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# Company Visit Note



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## AT A GLANCE

**Price band** KRW16,000-KRW27,000

Market cap KRW1,013b-1,709b

Shares (float) 60,443,085 DR (36.8%)

## TissueGene (950160)

### Invossa could be osteoarthritis game-changer

- TissueGene, a US-based cell and gene therapy developer and Kolon Group affiliate, is planning a Nov 6 IPO on the Kosdaq at KRW16,000-27,000/depository receipt and holds the global rights outside Asia to market Invossa, a potential game-changing osteoarthritis treatment. The firm has co-developed Invossa with affiliate Kolon Life Science, looking to meet demand for a treatment that can fill the gap between existing medications and knee-replacement surgery. Kolon Life Science has been approved to market the drug in Korea and holds its Asian marketing rights.
- Invossa will soon begin phase III trials in the US to prove its capacity as a disease-modifying osteoarthritis drug. The trials will last longer than the two years that Invossa was tested in Korea and involve a wider range of patient severity.
- We believe the bottom of TissueGene's IPO price band is supported by Korea Exim Bank's preferred share holdings and Kolon Life Science's market cap.

### WHAT'S THE STORY?

**Changing the game:** TissueGene, a US-based cell and gene therapy developer and Kolon Group affiliate, is planning a Nov 6 IPO on the Kosdaq at KRW16,000-27,000/depository receipt and holds the global rights outside Asia to market Invossa, a potential game-changing osteoarthritis treatment. The Kolon Group's biopharmaceutical arm, the company was founded in 1999 and has 38 employees. As of its filing, Kolon Corporation owned 31.16% of the firm, Kolon Chairman Lee Woong-yeul 20.38%, Kolon Life Science 14.37%, Kolon Glotech 3.23%, and other parties 30.86%. After it lists, Kolon Holdings will own 27.52%, the chairman 18%, Kolon Life Science 12.69%, Kolon Glotech 2.85%, those who buy into the public offering 12.41%, and other parties 26.53%.

**Clear demand:** TissueGene and Kolon Life Science have co-developed Invossa, looking to fill the gap between existing osteoarthritis medications and knee-replacement surgery. There is clear demand for a treatment that can slow the progress of osteoarthritis, a disease TissueGene estimates affects 236m patients globally and constitutes a USD3.58b market. There is no cure, and patients prescribed anti-inflammatories, steroids, and hyaluronic acid tend to be dissatisfied. Knee replacement surgery is a final resort.

**Kolon Life Science holds rights in Asia:** In July, Korea's Ministry of Food and Drug Safety approved Kolon Life Science to market Invossa in Korea as a treatment for patients with moderate symptoms and for which other medications and physical therapy have failed. The company also holds the drug's marketing rights for 22 Asian nations. In Nov 2016, Kolon Life Science out-licensed Invossa to Japan's Mitsubishi Tanabe in a KRW498.9b deal (for an upfront payment of KRW27.3b and milestone payments of up to KRW471.6b plus running royalties). Kolon Life Science will produce and supply the drug in Japan, while dividing out-licensing revenue 50:50 with TissueGene.

### SUMMARY FINANCIAL DATA

	2014	2015	2016
Revenue (KRWb)	0.0	0.3	13.3
Net profit (adj) (KRWb)	(7.0)	(6.3)	7.3
EPS (adj) (KRW)	n/a	(1,822)	2,112
EPS (adj) growth (% y-y)	n/a	(1,822)	2,112
EBITDA margin (%)	n/a	(1,851.0)	48.0
ROE (%)	n/a	n/a	n/a
P/E (adj) (x)	n/a	n/a	n/a
P/B (x)	n/a	n/a	n/a
EV/EBITDA (x)	n/a	n/a	n/a
Dividend yield (%)	0.0	0.0	0.0

Source: Company data, Samsung Securities estimates

**Approved in Korea:** With a single intra-articular injection, Invossa has shown it relieves pain and increases mobility (although not that it promotes cartilage regeneration). The drug has the potential to delay knee replacement surgery—in Korean phase III trials, five patients in the control group had to undergo a knee replacement within two years, while not and none in the infusion group did. Meanwhile, a reanalysis of the trials using a Wilcoxon non-parametric test revealed that expanding the size of clinical studies to 800 patients would produce statistically significant results.

