



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Osteopore

By **TIM BOREHAM**

**ASX code:** OSX

**Share price:** 52.5 cents

**Shares on issue:** 117,268,238 (including 39,230,438 ASX escrow shares)

**Market cap:** \$61.6 million

**Chief executive officer:** Khoon Seng Goh

**Board:** Brett Sandercock (chairman), Geoff Pocock, Prof Swee Hin Teoh, Stuart Carmichael

**Financials (half year to June 30, 2020):** revenue \$672,774, loss of \$708,912, cash balance \$10.7 million\*

\* Post \$8.5 million placement in August

**Major identifiable holders:** The Rain Maker Management 15.1%, Harry Yu 9%, Marcus Liew 7.1%, Prof Swee Hin Teoh 7%, Khoon Seng Goh 6.8%.

Osteopore is a company that patients need like a hole in the head or - more precisely - when they have a hole in their head.

You see, the Perth based, Singapore-centric Osteopore provides three-dimensional (3-D) bio-resorbable implants that are used in conjunction with surgical procedures, to assist the natural stages of bone replacement.

As executive director Geoff Pocock puts it, the devices fill a void when the missing bone is just too big to be filled by traditional grafts.

Cleared by the US and European gatekeepers, Osteopore's products have been used in more than 40,000 procedures with minimal complications.

The company deploys in-house 3-D technology that "precisely bio-mimics the cancellous bone and allows for customization of shape and geometry."

"Cancellous", by the way, denotes bone tissue with a porous, mesh-like structure.

Osteopore's key selling point is that the implants dissolve naturally, leaving only the healthy bone.

Currently, the gold standard treatment is grafts from material harvested from the patient's own body, another person or an animal. Grafts commonly result in complications such as infections, either at the wound site or the donor site.

Then there are non-biodegradable permanent implants, which are hard to manage with limited shape options.

The procedures use natural or synthetic materials, with the former requiring pre-treatment with chemicals.

While there are other 3-D products around, Osteopore claims to be the only one that is bio-resorbable with a microporous structure.

"These products are in the market and generating revenue, which is unusual in the small to mid-cap space," Mr Pocock says.

"We also have all the regulatory approvals we need."

## **About Osteopore**

The company won the title of last year's hottest ASX initial public offer after listing on September 23, having raised \$5.25 million at 20 cents apiece.

The company's core technology is licenced from Singapore's Nanyang Technical University and National University of Singapore.

Osteopore was founded in 2003 by biomedical engineer Prof Swee Hin Teoh, of Nanyang Technical University.

In 2006, the US Food and Drug Administration approved the products, followed by European assent in 2006 and a nod from the local Australian Therapeutic Goods Administration in April this year.

The company expects to announce an Australian distributor by the end of 2020.

While the approvals pertain to cranio-facial work, the devices have also been used for osteo-arthritis on an 'off label' basis.

“As largely customized products, they come under patient specific authorizations where usage is at the surgeon’s discretion,” Mr Pocock says.

As is usually the case in medical technology, the US is the most important geography for Osteopore, accounting for roughly one third of the market. So, it’s material that on July 2 this year the company struck a US distribution deal with Bioplate Inc.

The deal is non-exclusive and covers six states, albeit some big ones (Texas, California, Wyoming, Ohio, Arizona and Indiana). It also covers Puerto Rico, which has FDA coverage as a major drug and device supplier to the US.

“We are continuing to talk to a variety of other groups about distribution agreements,” says Mr Pocock, noting that the vast Florida and East Coast markets such as New York and Boston are not covered.

But there won’t be an immediate sales surge because the 'early adopter' surgeons will test it first and then wait for up to two years to make sure the patient recovery is as expected.

Naturally, the company is drawn to Europe and its 23 member countries, which account for another third of the market.

But dealing with so many different health systems is tricky.

“We haven’t had the balance sheet or resources to attack those markets but the [recent] capital raising gives us the opportunity,” Mr Pocock says.

Osteopore is also eyeing the slow boat to China, having inked a cooperation agreement with the Qionghai, Hainan Province-based Boao Yiling Life Care Centre.

While initial orders are pending, we doubt any of the Australian executives will be rushing to China to check physically on progress, just at the moment.

“China is also an attractive market but you can spend a lot of time banging your head against the wall,” Mr Pocock says.

## **Management strength**

Osteopore is steered by some interesting names with diverse talents.

The Perth-based Mr Pocock is the former CEO of Hazer Group, which is seeking to develop a more efficient way of creating and storing hydrogen. More broadly he has three decades of commercialization experience with ASX-listed companies.

Readers might also recognize the name of chairman Brett Sandercock. In his day job he's chief finance officer of sleep device outfit Resmed, so with this moonlighting role he mustn't be getting much slumber.

CEO Khoon Seng Goh has more than two decades' experience in medical devices, at Medtronic and Edwards Lifesciences Asia.

Adding further management oomph, Jack O'Mahony was hired as a board advisor. Grey-haired (but distinguished) readers might remember the name: he ran Cochlear for three years up to 2003, before Dr Chris Roberts began his marathon reign at the hearing implant house.

