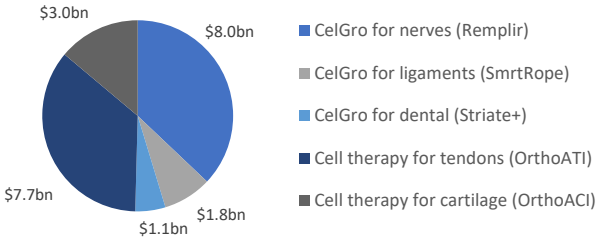
Orthocell

Growing human tissue and revenue

The repair of nerves, bones, tendons and ligaments is on the cusp of being revolutionised by Orthocell's CelGro platform. Recent licensing and distribution deals should turbocharge revenue growth and transform the Company into a medical device player. The advanced stage of Orthocell's products and the recent acquisition of competitors increases the likelihood of it being an M&A target.

- **Regenerative medicine pioneers:** Orthocell's founders, Paul Anderson CEO and Professor Ming Hao Zheng CSO previously commercialized a cell therapy for cartilage repair (MACI) in Australia which now underpins the US$1.5bn valuation of Vericel (VCEL-NASDAQ). Orthocell is their next venture with a significantly larger addressable market (Figure 1).
- **Superior patient outcomes:** Orthocell's CelGro platform helps restore pain free function to patients more effectively than competitor products including the leading BioGide dental barrier membrane and NeuraGen nerve wrap according to scientific studies.
- **Validation from BioHorizons opens a US$22bn addressable market:** The first major validation of the CelGro medical device platform was a licensing deal with BioHorizons, announced in June 2022, which followed FDA clearance of Striate+ in January 2021. BioHorizons paid US$16m upfront for an exclusive licence to distribute Striate+ in its dental barrier membrane portfolio. BioHorizons is the fifth largest dental implant manufacturer globally and is a subsidiary of Henry Schein Inc. which has a US$11bn market capitalisation.
- **Possible takeover target?** The acquisition playbook for orthopaedic device companies involves buying devices which solve an unmet clinical need with strong clinical data, FDA clearance and revenue. Orthocell should meet these requirements when it receives FDA clearance for Remplir which we expect to occur in late FY24.
- **More than 100% upside:** Our DCF derived fair value of $0.90 per share puts the stock on an EV/Revenue multiple of 8x in FY26 inline with the current year multiple of Vericel and a discount to Polynovo on 19x. Similar stage competitors Embody and Biorez were acquired for EV/Revenue of 92x and 104x respectively in January 2023 and August 2022.

Figure 1. Orthocell has a US$22bn addressable market



Source: Veritas estimates

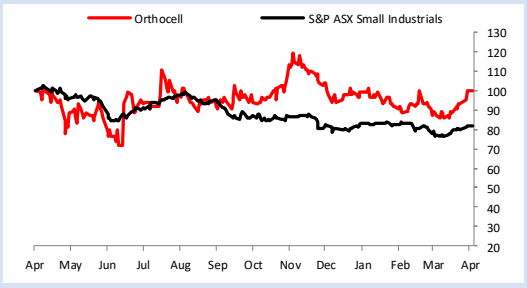
OCC.ASX BUY

Tuesday 18 April 2023

Share Price	$0.42
Price Target	$0.90
Valuation Method	DCF
Market capitalisation	$83m
Enterprise value	$56m
GICS sector	Biotechnology
12 month price range	$0.30 - $0.50
Average monthly t/o	1.7m
Shares in issue	197.2m
Top 20 holders	54.6m
Previous rating	Initiation

Year ended June 30	FY22	FY23E	FY24E	FY25E	FY26E
Revenue ($m)	1.5	3.4	4.6	9.8	17.7
Growth (%YoY)	50.5	121.1	35.9	113.9	79.5
EBITDA ($m)	(8.8)	(7.4)	(7.2)	(3.5)	2.8
Margin (%)	N/A	N/A	N/A	N/A	16.0
NPAT ($m)	(9.1)	(7.8)	(7.9)	(4.7)	0.9
EPS (cps)	(4.1)	(3.5)	(3.5)	(2.1)	0.4
CFPS (cps)	(2.8)	5.0	(4.0)	(2.3)	1.0
DPS (cps)	0.0	0.0	0.0	0.0	0.0
Franking (%)	0.0	0.0	0.0	0.0	0.0
Dividend Yield (%)	0.0	0.0	0.0	0.0	0.0
PER (x)	N/A	N/A	N/A	N/A	100.7
EV/Revenue (x)	36.9	16.7	12.3	5.7	3.2
EV/Gross profit (x)	73.2	19.6	15.2	7.3	3.9
EV/EBITDA (x)	N/A	N/A	N/A	N/A	20.0
EV/EBIT (x)	N/A	N/A	N/A	N/A	64.4
Fixed charge cover (x)	N/A	N/A	N/A	N/A	6.8

Orthocell vs. ASX Small Industrials



Source: Factset, Veritas

Orthocell are commercialising orthopaedic (nerve, bone, tendon and ligament) repair via the CelGro platform and cell therapies.

https://www.orthocell.com

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Orthocell Limited

Share Price: $0.42 ps **Valuation: $0.90 ps**

Financial Performance (A$m)

Year ended June 30	FY21	FY22	FY23E	FY24E	FY25E	FY26E
Revenue	**1.0**	**1.5**	**3.4**	**4.6**	**9.8**	**17.7**
Cost of goods sold	(0.6)	(0.7)	(0.5)	(0.9)	(2.1)	(3.3)
Gross profit	**0.4**	**0.8**	**2.9**	**3.7**	**7.8**	**14.4**
Other income	0.2	0.3	0.1	0.1	0.1	0.1
R&D tax offset	2.4	2.1	2.0	2.3	2.4	2.4
Operating costs	(11.8)	(12.0)	(12.4)	(13.3)	(13.8)	(14.0)
Normalised EBITDA	**(8.8)**	**(8.8)**	**(7.4)**	**(7.2)**	**(3.5)**	**2.8**
Depreciation and amortisation	(0.4)	(0.3)	(0.5)	(0.9)	(1.3)	(2.0)
Normalised EBIT	**(9.2)**	**(9.2)**	**(7.9)**	**(8.0)**	**(4.7)**	**0.9**
Associate income	0.0	0.0	0.0	0.0	0.0	0.0
Net interest	0.2	0.1	0.1	0.1	0.1	0.1
Normalised pre-tax profit	**(9.0)**	**(9.1)**	**(7.8)**	**(7.9)**	**(4.7)**	**0.9**
Normalised tax	0.0	0.0	0.0	0.0	0.0	0.0
Profit attributable to minorities	0.0	0.0	0.0	0.0	0.0	0.0
Normalised profit to holders	**(9.0)**	**(9.1)**	**(7.8)**	**(7.9)**	**(4.7)**	**0.9**
One off items (post-tax)	0.0	0.0	0.0	0.0	0.0	0.0
Reported profit to holders	**(9.0)**	**(9.1)**	**(7.8)**	**(7.9)**	**(4.7)**	**0.9**

Cash Flow Statement (A$m)

Year ended June 30	FY21	FY22	FY23E	FY24E	FY25E	FY26E
Normalised EBITDA	**(8.8)**	**(8.8)**	**(7.4)**	**(7.2)**	**(3.5)**	**2.8**
Cash net interest	0.2	(0.1)	0.1	0.1	0.1	0.1
Cash tax (paid)/received	0.0	0.0	0.0	0.0	0.0	0.0
Working capital/other	4.1	2.6	18.6	(1.8)	(1.7)	(0.7)
Operating Cash Flow	**(4.5)**	**(6.3)**	**11.3**	**(8.9)**	**(5.1)**	**2.2**
Capex	(0.2)	(0.5)	(0.4)	(0.7)	(1.4)	(2.0)
Payments on Finance Leases	(0.1)	(0.1)	(0.2)	(0.2)	(0.2)	(0.2)
Free Cash Flow	**(4.8)**	**(6.9)**	**10.7**	**(9.8)**	**(6.6)**	**0.0**
Net Borrowings	0.0	0.0	0.0	0.0	0.0	0.0
Equity raised/buybacks	0.7	1.6	0.0	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0	0.0
Other	(0.0)	(0.0)	0.0	0.0	0.0	0.0
Net increase/(decrease) cash	**(4.1)**	**(5.3)**	**10.7**	**(9.8)**	**(6.6)**	**0.0**
Cash at beginning	20.4	16.3	11.0	21.7	11.9	5.2
Cash at end	16.3	11.0	21.7	11.9	5.2	5.3

Balance Sheet (A$m)

Year ended June 30	FY21	FY22	FY23E	FY24E	FY25E	FY26E
Cash	16.3	11.0	21.7	11.9	5.2	5.3
Receivables	0.3	23.5	0.0	0.0	0.0	0.0
Inventories	0.5	0.6	0.4	0.6	1.1	1.0
Other current assets	0.0	0.1	0.1	0.1	0.1	0.1
Current Assets	**17.1**	**35.3**	**22.2**	**12.6**	**6.5**	**6.4**
Property, Plant & Equipment	0.3	0.9	1.2	1.4	1.8	2.5
Intangibles	1.3	1.2	1.0	0.9	0.8	0.3
Right-of-use assets	0.6	0.5	0.5	0.5	0.5	0.5
Other non current assets	0.0	0.0	0.0	0.0	0.0	0.0
Non Current Assets	**2.3**	**2.6**	**2.8**	**2.8**	**3.1**	**3.3**
Total Assets	**19.3**	**37.9**	**25.0**	**15.4**	**9.6**	**9.7**
Payables	1.0	3.5	0.1	0.3	0.9	1.9
Employee Benefits	0.6	0.7	0.7	0.7	0.7	0.7
Borrowings	0.0	0.0	0.0	0.0	0.0	0.0
Lease Liabilities	0.6	0.5	0.5	0.5	0.5	0.5
Contract liabilities	0.0	23.0	20.7	18.4	16.1	13.8
Other	0.3	0.3	0.3	0.3	0.3	0.3
Total Liabilities	**2.5**	**28.0**	**22.4**	**20.2**	**18.6**	**17.2**
Shareholder Funds	**16.9**	**9.9**	**2.6**	**(4.8)**	**(9.0)**	**(7.6)**

Directors and Key Management Personnel	Position	Shares	Holding
Paul Anderson	MD/co-founder	6.9m	3.5%
Dr Stuart Washer	Executive Chairman	1.1m	0.6%
Leslie Wise	Executive Director	0.0m	0.0%
Matthew Callahan	Non Executive Director	1.2m	0.6%
Professor Lars Lidgren	Non Executive Director	1.2m	0.6%
Qi Zhou	Non Executive Director	6.2m	3.1%

Major Shareholders (excluding nominees)		Shares	Holding
Paul Anderson & Jane Telford	MD/Co-founder & CFO	6.9m	3.48%
Ming Zheng & Fan Ying	Co-founder	6.8m	3.45%
Qi Zhou	NED	6.2m	3.1%
Sandhurst Trustees		5.1m	2.6%
Top 20 shareholders		**54.6m**	**27.7%**

Source: Company data, Veritas Research

Valuation Metrics

		Valution
Price Target (ps)	$0.90	113%
Share Price (ps)	$0.42	
FY25 EV/Revenue (x)	5.7	
Implied FY25 EV/Revenue (x)	15.3	166%
Implied FY26 EV/Revenue (x)	8.5	48%
Market Capitalisation (A$m)	83	
Enterprise Value (A$m)	56	

