Kolon TissueGene (950160)

Invossa Aims to Become Global Blockbuster

December 5, 2018

Taeyoung Lee Analyst
Pharmaceuticals, Biotechnology
82-2-6114-2931 ty.lee@kbfg.com

Company overview

Kolon TissueGene is an advanced cell therapy company that developed Invossa, a first-in-class cell and gene therapy targeting osteoarthritis (OA) of the knee. Invossa has been marketed in Korea since its approval in Nov, 2017. The drug began Phase III clinical trial in the US on Nov 20 and is scheduled to end in 1H22. The test involves 1,020 patients with grade 2 to 3 knee OA at 60 clinical sites. The company plans to submit a biologic license application (BLA) in 2H22. Barring any problems, Invossa's US debut is expected in 2H23.

Invossa: OA treatment

OA is a chronic disease that slowly damages joint cartilages, impairing or deforming the joints. This ultimately results in pain and limits the range of motion. OA is one of the most common muscular skeletal diseases and is cited as the biggest cause of disability among seniors. In particular, knee OA affects 3.8% of the global population. Invossa is designed to ease symptoms of moderate to severe knee OA, while delaying the need for replacement arthroplasty and other surgical interventions. The Phase III clinical test in Korea and Phase II test in the US have revealed that the drug significantly eases pain and improves range of motion.

Noteworthy points

1) Massive market potential
2) Heightened possibility of obtaining DMOAD status
3) Enhanced confidence in drug seen in expanding market coverage in Asia

We find three noteworthy points for Kolon TissueGene. First, there are approximately 30.87mn knee OA patients in the US. Considering there are no drugs to treat knee OA aside from painkillers, this is a massive market waiting to be tapped. Second, the drug has become increasingly likely to obtain DMOAD (Disease Modifying Osteoarthritis Drugs) status thanks to the US FDA's revisions to its guidelines and clinical endpoint assessment criteria. Third, the drug has already debuted in Korea and is boasting robust prescription numbers. In addition, confidence in the drug's commercial viability has improved following the signing of vendor and license-out deals in eight countries.

Not Rated

Target Price	NA
Upside/Downside	NA
Current price (Dec 4)	KRW 41,950
Consensus Target Price	NA
Market cap	USD2.4bn

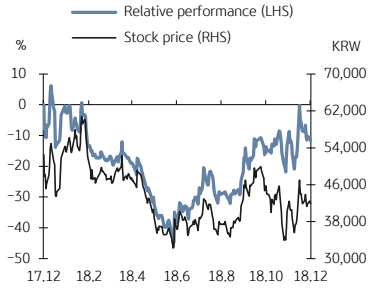
Trading Data	
Free float	38.0%
Avg T/O Val (3M, KRW bn)	25.6
Foreign owenership	5.4%
Major shareholders	KOLON CORPORATION and 6 others 62.0%

Share price performance

(%)	1M	3M	6M	12M
Absolute	4.4	-8.7	15.2	-20.1
Relative	1.7	6.6	42.7	-11.8

Forecast earnings & valuation

FY-end	2014A	2015A	2016A	2017A
OR (KRWbn)	NA	NA	13	3
OP (KRWbn)	NA	NA	6	-15
NP to parent (KRWbn)	NA	NA	7	-20
EPS (KRW)	NA	NA	2,987	-4,592
EPS Growth (%)	NA	NA	NA	NA
PER (x)	NA	NA	NA	NA
EV/EBITDA (x)	NA	NA	NA	NA
PBR (x)	NA	NA	NA	1.6
ROE (%)	NA	-698.3	62.5	-18.3
Div. Yield (%)	NA	NA	NA	NA



Source: Kolon TissueGene

I. Company Overview

Major businesses

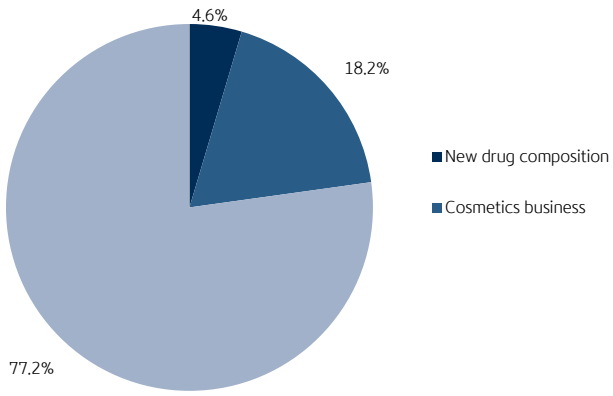
Kolon TissueGene is an advanced cell therapy company founded in Jun, 1999. The company developed Invossa, a first-in-class cell and gene therapy targeting osteoarthritis (OA) of the knee. Invossa is undergoing Phase III clinical trial for US FDA approval. Kolon Life Science, which holds the drug's Asian sales license, conducted the Phase III clinical test for Invossa in Korea and has been marketing the drug since its approval in Jul, 2017. Kolon TissueGene hopes to complete the ongoing Phase III clinical studies in the US in 1H22 and apply for BLA approval in 2H22. If approved without any hiccups, the drug will hit the US market in 2H23.

OR breakdown and shareholder composition

As of 3Q18, cumulative OR stood at KRW2.97bn, 77.2% of which was generated by the total retail business, 18.2% from cosmetics, and 4.6% from new drug pipelines. As of end-3Q18, Kolon TissueGene's largest shareholder was Kolon (27.3%), followed by President/CEO Woosok Lee (17.8%), Kolon Life Science (12.6%), and Kolon Glotech (2.8%).