**First-in-class:** Invossa is the world's first cell and gene therapy for osteoarthritis. It involves a mix of normal and modified cartilage cells, the latter produced with TGF beta 1 using a retrovirus within cartilage cells. With a single injection, Invossa attracts immune cells, facilitates M2 macrophage differentiation, and reduces inflammation, relieving pain and increasing patient mobility for at least two years and potentially delaying knee replacement surgery. It should be cost competitive as well, since it can be mass produced with allogeneic cells

**New plant to raise capacity 11-fold:** Kolon Life Science is likely to have Kolon Pharma and Mundi Pharma Korea market Invossa in Korea. In Jun 2016, the company offered up new shares at KRW125,600/share in a KRW115.6b rights offering, directing KRW95b to facility construction and KRW20.6b to a management fund. In May 2017, it dedicated KRW60b to begin building a plant that should increase its annual Invossa manufacturing capacity from 10,000 to 110,000 ones (assuming the price of one dose or injection at KRW5m). Upcoming clinical trials should involve repeated (rather than single) injections and patients with different Kellgren & Lawrence grades.

**Looking to prove disease-modifying status:** Invossa will soon begin phase III clinical trials in the US to prove its capacity as a disease-modifying osteoarthritis drug. TissueGene intends to target 1,020 patients with K&L grades 2-3 (with 340 given a placebo and 680 Invossa) and monitor them for 24 months, setting visual analogue scale and Western Ontario and McMaster Universities Arthritis Index as primary assessment variables and joint space width, international knee documentation committee, MRI, and liquid biomarker as secondary assessment ones. During trials in Korea, the company targeted 159 patients with a K&L grade of 3 (with 81 given a placebo and 78 Invossa) and monitored them for 12 months, setting IKDC and VAS as key evaluation variables and WOMAC, knee injury and osteoarthritis outcome score, MRI, JSW, and liquid biomarkers as additional evaluation variables).

The trials will last longer than the two years Invossa was tested in Korea and involve a wider range of patient severity. As such, the firm plans to gather statistically significant proof that Invossa is a disease-modifying osteoarthritis drug. It plans to conduct the trials over 2018-2021, win US FDA approval in 2022, and commercially launch Invossa in 2023. TissueGene expects Lonza to produce clinical materials and Parexel to manage the trials in 70 hospitals.

If approved as a first-in-class drug, Invossa would be granted a monopoly for 12 months. TissueGene estimates that if Invossa is approved as a DMOAD, one injection would be worth USD15,000 (vs USD9,000 if not approved as such), with maximum sales volume in the fifth year from launch potentially hitting 350,000 doses for revenue of USD5.3b (vs USD3.2b). TissueGene plans to expand the drug's indications to osteoarthritis for the hands and hips, musculoskeletal disorders, and animal diseases, enter into strategic alliances with multinational pharmaceuticals (over sales rights for the US market), and seek out-licensing deals to players in Europe and emerging markets.

**IPO market cap estimated to reach KRW1.01t-1.71t:** TissueGene plans to issue five depository receipts on the Kosdaq for every common US share in the company—ie, 60,443,085 DRs (based on 12,088,617 common shares, of which 1.5m will be newly issued). It has set an initial price range for the DRs of KRW16,000-27,000, which implies a market cap of KRW1.01t-1.71t and would raise the company KRW120b-202.5b.

