

# International Stem Cell

Financial update

Third cohort ready to go

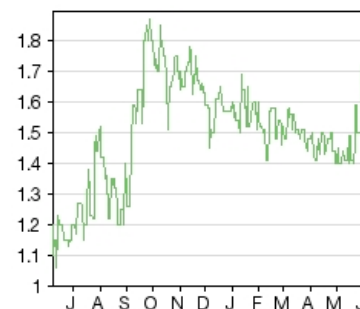
Pharma &amp; biotech

6 June 2018

**Price** **US\$1.68**  
**Market cap** **US\$10m**

Net cash (\$m) at 31 March 2018	0.10
Shares in issue	6.20m
Free float	26.4%
Code	ISCO
Primary exchange	OTC
Secondary exchange	N/A

## Share price performance



%	1m	3m	12m
Abs	16.7	8.4	40.0
Rel (local)	13.0	7.3	24.1
52-week high/low	US\$1.9	US\$1.1	

## Business description

International Stem Cell is an early-stage biotechnology company developing therapeutic, biomedical and cosmeceutical applications for its proprietary stem form of pluripotent stem cells – human parthenogenetic stem cells. Its lead candidate is a cell therapy treatment for Parkinson's disease.

## Next events

Publication of interim results in scientific journal	2018
Initiation of Phase II in traumatic brain injury and PD	2018

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International Stem Cell (ISCO) recently announced that the data safety monitoring board for its Phase I trial of ISC-hpNSC in Parkinson's disease (PD) has authorized the enrollment of the third cohort of four patients. The study has already enrolled eight patients at the 30m and 50m cell levels and will now enroll patients at the 70m cell level. Recruitment will begin immediately. The company announced interim six-month results from the first cohort of four patients in November and we expect additional data from this as well as the second cohort in the coming months.

Year end	Revenue (\$m)	PBT* (\$m)	EPS* (\$)	DPS (\$)	P/E (x)	Yield (%)
12/16	7.2	(4.9)	(0.34)	0.0	N/A	N/A
12/17	7.5	(4.9)	(1.46)	0.0	N/A	N/A
12/18e	8.8	(6.7)	(0.98)	0.0	N/A	N/A
12/19e	9.5	(8.5)	(1.27)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

## Trial in PD continues

Patients in the study are being treated in three cohorts with 30m, 50m and 70m stem cells, delivered via intracranial injection. The single-arm, open-label study is being conducted at the Royal Melbourne Hospital in Australia. Clinical assessments are scheduled at six and 12 months following surgery. The company expects to start a Phase II PD trial later in 2018.

## Traumatic brain injury Phase II coming later in 2018

The company has completed preclinical studies of ISC-hpNSC in traumatic brain injury (TBI) and is preparing for a Phase II trial that should begin in 2018. According to the Centers for Disease Control, TBI accounts for 2.5m emergency room visits in the US annually and approximately 3.2–5.3 million people are living with a TBI-related disability.

## Biomedical business growing well

ISCO's commercial operations leverage its hpSC technology and generate revenues to partially offset R&D spending for therapeutic development. Lifeline Skin Care develops and sells skincare products and Lifeline Cell Technology (LCT) produces human cell culture products for testing. Together they generated \$7.5m in sales and \$1.4m in operating profit in 2017. In Q118, LCT alone generated \$2.1m in revenues, providing \$837,000 in operating profit.

## Valuation: \$34m or \$5.46 per basic share

Our valuation remains \$34m, although on a per-share basis it has increased to \$5.46 from \$5.45. Increases to our revenue estimates for the base business were mostly cancelled out by an increase in long-term SG&A expense expectations. Additionally, net cash is slightly lower and there are slightly more shares outstanding. We project that the company will need at least \$62.5m in additional financing before profitability in 2024, of which a total additional \$7.5m will be required by the end of 2018.

## Q1 results

ISCO reported Q118 revenues of \$2.6m, up 28.1% compared to Q117 mainly due to the biomedical business, which had quarterly revenues of \$2.1m, up 51.6% compared to the same quarter last year. The cosmetics business, however, was down 16.6% in the quarter. The operating profit of the biomedical business increased substantially, up 68.4% to \$837,000, although the cosmetic business showed a loss for the quarter. The commercial businesses combined had a profit of \$631,000, up 10.3% compared to Q117. For the company as a whole, the operating loss was \$1.2m for Q118, a 13.2% increase compared to the same quarter last year due to increased spending on the pipeline. We have made some adjustments to our model, increasing our 2018 revenue estimate for the commercial business to \$8.8m from \$8.2m and our 2019 estimate to \$9.5m from \$8.8m due to significant strength in the biomedical segment. We have also reduced our 2018 R&D estimate by \$1.5m as the spending rate is lower than we had anticipated but left future years the same. We also increased our SG&A expense estimate by \$0.9m in 2018 and by \$0.2m in 2019 due to a higher than anticipated run rate.

**Exhibit 1: Changes to estimates**

\$000s	Revenue			Operating profit			Profit after tax		
	Old	New	% change	Old	New	% change	Old	New	% change
2018e	8,193	8,790	7.3%	(6,659)	(6,073)	8.8%	(7,259)	(6,673)	17.0%
2019e	8,846	9,527	7.7%	(6,942)	(7,079)	(2.0%)	(8,342)	(8,479)	(1.6%)

Source: Edison Investment Research. Note: Operating profit and profit after tax exclude amortization of acquired intangibles, exceptional items and share-based payments.