Total retail business 77.2%, cosmetics 18.2%, and new drug pipelines 4.6%

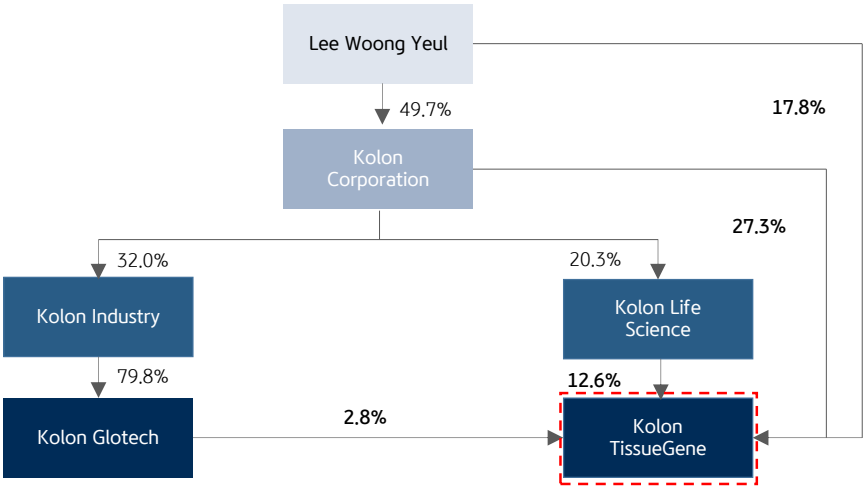
Fig 1. Sales composition



Source: Company data, KB Securities

Key shareholders: Kolon (27.3%), President/CEO Woosok Lee (17.8%), Kolon Life Science (12.6%), and Kolon Glotech (2.8%)

Fig 2. Shareholders composition



Source: Company data, KB Securities

3Q18 earnings results and cash holdings

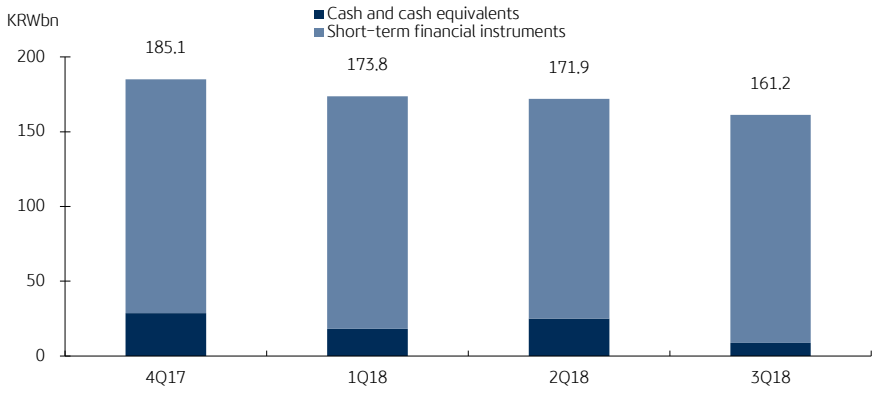
Kolon TissueGene turned in OR of KRW0.96bn (+0.8% QoQ) and operating loss of KRW3.38bn (-32.2% QoQ) for 3Q18. The value of cash equivalents and short-term financial products declined KRW23.9bn (-12.9%), from KRW185.1bn in 4Q17 to KRW161.2bn.

Capitalization of R&D costs into intangible assets and expenses

In May, 2015, Kolon TissueGene was cleared to begin Phase III clinical tests in the US and related expenses were capitalized since they qualify as development costs under K-IFRS rules (No. 1038). As of 3Q18, R&D costs reached KRW16.97bn, 85.9% (KRW14.57bn) of which has been capitalized.

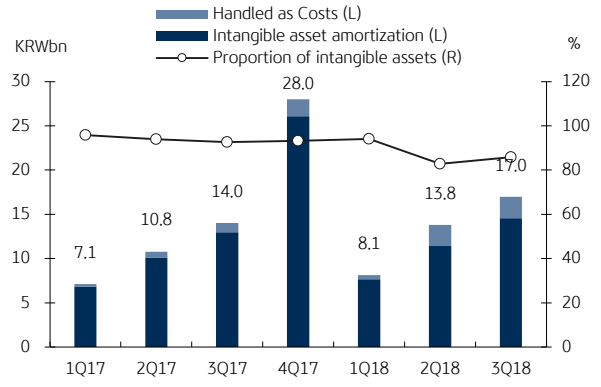
End-3Q18 value of cash equivalents and short-term financial products at KRW161.2bn

Fig 3. Cash equivalents and short-term financial instruments trend



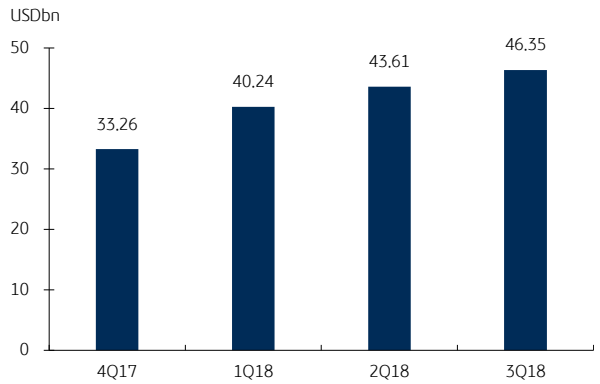
Source: Company data, KB Securities

Fig 4. Intangible asset amortization of R&D costs



Source: Company data, KB Securities

Fig 5. Cumulative asset development costs



Source: Company data, KB Securities

Table 1. Kolon TissueGene's quarterly earnings

(KRWbn)	2016	1Q17	2Q17	3Q17	4Q17	2017	1Q18	2Q18	3Q18	QoQ
OR	13.3	-	-	0.8	2.4	3.2	1.1	0.9	1.0	0.08
OP	6.0	-1.5	-1.8	-2.5	-9.4	-15.1	-3.6	-5.0	-3.4	-3.22
EBT	5.5	-1.7	-2.1	-2.5	-9.8	-16.1	-3.4	-4.8	-2.9	-4.08
NP	7.3	-1.7	-2.1	-2.5	-13.6	-19.8	-3.4	-4.8	-2.9	-4.07

Source: Company data, KB Securities

Status on sales rights license deals and marketing contracts

Kolon TissueGene held global sales rights for Invossa before it sold the rights for 22 Asian countries (including Korea) to Kolon Life Science in Mar 2000. Per terms of its contract, Kolon TissueGene receives from Kolon Life Science 2% of the drug's ordinary sales and exports as royalties and 50% of upfront payments, milestone payments and royalties from sub-license contracts. In addition, Kolon TissueGene temporarily transferred the UAE and Saudi Arabian sales rights to Kolon Life Science in Jun 2018 for 10-20% sales royalties (rate differs in accordance to amount of sales).

