







## **Corporate Presentation** Hong Kong February 2017

Paul Anderson Managing Director



## Disclaimer



This presentation prepared by Orthocell Limited ("Company") does not constitute, or form part of, an offer to sell or the solicitation of an offer to subscribe for or buy any securities, nor the solicitation of any vote or approval in any jurisdiction, nor shall there be any sale, issue or transfer of the securities referred to in this presentation in any jurisdiction in contravention of applicable law. Persons needing advice should consult their stockbroker, bank manager, solicitor, accountant or other independent financial advisor.

This document is confidential and has been made available in confidence. It may not be reproduced, disclosed to third parties or made public in any way or used for any purpose other than in connection with the proposed investment opportunity without the express written permission of the Company.

This presentation should not be relied upon as a representation of any matter that an advisor or potential investor should consider in evaluating the Company. The Company and its related bodies corporate or any of its directors, agents, officers or employees do not make any representation or warranty, express or implied, as to the accuracy or completeness of any information, statements or representations contained in this presentation, and they do not accept any liability whatsoever (including in negligence) for any information, representation or statement made in or omitted from this presentation.

This document contains certain forward looking statements which involve known and unknown risks, delays and uncertainties not under the Company's control which may cause actual results, performance or achievements of the Company to be materially different from the results, performance or expectations implied by these forward looking statements. The Company makes no representation or warranty, express or implied, as to or endorsement of the accuracy or completeness of any information, statements or representations contained in this presentation with respect to the Company.

It is acknowledged that the Company will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this presentation except as required by law or by any appropriate regulatory authority.

## **Company Overview**



## Delivering breakthrough products in regenerative medicine

#### Cell therapies:

- ► Ortho-ATI®. World's leading stem cell therapy to regenerate tendons
- ► Ortho-ACI®. 3rd generation arthroscopic cartilage repair
- ▶ Actively engaging strategic partners in US and Japan

#### **CelGro**<sup>®</sup> regenerative medicine collagen device

- ▶ Highest quality collagen scaffold to enhance soft tissue and bone regeneration
- ▶ Platform technology
- ► EU(CE Mark) and US(510K) approvals in progress



## **Corporate Overview**



#### **Experienced team to execute**

CEO	Paul Anderson	<ul><li>Verigen</li><li>Genzyme</li><li>Biomet</li></ul>
CSO	Prof. Ming Hao Zheng	<ul><li>Verigen</li><li>Genzyme</li><li>UWA</li></ul>
Executive Chairman	Dr Stewart Washer	<ul><li>Cynata</li><li>Minomic</li></ul>
Director	Matt Callahan	<ul><li>iCeutica Inc</li><li>Botanix Pharmaceuticals</li><li>Dimerix</li></ul>
Director	Prof. Lars Lidgren	<ul><li>UN Bone and Joint Chair</li><li>Biomet</li><li>Uni. Lund</li></ul>
Director	Qui Xiao Zhoa	<ul><li>Shenzhen Lightning Digital</li><li>Technology Co Ltd</li></ul>

<b>Key Facts</b>	
 ASX	OCC
Share Price	AU\$0.47 (@22nd Feb 2017)
 Ordinary Shares on Issue	101.4 million
 Market Cap	AU\$47 million
 Options & Warrants outstanding	24.3 million
Cash at bank	AU\$8 million (@ 2 Feb 2017)

#### **Shareholding Structure**

Shareholders 3,500

Directors & Management ---- 30%

### **Global Need & Opportunity**



#### Orthocell is deal ready and positioned for growth

#### Ageing population and rising musculoskeletal disorders

- ▶ Demand for safe, efficient, cost effective treatments
- ► Global soft tissue repair market US\$7B in 2013 expected US\$10B by 2020

#### Superior products with compelling clinical evidence

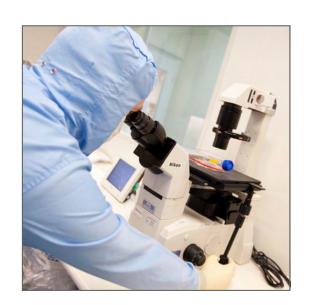
- ► Ortho-ATI® Tendon Regeneration 380 patients treated
- ▶ Ortho-ACI® Cartilage Regeneration 390 patients treated
- ► CelGro® Paradigm shift in soft tissue repair

