

Market data

EPIC/TKR	COS
Price (p)	8.0
12m High (p)	14.8
12m Low (p)	6.6
Shares (m)	179.6
Mkt Cap (£m)	14.4
EV (£m)	12.0
Free Float*	74%
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

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CFO	Gill Black
CSO	Stewart White
Chairman	David Evans
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Key shareholders

Directors + management	23.6%
Helium Rising Stars	7.2%
Northern Venture Trust	7.1%
Calculus Capital	6.0%
Legal & General	5.6%

Next event

Dec-16	Interims
Jly-17	Finals

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Collagen Solutions

Focus on R&D

Collagen Solutions is a biomaterials company developing and manufacturing medical grade collagen components for use in medical devices, *in vitro* diagnostics, and regenerative medicine. The strategic plan is to invest into its own pipeline of value added devices, such as the in-licensed Orthomimetics product family. It is also investing in earlier stage R&D by, in part, maintaining strong cross-sector relationships through collaborative research programmes. The recent award of a Horizon 2020 by the European Commission is the latest of five grants awarded to COS over the past two years for development of collagen-based medical devices.

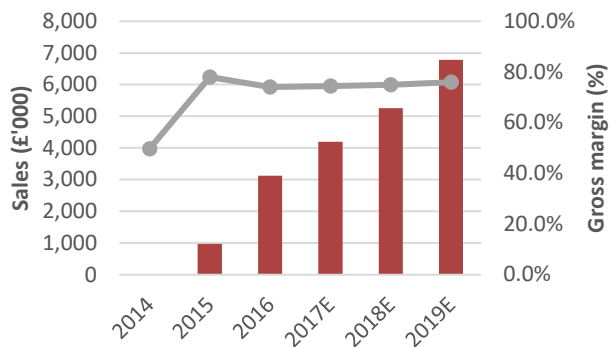
- **Strategy:** A refocused strategy was announced in July 2016 to add proprietary products to its medical-grade collagen and research services offerings. In parallel, R&D spend was increased. This has been complemented by public-sector grants for collaborative research into collagen-based medical devices.
- **Grant Opportunity:** Subject to a final grant agreement among consortium members and the European Commission, COS will receive a Horizon 2020 grant (€500K) for development of collagen scaffolds for therapeutic use in cell-based tissue regeneration. This is the second Horizon 2020 grant awarded to COS.
- **Valuation:** No changes have been made to our forecasts and the DCF valuation remains at £54m or 32p per share. There are few quoted competitors that could be considered a comparator for valuation purposes. The closest, Innocoll (INNL), is developing proprietary products and commands an EV of \$161m/£124m.
- **Risks:** Timing of development and manufacturing contracts, supply agreements, customers' regulatory delays, collagen sources and potential competition from alternate biomaterials. However, sequential half year sales growth and ca.70% of 2017 sales secured suggest that risks to forecasts have been minimised.
- **Investment summary:** 2016 was transformational for COS: the new leadership team has realigned strategy onto an accelerated growth platform, whilst maintaining core objectives. Investment in new opportunities (China JV and the in-licensed Orthomimetics family) continues to build strong pipeline that should drive long term growth, whilst delivering short term financial objectives.

Financial summary and valuation

Year end Mch (£000)	2014	2015	2016	2017E	2018E	2019E
Sales	24	973	3,130	4,107	5,144	6,651
Underlying EBITDA	-364	-726	-489	-639	-19	662
Underlying EBIT	-381	-793	-721	-1,085	-546	115
Underlying PBT	-381	-920	-983	-1,210	-775	-108
Statutory PBT	-480	-1,102	-867	-1,260	-825	-158
Underlying EPS (p)	-0.87	-0.98	-0.64	-0.79	-0.54	-0.19
Statutory EPS (p)	-1.10	-1.17	-0.57	-0.82	-0.56	-0.21
Net (debt)/cash	1,492	3,282	2,384	1,314	-432	-1,562
Capital increase	3,374	5,422	207	1,027	1,000	0
P/E (x)	-9.2	-8.2	-12.5	-10.1	-14.9	-43.0
EV/sales (x)	471.6	11.6	3.6	2.8	2.2	1.7
EV/EBITDA (x)	-	-	-	-	-	17.1