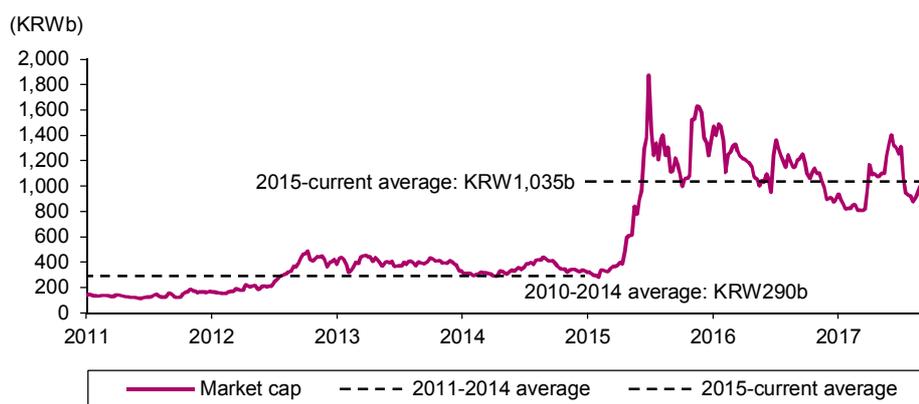
Book building is scheduled for Oct 17-18, subscription for Oct 23-24, and listing for Nov 6. The DR price band of KRW16,000-27,000 represents a 20.7-53% discount to TissueGene's estimated DR value of KRW34,040, which is based on: 1) the present value of the company's 2023 net profit target of KRW75.4b, derived from estimated profit of KRW187.1b based on a KRW/USD rate assumption of KRW1,142 and an annual discount rate of 15%; and 2) 28.6x P/E, the average multiple at which Humedix, Yuhan, Shinpoong Pharmaceutical, and Celltrion traded in 1H17.

Excluding those subject to lock-up, 22,220,835 DRs (equivalent to 36.76% of the total outstanding) should be tradable immediately after the IPO. Of the expected DR proceeds, TissueGene has already earmarked KRW98b for R&D and KRW19b for working capital. The firm plans M&As and technology in-licensing in the future.

**TissueGene's IPO price floor supported:** In May 2016, TissueGene privately placed USD10m worth of series-C preferred shares with Korea Export-Import Bank. Disregarding refixing terms, each share could be converted into one common share, based on which 588,235 DRs can be issued, giving Korea Exim Bank 1% ownership of TissueGene post-IPO. This means that Korea Exim Bank's series-C preferred shares should support the bottom end of TissueGene's IPO price band. Also supporting the IPO price floor is Kolon Life Science's market cap of KRW1t.

TissueGene is entitled to 70% of Invossa's value and Kolon Life Science 30%. Kolon Life Science's current market cap of KRW1t is the sum of its operating value (which we estimate at KRW300b), 30% of the value of Invossa, and the value of its 12.69% stake in TissueGene. This implies that Invossa is worth KRW1.8t (on par with ViroMed's market cap) and TissueGene is worth KRW1.26t (equal to 1.8x Kolon Life Science's non-operating value). Any changes to Kolon Life Science's fair market cap, operating value, or the value of the exclusive Asian marketing rights could alter the value of Invossa and TissueGene.

### Kolon Life Science: Market cap trend



Source: QuantiWise, Samsung Securities

**Invossa: Value estimates**

(KRWb)	Non-operating value of Kolon Life Science*						
		500	600	700	800	900	1000
Portion of value of marketing rights in Asia (%)	20	1,658	1,990	2,322	2,653	2,985	3,317
	25	1,449	1,738	2,028	2,318	2,607	2,897
	30	1,286	1,543	1,800	2,057	2,315	2,572
	35	1,156	1,387	1,619	1,850	2,081	2,312
	40	1,050	1,260	1,470	1,680	1,890	2,100

**TissueGene: Value estimates**

(KRWb)	Non-operating value of Kolon Life Science*						
		500	600	700	800	900	1000
Portion of value of marketing rights in Asia (%)	20	1,326.6	1,591.9	1,857.3	2,122.6	2,387.9	2,653.2
	25	1,086.4	1,303.7	1,521.0	1,738.2	1,955.5	2,172.8
	30	900.1	1,080.2	1,260.2	1,440.2	1,620.2	1,800.3
	35	751.5	901.8	1,052.1	1,202.4	1,352.6	1,502.9
	40	630.1	756.1	882.1	1,008.1	1,134.1	1,260.1

**TissueGene: Value over Kolon Life Science's non-operating value**

(KRWb)	Non-operating value of Kolon Life Science*						
		500	600	700	800	900	1000
Portion of value of marketing rights in Asia (%)	20	2.7	2.7	2.7	2.7	2.7	2.7
	25	2.2	2.2	2.2	2.2	2.2	2.2
	30	1.8	1.8	1.8	1.8	1.8	1.8
	35	1.5	1.5	1.5	1.5	1.5	1.5
	40	1.3	1.3	1.3	1.3	1.3	1.3

