Rules 4.3A

Appendix 4E

Preliminary final report

Name of entity

ORTHOCELL LIMITED

ABN or equivalent company reference

57 118 897 135

Financial year ended ('current period')

30 June 2016

For announcement to the market

	Current year reported amount $	Change up/(down) from previous year $	Change up/(down) from previous year %
Revenues from continuing operations	1,187,212	(503,096)	(29.7%)
Loss from ordinary activities after tax attributable to members	(3,784,864)	42,149	1.1%
Net loss for the period attributable to members	(3,784,864)	42,149	1.1%

Dividends (distributions)	Amount per security	Franked amount per security
Interim dividend	Nil	- ¢
Final dividend	Nil	- ¢
Previous corresponding period	Nil	- ¢

+Record date for determining entitlements to the dividend, (in the case of a trust, distribution)	N/A

The above results should be read in conjunction with the notes and commentary contained in this report.

Management Discussion and Analysis

1. Overview

Orthocell Ltd is a regenerative medicine company dedicated to the development of an important new class of tissue regeneration medical devices, cellular therapies and growth factors for the repair and regeneration of human tendons, ligaments, cartilage and soft tissue defects. Development to date has focused on two main products:

- 'CelGro®' a naturally derived collagen medical device for soft tissue repair currently in use as an augment to rotator cuff repair, guided bone regeneration and repair of articular cartilage; and
- Autologous Tenocyte Implantation ("Ortho-ATI®") for chronic, treatment resistant tendon regeneration.

CelGro® is targeted to a variety of orthopaedic, reconstructive and surgical applications and is being readied for first regulatory approval in Europe in 2016. Orthocell's CelGro® scaffold represents a paradigm shift in soft tissue reconstruction and exhibits a number of qualities that make it ideal for use as a guided tissue reconstruction and soft tissue repair device.

Orthocell's Ortho-ATI® is a unique regenerative treatment that uses a minimally invasive, non-surgical approach that uses each patient's own tendon derived stem cells to stimulate tendon regeneration and is delivered via ultrasound guided injection under local anaesthetic. Published data demonstrates that Ortho-ATI® is a durable disruptive technology facilitating the healing of tendons which are resistant to existing therapies.

Total revenue of the consolidated entity for the year ended 30 June 2016 was 1,187,212 (2015: 1,690,308). The decrease in revenue is largely due to Orthocell discontinuing its role as the Western Australian distributor for Biomet Pty Ltd as of 30 June 2015. The termination of this distributor agreement was due to the acquisition of the Biomet group internationally by Zimmer Holding Inc, which resulted in the Australian distributorships being taken over by Zimmer. Whilst this accounted for a reduction in revenues, this was a non-core business and the corresponding reduction in Biomet-related expenditure meant that the net effect to the company was not material, and there is minimal effect on the Company's performance.

The net loss after tax of the consolidated entity for the year ended 30 June 2016 was $3,784,864 (2015: net loss of $3,742,715). The increase in net loss is mainly due to a ramp up in research and development activities to support the imminent planned approval of CelGro® and working capital requirements in the current period.

2. Principal activities

The principal activity of the economic entity during the financial year was development, clinical trials, sales and marketing of cell therapies and commercialisation of related technologies.

3. Key Events during the year and to the date of this Report

Clinical Development of CelGro®.

CelGro® is a naturally derived collagen medical device that has been developed and manufactured by Orthocell in Australia, to address unmet clinical needs in the orthopaedic and general surgical soft tissue repair market. The global orthopaedic soft tissue repair market was worth approximately $US7 billion in 2013 and is expected to be worth more than $US10 billion by 2020.

The Company has achieved significant progress in the clinical development of CelGro® in 2015/16 by demonstrating that this novel medical device has unique characteristics and competitive advantages over existing tissue repair scaffolds, particularly in the areas of cell compatibility, tensile strength and promotion of quality tissue in-growth and scar-less repair. Orthocell commenced the Rotator Cuff Tendon and Hip Cartilage Study in 2015/16 and also released initial positive safety and tolerability data for the Dental Guided-Bone Regeneration and Rotator Cuff Tendon Studies.

