17	Global pharmas to announce the results of their technological review
Kolon Life Science		
	Notable pipeline	Osteoarthritis drug Invossa
	Development status	Sought approval in Korea/preparing Phase 3 in the US
	Differentiation	Once-weekly injection
	Event expected in 2H17	To be approved for domestic sale/to start Phase 3 in the US
SK Biopharm		
	Notable pipeline	Epilepsy treatment YKP3089, sleep disorder drug SKL-N05
	Development status	Phase 3 in US
	Differentiation	Confirmed superior efficacy in clinical trials
	Event expected in 2H17	To submit NDA to US FDA

Source: Mirae Asset Daewoo Research

Genexine's once-biweekly growth hormone drug to become best in class

- Notable pipeline: Long-acting growth hormone GX-H9
- Development status: Phase 2 in Europe
- Differentiation: Improved dosing convenience (once biweekly)
- Event expected in 2H17: To announce six-month Phase 2 clinical data

Among its pipelines, Genexine has made the most progress in GX-H9, a hybrid Fc-fused human growth hormone. The long-acting biobetter is currently undergoing Phase 2 clinical trials in Europe. For growth hormones, long-acting drugs have yet to be developed, unlike other biologics, such as EPO and G-CSF. Therefore, if a long-acting growth hormone drug were launched, its impact on the market would likely be significant. Genexine is conducting clinical trials simultaneously for both once-weekly and once-biweekly drugs.

As for once-weekly growth hormone drugs, Genexine ranks fourth in terms of progress of its clinical trials, following Pfizer, Versartis, Novo Nordisk, and Ascendis. Genexine ranks second in the progress of once-biweekly drug development, after Versartis. On April 1st, however, the company presented superior interim results (with the mean annualized height velocity of 12.4cm vs. 8.1~8.5cm for Versartis) from the Phase 2 clinical trials of GX-H9 in pediatric growth hormone deficiency at the 99th Annual Meeting of the Endocrine Society for Pediatric Endocrinology (ENDO). In addition, GX-H9 did not show any side effects, as opposed to Versatis' drug, which displayed high immunogenicity. Although a once-biweekly drug will likely be released later than a once-weekly drug, the growth hormone drug market should be driven by the former. We think the company's once-biweekly growth hormone drug has the potential to become the best in class.

Genexine plans to present the six-month Phase 2 clinical data on GX-H9 at the European Society for Pediatric Endocrinology 2017 (ESPE 2017), slated for September. If this data turns out to be positive, we expect an out-licensing deal.

Table 17. Status of long-acting growth hormone developers

		Genexine		Versartis	Ascendis	OPKO (Pfizer)	Novo Nordisk
Project		GX-H9		VRS-317	ACP-001	MOD-4023	NNC-0195-0092
Technology		hyFC		XTEN	TransCon PEG	CTP	Albumin
Stage	Adult	Phase 2		Phase 2	Completed Phase 2	Failed in Phase 3	Started Phase 3
	Pediatric	Phase 2		Phase 3	Started Phase 3	Started Phase 3	Phase 2
Designated as an orphan drug		Designated by FDA		Designated by FDA and EMA	Not designated	Designated by FDA and EMA	Not designated
Efficacy	Pediatric (Height)	0.8mg/kg: 10.7cm (3M) 1.2mg/kg: 15.3cm (3M)	2.4mg/kg: 12.4cm (3M)	8.5cm (6M) 8.1cm (1Y) 7.8cm (2Y)	12.9cm (6M)	13.6cm (6M) 10.0~11.5cm (1Y) 7.6~8.7cm (2Y)	No data
Stability		-		Immunogenic	Immunogenic	Immunogenic	-
Dosing frequency		Once-weekly	Once-biweekly	Once-biweekly	Once-weekly	Once-weekly	Once-weekly

Source: Genexine, Mirae Asset Daewoo Research

LegoChemBio's technology capability proven overseas

- Notable pipeline: ADC platform technology
- Development status: Pre-clinical trials
- Differentiation: Confirmed high efficacy and safety in pre-clinical trials
- Event expected in 2H17: Potential contract with Takeda in 2H

LegoChemBio is a biotech firm focusing on the development of antibody-drug conjugates (ADC), which boast reduced side effects based on strong selectivity (the merit of bio drugs) and higher efficacy (the benefit of chemical drugs). So far, only two ADC drugs had been introduced worldwide – Kadcyla (a breast cancer treatment) and Adcetris (a leukemia treatment). LegoChemBio is developing a variety of ADCs based on its proprietary platform technology, called ConjuALL.

