EDISON

International Stem Cell

Financial update

Strong biomedical sales and new clinical data

Pharma & biotech

International Stem Cell (ISCO) reported Q318 revenues of $3.2m, up 73.0% compared to Q317 mainly due to the biomedical business, which had quarterly revenues of $2.8m, up 112.8% year-on-year. Additionally, the company reported updated data from the Phase I trial of ISC-hpNSC in Parkinson's disease (PD). At the six-month time point, the percentage OFF-Time, a key endpoint for PD treatment, decreased an average of 49% for the second cohort of patients, compared to 24% for the first, with four patients in each cohort.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/16	7.2	(4.9)	(1.52)	0.0	N/A	N/A
12/17	7.5	(4.9)	(1.19)	0.0	N/A	N/A
12/18e	11.5	(3.2)	(0.50)	0.0	N/A	N/A
12/19e	13.5	(7.0)	(1.05)	0.0	N/A	N/A

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

Commercial business continues to grow briskly

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 produces human cell culture products for testing. Together they generated $3.2m in sales in Q218, up 73.0% compared to the same quarter last year and provided $0.8m in operating profit.

Positive efficacy signals

The company presented updated data from its Phase I trial in PD at the Society for Neuroscience Annual Meeting on 3 November. Although data are still early and the sample is small (four patients per cohort), some positive efficacy signals were seen. Percentage OFF-Time improved by 49% in the second cohort compared to 24% in the first. Additionally, ON-Time without dyskinesia increased an average of 33% for the second cohort after six months compared to 19% for the first.

Clean safety profile

So far, a total of 10 patients have received therapy in the trial. Importantly there have been no intra-operative complications and no serious adverse events associated with therapy. The most common adverse events include anxiety and headache.

Valuation: $42m or $6.16 per basic share

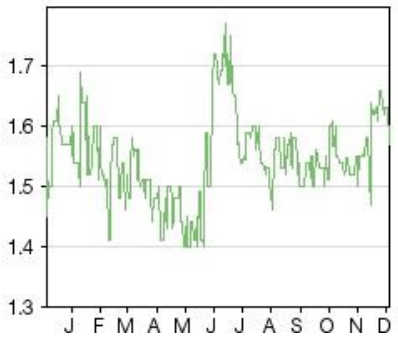
We have adjusted our valuation from $36m or $5.72 per basic share to $42m or $6.16 per basic share. The increase in valuation is mainly due to higher revenue estimates for the biomedical business and rolling forward our NPV. We project that the company will need at least $45m in additional financing before profitability in 2024 (down from $60m due to higher revenues and continued cost controls), of which an additional $8m will be required by the end of 2019.

4 December 2018

Price	**US$1.57**
Market cap	**US$11m**

Net debt ($m) at 30 September 2018	0.9
Shares in issue	6.8m
Free float	41%
Code	ISCO
Primary exchange	OTC
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	1.3	4.7	(1.3)
Rel (local)	(1.2)	8.8	(6.5)
52-week high/low	US$1.8		US$1.4

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

Announce clinical development plan in PD	2019

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Edison profile page

Q318 results

The company reported Q318 revenues of $3.2m, up 73.0% compared to Q317 (and up 5.2% sequentially compared to the previous quarter) mainly due to the biomedical business, which had quarterly revenues of $2.8m, up 112.8% compared to the same quarter last year (and up 7.0% sequentially). The cosmetics business, however, was down 30.1% in the quarter and now represents just 11.3% of total revenues compared to 27.9% in the same quarter last year. The operating profit of the biomedical business also increased substantially, up 75.8% to $1.0m, although the cosmetic business showed a loss for the quarter. The commercial businesses combined had a profit of $768,000, up 133.4% compared to Q317. For the company as a whole, the operating loss was $663,000 for Q318, a decline of 31.6% compared to last year. We have made some adjustments to our model, increasing our 2018 revenue estimate for the commercial business from $11.2m to $11.5m and our 2019 estimate from $12.2m to $13.5m due to higher than expected strength in the biomedical segment. We also decreased our SG&A expense estimate by $0.3m in 2018 due to a lower 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	11,165	11,459	2.6%	(3,508)	(3,057)	14.8%	(3,908)	(3,219)	21.4%
2019e	12,155	13,483	10.9%	(6,990)	(6,207)	11.2%	(8,190)	(7,009)	14.4%

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 $1.2m in cash on the balance sheet at the end of Q318. There was $2.0m 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 end, the maturity date was extended to 15 January 2019. We project that the company will need at least $45m in additional financing before profitability in 2024 (down from $60m due to higher revenues and continued cost controls), of which an additional $8m will be required by the end of 2019.

Data presentation at the Society for Neuroscience

The company presented updated data from its Phase I trial in PD at the Society for Neuroscience Annual Meeting on 3 November. As a reminder, the trial is a dose-escalation study designed to evaluate the safety of the intracranial injection of 30m, 50m and 70m cells. The trial is also evaluating the treatment for efficacy by monitoring changes in brain function via PET scan, as well as functional assessment via various measures over 12 months.