Initial positive safety and tolerability results for the Dental Guided-Bone Regeneration Study

- In November 2015 the Company announced initial positive safety and tolerability results for CelGro® in a pilot clinical study examining the safety and effectiveness of CelGro® for the treatment of bone defects around dental implants. The study is designed to demonstrate the CelGro® can be used as a barrier membrane to allow bone growth without competition from other connective tissue. Initial safety results showed no inflammation or rejection of the CelGro® and excellent compatibility with bone regrowth.

Commencement of the Rotator Cuff Tendon Study and release of initial positive safety results

- Orthocell also received approval in December 2015 for a human clinical study examining the safety and effectiveness of its CelGro® scaffold, to be used as an augment to the surgical repair of the rotator cuff tendon in the shoulder (The Rotator Cuff Tendon Study). The study involves 30 patients in Perth, Western Australia and is being conducted by some of Australia's leading orthopaedic surgeons.
- In June 2016, the Company released positive safety and tolerability results for its CelGro® Rotator Cuff Tendon Study. The interim review included the first 3 patients at 42 days post-operation and showed that the patients had no complications, thereby demonstrating that the scaffold is safe and has been well tolerated with no inflammatory reactions or complications.

Commencement of the Hip Cartilage Study

- Orthocell received human ethics approval to conduct a clinical trial for the use of CelGro® in the treatment and augmentation of articular cartilages surgeries (CelGro® Hip Study). The study is to being conducted in collaboration with a leading Australian orthopaedic surgeon and the St Vincent Hospital, Melbourne. The study involves 25 patients and aims to demonstrate that CelGro® can be used as an augment to hip cartilage surgery and is a safe and tolerable treatment.

Further Patents granted

The Company also received numerous national and international patents during 2015/16 for its world leading regenerative medicine technologies.

CelGro®

- Australian and Chinese patents for CelGro® relating to the method of manufacture of novel bio-scaffolds to aid in the surgical repair of soft tissue injuries such as tendon, cartilage, bone and soft tissue, as well as the delivery of stem cells to relevant surgical sites and is entitled: "Method for Producing a Collagen Membrane and Uses Thereof".
- US and Canadian patents for CelGro® that protects the process of combining tendon stem cells seeded onto collagen based scaffolds for the repair of torn rotator cuff tendons within the shoulder and is entitled "Tenocyte containing Bio-scaffolds and treatments using the same". The patent follows granted patents in Australia, Canada, Singapore, China and New Zealand which together provides a solid IP foundation for both Orthocell's tendon cellular therapy (Ortho-ATI®) and collagen based medical device platform CelGro®.

Ortho-ATI®

- Hong Kong patent for method to manufacture Ortho-ATI® for the regeneration of damaged tendons.

Cell Factory

- In January 2016, Orthocell announced issuance of a US patent for cell-factory derived bioactive molecules for the generation of tissue specific growth factors to enhance tissue regeneration. The innovative intellectual property is focused on the generation of 'tissue specific' growth factors for the regeneration of cartilage and bone.

Successful Equity Capital Raise

In November 2015 the Company raised $4.4m via a placement to selected institutional investors in the US, Australia and, following shareholder approval received on 27 January 2016, from various directors and officers of the Company. The capital raising was via the placement of 8,979,436 fully paid ordinary shares at an issue price of $0.493 per share, being a 15% discount to the 15 day VWAP of the Company's shares traded on the ASX in the 15 trading days prior to the date of the announcement (17 November 2015). The Company also issued investors who participated in the placement free attaching unlisted warrants on the basis of 1.35 warrants for each share issued in the placement.

R&D tax incentive cash refund

In May 2016, Orthocell received an R&D tax incentive cash refund of $1,507,774 for the financial year 2014/2015. The R&D refund strengthened the Company's balance sheet and increased the operational runway during a very active clinical trial program for its collagen platform technology, CelGro® and cellular therapy for tendon regeneration, Ortho-ATI®.

Further development of Ortho-ATI®, the world leading tendon regeneration technology

During 2015/16 the Company released positive results of a workers compensation study and held a significant user group meeting Sydney:

- In October 2015 Orthocell announced the release of new positive results from a study of its tendon cell treatment for tennis elbow in 25 workers compensation patients. The data shows Orthocell's autologous tenocyte injection treatment, Ortho-ATI®, significantly improved the clinical outcomes of patients with long-term tennis elbow degeneration, showing reduced pain and increased functionality enabling patients to return to work. A significant 88% of patients were able to return to work and more than 50% of these returned at full capacity following ATI treatment.
- The Company held its inaugural user group meeting in Sydney. Attendees included 40 leading orthopaedic surgeons, sports physicians, radiologists, physiotherapists and pain clinicians from Australia and New Zealand. The meeting brought together some of Australia's leading doctors to discuss their positive experiences and clinical outcomes which further demonstrated that Ortho-ATI® technology is a safe and effective treatment for degenerate tendons.

