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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Orthocell

By TIM BOREHAM

ASX Code: OCC

Share price: 38.5 cents; **Shares on issue:** 197,127,913; **Market cap:** $75.9 million

Chief executive officer: Paul Anderson

Board: Dr Stewart Washer (chair), Mr Anderson, Matthew Callahan, Prof Lars Lidgren, Qi Xiao Zhou, Leslie Wise

Finances (March quarter 2022): receipts $313,000, operating cash outflows $2.35 million, cash of $11.25 million*****, quarters of available funding - five.

***** This excludes the $23 million of proceeds from the recent dental deal and a $2.14 million Federal Research and Development Tax Incentive received in early June 2022.

Major shareholders: Prof Ming Hao Zheng (founder and chief scientific officer) 4.0%, Paul Anderson/Nicole Telford 3.5%, Qixiao Zhou 3.1%, Jia Xun Xu 2.7%.

Given the current unsympathetic market conditions, any biotech that tries to raise equity will suffer the equivalent of being stabbed in the eye with a syringe.

Other non-dilutive funding sources are vital, which explains the outbreak of investor joy at Orthocell's deal in late June to sell the rights to its dental regenerative tool for $23.1 million.

And just to be clear, that's in upfront cash.

Orthocell shares vaulted as much as 50 percent on the deal, which involves licencing its Striate+ device to Biohorizon Implant Systems, an arm of Fortune 500 company Henry Schein and the world's fourth biggest dental provider.

But it's not just about the money.

Orthocell chief Paul Anderson says the deal validates the bona fides of the Perth-based company's wider suite of Celgro collagen-based regenerative devices for skin, nerves, tendons and toes.

"We don't see ourselves as a dental company but we know we had some very effective products used in the dental field," Mr Anderson says. "We never intended to build an infrastructure for our dental business, it was always a partner-driven strategy."

The proceeds of the deal will be used for Orthocell's nerve repair program. Speaking of which, earlier in June, Orthocell shares also bounced on positive data from the final readout of its nerve regeneration trial (see below).

About Orthocell

Orthocell was founded in 2016 by Mr Anderson and chief scientific officer Prof Ming Hao Zheng, former chief executive of cell therapist Verigen. But Mr Anderson has been working with Prof Zheng, now of the University of Western Australia, since 2000.

The company listed on the ASX in August 2014, having raised $8 million at 40 cents a share.

At the core of Orthocell is a biological collagen membrane platform device, Celgro. Celgro is the basis of Striate + and the nerve product called Remplir.

Initially, Celgro was pitched at the surgical repair of bone and soft tissue, but after a recent trial involving quadriplegics, the company widened its horizons to nerve repair.

The collagen originally was derived from pigs but it's not an oink-ment.

In January last year, the US Food and Drug Administration approved Celgro as a 510(k) device for dental bone and tissue regeneration procedures.

In March 2022, Orthocell won local Therapeutic Goods Administration approval to use Remplir for peripheral nerve damage repair procedures.

To date, 300 patients have been treated with Celgro under the regulator's special access scheme, for nerve, tendon, cartilage and dental maxillo-facial procedures (teeth, jaw, bones and the face).

The company also has US, European and local approval to use Celgro in dental implant procedures. The European assent covers dental (bone) and facial (soft tissue) applications.

Dental deal delivers

Orthocell has granted the Birmingham, Alabama based Biohorizon an exclusive 25-year licencing and distribution deal for its Striate+ resorbable collage membrane, used for dental bone and regeneration procedures.

Mr Anderson notes that 40 percent of implants require a bone graft because the bone doesn't have enough oomph to support the implant.

The membrane is put on top of the bone graft to encourage the bone to grow more quickly.

Mr Anderson says the deal took nine months to negotiate. Because of Covid, the parties only met face-to-face three days before the paperwork was signed.

But he says the agreement was a culmination of two and a half years of building awareness among the clinicians who count.

The cold hard cash aside, Mr Anderson is chuffed that the deal included Orthocell having the right to manufacture the devices. The company is in the process of scaling up its 1,000 square metre (quarter acre) Perth facility to increase volume from 10,000 units a year to up to 100,000 units.

