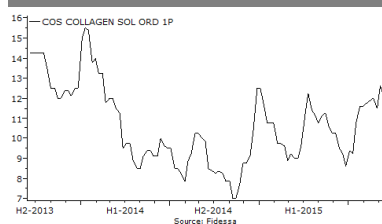


Healthcare Equipment & Services



Source: Fidessa

Market data

EPIC	COS
Price (p)	12.10
12m High (p)	14.75
12 Low (p)	6.75
Shares (m)	171.0
Mkt Cap (£m)	20.7
EV (£m)	18.4
Free Float* (%)	78%
Market	AIM

*As defined by AIM Rule 26

Description

Collagen Solutions develops and manufactures medical grade collagen components for use in regenerative medicine, medical devices and in-vitro diagnostics

Company information

CEO	Stewart White
CFO	Gill Black
Chairman	David Evans

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Interims Dec 2015

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Collagen Solutions plc

Product acquisition – regenerative medicine

Collagen Solutions is a biomaterials company developing and manufacturing medical grade collagen components for use in medical devices, regenerative medicine, and in vitro diagnostic products. It supplies value-added bio-functional collagen, provides R&D and contract manufacturing services to a broad range of clients, ranging from research organisations to multi-national corporates and, with this acquisition, now has the option of selling a regenerative medical product into the orthobiologics market, thereby capturing a greater share of the end-product margin. The addressable market for this product is in excess of \$500m.

- ▶ **First product acquisition:** Assets and an exclusive licence for the associated IP to Chondromimetic, a product for use in sports medicine, orthobiologics and regenerative medicine; satisfied by c.0.9m Ordinary shares (50% on completion, 50% deferred), a modest cash payment and future low single digit royalties.
- ▶ **Strategic relevance:** Chondromimetic provides COS with an entry level collagen-based medical device at relatively low cost but with previous sales traction and, Key Opinion Leader endorsement. Also, the associated IP is complementary to existing IP, potentially generating future products with broad commercial use.
- ▶ **Valuation:** Our DCF valuation remains unchanged at £73m or 39p per share. There is insufficient information with respect to execution of Chondromimetic's commercialisation strategy to warrant a change. Greater clarity and visibility of potential sales and EBITDA will likely increase forecasts and valuation.
- ▶ **Risks:** Integration of SLB appears to be well in hand. Exact timing of development and manufacturing contracts and supply agreements remains uncertain, but recurring revenues do exist. Regulatory delays for client products remain risks. Route to Chondromimetic commercialisation is currently in early stage planning.
- ▶ **Investment summary:** The Board's objective is to create a £100m business by 2020. This acquisition provides another building block to achieving this goal at minimal entry cost. It propels the company further up the value chain, enabling the capture of a more significant share of the end product sales and creating a vertically integrated business that should command a higher valuation.

Financial summary and valuation

Year end Mar (£000s)	2014	2015	2016E	2017E	2018E
Sales	24	973	3,700	6,500	10,500
Underlying EBITDA	-364	-726	-273	1,707	4,086
Reported EBIT	-480	-975	-768	1,147	3,456
Underlying PTP	-381	-921	-701	1,211	3,521
Statutory PTP	-480	-1,102	-751	1,161	3,471
Underlying EPS (p)	-0.9	-1.0	-0.4	0.5	1.4
Statutory EPS (p)	-1.1	-1.2	-0.4	0.5	1.4
Net (debt)/cash	1,492	3,282	1,951	1,095	2,493
Shares issued	3,374	5,422	0	0	0
P/E (x)	-13.3	-11.9	-27.7	22.6	8.2
EV/sales (x)	785.2	19.4	5.1	2.9	1.8

Source: Hardman & Co Research

Acquisition of Chondromimetic

Acquisition details

Novel orthobiologics product and associated IP portfolio acquired for limited up front cost

Collagen Solutions has acquired all of the assets and an exclusive licence for the associated intellectual property to Chondromimetic from Orthomimetics Limited and Cambridge Enterprise Limited, respectively. The consideration will be satisfied by the issuance of 869,900 Ordinary shares in Collagen Solutions (c.£0.1m). A modest cash sum has also been paid to enter into the exclusive licence agreement, deemed immaterial in the context of the group's current cash balances. On completion, Orthomimetics will be issued with 434,950 Collagen Solutions shares with the balance deferred over the following two years. A low single digit royalty will also be paid to Orthomimetics and Cambridge Enterprise on net sales of Chondromimetic.