Ortho-ACI® developments, the gold standard in articular cartilage repair

Orthocell's regenerative cell therapy treatment, Ortho-ACI® was applied to its first patient in Singapore in November 2015. Singapore is the latest international market Orthocell has expanded Ortho-ACI® into, following its successful entry to Hong Kong earlier this year where the therapy was used on patients with articular cartilage damage within the knee joint.

Orthocell's pipeline product development

The Company progressed its exciting pipeline regenerative medicine technologies in lab grown tendons and cell factory derive growth factors for the repair of tendon, ligament and bone defects. Orthocell has progressed yet another step towards the potential for an off the shelf product for doctors and patients seeking out cost effective treatments to alleviate symptoms that affect their mobility and quality of life.

- The Company partnered in the receipt of an Australian Research Council (ARC) grant of $430,000 to further investigate tendon tissue and develop novel therapies such as the laboratory fabricated tendon project announced by Orthocell in November 2014. The laboratory-fabricated human tendon potentially provides a solution to these significant challenges and meets a significant unmet patient need. More than 150,000 anterior cruciate ligament ruptures occur each year in the USA alone and the laboratory fabricated tendon would be a suitable solution to many of these surgical repairs. There are many additional tendon replacements that are also suitable targets for Orthocell and represent a significant market opportunity;
- Data from a collaborative research project involving centres in Sweden, Australia and India was published in the leading scientific publication Journal of Tissue Engineering and Regenerative Medicine and provides peer reviewed support for a new approach to regeneration of damaged cartilage within joints which is highly complementary to Orthocell's current Ortho-ACI® cartilage repair product;
- The presentation by Orthocell's collaborators of its successful 'cell factory' data at the European Bone and Joint Infection Society in Estoril Portugal September 2015. The data has supported the role of growth factors and extracellular matrix proteins which were derived by the researchers from bone cells cultivated in a cell factory, to be combined with scaffolds, to regenerate serious bone defects.
- In April 2016, the Company announced the publication of a study undertaken by leading researchers in the respected Journal ACS Applied Materials and Interfaces verifying that cell factory derived bioactive molecules in combination with a scaffold promotes bone healing.

MSAB developments

During the September quarter, the Company announced the appointment of Professor Rocky Tuan to its Medical and Scientific Advisory Board (MSAB). The MSAB advises the Company on strategic matters such as clinical research and product development. It provides valuable expertise to Orthocell as it expands its unique tendon and soft tissue specific growth factors and laboratory manufactured human tendons. Dr Tuan is a widely published and respected expert in Regenerative Medicine and stem cells. He is currently the Director of the Centre for Military Medicine Research.

Presentation of clinical trial results at key Australian and International health conferences

During the quarter the company presented at numerous leading national and international congresses further supporting the international interest, safety and effectives of its tendon regeneration product (Ortho-ATI®) and cartilage regeneration (Ortho-ACI®) products, as well as its pipeline products. Presentations included:

- Previously released positive follow up data for the treatment of recalcitrant tendon injuries in the hip (2 year data) and the elbow (4.5 year data) at the 16th Biennial Congress of the South African Sports Medicine Association;
- Positive two year follow up data for Ortho-ACI® treatment for articular cartilage defects of the knee and ankle at two leading regional orthopaedic association annual scientific meetings in

Brisbane (Australian Orthopaedic Association) and Singapore (Singapore Orthopaedic Association);

- Previously announced "tendon outside the body" tendon bioreactor work at the Australian Orthopaedic Association;
- Previously released positive data around its Ortho-ATI® treatment for degenerate tendon and pipeline opportunities at the international stem cell meeting in the US and Barcelona.
- Previously released positive two year follow up data for the treatment of recalcitrant tendon injuries in the hip at the 3rd Melbourne International Hip Arthroscopy meeting.

