# Osteopore<sup>™</sup>

Breakthrough 3D printed bioresorbable implants to assist with the natural stages of bone healing.

Osteopore Limited (ASX: OSX) Investor Presentation – February 2020

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## **Oste**<sup>™</sup> – Company Overview



Osteopore Limited (ASX: OSX) is an Australian / Singapore-based medical technology company that specialises in the production of **3D printed bioresorbable implants** to assist with the natural stages of bone healing.



Osteopore's products are fabricated in-house using proprietary **3D printing technology** that is precise, biomimics the cancellous bone and allows for customisation of shape and geometry.



**The implants naturally dissolve over time** to leave only natural, healthy bone tissue, significantly reducing post-surgery complication rates associated with long term permanent bone implants.



Our products are **FDA 510(k) cleared**, **and CE Mark approved** and have been successfully used in **over 30,000 surgical procedures**, generating **revenue of over \$1m per annum**.



Osteopore is embarking on an aggressive **global growth strategy** to increase revenue and penetrate new markets with additional breakthrough products.





## **Corporate and Capital Structure**



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Capital Structure	
<ul> <li>No debt</li> </ul>	
<ul> <li>51.4m shares un for 12-24 month</li> </ul>	der escrow Is
<ul> <li>Options could pr</li> </ul>	rovide an

additional **\$2.4m in** 

Shares on Issue	101.2m	
Total Options on Issue	9.7m	
Market Cap @ \$0.62c*	\$62.7m	
EV @ \$0.62c*	\$59.3m	
Current Cash Balance <sup>1</sup>	\$3.39m	

Shareholders —

- **Tight free float** with current Top20 holding 77.4% of issued capital
- 24% shares held by Inventors, Board, Management and Advisors

#### Substantial Shareholders

The Rain Maker Mgmt	15.1%
Marcus Liew	7.1%
Hanry Yu	9.0%
Professor Teoh Swee Hin	7.0%
Goh Khoon Seng	6.8%

1 - Cash balance shown at 31<sup>st</sup> December 2019 | 2 - Options strike price \$0.25 expiring 30<sup>th</sup> June 2022. Option incentives held by executive management, directors & advisors. |\* Closing price 31<sup>st</sup> Jan 2020 | Substantial Shareholders @ IPO

## **Investment Highlights**



Revenue Generating ——

**Over AUD\$1.1m in revenues** for the twelve month period to 31 December 2019, with over 30,000 successful treatments to date.



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#### Proprietary Technology –

Osteopore has **licensed a range of patented technologies** from Singapore's leading universities NTU and NUS, with the underlying technology being developed over a decade with \$13m invested.



Scalable Business Model

**High margin products** with low capital intensity of manufacturing provide significant opportunity to scale the business and enter new markets.



**Regulatory Clearance** 

Osteopore's products are **cleared by the US FDA** and some bear the CE marking of conformity.



#### Highly Credentialed Team

The Company has a highly **credentialed**, **collaborative and experienced** team to progress the commercialisation and expansion of the Company's technology.



#### Focused on Shareholder Value

Multiple important clinical and commercial inflection points in 2020 expected to **deliver sustained shareholder value** into 2020 and beyond.

## **Milestones Since IPO**

ANNUAL GROWTH CY QUARTER ON QUARTER 2016 - 2019 **GROWTH CY 2019** A\$1,101,833 A\$990,000 A\$363,000 A\$289,000 A\$650,000 A\$217,000 CY 2016 CY 2017 CY 2018 Q3 2019 Q4 2019 CY 2019

**OSTEOPORE – REVENUE GROWTH** 

#### ACHIEVEMENTS SINCE IPO

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Significant quarterly revenue growth, increasing 21% over previous quarter to A\$363,000
 Highest calendar year revenue in the company's history at over A\$1.1m
 Strategic revenue initiatives implemented over the quarter to drive CY20 growth
 Established partnership for initial entry in the Chinese market
 Significant success in orthopaedic procedures
 Building team and manufacturing capability to drive further revenue growth

## Founder, Management and Board of Directors

#### Prof Teoh Swee Hin

Founder & Non-Executive Director

Prof. Teoh's research focused on the study of mechanisms that promote cells proliferation and differentiation as a result of mechno induction through load bearing scaffolds for tissue regeneration and remodeling.

