BELL POTTER

19 December 2022

Speculative
See key risks on Pages 18-19 and Biotechnology Risk Warning on Page 22. Speculative securities may not be suitable for Retail Clients.

Analyst
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Authorisation
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Orthocell (OCC)

Nerves, shoulders, knees and toes

Recommendation
Buy (Initiation)
Price
$0.41
Valuation
$0.55 (initiation)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

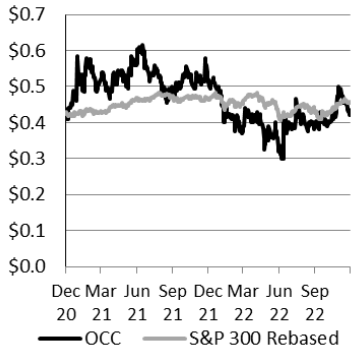
Expected Return	
Capital growth	**34.1%**
Dividend yield	**0.0%**
Total expected return	**34.1%**

Company Data & Ratios	
Enterprise value	**$50.9m**
Market cap	**$79.9m**
Issued capital	**197.2m**
Free float	**91.6%**
Avg. daily val. (52wk)	**$73,663**
12 month price range	**$0.30 - $0.54**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.44	0.40	0.57
Absolute (%)	-4.55	6.33	-25.66
Rel market (%)	-5.16	2.13	-23.08

Absolute Price



SOURCE: IRESS

A platform of proprietary treatment products

Orthocell is a Perth-based biotech company focused on products aimed at treating musculoskeletal diseases and peripheral nerves. While much of the Orthocell branding material uses the term 'regenerative medicine', this description often invokes thoughts of stem cell therapies – although this is not the approach Orthocell takes. Orthocell has two products in market from their proprietary CelGro™ Platform of collagen medical devices – an absorbable collagen membrane used to augment and guide the repair of bone (marketed as Striate+™) and a collagen membrane to repair nerve injuries (marketed as Remplir™) and return function to paralysed upper limbs. Orthocell also markets an approved autologous cell therapy in Australia (using the patient's own cells) aimed at treating damaged cartilage (OrthoACI™).

In July 2022, Orthocell signed a global 25-year exclusive licence and distribution agreement with BioHorizons Implant Systems Inc. (BioHorizons), one of the largest dental implant companies in the world, for Striate+™. Orthocell received AUD$21.5m (USD $14.8m) in consideration of this agreement. We anticipate BioHorizons will supply ~ 2,000 units in FY23, increasing to 100,000+ units per annum by FY28.

In March 2022, Orthocell received market approval by the TGA in Australia for its Remplir™ peripheral nerve repair device. We expect penetration into the market will begin at around 3% (~300 units) in FY23 and ramp up to 30% (~3,000 units) over ten years (with only one other comparable collagen wrap device available). The company is running a clinical trial using Remplir™ for a future FDA regulatory application.

Investment view: Valuation $0.55, Initiate with Buy (Spec.)

We initiate coverage with a Buy (speculative) and a valuation of A$0.55 – a 34.1% expected return on the current share price of $0.41. Valuation is DCF driven and incorporates conservative assumptions around successful growth in the sales and distribution of Striate+™ by BioHorizons in the US commencing in FY23, and the sale and distribution of Remplir™ across Australia, followed by the same in the US in future years. Our model also includes smaller sales from the company's OrthoATI™ product.

Table 1 - Earnings Forecast

June Year End	FY22	FY23e	FY24e	FY25e
Revenues ($m)	1.8	4.3	4.9	13.1
EBIT ($m)	-10.9	-7.8	-9.2	-8.3
NPAT (underlying) ($m)	-9.1	-7.8	-9.2	-8.3
NPAT (reported) $m	-9.1	-7.8	-9.2	-8.3
EPS underlying (cps)	-4.7	-3.9	-4.7	-4.2
EPS growth (%)	nm	nm	nm	nm
PER (x)	nm	nm	nm	nm
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	nm	nm	nm	nm
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield (%)	0%	0%	0%	0%
ROE (%)	-44%	20%	0%	0%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Contents

Company and product overview

Orthocell (ASX:OCC)

Orthocell is a Perth-based biotech company focused on products aimed at treating musculoskeletal diseases. Orthocell has developed two product lines for tissue regeneration – first a collagen medical device (CelGro™ Platform) to augment surgical repair of bone and soft tissue, and secondly, autologous cell therapies that are aimed at treating diseased or damaged tissue, by local implantation or injection 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's products are manufactured at its quality-controlled facility in Western Australia. A facility upgrade to scale-up manufacturing capacity of the collagen medical device to >100,000 units per year is on track. Construction was completed in July, 2022, and final validations expected to be completed in Q4 CY2022.

Co-founders CEO Paul Anderson and CSO Professor Ming Hao Zheng, from the University of Western Australia, have previously commercialized cell therapy based cartilage repair technology together, successfully selling it to a US-based company. Following this, with two promising products in the pipeline, they secured venture capital funding from a Western Australian-based VC firm, along with non-diluted funding from the WA State government, to build the laboratory and fund the clinical trial programs. Orthocell's IPO was in 2014.

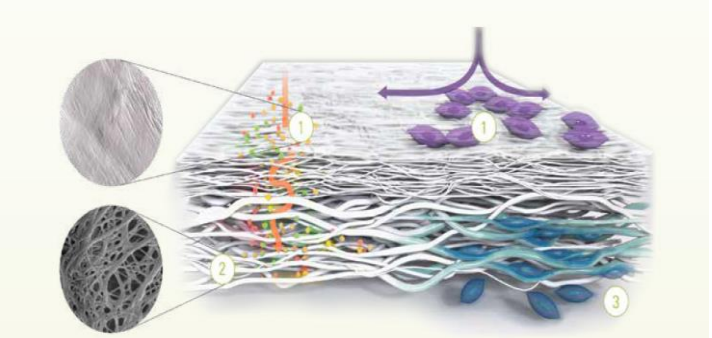
Orthocell has two products in market from their proprietary CelGro™ Platform of collagen medical devices – an absorbable collagen membrane used to augment and guide the repair of bone (marketed as Striate+™) and a collagen membrane to repair nerve injuries (marketed as Remplir™) and return function to paralysed upper limbs. Orthocell also markets an approved autologous cell therapy in Australia (using the patient's own cells) aimed at treating damaged cartilage (OrthoACI™).

CelGro™ Platform Collagen Medical Devices

The CelGro™ platform of collagen medical devices are highly purified porcine (pig)-derived collagen membranes designed to augment surgical repair of bone and soft tissue. CelGro™ is manufactured using a proprietary SMRT™ manufacturing process that preserves the natural collagen structure even following decellularisation (removal of cellular and genetic material). The membranes are completely absorbed by the body after surgical or implantation and can be used alone or combined with cell therapies, to augment the repair of bone, peripheral nerves, and tendon and cartilage defects. The product has distinct competitive advantages over existing tissue repair devices, particularly in the areas of cell compatibility and mechanical strength and handling properties (it is both tensile and strong – making it easy to place and durable).