In addition to Chondromimetic, Collagen Solutions has acquired a significant portfolio of patents and patent applications, covering a range of related collagen-based bioactive materials that are applicable for use in the orthobiologics and regenerative medicine markets providing structural repair for bones and joints as well as the delivery of biological agents such as stem cells and other therapeutic agents.

Chondromimetic, its related products and IP will be transferred to a newly formed subsidiary of Collagen Solutions plc, which will be tasked with bringing the production in-house, gaining regulatory clearance and ultimately commercialising it and any future related products.

Chondromimetic

For use in orthobiologics, regenerative medicine and sports medicine markets

Chondromimetic is an off-the-shelf functional collagen-based resorbable implant for the minimally invasive regenerative repair of small osteochondral defects in cartilage and bone within the broader orthobiologics market; a market driven by the need to reduce worldwide healthcare expenditures on total joint replacement surgery. By treating younger patients more effectively when they first suffer injuries to soft tissues such as articular cartilage, meniscus and ligaments, products such as Chondromimetic hold the potential to slow the pathological degeneration that ultimately leads to joint replacement.

Previous CE Mark approval...

Chondromimetic was originally developed as part of a collaboration between the University of Cambridge and the Massachusetts Institute of Technology and subsequently commercialised by Orthomimetics and TiGenix NV. It is delivered in a single-use procedure pack and received CE-mark approval for sale throughout Europe in 4Q 2008.

...with early market adoption and sales

Chondromimetic has been used in over 300 procedures to date. Although only limited commercial access was garnered, the relationship with and feedback from surgeons and distributors was understood to have been generally positive.

History of Chondromimetic

Orthomimetics started the development of Chondromimetic in 2002, culminating in its CE-Mark approval in 2008, which enabled it to sell in all European markets and many non-US and Japanese markets. In December 2009, Orthomimetics was acquired by TiGenix NV for €16.3m (£14.8m). Chondromimetic was launched in

September 2010 through TiGenix's salesforce and distributor network (including Greece, Italy, Spain, Poland, Turkey, South Korea and Mexico). TiGenix reported early sales of €0.1m in its financial results for the 9 months to 30 September 2011. Due to funding constraints, however, and a focus on its cell-therapy product portfolio, TiGenix took the decision in 2011 to write-off the Orthomimetics' investment and looked for an exit. The assets were re-acquired by Orthomimetics Ltd in 2014.

Strategic rationale

Entry level product opportunity in regen/orthobiologics space...

Chondromimetic provides Collagen Solutions with an entry level collagen-based medical device, with some previous sales traction and, equally importantly, Key Opinion Leader (KOL) endorsement. It provides Collagen Solutions with a product that has application in the sports medicine, orthobiologics and regenerative medicine markets.

...with the capacity to capture greater share of end product margin...

It also enables Collagen Solutions to move up the value chain, capturing a greater share of the end product's value, not only through the in-house production of the functional collagen, but also some or all of the end product's gross margin (depending on commercialisation route)

...and complementary to existing IP

In addition, it strengthens further the company's IP for collagen scaffolds. We expect the patent estate to be both complementary to and synergistic with the exclusive licence granted to Collagen Solutions from UCL in June 2014, and for which a US patent has issued. This enables the production of collagen with substantially enhanced physical strength, speed of production and concomitant seeding of the collagen scaffold with cells. The process allows polymeric collagen to be purified and seeded with cells and other components of biomaterials which are mechanically stronger than monomeric collagen gel-based biomaterials and which can be engineered according to specific applications and requirements, unlike the preparation of whole tissues.

Route to commercialisation

Route to commercialisation to be elucidated but likely to involve...

