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# NOVEL IMPLANTS THAT FACILITATE BONE & TISSUE REGENERATION

## **Breakthrough Technology**

World first biomimetic implants developed in collaboration with leading research institutions and supported by granted patents.

## **Superior Products**

Superior, commercially ready products for off-the-shelf use by surgeons conducting high volume routine procedures.

## **Craniofacial Regulatory Clearance**





**Department of Health**Therapeutic Goods Administration



A clear focus on developing revenue streams to deliver high margin growth underlies the drive toward sustainable value creation.

## +US\$100Bn Markets

Global expansion underway and distribution partners secured in most major markets to penetrate the US\$3.9bn bone graft and US\$100bn permanent implant sectors.

## **Near-term Growth Catalysts**

Significant opportunity to regain revenue momentum as the effects of COVID-19 diminish.

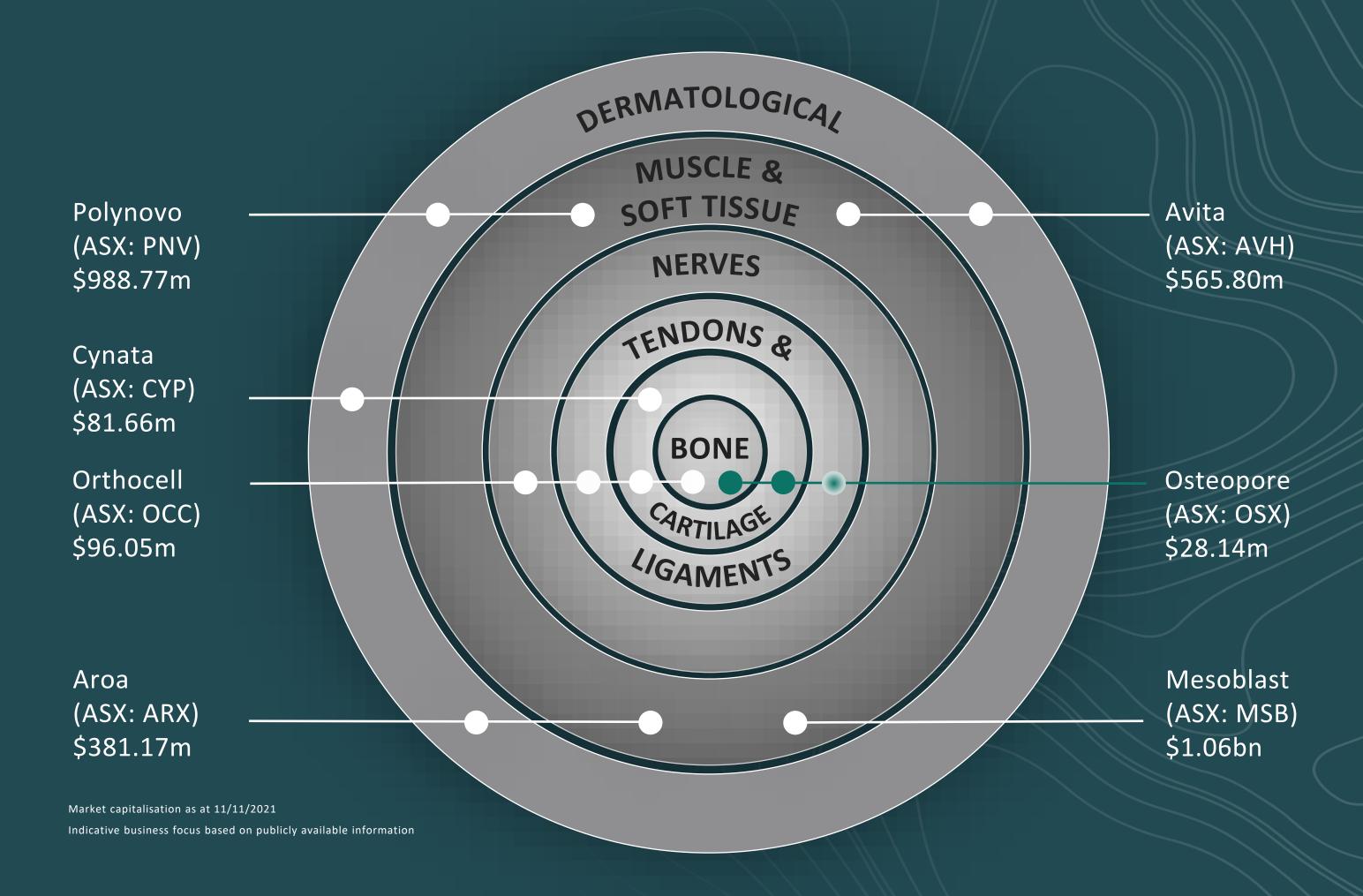


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# ASX REGENERATIVE MEDTECH LANDSCAPE

- Regenerative medicine treats injuries and diseases by harnessing the body's own regenerative capabilities to regrow, repair or replace damaged or diseased cells, organs or tissues.
- Treatments include the generation and use of therapeutic stem cells, tissue regeneration and the production of select artificial organs.

Osteopore is focused on the bone, cartilage and tendon sectors and is the only company using biomimetic scaffolds that dissolve over time leaving only healthy bone and tissue.