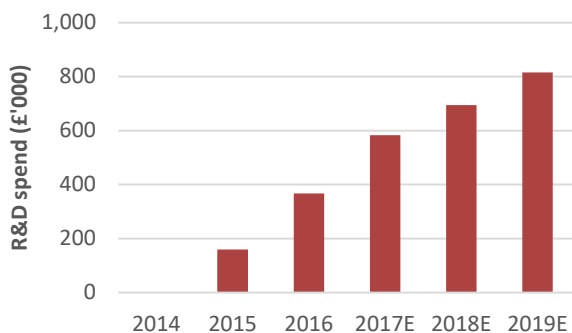
Source: Hardman & Co Life Sciences Research

Sales & Gross margin



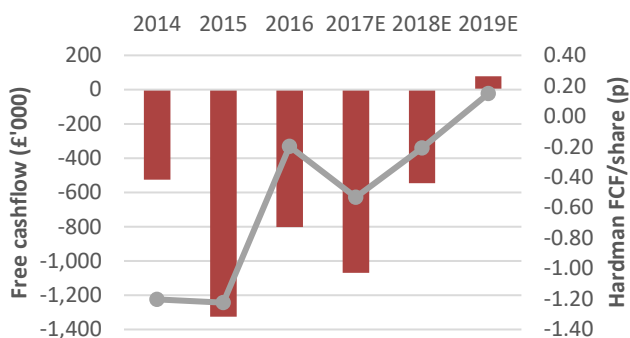
- ▶ Sales are expected to grow substantially as customers receive regulatory approvals
- ▶ Numerous new opportunities, but timing of their contribution is complex and, therefore, not included in our conservative forecasts
- ▶ The gross margin is dependent on the mix of business – contract manufacturing commands lower margins
- ▶ Gross margin is stable around 74-75% and is likely to go higher as COS moves up the value added chain

R&D spend



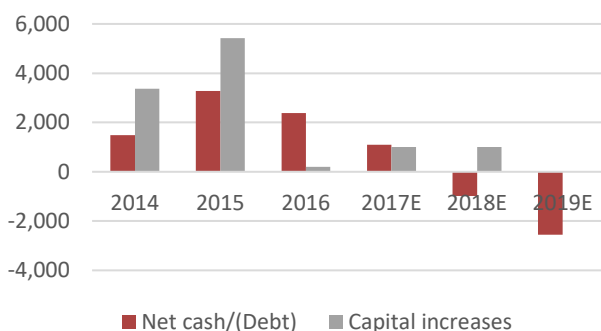
- ▶ COS currently invests about 12% of sales into R&D, but this is modest in absolute terms
- ▶ Investment in R&D spend will rise substantially in order to deliver the strategy of developing 'owned products'
- ▶ COS adds value through development of customer formulations
- ▶ Internal development is capable of supporting ongoing R&D

Free cashflow



- ▶ Accelerated spend on R&D, China JV and increasing the commercial team to drive medium to long term revenues affects short term cash flow
- ▶ Uncommitted cap-ex investment could be delayed to preserve cash
- ▶ Forecasts are conservative and any future change is more likely to be upwards with resulting improvement in cashflows
- ▶ Cash position is affected by deferred consideration over the in 2018 and 2019