Given the lack of attention given to Chondromimetic since TiGenix's decision to divest in 2011, the CE-Mark has lapsed. Consequently, Collagen Solutions will have to regain CE Mark certification. The key steps to commercialisation are likely to involve:

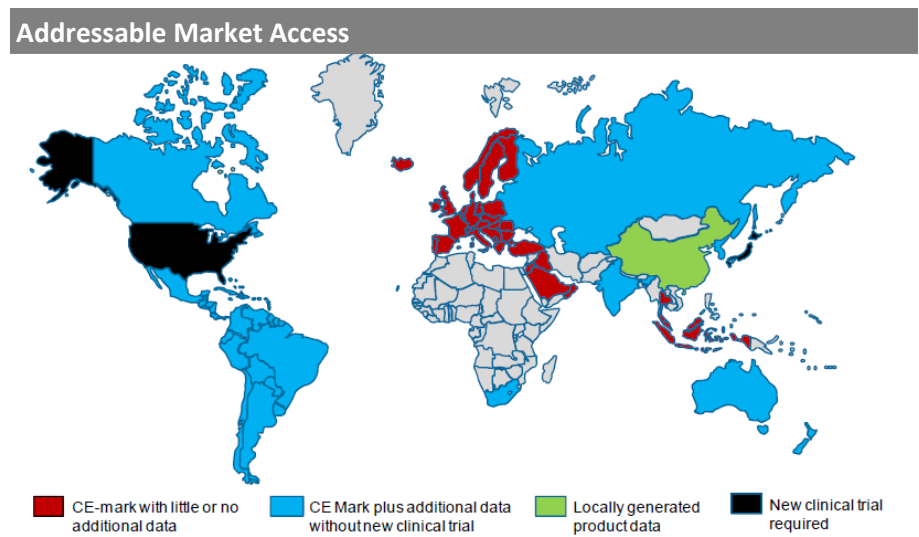
- ▶ Developing in-house production capability, the costs of which are expected to be minimal given Collagen's ability to source and functionalise relevant collagen and the existing clean room facilities that the company has
- ▶ Appointing subsidiary CEO to execute the exploitation of Chondromimetic and associated technologies
- ▶ Re-applying for CE-Mark, the cost of which is expected to be minimal and within the company's current cash balances
- ▶ Appointing distributor network (some of whom are likely to have previously sold Chondromimetic) to focus on those markets where CE Mark is accepted. Initial focus is expected to be targeted on territories in which revenues can be achieved relatively quickly with a CE Mark.

We expect the US and Japanese markets to be exploited via partnerships given the specific regulatory and registration uncertainty and the associated high clinical trial investment required. By pursuing such a route, therefore, reduces the financial risk and exposure to Collagen Solutions.

Addressable market

Global market is in excess of \$500m

Whilst the global market for cartilage repair products is currently estimated at over \$500m¹, the targeted markets in which a CE mark is respected and where additional data (although not new clinical data) are required, are worth c.\$290m. Even a small share of this market (eg. 10%) and taking account of the distributor margin would imply sales to Collagen Solutions of c.£10m (\$15m).



Source: Collagen Solutions

NovaBone – FDA approval

On 3rd September Collagen Solutions announced that one of its clients, NovaBone Products LLC, has had its novel collagen bone graft product, MacroFORM, approved by the US FDA for minimally invasive orthopaedic procedures. The system was developed for surgeons requiring controlled and precise delivery of collagen bone grafting material to surgical sites that aren't readily accessible and represents NovaBone's sixth new collagen product introduced over the past year for use in the wound care and bone graft markets, all of which utilise Collagen Solutions' collagen.

This underpins the anticipated growth in revenues and is included in our current forecasts.