With regards to the efficacy data, the percentage OFF-Time (percentage of the day when levodopa medication is not performing optimally and PD symptoms return) improved 49% in the second cohort compared to 24% in the first. Additionally, the percentage ON-Time without dyskinesia (percentage of day that medication is working optimally without dyskinesia) increased an average of 33% for the second cohort after six months compared to 19% for the first. Quality of life as measured by the Parkinson's Disease Quality of Life Score-39 Summary Index improved 47% for the second cohort and 15% for the first at the six month time point. Beck Depression Inventory (BDI) and Questionnaire for Impulsive-Compulsive Disorders in Parkinson’s Disease scores also improved with greater improvement for the higher dosed second cohort than the first.

One area of concern is in the 12-month follow up data for the first cohort as both the percentage OFF-Time and BDI rebounded from the six-month time point. This could be because the dose is too low as this is for the lowest dose cohort, it could also mean there might be a need for retreatment of

patients or it could simply be due to individual patient circumstances (which has the capability of moving the data markedly considering there were only four patients in the sample). Additionally, certain caveats apply to the data in general as this is a single-arm, open-label study, and no p-values were provided (although the trial was not powered to achieve statistical significance) making it difficult to draw any efficacy conclusions.

The safety profile of ISC-hpNSC continues to be clean. So far, a total of 10 patients have received therapy in the trial and there have been no intra-operative complications or serious adverse events associated with therapy. There is also no evidence of tumors, cysts, enhanced inflammation or infection. The most common adverse events include anxiety and headache.

Valuation

We have adjusted our valuation from $36m or $5.72 per basic share to $42m or $6.16 per basic share. The increase in valuation is mainly due to higher revenue estimates for the base business and rolling forward our NPV.

Exhibit 2: International Stem Cell valuation

Product	Status	Launch	Peak sales ($m)	NPV ($m)	Probability	rNPV ($m)	NPV/share ($/share)
Cosmetic and biomedical business	Commercial	Current	18	34	90%	34	5.00
Parkinson's disease (royalties at 12% of sales)	Phase I/IIa	2024	2,800	559	7.5%	42	6.19
G&A expense - after tax					100%	(33)	(4.91)
Net cash (Q318)				(0.9)	100%	(0.9)	(0.13)
Valuation				596		42	6.16

Source: Edison Investment Research

Exhibit 3: Financial summary

US$000	2016	2017	2018e	2019e
Year end 31 December	GAAP	GAAP	GAAP	GAAP
PROFIT & LOSS				
Revenue	7,165	7,456	11,459	13,483
Cost of Sales	(1,944)	(2,122)	(4,011)	(4,719)
Gross Profit	5,221	5,334	7,448	8,764
Research and development	(2,856)	(2,658)	(2,500)	(6,500)
EBITDA	(4,520)	(4,616)	(2,771)	(5,921)
Operating Profit (before amort. and except.)	(4,851)	(4,942)	(3,057)	(6,207)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Other	3,772	(1,127)	1,137	0
Operating Profit	(1,079)	(6,069)	(1,920)	(6,207)
Net Interest	0	0	(162)	(802)
Profit Before Tax (norm)	(4,851)	(4,942)	(3,219)	(7,009)
Profit Before Tax (reported)	(1,079)	(6,069)	(2,082)	(7,009)
Tax	0	0	0	0
Profit After Tax (norm)	(4,851)	(4,942)	(3,219)	(7,009)
Profit After Tax (reported)	(1,079)	(6,069)	(2,082)	(7,009)
Average Number of Shares Outstanding (m)	3.2	4.2	6.4	6.7
EPS - normalised ($)	(1.52)	(1.19)	(0.50)	(1.05)
EPS - normalised fully diluted ($)	(0.34)	(1.46)	(0.32)	(1.05)
EPS - reported ($)	(0.34)	(1.46)	(0.32)	(1.05)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	72.9	71.5	65.0	65.0
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	4,553	4,009	4,457	4,914
Intangible Assets	3,484	2,922	3,279	3,636
Tangible Assets	1,011	1,013	1,103	1,203
Investments	58	74	75	75
Current Assets	2,492	2,855	5,250	6,088
Stocks	1,390	1,307	1,682	2,407
Debtors	574	465	1,905	962
Cash	110	304	1,096	2,151
Other	418	779	567	567
Current Liabilities	(3,601)	(4,800)	(4,290)	(5,040)
Creditors	(3,601)	(4,800)	(4,290)	(5,040)
Short term borrowings	0	0	0	0
Long Term Liabilities	0	0	(2,025)	(10,025)
Long term borrowings	0	0	(2,025)	(10,025)
Other long term liabilities	0	0	0	0
Net Assets	3,444	2,064	3,392	(4,063)
CASH FLOW				
Operating Cash Flow	(4,197)	(2,142)	(1,010)	(3,400)
Net Interest	0	0	(162)	(802)
Tax	0	0	0	0
Capex	(944)	(864)	(706)	(743)
Acquisitions/disposals	0	0	0	0
Financing	4,018	3,200	645	(2,000)
Dividends	0	0	0	0
Net Cash Flow	(1,123)	194	(1,233)	(6,945)
Opening net debt/(cash)	(532)	(110)	(304)	929
HP finance leases initiated	0	0	0	0
Other	701	0	0	0
Closing net debt/(cash)	(110)	(304)	929	7,874

Source: International Stem Cell accounts, Edison Investment Research

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