The company has already signed two significant out-licensing deals. In August 2015, it transferred marketing rights for an ADC of Herceptin in China, Taiwan, Hong Kong, and Macau to Shanghai Fosun Pharma for W20.8bn. In January 2017, it signed a research license agreement for the ADC platform technology with Millennium Pharmaceuticals, an oncology subsidiary of Takeda Pharmaceutical, Japan's leading pharmaceutical firm.

We think it noteworthy that Shanghai Fosun Pharma and Takeda Pharmaceutical had already adopted ADC technology from external sources before signing the deals with LegoChemBio. Shanghai Fosun Pharma acquired a US-based Ambrx and Takeda was developing drug pipelines based on the technologies of Mersana, the leader in ADC technology. This suggests that the company's technological competitiveness is recognized by global players.

Meanwhile, there were concerns that royalties from the deal with Takeda might be insignificant, as the two companies did not disclose the exact amount. However, Takeda is expected to sign a main contract after developing and testing candidate materials by combining its antibody and chemical drugs based on LegoChemBio's technology. Accordingly, the amount of royalties could increase in the main contract. Indeed, Takeda closed a main contract nine months after signing a research license agreement with Mersana.

Table 18. Pipeline status

Type	Drug	Target/feature	Phase	Note
Antibiotics	LCB01-0371 (oral)	Gram-positive bacteria	Phase 2	RMX Biopharma
	LCB01-0371 (IV)	Gram-positive bacteria	Phase 1	RMX Biopharma
	LCB10-0200	Gram-positive bacteria	Phase 1	Geom Therapeutics
Anticoagulant	Nokxaban	Anticoagulant	Phase 2	Green Cross
ADC	HER2	Anticancer	Pre-clinical	Fosun Pharma (China)
	HER2	Anticancer	Pre-clinical	An European company
	LCB14-15nn	Undisclosed	Under development	Millennium (US, Takeda's subsidiary
	Mesothelin	Anticancer	Pre-clinical	Green Cross
	Multi Targets	Undisclosed	Under development	Theranyx
	CD37	Blood cancer	Under development	Nordic Nanovector
	Undisclosed	Anticancer	Under development	ABL bio
	Undisclosed	Anticancer	Under development	Y Biologics
	EGFRvIII	Anticancer	Under development	Samsung Medical Center
	PNS	Undisclosed	Under development	SEASUN Biomaterials

Source: Mirae Asset Daewoo Research

Oscotec expects positive results from US clinical trials for rheumatoid arthritis treatment

- Notable pipeline SKI-O-703
- Development status Phase 1 clinical trials in the US
- Differentiation Reduced side effects
- Event expected in 2H17 Announcement of Phase 1 clinical trial results in US

Among Oscotec's pipeline drugs, we think that SKI-O-703, a rheumatoid arthritis treatment, deserves the greatest attention, for the following reasons:

First, while 80% of rheumatoid arthritis treatments, including Humira and Remicade, are TNF-α inhibitors administered intravenously, SKI-O-703 can be taken orally. Accordingly, once launched, the drug should boast greater convenience and lower prices, compared with rival drugs.

Second, the drug is expected to have fewer side effects, relative to other drugs based on spleen tyrosine kinase (SYK) inhibitors. AstraZeneca and Biogen suspended clinical trials for their respective new SYK-inhibitor drugs due to issues like side effects, including hypertension and diarrhea, (AstraZeneca) and toxicity and low absorption rate (Biogen). However, SKI-O-703 showed few side effects in Phase 1 clinical trials until a dose of 800mg is reached (versus a daily dose of 200mg for AstraZeneca's drug candidate).

Currently, dose-range finding trials for the drug are underway, with results scheduled to be announced in 2H.

Table 19. Major rheumatoid arthritis treatments in the pipeline

Administration	Feature	Drug	Detail	Current status
IV	TNF-α inhibitor	Humira, Remicade, etc.	Developed by AbbVie and J&J	Blockbuster drugs
Oral	JAK inhibitor	Xeljanz	Launched by Pfizer	2016 sales of US$930mn
	SYK inhibitor	R788	AstraZeneca licensed in for US$445mn	Clinical trials suspended for side effects
		P505-15	Biogen licensed in for US$550mn	Clinical trials suspended for toxicity and low absorption rate
		SKI-O-703	Phase 1 clinical trials are underway in the US	Resolved competitive drugs' side-effect issues

