Healthcare
Biotechnology
Equity – Korea

Pharmicell (005690 KS)

Overweight (V)

Target price (KRW)	**8,100**
Share price (KRW)	**6,330**
Forecast dividend yield (%)	**0.0**
Potential return (%)	**28**

Note: Potential return equals the percentage difference between the current share price and the target price, plus the forecast dividend yield

Performance	1M	3M	12M
Absolute (%)	2.9	-24.4	-29.7
Relative^ (%)	6.5	-26.0	-29.7

Index^	KOSPI INDEX
RIC	005690.KS
Bloomberg	005690 KS
Market cap (USDm)	243.0
Market cap (KRWb)	265.0
Enterprise value (KRWb)	257.6
Free float (%)	72

Note: (V) = volatile (please see disclosure appendix)

8 November 2012

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OW(V): Steady progress

- **HCG-AMI sales to surge in 2-3 years on better hospital reach, patient/physician education and drug reimbursement**
- **Livercellgram (alcoholic liver cirrhosis treatment) KFDA P2 approved, to be distributed in new tie-up with JW Pharma**
- **Reiterate OW(V) with unchanged DCF-based TP of KRW8,100**

Sales to accelerate on strengthening data, reach, reimbursement. With HCG-AMI (stem cell drug for heart attacks) approved in Korea, a key question asked during the recent road show with the company was the drug's take-up rate. Initial take-up has been relatively slow, but within expectations; our forecasts remain unchanged. In the next 2-3 years, we expect Pharmicell's stem cell sales to surge on better hospital reach, patient / physician education, drug reimbursement and more data. In this respect, we expect follow-up two year-plus data on HCG-AMI to emerge in the next couple of quarters to support efficacy and safety profiles. A new dose-dependent P3 trial is now under way with a larger and more severe left ventricular ejection fraction (LVEF) group, which may strengthen further the case for the use of the drug.

High-potential liver cirrhosis P2 trials approved. Pharmicell announced that the KFDA approved P2 trials for its alcohol-induced liver cirrhosis stem cell drug Livercellgram. This candidate has good potential; P2 investigator trials showed that stem cells reverse damage from liver cirrhosis. Pharmicell plans to run trials in the US with Livercellgram, where competition is limited compared to the multitude myocardial infarction candidates. In Korea, we are positive on the alliance with JW Pharma to develop and commercialise this drug. Pharmicell remains responsible for trials, while JW Pharma would handle marketing and distribution.

Reiterate OW(V). Our KRW8,100 target price is based on an unchanged DCF-based analysis. Catalysts include rising patient / physician take-up of HCG-AMI, strong data from follow-up study on HCG-AMI, start of KFDA P2 trials for liver cirrhosis, approval of pipeline drugs starting 2014-15 for acute ischemic stroke and spinal cord injuries, tie-up with partners for global clinical trials, marketing and distribution, potential additional government R&D funding. Downside risks include slower-than-expected patient take-up of HCG-AMI, delays in approval or non-approval of pipeline, delays in US FDA IND approval for liver cirrhosis treatment.