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# GROUND-BREAKING UNIVERSITY RESEARCH









University











## LEADERS IN LIFE SCIENCES







MANUFACTURING TECHNOLOGY





# Osteopore®

# STRONG FOCUS ON COLLABORATIVE PARTNERSHIPS

- Product development partnerships
- Cross-promotion sales agreements
- Combining complementary technology

# HOSPITALS AND HEALTHCARE INSTITUTES











# SCIENCE AND INDUSTRY PARTNERS







CAD & AI



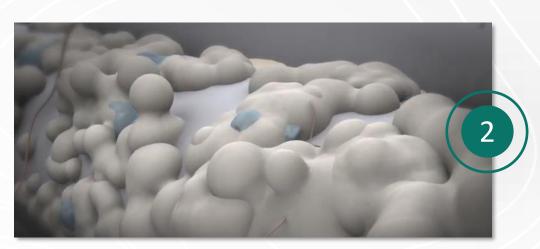
# FOUNDATIONAL PLATFORM TO EMPOWER TISSUE REGENERATION

## Novel process to regenerate bone



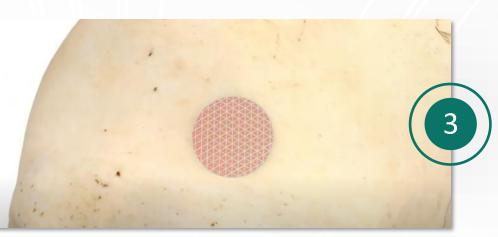
## IMPLANT DRAWS IN BLOOD

Biomimetic microstructures allow blood to be drawn into the implant before inserting into the body.



# BONE GROWS ON SCAFFOLDS

Once in the body the scaffold attracts cells and blood vessels, facilitating bone growth inbetween the microstructures.



## IMPLANT DISSOLVES

The implants naturally and predictably dissolve over a period of 18-24 months to leave only natural healthy bone.



### CRANIOFACIAL & ORAL MAXILLOFACIAL

Multiple products that support craniofacial surgeries for regenerating bone within the head, skull, face and jaw.

### AESTHETIC

Applications for aesthetic surgery procedures that improve the appearance of the face and body.

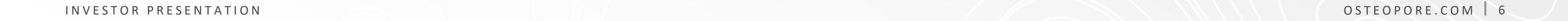
### DENTAL - OMF

Applications that promote vertical bone growth in the jaw following tooth removal.

### ORTHOPAEDIC\*

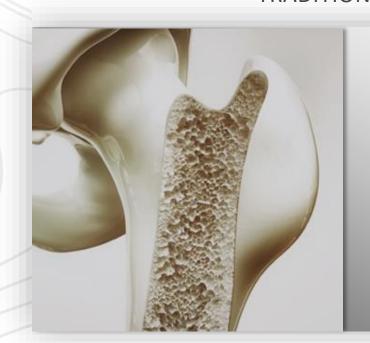
A range of orthopaedic applications, where significant lengths of long bones need to be regenerated.

