hardman&co

Collagen Solutions

Closing in on first proprietary product

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. Eight years after implantation, clinical outcomes with ChondroMimetic were at least as good as could be expected, and better than those published in the literature for alternative methods of cartilage repair.

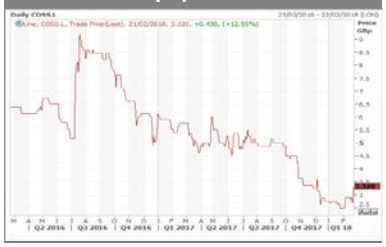
- **Strategy**: Management has embarked on an investment strategy through a series of initiatives to increase the growth opportunities. This strategy is moving COS from a reliable, quality collagen supplier to one that also has proprietary products that will make it into profitable, and cash-generative, at a faster pace.
- **ChondroMimetic:** Best described as a clever, bi-layered and easy-to-use sponge that allows the regeneration of cartilage and bone, the product has good provenance having received CE Mark in 2008 and implanted into ca.600 patients. However, for reasons prior to COS's ownership, the CE Mark lapsed.
- **Eight-year outcomes:** As part of the process of re-applying for CE Mark, 15/17 patients from the original trial in 2009-10 have been reassessed. The ChondroMimetic scaffold produced a sustained long-term regeneration of cartilage, undifferentiated from native cartilage, with improved clinical symptoms.
- **Next steps:** COS has initiated the submission for CE Mark, which will be supplemented by these data, allowing the re-issuance of CE Mark during 2H'18. Meanwhile, COS is continuing active discussions with potential commercial partners, on both a local (e.g. deal for South Korea) and more global basis.
- **Investment summary:** ChondroMimetic fulfils COS's stated strategy to move further up the value chain. These exceptional eight-year clinical outcomes will significantly differentiate it from competing therapies. In order to maximise returns, COS needs to conclude commercial arrangements in readiness for a European launch in 2H'18, and with a strong partner capable of undertaking the trials needed to launch the product in the US.

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)	-4.2	-6.4	-3.9	-6.0	-10.1	-28.8
EV/sales (x)	9.7	3.0	2.4	2.3	1.7	1.2
EV/EBITDA (x)	-	-	-	-	-	27.9

Source: Hardman & Co Life Sciences Research

Healthcare Equipment &Services



Source: Eikon Thomson Reuters

Market data

EPIC/TKR	**COS**
Price (p)	4.10
12m High (p)	6.45
12m Low (p)	2.30
Shares (m)	324.5
Mkt Cap (£m)	13.3
EV (£m)	9.5
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	Hilary Spence
Chairman	David Evans
	+44 141 648 9100
	www.collagensolutions.com

Key shareholders

Directors + management	17.2%
Seneca	13.2%
Calculus Capital	9.5%
Rathbones IM	4.9%
Livingbridge	4.6%
Helium Rising Stars	4.0%

Diary

Jul-18	Finals
2H'18	ChondroMimetic CE Mark

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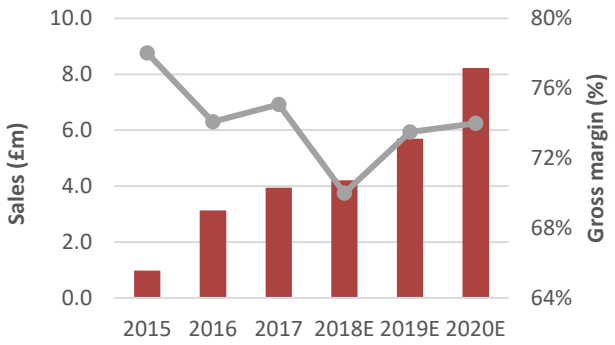
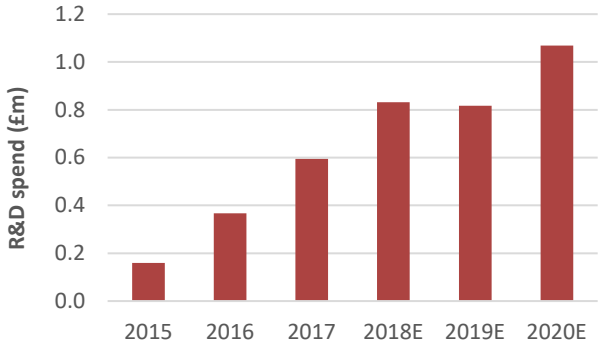
Sales and gross margin