Valuation Multiples

Year ended June	FY21	FY22	FY23E	FY24E	FY25E	FY26E
P/E (x)	N/A	N/A	N/A	N/A	N/A	100.7
Price/Cash Flow (x)	N/A	N/A	8.4	N/A	N/A	43.3
EV/Revenue (x)	55.5	36.9	16.7	12.3	5.7	3.2
EV/Gross profit (x)	144.0	73.2	19.6	15.2	7.3	3.9
EV/EBITDA (x)	N/A	N/A	N/A	N/A	N/A	20.0
EV/EBIT (x)	N/A	N/A	N/A	N/A	N/A	64.4
Equity FCF yield (%)	-5.8	-8.4	12.9	-11.9	-8.0	0.0
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0
EV/capital (x)	1.7	2.8	2.4	8.6	-13.2	-20.2
Price to book value (x)	5.3	9.4	36.3	-19.5	-10.5	-12.5

Per Share Data

Year ended June 30	FY21	FY22	FY23E	FY24E	FY25E	FY26E
EPS diluted - adjusted (¢ps)	**(4.22)**	**(4.10)**	**(3.48)**	**(3.54)**	**(2.08)**	**0.42**
EPS diluted (¢ps)	(4.84)	(4.68)	(3.96)	(4.03)	(2.37)	0.48
Cash flow per share (¢ps)	(2.11)	(2.82)	5.01	(3.97)	(2.27)	0.97
Free cash flow per share (¢ps)	(2.25)	(3.13)	4.76	(4.37)	(2.96)	0.01
Cash (¢ps)	7.62	4.96	9.67	5.30	2.34	2.35
Net assets (¢ps)	7.88	4.46	1.16	-2.16	-4.01	-3.37
DPS (¢ps)	0.00	0.00	0.00	0.00	0.00	0.00
Franking (%)	0	0	0	0	0	0
Shares on issue - avg. basic (m)	187	195	197	197	197	197
Shares on issue - avg. diluted (m)	214	222	225	225	225	225

Revenue by product (A$m)

Year ended June 30	FY21	FY22	FY23E	FY24E	FY25E	FY26E
Striate - US	0.0	0.2	0.4	0.9	2.2	3.3
Remplir - Australia	0.0	0.0	0.2	0.8	1.5	3.0
Remplir - US	0.0	0.0	0.0	0.0	1.7	5.1
SmrtGraft	0.0	0.0	0.0	0.0	0.4	0.8
Cell Therapies ATI	0.4	0.4	0.3	0.4	1.1	2.3
Cell Therapies ACI	0.5	0.3	0.2	0.3	0.7	1.0
Revenue from consumables	1.0	1.5	1.1	2.3	7.6	15.4
Revenue from contracts	0.0	0.1	2.3	2.3	2.3	2.3
Revenue	**1.0**	**1.5**	**3.4**	**4.6**	**9.8**	**17.7**

Performance Ratios (%)

Year ended June 30	FY21	FY22	FY23E	FY24E	FY25E	FY26E
Revenue growth		50.5	121.1	35.9	113.9	79.5
Gross profit growth		96.9	272.4	29.6	109.1	84.2
Cost growth		1.7	3.3	6.9	3.9	1.6
Operating cost margin		784.2	366.4	288.2	140.0	79.3
EBITDA margin		N/A	N/A	N/A	N/A	16.0
Tax rate		0.0	0.0	0.0	0.0	0.0
Return on capital		N/A	N/A	N/A	N/A	N/A

Balance Sheet Ratios

Balance Sheet (A$m)	FY21	FY22	FY23E	FY24E	FY25E	FY26E
Gross debt ($ m)	0.6	0.5	0.5	0.5	0.5	0.5
Net debt/(cash) ($ m)	(15.7)	(10.5)	(21.2)	(11.4)	(4.7)	(4.8)
Fixed charge cover (x)	N/A	N/A	N/A	N/A	N/A	6.8

Contents

Commercialising orthopaedic repair technology

Orthocell is a biotech company focussed on regenerating mobility, by unlocking the power of the human body to heal itself and also commercialising novel biological products to optimise the repair of bone, nerve, tendon and cartilage injuries.

CEO Paul Anderson and CSO Professor Ming Hao Zheng, from the University of Western Australia, have extensive experience in the regenerative medicine space, having previously commercialized a cartilage cell therapy together at Verigen, and then selling the technology to US-based company Genzyme. The two colleagues co-founded Orthocell to continue their passion in developing creative and effective regenerative medicine solutions for patients suffering from musculoskeletal injuries. They secured venture capital funding from a Western Australian-based VC firm, along with funding from the WA State government in 2010, to build the laboratory and fund the initial clinical trial program. Orthocell's IPO was in 2014.

Orthocell have developed two product lines for tissue regeneration – a collagen medical device (CelGro platform) to augment surgical repair of bone and soft tissue, and two autologous cell therapies used to treat injured or degenerate cartilage and tendon tissue by local implantation of the patient's own healthy cells. These products are designed for use by Orthopaedic and Plastic surgeons to assist patients in returning to pain free function.

Orthocell manufactures its products at their quality-controlled facility in Perth, Western Australia. Orthocell recently completed a facility upgrade to scale-up manufacturing capacity of the collagen medical device from 10,000 to >100,000 units per year.

The Company has two medical devices from the CelGro Platform in the market. The first device to achieve regulatory approval and secure a US partner was Striate+, for use in guided bone regeneration around dental implants. Approvals in Europe, Australia and the US validated the product and culminated in a distribution partnership with BioHorizons, a multi-national dental product company.

The company's second device to gain approval, reimbursement and secure a partner was Remplir, for use as a wrap to augment the repair of peripheral nerves. It is currently exclusively distributed by Device Technologies Pty Ltd in Australia, but is being prepared for US and other global regulatory approvals.

Orthocell also markets an approved autologous cell therapy in Australia (using the patient's own cells) aimed at treating damaged cartilage (OrthoACI).

Product Pipeline

The product pipeline is focused firmly on US market entry (Figure 1). Two additional CelGro platform products are in development for nerve and ligament repair, as well as a cellular therapy for the treatment of chronic tendon injuries, initially in the shoulder and elbow.

Remplir (CelGro for peripheral nerve repair) - Studies to support an application for US FDA market clearance of Remplir, for use as a wrap to augment the repair of peripheral nerves should commence imminently, with approval anticipated by the end of FY24.

SmrtRope (CelGro for ligament replacement) - Further development of this technology is planned in CY 2023, to position Orthocell's collagen rope as a first off-the-shelf biological device for improving anterior cruciate ligament (ACL) reconstruction outcomes.

OrthoATI (cell therapy for chronic tendon injuries) - The Company has successfully completed a randomised study comparing OrthoATI to steroids and is accelerating US market access and planning a larger clinical study under FDA supervision.

US regulatory approvals are the most important, because the US is the biggest market globally with 70% of the global market; many other countries accept US approvals; reimbursement for medical treatments is substantially higher in the US and most potential acquirers are US companies.

Figure 2: Regulatory status of Orthocell products in the US, the world's largest market

Product	Application	Clinical Development Phase	US Regulatory Phase			Upcoming Catalysts
			Design Trial	Implement Trial	Approved	
CelGro™ Medical Device	Striate+ (1)					**Engaged BioHorizons** - exclusive license and manufacturing partner
	Remplir (2)					**US commercialisation strategy** - finalise US regulatory/reimbursement study
	SmrtRope (Ligament replacement)					**Commence pre-clinical study** - ACL repair
OrthoATI™ Cell Therapy	Rotator Cuff					**Release RCT results** - OrthoATI v corticosteroids
	Lateral epicondyle					**Recruitment complete** - OrthoATI vs surgery

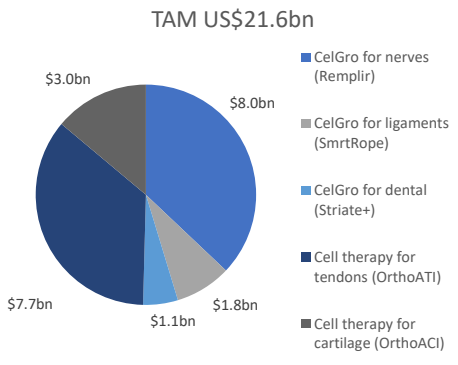
(1) Approved in the US, AUS & EU
(2) Approved in AUS

Source: Veritas research, company data.

A US$22bn total addressable market

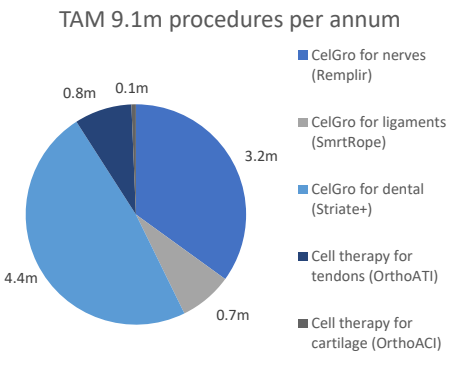
We estimate Orthocell has a US$22bn total addressable market which is split approximately 50/50 between CelGro and cell therapies (Figure 3). CelGro is vastly more applicable in terms of addressable procedure *numbers* due to there being >3m peripheral nerve injuries per year that are treatable by Remplir and >4m dental barrier implants treatable with Striate+, versus approximately 800,000 tendon repairs and 100,000 knee repairs eligible for OrthoACI (Figure 4).

Figure 3: Orthocell's total addressable market by product (US$m)



Source: Veritas research, company data.

Figure 4: Orthocell's total addressable market by product (million procedures per annum)



Source: Veritas research, company data.

The CelGro platform

Orthocell is unique in the regenerative medicine field, manufacturing both cell therapies and biological "scaffolds" which are used to deliver cells to the site of tissue repair and augment the healing process. Following the sale of Verigen to Genzyme, the Chief Scientific Officer and inventor of Orthocell's technologies, Professor Ming Hao Zheng, reviewed all available scaffolds used in the repair of tendon injuries. He was dissatisfied with their tissue repair characteristics, including toxicity to certain cells, poor biocompatibility and stiffness that impedes surgical application. To address these deficiencies he invented CelGro, which was patented in 2013 (link). It soon became apparent that CelGro was so effective that it could be used successfully without cell therapy to augment the surgical repair of most orthopaedic tissues including bone, nerve, tendon, ligament and cartilage.

How CelGro works

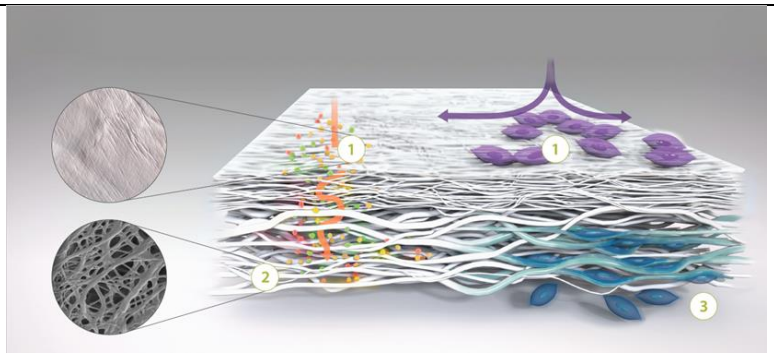
CelGro is made from porcine peritoneum - the stomach lining of pigs - processed to remove contaminants which the body may reject such as DNA, glycosaminoglycans and lipids using the proprietary SMRT process. The process leaves behind Type I collagen formed in its native structure.

Collagen is the main component of many tissues and has been successfully used as a medical biomaterial for decades. This and the preservation of the native collagen structure produces: a stronger membrane, improved handling characteristics, an optimal degradation profile and an environment that promotes the regrowth of orthopaedic cells.

Biologically formed collagen membranes such as CelGro provide a demonstrably more accommodative scaffold for cell growth than man-made structures such as cross-linked (e.g., Integra NeuraWrap) or electrospun collagen (e.g., Embody Tapestry).