The design of the membrane prevents the infiltration of cells not involved in the repair, while allowing the passage of smaller bioactive molecules and proteins (growth factors) that stimulate and support the repair process being undertaken by the patient's bone or nerve cells. These relevant cells happily attach to the underside of the collagen membrane, where they proliferate (divide), and the overall placement achieves a 'bioactive chamber', within which the new tissue is supported to form.

Figure 1 - CelGro Platform membrane design



① Striate+ provides a barrier to prevent ingrowth of gingival tissue, while ② allowing passage of nutrients and growth factors. ③ The porous network of collagen fibres promotes cellular attachment and proliferation at the repair site, supporting new bone growth

How it works
CelGro™'s natural bilayer structure, featuring one smooth side and one rough side, acts to both guide new tissue formation and protect the repair site.
Smooth layer – a parallel arrangement of densely packed collagen bundles with abundant pores facilitates the passage of fluids and nutrient molecules, while preventing the invasion of external tissue (non-relevant cells) into the site of repair.
Rough layer – consists of loosely arranged collagen bundles to provide a scaffold to support new cell growth.
Tissue remodelling – cells from the regenerating tissue integrate with the collagen fibres to guide tissue regeneration.

SOURCE: COMPANY

Striate+™

The successful use of dental implants depends on osseointegration (OI) as defined by direct bone-to-implant contact (BIC) and bone tissue growth surrounding the implant. The process of osseointegration must be initiated when the implant is initially placed into a prepared surgical site (in the jaw bone) and then maintained. The process is dependent on sufficient bone volume and healthy bone metabolism. Implants have been shown to be a safe treatment option for the elderly, with similar outcomes to younger patients so long as there is sufficient bone, and with an ageing population worldwide, more elderly patients will receive implants[1]. Clinically, common risk factors for implant failure as a result of progressive marginal bone loss have been identified as bruxism (grinding), poor bone quality, antidepressant medications, proton pump inhibitor medications, smoking, and diabetes[2]. As bone volume is dependent on mechanical forces (chewing with teeth present

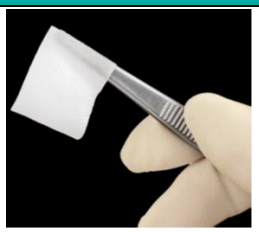
[1] King, S., Klineberg, I., Levinger, I. and Brennan-Speranza, T.C., Archives of Osteoporosis 2016. 11, 29

[2] King, S., Klineberg, I. & Brennan-Speranza, T.C. Calcified Tissue International. 2022. 110, 32–40

in the case of the jaw), it is often the case that a bone graft needs to be first placed into the site where the implant will go, in order to generate new and more bone to achieve successful implant osseointegration. Starting with more robust bone or including a bone graft at the time of implant placement to improve osseointegration, are the most important factors for warding off implant failure.

Once a bone graft has been placed (with or without the implant in place) the site needs a membrane cover to support and protect the bone graft. Enter OCC's Striate+™ (or CelGro™ Dental in Australia), which is a resorbable collagen membrane used for guided jaw bone and tissue regeneration. It is designed to protect the bone defect space from ingrowth of gingival tissue, to provide a favourable environment for robust and high quality osteogenesis (bone formation).

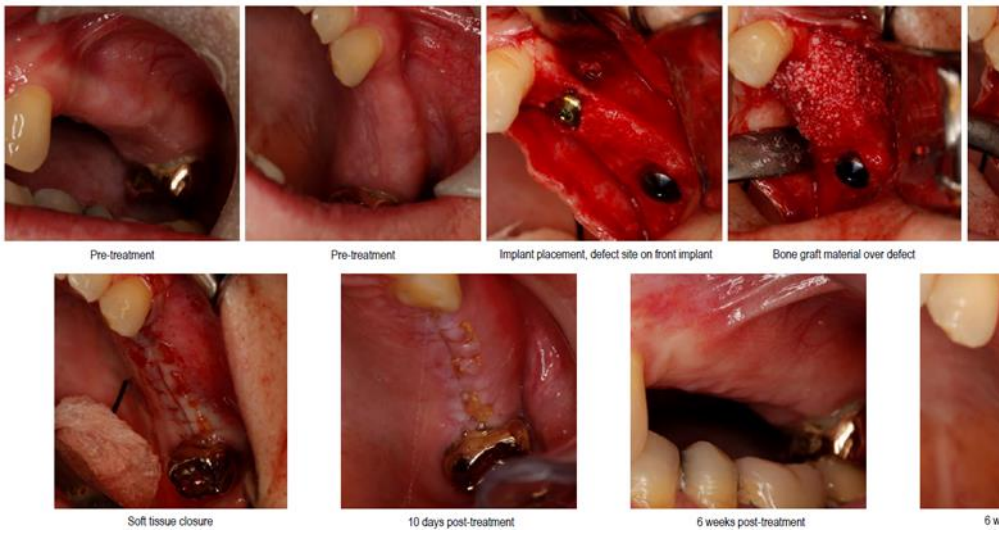
Figure 2 - CelGro Membrane



SOURCE: COMPANY

Figures 3 and 4 below depict real and schematic implant placements at a site with insufficient bone. 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 3 - Photographs of real implant procedure using Striate+ membrane post-graft



SOURCE: COMPANY

SUMMARY OF CLINICAL EVIDENCE

The company performed a clinical study to evaluate the performance of Striate+™ when used as a barrier membrane in Guided Bone Regeneration (GBR) procedures for bone augmentation in dental implant placement. Twenty participants received GBR treatment with Striate+™. Ten participants underwent the conservative two-stage implant procedure (16 implants, Schematic in Figure 4a), and ten participants received single stage implant procedures (11 implants) to assess effectiveness in accelerating treatment timeframes. (Schematic in Figure 4b). The Company announced to the ASX that bone regeneration was successful in all study participants (100% treatment success) undergoing either two stage, or single stage implant procedures. No complications or adverse events were reported.

Figure 4 - Schematic of two-stage and single-stage dental implants with graft and Striate+

Figure 4a: 2-stage procedure with GBR simultaneous with implant placement and Striate+ membrane; wound closure and healing; healing abutment placed 2-4 months after implant placements; crown placement 4 - 6 weeks after healing abutments.

Figure 4b: Single-stage GBR simultaneous with implant placement; wound closure with exposed healing abutment placed; crown placement 3- 4 months later.