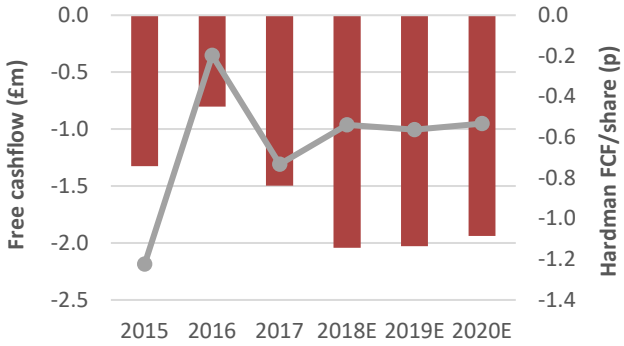
- Sales are forecast to grow substantially as customers receive regulatory approvals and investment in marketing generates new business
- There are numerous new opportunities, but the timing of their contribution is complex and, therefore, not included in our forecasts
- The gross margin is dependent on the mix of business – contract manufacturing commands lower margins
- The gross margin will start to trend upwards when proprietary products reach commercialisation

R&D investment



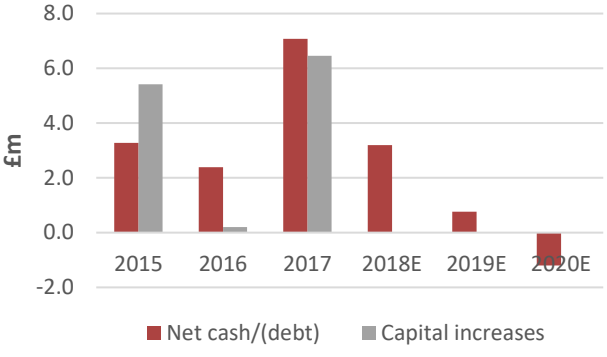
- COS invests about 12-13% of sales into R&D, but this is modest in absolute terms
- Management's strategy to develop more 'owned products' will lead to a rise in R&D investment
- COS adds value through the development of customer formulations
- Additional R&D spend is being capitalised on the balance sheet for late-stage proprietary products

Free cashflow and FCF/share



- Accelerated spend on infrastructure and the commercial team to drive medium- to long-term revenues affects short-term cashflow
- There is some flexibility regarding the timing of capex
- Cashflow forecasts are conservatively based with future changes more likely to be in an upward direction
- The cash position is affected by deferred considerations due in 2018 and 2019

Net cash/(debt) and capital increases



- Deferred considerations – Southern Lights and CS (US) – influence the cash position
- Net cash at 31st March 2018 is forecast to be ca.£3.2m (cash £6.1m, debt £2.9m)
- Licensing deals for ChondroMimetic could result in up-front cash payments to COS, which are not included in forecasts

Source: Company data; Hardman & Co Life Sciences Research

ChondroMimetic

Positive eight-year follow-up data

As part of the CE Mark re-submission process for ChondoMimetic, COS embarked on 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. Fifteen of these patients were contactable and indicated their willingness to take part in this extension study, to generate data on average eight years after the implant surgery. COS has released the outcomes of the study which show that patients have regenerated cartilage in their defects implanted with the ChondroMimetic scaffold that has a structural quality almost identical to native cartilage. These data represent an unparalleled depth of clinical knowledge on this subject, support the application for CE Mark, and provide powerful marketing literature for use by commercial partners. ChondroMimetic will be COS' first proprietary product to reach the market, supporting management's strategy to move up the value chain.

Background

Orthomimetics (OM) was a spin-out from the Cambridge-MIT Institute (CMI) in 2015, aimed at commercialising a family of surgical implants for the repair of cartilage, ligaments and tendons. OM undertook two large-animal (goat) trials with its lead product, ChondroMimetic, for the repair of articular cartilage, and obtained CE Mark in 2008. Following this, the company commissioned a small confirmatory trial in humans undertaken by a key opinion leader in surgical cartilage repair – Dr Laszlo Hangody at the Sándor Károlyi Hospital, Budapest.