#### Goh Khoon Seng

CEO

30-year career spanning both start-ups and global multinational corporations, with responsibilities in research and development, manufacturing, regional sales and marketing, and country management. The last 20 years were at Medtronic Inc and Edwards Lifesciences Asia.



Current CFO of Resmed (ASX:RMD / NYSE: RMD) and Senior executive at Norton Abrasives (Saint-Gobain)





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private companies

Partner of Ventnor Capital, Non-Executive Chairman or Director of a number of ASX listed entities

**Stuart Carmichael** Non-Exec Director







## **Regenerative Medicine**

Tissue engineering, 3D printed microarchitecture and regenerative medicine concepts are at the heart of the **Osteopore technology.** 

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.

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Regenerative treatments include the generation and use of therapeutic stem cells and growth factors for the generation of bone.

Osteo pore

## Osteo pore

**Customisable 3D printed** bioresorbable implants to enable the natural stages of bone healing across multiple applications.



Highly customisable to biomimic different bone types



Naturally dissolves over time



Leaves only healthy bone tissue



Reduces post surgery complication rates



Unlikely inflammation or infection

## Proprietary Bioresorbable Scaffold Technology



Osteopore's proprietary **3D printed polymer scaffold** is made up of biomimetic microstructures that **facilitate natural tissue regeneration** after insertion into the human body.



The unique 3D printed scaffolding allows for infiltration of cells and blood vessels, both of which play key roles in wound healing and tissue repair.



Osteopore products are made from polycaprolactone (PCL), a polymer that is extensively used in many US FDA approved devices. PCL is bio-resorbable, malleable, slow-degrading and possesses mechanical strength similar to trabecular bone.



The rate of resorption of PCL is very much in tandem with the natural stages of bone healing, making it a predictable material for **matching to the natural stage of bone healing.** 

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Comparisons with Titanium Implants

## **Current Approaches** to Bone Regeneration

Currently, there are three main treatment strategies to augment the bone-regeneration process, including the 'gold standard' bone graft.

However there can be **limitations** and **complications associated with existing alternative treatments.** 



Bone Graft —

A surgical procedure where bone material is harvested from the patient's own body, animals, or a different person and applied to the area to promote bone healing.

Potential for infection and lasting pain at site of harvest

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



#### Permanent Implants –

Permanent materials used for a wide variety of different bone regeneration applications. Generally, the implants are made from metal, ceramic and / or polymeric materials.

Non-biodegradable with

potential for onset infections

and implant extrusion through



the skin
Difficult

**Difficult to manufacture** and limited size and shape options



Bio-Materials -

Biomaterials (Natural and Synthetic) play an important role in providing a template and extracellular environment to support regenerative cells and promote tissue regeneration.



Synthetic materials have limited customisable manufacturing capabilities

## **Products & Applications**



## Osteciplug" –

Bioresorbable implant that is used for covering Burr Holes (holes in skull) after neurosurgery.



## Osteo mesh" —

Bioresorbable implant that is used in craniofacial surgery to repair various types of fractures, including the repair of bone in the skull, neck and jaw.



## Ostee strip —

Provides a durable, biodegradable method of filling the void following a craniotomy (the surgical removal of part of the bone from the skull to expose the brain).



#### 

**Patient Specific Implants (PSI)** based on CT and MRI-imaging of the affected anatomy. These products are used in any part of the body, and are necessary for major bone reconstructions, in cases of trauma or where significant bone degeneration has occurred.



Months

Patients needing surgical repair for skull fractures usually receive a "burr hole" during surgery, which is drilled into the skull to relieve pressure from haemorrhage.