#### Validated pathway to market and tech transfer ready

> Optimised manufacturing facility in Australia approved for commercial production

#### **Significant partner interest**

- ► Large pharma currently investing/partnering in cell therapies and scaffolds/devices
- ▶ Recent M&A deals show strong interest for innovative treatments



## **Product Pipeline**



#### **Near term regulatory approvals**

Product		Stage of Development			Markets	Regulatory Targets <sup>1</sup>	
	Current Applications/Study		Pre- clinical	Clinical		0-6 months	Thereafter
Ortho-ATI®	Tennis elbow, gluteal, patella, achilles & rotator-cuff				AUS, SG, HK, NZ		PMDA (JP) PreIND (US) ARTG (AUS)
Ortho-ACI®	Knee & ankle cartilage repair				AUS, SG, HK, NZ		Asia Pacific ARTG (AUS)
CelGro <sup>®</sup>	Dental, guided bone, soft tissue regeneration					CE Mark (EU)	FDA (US) ARTG (AUS)
	Rotator-cuif tendon repair						GE Mark (EU FDA(US) ARTG (AUS)
Celaro	Peripheral nerve repair						CE Mark (EU) FDA (US)
	Cartilage repair						CE Mark (EU)
Pipeline	Ligament replacement - ACL, growth factors, lab grown tendor						In developmen

<sup>1.</sup> Orthocell's estimates for regulatory applications



#### **Autologous Tenocyte Implantation**

- ▶ Breakthrough regenerative medicine therapy
- Multiple tendon applications
- ▶ TGA Licence
- ▶ Published long term clinical data





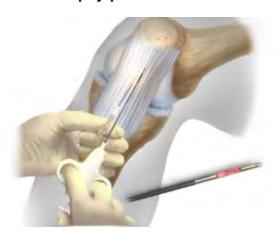
#### **Collaboration with Johnson & Johnson Innovation**

- **▶** Collaboration agreement signed January 2017
- ▶ Cooperative study designed to support US pivotal study
- ▶ Planned to commence in Q1 2017 and will be enrolling 20 patients, randomized to receive either Ortho-ATI® or corticosteroids.
- The trial will be led by Professor Allan Wang, current President of the Australian Elbow and Shoulder Society.
- ▶ The DePuy Synthes companies are part of the Johnson & Johnson Family of Companies
- DePuy Synthes offers the world's most comprehensive portfolio of orthopaedic and neuro products as well as services for joint reconstruction, trauma, spine, sports medicine, neuro, cranio-maxillofacial, power tools and biomaterials.

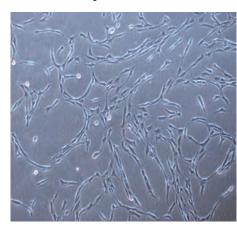


#### Two stage, minimally invasive, walk-in & walk-out process.

1. Biopsy procedure



2. Tenocyte cultivation



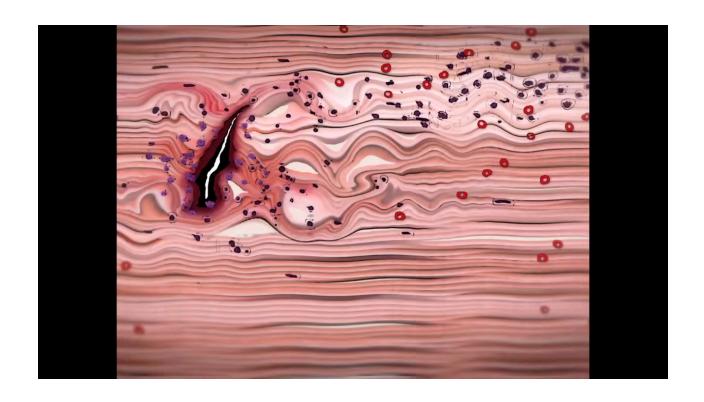
3. Ultrasound guided tenocyte implantation