HSBC

Financials & valuation

Financial statements

Year to	12/2011a	12/2012e	12/2013e	12/2014e
Profit & loss summary (KRWb)				
Revenue	9.7	13.7	23.9	37.5
EBITDA	-13.6	-10.6	-2.9	8.2
Depreciation & amortisation	-0.4	-1.4	-1.7	-2.0
Operating profit/EBIT	-14.0	-12.1	-4.6	6.2
Net interest	-1.3	-1.1	-1.6	-2.8
PBT	-16.1	-13.9	-6.9	2.7
HSBC PBT	-16.1	-13.9	-6.9	2.7
Taxation	0.3	0.0	0.0	0.0
Net profit	-15.8	-13.9	-6.9	2.7
HSBC net profit	-15.8	-13.9	-6.9	2.7
Cash flow summary (KRWb)				
Cash flow from operations	-14.7	-11.8	-4.5	5.4
Capex	11.5	23.2	-6.0	-4.8
Cash flow from investment	4.6	20.8	-7.1	-5.9
Dividends	0.0	0.0	0.0	0.0
Change in net debt	0.7	-13.4	15.0	5.2
FCF equity	-3.2	11.4	-10.5	0.6
Balance sheet summary (KRWb)				
Intangible fixed assets	77.9	77.9	77.9	77.9
Tangible fixed assets	3.6	6.7	11.0	13.9
Current assets	15.0	30.3	34.1	40.3
Cash & others	9.3	23.2	22.2	22.1
Total assets	100.9	119.3	127.4	136.5
Operating liabilities	2.8	3.2	4.3	5.6
Gross debt	15.2	15.8	29.8	34.8
Net debt	5.9	-7.4	7.6	12.7
Shareholders funds	82.9	100.3	93.4	96.1
Invested capital	84.4	88.5	96.6	104.4

Ratio, growth and per share analysis

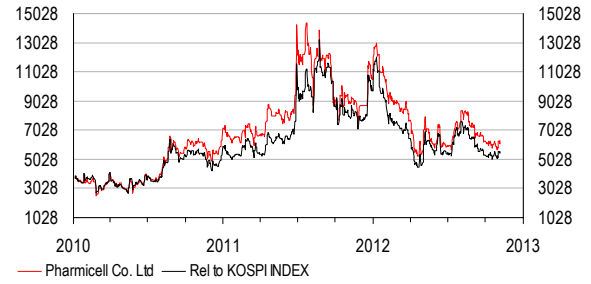
Year to	12/2011a	12/2012e	12/2013e	12/2014e
Y-o-y % change				
Revenue	51.7	41.3	74.8	57.2
EBITDA				
Operating profit				
PBT				
HSBC EPS				
Ratios (%)				
Revenue/IC (x)	0.2	0.2	0.3	0.4
ROIC	-30.1	-13.0	-4.1	7.0
ROE	-34.6	-15.2	-7.2	2.8
ROA	-21.9	-10.9	-3.4	5.0
EBITDA margin	-140.9	-77.9	-12.3	21.9
Operating profit margin	-145.2	-88.3	-19.3	16.6
EBITDA/net interest (x)				3.0
Net debt/equity	7.2	-7.4	8.1	13.3
Net debt/EBITDA (x)	-0.4	0.7	-2.6	1.6
CF from operations/net debt				42.6
Per share data (KRW)				
EPS reported (fully diluted)	-475	-334	-166	65
HSBC EPS (fully diluted)	-475	-334	-166	65
DPS	0	0	0	0
NAV	2,493	2,406	2,240	2,305

Valuation data

Year to	12/2011a	12/2012e	12/2013e	12/2014e
EV/sales	28.0	18.9	11.4	7.4
EV/EBITDA				33.9
EV/IC	3.2	2.9	2.8	2.7
PE*				97.8
P/NAV	2.5	2.6	2.8	2.7
FCF yield (%)	-1.2	4.3	-4.0	0.2
Dividend yield (%)	0.0	0.0	0.0	0.0

Note: * = Based on HSBC EPS (fully diluted)

Price relative



Source: HSBC

Note: price at close of 06 Nov 2012

Upside risk factors for HCG-AMI take-up

Pharmicell's experience with marketing cutting-edge stem cell treatments is instructive. To date, Pharmicell has produced 150 doses of its KFDA-approved product HCG-AMI. Of these, 30 were produced for acute myocardial infarction (AMI) with the remainder made for the expanded access program (EAP) and emergency/investigative trials conducted by various hospitals. We expect initial take-up to be relatively slow even though no alternative treatments for AMI exist. For 2013, we forecast just 2.5% penetration of the addressable market of c7,000 patients annually in Korea. But in the next 2-3 years, we expect Pharmicell's stem cell sales to surge on reimbursement, better hospital reach, and better patient/physician education:

- **Drug reimbursement.** HCG-AMI is still non-reimbursable. Out-of-pocket patient costs are cKRW18m (cUSD16,500), which is an affordable figure for the majority of Koreans and competitive versus other cell therapies such as Dendreon's Provenge. Korea's accommodative national health insurance has conditioned patients to very low treatment costs; patient co-pay even for severe cancer treatments, which can be as low as 5-10% of the total cost. We expect HCG-AMI to be made reimbursable by the Ministry of Health and Welfare in the next 2-3 years.
- **Increased hospital reach.** The number of key hospitals at which the treatment is available remains at 16 of the 132 major hospitals with cardiac centres (required due to need for catheter treatment). The firm is relying mostly on its in-house sales force. For the liver cirrhosis product Livercellgram, we are positive on the recent marketing and distribution agreement with JW Pharma (similar to the ones that Medipost has with Dong-A Pharma and Innocell has with Green Cross).
- **Patient and physician education.** For patients, bone marrow aspiration is considered a painful and complex procedure, which can be true for bone marrow transplants that require c700ml of bone marrow. However, HCG-AMI is manufactured from only 10-20ml of bone marrow; extraction of bone marrow is a short, painless outpatient procedure.

Accumulation of more data for AMI, stroke

Pharmicell is conducting two additional trials that would support HCG-AMI's long-term safety and efficacy profiles, as providing more data on dosing levels.

- Durability of the response should be visible with a follow-up study (NCT01595113) on 40 of the original 80 patients who participated in the KFDA P3 trial (SEED-MSC, completed in May 2010) that led to KFDA approval. We expect at least two-year data to be released by 1Q13. Recall that Pharmicell and Osiris did not see any differences in adverse events (AE) in their respective trials whereas Mesoblast reported a reduction in AE; we think this may be due to differences in follow-up periods (6 months for Pharmicell and Osiris, 22 months for Mesoblast).
- Pharmicell is running RELIFE, another KFDA P3 trial (randomized, open labelled, multicenter trial for safety and efficacy of intracoronary adult human mesenchymal stem cells AMI; NCT01652209). This study enrols 135 patients with an estimated primary completion date of January 2014, compared to SEED-MSC's 80-patient enrolment (as recommended by the KFDA). Primary endpoint remains LVEF, but with a 13-month follow-up compared to the original study's 6 months, which should further verify efficacy and safety. Importantly, this study only includes patients with LVEF below 45%, the patient group that should benefit the most from the treatment. Ironically, this trial could

pose a risk to nearer-term HCG-AMI sales as AMI patients would want to enrol in the RELIFE programme, rather than pay out of pocket for treatment. This study also improves on the SEED-MSC study with a dose escalation arm, MRI imaging (as opposed to SPECT).

- Safety has not been an issue with Pharmicell's autologous treatments. In fact, the company's clinical trials have involved c500 patients in its various trials, making it one of (if not the largest) stem cell trial to date. It has shown no severe side effects; the most common side effects have been chills and fever, which are readily treated with paracetamol. In fact, a key risk of allogeneic stem cells is the possibility of unknown viral infections integrated with host DNA.

Stroke, spinal cord injury clinical trials status. For stroke, Pharmicell is starting another KFDA P3 trial (NCT01716481; The STem Cell Application Researches and Trials In NeuroloGy-2 (STARTING-2) Study) with a 60-patient enrolment in November 2012 and with estimated primary completion in 2015. This may be a redesign of the original stroke study, which was having difficulties in patient recruitment. The current spinal cord injury trial (NCT01676441) continues with 32 patients, with primary completion in September 2014. We forecast Cerecellgram-stroke and Cerecellgram-spine to commercialise in 2015.