CelGro membranes possess the ideal microstructure for cellular attachment and proliferation integrating with the tissue and degrading commensurate with the tissue healing process. The membrane is designed to prevent the infiltration of cells not involved in tissue repair, while allowing the passage of smaller bioactive molecules and growth factors that stimulate and support the repair process being undertaken by the cells within the repair site (Figure 5).

Figure 5: How CelGro works



1. CelGro provides a barrier to prevent infiltration of cells not involved in tissue repair and enables the passage of bioactive molecules and proteins.
2. Porous network of collagen fibres promotes cellular attachment and proliferation.
3. Bioactive chamber supports new tissue formation and integration of the membrane at the repair site.

Source: Veritas estimates, Company data (www.orthocell.com)

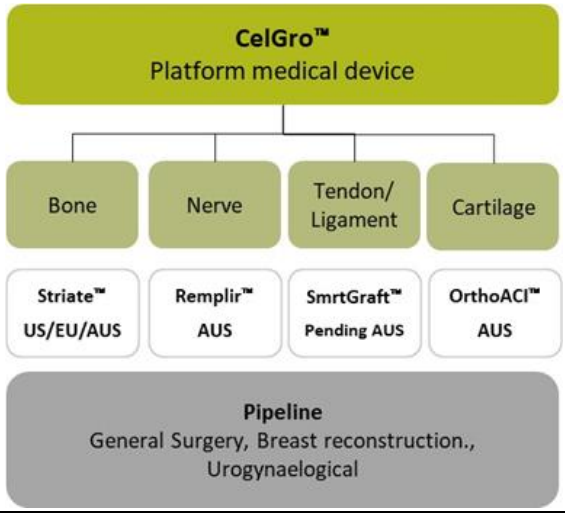
Products in market and an advanced pipeline

Orthocell design, develop and manufacture collagen medical devices (CelGro Platform) to augment the surgical repair of multiple tissue types including bone, nerve, tendon/ligament and cartilage (Figure 6). Each device is tailored to the needs of the tissue requiring surgical reconstruction or repair and is marketed under different trade names.

Orthocell has two products in market from the CelGro Platform. The first is Striate+ which is approved for use (EU/US/AUS) in various dental bone and tissue regeneration procedures. The second is Remplir which is approved (AUS) for use in peripheral nerve repair. SmrtGraft for tendon/ligament repair and the OrthoACI collagen scaffold is supplied in Australia under the Special Access Scheme.

Other applications for CelGro may be trademarked in future, include general surgery, breast reconstruction and urogynaelogical applications.

Figure 6: The CelGro Platform



Source: Company data (www.orthocell.com)

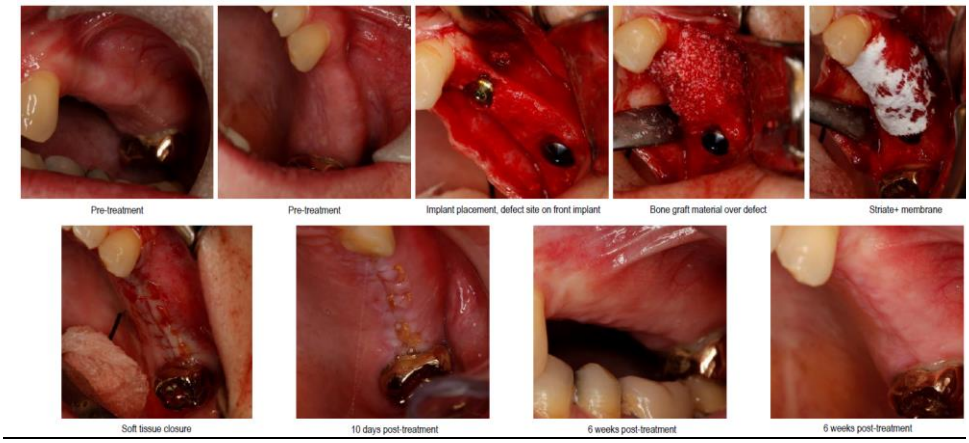
Striate+ growing better bone, faster

Dental implants are favoured over dentures to replace missing teeth due to damage or disease. A dental implant is a titanium rod screwed into the jaw, with a false tooth fixed to the implant above the gum. Treatment success is dependent on sufficient bone available in the jaw to stabilise the implant, and bone must grow around the new implant to keep it secure (osseo-integrated) over time. Sometimes, a bone graft or other bone substitute, is needed to make sure the implant stays in place until osseointegration occurs.

Striate+ is a resorbable collagen membrane used for guided bone and tissue regeneration (GBR) which is a procedure where a membrane is implanted underneath the gum around the dental implant/bone graft. The barrier membrane creates a protected environment around the implant and prevents cells from the gum invading the space before the bone has had a chance to grow. Studies have shown that use of a barrier membrane facilitates better bone regeneration around the implant.

An implant at a site with insufficient bone is shown in Figure 7. Bone grafting material is used at the defect to support bone growth around the new implant(s) and the site is wrapped with Orthocell's Striate+.

Figure 7: Striate+ implantation procedure



Source: Company data (www.orthocell.com)

Striate+ offers clinically superior bone repair to Bio-Gide

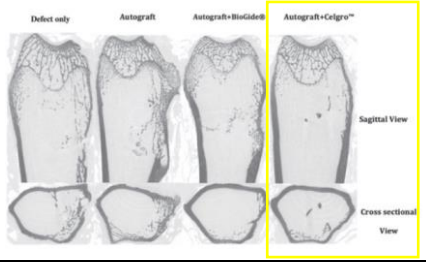
The company compared the performance of Striate+ to Bio-Gide, the market-leading dental barrier membrane globally, in preclinical and clinical studies. Bio-Gide is widely considered the gold standard dental barrier membrane as one of the first resorbable and natural bi-layer collagen membranes, and is manufactured and distributed by Geistlich.

Studies showed that the performance of the Striate+ membrane in assisting bone regeneration was equal to or better than the performance of Bio-Gide:

- Use of Striate+ resulted in more rapid, and more mature bone regeneration at an earlier time point than Bio-Gide (ASX release 17 Sept 2020); *Tissue Engineering* (Allan et. al, 2021, link).
- Use of Striate+ resulted in bone growth around a dental implant that was equivalent to Bio-Gide (ASX release 11 March 2020 – link)
- The quality of regenerated bone was shown to be superior to that observed in two published studies using Bio-Gide in guided bone regeneration treatments (ASX release May 2018 – link).

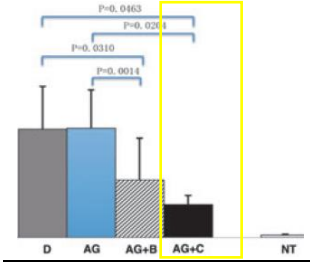
The peer reviewed paper published in the Tissue Engineering journal tested four approaches to repair a defect (hole) created in the cortical part of the femur bone of 25 rabbits: no treatment, application of a bone graft obtained from the same patient (i.e., an autograft), application of an autograft wrapped in a Bio-Gide membrane and application of an autograft wrapped in the CelGro membrane. Near normal repair of the bone occurred in the CelGro group, with defects remaining in all other groups (Figure 8). The CelGro treatment also exhibited more bone regrowth as indicated by a lower porous bone volume after 60 days (Figure 9).

Figure 8: CT scans of bone defects



Source: Allan et. al. Tissue Engineering, 2021.

Figure 9: Porous bone volume after 60 days



Source: Allan et. al. Tissue Engineering, 2021.

In an Orthocell-sponsored clinical study, successful bone regeneration was observed in all patients within 4 to 6 months, with no reported adverse events. Patients undergoing single-stage treatment successfully generated enough new bone to stabilise their implants and complete their treatment in about half the time of the usual two-stage dental implant treatment (ASX release June 2019 – link).

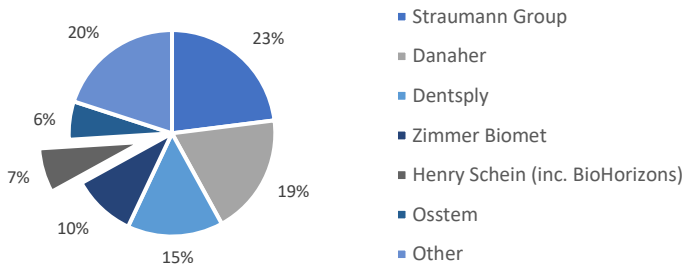
Validation from a top five dental implant company

The overall superior performance of the Striate membrane, FDA clearance and strength of the Companies KOL group led to the first major validation of the CelGro medical device platform - a significant licencing deal with BioHorizons, announced in June 2022. In consideration for the licence granted, Orthocell received US$16m in cash. BioHorizons will pay Orthocell for the devices, manufactured by Orthocell, on delivery.

BioHorizons is the fifth largest provider of dental implants and tissue regeneration products for dentists and dental specialists globally (Figure 10) and a subsidiary of Henry Schein which has a US$11bn market capitalisation. BioHorizons plan to reduce their current range of collagen dental barrier membranes, focussing on Orthocell manufactured Striate+, starting in FY23.

We believe that BioHorizons chose Orthocell over other membranes due to evidence that Striate+ performs better than incumbent products, in particular the popular Bio-Gide. The Bio-Gide membrane has been used in over 2 million patients over the past 20 years according to its website which if replicated could earn Orthocell >$80m of revenue, on our estimates.

Figure 10: Market share of global dental implants market with Henry Schein highlighted



Source: Veritas research, Addbio market share data from 2017.

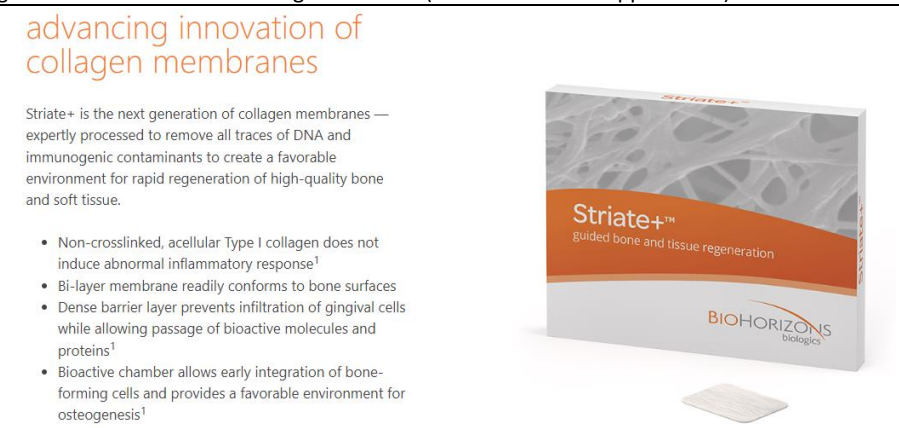
The BioHorizons licensing and distribution deal is one of the largest, in terms of upfront cash payments, that we've seen for a small capitalisation ASX biotech company. Other benefits of this deal include:

- **Providing scale to manufacturing operations** - enables the scale up of manufacturing alongside the expected rapid growth in size of purchase orders from BioHorizons.
- **Advancing the FDA clearance pathway for Remplir** – The use of a CelGro portfolio product Company is now in a strong capital position to advance the US market access program for Remplir. The 501k approval pathway (for products that already have clearance for a different indication) is relatively straightforward as patient safety has already been demonstrated. We anticipate US approval in late FY24.

A US$1.1bn market

We estimate 4.4 million dental membranes are sold globally every year generating $1.1bn for distributors such as Geistlich and BioHorizons. We expect the Striate+ uptake will be driven by BioHorizons communicating the benefits of Striate+ relative to Geistlich's BioGide and older BioHorizons products (Figure 11).

Figure 11: BioHorizons marketing for Striate+ (CelGro for dental applications)



Source: Veritas research, company data.