4-5 week end-to-end process



MOVIE 1.1 Ortho-ATI $^{\rm @}$  and tendon repair





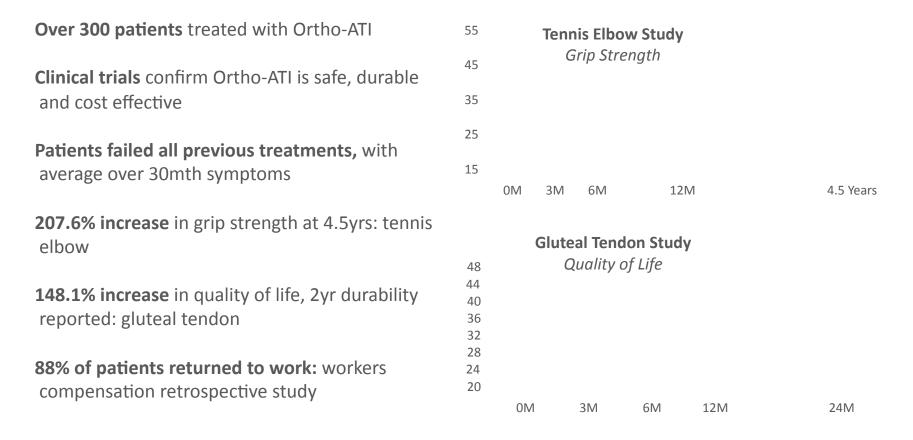
### Only therapy addressing underlying pathology Long term efficacy

	Ortho-ATI®	PRP	Corticosteroids	Surgery
Minimally invasive	✓	1	<b>√</b>	×
Long term durability	1	+/-	×	+/-
Safe	✓	1	+/-	+/-
Cost effective	1	+/-	+/-	X

Total cost of surgery is up to four (4) times more than Ortho-ATI



#### Clinical data supports efficacy and durability





#### Orthocell is tech transfer ready

#### **AUS and US addressable markets**

- ▶ Tennis elbow market >\$850M
- ▶ Rotator cuff market >\$900M

#### **Regulatory targets**

- ▶ US application (IND ) in preparation
- ▶ AUS application (ARTG) in progress
- ▶ JP application (PMDA) commencing

#### **Strategic partnering**

- ▶ Discussions ongoing with US & EU potential partners
- Discussions in Japan underway to leverage abridged approval process

## THE AUSTRALIAN \*\* "How stem cells gave violinist her life back"



Jasmine Trebse got back her mobility six months after Orthocell's treatment. Picture: Colin Murty



## CelGro®

A true regenerative medicine scaffold

- ▶ Highest quality available
- ▶ Multiple applications



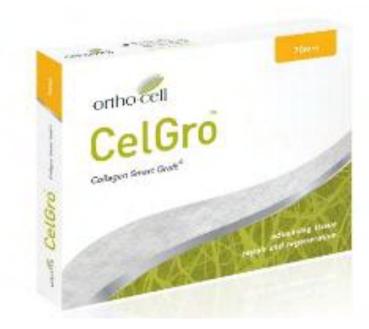
## **CelGro**®



## CelGro® is a true regenerative medicine scaffold manufactured by Orthocell to augment soft tissue

#### A paradigm shift in soft tissue reconstruction

- ▶ Regenerative medicine focus in design and development
- ▶ Highest quality scaffold available that directly meets the requirements of soft tissue reconstruction
- ► Versatile platform with applications in bone, tendon, nerve, MATT and others
- ▶ Cell/scaffold combined product
- ▶ Fit for purpose