Investor Roadshows

In March 2016, Paul Anderson (CEO, Orthocell) presented at the 28th Annual Roth Capital Partners conference in California highlighting the Company's progress and confirming that the Company is deal ready and positioned for growth. Mr Anderson also presented during extensive promotional roadshows in Perth (December 2015) and Melbourne and Sydney (April 2016).

4. Future outlook

The Company continues to progress clinical trials for the evidence base development of its market leading biological medical device and cell therapies. The Company is focused on undertaking trials to gain regulatory approvals in the significant US, European and Japanese markets. The Company also continues to grow sales in the Australian and some Asian markets to assist with cash flow needs whilst progressing strategic partnering discussions with US and EU parties to assist in driving products to market.

Near term milestones include:

CelGro®

- European regulatory application (CE Mark) being finalised for submission targeting an approval in 2016
- USA (510k) and Australian (ARTG) regulatory submissions planned for end 2016
- Further clinical trials planned to expand clinical applications including tendon augmentation and repair, guided bone regeneration and nerve repair
- Progressing discussions with strategic and distribution partners in Europe

Ortho-ATI®

- IND being prepared for US Phase 2 tennis elbow study
- Progressing discussions with US and EU potential partners
- Progressing discussions in Japan to leverage abridged approval process for stem cell based therapies

Ortho-ACI®

- Progress discussions in Japan to leverage abridged approval process for stem cell based therapies.

Condensed Income Statement
For the year ended 30 June 2016

	Notes	for the year ended 30 June 2016 $	for the year ended 30 June 2015 $
Operating revenue	**4**	**1,187,212**	**1,690,308**
Operating expenses	**4**	(6,479,850)	(6,590,844)
Profit / (loss) from continuing operations before income tax		**(5,292,638)**	**(4,900,536)**
Income tax benefit		1,507,774	1,157,821
Net profit / (loss) attributable to members of Orthocell Limited		**(3,784,864)**	**(3,742,715)**

Earnings per share	for the year ended 30 June 2016 $	for the year ended 30 June 2015 $
Basic earnings/(loss) per share from continuing operations	(0.04)[(1)]	(0.05)[(1)]
Diluted earnings/(loss) per share from continuing operations	(0.04)[(1)]	(0.05)[(1)]

[(1)] Based on a weighted average number of shares totalling 87,965,279 (ordinary shares) as at 30 June 2016 (2015: 75,657,100 ordinary shares). The Company currently has 91,479,437 ordinary shares on issue.

Condensed Statement of Financial Position
As at 30 June 2016

	Notes	as at 30 June 2016 $	as at 30 June 2015 $
Current assets			
Cash and cash equivalents	**1**	5,181,812	4,774,108
Receivables		185,147	178,377
Inventories		134,161	150,665
Other		58,862	82,052
Total current assets		**5,559,982**	**5,185,202**
Non-current assets			
Property, plant and equipment		289,172	306,129
Intangibles		1,264,030	1,044,802
Total non-current assets		**1,553,202**	**1,350,931**
Total assets		**7,113,184**	**6,536,133**
Current liabilities			
Trade and other payables		736,942	755,863
Employee benefits		338,193	310,395
Other		444,912	235,849
Total current liabilities		**1,520,047**	**1,302,107**
Non-current liabilities			
Other		708,540	850,236
Total non-current liabilities		**708,540**	**850,236**
Total liabilities		**2,228,587**	**2,152,343**
Net assets		**4,884,597**	**4,383,790**
Equity			
Issued capital	**6**	19,359,578	15,302,482
Option reserve		1,026,980	798,405
Accumulated losses		(15,501,961)	(11,717,097)
Total equity		**4,884,597**	**4,383,790**

Condensed Cash Flow Statement
For the year ended 30 June 2016

	Notes	for the year ended 30 June 2016 $	for the year ended 30 June 2015 $
Cash flows from operating activities			
Receipts from customers (inclusive of GST)		924,551	1,266,115
Payments to suppliers & employees (inclusive of GST)		(5,938,693)	(5,647,332)
Receipt from license fee		3,480	270,356
Grants received		119,926	62,058
Interest received		61,844	123,369
R&D tax concession received		1,507,774	1,157,821
Net cash flows from / (used) in operating activities		**(3,321,118)**	**(2,767,613)**
Cash flows from investing activities			
Payments for patent and IP costs		(287,316)	(263,235)
Payments for property, plant and equipment		(40,958)	(56,111)
Net cash flows used in investing activities		**(328,274)**	**(319,346)**
Cash flows from financing activities			
Proceeds from issue of shares		4,426,862	5,014,900
Share issue costs		(369,766)	(621,185)
Net cash flows from financing activities		**4,057,096**	**4,393,715**
Net increase (decrease) in cash held		407,704	1,306,756
Cash and cash equivalents at beginning of period		4,774,108	3,467,352
Cash and cash equivalents at end of period	**1**	**5,181,812**	**4,774,108**