Market entry status and next steps

Orthocell are actively working alongside BioHorizons to implement a key opinion leader driven market entry strategy. The Companies are jointly promoting the use of Striate+ at industry events such as the US Academy of Osseointegration annual meeting in March 2023 and the upcoming Oral Reconstruction Foundation meeting in June this year.

Channel checks indicate that the sell through of Striate+ has been strong. Orthocell management has indicated that it is in discussions with Henry Schein (the BioHorizons parent company) to increase distribution in the US. It is also working with BioHorizons to enter European and Australian markets with initial product launches expected in 4Q23.

Remplir - returning function to paralysed limbs

> *"Peripheral nerve injury is a major clinical problem and is estimated to affect more than five million people worldwide every year."*

Simon Archibald PhD, Chief Scientist of Integra LifeSciences (link)

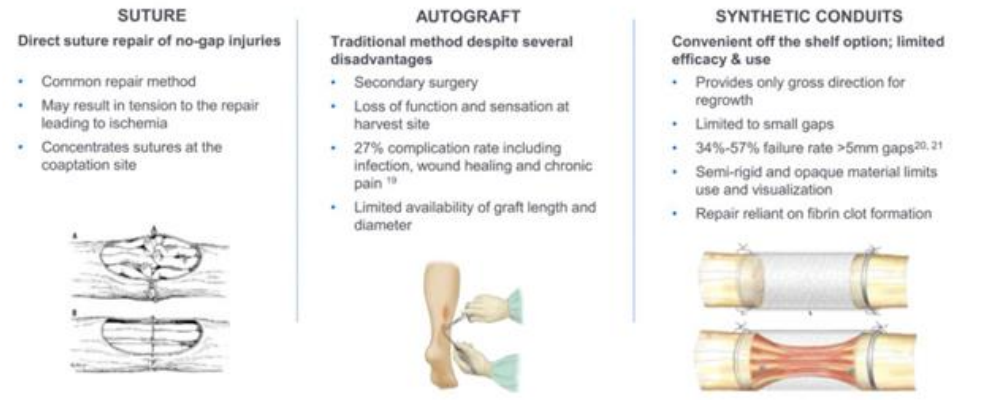
Orthocell's second CelGro platform product, Remplir, has an opportunity to disrupt the peripheral nerve repair market. Peripheral nerve injuries can be relatively minor, such as a laceration causing numbness, or can have devastating consequences such as partial or complete paralysis.

Traditional repair methods suboptimal

Unlike nerves of the brain and spinal cord, peripheral nerves have the capacity to regenerate if damaged. If severed nerves are re-joined, new nerve fibres grow through the nerve structures to reconnect the brain to the target organs (e.g., muscles). Traditional repair methods include direct suturing, grafts and conduits. However, these methods have their limitations and may be detrimental to the regenerating nerve (Figure 12). For example:

- **Sutures**: Traditionally, severed nerves are re-joined using multiple sutures. The sutures themselves can impede nerve regeneration, either by creating inflammation and scar formation, or by creating an obstacle to the regenerating nerve's growth.
- **Autograft:** Replacing the damaged nerve with a healthy nerve from the same patient. This has long been considered the gold standard approach – especially for longer nerve gaps. However, doing this causes loss of function and sometimes pain in the spot where the nerve is harvested from. Often an appropriate replacement nerve may not be available.
- **Nerve conduits**: hollow tubes made of synthetic or biological material, are used to bridge gaps between the nerve ends, but they are designed to be rigid and are difficult to manipulate. The rigidity may cause nerve compression, inflammation and scar tissue to form at the repair site.

Figure 12: Traditional methods for repairing severed nerves have major limitations

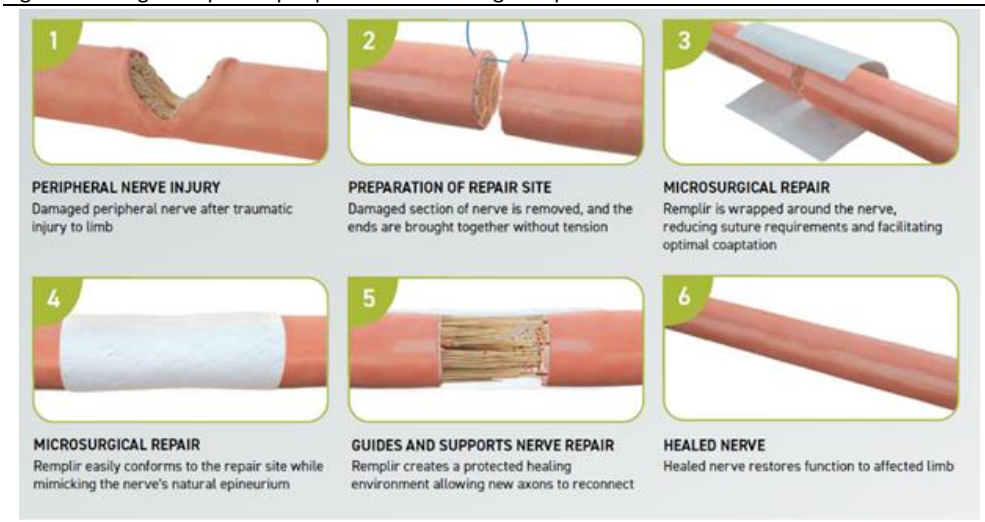


Source: Veritas research, company data.

A potential market leader

Remplir was designed to directly address the limitations of current repair methods including their difficulty of use, scar tissue formation and inconsistent return of muscle function. Remplir is wrapped around the repair site to form a non-compressive protective barrier (Figure 13). Remplir is flexible and self-adhesive, reducing the requirement for damaging sutures, leading to less scar tissue formation, and provides an optimal environment for the regeneration of damaged peripheral nerves.

Figure 13: Surgical repair of peripheral nerves using Remplir

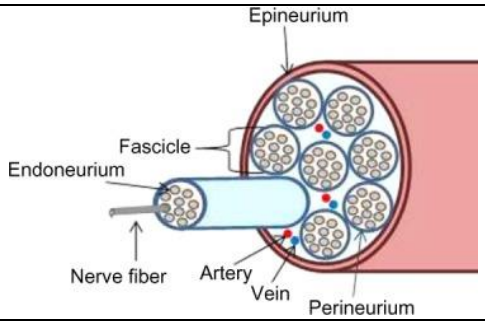


Source: Veritas research, company data.

A natural bi-layer structure that mimics the human epineurium

Epineurium, the outermost connective tissue layer of a peripheral nerve, is crucial for nerve health (Figure 14). It encloses the nerves and provides mechanical and biological support to the axons which transmit signals to and from the brain. Remplir's natural bi-layer structure is designed to mimic the epineurium (Figure 15), creating the ideal environment for nerve regeneration and subsequent return of muscle function. It acts as a barrier structure to protect the nerve repair site, reduces the risk of adhesions and facilitates free gliding of the repaired nerve. Remplir's mechanical properties reduces the need for sutures (facilitating a tensionless repair), minimises compression, and provides a favourable microenvironment to retain growth factors required for axonal regeneration.

Figure 14: Nerve components

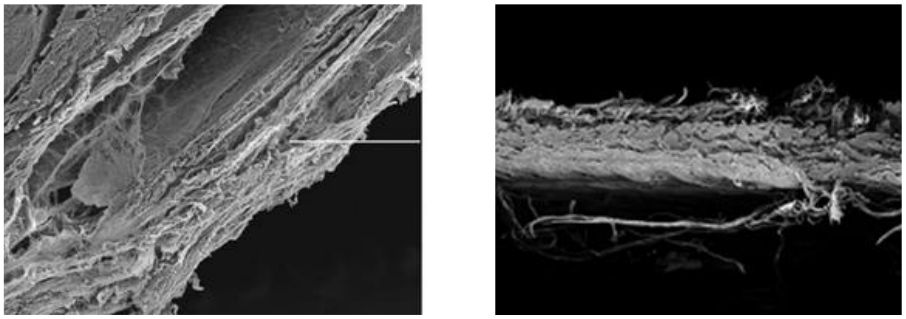


Source: Veritas research, company data.

Orthocell believes that Remplir's similarity to normal human epineurium is a key differentiator to other devices in this market (Figure 16). The comparator devices, like Integra's NeuraWrap or Axogen's Axoguard Nerve Protector devices are designed to bridge gaps at the site of peripheral nerve injury, hence they are designed to be more rigid, with a longer degradation time to suit this

purpose. These features are not ideal for nerve regeneration – the rigidity leads to compression of the nerve and adhesions to the surrounding soft tissue, while the long degradation time contributes to inflammation and scar tissue formation. US health insurers exclude nerve conduit devices from reimbursement due to lack of evidence of clinical efficacy. The absence of a fit for purpose nerve repair device in the US creates a unique opportunity for Orthocell – to bring a nerve repair device that assists the surgeons perform surgical repairs while providing consistent high-quality return of muscle function.

Figure 15: Remplir mimics normal epineurium - Scanning Electron Microscopy (SEM) images



Human epineurium | Remplir

Source: Veritas research, company data. Reina, M.A., Sala-Blanch, X. (2015). Ultrastructure of the Epineurium. In: Reina, M., De Andrés, J., Hadzic, A., Prats-Galino, A., Sala-Blanch, X., van Zundert, A. (eds) Atlas of Functional Anatomy for Regional Anaesthesia and Pain Medicine. Springer, Cham.

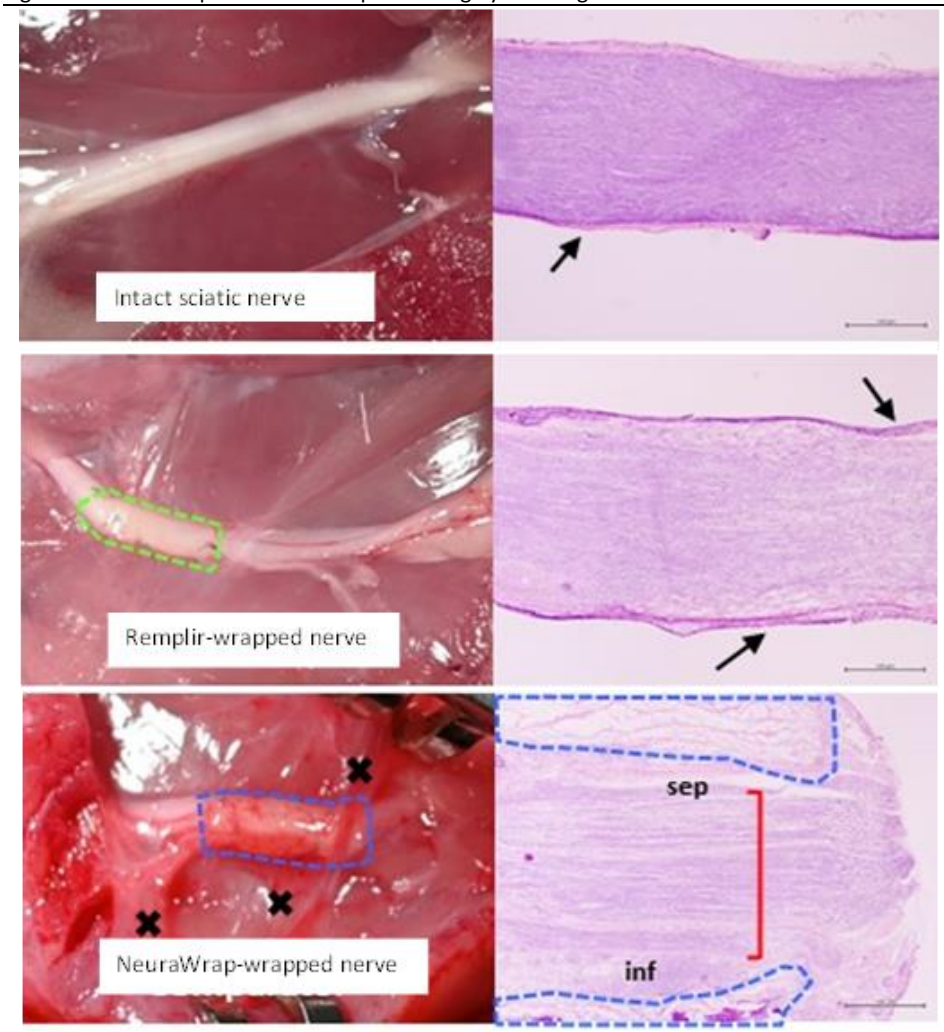
Remplir provides superior nerve repair to incumbents

A pilot study compared the repair of severed nerves using Orthocell Remplir and Integra NeuraWrap. It clearly demonstrates how Remplir produces superior nerve repairs to the incumbent (Figure 16, ASX release April 2021– link).