Source: Oscotec, Mirae Asset Daewoo Research

Table 20. Pipeline status

Drug	Feature	Indication	Phase	Note
SKI-O-703	SYK inhibitor	Rheumatoid arthritis	Phase 1 trials	Supported under the government's new drug development initiative
SKI-G-801	FLT3 inhibitor	Leukemia	Ready for Phase 1 trials	Supported by the Ministry of Health and Welfare
GNS-1480	EGFR inhibitor	Lung cancer	Ready for Phase 1 trials	Partnering with Yuhan
4G lung cancer treatment	EGFR inhibitor	Lung cancer	Under development	Partnering with Yuhan
Liver cancer treatment	FGFR4 inhibitor	Liver cancer	Under development	Partnering with Yuhan
2G SYK inhibitor	SYK inhibitor	Blood cancer	Under development	

Source: Oscotec, Mirae Asset Daewoo Research

Qurient expected to license out atopic dermatitis treatment

- Notable pipeline — Atopic dermatitis treatment Q301
- Development status — Completed Phase 2a trials in US
- Differentiation — Confirmed positive Phase 2a clinical data
- Event expected in 2H17 — Likely to sign out-licensing deal

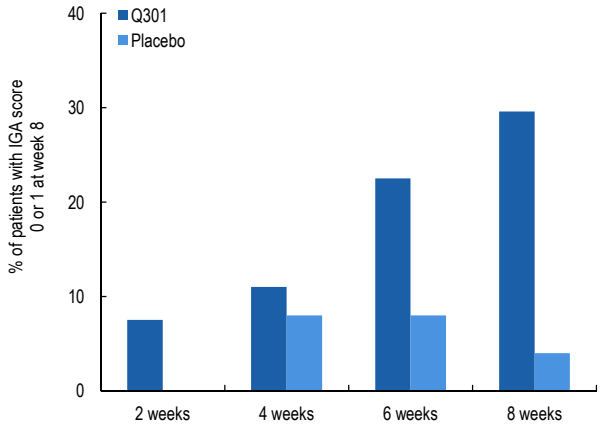
The most promising drug in the Qurient's pipeline is an atopic dermatitis treatment, Q310, which inhibits leukotriene that causes inflammation. The company recently completed Phase 2a clinical trials in the US. The safety of Q310 has already been proven, as the drug was developed by repositioning Zyflo, an asthma treatment that has been on the market for 20 years.

The efficacy of the drug was confirmed in Phase 2a trials. The primary endpoint of the trials was the proportion of subjects with treatment success, i.e., a score of 0 or 1, based on the Investigator's Global Assessment (IGA) at the end of treatment. In the eight-week trial (a twice-daily administration), 29.6% of patients achieved IGA scores of 0 or 1 (versus 4% for placebos).

Meanwhile, the pipeline drug of Anacor, which was acquired by Pfizer, reported higher proportions of patients achieving an IGA 0/1 response in two Phase 3 clinical trials (32.8% and 31.4%, respectively, at week four). However, while Anacor's subjects were patients with an IGA score of 2 or 3, Qurient carried out trials for patients with a score of 3 or 4. In addition, the concentration of Anacor's drug was 2%, while that of Qurient was 1%.

In light of the proven safety and efficacy of Q301, the company will likely license out its technology in the foreseeable future.

Figure 21. Q301's Phase 2a clinical trial results in the US



Source: Qurient, Mirae Asset Daewoo Research

Figure 22. IGA score

IGA score	Description
0	Clear
1	Almost clear
2	Mild severity
3	Moderate severity
4	Severe

Source: Mirae Asset Daewoo Research

Table 21. Pipeline status

Project	Indication	Phase	Note
Q301	Atopic dermatitis	Phase 2a US clinical trials completed	Out-licensing deals under negotiations
Q203	Drug-resistant TB	Phase 1b clinical trials in the US	Licensed in from Institut Pasteur Korea
Q701	Cancer/resistant cancer	Non-clinical trials	Licensed in from Max Planck Society in Germany
5LO inhibitor asthma treatment	Asthma	Development candidate	Developed in-house
CDK7 inhibitor anti-cancer treatment	Cancer	Development candidate	Licensed in from Max Planck Society in Germany

Source: Qurient, Mirae Asset Daewoo Research

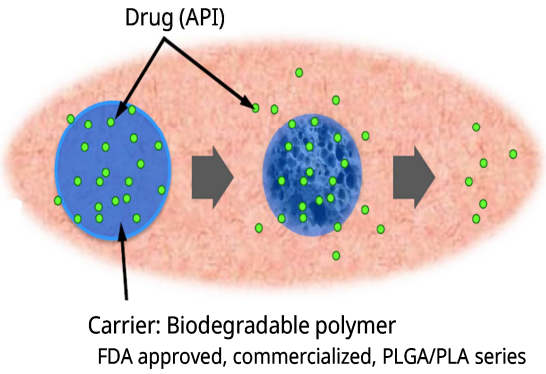
Peptron signs technology review deal with global pharma

