

Source: Eikon Thomson Reuters

Market data		
EPIC/TKR		COS
Price (p)		2.9
12m High (p)		8.5
12m Low (p)		2.3
Shares (m)		324.5
Mkt Cap (£m)		9.3
EV (£m)		5.5
Free Float*		70%
Market		AIM

\*As defined by AIM Rule 26

#### Description

COS develops, manufactures and supplies medical grade collagen biomaterials, tissues and devices. Its products are used in research, *in vitro* diagnostics, medical devices and regenerative medicine. The company provides R&D and contract services to a global and diverse customer base.

#### Company information

CEO	Jamal Rushdy
CFO	Gill Black
Chairman	David Evans

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www.collagensolutions.co.uk

Key shareholders	
Directors + management	17.3%
Seneca	13.2%
Calculus Capital	9.5%
Livingbridge	4.6%
Helium Rising Stars	4.0%
Rathbones IM	4.0%

Diary	
1Q-18	CM CE Mark filing
Jul-18	Finals

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## **Collagen Solutions**

## Targeting long-term sustainable growth

Collagen Solutions is a biomaterials company developing and manufacturing medical grade collagen components for use in medical devices, research, and regenerative medicine. A number of investment initiatives have been introduced to accelerate the rate of growth, including global commercial infrastructure and development of a pipeline of finished medical devices, the first of which will be ChondroMimetic for repair of small cartilage lesions. Although considerable progress has been made, recent results highlight the time lag between making the investment and generating long-term sustainable growth.

- ▶ **Strategy**: Management has embarked on an investment strategy through a series of initiatives to increase the growth opportunities. This strategy is moving COS from a reliable quality collagen supplier to one that also has proprietary products that will move it into profitability, and cash generative, at a faster pace.
- ▶ Interims: Underlying sales eased back -12% to £1.73m (£1.83m) largely due to reasons beyond COS's control internal customer processes and regulatory delays and forex. In addition, a higher contribution of below average gross margin products (e.g. pericardium) led to a bigger than expected fall in the gross margin.
- ▶ ChondroMimetic: The company has completed successfully the re-evaluation of 15/17 patients from the original trial in 2009-10. This will provide unprecedented 8-year follow-up data about the quality of the cartilage repair and support CE Mark submission (1Q 2018) and marketing material (2Q 2018).
- ▶ Forecasts: Investment in marketing has resulted in 8 new accounts in 1H'18, compared to 9 for the whole of 2017, and a large number of live deals under negotiation. However, these are unlikely to come through sufficiently fast enough to benefit FY 2018, therefore sales forecasts have been reduced by 20%.
- ▶ Investment summary: ChondroMimetic fulfils COS's stated strategy to move further up the value chain. The 8-year data will significantly differentiate it from competing therapies, with all the patients re-assessed the focus is now on data analysis in preparation for submission for CE Mark in 1Q 2018. Although the FY 2018 outcome is largely out of the company's hands, management is confident that everything is in place for long-term sustainable growth.

Financial summary and valuation							
Year end March (£000)	2015	2016	2017	2018E	2019E	2020E	
Sales	973	3,130	3,946	4,210	5,700	8,220	
Underlying EBITDA	-663	-374	-1,209	-1,395	-443	339	
Underlying EBIT	-793	-721	-1,658	-1,915	-983	-221	
Underlying PBT	-920	-983	-1,790	-2,142	-1,217	-316	
Statutory PBT	-1,102	-866	-1,614	-1,977	-1,317	-416	
Underlying EPS (p)	-0.98	-0.64	-1.04	-0.68	-0.41	-0.14	
Statutory EPS (p)	-1.17	-0.57	-0.95	-0.63	-0.44	-0.17	
Net cash/(debt)	3,282	2,384	7,072	3,199	762	-1,206	
Capital increase	5,422	207	6,462	0	0	0	
P/E (x)	-5.1	-7.8	-4.8	-4.2	-7.1	-20.2	
EV/sales (x)	9.4	2.9	2.3	1.3	1.0	0.7	
EV/EBITDA (x)	-	-	-	-	-	16.3	