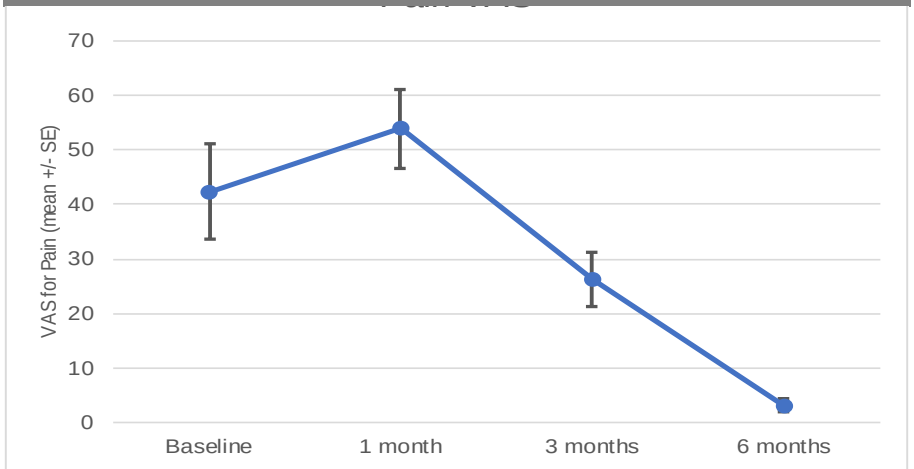
At this point, OM was acquired by TiGenix BV, for £14.8m/$26.9m. However, a management change and restructuring resulted in the loss of interest in ChondroMimetic. In 2012, the assets of ChondroMimetic and associated IP were re-acquired by the founders of OM, which were purchased subsequently by COS in September 2015 for £200k plus a single-digit royalty, with the aim of re-applying for CE Mark and re-launching the product.

Original open label study

- A single centre (Sándor Károlyi Hospital) study to confirm the safety and early outcomes with Chondro-Mimetic for osteochondral repairs of the knee
- A clinical trial in 17 humans with cartilage defects under $2cm^2$ conducted during 2009-10 by Dr Hangody
- An assessment of repairs six months following implantation using both MRI scans and biopsies
- Clinical outcomes were supported by a patient survey where 94% gave an overwhelming acclamation, rating the results "very good or excellent"

In the original study, ChondroMimetic was very well tolerated and gave a lower level of post-surgery complications compared with other methods. Although there was an initial increase in the pain and disability scores for patients, this was due to the normal inflammation and swelling expected after surgery. After three and six months post-surgery, scores from repeating the tests were noticeably improved, with clear recovery and a diminished knee pain level for all the patients.

Results from original ChondroMimetic trial – Pain Visual Analogue Scale



Pain Visual Analogue Scale (VAS)

Source: Collagen Solutions; Orthomimetics

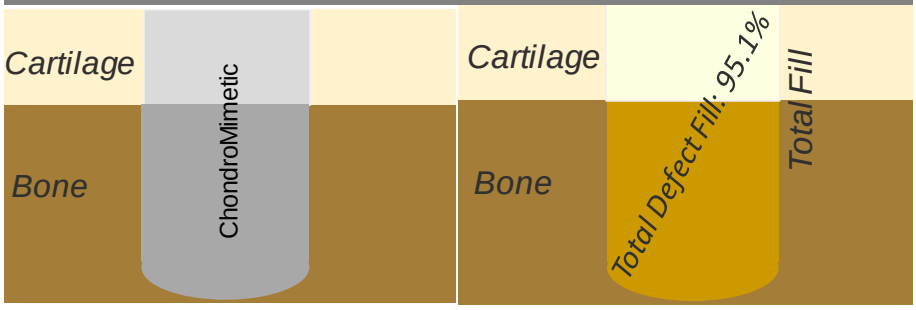
Extension study – eight-year follow-up

- MRI scans were used to enable quantitative 3D fill assessment and T2 mapping to analyse the structure and quality of the replacement cartilage.
- Modified Cincinnati Rating System was used to score the knee condition for activity and function. This measures a variety of symptoms, sports and daily activity functions, patient satisfaction, and objective physical findings.
- Knee injury and osteoarthritis outcome scores (KOOS) were used to evaluate short- and long-term symptoms and function in subjects with knee injury and osteoarthritis.