Condensed Statement of Changes in Equity
For the year ended 30 June 2016

	Issued Capital $	Option reserve $	Accumulated losses $	Total equity $
At 30 June 2014	**8,050,570**	**-**	**(7,974,382)**	**76,188**
Issue of shares, net of costs	7,251,912	-	-	7,251,912
Issue of options	-	798,405	-	798,405
Loss for period	-	-	(3,742,715)	(3,742,715)
At 30 June 2015	**15,302,482**	**798,405**	**(11,717,097)**	**4,383,790**
Issue of shares, net of costs	4,057,096	-	-	4,057,096
Issue of options	-	228,575	-	228,575
Loss for period	-	-	(3,784,864)	(3,784,864)
At 30 June 2016	**19,359,578**	**1,026,980**	**(15,501,961)**	**4,884,597**

1. Reconciliation of cash

Reconciliation of cash at the end of the period (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows:	As at 30 June 2016 $	As at 30 June 2015 $
Cash at bank	5,181,812	4,774,108
Cash at bank held on trust	-	-
Total cash at end of period	**5,181,812**	**4,774,108**

2. Non-cash financing and investing activities

No significant non-cash financing and investing activities have occurred during the period.

3. NTA backing

	30 June 2016 $	30 June 2015 $
Net tangible asset backing	0.04[(1)]	0.04[(1)]

(1) Based on shares totalling 91,479,437 (ordinary shares shares) as at 30 June 2016 (2015: 82,500,000 ordinary shares and preference shares). The Company currently has 91,479,437 ordinary shares on issue.

4. Revenue and expenses

	for the year ended 30 June 2016 $	for the year ended 30 June 2015 $
Operating revenue		
Sales and services revenue	666,499	790,430
Finance revenue - interest received	61,844	123,369
Other income	458,869	776,509
Total operating revenue	1,187,212	1,690,308
Operating expenses		
Cost of sales	497,589	652,856
Employment related expenses	3,333,342	3,339,507
Amortisation and depreciation	100,181	59,355
Other expenses	2,548,738	2,539,126
Total operating expenses	6,479,850	6,590,844

5. Dividends paid and proposed

No dividends have been paid or proposed during the year.

6. Issued capital

	for the year ended 30 June 2016 $	for the year ended 30 June 2015 $
Ordinary shares (net of issue costs)	19,359,578	15,302,482
Issued and fully paid	19,359,578	15,302,482

	Number of shares	$
At 30 June 2015	82,500,000	15,302,482
At 30 June 2016	91,579,437	19,359,579

7. Group structure

Companies within the Orthocell Group (all wholly owned) carry out designated activities:

Ausbiomedical Pty Ltd – nil activity

8. After balance day events

No matters or circumstances have arisen since the end of the financial year which significantly affected or may significantly affect the operations of the Company, the results of those operations or the state of affairs of the Company in future financial years.

9. Annual meeting

(Preliminary final report only)

The annual meeting will be held as follows:

Place	Building 191 Murdoch University South Street Murdoch WA 6150
Date	On or before 30 November 2016
Time	11.00am
Approximate date the +annual report will be available	On or before 28 October 2016

Compliance statement

1 This report has been prepared in accordance with AASB Standards, other AASB authoritative pronouncements and Urgent Issues Group Consensus Views or other standards acceptable to ASX.

2 This report, and the +accounts upon which the report is based (if separate), use the same accounting policies.

3 This report does give a true and fair view of the matters disclosed.

4 This report is based on +accounts to which one of the following applies.
(Tick one)

☐	The +accounts have been audited.	☐	The +accounts have been subject to review.
☑	The +accounts are in the process of being audited or subject to review.	☐	The +accounts have *not* yet been audited or reviewed.

Sign here: _____ Date: 31 August 2016
(Managing Director)

Print name: Paul Anderson