\*Promising outcomes in early clinical evaluation based on pipeline technology



# COMPETIVITE STRENGTHS LEVERAGED BY SOLVING UNMET CLINICAL NEEDS

#### TRADITIONAL PROCEDURES

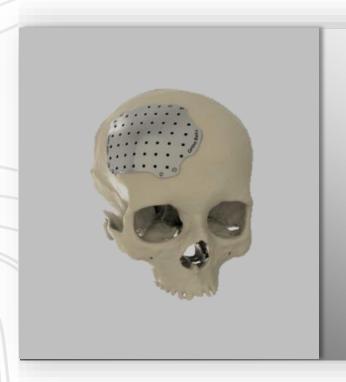


#### **BONE GRAFT**

Potential for **infection** and lasting pain at harvest site

Potential for body to completely absorb the graft with no bone regeneration



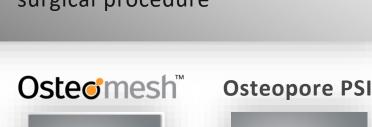


Osteoplug<sup>™</sup>

#### **PERMANENT IMPLANTS**

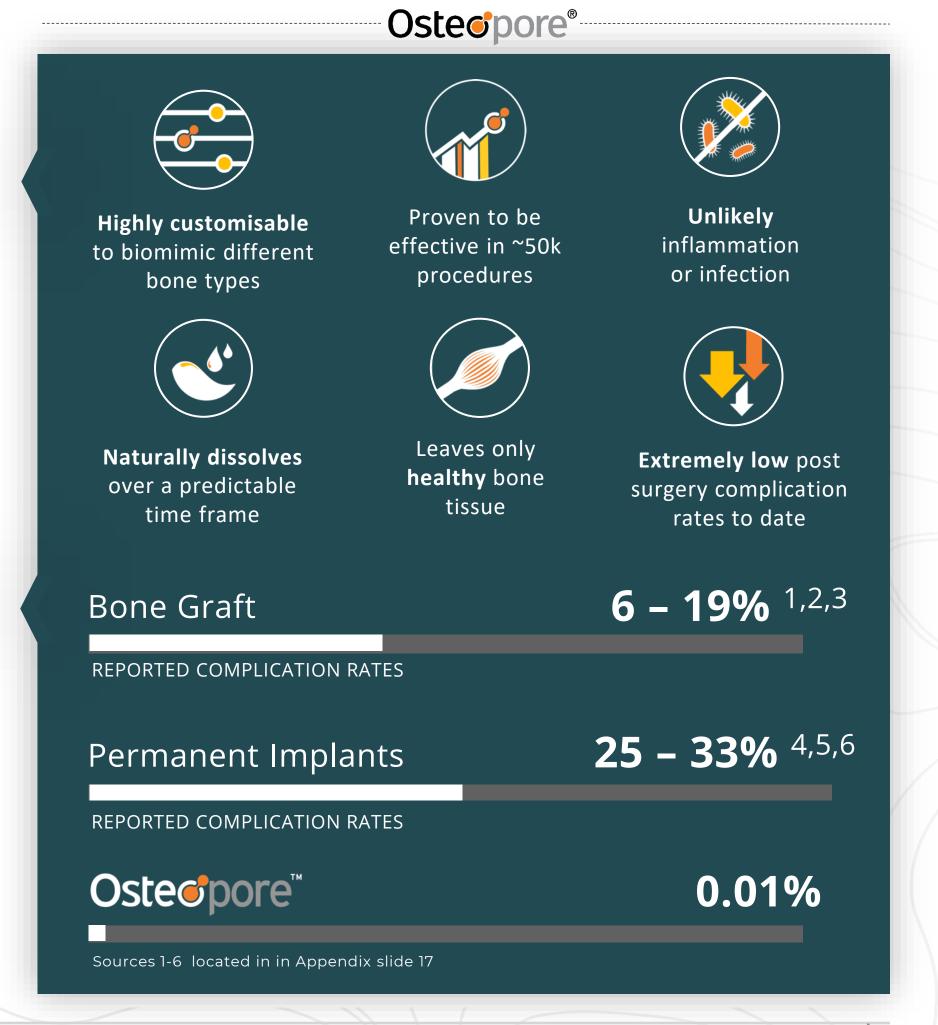
Non-biodegradable with a high potential for post surgical complications

**Difficult to micro-adjust** for a better fit during the surgical procedure





Sales



#### INVESTOR PRESENTATION

Source for market size data: Allied Market Research, BCC Research

Osteopore's current market penetration is evident in its annual revenue figures announced on 26 Feb 2021 and in subsequent financial reporting. Osteopore cautions investors that there are regulatory barriers and unique access challenges associated with entry into new markets, which may adversely impact entities' ability to access such markets.

