Rules 4.3A

Appendix 4E

Preliminary final report

Name of entity

ORTHOCELL LIMITED

ABN or equivalent company reference	Financial year ended ('current period')
57 118 897 135	30 June 2017

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	1,076,588	(110,625)	(9.3%)
Loss from ordinary activities after tax attributable to members	(4,177,416)	392,552	10.4%
Net loss for the period attributable to members	(4,177,416)	392,552	10.4%

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, bone, cartilage and soft tissue. Development to date has focused on two main products:

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

CelGro is targeted to a variety of orthopaedic, reconstructive and general surgical applications and is being readied for first regulatory approval in Europe in 2017. 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 2017 was 1,076,588 (2016: 1,187,212). The net loss after tax of the consolidated entity for the year ended 30 June 2017 was $4,177,416 (2016: net loss of $3,784,864). 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 its collagen medical device platform technology and has advanced regulatory applications for marketing authorisation of CelGro.

Clinical studies in the areas of bone, tendon and nerve repair have demonstrated and confirmed that CelGro is a novel medical device with 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.

CelGro human nerve regeneration study

In October 2016, the Company received ethics approval for a human clinical study examining the safety and performance of its CelGro scaffold, to be used as an augment to the surgical repair of peripheral nerve injuries. In February 2017, the Company released initial positive safety and tolerability results for nerve study demonstrating that the scaffold is safe and has been well tolerated with no inflammatory reactions or complications.

Clinical Development of Ortho-ATI

Research collaboration with DePuy Synthes Products, Inc ("DPS"), a Johnson & Johnson Company

The company's world leading cell therapy for tendon regeneration, Ortho-ATI, was further validated during the year with the announcement in January 2017 of a research collaboration agreement with DePuy Synthes Products, Inc ("DPS"), a Johnson & Johnson Company for its Ortho-ATI stem cell approach for the regeneration of degenerate tendons and ligaments. The study obtained ethics approval in October 2016, has commenced recruitment and will be led by Professor Allan Wang, current President of the Australian Elbow and Shoulder Society, in conjunction with Professor Ming Hao Zheng, Division of Surgery, School of Medicine at the University of Western Australia.

The Company continued the clinical development of its' minimally invasive cell therapy for tendon regeneration receiving ethics approval to conduct a study comparing surgery for severe tennis elbow to Orthocell's Ortho-ATI. The study is being conducted by two of Australia's leading elbow surgeons and follows publication of Orthocell's positive pilot study results announced in April 2015 in the prestigious American Journal of Sports Medicine. Patient recruitment has commenced and the study is designed to show that a single non-invasive treatment of Ortho-ATI is superior or equivalent to the more costly and invasive surgical intervention for the repair of severe, treatment resistant Lateral Epicondylitis. This program will support the continued demonstration of clinical efficacy and the cost effectiveness of Ortho-ATI as a minimally invasive injectable treatment for resistant tendon injuries of the elbow.

Publication of 2-year gluteal tendon data

On 27 February 2017, Orthocell announced the publication of 2-year data for Ortho-ATI in degenerate hip (gluteal) tendons in the Orthopaedic Journal of Sports Medicine. The data shows positive outcomes including reduced pain and increased functionality out to 24 months following Ortho-ATI. This paper further supports Orthocell's Ortho-ATI as a durable, long-term solution for degenerate, treatment-resistant tendons.

Clinical Development of Ortho-ACI®

Orthocell's regenerative cell therapy for cartilage repair, Ortho-ACI was included on the Australian Register of Therapeutic Goods (ARTG). Orthocell's Autologous Chondrocyte Implantation (Ortho-ACI) for cartilage repair and regeneration has previously been approved for sale in Australia pursuant to a TGA issued manufacturing license. Inclusion on the ARTG marks a significant milestone for the Company enabling the commencement of the process for reimbursement and the wider sale and distribution of Ortho-ACI for cartilage repair and regeneration within Australia, Hong Kong, Singapore and New Zealand and other regions. This milestone also represents the first cell therapy for cartilage repair to be included on the ARTG.