To repair the burr hole, common methods include harvesting bone from another part of the body or using titanium plates, with both having **potential drawbacks and compilations.** 



**Osteoplug** is an alternative scaffold designed to snap-fit into the burr-hole skull defect allowing natural osteogenesis to occur into the burr-hole defect.

Osteopore Solution

## Proven to Facilitate Bone Healing – Burr Hole Example

## **Clinical Success - Patient Specific Implants**

#### Bone Defect —

150mm bone loss due to tumor resection



Pre-surgery

Early Mineralisation —

Initial osseous ingrowth with 20kg partial weight-bearing



3 Weeks

4



Able to walk without assistance



4 Months



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**Post Tumor Reconstruction (Patient Specific Implant)** 

Microporous (Biomimetic Structure)

> Solid Structure



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#### Osteopore Solution

## **Osteopore Offers Unique Therapeutic Value Proposition**

There are no other FDA or CE Mark cleared products that offer Osteopore's key technology characteristics - bio-resorption and biomimetic structure - which offer improved patient outcomes over alternative therapeutic strategies.

#### Advantages of Osteopore over Bone Graft:



- Easier to use
- Better guides tissue regeneration
- Better maintains height and width

#### Advantages of Osteopore over Permanent Devices



- Prevents Stress Shielding
- Minimise / Eliminate Late Morbidity
- Minimise Revision Surgery

#### Advantages of Osteopore over Autologous Bone Graft



- No donor site morbidity
- Can be customised to fit
- Can combine with biologics

Permanent Implants

Temporary (Bioresorbable)

## Market Opportunities & Growth Strategy

Market Opportunity & Growth Strategy

## **Business and Revenue Model**

#### Distribution Networks

Given the high wholesale margins and low capital intensity of the 3-D printing-based manufacturing process, Osteopore is focused on building distribution networks for its products while retaining control over the key manufacturing process.



Highly successful distributor agreements are already in place in key Asian markets



The company will aim to replicate this model in US and key EU markets

Osteopore will seek the right distributors with appropriate performance KPI's



#### **Future Expansion**

Future expansion possible through distributed manufacturing owned and controlled by Osteopore.

Can reduce time from scan to product delivery by reducing international shipping / customs periods

De-risks business for supply chain bottlenecks (for example, gamma-sterilisation)





Market Opportunity & Growth Strategy

## **Opportunities in Multi-Billion Dollar Global Markets**

#### Current Sales —

Current sales of Osteopore products are predominantly in **Cranial / Maxillofacial (CMF) area,** which represents less than 20% of the total Bone Graft Substitute market.

#### Additional Segments

Osteopore is now starting to penetrate **additional market segments**, including Dental and Cosmetic (nasal) markets, both markets comparable in size to CMF.

#### Untapped Market

Orthopedic and Spine, which amount to over 40% of the total Bone Graft Substitute market, represent minimal sales to date and offer a **significant untapped opportunity for Osteopore's products.**  Current market opportunities (Bone Graft substitutes, US\$3.9bn by 2025)



**Ostee**pore

Permanent Implants sales are currently estimated at over \$100bn pa, more than 20 times the entire Bone Graft Substitute market.

Regenerative procedures enabled by technologies including the Osteopore scaffold are expected to strongly compete in this market in the future. Market Opportunity & Growth Strategy

## **Revenue Growth Strategy**

Osteopore is now looking to build value through short, medium and long term strategic goals.

Phase One

#### **Revenue Expansion**

Increase underlaying revenue from its current **commercially ready** products.

- o Growth in revenue from existing Asian markets
- Establish **new geographic markets** (US, Europe, Australia, China) for current products, therapeutic areas (CMF, cosmetic)

Phase Two



#### **New Therapeutic Segments**

Expand Osteopore's therapeutic scope with applications of Osteopore's bone regeneration scaffold in **new therapeutic areas** 

- Dental
- **Orthopaedic** (long bone / spine)

Phase Three



#### **Future Horizons**

Additional applications of Osteopore technology that could present significant commercial opportunities.