Clinical outcomes

The implantation procedure for ChondroMimetic is relatively straight-forward and, from the surgeon's point of view, is one additional component to the existing key-hole (arthroscopic) procedure. It is delivered into the osteochondral defect with a device designed specifically for this procedure. When rehydrated with the patient's blood, ChondoMimetic has the characteristics of a sponge and, therefore, 'springs' into position when released to give a tight fit that anchors the cartilage scaffold in place. This theory was backed up by the eight-year morphology data, which showed that the average defect fill was 95.1% (range 95.0-100.0%) in the 15 patients that were re-evaluated.

Tissue repair morphology

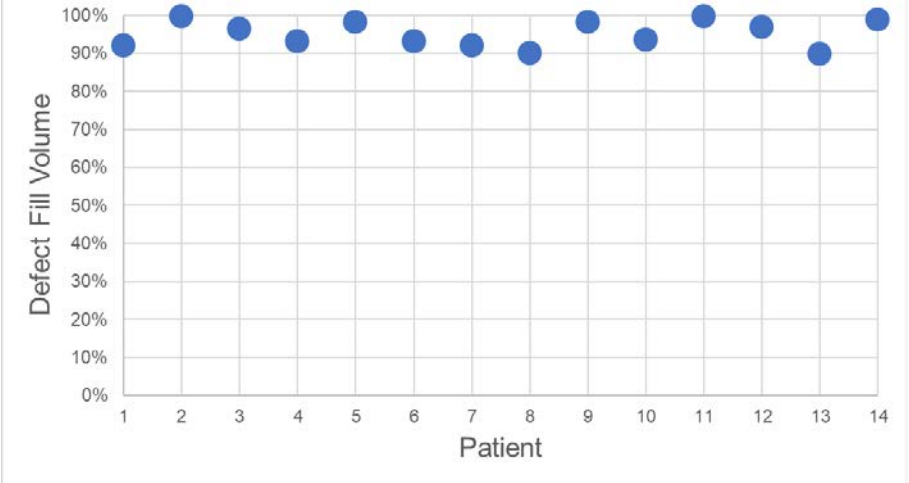


Baseline: 10 days post-implant **Eight years post-operative**

Source: Collagen Solutions

This demonstrates that, once in position, the scaffold implant remains firmly in place allowing the natural repair and replacement of both the bone and the cartilage by natural materials.