SOURCE: COMPANY

REGULATORY STATUS

With clearance for use in Australia (ARTG), the US (FDA 510k) and Europe (CE Mark) in hand, Striate+™ is being used by dentists and oral surgeons both locally and internationally, for building up new bone in the jaw where an implant has been, or will be placed. The Striate+™ membrane, however, is also used for numerous other dental procedures where the jaw bone needs to model new bone. Thus, to date, we are aware of Striate+ being used in the following dental procedures:

- Augmentation around implants placed in immediate extraction sockets;
- Augmentation around implants placed in delayed extraction sockets;
- Localised ridge augmentation for later implantation;
- Alveolar ridge reconstruction for prosthetic treatment;
- Filling of bone defects after root resection, cystectomy or removal of retained teeth;
- Guided bone regeneration in dehiscence defects; and
- Guided tissue regeneration procedures in periodontal defects.

BIOHORIZONS PARTNERSHIP

In July 2022, Orthocell signed a global 25-year exclusive licence and distribution agreement with BioHorizons Implant Systems Inc. (BioHorizons), one of the largest dental implant companies in the world, for Striate+™. Orthocell received AUD$21.5m (USD $14.8m), net of fees in consideration of this agreement. BioHorizons is part of Henry Schein, Inc. (NASDAQ: HSIC) and a leading global provider of dental implants and tissue regeneration products for dentists and dental specialists. The company has a broad product offering, including dental implants, guided surgery, digital restorations and tissue regeneration solutions for the replacement of missing teeth. BioHorizons will purchase Striate+™ units wholesale from Orthocell. Absorbable collagen membranes for dental procedures are available for between $16 (cheap, non-sterile, low quality) and almost $700 depending on quality, efficacy and size. We expect the average retail price per unit of Striate+™ to be ~$200

BioHorizons has been preparing for US market entry with input from Orthocell, by hosting targeted Striate+ education programs. In addition, BioHorizons has been actively promoting the use of Striate+ at key industry meetings. First orders were shipped to BioHorizions in September 2022. Active US sales representation of the product commenced in November, 2022 with an initial focus on existing key accounts.

EXPECTED MARKET SHARE

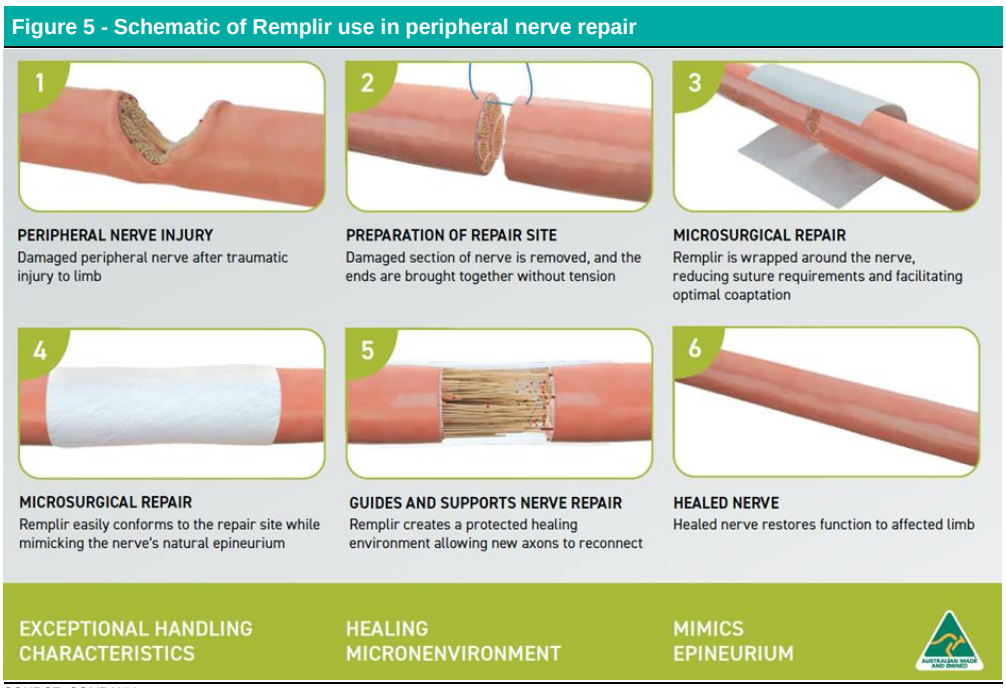
According to iData Research 2021 report, the US resorbable dental barrier membrane market is controlled by five main players – Geistlich ~30%, Zimmer Biomet ~20%, Ace Surgical ~20% (subsidiary of Henry Schein), BioHorizons ~10% (subsidiary of Henry Schein) and Dentsply Sirona ~5%.

The proportion of dental implant procedures performed that require the use of bone grafts has been estimated at between 40% and 50%[3,4]. The estimated total number of bone graft procedures also differs somewhat – with reports of approximately 2.2 million bone graft procedures performed annually across the globe in one citation[4], and higher numbers provided by the iData Research 2021 report[3] – that identified that there were 2 million of these graft + membrane procedures performed in the USA alone in 2021 – and 3.6 million in the US, Australia and Europe combined. For the purposes of our modelling, we will apply a total number of 2 million per annum in the US by FY23, with a 2% annual growth rate, and an initiating market penetration of 1% by BioHorizons (or 2,000 units sold in FY23), increasing to 100,000+ units per annum by FY28.

Remplir™

With millions of peripheral nerve injury repairs performed each year, Orthocell's second CelGro™ product, Remplir™, has the opportunity to make a large dent in the market with current practice limited to the use of traditional sutures on delicate nerve tissue, or non-pliable and difficult to handle tubing used in such repair procedures. Remplir™ is a collagen nerve wrap that is non-adhesive and easy to handle, thereby reducing the requirement for damaging sutures, leading to less scar tissue formation, and provides an optimal environment for the regeneration of previously damaged peripheral nerves. Animal studies have shown that Remplir™ is still visible 5-13 weeks after implantation, but is fully resorbed through normal physiological processes within 26 weeks. Thus, Remplir™ mimics the epineurium (the membrane layer that naturally surrounds our nerves) by providing a barrier to stop non-relevant cells and molecules from invading the site of repair while the neuronal axons grow and regenerate. See Figure 5 below.

Figure 5 - Schematic of Remplir use in peripheral nerve repair



SOURCE: COMPANY

[3] iData Research EU dental membrane use, Dental Implants Market Size, Share & COVID19 Impact Analysis | United States | 2021-2027

[4] MedSuite; and Zhao R, Yang R, Cooper PR, Khurshid Z, Shavandi A, Ratnayake J. Bone Grafts and Substitutes in Dentistry: A Review of Current Trends and Developments. Molecules. 2021 May 18;26(10):3007

SUMMARY OF CLINICAL EVIDENCE

The company performed a clinical study to assess the effectiveness of nerve reconstruction with Remplir™ in 33 upper limb nerve repairs in 19 patients. 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 and toileting), play sport and/or work. Without surgery they would not have regained normal use of their injured arm and hand.