### **Plugging market gaps**

Osteopore uses a polymer called polycaprolactone, which was chosen for its bio-resorbable, malleable and slow degrading properties, as well as mechanical strength. It's a well-known material that's already used in dissolvable stitches.

"After two years the patient is only left with natural bone," Mr Pocock says. "That has a significant impact on the complication rate of grafts and implants."

Currently Osteopore's product range consists of Osteoplug (to cover 'burr holes' drilled in neurosurgery), Osteomesh (cranio-facial surgery to repair skull, neck and jaw fractures) and Osteostrip skull filler after a craniotomy to expose the brain).

Osteopore also has a bespoke product called Osteocustom, by which the inserts are shaped according to computed tomography or magnetic resonance imaging and produced on a scanner, anywhere.

The company claims it can get a product to a surgeon within 21 days.

"That's an acceptable time frame in line with surgical needs, but we are looking at improving delivery times with additional manufacturing, which would not be expensive," Mr Pocock says.

To date, most of the applications have been in the cranial and neurological space but of course management is also eyeing the more capacious orthopaedic, spinal, cosmetic and dental markets.

Mr Pocock says two and a half years ago, a Gold Coast man received a scaffold implant to replace 36 centimetres of bone after a tibia removal.

"We were able to regrow the tibia and the gentleman is now walking again," he says. "The alternative would have been an above-knee amputation and a prosthetic leg."

"We have had a number of successes in the orthopaedic space where we have been able to regenerate that bone."

In the dental sector, an Osteopore plug would reduce the time required between extraction and insertion of a dental implant.

In a new collaboration with the National University of Singapore and the Lion State's National University Hospital, the company has launched a research project on the potential use of its implants for mandibular (lower jaw) reconstructions.

The company is also eyeing an orthopaedic scaffold (for knee cartilage) as well as veterinary market applications (at which point we rename the company Osteopaw).

## **Finances and performance**

While Covid-19 created some logistics challenges and slowed down clinical trials, it did not slow the rate of brain surgery.

In the six months to June 30, 2020, Osteopore chalked up "encouraging" revenue of \$672,774.

Notably the company posted record revenue \$348,000 in the Covid-blighted three months to June 30, up from \$270,000 in the March quarter and \$228,000 in the previous June quarter.

While Osteopore has distribution agreements in more than 20 countries, South Korea accounted for \$413,765 (61 percent) of the turnover.

Cranial work aside in the 'good' Korea, the devices have been used for aesthetic stuff such as rhinoplasty (nose jobs).

Vietnam chipped in a further \$124,990 (18 percent) while Singapore, the Philippines and Australia shared most of the rest.

Osteopore also pocketed \$506,874 in grants; \$229,262 from Singapore's National Additive Manufacturing Innovation Cluster and \$216,240 from other government largesse.

Osteopore shares have traded between 27.5 cents (March 23 this year) and \$1.05 (October 1 last year)

The July news of the US distributor deal sent the stock from 40 cents to 83 cents so it's been a wild ride.

Osteopore's coffers were bolstered by an \$8.5 million placement carried out in August at 53 cents per share, a 13 per cent discount.

One-third of Osteopore shares remain escrowed for 12 months, a condition of last year's listing.

## **Dr Boreham's diagnosis:**

Churlish as it is for us to observe this, but Osteopore's revenues don't exactly move the dial yet. The US push will entail a three-stage process of expanding revenue from existing products, entering the orthopaedic and dental sectors and then dabbling in alternative polymers and applications.

Osteopore's key advantage is that the manufacturing process requires low capital expenditure, is easy to scale up and can be done anywhere.

As mentioned earlier, it doesn't need any more regulatory boxes to be ticked. The challenge lies in displacing the graft standard of care - and competitors - in these markets. The company cites Allied Market Research numbers that forecast a \$US3.9 billion (\$A5.5 billion) market for bone graft substitutes by 2025. The permanent implant market is worth about \$US100 billion.

Bear in mind that Osteopore is in the cranial and maxillofacial sector, which is only about 20 percent the size of the bone graft substitute market. The orthopaedic and spine sectors account for almost half, while dental and cosmetic applications make up the rest.

At first blush, Osteopore presents a similar yarn to the ASX-listed Allegra Orthopaedics which is developing a resorbable synthetic bone substitute "with the ability to be 3-D printed". Allegra generated just under \$5 million last year and is valued at under \$20 million, so one wonders what the painfully shy company would be worth if it better promoted itself.

As a rule of thumb, Mr Pocock says the sweet spot for a device company is reaching \$7 million to \$10 million of annual revenues - eminently achievable once US sales gain traction.

Interestingly, ASX-listed regenerative wound sector companies Polynovo and Avita Therapeutics both chalked up about \$19 million of revenue in the year to June 2020. Their market valuations? \$1.47 billion and \$740 million respectively.

"Investors can see a path for Osteopore to build these revenues to comparative levels," Mr Pocock says.

"At that point you are past the noise and in a much more credible position in the market."

Just remember where you read this first.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He needs brain surgery like a hole in the head, but if the occasion arises it's good to know that Osteoplug is out there.***