Nerves repaired with Remplir exhibited no inflammation or scar tissue formation. Remplir integrated into the host epineurium and was remodelled into natural tissue. Remplir was also easier for surgeons to work with.

Nerves repaired with NeuraWrap showed: significant inflammation; foreign body reaction; fibro-adhesions between the nerve and surrounding soft tissue; compression of the nerve, fibro-encapsulation; and separation of the epineurium from the nerve fibres. All of which are associated with adverse clinical outcomes including reduced nerve function.

Figure 16: Nerves repaired with Remplir are largely indistinguishable from intact nerves



Top panel: Nerve fibres are surrounded with a protective outer layer of connective tissue called the epineurium (black arrow).

Middle panel: Macroscopic appearance of repaired sciatic nerve resembles pre-injured state. Histology shows integration of CelGro (green dashes) into the regenerated epineurium (black arrow), nerve fibres resemble normal architecture.

Bottom panel: Macroscopic appearance of repaired sciatic nerve showed adhesion to the surrounding soft tissue and muscle (black cross) with signs of traumatic neuroma formation. Histology shows that the comparator device (blue dashes) exhibited significant inflammation (inf) with fibro-encapsulation, entrapment (red bracket) and separation of epineurium to nerve (sep).

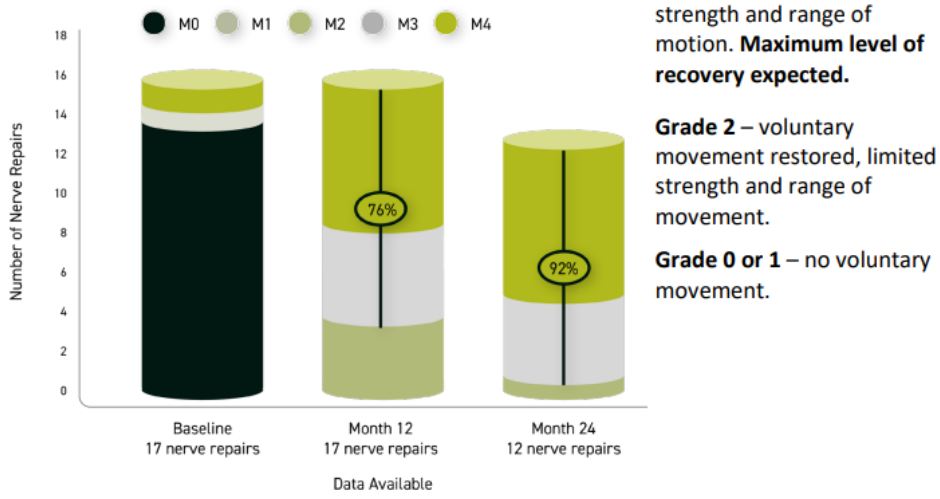
Source: Veritas research, company data.

Clinical evidence for restored muscle function

The clinical data from Remplir is even more compelling than Striate+ which is validated by BioHorizons. Orthocell sponsored a clinical study to assess the effectiveness of nerve reconstruction with Remplir. Patients in the clinical trial suffered traumatic nerve injuries following motor vehicle, sporting and/or work-related incidents, resulting in partial or total loss of use of their arms and, in more severe cases, their legs and torso as well (quadriplegia). Patients experienced significant pain and were unable to perform basic activities of daily living (i.e., eating, bathing, dressing etc). Without surgery they would not have regained normal use of their injured arm and hand.

Nineteen patients received one or more nerve repairs (27 in total) augmented with Remplir in one or both upper limbs. Recovery after treatment was assessed by grading the strength of target muscles closest to the site of nerve repair. Follow up data at 12 months was available for 16 of 19 patients involving 33 nerve repairs. Functional recovery of muscles controlled by the repaired nerve was observed in 76% (25 of 33) of nerve repairs, increasing to 85% (23 of 27) of nerve repairs at 24 months post-treatment (Figure 17).

Figure 17: Functional improvement for tetraplegic patients that received nerve transfer surgery and Remplir – return of function after 12 months.



Source: Veritas research, company data. British Medical Research Council Grading System (MRC grade), with a score of 0 to 5. A score of zero (0) indicates no nerve connection to the muscle (i.e.., no recovery), a score of five (5) is given to muscles with normal power/strength. A score of 3 or better is clinically defined as a meaningful functional recovery.

This positive clinical data demonstrates that nerve repair with Remplir following injury to the spinal cord, brachial plexus and other peripheral arm/hand nerves, consistently restores arm and hand function to previously paralysed limbs.

Competitive advantages

The advantages of Remplir relative to incumbent products include:

- **Ease of use:** Remplir is the same thickness as the epineurium (0.1-0.3 mm) yet is strong and pliable. Traditional nerve wraps such as NeuraWrap are significantly thicker (0.7-1.0 mm) which makes them more difficult to apply. Competitor products, such as NeuraWrap, need to be hydrated with saline solution for 30 minutes pre-use. Remplir can be applied immediately.
- **Resorbable:** Remplir is fully resorbable into the epineurium such that after there is no observable difference from the control nerve after as little as four weeks (see the Middle panel Figure 16). Many competitor products such a NeuraWrap can take longer than a year to be fully absorbed.
- **Compression free:** Competitor products have struggled to achieve wide adoption due to compressing nerves (see the red bar in the Bottom panel Figure 16). Remplir's mechanical similarity to the epineurium avoids placing the nerve under tension or compressing the nerve during repair.
- **Does away with sutures:** Alternative nerve wrap devices require sutures through the nerve to hold them in place. Remplir's natural flexibility and adhesive qualities means it can re-connect nerves without sutures or reduce the number of sutures used.

- **Promotes metabolic exchange:** A protective outer layer permits the exchange of oxygen and nutrients but prevents harmful cells and soft tissue invasion. Soft tissue invasion can be seen in the NeuraWrap repair (see black Xs on lower Bottom panel of Figure 16)
- **Bioactive:** The longitudinally aligned porous channels of the inner layer of the membrane creates a bioactive chamber which maximises and guides cell growth. No competitor products promote cell growth to the same extent according to our review of the published literature.

Australia is a $9m revenue opportunity

In March 2022, Orthocell achieved Australian TGA market approval for Remplir and reimbursement approval in early November 2022. Orthocell appointed Device Technologies ("DVT") as the exclusive distributor of Remplir across Australia and New Zealand in September 2022 and the first orders were also shipped in September 2022. Device Technologies is a distributor of medical devices with over 200 brands and 1,000 staff across Australia, New Zealand and Asia.

There were 11,780 surgical repairs of peripheral nerves completed across both public and private hospitals in FY20 according to the Australian Institute of Health and Welfare link which would generate $9m revenue per year if all used Remplir.

US is a $600m revenue opportunity

The company is planning to commence a pre-clinical comparator trial and other clinical studies as part of a comprehensive program to achieve US and EU regulatory clearance and reimbursement. There are c700,000 peripheral nerve injuries per year in the US which would generate c$600m revenue for Orthocell if all used Remplir. If the planned pre-clinical trial achieves the primary outcomes, we expect US registration during FY24.

Cell therapies

Orthocell offers autologous cell therapies for the treatment of cartilage and tendon injuries. Both cell therapies use the patient's own cells to assist the regeneration of tissue.

OrthoATI - tendon repair for restoring pain-free function

Orthocell are also in the process of developing, using the same principals as OrthoACI, an injectable tendon cell therapy (OrthoATI), using the patients' own tenocytes (tendon derived cells) for the treatment of chronic tendon injuries (Tendinopathy) in the shoulder and the elbow.

Orthocell manufactures the cellular therapy at its GMP-certified and TGA-licensed facility in Western Australia with established release criteria in place. The product is provided to patients in Australia under the Special Access Scheme.

Current remedies address the symptoms not the disease

Tendinopathy is characterised by activity-related tendon pain, local tenderness and loss of function or strength. Tendinopathy is a common and painful disorder affecting millions of people every year with no effective, non-surgical treatments currently available.

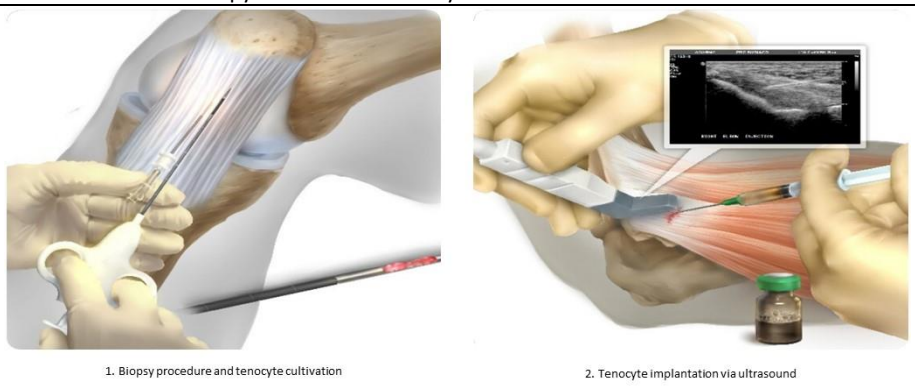
Chronic, or long-term, tendinopathy is associated with depletion of tenocytes (tendon cells), which play a critical role in tendon repair. If rest and physiotherapy don't resolve tendinopathy symptoms, steroid or platelet-rich plasma (PRP) injections are the next treatment option. However, a side effect of steroid use is reduced tendon cell viability and tendon strength (Puzzitello, 2020, link). Surgery is a last resort and even then, is not appropriate for all patients. Further, these treatment options do not appear to have long term effectiveness and success is variable.

OrthoATI is a biological, non-surgical treatment for tendon injuries, delivering the patient's own healing cells (tenocytes) directly back into the injury site. OrthoATI treats the underlying tendon disease by replenishing tendon cell numbers to the amount required to restore tissue growth.

OrthoATI - how it works

Like OrthoACI, the tendon cell therapy OrthoATI is a two-stage procedure. First a biopsy of healthy tendon, typically from the patella tendon, is performed in a doctor's rooms under local anaesthetic. The biopsied tissue is sent to Orthocell's laboratory where the tenocytes (tendon cells), are isolated and grown to therapeutic numbers under controlled conditions. Unlike the cartilage cells, the tendon cells are implanted into the affected tendon, approximately 4 – 5 weeks after the initial biopsy, via ultrasound-guided injection under local anaesthetic and does not require surgery.

Figure 18: Tendon cell therapy - method of delivery



Source: Veritas research, company data.