Recovery after treatment was assessed by grading the strength of target muscles[5] closest to the site of nerve repair. Follow up data at 12 months was available for 16 of 19 patients involving 33 nerve repairs. Results showed 76% (25 of 33) of nerve repairs resulted in functional recovery of muscles controlled by the repaired nerve. Follow-up data at 24 months treatment was available for 14 of 19 patients involving 27 nerve repairs. Results showed that 85% (23 of 27) of nerve repairs resulted in functional recovery of target muscles closest to the repair site.

REGULATORY STATUS

In March 2022, Orthocell was given market approval by the TGA in Australia for its Remplir™ peripheral nerve repair device, which saw the inclusion of Remplir™ on the Australian Register of

Therapeutic Goods (ARTG), and inclusion on the Australian Prostheses List (ie, reimbursement approval) in early November 2022.

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. The Company also continues to work with its regulatory advisers, to determine whether an expedited US regulatory approval is possible and what this will mean for reimbursement value for the product.

DEVICE TECHNOLOGIES DISTRIBUTION AGREEMENT

In September 2022, Orthocell appointed Device Technologies ("DVT") as the exclusive distributor of Remplir™ across Australia and New Zealand. DVT is responsible for marketing and distribution of Remplir™ and the first orders were shipped in September.

EXPECTED MARKET SHARE

Australia: According to the AIHW, there were 11,780 surgical repairs of peripheral nerves completed across both public and private hospitals in FY20 (The Australian Institute of Health and Welfare, https://www.aihw.gov.au/reports-data/myhospitals). Meanwhile, an older report from 2014 indicated the number was closer to 5,000 per annum (Grinsell D, Keating CP. 2014. Peripheral nerve reconstruction after injury: a review of clinical and experimental therapies. Biomed Res Int 2014:698256). This translates to an annual incidence of between 0.019% and 0.046%. In our modelling, we have taken the average of these studies to determine the incidence of peripheral nerve injuries that require surgery in Australia and New Zealand, an incidence of 0.033% (or ~9,900 surgical repairs per year).

We expect that, with recent reimbursement approval granted for $1,354 per unit in Australia, and a dedicated distribution partner in Australia, OCC is likely to be receiving approximately half of the retail price for wholesale distribution, which is ~$600-$700 per unit. We also expect that penetration into the market will begin at around 3% (~300 units) and ramp up to 30% (~3,000 units) over ten years (with one other comparable collagen wrap device available for peripheral nerve repair in Australia: NeuraWrap - by Integra, which has been around for over a decade).

[5] 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 (ie., 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.

USA: Studies from The American Society of Anesthesiologists (ASA) Closed Claims Project database in the US found the incidence of pre-operative peripheral nerve injury to be up to 0.11% (Miller's Anesthesia, Chapter 34: Patient Positioning and Associated Risks, Breyer K.E.W., Roth S., Elsevier,

2020), and a retrospective study of 380,680 patients at a single university tertiary care institution, 112 peripheral nerve injuries were observed in the perioperative period, an incidence of 0.3% (Kamel I.R., Drum E.T., Koch S.A., et. al, Anesth Analg 2006; 102: pp. 1538-1542). In our modelling, we have taken the average of these studies to determine the incidence of peripheral nerve injuries that require surgery, that is an incidence of 0.21% or 695,000 peripheral nerve injuries

If the planned pre-clinical trial achieves the primary outcomes, we expect US registration via the 510(k) pathway during FY24 and penetration commencing at just under 1%, climbing to around 10% of the addressable market over ten years. Although our expectation is the 510k pathway, OCC indicates it continues to work with its regulatory advisers, to evaluate higher value opportunities for expedited approval of Remplir for nerve regeneration in the US.

MARKET DYNAMICS AND PRODUCT PERFORMANCE COMPARED TO A PREDICATE

Other players in the US market include Stryker – who has a number of collagen tubes/conduits and wraps in the peripheral nerve repair portfolio; Integra Life Sciences – with a flexible collagen wrap called the NeuraWrap that was approved back in 2004, Collagen Matrix – with NeuroMend®, a collagen wrap and a number of tubular collagen products, as well as AxoGuard® Nerve Protector, a porcine extracellular matrix-derived wrap by AxoGen – who also has a tubing product called AxoGuard® Nerve Connector.

Cell therapies

OrthoACI™

Orthocell is in the process of developing a number of cell therapies for connective tissue repair, including OrthoACI™ - an autologous chondrocyte implantation (using the patients' own cartilage cells) used for the treatment of articular cartilage defects in the knee and ankle - the first of these therapies to be available to patients in Australia. To date, over 550 patients have received the treatment.

Figure 6 - Schematic of the method of administration OrthoATI therapy

SOURCE: COMPANY

HOW IT WORKS

A biopsy of healthy articular cartilage is collected from the patient using keyhole surgery, and sent to Orthocell's Perth laboratories, where the chondrocytes are cultured (proliferated) for approximately 5 weeks. The cells are then loaded via a custom-designed cell delivery scaffold that is implanted into the damaged joint by an orthopaedic surgeon (see figure xx), again employing keyhole surgery. The newly implanted chondrocytes, loaded onto the scaffold, begin regenerating new cartilage.

COMMERCIALISATION PLAN

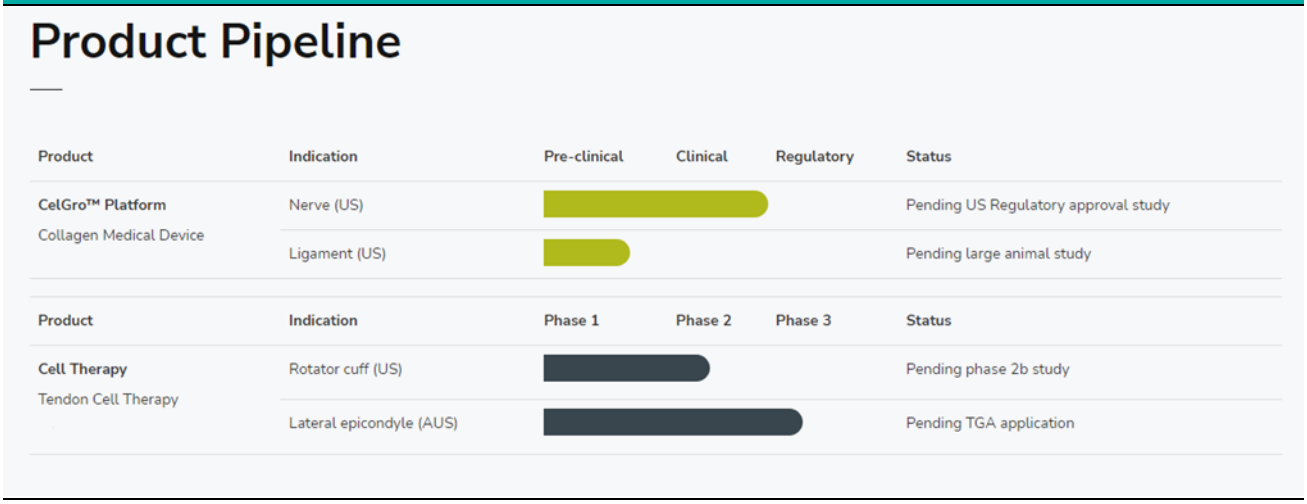
The Company is investigating commercialisation options, including potential reimbursement of Ortho-ACI™ in Australia and a potential pathway to the US market. One publicly traded US-based company, Vericel, with a market cap of approximately US$1B, is the sole provider of autologous cartilage repair in the USA and is currently generating more than US$120 million in annual sales.