Note: \* Value of marketing rights of Invossa in Asia + value of TissueGene's shares  
(value of global marketing rights of Invossa excluding Asia x 12.69%)

Source: Samsung Securities estimates

**TissueGene: IPO overview**

(KRWb)	
Shares offered (DRs)	7,500,000
IPO price band (KRW)	16,000-27,000
Offering size	120.0-202.5
Market cap	1,013.0-1,709.1
Post-listing shares outstanding (DRs)	60,443,085

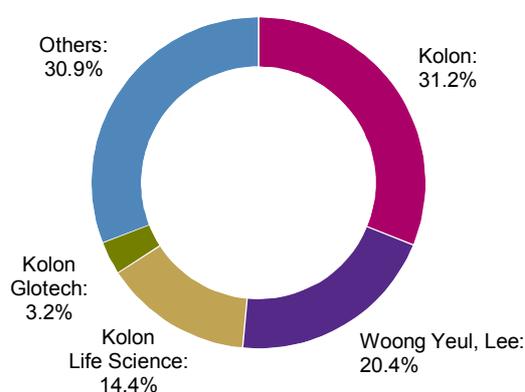
Source: Company data, Samsung Securities

**TissueGene: IPO schedule**

Event	Date
Registration	Sep 8
Book-building	Oct 17-18
Subscription	Oct 23-24
Tentative listing	Nov 6

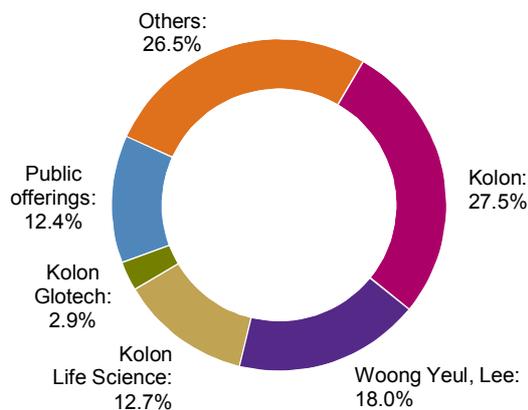
Source: Company data, Samsung Securities

**TissueGene: Shareholding structure (pre-IPO)**



Source: Company data, Samsung Securities

**TissueGene: Shareholding structure (post-IPO)**



Source: Company data, Samsung Securities

**TissueGene: Expected use of IPO proceeds**

(KRWb)	2017E	2018E	2019E	2020E	Total
Operating expenses	1.0	6.1	6.3	5.6	19.0
R&D expenses	4.4	36.3	32.6	24.7	98.0
Total	5.3	42.4	39.0	30.3	117.0

Source: Company data

### TissueGene: IPO band calculation

(KRWb)		Note
<b>Discounted 2023E earnings per DR at end-1H17 (KRW, A=B/E)</b>	<b>1,191</b>	
Present value of 2023E net profit (B=C/(1+D)^6.5)	75.4	
2023E net profit (C)	187.1	Forex assumption: KRW1,142.06/USD
Discount rate (% , D)	15.0	
Number of DRs* (E)	63,315,495	
<b>Peer 2017E P/E (x, F)</b>	<b>28.6</b>	Average of Humedix, Yuhan, Shinpoong Pharm, Celltrion**
<b>DR value/share (KRW, G=AxF)</b>	<b>34,040</b>	
<b>Offering price band (KRW)</b>	<b>16,000-27,000</b>	20.7%-53.0% discount to per DR value