Sales royalties differ by region

Kolon Life Science signed contracts to export Invossa to Hong Kong, Macau, Mongolia, Saudi Arabia, the UAE and Hainan Province (China), while clinching a sub-license deal for the Japanese market. Accordingly, Kolon TissueGene's top-line is expected to include: 1) 2% of the drug's sales in Korea, Hong Kong, Macau, Mongolia and Hainan Province, 2) 10-20% of the revenues from Saudi Arabia and the UAE and 3) 50% of milestone payments and sales royalties Kolon Life Science gains from Japan, assuming development progresses smoothly.

Kolon Life Science and Lonza take charge of Invossa productions

Kolon Life Science and Lonza are in charge of Invossa production. Kolon Life Science exclusively produces Invossa for sales in Korea, while CMO (contract manufacturing organization), Lonza, assumed production of investigational products and initial shipments in the US market. Kolon Life Science is ramping up facilities in Chungju in preparation for increases in demand.

Table 2. Invossa export contracts, licencing deals

	Licensor	Licensee / Sub Licensor	Sub Licensee	Marketing Partner	
North America	Kolon Tissuegene	Selection of sales partner planning			
Europe		License Out Planning			
Asia		Kolon Life Science			
Korea				Kolon pharma, Mundipharma	Mundi oversees general hospitals
Japan				Mundipharma	Overall License Out size $667.7bn
China (Hainan)				China Life Medical Center	Minimum contract of $230bn for 5 years
HongKong				Zhong Ji	Minimum contract of $16.9bn for 5 years
Macau					
Mongolia				Vim Med	Approximately $10bn for 5 years
ROW					
Saudi				Mundipharma	Size of contract - Unknown
UAE					
Others					

Source: Kolon Life Science, Kolon TissueGene, KB Securities

II. Invossa, the OA Treatment

OA, a common disease afflicting 3.8% of global population

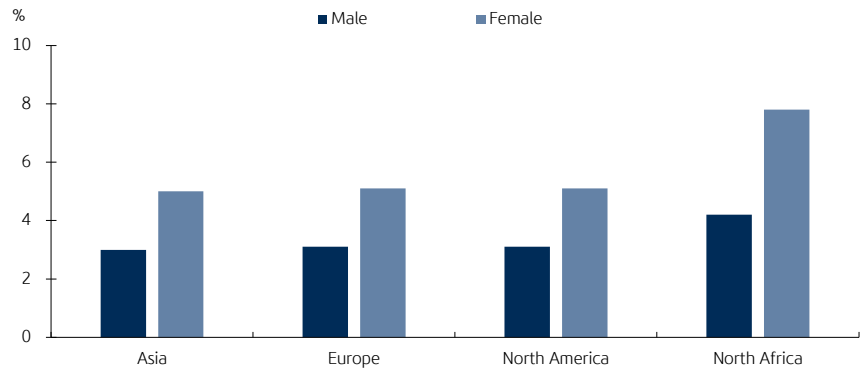
OA is a chronic disease that causes steady damage to the joint cartilage, impairing or deforming the joints. This ultimately results in pain and limits the range of motion. Major symptoms include regional joint pain, cellular/biochemical changes, osteophyte formation, asymmetric joint space narrowing, and cartilage hardening. OA is one of the most common muscular skeletal diseases and is cited as the biggest cause of disability among seniors. In particular, knee OA is affecting 3.8% of the global population

OA progression

Simply put, cartilages cushions the shock joints receive and protects the joints during movement. . When moving joints, joint cartilage covering the end (② in Fig 5) of each bone (①) is repeatedly worn down and replenished. If the cartilage is not sufficiently replenished after damage, protective layer wears away and exposes the bones underneath (③). As OA worsens over time, cartilage or bones break off and the fragments float around in synovial fluid. The floating bits irritate the synovium around joints and causes inflammation, resulting in pain and swelling (④, ⑤).

Fig 6. Worldwide cases of knee joint inflammation (2010 basis)

3.8% of global population suffering knee OA

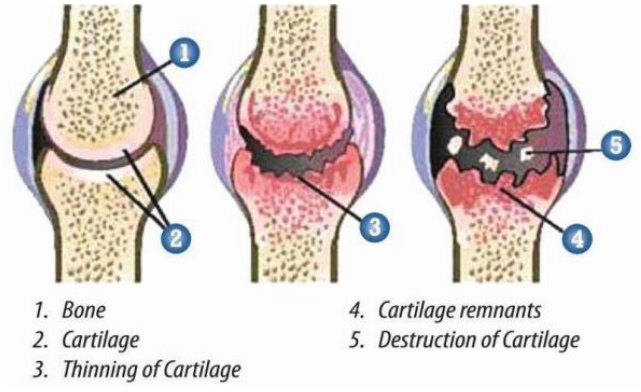


Source: Cross M, et. al, KB Securities

Fig 7. Knee OA progression

Progression of knee OA

: Thinning of joint cartilage → wearing of protective tissue → exposure of bones under cartilage → chipping of cartilage/bones → irritation of synovium by fragments → pain and swelling



Source: KB Securities

Focus of treatment: pain relief and mobility improvement

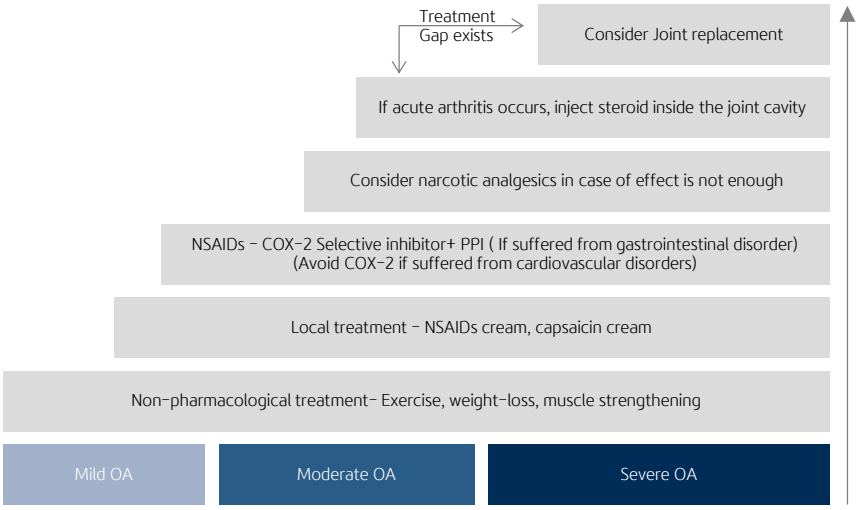
If the pain worsens, physical mobility may deteriorate to a point that renders normal economic activities nearly impossible. According to the US Arthritis Foundation, more than 20mn OA patients have lost their jobs, which incurs whopping economic costs of USD100bn per year. For this reason, pain relief and mobility have become the focus of OA treatment.