Future product pipeline

The company is focused on developing products for US market entry with the pipeline including additional CelGro™ products for nerve and ligament repair, as well as a cellular therapy for the treatment of chronic tendon injuries, initially in the shoulder and elbow. Using the same principals as devised for OrthACI™, an injectable tendon regeneration process, using the patients' own tenocytes (tendon derived cells), for the treatment of tendinopathies (chronic tendon injuries) in the shoulder and the elbow.

Given the product development stage, our valuation model has only included potential revenues from the AUS market.

Figure 7 - OCC's future product pipeline



SOURCE: COMPANY

Valuation and Financials

Valuation

Our valuation of $0.55 is derived from a discounted cash flow model. Due to the company's negative earnings, and low R&D spend per annum (between $5m and $10m p/a), we have deduced that a single, risk-weighted NPV-backed DCF method is the most appropriate method for our valuation model. Increased future earnings for OCC are likely to materialise in the form of non-dilutive wholesale revenue and milestone payments from the company's license and distribution partners, including BioHorizons, as well as direct sales, particularly of the company's cell therapies.

We apply a WACC of 10.3% and have assumed a terminal growth rate of 3%. The company is well funded following the global 25-year exclusive license and distribution agreement with BioHorizons, from which Orthocell received an upfront payment of A$21.5m (USD$14.8m) earlier this year.

Table 2 - DCF for OCC

	30-Jun-24	30-Jun-25	30-Jun-26	30-Jun-27	30-Jun-28	30-Jun-29	30-Jun-30	30-Jun-31	30-Jun-32
Operating cash flow	-11.1	-5.8	2.3	8.3	20.1	25.1	40.2	43.0	59.8
Capex	-0.7	-0.7	-0.7	-0.7	-0.7	-0.7	-0.7	-0.7	-0.7
Free cash flow	-11.8	-6.5	1.6	7.5	19.4	24.4	39.4	42.2	59.1
Present value of cash flows	-11.2	-5.6	1.3	5.3	12.4	14.2	20.8	20.2	25.6
Sum of present values	**83.0**								
Market value of investments									
Net debt/(cash)	-25.5								
Equity value (AUD$m)	**108.5**								
Equity value per share (A$)	$0.55								
WACC calculation									
Risk free rate	4.0%								
Market risk premium	6.0%								
Beta	1.05								
Borrowing rate	5.0%								
Tax rate	30.0%								
Target gearing	0.0%								
Cost of equity	10.3%								
Cost of debt	3.5%								
WACC	10.3%								
Terminal growth rate	3.0%								

SOURCE: BELL POTTER SECURITIES ESTIMATES

POTENTIAL NEXT CATALYSTS FOR INCREASED PRODUCT SALES

- We expect an initiating market penetration in the US for Striate+™ of 1% by BioHorizons (or 2,000 units to be sold in FY23), increasing to 100,000+ units per annum by FY28.
- In relation to sales of Remplir™ in Australia, we expect penetration into the market will begin at around 3% (~300 units) and ramp up to 30% (~3,000 units) over ten years.
- Regarding Remplir™ approval in the US, if the company's pre-clinical trial achieves the primary outcomes, we expect US registration via the 510(k) pathway during FY24 and penetration commencing at just under 1%, climbing to around 10% of the addressable market over ten years.
- OCC has been progressing its US commercialisation plans for OrthoATI™, including investigations into technology scale up, FDA engagement and commercial preparation activities being to support a Phase 2b randomised controlled study for FDA submission.

LISTED PEERS

With 2 distinct markets for OCC's CellGro™ products, the companies we have chosen to compare are either international companies in the dental implant and membrane market, or in the nerve regeneration market; or local ASX listed peers in the cellular regeneration market.

Table 3 - Comparison with listed peers

Code and market	Name	Currency	Market Price	Market Cap ($m)	Price/Book	Enterprise Value
OCC.ASX	Orthocell Ltd.	AUD	$0.41	80.8	8.96	51.8
Local Peers						
OSX.ASX	Osteopore Ltd.	AUD	$0.20	23.45	6.93	19.03
CYP.ASX	Cynata Therapuetics Ltd.	AUD	$0.30	48.00	1.30	24.20
PNV.ASX	PolyNovo	AUD	$1.97	1314.31	72.46	1319.20
ARX.ASX	Aroa Biosurgery	AUD	$1.10	377.00	3.70	376.71
MSB.ASX	Mesoblast	USD	$1.05	762.92	0.97	809.38
International competitors						
ZBH.NYSE	Zimmer Biomet	USD	$121.39	25473.98	2.08	30649.28
SYK.NYSE	Stryker Corporation	USD	$235.62	89165.66	5.42	100892.66
STMN.SWX	Straumann Group	CHF	F104.9	16734.83	9.57	16724.93
IART.NASDAQ	Integra Life Sciences	USD	$54.75	4572.62	2.65	5775.10
AXGN.NASDAQ`	AxoGen	USD	$10.57	446.97	4.40	461.53

SOURCE: BLOOMBERG

International

Zimmer Biomet Holdings Inc. is a US-based (Warsaw, Indiana) publicly listed company that designs, manufactures, and markets orthopedic reconstructive implants, as well as supplies and surgical equipment for orthopaedic, neuro- and oral surgery. The company also services dentists, hospitals, stocking distributors, healthcare dealers, and other specialists, as well as agents, healthcare purchasing organizations, or buying groups. With the acquisitions of Centerpulse in 2003 and Biomet in 2015, Zimmer holds the leading share of the reconstructive market in the United States, Europe, and Japan. Roughly 70% of total revenue is from sales derived of large joints, another quarter comes from extremities, trauma, and related surgical products.

Stryker Corp. is a medical technology products and services manufacturer. It operates in products and devices for medical specialities including: orthopaedics, neurology and spinal medicine. The orthopaedics segment of the company provides reconstructive and trauma implant systems. The surgical segment deals with surgical equipment and navigation systems, endoscopy, patient handling, and reprocessed medical devices. The Neurotechnology and Spine segment pertains to spinal implants and neurovascular products. The company was founded by Homer H. Stryker in 1941 and is headquartered in Kalamazoo, MI, USA.