• Notable pipeline	Once-weekly diabetics/obesity treatment
• Development status	Non-clinical
• Differentiation	Improved dosing convenience
• Event expected in 2H17	Global partner to announce results of its technological review

Peptron is a Korea-based company engaged in the development and distribution of sustained-release (SR) medications, or biobetters, based on its proprietary platform technologies. SmartDepot is Peptron's proprietary ultrasonic spray-drying technology, based on the microspheres manufactured through a combination of active pharmaceutical ingredients and a biodegradable polymer. As this technology does not cause any chemical modifications, the efficacy of drugs can be maintained, and both time and cost required to develop new drugs can be reduced. SmartDepot is based on the ultrasonic spray drying process, which allows for the production of uniformly-sized microspheres and mass-production. The firm is now carrying out clinical trials for its proprietary long-acting insulin and GLP-1 products (diabetes treatments).

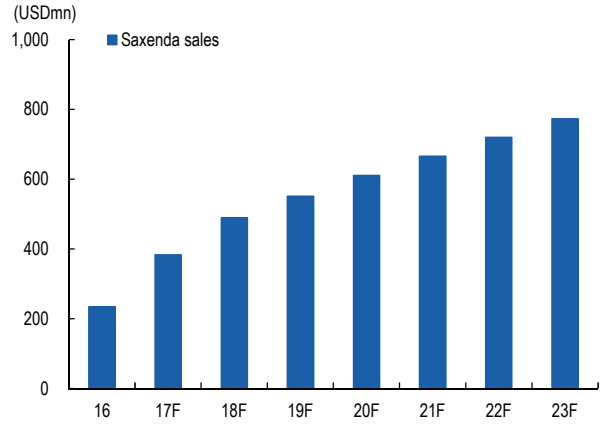
In October 2016, Peptron signed a contract with a global pharma for technology reviews regarding the development of diabetes and obesity treatments. The deal allowed the global pharma to apply Peptron's SmartDepot technology in the development of peptides, and confirm the success probability of the new drug. The results of the technology reviews are expected to be announced in 2Q. Should the review yield positive results, we expect Petron to forge a licensing deal over its SmartDepot technology with the global pharma, leading to increases in the values of its proprietary long-acting insulin and GLP-1.

Figure 23. Regulation of drug releases through microspheres



Source: Company data, Mirae Asset Daewoo Research

Figure 24. Expected revenue from GLP-1-applied obesity treatment Saxenda



Source: GlobalData, Mirae Asset Daewoo Research

Kolon Life Science: Growing expectations for Invossa

• Notable pipeline	Osteoarthritis drug Invossa
• Development status trials in US	Sought approval in Korea/preparing Phase 3 clinical
• Differentiation	Once-weekly injection
• Event expected in 2H17 in US	Approval for domestic distribution/ start of Phase 3 trials

In 2H, we think that Kolon Life Science's Invossa (a cell therapy drug to treat degenerative arthritis) deserves attention. The drug is set to obtain the final approval for Korea's domestic distribution in around June-July, with its Phase 3 clinical trials likely to begin in the US by year-end.

We are positive on Invossa, due to the following:

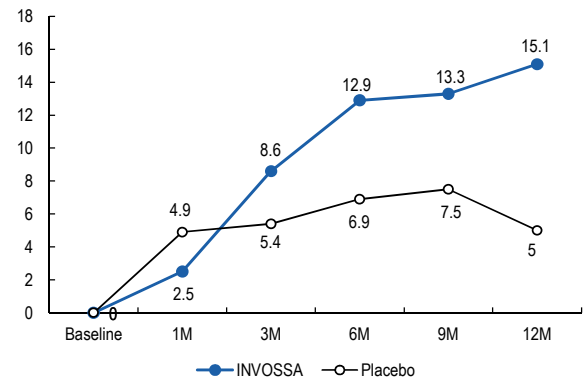
1) The market for the drug has immense growth potential, with the number of global degenerative arthritis patients rising steadily, amid population aging and an increase in the obese population. For reference, the number of global and Korean degenerative arthritis patients currently stands at over 400mn and 5mn, respectively.

2) The first-in-class osteoarthritis drug, based on single intra-articular injection, is differentiated from existing surgery-based treatments, such as joint replacement and stem cell therapies.

3) Clinical trials conducted in both Korea (Phase 3) and the US (Phase 2) have confirmed the efficacy of the drug. Indeed, Invossa outperformed a placebo in both International Knee Documentation Committee (IKDC) and Visual Analog Scale (VAS) scores.