Note: \* Including share dilution

\*\* Estimated based on 1H17 net profits

Source: Company data, Samsung Securities

### TissueGene: Income statement forecasts

(KRWb)	2017E	2018E	2019E	2020E	2021E	2022E	2023E
<b>Sales</b>	<b>8.4</b>	<b>10.2</b>	<b>10.3</b>	<b>11.2</b>	<b>17.6</b>	<b>19.5</b>	<b>704.6</b>
Royalty income*	0.1	0.4	0.6	0.9	1.0	2.4	11.4
Milestone income**					5.1	5.1	
Invossa sales							681.0
Sales from acquired businesses***	8.3	9.8	9.6	10.3	11.5	12.0	12.2
Gross profit	3.8	5.8	5.8	6.3	12.1	13.6	483.8
SG&A costs	12.0	13.8	15.6	14.5	14.4	19.9	244.0
<b>Operating profit</b>	<b>(8.2)</b>	<b>(8.0)</b>	<b>(9.8)</b>	<b>(8.2)</b>	<b>(2.3)</b>	<b>(6.3)</b>	<b>239.8</b>
Non-operating profit	(1,108.0)	(1.3)	(1.0)	(0.7)	(0.3)	(0.0)	0.0
<b>Pre-tax profit</b>	<b>(9.3)</b>	<b>(9.3)</b>	<b>(10.8)</b>	<b>(8.8)</b>	<b>(2.6)</b>	<b>(6.3)</b>	<b>239.8</b>
Tax expense	0.0	0.0	0.0	0.0	0.0	0.0	52.7
<b>Net profit</b>	<b>(9.3)</b>	<b>(9.3)</b>	<b>(10.8)</b>	<b>(8.8)</b>	<b>(2.6)</b>	<b>(6.3)</b>	<b>187.1</b>

Note: Forex assumption: KRW1142.06/USD (1H17 average)

\* Running royalty income from Invossa sales of Kolon Life Science and Mitsubishi Tanabe

\*\* Assumes BLA submitted to Japanese Minister of Health, Labor and Welfare by 2021 and approval by 2022

\*\*\* Cosmetic and drug store business acquired from Kolon Wellcare in Aug 2017

Source: Company data, Samsung Securities

**TissueGene: Expected ownership post-IPO**

	Note	Number of DRs	Stake (%)	Lock-up
Major shareholders, <i>et al</i>	Kolon	Largest shareholder	16,631,495	27.5 1 year
	Lee Woong Yeul	Largest shareholder of Kolon	10,879,390	18.0 1 year
	Kolon Life Science	Related company	7,672,330	12.7 1 year
	Kolon Glotech	Related company	1,723,520	2.9 1 year
	Seo Chang Hee	Wife of Lee Woong Yeul	526,875	0.9 1 year
	Kolon Global	Related company	344,790	0.6 1 year
	Other executives	Executives of related companies	187,600	0.3 1 year
	Subtotal		37,966,000	62.8 1 year
Financial investors	Kiwoom Securities	Financial investor	100,000	0.2 1 month
Other	Other previous shareholders		14,720,835	24.4
	New shareholders		7,500,000	12.4
	Underwriter	Financial investor	156,250	0.3 1 year
<b>Total</b>			60,443,085	100.0

Source: Company data, Samsung Securities

**Refixing details on preferred series C stock held by Korea Exim Bank**

Conversion price (KRW)	Number of convertible shares	Number of DRs
20,000	117,647	588,235
18,000	119,048	595,240
16,000	120,482	602,410
14,000	121,951	609,755
12,000	123,457	617,285

Source: Company data, Samsung Securities

**Income statement**

Year-end Mar 31(KRWb)	2012	2013	2014	2015	2016
<b>Operating revenue</b>				<b>0.3</b>	<b>13.3</b>
<b>Operating expense</b>				<b>6.4</b>	<b>7.3</b>
<b>Operating profit</b>				<b>(6.1)</b>	<b>6.0</b>
Operating margin (%)				(1,962.4)	45.2
<b>Non-operating gains (losses)</b>				<b>(0.2)</b>	<b>(0.5)</b>
Financial profit				0.0	0.0
Financial costs				0.1	0.5
Equity-method gains (losses)				0.0	0.0
Other				(0.0)	(0.1)
<b>Pre-tax profit</b>				<b>(6.3)</b>	<b>5.5</b>
Taxes				0.0	(1.9)
Effective tax rate (%)				0.0	(33.9)
Profit from continuing operations				(6.3)	7.3
Profit from discontinued operations				0.0	0.0
<b>Net profit</b>				<b>(6.3)</b>	<b>7.3</b>
Net margin (%)				(2,013.9)	55.0
Net profit (controlling interests)				(6.3)	7.3
Net profit (non-controlling interests)				0.0	0.0
EBITDA				(5.7)	6.4
EBITDA margin (%)				(1,851.0)	48.0
EPS (parent-based) (KRW)				(1,822)	2,112
EPS (consolidated) (KRW)				(1,822)	2,112
Adjusted EPS (KRW)*				(1,822)	2,112