# STRONG PRODUCT PIPELINE WITH SIGNIFICANT ADDRESSABLE MARKETS

SURGICAL SUBSPECIALTY	PRODUCTS FOR INDIVIDUAL APPLICATIONS	REGULATORY CLEARANCE	FY20 FY21 FY22 FY23 FY24 FY25	MARKET OPPORTUNITY	SALES AVENUE
CRANIOFACIAL	Burr Hole Procedure Neurological Shunt Procedure Craniotomy Cranioplasty Craniosynostosis Endoscopic Skull Base Surgery Orbital Floor Reconstruction Septoplasty Patient Specific Implants	Australian Government  Department of Health Therapeutic Goods Administration  Multiple SEA territories		~USD 1.0 bn <sup>1</sup>	DIRECT & DISTRIBUTION PARTNERS
DENTAL	Socket Preservation Guided Bone Regeneration Immediate Implant Loading Guide Tissue Regeneration	Singapore & Multiple SEA To initiate clinical validation to support wider adoption To initiate clinical trials for EU access	Initial Singapore & SEA Sales	DIRECT (SINGAPORE ONL	
ORAL MAXILLOFACIAL	Cleft Palate reconstruction Mandible reconstruction Buccal Defect reconstruction	<ul> <li>Undergoing trials to gain regulatory indication for use</li> </ul>		in 2028 8.46% CAGR <sup>2</sup>	SPECIAL ACCESS SALES
ORTHOPAEDIC	Tibia reconstruction High Tibia Osteotomy Clavicle reconstruction Tendon repair Radial reconstruction	<ul> <li>Special access product whereby surgeon requests its use</li> <li>To initiate clinical trials</li> <li>Preparing 510k submission by Q1 2022</li> </ul>		USD 2.0 bn <sup>1</sup>	SPECIAL ACCESS SALES
AESTHETIC	Genioplasty (chin) Nipple reconstruction Breast reconstruction	<ul> <li>To initiate trials to gain regulatory indication for use</li> </ul>		USD 1.0 bn <sup>3</sup>	SPECIAL ACCESS SALES

INVESTOR PRESENTATION

- (1) Cetas Healthcare 2020(2) Verified Market Research 2021: Dental Membrane And Bone Graft Substitutes Market Size And Forecast
- (3) Based on the 2019 annual survey statistics provided by the International Society of Aesthetic Plastic Surgery

Product
Development

Clinica





# ANTICIPATED REGULATORY MILESTONES

#### China

- [expected] Guangdong-Hong Kong-Macau
   Greater Bay Area market access for
   craniofacial products
- Initiate market entry process for NMPA for craniofacial products

#### **Australia**

 Authorised Prescriber market access in Australia for rhinoplasty application

#### **USA**

Lodge US 510(k) submission for orthopaedic application

#### Korea

 Lodge MFDS application for orthopaedic application with new generation material

#### **Pakistan**

[expected] DRAP approval for craniofacial products

#### **Switzerland**

[expected] Swissmedic approval for craniofacial products

#### Europe

- Lodge EU application for Custom Made
   Device with new generation material
- Launch clinical trials for cranioplasty
   application with new generation material

#### Australia

 Authorised Prescriber market access in Australia for orthopaedic application

#### Colombia

[expected] INVIMA approval for craniofacial products

#### UK

Lodge UKCA application for craniofacial products

#### Singapore

Lodge HSA submission for Patient Matched
 Device with new generation material

#### China

 Initiate market entry process for NMPA (clinical trial) with craniofacial products

#### Europe

- [expected] EU approval for Custom Made
   Device with new generation material
- Lodge EU application for Custom Made
   Device, Long Bone Reconstruction with new generation material

#### Australia

 Lodge TGA submission for cranioplasty
 Patient Matched Device with new generation material