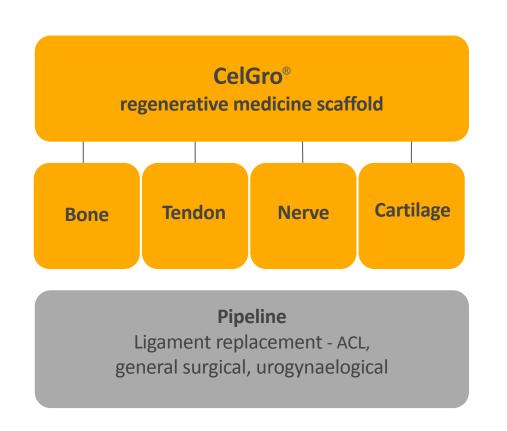
## **Key Benefits and Features**



## CelGro® is a platform technology with significant competitive advantages

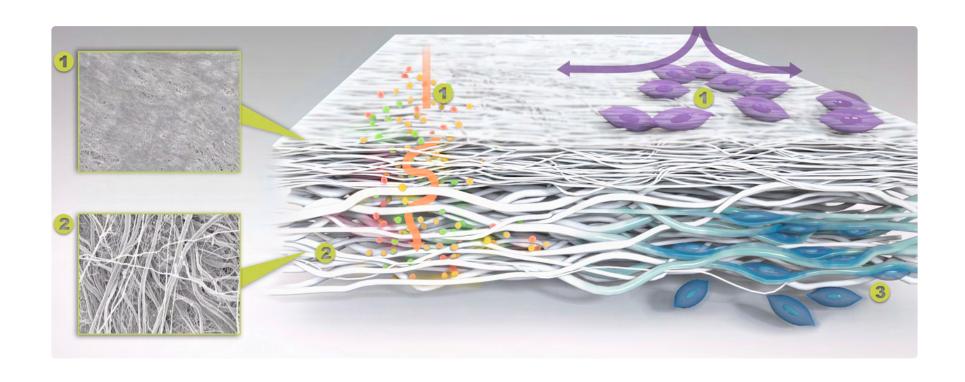
#### Superior soft tissue and bone repair qualities

- ✓ Guided tissue repair / optimal tissue integration and remodelling
- √ Versatile platform
- ✓ Proven compatibility, pure collagen and acellular
- √ High tensile strength
- √ Highest quality raw material globally available



## **How CelGro® Works**





#### 1. Smooth layer

Densely packed collagen Passage of fluids

#### 2. Rough layer

Loosely arranged collagen Applied to tissue defect

#### 3. Tissue remodelling

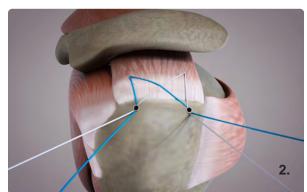
Integration of cells
Guiding quality tissue regeneration

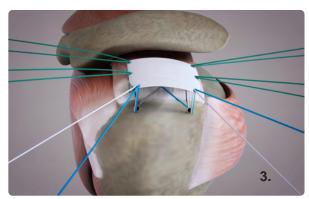
## **Tendon Opportunity**



### **Applications - rotator cuff**









## **Opportunity**



650,000

# annual rotator cuff procedures suitable for Celgro 1. \$1.6 billion

Value of addressable market in rotator cuff surgeries 1.

## **Dental Opportunity**



### **Applications - Dental**

### **Opportunity**











#### 2 million

# annual dental
membranes used in
conjunction with
bone graft
substitutes 1.

# \$800 million

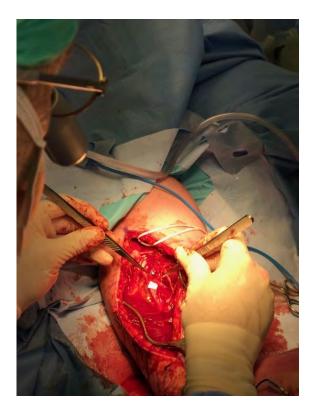
Value of addressable market in dental

1. US. JP. EU & AUS - 2015

## **Nerve Opportunity**



- •Twenty million Americans suffer from peripheral nerve injury caused by trauma and medical disorders
- •\$150 billion spent in annual health-care dollars in the US
- Devastating impact on a patient's quality of life
- •Clear unmet market need for a fit for purpose pure collagen scaffold:
  - ✓ Superior handling qualities
  - **√**Biocompatible
  - **√**Guides nerve regeneration
  - ✓ Accelerates healing