Source: Hardman & Co Life Sciences Research



## 2018 interims

#### **Key features**

#### Operational

- ► ChondroMimetic: Highlight of the period has been the re-evaluation of 15 out of the 17 patients originally implanted with ChondroMimetic on average eight years ago. Full analysis is being undertaken and results are due early in 2018
- ▶ Commercial: Investment in marketing over the last 18 months is bearing fruit, with 8 new customers signed in 1H'18 compared to 9 for the whole of 2017. The pipeline is strong, but deal timing has an important influence on FY numbers
- ▶ **US operations:** Relocation of R&D and commercial teams to a single site in Minneapolis has been completed at a cost of \$115k/£89k
- ► Cre8tive: Important clearances for COS biomaterials into China was received which has paved the way to its first customer supply agreement; highlights the importance of local relationships and positions COS well for the future

#### **Financial**

- ▶ Sales: In a trading update on 26<sup>th</sup> October, the company reported that total revenues (product sales + grants) were £1.86m. Underlying product sales declined -12% to £1.73m compared to our forecast of £1.79m.
- ▶ **Gross margins:** Given the increased supply of lower margin pericardium material, margins had been expected to decline to 70.0% from 71.3%. The outcome was more severe (63.6%) than anticipated due to the sales decline
- ▶ **R&D:** Increased investment in R&D from -£274k to -£440k was in-line with forecasts, largely due to the ChondroMimetic extension study
- ▶ **Net cash/(debt):** At 30<sup>th</sup> September the group had net cash of £3.82m, comprised of £6.74m cash and debt of -£2.92m, in-line with expectations

Actual vs expectati	ons				
£000	1H'17	1H'18	CER change	1H'18	Delta
	actual	actual	%	forecast	Δ
Sales	1,831	1,726	-12%	1,790	-64
COGS	-526	-629	+19%	-537	-92
Gross margin	71.3%	63.6%		70.0%	-6.4pp
G&A	-1,068	-1,504	+36%	-1,444	-60
Marketing	-417	-483		-438	-45
Other income	60	133		70	+63
EBITDA	-393	-1,197	-43%	-1,004	-193
Underlying EBIT	-600	-1,431	+77%	-1,360	-71
Underlying EPS (p)	-0.42	-0.49	+75%	-0.47	-0.02
Net cash/(debt)	1,572	3,824		3,870	-46
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Source: Hardman & Co Life Sciences Research

#### Outlook

▶ Sales: Although the underlying business performance of the group is improving through the faster uptake of customer supply agreements, many of the sales are outside the control of COS and at the behest of customers awaiting regulatory approvals. Management indicated that FY sales are likely to be below market expectations, whilst reiterating its five year goal to increase sales 5x from the 2016 level.



# **Operational update**

## ChondroMimetic

ChondroMimetic will be Collagen Solutions' first proprietary product to reach the market, supporting management's strategy to move up the value chain. This product has very good provenance having received CE Mark in 2008, which was followed by a clinical study for osteochondral defects of the knee undertaken by a key opinion leader in 2009-10, looking at safety and early efficacy of the implant. However, the then owners of ChondroMimetic changed strategy and allowed the CE Mark to lapse.

Key to the re-submission of ChondroMimetic for renewal of the CE Mark is an open label extension of the original study to reassess the cartilage defect repairs in the 17 patients involved in the trial in 2009-10. Amazingly, 15 of these patients were contactable and indicated their willingness to take part. New techniques previously unavailable, are being used to generate more sophisticated data on average 8 years after the implant surgery, representing unparalleled depth of clinical knowledge on this subject.

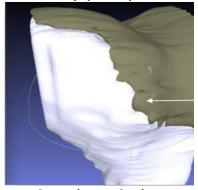
On 30<sup>th</sup> June 2017, the first of these patients returned to have their cartilage repair re-assessed. COS announced in September that the final (15<sup>th</sup>) patient had been re-scanned. All the data that have been collected are undergoing advanced MRI analysis, such that COS will end up with 6 month and ca.8 year paired data for each of the 15 patients. This is due to be released in 1Q 2018, allow re-submission of ChondroMimetic for CE Mark, and target launch in Europe in mid-2018.