Further Patents granted

The Company also received several key national and international patents during 2016/17 for its world leading regenerative medicine technologies. The patents provide important protection of its technologies as Orthocell prepares for registration and commercialisation in global markets.

CelGro

A Singapore patent was granted 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, nerve, cartilage and bone, as well as the delivery of stem cells to relevant surgical sites.

Cell Factory

The Company also announced it had received a European patent for its pipeline 'Cell Factory' technology that produces tissue specific growth factors and bioactive proteins to enhance tissue repair. This IP for cell factory concept is now granted in two key jurisdictions – USA and EU.

Successful Equity Capital Raise

In December 2016 the Company completed a $4 million capital raise via the Placement of 10,000,000 fully paid ordinary shares at an issue price of $0.40 per share. The funds raised from the Placement (after costs) will be used to progress the Company's portfolio of products and for working capital purposes.

R&D tax incentive cash refund

In January 2017, Orthocell received an R&D tax incentive cash refund of $1,947,998 for the financial year 2015/2016. 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.

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

During the year the company presented at numerous leading national and international congresses further supporting the international interest, safety and effectives of its tendon regeneration (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; and
- 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 2017, Paul Anderson (CEO, Orthocell) presented at the 29th 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, Adelaide, Melbourne and Sydney (September 2016) and Hong Kong (February 2017).

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 as required. The Company also intends 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 approval (CE Mark) for use in various dental soft tissue and bone regeneration procedures
- Implement European dental market entry plans including key opinion leader development in key European markets and engagement of strategic partners and distributor/s
- Progress USA (510k), Australian (ARTG) and Japan (PMDA) regulatory submissions for dental soft tissue and bone regeneration, tendon augmentation, peripheral nerve repair and articular cartilage repair
- Progress clinical trials to expand clinical applications including tendon augmentation, peripheral nerve repair, articular cartilage repair and guided bone regeneration
- Progress discussions with strategic partners to drive the CelGro platform technology to markets

Ortho-ATI

- Progress collaborative study with with DePuy Synthes Products, Inc ("DPS"), a Johnson & Johnson Company for its Ortho-ATI stem cell approach for the regeneration of degenerate tendons and ligaments
- Pre-IND meeting with the FDA to determine requirements to register Ortho-ATI in the US for repair of degenerate tendons and ligaments
- Progressing discussions in Japan to leverage abridged approval process for regenerative medicine 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 2017

	Notes	for the year ended 30 June 2017 $	for the year ended 30 June 2016 $
Operating revenue	**4**	**1,076,588**	**1,187,212**
Operating expenses	**4**	(7,202,002)	(6,479,850)
Profit / (loss) from continuing operations before income tax		**(6,125,414)**	**(5,292,638)**
Income tax benefit		1,947,998	1,507,774
Net profit / (loss) attributable to members of Orthocell Limited		**(4,177,416)**	**(3,784,864)**

Earnings per share	for the year ended 30 June 2017 $	for the year ended 30 June 2016 $
Basic earnings/(loss) per share from continuing operations	(0.04)[(1)]	(0.04)[(1)]
Diluted earnings/(loss) per share from continuing operations	(0.04)[(1)]	(0.04)[(1)]

[(1)] Based on a weighted average number of shares totalling 96,958,889 (ordinary shares) as at 30 June 2017 (2016: 87,965,279 ordinary shares). The Company currently has 101,479,437 ordinary shares on issue.