#### Singapore

 Lodge HSA submission for orthopaedic application with new generation material

#### **USA**

 [expected] US 510(k) clearance for orthopaedic application with new generation material

#### Korea

 [expected] MFDS approval for orthopaedic application with new generation material

#### China

[expected] NMPA approval for craniofacial products

#### Europe

- Lodge CE mark application for Patient
   Matched Devices with new generation
   material
- [expected] EU approval for Custom Made
   Device, Long Bone Reconstruction with new
   generation material

#### **Australia**

[expected] TGA approval for Patient
 Matched Device with new generation
 material

Abbreviations		
NMPA	National Medical Products Administration, China	
DRAP Drug Regulatory Authority of Pakistan		
INVIVMA	Instituto Nacioinal de Vigilancia de Medicamentos y Alimentos	
HSA	Health Sciences Authority	
UKCA UK Competent Authority		
MFDS	Ministry of Food and Drug Safety	

# POST-COVID GROWTH STRATEGY

**Horizon 1: Next 12 to 18 months** 

**Horizon 2: Next 18 to 36 months** 

Horizon 3: >36 months

Grow revenue across current commercial product line

Strategy

Build upon existing regulatory clearances to develop and strengthen brand recognition and uptake in core bone regeneration applications.

Drivers

- Global regulatory approval.
- Fully trained sales team.
- Building revenue in established and new markets through relationships with specialist distributorships with existing links to craniofacial surgeons.

Launch additional products for <u>new areas</u> of treatment

Strategy

Secure regulatory clearance in existing key markets for new geometric shapes suitable for applications in new areas of regenerative bone treatment.

**Drivers** 

- Proven ability to successfully develop and launch products globally.
- New products under development use the same regulatory approved materials and technology.
- Previous clinical data from commercial products allows for accelerated development timeframes.

Develop and commercialise breakthrough technology

Strategy

Investigating the viability of new materials and biologics to accelerate bone and tissue growth and developing new implants to potentially assist in growing cartilage and other tissue types.

**Drivers** 

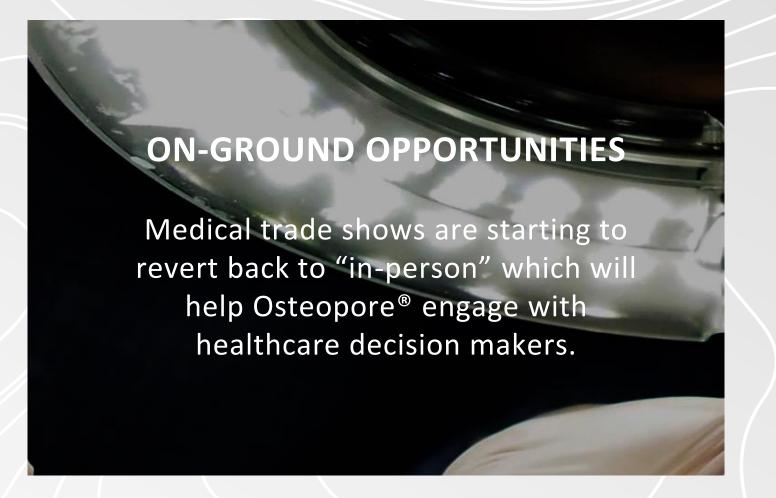
- World class development partners.
- Highly credentialed research and clinical advisor teams.
- Unprecedented access to surgeon's and hospitals with innovative, early adoption protocols for clinical trials.