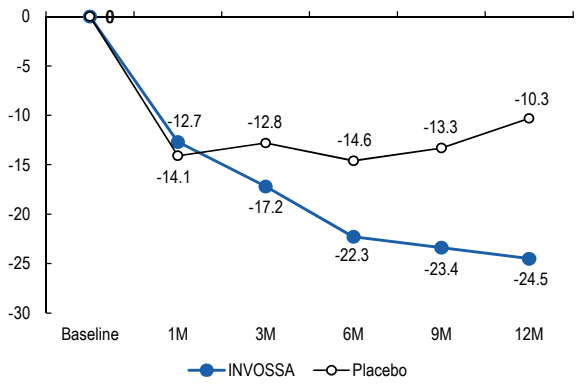
For reference, in November 2016, Kolon Life Science licensed the exclusive rights to commercialize Invossa only in Japan to Mitsubishi Tanabe Pharma for a whopping W500bn. The recent announcement of positive clinical study results for Invossa and exclusive license deals for its domestic and Japan distribution should heighten expectations for the conclusion of a global licensing deal for the drug going forward. As TissueGene currently owns rights to the exclusive distribution of Invossa in the US and Europe, additional licensing deals (for exclusive distribution) should not have a direct impact on Kolon Life Science. However, the deals should still help boost the firm's CMO sales. We also recommend that investors accumulate shares of either TissueGene (upon the completion of its IPO procedures) or Kolon, which has a 31.5% stake in TissueGene.

Figure 25. Effectiveness of Invossa confirmed in Phase 3 clinical trials (in Korea): IKDC score



Source: Company data, Mirae Asset Daewoo Research

Figure 26. Effectiveness confirmed in Phase 3 clinical trials (in Korea): VAS score



Source: Company data, Mirae Asset Daewoo Research

SK Biopharmaceuticals: Two pipeline drugs to be approved by US FDA

• Notable pipeline	Epilepsy treatment YKP3089, sleep disorder drug SKL-N05
• Development status	Phase 3 clinical trials in US
• Differentiation	Confirmation of superior efficacy in clinical trials
• Event expected in 2H17	Submission of NDA to US FDA

SK Biopharmaceuticals (SK Biopharm) is expected to file with the US FDA the new drug application (NDA) for its two pipeline drugs by end-2017.

YKP3089 (Cenobamate) is an investigational epilepsy drug, which is currently undergoing Phase 3 clinical trials centered on safety testing. Indeed, it obtained U.S. FDA permission to skip the efficacy testing stage for Phase 3 trials, as the Phase 2 trials showed that YKP3089 outperformed a placebo by 31%p, in terms of seizure frequency reduction (-55% versus -24%). For reference, its competing drug Vimpat was 19% more effective than a placebo. Should Phase 2 clinical trials find no significant side effects, we expect YKP3089 to be ready for global release by early 2019.

SKL-N05, a treatment for excessive daytime sleepiness (ESD) in narcolepsy or obstructive sleep apnea, is also expected to receive NDA from the US FDA this year. Indeed, rights to develop SKL-N05 were transferred to Jazz Pharmaceuticals back in 2011.

In March and April, Jazz Pharmaceuticals unveiled results of the Phase 3 clinical trials for SKL-N05, which showed a significant reduction in the level of sleepiness in patients with sleep apnea. The trials also showed the drug's outperformance versus existing drugs in terms of patient satisfaction. For reference, Xyrem, Jazz Pharmaceuticals' flagship narcolepsy drug, (which posted sales of USD1.1bn as of end-2016, representing 74% of its total sales) is set to lose its patent protection in 2020. As such, upon the commercial launch of SKL-N05, the new drug should replace Xyrem as the firm's largest revenue contributor.

Figure 27. Clinical trial results: Seizure frequency reduction

Substance		Drug	Placebo	Difference
YKP3089 (Cenobamate)	Phase 2 late stage	55%	24%	31%p
	Phase 2 early stage	56%	22%	34%p
Vimpat (2007~2010 clinical trial results)		37%	18%	19%p
Difference (Phase 2 late stage vs. Vimpat)		18%p	6%p	12%p

Source: Company data, Mirae Asset Daewoo Research

Figure 28. Clinical trial results: % of patients that saw seizures disappear

Substance		Drug	Placebo	Difference
YKP3089 (Cenobamate)	Phase 2 late stage	11%	1%	10%p
	Phase 2 early stage	28%	9%	19%p
Vimpat (2007~2010 clinical trial results)		3%	1%	2%p
Difference (Phase 2 late stage vs. Vimpat)		8%p	-	8%p

Source: Company data, Mirae Asset Daewoo Research

APPENDIX 1

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