- New polymers to improve patient outcomes
- Application of Osteopore's 3-D printed scaffolds for regeneration of other tissues

## Phase

Phase Two

Phase Three

Revenue Growth Strategy

## **Revenue Expansion**

The Company aims enhance market penetration of the commercially ready Osteoplug, Osteomesh and Osteostrip products



**Building underlying revenue base organically from Asian markets** and building distribution networks into US and key EU markets to significantly increase revenue streams



**Obtaining necessary regulatory approval to expand sales** in additional target jurisdictions (Australian TGA, China FDA registration) and Registering 2nd generation materials with US FDA and CE Mark



**Investing in sales and marketing** activities and infrastructure in USA, EU, Australia and Asia



Undertaking market development and business development activities to further **enhance revenue in key markets** 

#### Phase One

### Phase Tw

Phase Three

## New Therapeutic Segments

Expand Osteopore's product offering with new applications that are complementary to the Osteomesh, Osteoplug and Osteostrip products – in particular dental and spinal/orthopaedic market segments.



Dental

Osteopore has developed an enhanced bioresorbable 3D-printed dental plug which promotes bone growth in the jaw, reducing the likelihood of bone shrinkage after tooth extraction.

Currently, patients requiring dental implants have to wait 3-6 months for bone to grow in the tooth socket after extraction.

Osteopore aims to deliver a shorter, reliable and less painful treatment process as the plugs are placed immediately after extraction, eliminating the need for bone grafts.

The market for dental bone graft alternatives is estimated at nearly **\$1bn** per annum

Lab Development	🥑
Pre-Clinical Trials	🕑
Clinical Trials	ongoin
Regulatory Approval	
Sales	



- Orthopaedic



Osteopore has successfully conducted first in human trials using the Osteopore scaffold in a range of orthopaedic procedures, where significant lengths of long bones have been damaged.

Spinal / orthopaedic procedures represent the largest single segment of the bone graft alternative market, with global sales estimated at nearly **\$2bn per annum** 

The Osteopore scaffold has recently demonstrated significant clinical success in tibia regenerations in Australia, Singapore and Oman.



Phase One

Phase Two

## Phase Three

Revenue Growth strategy

## **Future Horizons**



#### **Accelerating Bone Regeneration**

Osteopore is investigating the viability of incorporating bioactive materials into polycaprolactone polymer material, which could be used to improve patient outcomes. These new polymer compounds could lead to the development of additional products for new therapeutic and surgical areas and present Osteopore with significant commercial opportunities.



#### **Regeneration of Other Tissue Types**

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



#### **Opportunities in Veterinary Markets**

Osteopore has successfully completed multiple animal trials for a number of different surgical applications which could possibly translate into products for the veterinarian market

# Building blocks in place for executing growth strategy

## Scalable & Customisable Manufacturing



Low cost 3D printing process to customise products and maintain IP advantage with the ability to scale as sales increase.

Production process embeds both **patented technology and trade secrets** to maintain competitive advantage.

Ability to set up **additional cost effective manufacturing** centres outside of Singapore to increase flexibility and reduce potential supply chain bottlenecks.

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**Currently expanding production capacity**, with increased staffing, as well as purchasing additional 3D printers to raise output levels

#### Integration of Medical Imaging, Computational Mechanics & Biomaterials Technology

Ostecipore

**Step One** ——— The hospital undertakes a CT scan.

**Step Five** ——— The scaffold is produced using Osteopore's 3D printer micro-extruder and sent anywhere in the world



## Global Regulatory Approval

Products	Neurosurgery	Plastic Surgery	Oculplastic Surgery	Craniofacial Surgery
Osteoplug US FDA 510k 2006/CE Mark approved	<ul> <li>Burr Hole for craniotomy</li> <li>Evacuation for chronic subdural hematoma</li> <li>Cranial spinal fluid shunt</li> </ul>			
Osteomesh US FDA 510k 2006 approved	Craiosynostosis	Facial reconstruction	Orbital reconstruction	Facial reconstruction
	Cranioplasty	Orbital reconstruction	(CE Mark approved)	Orbital reconstruction
Osteostrip US FDA 510k 2006 approved	Cranioplasty gap filler to minimise bone edge necrosis	Cranioplasty gap filler to minimise bone edge necrosis		Cranioplasty gap filler to minimise bone edge necrosis