¹ Frost & Sullivan 2009

Financial summary

Profit & Loss Account					
Year end Mar (£000s)	2014	2015	2016E	2017E	2018E
Sales	24	973	3,700	6,500	10,500
Cost of goods	-12	-214	-798	-1,469	-2,415
Gross Profit	12	759	2,903	5,032	8,086
Administrative expenses	-304	-1,266	-1,575	-1,500	-1,800
Selling and marketing costs	-72	-219	-1,150	-1,275	-1,550
R&D	0	0	-450	-550	-650
Underlying EBITDA	-364	-726	-273	1,707	4,086
Depreciation	-13	-75	-200	-265	-335
Amortisation	-4	-55	-245	-245	-245
Other income	0	63	0	0	0
Underlying EBIT	-381	-793	-718	1,197	3,506
Share based costs	-25	-27	-50	-50	-50
Exceptional items	-75	-155	0	0	0
Statutory Operating profit	-480	-975	-768	1,147	3,456
Net financial income	0	-128	17	15	15
Underlying Pre-tax profit	-381	-921	-701	1,211	3,521
Exceptional items	0	0	0	0	0
Reported pre-tax	-480	-1,102	-751	1,161	3,471
Reported taxation	0	-21	-18	-323	-854
Underlying net income	-381	-942	-719	888	2,666
Statutory net income	-480	-1,124	-769	838	2,616
Period-end shares (m)	63.8	171.0	179.0	187.0	187.0
Weighted average shares (m)	43.7	96.4	171.0	172.3	187.0
Fully diluted shares (m)	47.7	102.3	176.9	178.2	192.9
Underlying Basic EPS (p)	-0.87	-0.98	-0.42	0.52	1.43
U/I fully-diluted EPS (p)	-0.87	-0.98	-0.42	0.50	1.38
Statutory basic EPS (p)	-1.10	-1.17	-0.45	0.49	1.40
Statutory fully-diluted EPS (p)	-1.10	-1.17	-0.45	0.47	1.36
DPS (p)	0.00	0.00	0.00	0.00	0.00
Key metrics	2014	2015	2016E	2017E	2018E
Growth					
Sales		3950%	280%	76%	62%
Gross profit		6257%	282%	73%	61%
Operating profit		n/a	n/a	n/a	193%
EPS		n/a	n/a	n/a	177%
DPS		n/a	n/a	n/a	n/a
Operating ratios					
Cost of goods	50.3%	22.0%	21.6%	22.6%	23.0%
Gross margin	49.7%	78.0%	78.4%	77.4%	77.0%
Admin	1264.0%	130.1%	42.6%	23.1%	17.1%
Sales & Marketing	299.4%	22.5%	31.1%	19.6%	14.8%
EBITDA	nm	-74.6%	-7.4%	26.3%	38.9%
Operating profit	nm	-81.5%	-19.4%	18.4%	33.4%
Reported tax rate	0.0%	-1.9%	-2.5%	27.8%	24.6%

Source: Hardman & Co Life Sciences Research

Balance Sheet					
At 31 March (£000s)	2014	2015	2016E	2017E	2018E
Shareholders funds	6,256	12,853	12,294	14,182	16,849
Cumulated goodwill	0	0	0	0	0
Total equity	6,256	12,853	12,294	14,182	16,849
Share capital	683	1,755	1,835	1,915	1,915
Reserves	5,573	11,099	10,460	12,268	14,934
less: Cash	1,492	3,391	2,061	1,204	2,602
less: Marketable securities	0	0	0	0	0
less: Non-current investments	-2,409	-4,320	-4,320	-911	89
Invested capital	7,174	14,176	14,948	14,283	14,552
Fixed assets	232	794	1,319	1,879	2,494
Intangible assets	6,894	12,919	12,674	12,429	12,184
Stocks	39	219	369	569	819
Trade debtors	0	419	569	794	1,094
Other debtors	167	226	497	-506	-201
Trade creditors	0	-215	-295	-395	-515
Tax liability	0	-40	-40	-342	-1,178
Other creditors	-160	-144	-144	-144	-144
Debtors less creditors	7	245	587	-593	-944
Invested capital	7,174	14,176	14,948	14,283	14,552

Source: Hardman & Co Life Sciences Research

Cashflow					
Year end Mar (£000s)	2014	2015	2016E	2017E	2018E
Operating profit	-381	-793	-718	1,197	3,506
Depreciation	13	75	200	265	335
Amortisation	4	55	245	245	245
Stocks	-13	-127	-150	-200	-250
Working capital	-72	-166	-70	-125	-180
Exceptionals/provisions	-75	-155	0	0	0
Other (Fx)	-1	-87	0	0	0
Net cash used in operations	-525	-1,199	-493	1,382	3,656
Net interest	0	-4	17	15	15
Tax	0	-25	-21	-18	-323
Operational cashflow	-525	-1,227	-497	1,378	3,348
Capital Expenditure	0	-159	-725	-825	-950
Free cashflow	-525	-1,373	-1,222	553	2,398
Dividends	0	0	0	0	0
Acquisitions	-1,357	-2,190	0	-1,409	-1,000
Other investments	0	-68	0	0	0
Cashflow after investments	-1,882	-3,631	-1,222	-856	1,398
Share issues	3,374	5,422	0	0	0
Currency effect	0	0	0	0	0
Change in net debt	1,492	1,791	-1,222	-856	1,398
Opening net cash	0	1,492	3,282	2,061	1,204
Closing net cash	1,492	3,282	2,061	1,204	2,602
Hardman CF/share (p)	-1.20	-1.27	-0.29	0.80	1.79

Source: Hardman & Co Life Sciences Research

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