Medication and surgical treatments

Non-steroidal anti-inflammation drugs (NSAIDs), most commonly administered for OA treatment, can be used without any significant troubles over a short period. For OA and other chronic diseases, however, patients must regular doses over an extended period, which could result in side effects, such as gastric ulcer. If pain cannot be relieved with the administration of NSAIDs, patients resort to stronger drugs, such as opioids. Beyond that, replacement arthroplasty is the only option.

Stages of treatment: Non-medicinal therapy → drugs → surgery

Fig 8. OA treatment by grade



Source: Sinusas et al. KB Securities

Invossa, world's first cell and gene therapy for OA

Invossa is a cell therapy involving: 1) unmodified allogenic human chondrocyte and 2) modified allogenic human chondrocyte to produce TGF-β1 (transforming growth factor beta 1), a material required for cartilage maintenance. TGF-β1 promotes the regeneration of cartilage, while insufficient amounts cause OA-like symptoms. On the other hand, TGF-β1 activation in subchondral bone cause abnormal bone remodeling and cartilage degeneration. Therefore, effective adjustment of TGF-β1 activation and function is crucial in developing OA remedies and treatments.

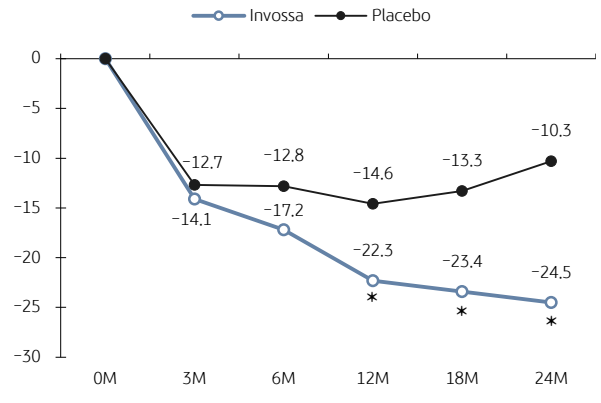
Anti-inflammatory effects, improved bone structure and functioning

Invossa is a 3:1 mixture of two cells and is injected into joint space. The drug is designed to alleviate pains of moderate to severe knee OA (Kellgren & Lawrence (K&L) grade 2 to 3; K&L is a method of classifying the severity of knee OR using five stages from 0 to 4; grade 2 to 3 patients are treated with hyaluronic acid and local steroid injections) and delay the need for replacement arthroplasty and other surgical interventions.

Outcomes of Phase III clinical trial in Korea and Phase II clinical trial in US : Pain-relieving effects and range of motion improvement verified

Invossa's significant efficacy is evident in the primary outcome measures of its placebo-controlled Phase III clinical trial (conducted on 159 patients) in Korea. Outcome measures were VAS scores (Visual Analog Scale: a method for the assessment of the intensity of pain on a scale from 0, no pain, to 10, the severest degree of pain) and IKDC scores (International Knee Documentation Committee: used in detecting improvements or deteriorations in knee OA symptoms and knee functionality through 18 questionnaires including sports activities). After completing Phase III trials in Korea and proving its pain-relieving effects, Invossa obtained KFDA approval in Jul 2017 and hit the Korean market in Nov. The drug also proved its statistically significant results in alleviating pain during Phase II tests in the US. Injections in US Phase III subjects began on Nov 20.

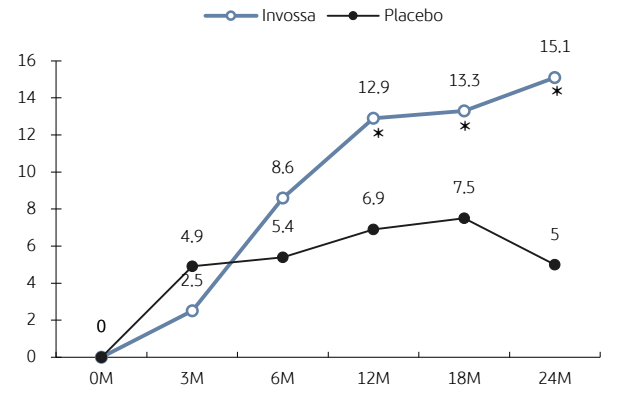
Fig 9. Korea Phase III Outcome – VAS score (Pain index)



Source: Company data, KB Securities

Note: P-value of Invossa administered group<0.05

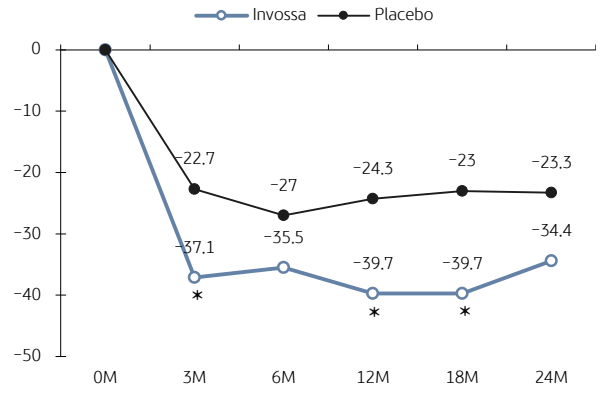
Fig 10. Korea Phase III Outcome – IKDC score (Functionality index)