## **Competitors Limitations**

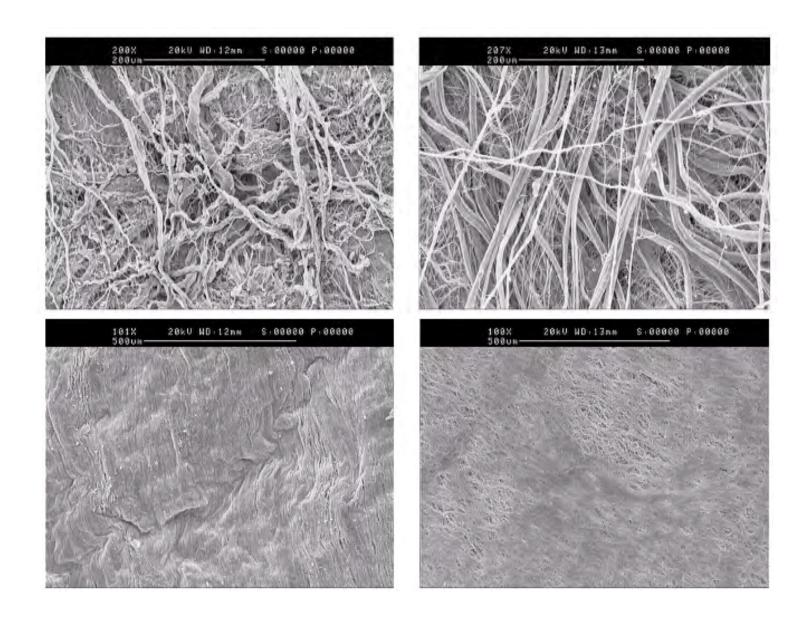


## Competitors limitations include: not fit for purpose, poor integration and limited application

		De	ntal	Tendon		Nerve		
	CelGro®	Biogide® (porcine mesentery)	BioMend Extend® (bovine tendon)	GraftJacket® (human dermis)	Tissuemend® (bovine dermis)	AxoGuard® (porcine s.i.s)	Neuroflex® (bovine tendon)	
Highest quality raw material	<b>√</b>	×	X	×	X	X	X	
Proven compatibility	<b>√</b>	<b>√</b>	+/-	+/-	+/-	+/-	+/-	
Native bi-layer structure	<b>√</b>	<b>√</b>	×	×	X	X	X	
Strong mechanical properties	<b>√</b>	+/-	<b>√</b>	<b>√</b>	<b>√</b>	<b>√</b>	<b>√</b>	
Versatile platform	<b>√</b>	×	×	×	X	X	X	
Superior handling characteristics	<b>√</b>	+/-	+/-	+/-	+/-	+/-	+/-	

## The CelGro® Advantage





### CelGro® - CE Mark



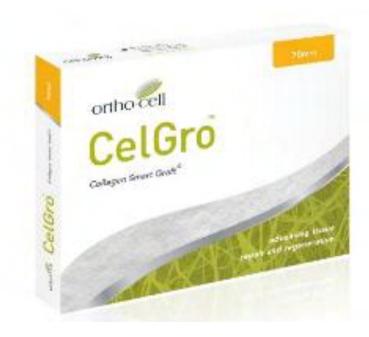
## EU approval for "guided bone regeneration and soft tissue reconstruction" in final stages

**EU approval provides a foundation** for regulatory applications in US (FDA), JP (PMDA) and AUS (ARTG):

- ✓ Tendon
- ✓ Nerve
- ✓ Cartilage

#### **Strategic Partnering & Distribution**

- EU discussion continue for Dental application
- US and Japan commenced



## **Next Generation Pipeline**



#### **Strong product pipeline:**

#### **CelGro**®

- ACL ligament replacement
- collagen powder for bone void fillers

#### **Lab Grown Tendons**

- laboratory manufactured human tendon
- replacement tendons for hands and other applications

#### **Growth Factors**

- tissue specific growth factor 'Cell Factory'
- off the shelf growth factors bone, cartilage and tendon

These pipeline products and concepts are early stage opportunities that require further research and development prior commercialisation