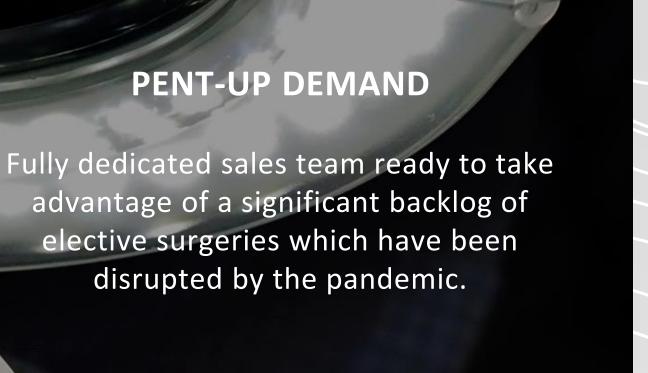
**EXISTING OSTEOPORE TECHNOLOGY** 

**NEW TECHNOLOGY** 

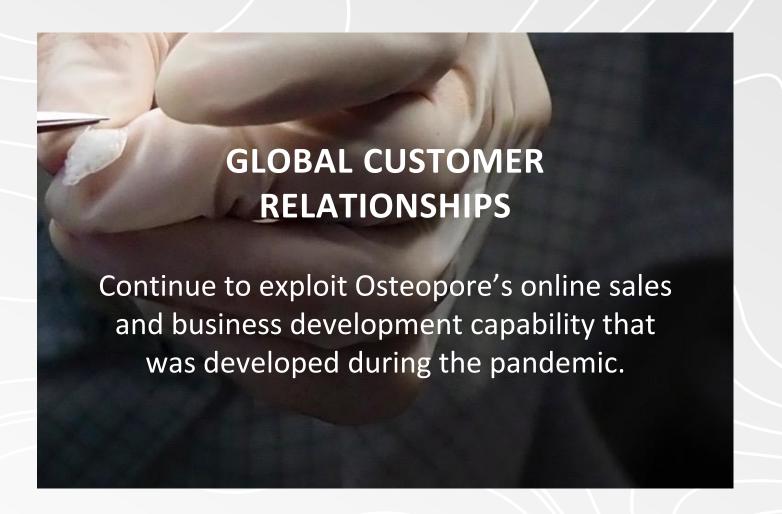
# ENCOURAGING TAILWINDS EXPECTED TO DRIVE PRODUCT UPTAKE











# NEW APPLICATIONS

## DENTAL

Application	Early clinical investigation	Market access status	Market growth strategy
Socket preservation		Singapore Multiple ASEAN countries	<ul> <li>Leverage approval in Singapore to drive sales in ASEAN</li> <li>Sign-up KOL to conduct training (Q2 2022)</li> <li>Conduct multi-centre post-market study for further clinical validation (Q2 2022)</li> </ul>
Buccal alveolar wall defect		Singapore Multiple ASEAN countries	<ul> <li>Leverage approval in Singapore to drive sales in ASEAN</li> <li>Sign-up KOL to conduct training (Q1 2022)</li> <li>Authorised Prescriber Scheme for Australia (Q2 2022)</li> <li>Initiate clinical trials for market access to Europe (Q1 2023)</li> </ul>
Buccal alveolar wall defect with Immediate Implant Loading		Singapore Multiple ASEAN countries	<ul> <li>Leverage approval in Singapore to drive sales in ASEAN</li> <li>Sign-up KOL to conduct training (Q1 2022)</li> <li>Authorised Prescriber Scheme for Australia (Q2 2022)</li> <li>Initiate clinical trials for market access to Europe (Q1 2023)</li> </ul>

## AESTHETIC

Application	Early clinical investigation	Next evolution
Nipple reconstruction	<ul><li>In progress</li></ul>	<ul> <li>Systematic clinical development</li> </ul>
Genioplasty	<ul> <li>Achieved early clinical success</li> <li>To conduct more clinical evaluation with KOLs</li> </ul>	<ul> <li>Systematic clinical development</li> </ul>

## ORTHOPAEDIC

Application	Early clinical investigation	Market access status	Next evolution
Patient Specific Long Bone Reconstruction	Completed First- in-human implantation Initiated Clinical Trial in Q3 2021	<ul> <li>To lodge Custom Made Device submission in EU Q4 2022</li> </ul>	<ul> <li>Special access sales where permitted and upon surgeon prescription</li> </ul>
Orthopaedic bone filler (standard device)	<ul><li>Initiated First-in- Man implantation in Q1 2021</li></ul>	<ul> <li>To lodge US FDA 510k submission in Q1 2022</li> <li>To lodge Korea MFDS submission in Q2 2022</li> <li>To lodge Singapore HSA submission in Q3 2022</li> </ul>	<ul> <li>Market access activity</li> <li>Special access sales where permitted and upon surgeon prescription</li> </ul>