Source: Company data, KB Securities

Note: P-value of Invossa administered group<0.05

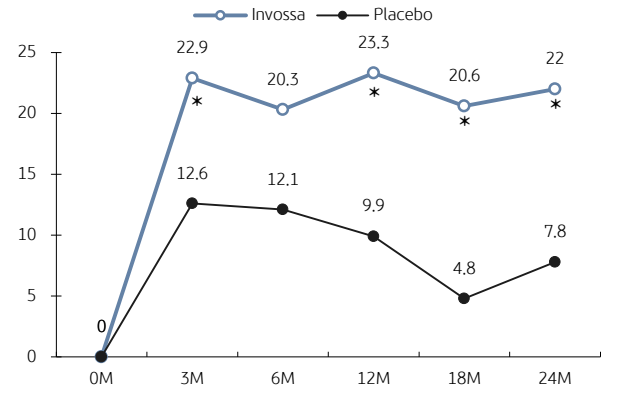
Fig 11. US Phase II Outcome – VAS score (Pain index)



Source: Company data, KB Securities

Note: P-value of Invossa administered group<0.05

Fig 12. US Phase II Outcome – IKDC score (Functionality index)



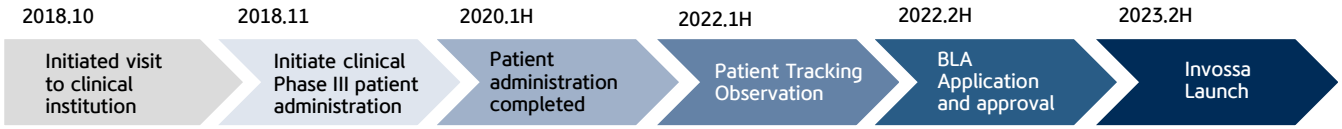
Source: Company data, KB Securities

Note: P-value of Invossa administered group<0.05

Design and schedules of Phase III clinical trial in US

The FDA granted SPA approval for Invossa (Special Protocol Assessment: An advanced declaration of clinical objectives set through prior consultations with the FDA; If clinical outcomes match the objectives, sales approval is granted) in May 2015 and cleared investigational products produced by the Switzerland-based CMO, Lonza, for use in Phase III clinical tests in Jul 2018. The Phase III trials will be conducted on grade 2 to 3 knee OA patients in 60 hospitals across the US. Kolon TissueGene plans to test the drug on patients until 1H20, who will be monitored for an additional 24 months for safety and efficacy, before filing for BLA (Biologics License Applications) approval in 2H22. The company hopes to obtain BLA approval by 2023 and begin marketing the product.

Fig 13. US Phase III Timeline



Source: Company data, KB Securities

Table 3. Comparison of Phase III trials in Korea and US

		US	Korea
Clinical		Randomized, Double-blind, Placebo-controlled, Multicenter	Randomized, Double-blind, Placebo-controlled, Multicenter
Clinical sites		60 sites in US	12 sites in Korea
No. patients		1,020	159
K&L Grade		Grade 2/3	Grade 3
Treatment group		Invossa 680 / Placebo 340	Invossa 78 / Placebo 81
Screening period		24months	12months
Endpoint	Primary endpoint	VAS, WOMAC (@12 months)	IKDC, VAS
	Secondary endpoint	MRI, SF-12, WOMAC (@24 months), HAQ-DI	WOMAC, KOOS, MRI, X-ray (JSW), Biomarkers
Claim Range		Primary endpoint, Secondary endpoint	Primary endpoint

Source: Company data, KB Securities

III. Check Points

Key check points

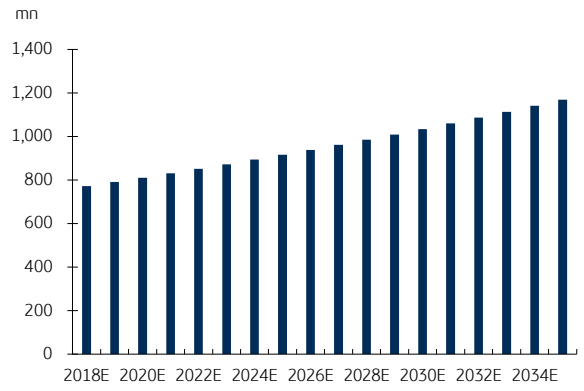
1) Strong market potential

According to GlobalData, there are 600mn people afflicted by OA in 16 countries around the world, 37% (about 200mn) of which are knee OA patients. The number of knee OA patients in the US alone reaches 30.87mn, pointing to the drug's huge potential market. Among knee OA patients in the US, approximately 7.22mn people are classified as grade 2 and 3 (25% of total knee OA patients). However, they have no viable treatment options other than painkillers and steroid injections. Against this backdrop, we estimate Invossa to rake in sales of KRW2.6tr during its first year in the US market assuming: 1) a selling price of USD9,000 (Kolon TissueGene's estimate) and 2) 3% of patients with grade 2 to 3 knee OA transiting to Invossa

Indication expansion also a goal

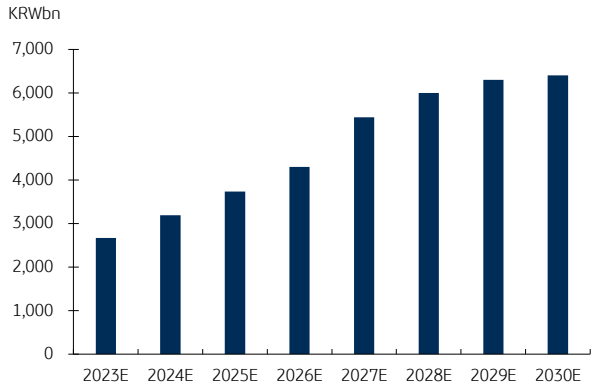
In 2019, Kolon TissueGene plans to file for IND (investigational new drug) approval of Invossa for Phase II tests to add hip OA to the drug's indications. The number of hip OA patients stands at 71.04mn, which represents 12% of world's OA-afflicted population. In addition, Invossa is currently undergoing preclinical studies to gauge its potential for veterinary applications.