Lab grown tendon

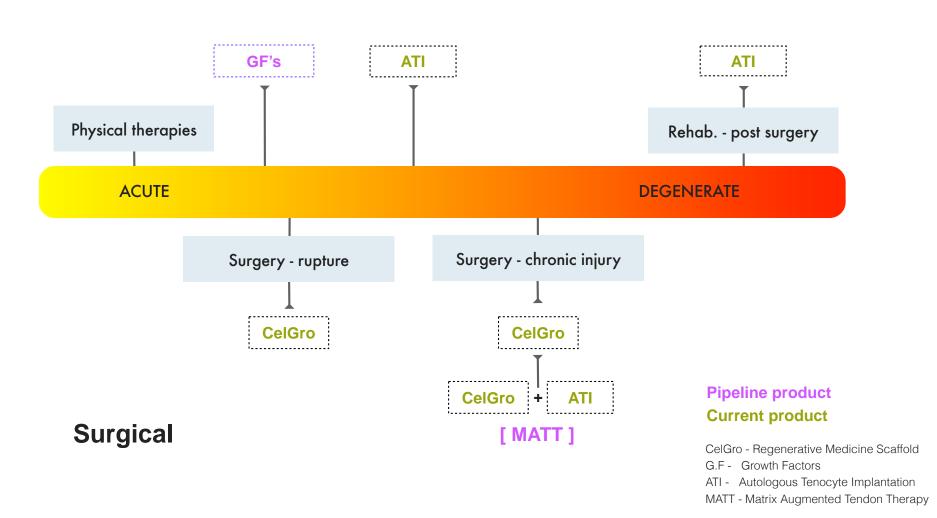


**ACL Ligament Replacement** 

## **Tendon Therapy Continuum**



#### **Non-Surgical**



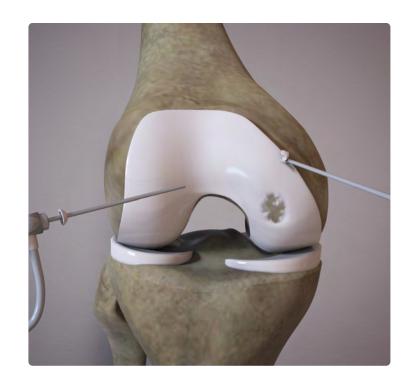


## Ortho-ACI®

**Autologous Chondrocyte Implantation** 

✓ Gold standard cartilage repair

✓ Multiple applications



## Ortho-ACI®



#### Arthroscopic 3<sup>rd</sup> generation autologous chondrocyte implantation

**FDA approves first autologous cellularized scaffold** for the repair of cartilage defects of the knee (December 13, 2016)

**Ortho-ACI** is the gold standard intervention for symptomatic defects of the articulating cartilage of the joints, predominately the knee and ankle (lesions greater than 2cm<sup>2)</sup>

Over 380 patients treated in AUS, HK and SG

**Highly customised**, highest quality cells, lesion-focused treatment therapy

Significantly more cost effective treatment

Therapeutic Goods Administration (TGA) license
MI-19052008-LI-002420-11
Orthocell is the only accredited manufacturer and supplier of
ACI in SE Asia

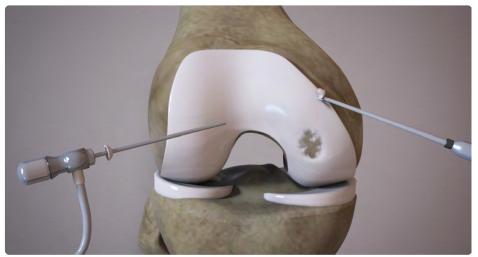


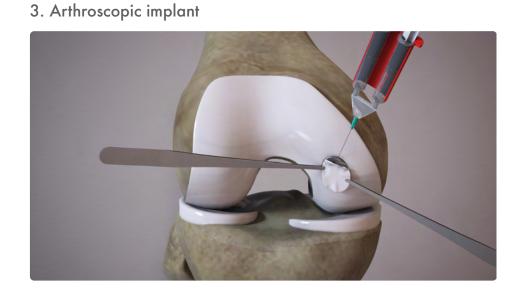


## Ortho-ACI®



#### 1. Biopsy procedure





2. Seeding scaffold in theatre



4. Implant completed



## **Upcoming Milestones**



#### Regulatory applications and approvals

- •CelGro® EU approval for "Guided Bone Regeneration and Soft Tissue Reconstruction"
- •CelGro® Regulatory applications/approvals for Dental, Tendon and Nerve in EU, US, AUS and JP
- Ortho-ATI® Advance US tendon and ligament application (pre IND meeting)

#### Generating further clinical data

- CelGro® dental study completion and publication submission
- •CelGro® interim trial results for tendon, cartilage and nerve studies
- •Ortho-ATI® v Surgery for tennis elbow interim results
- •Ortho-ATI® Gluteal Tendon study and Workers Compensation retrospective study publication

#### **Strategic partnering**

- •CelGro® EU partner/distributor deal for the Dental application
- Ortho-ATI® US/AUS partnering deal
- •Ortho-ATI® and Ortho ACI® Japan partnering/licensing deal

## **Investment Highlights**



- > Superior products
- > Significant de-risked opportunity
- > Clear pathway to large markets
- >> Strong partner interest
- > Expertise to partner and execute









# Advancing tissue repair and regeneration

Paul Anderson Managing Director