Net cash



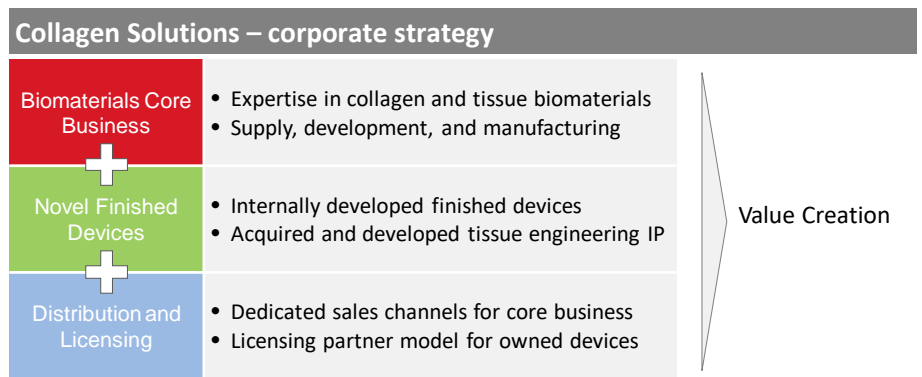
- ▶ Accelerated R&D and marketing spend is utilising cash that would otherwise be used for deferred considerations
- ▶ Deferred considerations – Southern Lights and CS (US) – will push net cash into a net debt position from 2018
- ▶ Capital increases in 2017 & 2018 currently reflect deferred consideration for acquisition in shares
- ▶ Any decisions regarding a ChondroMimetic US clinical trial programme will determine the timing/need for more cash and/or a strategic partner

Source: Company data; Hardman & Co Life Sciences Research

Implementing revised strategy

Refocused strategy detailed in our previous report on 19th July 2016

In July, Hardman reported that Collagen Solution had refocused the group strategy to accelerate its growth opportunities – *Focused scalable approach to growth opportunities 19th July 2016*. The new leadership team has introduced several initiatives aimed at improving and accelerating its core business performance and, in doing so, to create shareholder value.



Source: Collagen Solutions

Novel finished devices

Accelerated growth strategy...

...aided by internal R&D programme

One of the key components of this new strategy focuses on accelerating growth through the development and commercialisation of proprietary products. These could be acquired from external sources when suitable opportunities arise, as was the case with the in-licensed Orthomimetics family of products acquired in September 2015. Or they will come from the company’s own internal R&D programmes. R&D spend increased by 129% to -£0.37m in 2016 and is expected to rise further in 2017 and 2018, as the company invests in ChondroMimetic and embarks upon more early stage R&D projects.

Orthomimetics Limited

The in-licensed Orthomimetics family of products takes COS to end of value chain with proprietary products.

In September 2015, Collagen Solutions acquired the assets of Orthomimetics Ltd and an exclusive license to the IP, moving the company up the value chain through the offering of proprietary end products. Exploitation of this technology platform is expected to generate multiple product opportunities – cartilage, ligament, rotator cuff, meniscus and bone graft – over the medium term. The most advanced is ChondroMimetic, a collagen implant for the repair of small articular cartilage defects.

ChondroMimetic family of products



COS acquired an exclusive licence to the IP of the ChondroMimetic family of products in Sept 2015

- Cartilage, bone, meniscus, tendon, and ligament orthopaedic regenerative platform

ChondroMimetic is the primary opportunity

- Previously used in Europe, 6+ years evidence in patients
- Retro study and CE mark for OUS launch early 2017

Source: Collagen Solutions

Grant funding

Shareholder investment boosted by non-equity funding

As part of the revised R&D initiative, and to supplement the COS's own investment, non-equity funding in the form of grants, wherever possible, will be sought. To that end, COS has been successful in securing public sector grant funding for five research programmes over the last two years that will support development of collagen-based devices for a range of diseases. These augment internal R&D resources and further strengthen the company's long-term, cross-sector relationships.