Repair fill by patient – eight years post-implant

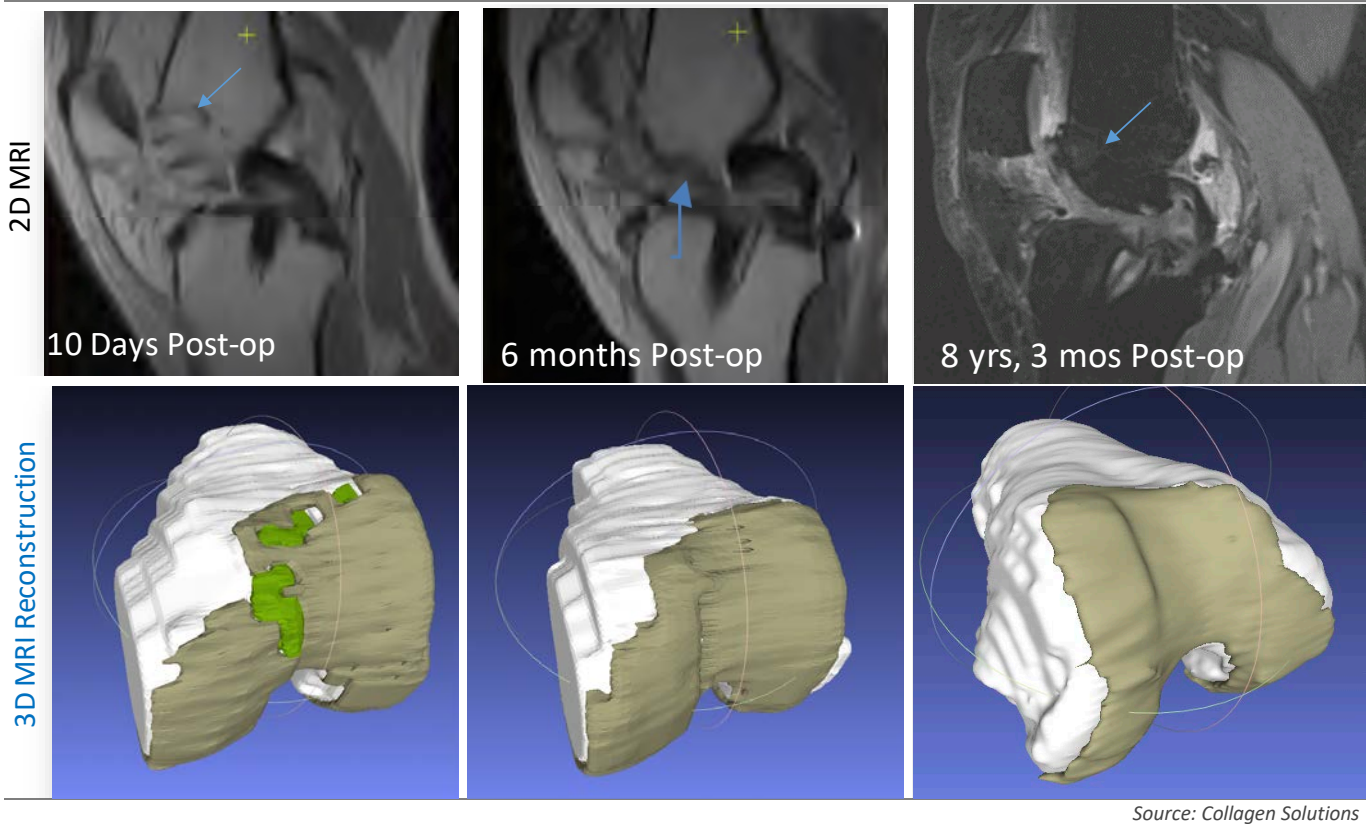


Source: Collagen Solutions

MRI scans

The degree of defect repair and filling was assessed by MRI scans using the magnetic resonance observation of cartilage repair tissue (MOCART).

ChondroMimetic clinical case report – post-operative MRI scans



Source: Collagen Solutions

The example photographs above illustrate the outcomes from a single patient (study subject 03, female, 29 years of age) receiving five implants, at 10 days, six months and eight-years post-surgery. Although difficult to visualise by the untrained eye, after 10 days, boundaries between the implants and the bone are clearly defined and there is no cartilage repair. However, six months after surgery, there is little differentiation between the implant and the bone with the scaffold being fully integrated and filled with new 'bone'. More importantly, however, the cartilage scaffold has been filled by cartilaginous repair. After eight years and three months, the results in this patient remained the same, with the cartilage repair nearly indistinguishable from native cartilage. Similar outcomes were found in all 15 patients.