Fig 14. US Knee OA grade 2/3 patients forecast



Source: Globaldata, KB Securities estimates

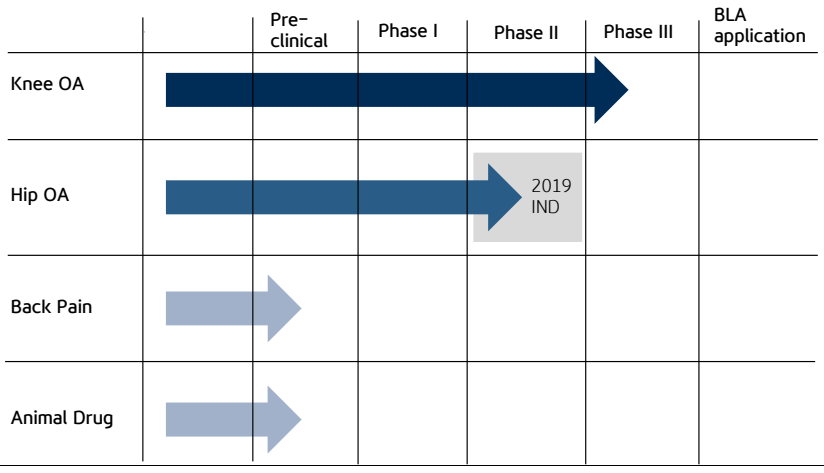
Fig 15. Invossa US sales forecast



Source: Globaldata, KB Securities estimates

Indications of Invossa to expand: knee→ hip → lumbar

Fig 16. Invossa's indication expansion plan



Source: Company data, KB Securities

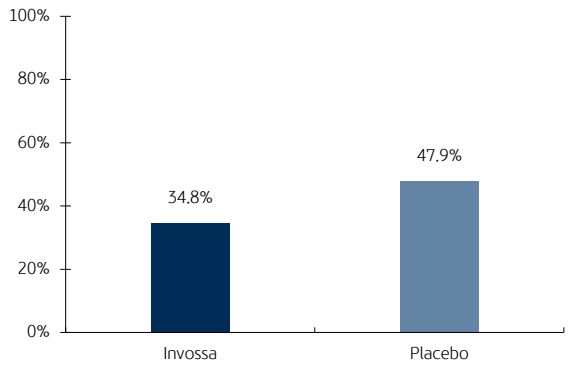
2) Heightened possibility for gaining DMOAD status

Existing OA treatments usually focus on pain relief or involve surgical procedures, such as replacement arthroplasty. But Kolon TissueGene is hoping Invossa relieves pain, brings functional and structural improvements, and inhibits OA progression, which would earn the drug DMOAD designation. Being a degenerative disease, it is impossible to bring OA progression to a complete stop. Hence, Invossa focuses on delaying progression as much as possible in order to postpone replacement arthroplasty and improve the patients' quality of life.

FDA's new DMOAD guideline

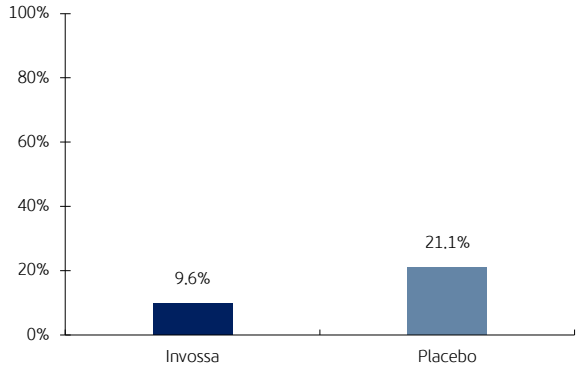
The FDA's previous DMOAD guidelines required: 1) VAS scores, which indicates the degree of pain reduction, 2) Western Ontario and McMaster Universities (WOMAC) scores, which gauges the extent of improvements in function and strength, and 3) a radiographic JSNs (joint space narrowing gauged through X-ray), which shows the suppression of structural progression. However, the US FDA unveiled revised guidelines in Oct 2018, which reduces on the prominence of JSN and instigates versatile use of various biomarkers, including MRI.

Fig 17. US Phase II MRI WORMS outcome – Deteriorating cartilage structure



Source: Company data, KB Securities

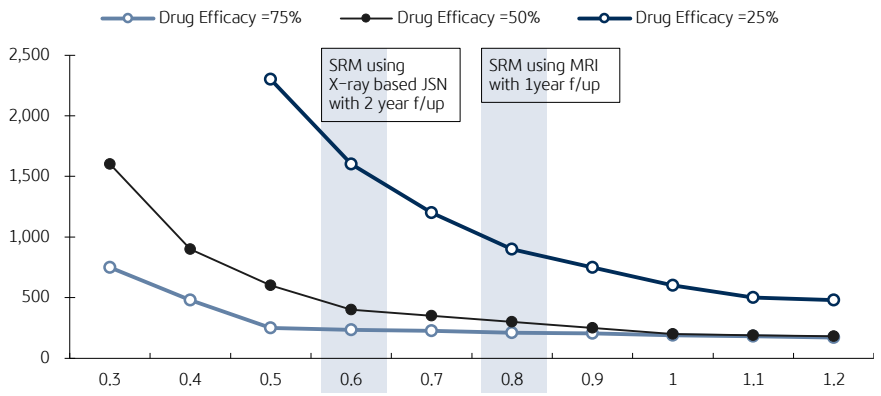
Fig 18. US Phase II MRI WORMS outcome – Worsening synovial inflammation



Source: Company data, KB Securities

MRI produces same effects as X-ray (JSN) with smaller sample size and in shorter period of time