Condensed Statement of Financial Position
As at 30 June 2017

	Notes	as at 30 June 2017 $	as at 30 June 2016 $
Current assets			
Cash and cash equivalents	**1**	5,046,257	5,181,812
Receivables		116,848	185,147
Inventories		88,397	134,161
Other		33,887	58,862
Total current assets		**5,285,389**	**5,559,982**
Non-current assets			
Property, plant and equipment		357,813	289,172
Intangibles		1,515,694	1,264,030
Total non-current assets		**1,873,507**	**1,553,202**
Total assets		**7,158,896**	**7,113,184**
Current liabilities			
Trade and other payables		1,074,700	736,942
Employee benefits		428,074	338,193
Other		376,791	444,912
Total current liabilities		**1,879,565**	**1,520,047**
Non-current liabilities			
Other		566,844	708,540
Total non-current liabilities		**566,844**	**708,540**
Total liabilities		**2,446,409**	**2,228,587**
Net assets		**4,712,487**	**4,884,597**
Equity			
Issued capital	**6**	23,102,888	19,359,578
Option reserve		1,288,976	1,026,980
Accumulated losses		(19,679,377)	(15,501,961)
Total equity		**4,712,487**	**4,884,597**

Condensed Cash Flow Statement
For the year ended 30 June 2017

	Notes	for the year ended 30 June 2017 $	for the year ended 30 June 2016 $
Cash flows from operating activities			
Receipts from customers (inclusive of GST)		986,095	924,551
Payments to suppliers & employees (inclusive of GST)		(6,527,317)	(5,938,693)
Receipt from license fee		2,097	3,480
Grants received		-	119,926
Interest received		35,747	61,844
R&D tax concession received		1,947,998	1,507,774
Net cash flows from / (used) in operating activities		**(3,555,380)**	**(3,321,118)**
Cash flows from investing activities			
Payments for patent and IP costs		(255,538)	(287,316)
Payments for property, plant and equipment		(107,947)	(40,958)
Net cash flows used in investing activities		**(363,485)**	**(328,274)**
Cash flows from financing activities			
Proceeds from issue of shares		4,000,000	4,426,862
Share issue costs		(216,690)	(369,766)
Net cash flows from financing activities		**3,783,310**	**4,057,096**
Net increase (decrease) in cash held		135,555	407,704
Cash and cash equivalents at beginning of period		5,181,812	4,774,108
Cash and cash equivalents at end of period	**1**	**5,046,257**	**5,181,812**

Condensed Statement of Changes in Equity
For the year ended 30 June 2017

	Issued Capital $	Option reserve $	Accumulated losses $	Total equity $
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**
Issue of shares, net of costs	3,743,310	-	-	3,743,310
Issue of options	-	261,996	-	261,996
Loss for period	-	-	(4,177,416)	(4,177,416)
At 30 June 2017	**23,102,888**	**1,288,976**	**19,679,377**	**4,712,487**

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 2017 $	As at 30 June 2016 $
Cash at bank	5,046,257	5,181,812
Cash at bank held on trust	-	-
Total cash at end of period	**5,046,257**	**5,181,812**

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 2017 $	30 June 2016 $
Net tangible asset backing	0.03(1)	0.04(1)

(1) Based on shares totalling 101,479,437 (ordinary shares) as at 30 June 2017 (2016: 91,479,437 ordinary shares). The Company currently has 101,479,437 ordinary shares on issue.

4. Revenue and expenses

	for the year ended 30 June 2017 $	for the year ended 30 June 2016 $
Operating revenue		
Sales and services revenue	529,818	666,499
Finance revenue - interest received	35,747	61,844
Other income	511,023	458,869
Total operating revenue	1,076,588	1,187,212
Operating expenses		
Cost of sales	438,137	497,589
Employment related expenses	3,364,974	3,333,342
Amortisation and depreciation	147,752	100,181
Other expenses	3,251,139	2,548,738
Total operating expenses	7,202,002	6,479,850

5. Dividends paid and proposed

No dividends have been paid or proposed during the year.

6. Issued capital

	for the year ended 30 June 2017 $	for the year ended 30 June 2016 $
Ordinary shares (net of issue costs)	23,102,888	19,359,578
Issued and fully paid	23,102,888	19,359,578

	Number of shares	$
At 30 June 2016	91,579,437	19,359,579
At 30 June 2017	**101,479,437**	23,102,888

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 Corner of Campus Drive & Discovery Way Murdoch WA 6150
Date	On or before 30 November 2017
Time	To be advised
Approximate date the +annual report will be available	On or before 30 October 2017

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 2017
(Managing Director)

Print name: Paul Anderson