Clinical Evidence

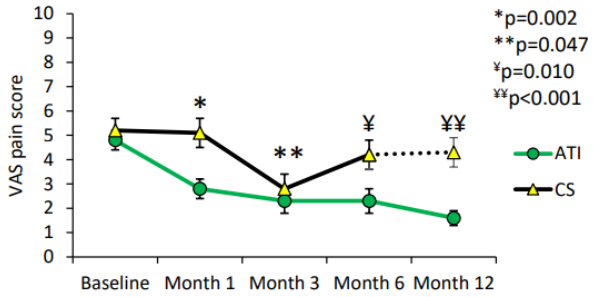
OrthoATI is the only injectable (non-surgical) cell therapy for the repair of tendons with publicly available clinical data to support its use. A search of published literature and the primary international clinical trial registers conducted by Orthocell confirmed there are no registered clinical trials accessing the effectiveness of an autologous cell therapy for the treatment of chronic tendon injuries. More than 1,000 OrthoATI procedures have been undertaken in Australia since 2010.

Orthocell has numerous published studies including clinical data up to 4.5 years post treatment in peer-reviewed journals such as the American Journal of Sports Medicine demonstrating efficacy and durability of this novel treatment option.

Orthocell recently completed a multicentre, randomised controlled trial comparing the tendon cell therapy to steroid injections for the treatment of rotator cuff tendinopathy (link). OrthoATI patients experienced almost complete resolution of pain (VAS score <3) by month 1 post-treatment, which was sustained for over 12 months (Figure 19).

Participants receiving a steroid injection had no meaningful improvement in function, and only a transient improvement in pain by 3 months post-treatment, which returned to pre-treatment levels by 12 months. Over half of study participants who received steroids withdrew early due to treatment failure.

Figure 19: Visual analogue scale pain assessment score: OrthoATI (green) vs. cortical steroids (black)



.5Source: Veritas research, company data.

Orthocell is also conducting a clinical trial using tendon cell therapy for the treatment of tennis elbow. The randomised clinical study compares the tendon cell therapy to surgery for the repair of lateral epicondylitis. The study is fully recruited, and the last patient received treatment in May 2022. Data will be released following the last patient 12 month follow up. The study is an important prerequisite for Australian reimbursement and listing on the Australian Register of Therapeutic Goods (ARTG).

The market opportunity and commercialization plan

We estimate cell therapy could be applicable to >480,000 rotator cuff patients per year in the US alone, which equates to a market opportunity of approximately US$4-5 billion. We estimate the global market for OrthoATI is US$7.7bn.

The Company continues to progress its Australian and US plans for this pipeline product. Following completion of the tennis elbow study, the Company plans to submit an application to the TGA for Australian regulatory approval. In addition, the Company is evaluating US third party manufacturers, FDA engagement and commercial preparation activities to prepare for a potential randomised controlled study under FDA supervision.

Orthocell's tendon cell therapy is an attractive prospect as it is less invasive and has a much larger addressable market than OrthoACI. However, as the tendon cell therapy is considered to be a drug, rather than a device, the clearance process is likely to take longer than for CelGro. This is because the FDA requires three stages of clinical trials prior to conditional clearance with hundreds of patients and a US based current Good Manufacturing Practice (cGMP) production facility. It is not practical to ship cells to and from US patients from the Australian cGMP facility.

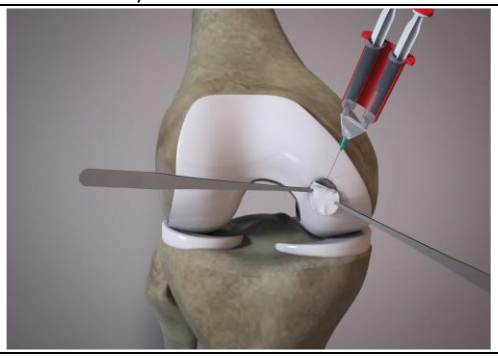
OrthoACI – cartilage repair

OrthoACI is an autologous chondrocyte cell therapy provided to patients in Australia to treat cartilage defects in the knee and ankle. OrthoACI is listed on the Australian Register of Therapeutic Goods (ARTG) and was the first autologous cell therapy to be approved for use in Australia. To date Orthocell have provided over 550 patients with OrthoACI.

How it works

OrthoACI is a two-step process. First, a biopsy of healthy articular cartilage is collected from the patient using keyhole surgery, and sent to Orthocell's laboratory, where the chondrocytes are cultured for approximately 5 weeks to increase cell numbers to therapeutic levels. Then, the cells are loaded onto CelGro, which is then implanted into the damaged joint by an orthopaedic surgeon. The newly implanted chondrocytes, loaded onto CelGro, begin regenerating new cartilage.

Figure 20: OrthoACI - Method of delivery



Source: Veritas research, company data.

Orthocell's founders Paul Anderson and Professor Ming Hao Zheng had previously commercialised a cartilage cell therapy (Matrix-induced Autologous Chondrocyte Implantation - MACI) at Verigen AG, which is now owned by Vericel (VCEL-NASDAQ). MACI is a leading cell therapy for the repair of knee cartilage in the US, but Orthocell is the only supplier of cartilage cell therapy in Australia. Vericel shares have risen by nearly 300% over the past five years to a US$1.4bn market capitalisation. The company reported revenue from MACI of US$156m (71% of the total) from an estimated 3,000 treatments over the year to December 2022.

Market opportunity and commercialisation plan

Vericel dominate the knee cartilage repair market where each procedure attracts reimbursement of >US$50k. This potentially creates an opportunity for Orthocell to bring OrthoACI to the US market, which could be more effective than MACI. OrthoATI is currently provided in Australia for cA$7,500 per unit without reimbursement.

Orthocell is currently investigating commercialisation options in Australia, including reimbursement of Ortho-ACI, and a potential pathway to the US market. Vericel – the major player in this market – estimates the total market size as US$3bn as per its February 2023 corporate presentation (link).

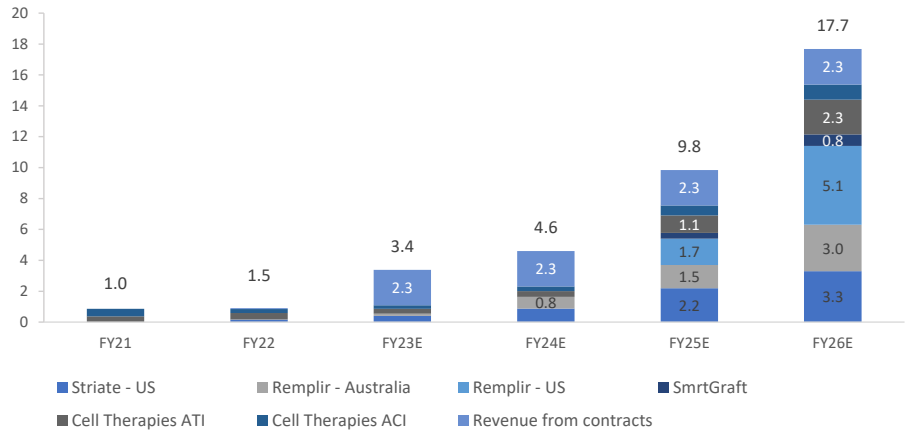
On the cusp of widespread adoption

The wait looks to be over for Orthocell investors. It typically takes 7-12 years for a novel medical treatment to contribute meaningful revenues. It is now 8 years since the Company commenced the pilot CelGro study. With the validation of the CelGro platform from the BioHorizons deal and scale up of manufacturing capacity recently completed the transition to a global medical device manufacturer has begun.

Revenue inflection

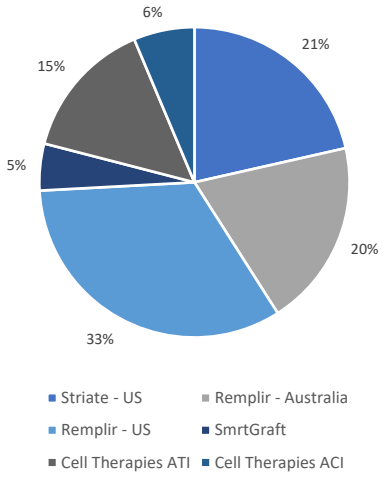
We expect the superior performance of CelGro (Striate+ for dental, Remplir for nerves and SmrtGraft for tendons) versus incumbent devices to spur adoption. We forecast group revenues will grow to $17.7m in FY26 from less than $4m in FY23 (Figure 21). We forecast that the CelGro products will comprise c80% of group revenue by FY26 versus an insignificant amount in FY22 (Figure 22).

Figure 21: Orthocell revenue by product ($m)



Source: Veritas estimates.

Figure 22: Orthocell revenue in FY26E (%)



Source: Veritas estimates. Excludes R&D and corporate costs.

BioHorizons is switching its customers to Striate+

The first Striate+ product was listed in the BioHorizons US product range in November 2022. We estimate that BioHorizons currently sells c50k dental barrier membranes per year which will be gradually switched to Striate+. We anticipate that the superior performance of Striate+ to incumbent products will grow the category for BioHorizons.

The Company has indicated that it is in discussions with Henry Schein (the Biohorizons parent company) to increase distribution to other subsidiaries. We also note BioHorizons is planning a Europe and Australia launch in 4Q23 with an initial focus on establishing key opinion leader accounts in major cities.

We forecast 9k units sold in FY23 rising to 75k units in FY26 due to market share gains driven by superior performance. Whilst Striate+ attracts lower pricing per unit when compared to Remplir, the volumes should assist in driving down COGS per unit. The $23m upfront licence fee received in 1H23 will be recognised as revenue over ten years in line with the term of the agreement (in the revenue from contracts category) and funds the FDA clearance pathway for Remplir.

Remplir growth to take off in Australia following reimbursement

Remplir growth in Australia should accelerate with: Australian reimbursement approval granted at $1,354 per unit in November 2022; Device Technologies appointed as distributor in September 2022 and key opinion leaders increasing using the product in nerve surgeries.

We forecast Remplir Australian sales will increase from 0.2k units in FY23 to 4k units in FY26.

Remplir US entry a major revenue catalyst

The clinical studies required for Remplir US and EU regulatory clearance and reimbursement should commence in coming months. We expect US FDA clearance for Remplir in late FY24 or early FY25.

The Company is preparing for US market access by appointing US based medical executive Dr Ravi Thadhani to the Board and specialist doctors Christopher Dy and David Brogan to the Advisory Board.

Orthopaedic membranes similar to Remplir are attracting significantly higher reimbursement pricing than dental guided bone regeneration membranes. Accordingly, we estimate wholesale pricing for Remplir will be 15-20x higher than Striate+ per unit.

We forecast sales of $1.7m from 2k units in FY25 and $5.1m from 6k units in FY26. For reference we estimate that the Axogen Axoguard is doing around 40k units per year, and we believe Remplir is a better product.

OrthoATI a contributor from FY25 onward

Whilst we believe that OrthoATI could easily be a $15m annual revenue business in Australia alone (assuming reimbursement at $7,500 and c2,000 procedures per year) we do not expect this level of sales until after TGA clearance and reimbursement is obtained which we expect should occur in late FY25.

The US is the $4-5bn revenue opportunity for OrthoATI. Realistically product clearance is likely to take around 5 years. A pre-IND meeting for targeted for November 2023, which maps out the milestones required by the FDA for approval. The cost and timing of the process will not be accurately known until this meeting occurs. The company will most likely need to engage a 3rd party US manufacturing partner before any US clinical trials are conducted due to the infeasibility of using the Australian labs for US patients.

Fully costed to scale CelGro

Increases in revenue should drop through to improved profitability – we expect operating costs to remain in the $12-13m per annum range over the forecast period. Accordingly, we expect the company will reach positive EBITDA and operating cashflow by FY26.

Capex, mostly investments in laboratories required to manufacture CelGro, should ramp up in line with volume to $4.5m by FY26 versus $0.5m in FY22. The capital intensity of the manufacturing process is relatively low due to the high yield on the CelGro source material.