Fig 19. Relationship between responsiveness and patient size



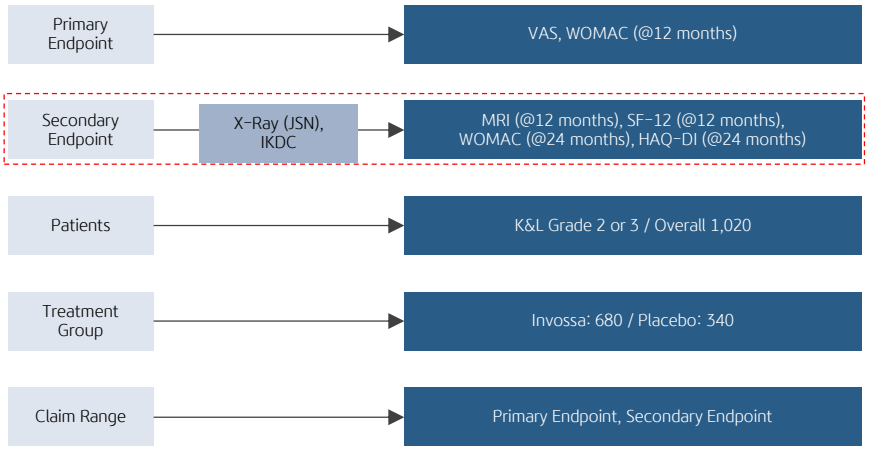
Source: Company data, KB Securities

MRI repositioned as top-tier secondary outcome measure

A noteworthy point in the design of Phase III clinical trials for Invossa is that MRI, which used to be one of the lesser outcome measures, was elevated to one of the most crucial secondary outcome measures. MRI, which is more sensitive than X-ray, can produce the same effects as the latter, but with a smaller sample size and in a shorter period of time. The FDA also labels drugs that perform well against secondary outcome measures. Thanks to the guideline revisions, Invossa is closer to becoming the world's first drug to gain DMOAD status.

X-ray (JSN) excluded from secondary outcome measures, while MRI repositioned to top of list

Fig 20. Change of US Phase III endpoint



Source: Company data, KB Securities

3) Confidence in drug growing on expanding market coverage in Asia

We see expanding sales in Korea and signing of vendor contracts and license deals for numerous Asian markets as positives. In Oct, 2018, less than a year since hitting the market on Nov 8, 2017, the total number of Invossa prescriptions surpassed 2,200 cases. A total of 332 clinics and 73 general hospitals are prescribing the drug. Kolon Life Science, which holds the Asia license, has set the foundation for launching Invossa in six (Korea, China, Japan, Hong Kong, Macau, Mongolia) out of 22 Asian nations. The company also sealed deals in Saudi Arabia and the UAE. The company's contracts in Asia are worth a combined KRW906.9bn - KRW650bn from its license-out contract in Japan and a reported KRW256.9bn from the remaining seven Asian countries. Confidence in Invossa's commercial viability has become stronger considering: 1) soaring prescription numbers in Korea and 2) the vendor contracts in eight countries.

IV. Risk Analysis

1) Uncertainties over termination of license deal with Mitsubishi Tanabe

Kolon Life Science, the sole holder of the Asian license for Invossa, signed a KRW500bn out-licensing deal with Mitsubishi Tanabe in Nov, 2016. However, Mitsubishi Tanabe cancelled the deal and demanded Kolon Life Science return the upfront payment of KRW25.3bn, stating that: 1) when signing the deal in Dec, 2017, Kolon TissueGene was considering changing the manufacturer of investigational products for Invossa's Phase III clinical trial in the US and 2) the developer did not inform Mitsubishi Tanabe about the receipt of the CHL (Clinical Hold Letter) from the FDA, which stated IND approval is a perquisite for Phase III clinical tests.

Kolon Life Science refuted Mitsubishi Tanabe's claims, claiming that: 1) when two companies were entering the agreement, the production of investigational products was initially going to be outsourced the China-based Wuxi, one of Kolon TissueGene's existing manufacturers, but ultimately went to Lonza, a development that Mitsubishi Tanabe was sufficiently made aware of, and 2) the CHL from the FDA was merely a notice stating IND approval is normal procedure that needs to be fulfilled before beginning administration of investigational products on patients and did not constitute grounds for cancelling the contract. Failing to reach a compromise, Mitsubishi Tanabe Pharma filed a request for arbitration against Kolon Life Science in Apr 2018. If the two companies fail to reach an agreement, the lawsuit and related issues could have adverse effects on Kolon Life Science.

2) Potential for quality and supply issues due to complexity of production procedures

Being a cell and gene therapy, the production process for Invossa is complex. This may prompt uncertainties involving production procedures. Invossa is a mixture of allogenic human chondrocytes and human chondrocytes transduced with the human TGF-β1 gene, thus involving complex production procedures, including: 1) the use of viruses to transduce genes and 2) irradiation of gene-transduced cells. Therefore, the drug requires a more intense quality control regime than other drugs. An annual production capacity of at least 300,000 doses will be needed to cope with the anticipated explosive demand in the US market.

As part of its thorough preparations, Kolon TissueGene streamlined its manufacturing processes in a joint effort with the leading cell-based therapy CMO, Lonza. The FDA deemed the addressment of all issues "satisfactory" and retracted the CHL, clearing Invossa for Phase III clinical testing. In addition, the company is stepping up efforts to develop a 3D cultivation system to boost productivity.

Profit & Loss

(KRWbn)	2013A	2014A	2015A	2016A	2017A
(Reporting standard)	(GAAP-)	(GAAP-)	(IFRS-)	(IFRS-)	(IFRS-)
Operating revenue	NA	NA	0	13	3
Cost of sales	NA	NA	0	0	2
Gross profit	NA	NA	0	13	2
SG&A expenses	NA	NA	6	7	17
Operating profit	NA	NA	-6	6	-15
EBITDA	NA	NA	-6	6	-15
Non-operating accounts	NA	NA	0	-1	-1
Interest income	NA	NA	0	0	1
Interest expenses	NA	NA	0	1	1
Profit on equity method	NA	NA	0	0	0
Net other non-operating income	NA	NA	0	0	-1
Profit before tax	NA	NA	-6	5	-16
Income tax expense	NA	NA	0	-2	4
Net profit	NA	NA	-6	7	-20
NP to profit	NA	NA	-6	7	-20
Adj. net profit	NA	NA	-6	7	-20

Operating Statistics & Ratios

(%)	2013A	2014A	2015A	2016A	2017A
OR growth	NA	NA	NA	4,187.1	-76.0
OP growth	NA	NA	NA	TB	TR
EBITDA growth	NA	NA	NA	TB	TR
NP growth of parent	NA	NA	NA	TB	TR
GP margin	NA	NA	100.0	100.0	48.0
OP margin	NA	NA	-1964.5	45.2	-474.6
EBITDA margin	NA	NA	-1848.4	48.2	-458.0
EBT margin	NA	NA	-2016.1	41.1	-504.1
NP margin	NA	NA	-2016.1	55.0	-621.6