Long-term research grants awarded

Funding Body	Research programme	Value to COS	Programme start
EU H2020	Industrial collaborator: 4 years; cell-based tissue regeneration	€500k	Dec '17
Medical Research Scotland	PhD funding: Leukaemia	>£100k	Sep '17
EU H2020	Consortium partner: 4 years; Parkinson's disease	>€500k	Dec '16
Medical Research Scotland	PhD funding: Matrix modulation	>£100k	Ongoing
Arthritis Research UK	Proof-of-Concept grant: 18 months; osteochondral injury	In kind contribution	Ongoing

Source: Collagen Solutions

Two programmes funded by the European Union



Source: Hardman & Co Life Sciences Research

Horizon 2020 (H2020)

A European Commission initiative

H2020 is the financial vehicle behind 'Innovation Union', the European Commission's innovation and research initiative, which facilitates public-private scientific collaboration in tackling societal challenges. H2020 has €80bn available for research organised as multi-annual 'work programmes' taking place between 2014 and 2020. Application calls are open to everyone, and with 31k eligible full proposals made for the first 100 calls, they are hugely competitive. Collagen's selection for two H2020 projects illustrates its strength in the collagen-based biomaterials market.

Parkinson's disease research

In December, Collagen Solutions will commence research under its first H2020 grant as a member of a seven participant consortium coordinated by the Centre for Research in Medical Devices at the National University of Ireland, Galway. The project, BrainMatTrain, was funded as a €4m Marie Skłodowska-Curie Innovative Training Network: 15 researchers will be trained in functionalised biomaterials and related fields. The aim of BrainMatTrain is to develop multi-modal collagen reservoir scaffolds as therapeutic devices that act to slow progression of Parkinson's disease.

H2020 Parkinson's disease therapeutic device research consortium

Partner	Type
Innsbruck Medical University, Austria	Research institution
Lund University, Sweden	Research institution
Commission for Atomic Energy and Alternative Energies (CEA), France	Research body
Technical University of Denmark, Denmark	Research institution
Radboud University Nijmegen, Netherlands	Research institution
Collagen Solutions (UK) Ltd	SME
Orbsen Therapeutics Ltd, University of Ireland	SME
National University of Ireland, Galway	Research institution

Source: Collagen Solutions

Second Horizon 2020 grant worth about EURO.5m over five years

Cell-based tissue regeneration techniques

On 15th September 2016, Collagen Solutions announced it had been invited to participate in a second H2020 grant as an industrial collaborator on another cell-based tissue regeneration techniques/regenerative medicine programme. COS will receive approximately EUR500,000 of EU funding over five years, awarded under the Health section of the initiative, subject to a formalised Grant Agreement between the consortium members and the European Commission. Further details are expected to be available in the near future following the signing of this Grant Agreement.

Medical Research Scotland funding for two PhD students

Medical Research Scotland

Medical Research Scotland is an independent Scottish charity dedicated to funding research towards improving the diagnosis, treatment, or prevention of any disease. The award of two PhD research grants to Collagen Solutions in collaboration with Scottish universities illustrates Collagen's reputation and expertise in development of collagen products for research and regenerative medicine applications.

Leukaemia PhD

Collagen Solutions was awarded most recently a Medical Research Scotland grant for a PhD to start in September 2017 with the University of Glasgow, supervised by Dr Catherine Berry. The aim of the study is to better understand progression of leukaemia through use of artificial bone marrow models, which are created from collagen gel cultures seeded with resident niche cell types.

Matrix modulation PhD

Extra-cellular matrix is constantly remodelled through collagen degradation and synthesis. Implanted collagen is similarly degraded, thus development of methods that control the rate of degradation of medical devices is critical. A PhD conducted in collaboration with the University of Strathclyde is underway to test the utility of existing clinically-approved drugs in manipulating collagen degradation profiles. Findings will help develop new collagen based products for regenerative medicine.