Integra LifeSciences Holdings Corp. is a global integrated medical device company that manufactures products including implants, instruments and equipment for orthopedic surgery, neurosurgery and general surgery. Integra's orthopedic products include devices, instruments and implants for foot and ankle, hand and wrist, tendon and peripheral nerve protection and repair, wound repair and spineIn the United States, Integra provides surgical instruments to hospitals, surgery centres and alternate care sites, including physician and dental offices.

Axogen Inc. is a medical technology company based in the US that develops, manufactures and markets surgical solutions for peripheral nerve injuries. AxoGen's portfolio of products includes Avance® Nerve Graft, an off-the-shelf processed human nerve allograft for bridging severed nerves without the comorbidities associated with a second surgical site; AxoGuard® Nerve Connector, a porcine submucosa extracellular matrix ("ECM") coaptation aid for tensionless repair of severed nerves; and AxoGuard®

Nerve Protector, a porcine submucosa ECM product used to wrap and protect injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments.

Straumann Holding AG is a Switzerland-based medtech company that produces and markets products for implant and restorative dentistry and oral tissue regeneration. In collaboration with clinics, research institutes and universities, the Group researches and develops implants, instruments, computer-aided design/manufacturing (CAD/CAM) prosthetics and tissue regeneration products for use in tooth replacement and restoration solutions or to prevent tooth loss, as well as training and education services to the dental field, provided in collaboration with the International Team for Implantology (ITI). Its products and services are available in many countries through a network of subsidiaries and technology partners located in Europe, North America, the Asia/Pacific region and in Latin America.

Domestic cell and regenerative therapy peers

Osteopore Ltd. develops, manufactures and markets bioresorbable polymer implants for neurosurgical, orthopedic, and maxillofacial surgery applications. The company focussed on the production of 3D printed bioresorbable implants that are used in conjunction with surgical procedures to assist with the natural stages of bone healing. The company offers Osteoplug, a bioresorbable implant, which is used for covering trephination burr holes in neurosurgery; Osteomesh, a bioresorbable implant that is used in craniofacial surgery to repair various types of fractures, such as orbital floor fracture, as well as to fill surgical defects; and Osteostrip. It operates in Singapore, Korea, Vietnam, and internationally. Listed on the ASX, the company was founded in 2003 and is headquartered in Singapore.

Cynata Therapeutics Ltd. is a stem cell and regenerative medicine company that is involved in the development and commercialisation of mesenchymal stem cell technologies under the brand Cymerus - a proprietary therapeutic stem cell platform technology. The company is investigating its assets for the treatment of: graft-versus-host-disease; osteoarthritis; Acute Respiratory Distress Syndrome; and Diabetic Wounds among other pathologies. The company is based in Australia, listed on the ASX and still in the clinical trials phase.

PolyNovo Ltd. is an Australian medtech company, based in Melbourne, which develops innovative medical devices utilising the patented bioabsorbable polymer technology Novosorb. NovoSorb is a family of proprietary medical grade polymers that can be expressed in a variety of physical formats. NovoSorb polymers have advantageous properties such as biocompatibility and design flexibility, in the treatment of burns, surgical wounds and Negative Pressure Wound Therapy.

Aroa Biosurgery Ltd. is an ASX-listed soft-tissue regeneration company that develops, manufactures, sells and distributes medical and surgical products to improve healing in complex wounds and soft tissue reconstruction. The company develops its products based on its proprietary extracellular matrix technology, enabling the repair of soft-tissue injuries.

Mesoblast Ltd. is a Melbourne-based, ASX-listed stem-cell therapy company that aims to commercialise a stem cell treatment known as remestemcel-L for conditions such as acute graft versus host disease, advanced heart failure and chronic lower back pain due to degenerative disc disease. Mesoblast acquired remestemcel-L from US-based Osiris Therapeutics in 2013. The company's proprietary process selects precursor cells and stem cells from the bone marrow of healthy adults, creating a master cell bank. This cell bank is then expanded into thousands of doses for off-the-shelf use, without the need for tissue matching.

Financials

OCC had a cash balance of A$29m at 30 September 2022. Net operating cash flow for the September FY22 quarter was +$18.8 million, primarily related to the $21.4m received from BioHorizons and ~$2m spent on R&D. We are expecting the company to generate revenues of ~$4m in FY23, ~$5m in FY24, and $13m in FY25. Our model indicates a breakeven EBITDA in FY26, and positive EBITDA and NPAT in FY27.

Table 4 - Cash balance, EBITDA and NPAT for OCC FY22 - FY28

	Jun-22	Jun-23	Jun-24	Jun-25	Jun-26	Jun-27	Jun-28
Cash ($m)	11.0	25.5	13.7	7.2	8.8	16.4	35.8
EBITDA ($m)	-11.3	-7.4	-8.9	-8.0	0.0	7.8	18.0
NPAT ($m)	-9.1	-7.8	-9.2	-8.3	-0.3	7.4	17.6

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

We note the balance sheet forecast is for negative net equity in FY24 and FY25. This was a consequence of the Company's accounting for the BioHorizons upfront payment spread over four years. We do not expect the company will require further capital from shareholders in the short term.

Board of Directors

Dr Stewart James Washer (Ph.D) – CHAIRMAN

Stewart has 25 years of CEO and ASX Board experience in medical technology and biotech companies. He is currently the Chairman of Emyria Ltd (ASX:EMD), Director of Botanix Ltd (ASX:BOT) and Director of Cynata Therapeutics Ltd (ASX:CYP).

Stewart was previously the CEO of Calzada Ltd (ASX:PNV), the founding CEO of Phylogica Ltd (ASX:PYC) and before this, he was CEO of Celentis and managed the commercialisation of research from AgResearch in New Zealand with 650 Scientists and $130m revenues. This included a number of nutraceutical products. He was also a founder of a NZ$120m New Zealand based life science fund and Venture Partner with the Swiss based Inventages Nestlé Fund. He was an Investment Director with Bioscience Managers.

Stewart has held a number of Board positions in the past including Founding Chairman of Hatchtech Pty Ltd that sold in 2015 for A$279m, Director of iCeutica Pty Ltd that sold to a US Pharma and a Director of AusBiotech Ltd, the Federal industry body. He was also a Senator with Murdoch University.

Mr Paul Anderson – Managing Director and CEO

Paul has over 20 years' experience in the medical device and cellular therapeutic fields with expertise in bridging the gap between research and clinical practice in the development of emerging medical technologies. This encompasses applying the regulatory framework to the product, navigating regulatory and rebate pathways, marketing, sales, developing key opinion leader relationships, strategic and financial planning. Paul has a strong track record with his previous board position with Verigen Australia Pty Ltd, a human cell therapies company.