- ► Analysis of the data by Qmetrics Technologies using advanced MRI analysis (ongoing since first patient re-scanned), including T2 Mapping and 3D MRI
- Preparation and completion of the clinical study report
- Complete internal manufacturing validation
- ► In conjunction with the Notified Body, submit package to the regulatory authorities for re-establishment of CE Mark
- ▶ Continue to discuss/negotiate with potential commercial partners

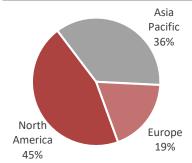


10-days post implant



6-months post implant
Source: Collagen Solutions

#### Sales by geography – 1H'18



Source: Hardman & Co Life Sciences Research

#### **Financials**

#### **Sales**

Underlying product sales in 1H'18 reduced -12% to a reported figure of £1.73m (CER £1.60m vs £1.79m in 1H'17). The primary cause of this was a -25% decline in sales from North America to \$1.01m (\$1.35m) that resulted from unusual customer buying patterns as they await regulatory approvals, or a funding increase to undertake perform clinical trials. Also, there was a different mix of business in 1H'18 compared to 1H'17 which benefited from sales of a high margin matrix product.

Underlying sales in Asia were down -13% to £0.62m (£0.66m), again caused by uneven customer buying patterns. COS's largest customer in South Korea has been buying minimum levels of product as per its contractual obligation, but this has resulted in an inventory build-up. COS is working with the company on a number of



opportunities to mitigate this issue. However, while some offset will be achievable, this will not be fully recoverable in the short-term and will also affect 2018-19 as reported in the full year statement for fiscal 2017.

Countering these effects, there was a very strong performance in Europe, where sales increased by +60% CER to €0.37m/£0.32m. The two development projects that have driven this growth are manufacture of an advanced woundcare scaffold for SmartMatrix® and of a component for a vascular graft for a cardiovascular company. Also, COS has performed some development services for a company which will lead to a commercial supply agreement in future periods.

# Development Manufacturing 22% 43% Tissue Materials 31% 4%

Source: Hardman & Co Life Sciences Research

#### **Gross margin**

As mentioned earlier, the gross margin declined further than expected to 63.6% (71.3%). There were a number of reasons behind this decline:

- ▶ 1H'17 benefited from the supply of a high margin (>80%) matrix product which was not repeated in the current period while the purchasing company seeks funding for the next phase of clinical trials
- ► Although the contribution from Tissue sales mostly pericardium remained constant at 31%, these are at a lower margin (ca.60-65%)
- ► The contribution from Development Services, included some early stage passthrough costs which attract below average gross mark-up in the earlier part of the project, rose from 8% of product sales to 22%

#### Changes to forecasts

Following these results, our medium-term forecasts have been reduced (see pages 5-7). Sales for fiscal 2018 and 2019 have been reduced by -20% and -11% respectively. Although management has a strong pipeline of potential deals, the time to reach closure is very difficult to predict. For 2018, the key assumption is that about 50% of these deals will be concluded by the financial year end in March 2018. In the event that more or less are signed, forecasts would be adjusted in an upward or downward direction as appropriate, because many involve up-front access fees. Management is looking to mitigate these lower sales by actively seeking cost reductions in all parts of the organisation over the next two financial years.

## **Management changes**

On 14<sup>th</sup> December, COS announced the appointment of Hilary Spence as CFO and Board member from 3<sup>rd</sup> January 2018. She is a Chartered Accountant, member of ICAS and has a BA in Business Economics and MBA from Strathclyde University. Hilary will bring over 30 years' experience in finance across a number of multi-sector businesses. She has been involved in a number of successful business transformations where her diverse skills have been used to create, financially evaluate and implement growth strategies. Hilary has worked with a broad range of companies from large corporates – including Heineken, Vodafone, Motorola and Premier Foods – and small entrepreneurial businesses. Most recently, Hilary was interim CFO at the private equity funded Powerleague, where she was integral to the restructuring and transformation of its finance systems. Hilary will be based ay COS's HQ in Glasgow, replacing Gill Black, who will remain with the company in a less time-consuming role as Company Secretary, and assure a smooth transition.