## **Intellectual Property**

Osteopore technology is supported by granted patents from leading Singaporean research institutions.



**Trade secrets** include construction of 3-D printer micro-extruder, algorithm to convert 3-D image to 3-D printing codes, process parameters and quality controls.







## Research & Development Partners

Osteopore has exclusive license arrangements with Nanyang Technological University (NTU), National University of Singapore (NUS) and Temasek Polytechnic. And a number of key research and development relationships with world class institutions across a number of jurisdictions.

## Media & Awards Exposure

Unique nature of Osteopore's products and procedures provides the Company with a high level of public exposure through media coverage and prestigious awards

Recent coverage of Australian regenerative success with 30cm tibia reconstruction using Osteopore scaffold technology

Osteopore has been awarded a number of prestigious awards, highlighting both the innovative nature of the technology and the transformative nature of the procedures enabled by the technology

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FINANCIAL REVIEW

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3D-printed tibia patient Reuben Lichter walking unaided, two years on from experimental surgery





 In 2017, Reuben Lichter developed a bone infection that destroyed 36 centimetres of his right tibia

surgery to implant a 3D-printed bone into his right He is the only person to have his tibia "scaffolded" by a 3D-printed implant Mr Lichter has plans to pursue a career in Mr Lichter said the journey has been a long and painful, but worth it now he can finally walk again





**Business Model** Innovation Award 2018





2018 Honourable Mention



OSTEOPORE INTERNATIO NAL PTE LTD 2016 FROST & SULLIVAN SINGAPORE 3D SCAFFOLD ENTREPRENEURIAL COMPANY OF THE YEAR

Analyst Que ors as it facilitates natural tissue healing and regard











world-first surgery and transplanted a 3D printed shinbone into the leg of a man who faced losing his leg. Two weeks ago, the 3D printed tibia was transplanted into the Reuben Lichter's right leg.



Join us



## **Management Team**



## Geoff Pocock Executive Director

Formerly Managing Director of Hazer Group Ltd (ASX:HZR) and Non-Executive Director of various ASX listed and private companies.

#### Deborah Ho

Company Secretary-



Ms. Ho has over six years of experience in company secretarial, corporate compliance and financial accounting matters. She has acted as Company Secretary and financial accountant for a number of ASX companies





Chief Executive Officer

Mr Goh has a 30-year career spaning both start-ups and global multinational corporations, with responsibilities in research & development, manufacturing, regional sales and marketing.



Chief Technology Officer

Dr. Lim holds a PhD from Nanyang Technological University, Singapore. Prior to joining Osteopore, Dr. Lim conducted research on biomaterials for tissue engineering and regenerative medicine, and developed material fabrication platforms.



## **ASX Peers Show Potential for Value Re-rating**

PolyNovo (ASX: PNV)

Medical devices for the treatment of burns, surgical wounds and Negative Pressure Wound Therapy.

#### Mesoblast (ASX: MSB) ——

Cellular medicines to treat complex diseases in which inflammation plays a central.

#### Avita Medical (ASX: AVH)

Regenerative medicine company using sprayon skin cell therapy for an array of dermal applications.

Osteo pore"



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Revenue figures for peers taken from 2019 Annual Reports | Market capitalisation calculated by number of ordinary shares quoted on the ASX in latest 3B Announcement with closing share prices @ 31<sup>st</sup> Jan 2020

# Osteopore<sup>™</sup>

## **Geoff Pocock**

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