Professor Lars Lidgren – NON-EXECUTIVE DIRECTOR

M.D., Ph.D. Professor in Orthopedics at the University Hospital of Lund. Professor Lidgren leads a productive regenerative medicine research group at the University Hospital of Lund. The hospital is a member of the ISOC group of worldwide leading hospitals and Professor Lidgren is an honorary member and past president of several major societies. He initiated the worldwide Bone and Joint Decade 2000-2010 and is a successful serial entrepreneur who founded the companies Scandimed (Biomet), Bone Support, AMeC and GWS in Sweden.

Ms Leslie Wise - EXECUTIVE DIRECTOR

Leslie has extensive experience working for both medical device and pharmaceutical companies, including Bristol Myers-Squib, Sanofi, Biomet Orthopedics and AngioDynamics. Ms Wise has developed expertise in reimbursement, value evidence generation, clinical research strategy and frontline regulatory and payer experience.

Leslie regularly engages with leading experts in health technology assessment, health economics and is at the forefront of developing policies that support greater access for medical technologies. In recognition of her expertise, Leslie was re-appointed to the Medicare Evidence Development Coverage and Advisory Committee (MEDCAC) for 2018-2020. She also partnered with Advamed to facilitate the MedTech Value Summit inaugural event in Minneapolis in 2019.

Mr Matthew Callahan - NON-EXECUTIVE DIRECTOR

Matthew is an experienced life sciences executive based in Philadelphia. He is the founding CEO or Executive Director of a number of pharmaceutical and health tech companies including iCeutica Inc, Churchill Pharmaceuticals Inc, Dimerix Biosciences

(ASX:DMX), Emyria (ASX:EMD), Botanix Pharmaceuticals Limited (ASX:BOT) and Orthocell.

He has led the development of four products that have received FDA approval and he has more than 25 years of legal, IP and investment management experience. Mr Callahan has also worked as an investment director for two venture capital firms investing in life sciences, technology and other sectors, and was general manager of Australian listed technology and licensing company ipernica (now Nearmap ASX:NEA), where he was responsible for the licensing programs that generated more than A$120M in revenue and was recently acquired for more than A$1 billion.

Mr Qi Xiao Zhou - NON-EXECUTIVE DIRECTOR

Mr Zhou has 15 years' experience within China as a senior business manager and executive. He has been General Manager of Shenzhen Lightning Digital Technology Co Ltd since 2001, focused on the manufacture and distribution of Semiconductor/Integrated Circuit technology.

Mr Zhou has experience within the public markets in Hong Kong, China and Taiwan and brings to the Board a wealth of business management and business development experience within the Asian regions. In particular Mr Zhou has broad connections and experience in the licensing of technologies into China and licensing into the Asian region.

Table 5 - Directors' status and interests

Name	Position	Shares
Dr Stewart Washer	Executive Charirman	1,127,647
Mr Paul Anderson	CEO and Managing Director	6,862,555
Professor Lars Lidgren	NED	1,236,060
Mr Matthew Callahan	NED	1,229,622
Mr Qi Xiao Zhou	NED	6,197,117
Mrs Leslie Wise	ED	0
Total shares held by internal members		16,653,001
Total shares on issues		197,203,071
% shares held by internal		**8.4%**
Free Float		**91.6%**

SOURCE: COMPANY

Orthocell– description and risks

Company description

Orthocell is a Perth-based biotech company focused on products aimed at treating musculoskeletal diseases. Orthocell has developed two product lines for tissue regeneration – first a collagen medical device (CelGro™ Platform) to augment surgical repair of bone and soft tissue, and secondly, autologous cell therapies that are aimed at treating diseased or damaged tissue, by local implantation or injection 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's products are manufactured at its quality-controlled facility in Western Australia. A facility upgrade to scale-up manufacturing capacity of the collagen medical device to >100,000 units per year is on track. Construction was completed in July, 2022, and final validations expected to be completed in Q4 CY2022.

Co-founders CEO Paul Anderson and CSO Professor Ming Hao Zheng, from the University of Western Australia, have previously commercialized cell therapy based cartilage repair technology together, successfully selling it to a US-based company. Following this, with two promising products in the pipeline, they secured venture capital funding from a Western Australian-based VC firm along with non-diluted funding from the WA State government, to build the laboratory and fund the clinical trial programs. Orthocell's IPO was in 2014.

KEY RISKS

Key risks we consider to be specific to OCC include, but are not limited to:

- **Reliance on partnerships to unlock value and drive sales** – The success of OCC's business model is underpinned by its ability to ultimately attract valuable partnering deals for its products, given OCC lacks the commercial infrastructure to support commercialisation. Our valuation is underpinned, in part, by OCC's ability to attract ongoing valuable partnering deals. Failure to attract partners or to negotiate attractive deal terms as we have postulated will impact our forecasts. So too will failure of these partners to engage with clinicians to drive the sales of the products. OCC has, to date, had success in attracting such partners, but this requirement is ongoing.
- **Regulatory Approval risk** – Both Remplir and OrthoATI (and future products) will be required to be approved for human use by appropriate regulatory agencies (eg FDA, EMA and TGA). The company has shown it is able to successfully navigate these pathways with Striate+, and Remplir in Australia. Successful commercialisation of Remplir in the US is ultimately dependent on getting approval from the FDA to commercially launch the product. OCC is likely to continue to use its regulatory committee to help prepare the regulatory submissions Failure to satisfy regulatory requirements could result in the products failing to reach the market.
- **Financial risk** - The payment from the BioHorizons agreement in 2022 (A$21m) strengthens the balance sheet and reduces the financial risks for the company. This will provide funding for geographic growth, manufacturing facility expansion and R&D (Remplir™ and new cell products). We recognise that the company may still require additional shareholder equity or debt to fund this growth strategy.
- **Intellectual property risk** - Protection of IP is critical to the commercial success of OCC. Current patent portfolio provides protection of the biodegradable collagen composition, its preparation techniques including design features. There is a risk that competitors may be able to compete with OCC by designing around the patent claims.

Our forecasts are dependent on the ability of the company to maintain its current IP and protect ongoing product development.

- **Competitor risk -** There are a number of key competitors within the dental membrane market including Geistlich ~30%, Zimmer Biomet ~20%, Ace Surgical ~20% (subsidiary of Henry Schein), BioHorizons ~10% (subsidiary of Henry Schein) and Dentsply Sirona ~5%. There are fewer (and smaller) competitors in the peripheral nerve repair market. Larger companies in both markets have greater access to resources for ongoing clinical trials and validation studies. Accordingly, it is imperative that OCC continues its efforts in optimising its product pipeline and evaluating its clinical performance. The successful commercialisation of OCC relies upon superior performance of its products as this will drive clinical adoption and revenue growth. If competitors are able to illustrate superiority in valid head-to-head clinical trials, this will significantly affect utilisation of the OCC portfolio.