Cash Flow

(KRWbn)	2013A	2014A	2015A	2016A	2017A
Cash flow from operating activities	NA	NA	-6	6	-15
Net profit	NA	NA	-6	8	-19
Depreciation & amortization	NA	NA	0	0	1
Other non-cash adjustments	NA	NA	1	-1	4
Investments in working capital	NA	NA	0	2	0
Decrease(Increase) in Receivables	NA	NA	0	0	0
Decrease(Increase) in Inventories	NA	NA	0	0	0
Increase(Decrease) in Payables	NA	NA	0	0	0
Other operating cash flow	NA	NA	0	-3	-1
Cash flow from investing activities	NA	NA	-3	-11	-181
Capital expenditure	NA	NA	0	0	0
Investments in intangibles	NA	NA	-2	-10	-22
Changes in investment assets	NA	NA	0	0	0
Other investment cash flow	NA	NA	0	0	-2
Cash flow from financing activities	NA	NA	8	21	204
Proceeds from (repayments of) debt	NA	NA	8	8	9
Changes in equity	NA	NA	0	12	195
Dividends paid	NA	NA	0	0	0
Other financing cash flow	NA	NA	0	0	0
Other cash flow	NA	NA	0	0	0
Increase/decrease in cash	NA	NA	0	17	8
Cash and cash equivalents at FYE	NA	NA	7	23	29
Free cash flow	NA	NA	-6	6	-15
Net cash flow	NA	NA	-2	8	155
Net cash (net debt)	NA	NA	-2	7	161

Statement of financial position

(KRWbn)	2013A	2014A	2015A	2016A	2017A
(Reporting standard)	(GAAP-)	(GAAP-)	(IFRS-)	(IFRS-)	(IFRS-)
Total assets	NA	NA	11	42	228
Current assets	NA	NA	7	24	189
Cash and cash equivalents	NA	NA	7	23	29
Current financial assets	NA	NA	0	0	156
Trade receivables	NA	NA	0	0	1
Inventories	NA	NA	0	0	1
Other current assets	NA	NA	0	1	3
Non-current assets	NA	NA	4	18	39
Investment assets	NA	NA	0	0	0
Property, plant and equipment	NA	NA	1	1	1
Intangible assets	NA	NA	3	13	37
Other non-current assets	NA	NA	0	0	1
Total liabilities	NA	NA	9	21	32
Current liabilities	NA	NA	0	3	13
Trade payables	NA	NA	0	0	1
Short-term financial liabilities	NA	NA	0	0	5
Other current liabilities	NA	NA	0	3	7
Non-current liabilities	NA	NA	8	18	19
Non-current financial liabilities	NA	NA	8	17	19
Other non-current liabilities	NA	NA	0	1	1
Total equity	NA	NA	2	22	196
Issued capital	NA	NA	0	0	0
Share premium	NA	NA	72	86	272
Other equity interest	NA	NA	0	0	0
Accumulated other comprehensive income	NA	NA	0	0	0
Retained earnings	NA	NA	-70	-65	-76
Equity attributable to owners of parent	NA	NA	2	22	196
Non-controlling Interests	NA	NA	0	0	0

Key Ratio

(X, %, KRW)	2013A	2014A	2015A	2016A	2017A
Multiples					
PER	NA	NA	NA	NA	NA
PBR	NA	NA	NA	NA	1.6
PSR	NA	NA	NA	NA	70.1
EV/EBITDA	NA	NA	NA	NA	NA
EV/EBIT	NA	NA	NA	NA	NA
Dividend yield, ordinary (%)	NA	NA	NA	NA	NA
EPS	NA	NA	-2,576	2,987	-4,592
BPS	NA	NA	733	8,814	32,320
SPS	NA	NA	128	5,431	739
DPS (Annual, Ordnry.)	NA	NA	NA	NA	NA
Cash dividends payout ratio (%)	NA	NA	NA	NA	NA
Operating performance					
ROE	NA	NA	-698.3	62.5	-18.3
ROA	NA	NA	-115.6	29.6	-14.1
ROIC	NA	NA	-362.5	53.3	-65.6
Financial structure (%)					
Total liab./equity	NA	NA	491.6	95.3	16.6
Net debt/equity	NA	NA	87.7	Net Cash	Net Cash
Current Ratio	NA	NA	15.9	7.8	14.6
Interest coverage (x)	NA	NA	-44.1	12.8	-19.2
Activity ratios					
Asset turnover (x)	NA	NA	0.1	0.5	0.0
Receivables turnover (x)	NA	NA	NA	NA	8.9
Inventory turnover (x)	NA	NA	NA	NA	7.7

Source: Kolon TissueGene, KB Securities

Disclosures

Rating and Target Price Changes (Share price —, Target Price —)

KB Securities has not provided in advance the material contained in this report to any institutional investor or third party. The analyst(s), who wrote this report, does not have any financial interest in the company(ies) covered herein. The author(s) of this report confirms that the material contained herein correctly represents his/her/their opinion and that it has been prepared faithfully without any undue influence or intervention.

Classification and Standards for Investment Rating

Investment Rating for Company
(based on estimation of six-month absolute returns)

Buy: +15% or beyond	Hold: Between 15% and -15%	Sell: -15% or beyond

Note: KB Securities's classification of investment ratings has shifted from four stages (Strong BUY, BUY, Marketperform, Underperform) to three stages (Buy, Hold, Sell) based on Korean reports since February 23, 2017.

Investment Rating for Industry
(based on estimation of six-month absolute returns)

Positive:	Neutral:	Negative:
To outperform market	To match market performance	To underperform market

Notes: The industry rating system of KB Securities has shifted from (Overweight, Neutral, Underweight) to (Positive, Neutral, Negative) as of Jun 28, 2017

Proportion of investment rating (as of September 30, 2018)

Buy	Hold	Sell
75.2	24.8	-

* Note: Based on reports presented with investment ratings over the past one year

All KB Securities Research is available via the following electronic databases: Bloomberg, Thomson Reuters, FactSet. Contact your KB Securities sales representative for access.