**Cash flow statement**

Year-end Mar 31(KRWb)	2012	2013	2014	2015	2016
<b>Cash flow from operations</b>				<b>(5.4)</b>	<b>6.0</b>
Net profit				(6.3)	7.3
Non-cash profit and expenses				1.0	(1.0)
Depreciation				0.2	0.2
Amortization				0.1	0.1
Other				0.6	(1.4)
Changes in A/L from operating activities				(0.0)	2.1
<b>Cash flow from investments</b>				<b>(2.6)</b>	<b>(10.1)</b>
Change in tangible/intangible assets				(2.6)	(10.1)
Change in financial assets				0.0	0.0
Other				0.0	0.0
<b>Cash flow from financing</b>				<b>8.0</b>	<b>20.1</b>
Change in debt				7.9	8.1
Change in equity				0.0	11.6
Dividends				0.0	0.0
Other				0.1	0.4
Change in cash				0.0	16.0
Cash at beginning of year				6.4	6.6
Cash at end of year				6.4	22.5
<b>Gross cash flow</b>				<b>(5.3)</b>	<b>6.3</b>
<b>Free cash flow</b>				<b>(8.0)</b>	<b>(4.2)</b>

Note: \* Excluding one off items

\*\* Fully diluted, excluding one-off items

\*\*\* From companies subject to equity-method valuation

Source: Company data, Samsung Securities estimates

**Balance sheet**

Year-end Mar 31(KRWb)	2012	2013	2014	2015	2016
<b>Current assets</b>				<b>6.8</b>	<b>24.1</b>
Cash & equivalents				6.6	23.5
Accounts receivable				0.0	0.0
Inventories				0.0	0.0
Other current assets				0.2	0.7
<b>Fixed assets</b>				<b>3.8</b>	<b>18.1</b>
Investment assets				0.0	0.0
Tangible assets				0.8	0.9
Intangible assets				2.9	13.2
Other long-term assets				0.0	4.0
<b>Total assets</b>				<b>10.6</b>	<b>42.2</b>
<b>Current liabilities</b>				<b>0.4</b>	<b>3.1</b>
Accounts payable				0.0	0.0
Short-term debt				0.0	0.0
Other current liabilities				0.4	3.1
<b>Long-term liabilities</b>				<b>8.4</b>	<b>17.5</b>
Bonds & long-term debt				8.2	16.9
Other long-term liabilities				0.2	0.6
<b>Total liabilities</b>				<b>8.8</b>	<b>20.6</b>
<b>Owners of parent equity</b>				<b>1.8</b>	<b>21.6</b>
Capital stock				0.1	0.1
Capital surplus				71.7	86.1
Retained earnings				(70.0)	(64.5)
Other				(0.0)	(0.0)
<b>Non-controlling interests' equity</b>				<b>0.0</b>	<b>0.0</b>
<b>Total equity</b>				<b>1.8</b>	<b>21.6</b>
Net debt				1.6	(6.6)

**Financial ratios**

Year-end Mar 31	2012	2013	2014	2015	2016
<b>Growth (%)</b>					
Operating revenue				n/a	4,183.1
Operating profit				nm	nm
Net profit				nm	nm
Adjusted EPS**				nm	nm
<b>Per-share data (KRW)</b>					
EPS (parent-based)				(1,822)	2,112
EPS (consolidated)				(1,822)	2,112
Adjusted EPS**				(1,822)	2,112
BVPS				521	6,242
DPS (common)				0	0
<b>Valuations (x)</b>					
P/E***				n/a	n/a
P/B***				n/a	n/a
EV/EBITDA				n/a	n/a
<b>Ratios (%)</b>					
ROE				(349.6)	33.8
ROA				(59.0)	17.3
ROIC					
Payout ratio				0.0	0.0
Dividend yield (common)				n/a	n/a
Net debt to equity				87.9	(30.3)
Interest coverage (x)				n/a	12.1

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