Table 6 - Financial summary

A$m	FY21	FY22	FY23e	FY24e	FY25e
Year Ending 30 June					
Total Revenues	**1.3**	**1.8**	**4.3**	**4.9**	**13.1**
Revenue growth	36.7%	43.8%	139.4%	12.3%	169.3%
Cost of Sales	-0.6	-0.7	-1.7	-1.9	-5.1
Gross profit	0.6	1.1	2.6	3.0	8.0
GP Margin	0.5	0.6	0.6	0.6	0.6
Research & Development	-7.3	-6.8	0.0	0.0	0.0
Administrative & Corporate	-3.3	-2.2	0.0	0.0	0.0
Sales & Marketing	-1.5	-3.3	0.0	0.0	0.0
Total Expenses	-12.1	-12.4	-10.1	-11.9	-16.0
EBITDA	**-11.4**	**-11.3**	**-7.4**	**-8.9**	**-8.0**
Add back D&A	-0.4	-0.3	0.3	0.3	0.3
EBIT	**-11.0**	**-10.9**	**-7.8**	**-9.2**	**-8.3**
Interest expense	2.4	2.1	0.0	0.0	0.0
Pre tax profit	**-8.6**	**-8.8**	**-7.8**	**-9.2**	**-8.3**
Tax expense	0.0	0.0	0.0	0.0	0.0
NPAT- reported	**(8.6)**	**(9.1)**	**(7.8)**	**(9.2)**	**(8.3)**

Cashflow (A$m)	FY21	FY22	FY23e	FY24e	FY25e
Gross cashflow	**-4.8**	**-6.3**	**15.2**	**-11.1**	**-5.8**
Interest received	0.2	0.1	0.0	0.0	0.0
Interest paid on lease liabilities	0.0	0.0	0.0	0.0	0.0
Operating cash flow	**-4.6**	**-6.3**	**15.2**	**-11.1**	**-5.8**
Payments for plant and equipment	0.0	-0.5	-0.5	-0.5	-0.5
Payments for clinical trials and developme	-0.2	0.0	-0.2	-0.2	-0.2
Investing cash flow	**-0.2**	**-0.5**	**-0.7**	**-0.7**	**-0.7**
Subscription funds received on issue of s	0.0	0.0	0.0	0.0	0.0
Subscription funds received on exercise	0.7	1.6	0.0	0.0	0.0
Share equity costs	0.0	0.0	0.0	0.0	0.0
Lease payments	**0.0**	**-0.1**	**0.0**	**0.0**	**0.0**
Financing cash flow	**0.7**	**1.5**	**0.0**	**0.0**	**0.0**
Cash at start of period	**20.4**	**16.3**	**11.0**	**25.5**	**13.7**
Net change in cash	-4.1	-5.3	14.5	-11.8	-6.5
Cash at end of period	**16.3**	**11.0**	**25.5**	**13.7**	**7.2**

Balance Sheet (A$m)	FY21	FY22	FY23e	FY24e	FY25e
Cash and cash equivalents	16.3	11.0	25.5	13.7	7.2
Trade and other receivables	0.3	23.5	0.9	1.0	2.6
Inventories	0.5	0.6	1.5	1.7	4.6
Other	0.0	0.1	0.1	0.1	0.1
Total current assets	**17.1**	**35.3**	**28.0**	**16.5**	**14.5**
Plant and equipment	0.3	0.9	1.3	1.7	2.1
Right-of-use assets	0.6	0.5	0.4	0.2	0.1
Intangibles	1.3	1.2	1.3	1.4	1.5
Total non-current assets	**2.3**	**2.6**	**3.0**	**3.4**	**3.7**
Total Assets	**19.3**	**37.9**	**31.0**	**19.8**	**18.2**
Trade and other payables	1.0	3.5	4.3	2.4	9.2
Lease liabilities	0.1	0.1	0.1	0.1	0.1
Employee benefits	0.5	0.6	0.6	0.6	0.6
Contract Liabilities	0.0	2.3	2.3	6.9	11.5
Other	0.3	0.3	0.3	0.3	0.3
Total current liabilities	**1.9**	**6.8**	**7.7**	**10.4**	**21.7**
Lease liabilities	0.5	0.4	0.4	0.4	0.4
Employee benefits	0.0	0.1	0.1	0.1	0.1
Contract Liabilities	0.0	20.7	18.4	11.5	0.0
Total non-current liabilities	0.5	21.2	18.9	12.0	0.5
Total Liabilities	**2.5**	**28.0**	**26.5**	**22.4**	**22.2**
Net Assets	**16.9**	**9.9**	**4.4**	**-2.5**	**-4.0**
Issued capital	55.8	57.5	57.5	57.5	57.5
Reserves	6.2	5.9	8.2	10.5	17.4
Accumulated losses	(45.1)	(53.5)	(61.2)	(70.5)	(78.8)
Total equity	**16.9**	**9.9**	**4.4**	**-2.5**	**-4.0**

Valuation Ratios (A$m)	FY21	FY22	FY23e	FY24e	FY25e
Reported EPS (cps)	-4.6	-4.7	-3.9	-4.7	-4.2
Normalised EPS (cps)	-4.6	-4.7	-3.9	-4.7	-4.2
EPS growth (%)	nm	nm	nm	nm	nm
PE(x)					
EV/EBIT (x)	nm	nm	nm	nm	nm
P/NTA (x)	9.2	-20.4	14.2	6.2	2.6
Book Value Per Share (cps)	0.1	0.1	0.1	0.1	0.0
Price/Book (x)	563.2	321.2	447.6	679.9	1,063.2
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	0%	0%	0%	0%	0%
FCF yield %	nm	nm	nm	nm	nm
Net debt/Equity	-111%	548%	-123%	-112%	-111%
Net debt/Assets	-29%	-69%	-31%	-43%	-54%
Gearing	0%	0%	0%	0%	0%
Net debt/EBITDA (x)	1.0	1.2	1.2	1.8	4.5
Interest cover (x)	4.6	5.1	-	-	-

	FY21	FY22	FY23e	FY24e	FY25e
Revenues Analysis					
Sales of goods	1.0	1.5	1.5	1.5	1.5
BioHorizon Striate wholesale revenue	0.0	0.0	0.1	0.5	1.1
Remplir wholesale revenue US	0.0	0.0	0.0	0.0	3.0
Remplir wholesale revenue AUS	0.0	0.0	0.2	0.3	0.4
Revenue from contracts with customers	0.0	0.1	2.3	2.3	6.9

Interim Results	2H21	1H22	2H22e	1H23e
Revenues	0.6	0.8	1.0	2.0
EBIT	-4.4	-4.3	-8.6	-3.4
NPAT	-4.4	-4.3	-7.6	-2.4

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

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