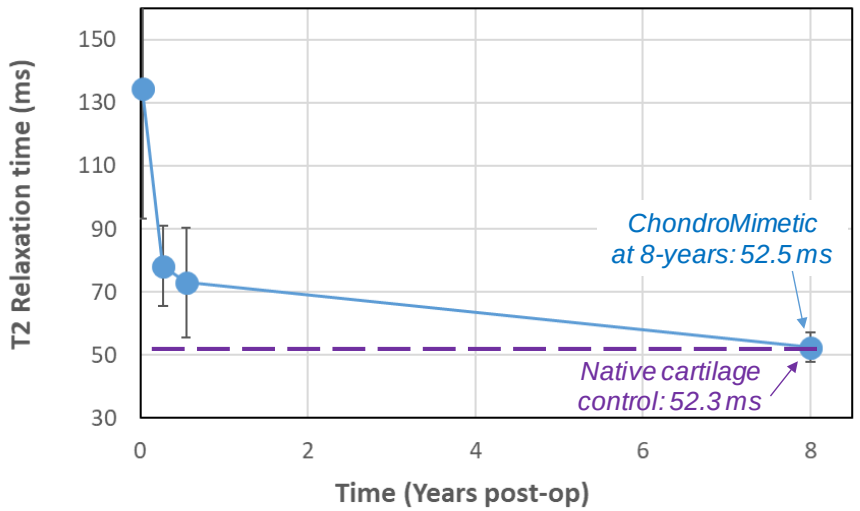
Transverse relaxation (T2) mapping

First described in 1946, T2 relaxation is a well-known process by which the transverse components of magnetisation decay (or de-phase). It is considered to follow first order kinetics which results in a simple exponential decay with time constant T2. Thus, T2 is the time taken for the transverse magnetisation to fall to approximately 37% of its initial value. In this instance, T2 relaxation is being used to assess the quality of the cartilage repair.

In 2015, Shive and co-workers[1] published data comparing clinical outcomes five years after cartilage repair using BST-CarGel® (now marketed as CARGEL®) compared with microfracture in a multicentre, randomised, trial. They concluded that: "*a significantly greater treatment effect for BST-CarGel was also found for repair tissue T2 relaxation times (P = 0.026), which were closer to native cartilage compared to the microfracture group*".

The outcomes in this study with ChondroMimetic indicated that the regenerated cartilage was almost indistinguishable from native cartilage, as evidenced from the T2 relaxation time – 52.5 ms versus 52.3 ms. These results are also very favourable compared with those published in the Shive study for BST-CarGel (75.7 ± 3.2 ms) and microfracture (90.4 ± 6.6 ms).

ChondroMimetic transverse relaxation results



Data represents means+SD;
N=14, 11, 9 and 14 for 10 Days, 3 months, 6 months and 8 years respectively

Source: Collagen Solutions

[1] Shive M.S. et al., Cartilage, 2015, 6(2): 62–72

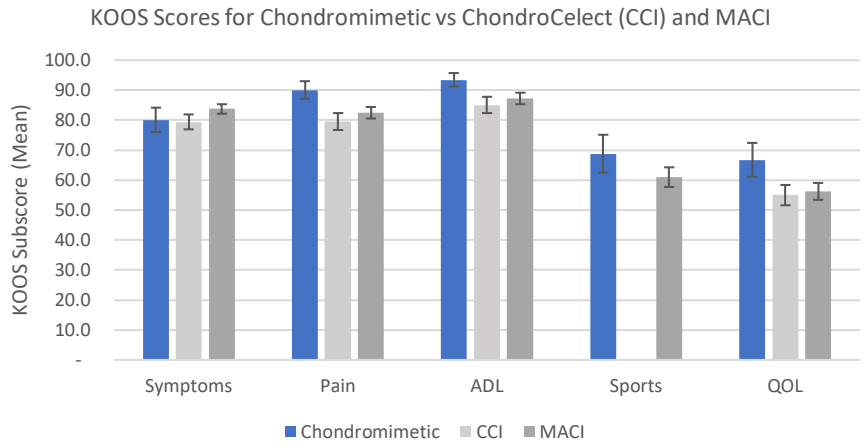
KOOS scores

The Knee Injury and Osteoarthritis Outcome Score is a well-established and generally accepted method used to assess patients' opinions about their knee and associated problems, by evaluating both short-term and long-term consequences of knee injury and repair. It is used to score a number of sub-scales, including pain, function in daily living (ADL), function in sport and recreation (Sport/Rec) and knee-related Quality of Life (QOL).

Saris and co-workers have published a series of articles in the American Journal of Sports Medicine (AJSM) over recent years comparing cartilage repair outcomes from chondrocyte implantation versus microfracture alone. The most recent being a three-year follow-up assessment in which they conclude that "*chondrocyte implantation for the treatment of articular cartilage defects…results in significantly better clinical outcome at 36 months in a randomized trial compared with microfracture alone*"[2]. However, we would point out that the results only just reached statistical significance. Moreover, it is difficult to understand why it took three years to publish the three-year data (2017) compared with the two-year data (2014). Irrespective of this, it does provide a suitable comparator for the eight-year data with ChondoMimetic.