The company had \$447,000 in cash on the balance sheet at 31 March 2018. There is \$351,000 in a related-party payable stemming from a promissory note that provided cash to the company from its co-chairman and CEO, with the note due and payable on 1 November this year. Subsequent to the quarter, the co-chairman and CEO provided an additional \$150,000 and agreed to provide an additional \$300,000 in increments based on the company's needs. We continue to project that the company will need at least \$62.5m in additional financing before profitability (which we include as illustrative long-term debt) in 2024, of which a total additional \$7.5m will be required by the end of 2018 and a further \$10m by the end of 2019.

## Cartilage generation paper published

The company also announced that a paper it prepared, *Supplementation of Specific Carbohydrates Results in Enhanced Deposition of Chondrogenic-Specific Matrix during Mesenchymal Stem Cell Differentiation* was published and featured on the cover of the May 2018 issue of the *Journal of Tissue Engineering and Regenerative Medicine*. The article discusses a scalable system that permits the generation of functional human cartilage tissue from human mesenchymal stem cells. As a result, the company subsequently announced plans to launch an advanced joint supplement, designed to potentially reduce joint pain associated with osteoarthritis, in Q318. Initially, it will be a soft launch geared towards existing Lifeline Skin Care customers, with a broader launch potentially coming afterwards.

## Valuation

Our valuation remains \$34m, although on a per-share basis it has increased to \$5.46 from \$5.45. Increases to our revenue estimates for the base business were mostly cancelled out by an increase in long-term SG&A expense expectations. Additionally, net cash is slightly lower and there are slightly more shares outstanding.

**Exhibit 2: International Stem Cell valuation**

Product	Status	Launch	Peak sales (\$m)	NPV (\$m)	Probability of success	rNPV (\$m)	NPV/ share (\$/share)
Cosmetic and biomedical business	Commercial	Current	18	24	90%	21	3.44
PD (royalties at 12% of sales)	Phase I/IIa	2024	2,800	528	7.5%	40	6.39
G&A expense – after tax					100%	(27)	(4.39)
Net cash				0.1	100%	0.1	0.02
<b>Valuation</b>				<b>552</b>		<b>34</b>	<b>5.46</b>

Source: Edison Investment Research

**Exhibit 3: Financial summary**

US\$000s	2015	2016	2017	2018e	2019e
Year-end 31 December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
<b>PROFIT &amp; LOSS</b>					
Revenue	7,551	7,165	7,456	8,790	9,527
Cost of Sales	(2,056)	(1,944)	(2,122)	(2,725)	(2,953)
Gross Profit	5,495	5,221	5,334	6,065	6,574
Research and development	(2,707)	(2,856)	(2,658)	(4,500)	(6,500)
EBITDA	(4,092)	(4,520)	(4,616)	(5,801)	(6,807)
Operating Profit (before amort. and except.)	(4,564)	(4,851)	(4,942)	(6,073)	(7,079)
Intangible Amortisation	0	0	0	0	0
Exceptionals	0	0	0	0	0
Other	1,929	3,772	(1,127)	355	0
Operating Profit	(2,635)	(1,079)	(6,069)	(5,718)	(7,079)
Net Interest	0	0	0	(600)	(1,400)
Profit Before Tax (norm)	(4,564)	(4,851)	(4,942)	(6,673)	(8,479)
Profit Before Tax (reported)	(2,635)	(1,079)	(6,069)	(6,318)	(8,479)
Tax	0	0	0	0	0
Profit After Tax (norm)	(2,635)	(1,079)	(6,069)	(6,318)	(8,479)
Profit After Tax (reported)	(2,635)	(1,079)	(6,069)	(6,318)	(8,479)
Average Number of Shares Outstanding (m)	2.0	3.2	4.2	6.4	6.7
EPS - normalised (\$)	(1.29)	(0.34)	(1.46)	(0.98)	(1.27)
EPS - normalised fully diluted (\$)	(1.29)	(0.34)	(1.46)	(0.98)	(1.27)
EPS - (reported) (US\$)	(1.29)	(0.34)	(1.46)	(0.98)	(1.27)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	72.8	72.9	71.5	69.0	69.0
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A
<b>BALANCE SHEET</b>					
Fixed Assets	4,147	4,553	4,009	4,693	5,363
Intangible Assets	3,223	3,484	2,922	3,538	4,154
Tangible Assets	864	1,011	1,013	1,080	1,134
Investments	60	58	74	75	75
Current Assets	2,991	2,492	2,855	5,407	7,407
Stocks	1,348	1,390	1,307	1,385	1,701
Debtors	539	574	465	939	680
Cash	532	110	304	2,444	4,387
Other	572	418	779	639	639
Current Liabilities	(5,544)	(3,601)	(4,800)	(5,478)	(5,244)
Creditors	(5,544)	(3,601)	(4,800)	(5,478)	(5,244)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	0	0	0	(7,500)	(17,500)
Long term borrowings	0	0	0	(7,500)	(17,500)
Other long term liabilities	0	0	0	0	0
Net Assets	1,594	3,444	2,064	(2,878)	(9,973)
<b>CASH FLOW</b>					
Operating Cash Flow	(4,120)	(4,197)	(2,142)	(3,832)	(5,714)
Net Interest	0	0	0	(600)	(1,400)
Tax	0	0	0	0	0
Capex	(738)	(944)	(864)	(928)	(943)
Acquisitions/disposals	0	0	0	0	0
Financing	1,169	4,018	3,200	0	0
Dividends	0	0	0	0	0
Net Cash Flow	(3,689)	(1,123)	194	(5,360)	(8,057)
Opening net debt/(cash)	(1,111)	(532)	(110)	(304)	5,056
HP finance leases initiated	0	0	0	0	0
Other	3,110	701	0	0	0
Closing net debt/(cash)	(532)	(110)	(304)	5,056	13,113

Source: Edison Investment Research, company accounts

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