## ORAL MAXILLOFACIAL

Application	Early clinical investigation	Next evolution
Cleft palate reconstruction	■ To initiate in Q2 2022	Systematic clinical development
Graft containment for segmental defects	<ul> <li>Achieved early clinical success</li> <li>To conduct more clinical evaluation with KOLs</li> </ul>	Systematic clinical development
Patient Specific Implant	<ul><li>Achieved early clinical success</li><li>To conduct clinical trial</li></ul>	<ul> <li>Special access sales where appropriate and upon surgeon prescription</li> </ul>



# NEW TECHNOLOGY

### ACCELERATING BONE REGENERATION

Osteopore is investigating the viability of incorporating compounds to produce novel polycaprolactone polymer composites which could be used to develop additional products for adjacent therapeutic and surgical areas

Large-scale collaboration currently in late stages of research and development programs



### REGENERATION OF OTHER TISSUE

Osteopore has successfully completed animal trials for knee cartilage regeneration, and the Osteopore scaffold may also potentially be used to assist with the regeneration of other tissue types.

Clinical evaluation underway of rotator cuff repair for improved shoulder ROM

# FINANCIALS

### REVENUE

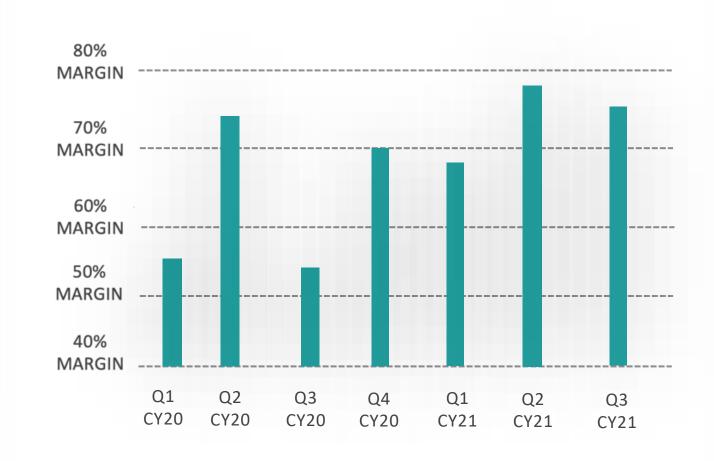
- Despite the considerable disruption COVID-19 has caused the healthcare eco-system, Osteopore® has continued generate consistent quarterly revenue.
- As global vaccinations increase and the pandemic eases, Osteopore® expects revenue to return to its post COVID levels with increased momentum.

#### QUARTERLY SALES REVENUE IN SGD (THOUSAND)



### **MARGINS**

- Osteopore® continues to work towards maintaining and improving its margins.
- A gross margin of **74.9**% of sales revenue was achieved in Q3 CY21.
- Osteopore® believes that its cost effective and high margin manufacturing process will ultimately become a major contributor towards the Company achieving profitability as revenue scales.



## CAPITAL STRUCTURE

Shares on Issue A	117.2m
Total Options on Issue <sup>B</sup>	13.4m
Market Cap @ \$0.29c <sup>c</sup>	A\$34m
EV @ \$0.29 <sup>c</sup>	A\$28m
CASH BALANCE D	A\$5.9m

CY21 Average Quarterly Net Operating Cash Used

(A\$894)

A: Shares on Issue includes 16.0m placement shares.

B: 9.7m options with an exercise price of \$0.25 and an expiry date of 30 June 2022, 0.4m options with an exercise price of \$1.00 and an expiry date in December 2022, 3m options with exercise price of \$1.20 and expiry August 2023. 0.375 options with an exercise price of \$0.624 and expiry Nov 2025 Option incentives held by executive management, directors & advisors.

C: Market Close, 30 Sept 2021

D: Cash balance at 30 Sept 2021

# KEY TAKEAWAYS

Regenerative medical device company with proven, superior products that empower tissue regeneration.

Fully trained and dedicated sales team expected to drive growth in the near term.

Global expansion underway with regulatory clearance and distribution partners secured in most major markets.

Significant opportunity to regain revenue momentum as the effects of COVID-19 diminish.

Systematic revenue growth strategy aimed at delivering and expanding revenue over three time horizons.

Complementary pipeline of products being developed for additional bone regeneration applications.



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