In all the KOOS assessments, the patient scores with ChondroMimetic were at least as good as those obtained after two years with ChondroCelect, a proprietary cell-based technology and microfracture.

KOOS score comparison



CCI = 18-month data from Saris AJSM 2008, n=14[3]
MACI = 24-month data from Saris AJSM 2014, n=72[4]
Source: Collagen Solutions

Conclusions

- Results are at least as good as could have been expected prior to commencing this study extension.
- ChondroMimetic implants provide an excellent repair of small cartilage defects with sustainable (eight-year) clinical benefits.

[2] Saris D.B.L. et al., Am. J. Sports Medicine, 2017, 37, 1_suppl: pp. 10-19
[3] Saris D.B.L. et al., Am. J. Sports Medicine, 2008, 36: 235
[4] Saris D.B.L. et al., Am. J. Sports Medicine, 2014, 42: 1364-1394

- The MRI scans showed that the cartilage and sub-chondral bone were successfully regenerated within the ChondroMimetic scaffold.
- The average fill of the defect in the 15 patients was 95.1%, with three patients (20%) obtaining 100% fill, and the lowest outcome being 90%.
- T2 relaxation scores (14/15 patients) at eight years were almost identical to scores for native cartilage, and superior to published outcomes for alternative methods of cartilage defect repair.
- The Modified Cincinnati Knee Rating Scores to assess the knee condition for activity and function significantly improved from the baseline, with an overall grading of 'excellent' at eight years (data not shown).
- Results from the KOOS scores were at least as good as those obtained three years after the implantation of expensive alternative procedures (e.g. two-stage autologous cell-based therapies) published in the literature.
- These data will be included in marketing literature and provide important support for commercial partners.

Next steps

COS has been working closely with its Notified Body and has already commenced the submission process for the re-establishment of CE Mark. This will involve a rolling process with the expectation of CE Mark being re-issued during 2H calendar 2018.

Meanwhile, the company will be seeking to conclude commercial arrangements for ChondroMimetic. This could involve a number of local partners as evidenced by the licence and distribution agreement signed by COS with an experienced industrial partner in South Korea in December 2017. Alternatively, several territories could be encompassed in a largely global arrangement with a major orthopaedics company.

Market opportunity

About one million procedures p.a. in the US and Europe…

An average of 600,000 procedures are performed in the US each year for the repair of articular cartilage. Therefore, by extrapolation, the number performed worldwide is estimated to be in the range 1.0-1.5 million. Approximately 50% of these repairs are thought to be small defects that could be addressed by ChondroMimetic.

Articular cartilage repair market

	Europe	US	Global
Number of surgical cases per annum	350,000	600,000	1,250,000
Number suitable for ChondroMimetic	175.000	300,000	625,000
Price per implant	€1,000	$1,200	$1,000
1.75 implants/procedure packs/patient	2	2	2
Addressable market	€350m	$720m	$1,250m
Distributor margin	50%	50%	50%
Market potential	**€175m**	**$360m**	**$625m**

Source: Hardman & Co Life Sciences Research

…giving an addressable market of $1,250m…

Based on these figures the addressable market equates to $625m globally after allowing for distributor margins, with $360m (58%) from the US. This assumes an average end-selling price of ca.$1,000 and that two procedure packs per patient will be required – based on the experience in Europe that, an average of 1.75 implants per patient were used when ChondroMimetic was available commercially.

When products have been de-risked and are available commercially, the larger players have been willing to pay good prices for the products, as evidenced by the original buy-out of Orthomimetics Ltd by TiGenix, and from the following deals done by Smith & Nephew (S&N).

BST-CarGel®/CARGEL®

In January 2016, S&N acquired Canadian-based Piramel Healthcare giving it access to BST-CarGel, a first-line cartilage repair product that is used alongside microfracture. The headline consideration was $42m, of which $37m was deferred and/or contingent on sales and penetration into new markets. At that point in time, BST-CarGel was approved for use in a number of countries around the world, including Australia, Canada and most of Europe.