The $23m of cash received from BioHorizons in 1Q23 for the global licence in dental applications gives the company sufficient funding to reach operating cash flow breakeven in FY26. We forecast the cash balance will trough at c$5m in FY25. We do not explicitly forecast a Remplir distribution deal (similar to BioHorizons) despite the expectation that one will occur as the timing and quantum of such a deal is unknown. We expect that such a deal would be more valuable than BioHorizons given the larger addressable market for nerve repair.

The right leadership for the next phase

MD Paul Anderson and Chief Scientific Officer Ming Zheng played an integral role in commercialising Vericel's MACI therapy before founding Orthocell.

The board and executive team of Orthocell contains the right mix of scientific and commercial expertise for the next phase of growth. The key people include:

Paul Anderson, Managing Director, co-founded the company in March 2006. Prior to Orthocell Paul was instrumental in the commercialisation of the MACI cell therapy for Verigen – which is now called Vericel (NASDAQ: VCEL) - as the MD of their Australian subsidiary – where it first received approval globally. Paul's shareholding, held jointly with his wife Nicole Telford, is the largest in the company at 3.5% of shares in issue.

Professor Minghao Zheng, Chief Scientific Officer and co-founder, is a pathologist and the inventor of OrthoATI and the CelGro platform. Professor Zheng led the first TGA approval of ACI implantation (MACI), has seven patents and has published over 200 papers. Professor Minghao was recognised by Genzyme, which was the third largest bio-tech company in the world at the time, for leadership and commitment to the advancement of MACI - the procedure that now underpins Vericel's US$1.4bn valuation. His expertise is finding better ways to treat orthopaedic injuries using cellular and molecular biology. Minghao is the second largest shareholder in the company with 3.5% of the shares in issue.

Dr Stuart Washer, Executive Chairman of Orthocell since April 2014. Stuart has 25 years of ASX listed board experience. He currently also chairs clinic and drug development company Emyria (ASX: EMD) and is a Non-Executive Director of Botanix Pharmaceuticals (ASX: BOT) and Cynata Therapeutics (ASX: CYP). Dr Washer was previously the Chairman of privately held Hatchtech which was sold to Indian pharmaceutical company Dr Reddy's Laboratories (US$9bn market cap) for $279m in 2015.

Leslie Wise, Non-Executive Director (US based) has been with Orthocell since 2020. Leslie also serves as CEO of Evidence Matters which is a consultancy which works with MedTech companies to achieve successful commercialisation. Prior to this Leslie was the Global Director of Reimbursement Biologics at Biomet (now called Zimmer Biomet). Leslie has extensive experience in senior roles at large orthopaedic and pharmaceutical companies leading US market access programs for new products with a focus on reimbursement, evidence generation, clinical research and regulatory aspects.

Dr Ravi Thadhani, Non-Executive Director (US based) was appointed in March 2023. With more than 30 years as a general and specialised physician, researcher, medical administrator and commercialisation adviser, Dr. Thadhani has extensive experience in US regulatory pathways and commercialisation. Dr Thadhani is currently the executive vice president for health affairs of Emory University, executive director of Emory's Woodruff Health Sciences Center, and vice chair of the Emory Healthcare Board of Directors. Most recently Dr Thadhani was a Professor of Medicine at Harvard Medical School and chief academic officer and dean for faculty affairs for Mass General Brigham hospital, where he oversaw a $2.3 billion research enterprise. Dr Thadani has sat as an expert on numerous FDA panels leaving him well placed to guide Orthocell through the process.

Other non-executive directors include: Matthew Callahan, since 2006, with 25 years legal experience predominantly in health technology companies and has developed 5 FDA approved products; Professor Lars Lidgren, since 2007, founder of Scandimed AB which was acquired by Biomet (now called Zimmer Biomet); Qi Xiao Zhou, since 2012, the founder and CEO of Shenzhen Lighting Digital Technology.

Alex McHenry is Orthocell's Chief Operating Officer since 2016. Prior to this Alex had 15 years experience in corporate advisory and management consulting at Deloitte, Arthur Anderson and AKMC Consulting.

Nicole Telford, Orthocell's CFO, is a chartered accountant with 20 years commercial experience in financial controller/group accountant roles including a publicly listed mining company. Nicole was appointed CFO in 2006.

Recent appointments should bolster the transformation into a medical device company:

- Dr Ravi Thadhani was appointed to the operating board on 8 March 2023 to help guide Remplir regulatory clearance and commercialisation in the US.
- Professor Christopher Dy and Professor David Brogan were appointed to the Medical Scientific Advisory Board 23 March 2023 to assist the Company to access the US nerve repair market. Both are recognised as leading peripheral nerve repair surgeons and are based at Washington University and Barnes-Jewish Orthopaedic Center respectively.

An acquisition target

> *"We've got to make sure that we're acquiring something that can move the mission. It would be faster growth areas outside of reconstruction, but still in orthopaedics and that would be mainly in our S.E.T. (Sports Medicine, Extremes and Trauma) category [Veritas note: where Orthocell sits]. So that diversifies our business away from just reconstruction in those faster-growth subcategories of orthopaedics. I don't want to say which of those we're going to prioritize, but just know that all of those vectors are on the table and we're looking at a number of assets in each of those categories."*

Bryan Hanson, Chairman & CEO of Zimmer Biomet on the acquisition of Embody, 2 November 2022.

The acquisition playbook for orthopaedic device companies involves buying devices which solve an un-met clinical need with strong clinical data, FDA clearance and revenue. Orthocell meets these requirements in the following ways:

1) **CelGro has the potential to transform the treatment of sports and trauma injuries:** Sports or trauma injuries are extremely common, yet it is rare to find medical devices which materially improve patient recovery. For instance, many car crash victims remain tetraplegics for life and the success rate from nerve transfer surgery with conventional wraps is not materially different from surgery without. The application of Orthocell's CelGro has been clinically shown to provide superior repair to the standard of care. Orthopaedic device companies such as Zimmer Biomet (NYSE: ZBH, US$26bn) currently generate most of their revenue from low incidence knee (0.8m per year), hip (1.6m per year) and spine reconstructions (0.5m per year). Conditions that can be treated successfully with CelGro have a 3-6x higher incidence (Figure 4).
2) **CelGro outperforms non-bioactive competitor membranes:** CelGro delivers superior performance to incumbent products in guided bone regeneration, nerve repair and tendon repair as demonstrated in clinical and pre-clinical studies outlined earlier.
3) **FDA clearance for CelGro has been awarded in one indication, with more likely:** CelGro has been cleared by the FDA for guided bone regeneration (Striate+). We anticipate clearance for the nerve repair (Remplir) by mid calendar 2024 with tendon repair (SmrtGraft) at a later date. The FDA clearance process for additional indications is relatively lower risk as patient safety has already been established.
4) **We expect the first material revenues from CelGro in FY23:** Historically Orthocell has generated its revenues from cell therapies. The BioHorizons licencing deal should deliver meaningful CelGro revenue for the first time in FY23. Revenue is an indicator of customer acceptance. The quantum of the revenue is less important to a potential acquirer as this can be significantly boosted by the brand name and distribution of the acquirer if the clinical benefits of the product are significantly better than the current standard of care – which we believe is the case for Orthocell. A long-term perspective on valuation is supported by the >90x EV/revenue multiples paid for largely loss-making competitors.

Similar companies are being acquired at >90x revenue

There have been a large number of acquisitions in the Orthopaedic biotechnology sector recently (Figure 17). A high proportion of these are companies with similar products to Orthocell (highlighted in yellow). The valuations of the similar companies – those specialising in regenerative orthopaedics - range between US$250m and US$465m despite revenue of less than or equal to US$3m per year for Embody and Biorez.

Figure 23: Recent transactions in the Orthopaedic bio-technology sector with companies similar to Orthocell highlighted

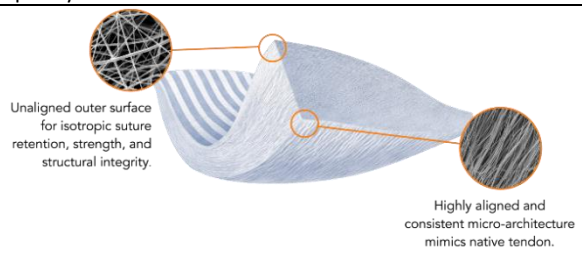
Annoucement	Reason for acquisition	Target	Acquirer	EV (US$m)	EV/Revenue (x)	EV/EBITDA (x)	Revenue (US$m)	EBITDA (US$m)	Margin
Feb-23	No.8 orthopaedic device player acquired by no. 7	**NuVasive**	Globus Medical	3,079	2.5	11.2	1,208	274	23%
Jan-23	Tapestry collagen membrane for healing tendons and ligaments - similar to CelGro (SmrtRope)	**Embody**	Zimmer Biomet	275	91.7	N/A	3	Not disclosed	Not disclosed
Aug-22	Biobrace (pre-clinical) bioinductive collagen scaffold for rotator cuff and ACL repair - similar to CelGro (SmrtRope)	**Biorez**	CONMED	250	104.2	N/A	2.4	-8.76	-365%
Oct-22	Diversifying away from allogenic cell therapies for healing fractures	**Medsenic**	Bone Therapeutics (renamed BioSenic)	39.2	35.6	N/A	1.1	-16.1	-1464%
Jun-22	Agili-C biocompatible scaffold to address osteochondral defects in the knee (competes with OrthoACI)	**Cartiheal**	Bioventus	465	N/A	N/A	Not disclosed	Not disclosed	Not disclosed
May-22	Portfolio of orthopaedic implants	**In2Bones Global**	CONMED	255	6.9	N/A	36.8	Not disclosed	Not disclosed
Mar-22	Bone implants for feet and ankles	**Nextremity Solutions**	Medartis	70	N/A	N/A	Not disclosed	Not disclosed	Not disclosed
Apr-22	Bone allografts and autologous cell therapies for knee cartiledge (competes with Ortho ACI)	**TheraCell**	Isto Biologics	Not disclosed	N/A	N/A	Not disclosed	Not disclosed	Not disclosed
Jan-22	3D printed cementless knee implants	**Engage Surgical**	Smith & Nephew	135	N/A	N/A	Not disclosed	Not disclosed	Not disclosed
Jul-21	Ultrasound based orthopaedic tools and human skin allografts for wound covering	**Misonix**	Bioventus	518	7.0	N/A	74	-4.6	-6%

Source: Veritas research, company data. Note: considerations include earn-outs.

The acquisition of Embody by Zimmer Biomet may be instructive

Embody is the most similar of the recently acquired companies to Orthocell. Zimmer Biomet announced an offer of US$275m (of which $120m is an earn out) for the company in January 2023. Embody generated $3m of revenue in 2022, the first year of commercialisation of its flagship Tapestry product, according to Bioworld (link). Tapestry is an engineered collagen membrane used to support tendon and ligament healing (link). It has the same applications as CelGro but differs in its fabrication. Tapestry is created by electrospinning - a fibre production method that uses electricity and a nozzle to print the fibrous structure. CelGro is created biologically.

Figure 24: Embody's Tapestry membrane is similar to CelGro



Source: Veritas research, company data.