Moving ahead with alcoholic liver cirrhosis treatment

KFDA approves P2 trials for alcoholic liver cirrhosis treatment. Pharmicell announced KFDA P2 approval to conduct trials for its alcohol-induced liver cirrhosis stem cell treatment Livercellgram (no clinicaltrials.gov entry yet). Trials are to be conducted in 11 major hospitals in Korea. Unlike other trials for this indication, this trial directly measures fibrosis using biopsies (there is no issue regarding biopsy sampling as fibrosis is homogenous). Whilst intrusive for the patient, we believe this provides direct information on the efficacy of the drug. P2 investigator trials showed that stem cells reverse damage from liver cirrhosis, with some patients experiencing a softening of tissue indicative of structural regeneration. Recall that this treatment is the one that Pharmicell is taking to the US.

Large potential market with few competitors. Compared to treatments for AMI there are very few competitors for this indication in the US, whilst the potential markets globally are large. In the US cirrhosis and chronic liver disease is the 12th largest cause of death, whilst in Korea liver failure is the 6th largest cause of death and the second largest cause of death in males in their 40s and 50s. The product could also help relieve pressure for liver transplants; there are c17,000 people in the US waiting for liver transplants. Assuming that P3 is also conducted (which is likely), we expect NDA submission to the KFDA in 2014/15. For the US, we expect Pharmicell to conduct a US FDA pre-IND meeting next year. Assuming that Pharmicell has to rerun toxicology studies and develop certain biomarkers, we believe US FDA P1 trials could start in 2013/14.

Alliance with JW Pharma. Pharmicell signed a strategic alliance with JW Pharma (001060 KS, Not rated) to develop and commercialise the product. Pharmicell remains responsible for domestic and international trials, whilst JW Pharma will be involved in drug out-licensing and technical exports. JW Pharma will also conduct domestic marketing and distribution post-approval.

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Valuation and risks

Our target price of KRW8,100 is derived from a DCF-based analysis of the firm's existing and pipeline drugs. About three-quarters of the firm's value lies in stem cell treatments for myocardial infarction and ischemic stroke. The latter is a much larger addressable market; the company is currently in KFDA P3 trials. We included the treatment for liver cirrhosis based on positive Korean investigator trials, though it has yet to start clinical trials. However, it accounts for only c10% of total value.

Valuation

KRWbn, %	NPV	% of total value	WACC
Hearticellgram-AMI (MCI)	115	34%	10.50%
MSC1(IS)	135	40%	15%
Cerecellgram-spine (SCI)	55	16%	15%
LC	33	10%	20%
Total	338	100%	

Source: HSBC estimates

Under our research model, for stocks with a volatility indicator, the Neutral rating band is 10% above and below the hurdle rate of 10.5% for Korea (risk-free rate plus risk premium). This translates into a Neutral band of 0.5-20.5% potential return from the current share price. Our target price implies 28% potential return. Hence we reiterate our OW(V) rating. Potential return equals the percentage difference between the current share price and the target price, including the forecast dividend yield when indicated.

Downside risks include slower-than-expected patient take-up of HCG-AMI, delays in approval or non-approval of pipeline, delays in US FDA IND approval for liver cirrhosis treatment.

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Disclosure appendix

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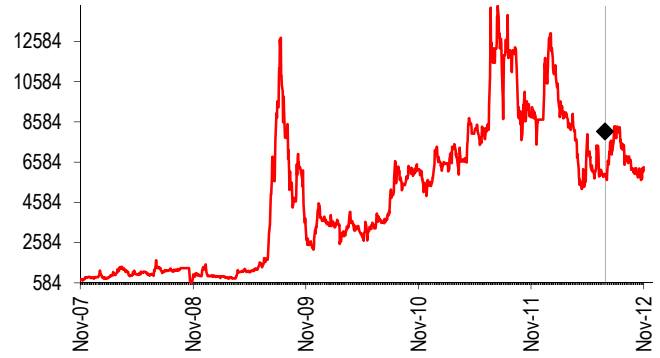
Share price and rating changes for long-term investment opportunities

Pharmicell Co. Ltd (005690.KS) Share Price performance KRW Vs HSBC rating history



Source: HSBC

Recommendation & price target history

From	To	Date
N/A	Overweight (V)	04 July 2012
Target Price	**Value**	**Date**
Price 1	8100.00	04 July 2012

Source: HSBC

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