BST-CarGel is a biopolymer-based product that is mixed with a patient's blood and implanted into the joint following microfracture. It is approved to treat damaged cartilage in synovial joints such as the knee, hip, ankle and shoulder, and is delivered arthroscopically. Once implanted, BST-CarGel acts as a scaffold, adhering to the cartilage surface to stabilise the blood clot while new cartilage is regenerated.

TruFit®

The acquisition of BST-CarGel was S&N's second foray into this market, having originally purchased OsteoBiologics, a San Antonio-based private company, in July 2006 for $72.3m in order to gain access to TruFit, an approved product for the repair of small osteochondral lesions.

With respect to ChondroMimetic, this was considered to be a very important acquisition, because TruFit was essentially a synthetic version of ChondroMimetic, with a bone scaffold to act as an anchor for the cartilage scaffold. S&N persevered with TruFit for a number of years, but poor sales and clinical outcomes eventually led to the product being removed from the market in 2013.

Financial summary

- No changes have been made to our forecasts in this document
- A full financial analysis of COS is available in our report dated 19th December 2017 '*Targeting long-term sustainable growth*':

  http://www.hardmanandco.com/docs/default-source/company-docs/collagen-solutions-plc-documents/19-12-2017-cos-report.pdf

Forecast summary

Year-end March (£000)	2015	2016	2017	2018E	2019E	2020E
USD:GBP	1.574	1.459	1.307	1.307	1.307	1.307
Profit & Loss:						
Sales	973	3,130	3,946	4,210	5,700	8,220
COGS	-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%
SG&A	-1,325	-2,440	-3,722	-3,810	-3,990	-4,850
R&D	-160	-367	-594	-832	-818	-1,069
EBITDA	**-663**	**-374**	**-1,209**	**-1,395**	**-443**	**339**
EBITDA margin (%)	-	-	-	-33.1%	-7.8%	4.1%
Depreciation	-130	-347	-449	-520	-540	-560
EBIT	**-793**	**-721**	**-1,658**	**-1,915**	**-983**	**-221**
EBIT margin (%)	-	-	-	-45.5%	-17.2%	-2.7%
Net interest	-128	-262	-132	-226	-234	-95
Pre-tax profit	**-920**	**-983**	**-1,790**	**-2,142**	**-1,217**	**-316**
Tax	-21	-114	-142	-75	-98	-147
Net income	-942	-1,097	-1,932	-2,217	-1,315	-463
Weighted av. shares (m)	96.4	171.2	185.8	324.4	324.5	324.5
Underlying EPS (p)	**-0.98**	**-0.64**	**-1.04**	**-0.68**	**-0.41**	**-0.14**
Fully diluted EPS (p)	-0.98	-0.64	-1.04	-0.68	-0.41	-0.14
Balance sheet @31st March:						
Share capital	1,755	1,759	3,288	3,245	3,245	3,245
Reserves	11,099	12,137	16,998	14,985	13,570	13,008
Provisions	285	253	222	207	155	117
Debt	109	109	1,906	2,915	1,695	0
less: Cash	3,391	2,493	8,978	6,114	2,457	-1,206
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
Cashflow:						
Operating profit	-793	-721	-1,658	-1,915	-983	-221
Change in working capital	-228	422	-130	-150	-106	-149
Tax & interest	-28	-191	-102	-368	-309	-193
Operational cashflow	**-1,180**	**-338**	**-1,360**	**-1,749**	**-1,827**	**-1,728**
Capital expenditure	-159	-464	-137	-294	-200	-210
Free cashflow	**-1,326**	**-801**	**-1,497**	**-2,043**	**-2,027**	**-1,938**
Acquisitions	-2,192	-207	-342	-1,227	-409	0
Share issues	5,422	207	6,462	-4	0	0
Change in net debt	**1,790**	**-898**	**4,687**	**-3,873**	**-2,436**	**-1,938**
Hardman FCF/sh. (p)	-1.22	-0.20	-0.73	-0.54	-0.56	-0.53

Source: Hardman & Co Life Sciences Research

Disclaimer

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The full detail is on page 26 of the full directive, which can be accessed here: http://ec.europa.eu/finance/docs/level-2-measures/mifid-delegated-regulation-2016-2031.pdf

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