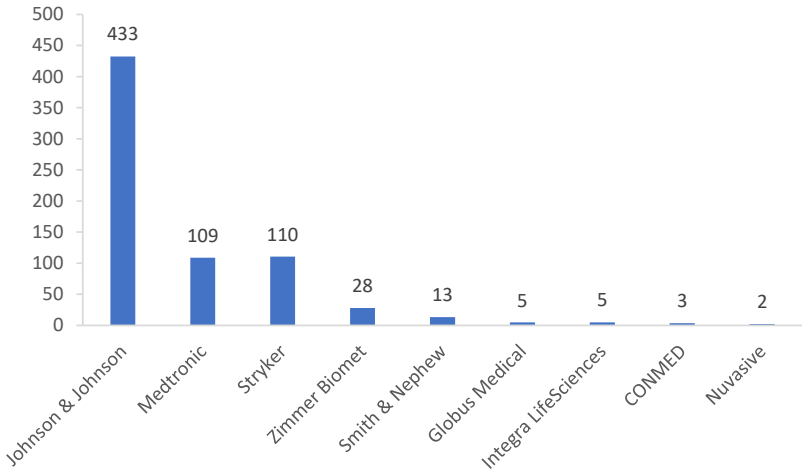
Embody received FDA clearance for the rotator cuff repair product in May 2022 and for tendon and ligament repair in October 2022 – the same indications that Orthocell is targeting with CelGro SmrtRope. The company was acquired by Zimmer Biomet shortly afterward.

Although, to our knowledge, there are no studies comparing the CelGro and Tapestry membranes head-to-head we believe that the biological structure of CelGro may lead to superior cell growth.

Electrospun membranes have been beset by poor cellular infiltration historically according to the journal Biomedical Materials (Maghdouri-White et. al, 2021, link). Additionally, the clinical evidence for the efficacy of CelGro across a range of indications is more established.

We view the Orthopaedic device majors as the most natural acquirers of Orthocell due to significant revenue synergies and subject matter knowledge (Figure 25).

Figure 25: Major Orthopaedic device companies by market capitalisation (US$bn)



Source: Veritas research, company data.

Fair value of 90c per share

Our DCF derived value for Orthocell is 90c per share (Figure 26). The primary assumptions of the DCF include revenue growth fading to 2%, a terminal EBITDA margin of 30% which is inline with the average of orthopaedic device peers, terminal capex to deprecation of 1.0x and a WACC of 10% which is higher than our sector standard of 8% to reflect the risk profile. We expect that tax loss assets will be fully utilised by FY28.

Figure 26: DCF valuation for Orthocell Limited

Year end July	Units	FY24	FY25	FY26	FY27	FY28	FY29	FY30	FY31	FY32	FY33	TV
Revenue	**$m**	**4.6**	**9.8**	**17.7**	**34.1**	**49.7**	**69.6**	**90.5**	**115.8**	**127.4**	**131.2**	**133.8**
Revenue growth	*%*	*35.9*	*113.9*	*79.5*	*92.8*	*45.9*	*40.0*	*30.0*	*28.0*	*10.0*	*3.0*	*2.0*
EBITDA	**$m**	**-7.2**	**-3.5**	**2.8**	**8.2**	**13.9**	**20.9**	**27.1**	**34.7**	**38.2**	**39.4**	**40.1**
EBITDA margin	*%*	*-155.4*	*-35.3*	*16.0*	*24.2*	*28.0*	*30.0*	*30.0*	*30.0*	*30.0*	*30.0*	*30.0*
EBIT	**$m**	**-8.0**	**-4.7**	**0.9**	**6.1**	**11.6**	**18.1**	**23.5**	**30.1**	**33.1**	**34.1**	**34.8**
Tax rate	*%*	*0.0*	*0.0*	*0.0*	*0.0*	*30.0*	*30.0*	*30.0*	*30.0*	*30.0*	*30.0*	*30.0*
NOPAT	**$m**	**-8.0**	**-4.7**	**0.9**	**6.1**	**8.2**	**12.7**	**16.5**	**21.1**	**23.2**	**23.9**	**24.4**
DA	$m	0.9	1.3	2.0	2.2	2.3	2.8	3.6	4.6	5.1	5.2	5.4
Margin	*%*	*18.5%*	*12.7%*	*11.0%*	*6.3%*	*4.5%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*
Working capital	$m	-2.3	-2.2	-1.2	-1.3	-1.0	-0.8	-0.8	-0.8	-0.3	-0.1	0.0
As % of incremental sales	*%*	*-191.4%*	*-41.5%*	*-15.4%*	*-7.8%*	*-6.2%*	*-4.0%*	*-4.0%*	*-3.0%*	*-3.0%*	*-3.0%*	*0.0%*
Capex	$m	-0.7	-1.4	-2.0	-3.2	-3.8	-4.2	-3.6	-4.6	-5.1	-5.2	-5.4
Capex/D&A	*x*	*0.9*	*1.1*	*1.0*	*1.5*	*1.7*	*1.5*	*1.0*	*1.0*	*1.0*	*1.0*	*1.0*
FCF	**$m**	**-10.2**	**-7.1**	**-0.4**	**3.8**	**5.6**	**10.5**	**15.6**	**20.3**	**22.8**	**23.8**	**24.4**
Discount factor	%	91%	83%	75%	68%	62%	56%	51%	47%	42%	39%	
NPV of FCF	**$m**	**-9.3**	**-5.8**	**-0.3**	**2.6**	**3.5**	**5.9**	**8.0**	**9.5**	**9.7**	**9.2**	

Item	Units	Value
NPV of the forecast period	$m	32.9
NPV of terminal value	$m	117.4
NPV of cash flows	**$m**	**150.3**
Plus net cash	$m	26.3
Fair value of equity	**$m**	**176.6**
Fair value of equity per share	**$ps**	**0.90**
Share count	m	197.1

Item	Units	Value
WACC	%	10.0
Terminal growth	%	2.0
Terminal EBITDA margin	%	35.0
Terminal value nominal	$m	304
Terminal EV/EBITDA	x	7.6
Terminal EV/NOPAT	x	12.5

Source: Veritas estimates

Fair value puts Orthocell on 8.5x EV/Revenue in FY26

Orthocell's portfolio is at an earlier stage of adoption than its competitors making peer multiples a less relevant valuation tool. Such multiples are instructive for how Orthocell will be valued when it reaches a stable market share of its addressable indications. We do not expect this to occur for many years.

The BioHorizons licencing deal and the strong evidence for the efficacy of Remplir gives us line of sight on $18m revenue by FY26.

Our fair value of 90c per share puts Orthocell on 8.5x EV/Revenue in FY26. This is broadly inline with where Vericel (7.4x) and Straumann (8.9x) trade one year forward and a significant discount to Polynovo on 18x and Mesoblast on 52x. It is also important to note that early-stage competitors Embody and Biorez were recently acquired for EV/Revenue multiples of 92 and 104x respectively.

The average revenue growth rate of the major orthopaedic device manufacturers is just 4% in FY23. These companies will need to acquire innovation – especially in Orthocell's regenerative orthopaedics space – in order to grow and have the valuations and the cash flows to facilitate this.

Figure 27: Orthocell valuation versus listed peers

Stock	Code	Price	Shares	Mkt Cap	EV	EV/Revenue (x)				EV/EBITDA(x)				Revenue Growth (%)			
		LC m	m	LC m	LC m	FY22	FY23E	FY24E	FY25E	FY22	FY23E	FY24E	FY25E	FY22	FY23E	FY24E	FY25E
Orthocell	OCC-ASX	0.42	197	83	56	36.9	16.7	12.3	5.7					50.5	121.1	35.9	113.9
Vericel Corporation	VCEL-USA	30.70	47.4	1,454	1,382	8.4	7.4	6.0	5.1	46.9	46.8	29.9	20.9	5.2	13.5	22.7	19.1
Straumann Holding AG	STMN-SWX	137.95	159.5	21,997	22,005	9.5	8.9	8.0	7.2	30.9	29.2	25.7	23.0	14.8	6.7	11.5	11.0
NuVasive, Inc.	NUVA-USA	44.15	52.3	2,311	3,069	2.6	2.4	2.3	2.1	11.1	10.1	9.0	8.3	5.5	6.5	6.3	6.6
Integra LifeSciences Holdings Corporation	IART-USA	58.75	81.6	4,796	5,955	3.8	3.7	3.5	3.4	14.5	13.8	13.1	12.2	1.0	3.3	4.8	4.9
CONMED Corporation	CNMD-USA	111.99	30.5	3,416	4,460	4.3	3.7	3.5	3.2	23.6	19.3	16.7	13.4	3.4	14.0	8.1	8.9
Axogen, Inc.	AXGN-USA	10.35	42.6	441	453	3.3	2.9	2.6	2.2			164.2	36.7	8.8	13.0	13.2	13.6
Direct competitor average						**5.3**	**4.8**	**4.3**	**3.9**	**25.4**	**23.8**	**43.1**	**19.1**	**6.5**	**9.5**	**11.1**	**10.7**
Johnson & Johnson	JNJ-USA	165.67	2604.3	431,452	448,892	4.7	4.6	4.5	4.4	13.8	12.9	12.5	11.9	1.2	2.8	2.6	2.5
Medtronic Plc	MDT-USA	82.12	1330.4	109,254	123,665	3.9	4.0	3.8	3.7	12.5	13.3	13.7	12.6	5.2	-2.4	4.4	4.5
Stryker Corporation	SYK-USA	292.78	378.8	110,914	122,512	6.6	6.2	5.8	5.4	25.8	23.8	21.4	19.7	7.8	7.2	7.1	6.7
Zimmer Biomet Holdings, Inc.	ZBH-USA	133.46	210.1	28,035	33,576	4.8	4.7	4.5	4.3	14.6	13.7	12.9	12.2	-11.4	3.0	4.2	4.3
Smith & Nephew plc	SN-LON	11.99	873.4	10,467	12,564	2.9	2.8	2.7	2.6	11.5	11.2	10.3	9.5	12.1	3.4	4.9	5.5
Globus Medical Inc Class A	GMED-USA	59.03	77.9	4,599	4,153	4.1	3.8	3.5	3.2	12.2	11.1	10.0	9.1	6.8	7.8	9.0	8.7
NuVasive, Inc.	NUVA-USA	44.15	52.3	2,311	3,069	2.6	2.4	2.3	2.1	11.1	10.1	9.0	8.3	5.5	6.5	6.3	6.6
Orthopaedic majors average						**4.2**	**4.1**	**3.9**	**3.7**	**14.5**	**13.7**	**12.8**	**11.9**	**3.9**	**4.0**	**5.5**	**5.5**
Polynovo Limited	PNV-ASX	1.72	690.2	1,184	1,189	214.9	18.0	12.2	8.8	1485.7		228.1	52.4	47.0	1094.7	46.9	39.9
Mesoblast Limited	MSB-ASX	1.00	737.1	737	805	54.0	52.4	9.9						45.2	3.2	430.7	
Aroa Biosurgery Ltd	ARX-ASX	1.05	343.1	360	313	8.7	5.3	4.3	3.5		602.5	58.8	21.5	73.3	64.1	22.5	24.3
Local indirect competitor average						**92.5**	**25.2**	**8.8**	**6.1**			**143.4**	**36.9**	**55.2**	**387.3**	**166.7**	**32.1**

Source: FactSet consensus, Veritas estimates. Prices as of market close on 17 April 2023.

A matrix comparing Orthocell with direct and indirect competitor products is shown in Figure 28.

Figure 28: Orthocell competing product matrix

Competitor	Orthocell product	Competitor product
Direct competitors (same indications)		
Straumann Group	CelGro Striate+	Membrane Flex
Integra Lifesciences	CelGro Remplir	Neurawrap
Axogen	CelGro Remplir	Axoguard
CONMED	CelGro SmrtRope	Biobrace
Zimmer Biomet (Embody)	CelGro SmrtRope	Tapestry
Vericel	OrthoACI	MACI
Indirect local competitors (different indications)		
Polynovo	CelGro	NovoSorb skin matrix
Aroa Biosurgery	CelGro	Myriad skin matrix
Mesoblast	OrthoACI	Allogenic cell therapies

Source: Veritas research, company data.

RATING

BUY – anticipated stock return is greater than 10%

SELL – anticipated stock return is less than -10%

HOLD – anticipated stock return is between -10% and +10%

SPECULATIVE – high risk with stock price likely to fluctuate by 50% or more

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