# **Financial analysis**

## **Profit & Loss**

To provide a better understanding of underlying performance, forecasts remain on a constant currency basis. If key currencies remain at current levels, forex would have a very slight negative impact for the full year:

- ▶ Sales: The 2018 sales forecast is dependent on about 50% of current late-stage deal discussions coming to fruition, which include up-front payments
- ► Gross margin: Improvement in the gross margin is expected when higher valueadded devices from COS's proprietary pipeline reach commercialisation from early fiscal 2019

Profit & Loss account						
Year end March (£000)	2015	2016	2017	2018E	2019E	2020E
GBP:USD	1.57	1.46	1.31	1.31	1.31	1.31
GBP:EUR	1.29	1.31	1.19	1.19	1.19	1.19
GBP:NZD	1.95	2.03	1.84	1.84	1.84	1.84
Sales	973	3,130	3,946	4,210	5,700	8,220
Cost of goods sold	-214	-811	-984	-1,263	-1,511	-2,137
Gross profit	759	2,319	2,962	2,947	4,190	6,083
Gross margin	78.0%	74.1%	75.1%	70.0%	73.5%	74.0%
Admin expenses	-1,106	-2,107	-3,003	-2,905	-2,993	-3,535
Selling & marketing	-219	-333	-719	-905	-998	-1,315
R&D	-160	-367	-594	-832	-818	-1,069
Other income/grants	63	114	145	300	175	175
Underlying EBITDA	-663	-374	-1,209	-1,395	-443	339
Depreciation	-75	-175	-234	-250	-250	-250
Amortisation	-55	-172	-215	-270	-290	-310
Underlying EBIT	-793	-721	-1,658	-1,915	-983	-221
Share based costs	-27	-36	-51	-100	-100	-100
Exceptional items	-155	152	227	265	0	0
Statutory EBIT	-975	-604	-1,482	-1,750	-1,083	-321
Net financials	-128	-262	-132	-226	-234	-96
Underlying pre-tax	-920	-983	-1,790	-2,142	-1,217	-316
Exceptional items	0	0	0	0	0	0
Reported pre-tax	-1,102	-866	-1,614	-1,977	-1,317	-416
Tax liability/credit	-21	-114	-142	-75	-98	-147
Underlying net income	-942	-1,097	-1,932	-2,217	-1,315	-463
Statutory net income	-1,123	-980	-1,756	-2,052	-1,415	-563
Ordinary 1p shares:				2245	224 5	2245
Period-end (m)	171.0	171.4	324.3	324.5	324.5	324.5
Weighted average (m)	96.4	171.2	185.8	324.4	324.5	324.5
Fully diluted (m)	102.3	180.4	203.8	342.4	342.5	342.5
Underlying Basic EPS (p)	-0.98	-0.64	-1.04	-0.68	-0.41	-0.14
Statutory basic EPS (p)	-1.17	-0.57	-0.95	-0.63	-0.44	-0.17
U/I Fully-diluted EPS (p)	-0.98	-0.64	-1.04	-0.68	-0.41	-0.14
Stat. fully-diluted EPS (p)	-1.17	-0.57	-0.95	-0.63	-0.44	-0.17
DPS (p)	0.00	0.00	0.00	0.00	0.00	0.00
			Source: Hardman & Co Life Sciences Research			



## **Balance sheet**

- ► Net cash/debt At 31<sup>th</sup> September 2017 net cash was +£3.82m, comprising a cash balance of £6.74m and debt of -£2.92m
- Norgine facility: To date, the company has drawn down £3m of its £4m facility from Norgine
- ▶ **Provisions:** There remains a modest financial liability in the balance sheet in relation to New Zealand and US earn-outs, which is due for payment in August 2018