Arthritic research work fits nicely with the ChondroMimetic programme

Arthritis Research UK

Arthritis Research UK is dedicated to preventing the onset of arthritis, developing a cure for arthritis, and transforming the lives of those with arthritis. In 2015, Collagen Solutions, University College London, and Oxford MESTar were awarded an ARUK Proof-of-Concept grant for development of an artificial scaffold for surgical treatment of larger osteochondral injuries. Osteochondral injury refers to damage to cartilage and underlying bone in joints, occurring particularly in the knee due to repetitive stress, which often leads to osteoarthritis.

Investment conclusion

Collagen Solutions is in an elite group of companies that have the ability to supply medical grade collagen on a global scale. In our opinion, there are five key players in the market. In addition, there are a number of other companies which can supply collagen to end-users and/or are capable of developing their own products.

A key problem in attempting to value COS is that there are few direct comparator companies that are quoted. However, Innocoll recently (22nd June 2016) raised gross new capital of \$40m and carries a market capitalisation of \$186m/£143m despite having sales below those of COS. It is undertaking phase III trials of proprietary products which highlights the potential for Collagen Solutions as it, too, moves up the value chain with 'owned' products.

Financial summary

There have been no changes to our forecasts. Detailed P&L, balance sheet and cashflow was published in our note published after the full year results on 14th July 2016. Only a summary of these financial statements is provided in the table below.

Forecast summary						
Year end March (£000)	2014	2015	2016	2017E	2018E	2019E
Profit & Loss:						
Sales	24	973	3,130	4,107	5,144	6,651
COGS	-12	-214	-811	-1,048	-1,287	-1,598
Gross profit	12	759	2,319	3,059	3,857	5,053
Gross margin (%)	49.7%	78.0%	74.1%	74.5%	75.0%	76.0%
SG&A	-376	-1,325	-2,440	-2,957	-3,086	-3,558
R&D	0	-160	-367	-741	-790	-833
EBITDA	-364	-726	-489	-639	-19	662
EBITDA margin (%)	-	-	-	-	-0.4%	9.9%
Depreciation	-17	-130	-347	-447	-527	-547
EBIT	-381	-793	-721	-1,085	-546	115
EBIT margin (%)	-	-	-	-	-10.6%	1.7%
Net interest	0	-128	-262	-124	-229	-223
Pre-tax profit	-381	-920	-983	-1,210	-775	-108
Tax liability/credit	0	-21	-114	-148	-193	-241
Net income	-381	-942	-1,097	-1,358	-968	-349
Weighted av. shares (m)	43.7	96.4	171.2	172.1	180.3	187.8
Underlying EPS (p)	-0.87	-0.98	-0.64	-0.79	-0.54	-0.19
Fully diluted EPS (p)	-0.87	-0.98	-0.64	-0.79	-0.54	-0.19
Balance sheet:						
Share capital	683	1,755	1,759	1,759	1,839	1,919
Reserves	5,573	11,099	12,137	10,729	9,631	9,152
Provisions	0	285	253	233	213	193
Debt	0	109	109	2,609	2,609	2,609
less: Cash	1,492	3,391	2,493	3,923	2,178	1,047
Invested capital	7,174	14,176	14,203	13,845	13,352	12,854
Net cash/debt	1,492	3,282	2,384	1,314	-432	-1,562
Cashflow:						
Operating profit	-381	-793	-721	-1,085	-546	115
Working capital	-86	-228	422	-175	-215	-153
Tax & interest	0	-28	-191	-102	-142	-230
Operational cashflow	-525	-1,180	-338	-916	-377	278
Capital expenditure	0	-159	-464	-153	-169	-200
Free cashflow	-525	-1,326	-802	-1,070	-546	78
Acquisitions	-1,357	-2,192	-207	-1,027	-2,200	-1,209
Share issues	3,374	5,422	207	1,027	1,000	0
Change in net cash	1,492	1,790	-898	-1,070	-1,746	-1,131
Hardman FCF/sh. (p)	-1.20	-1.22	-0.20	-0.53	-0.21	0.15

Summary only – numbers do not necessarily add up to the totals provided
Source: Hardman & Co Life Sciences Research

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