Balance sheet						
@ 31st March (£000)	2015	2016	2017	2018E	<b>2019E</b>	2020E
Shareholders' funds	12,853	13,896	20,286	18,230	16,816	16,253
Cumulated goodwill	0	0	0	0	0	0
Total equity	12,853	13,896	20,286	18,230	16,816	16,253
Share capital	1,755	1,759	3,288	3,325	3,400	3,485
Reserves	11,099	12,137	16,998	14,905	13,416	12,768
Provisions/liabilities	4,320	2,437	2,350	949	540	540
Deferred tax	285	253	222	207	155	117
Long-term loans	88	63	26	2,468	1,248	0
Short-term debt	22	46	1,880	447	447	0
less: Cash	3,391	2,493	8,978	6,114	2,457	-1,206
less: Deposits	0	0	0	0	0	0
less: Long-term invests.	0	0	0	0	0	0
Invested capital	14,176	14,203	15,786	16,188	16,749	18,115
Fixed assets	794	1,161	1,143	1,287	1,237	1,197
Intangible assets	12,919	12,971	14,582	14,020	14,139	13,829
Inventories	219	264	313	334	453	653
Trade debtors	419	429	541	577	781	1,127
Other debtors	226	207	266	266	266	266
Tax liability/credit	-40	0	-59	-72	<i>-75</i>	-98
Trade creditors	-215	-694	-690	-597	-714	-1,011
Other creditors	-144	-135	-310	373	663	353
Debtors less creditors	245	-193	-252	546	920	637
Invested capital	14,176	14,203	15,786	16,188	16,749	18,115
Net cash/(debt)	3,282	2,384	7,072	3,199	762	-1,206

Source: Hardman & Co Life Sciences Research



## **Cashflow**

Cashflow						
Year end March (£000)	2015	2016	2017	2018E	<b>2019</b> E	2020E
Underlying EBIT	-793	-721	-1,658	-1,915	-983	-221
Depreciation	75	175	234	250	250	250
Amortisation	55	172	215	270	290	310
Inventories	-123	-48	-54	-21	-118	-200
Receivables	-195	-10	-213	-36	-104	-245
Payables	90	479	191	-93	117	296
Change in working capital	-105	469	-76	-129	13	51
Exceptionals/provisions	-155	152	0	265	0	0
Other (Fx)	-106	-346	34	-100	250	0
Net cash used in ops.	-1,152	-147	-1,250	-1,380	-299	190
Net interest	-2	2	3	-226	-234	-95
Loan repayments	0	0	0	0	-1,220	-1,725
Tax paid/received	-26	-194	-105	-142	-75	-98
Operational cashflow	-1,180	-338	-1,360	-1,749	-1,827	-1,728
Capital expenditure	-159	-464	-137	-294	-200	-210
Sale of fixed assets	13	1	0	0	0	0
Free cashflow	-1,326	-801	-1,497	-2,043	-2,027	-1,938
Dividends	0	0	0	0	0	0
Acquisitions	-2,192	-207	-342	-1,227	-409	0
Other investments	-127	-93	0	0	0	0
Cashflow after invests.	-3,645	-1,101	-1,838	-3,269	-2,436	-1,938
Share issues	5,422	207	6,462	0	0	0
Currency effect	12	-18	63	-600	0	0
Change in net debt	1,790	-898	4,687	-3,873	-2,436	-1,938
Hardman FCF/share (p)	-1.22	-0.20	-0.73	-0.54	-0.54	-0.50
Opening net cash	1,492	3,282	2,384	7,072	3,199	762
Closing net cash	3,282	2,384	7,072	3,199	762	-1,206

Source: Hardman & Co Life Sciences Research

# **Changes to forecasts**

With lower than expected sales in each of the next two years, management is looking to make cost savings across all operational parts, and to preserve cash

Changes in forecasts							
Year end March	2017	2	018E	Change	2	019E	Change
(£000)	actual	*Old	New	%	*Old	New	%
Sales	3,946	5,200	4,210	-19%	7,230	-5,700	-11%
COGS	-984	-1,302	-1,263	-3%	-1,770	-1,511	-15%
G&A	-3,003	-3,172	-2,905	-8%	-3,326	-2,998	-10%
R&D	-594	-954	-832	-13%	-1,013	-813	-20%
Marketing	-719	-655	-905	+38%	-1,265	-998	-21%
Other income	145	150	300	+100%	175	175	
EBITDA	-1,209	-1,170	-1,395	-19%	30	-443	-
D&A	-449	-710	-520		-730	-540	
Underlying EBIT	-1,658	-1,880	-1,915	-2%	-700	-983	-40%
U/lying EPS (p)	-1.04	-0.72	-0.68		-0.38	-0.39	
Free cashflow	-1,497	-2,400	-2,043		-1,824	-2,027	
Net cash/(debt)	7,072	3,471	3,200	-8%	438	762	+74%

\*From research report published 21st September 2017 Source: Hardman & Co Life Sciences Research

19th December 2017



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