The company will add 10 staff to its current roster of 32 employees.

Apart from receiving a manufacturing margin, Orthocell also enjoys the scale benefits from the cost of goods sold being reduced across all of it products.

Oh, the nerve …

The Celgro procedure supersedes the old and primitive suture (needle and thread) method, which risks further damaging - rather than repairing - the delicate nerve tissue.

The "customized conduit" protects the nerves from outside influences such as agents that can cause scarring and also contains healing growth factors within the nerve site.

Other scaffold-type products act as conduits for the re-joined nerves to grow. But because they are hard rigid tubes, the surgeons cannot go around 'corners' and it is difficult to feed the nerves into the pipes.

In early June this year Orthocell reported "encouraging results" from the final data read-out of its nerve reconstruction trial, under the watchful eye of Dr Alex O'Beirne from Subiaco's Western Orthopaedic Centre (in Perth).

The result showed early recovery of muscle function to paralyzed upper limbs, with continued improvement over 12 and 24 months.

Patients had suffered traumatic nerve injuries following motor vehicle, sporting or work-related incidents, resulting in partial or total loss of use of their arms and, in more severe cases, their legs and torso as well (quadriplegia).

The June, 24-month readout showed 85 percent of the nerve reconstruction procedures - 23 of 27 - resulted in functional recovery of target muscles closest to the reconstruction site.

Even more encouraging, 11 of 12 of the quadriplegic cohort (92 per cent) showed improved function.

This was an improvement on the (also positive) 12-month data, which showed similar functional recovery in 76 percent of reconstructions (25 of 33).

With local TGA approval in the bag, the company is working on a US trial to win FDA consent. The size and design of the US nerve trial is yet to be decided, but it would likely enrol about 50 patients.

Also in the toolkit

Orthocell has two cell-based, regenerative products, Ortho-ATI (autologous tenocyte implantation) and Ortho-ACI (autologous chondrocyte implantation).

(Autologous means healthy cells are taken from the patient's own body, cultivated and reinserted into the affected area).

Ortho-ACI is approved for use in Australia, New Zealand, Singapore and Hong Kong under good manufacturing practice protocols. More than 500 patients have been treated to date.

Ortho-ATI is used for tendon injuries such as rotator cuff injuries and tennis elbow, while Ortho-ACI is deployed for cartilage restoration in dodgy knees and ankles. But as it's more of a drug than a device, it's harder to get to market.

While the company continues to sell Ortho-ACI, its focus is on Ortho-ATI. The latter is yet to approved, but is available here under a special access scheme.

Locally, the company has completed recruitment for a study comparing Ortho-ATI with elbow surgery.

"The next big piece for Ortho-ATI is Australian approval, which we expect in the next 18 months," Mr Anderson says.

"At the same time, we are working on a business plan for Ortho-ATI in the US."

He estimates an addressable market of 700,000 rotator cuffs in the US. "Ortho-ATI might be harder to get to get to market, but the need is huge and the product works."

Finances and performance

Orthocell clocked up $300,000 of receipts in the March quarter, from its suite of nerve bone and tendon products.

Revenue for the full year to June 30, 2022 should come in at $1.5 million compared with $1 million, last year.

Mr Anderson says the company has focused on “good” revenue from reputed clinicians who can advocate for the company. “We made a deliberate decision to sacrifice a little revenue to making sure we got the right people.”

Mr Anderson believes Orthocell’s cash of circa $30 million is enough to fund the US nerve trial. The company last raised funds in late 2019: $14.4 million at 50 cents apiece.

Locally, Orthocell has applied to the Australian Prosthesis List Assessment Committee for reimbursement for Remplir, under a code which would pay $1,380 per unit.

Hopefully this won’t cost patients an arm and a leg, either.

“We should hear about this in November,” Mr Anderson says. “We’re as optimistic as we can be, we stand an excellent chance.”

Mr Anderson notes the existence of several Federal and State collaborative grants to enable automation, which would be “tailor made” for Orthocell.

Immediately after the dental deal, Orthocell shares closed up nine cents to 39 cents, a 30 percent jump.

They also jumped seven percent on the back of the nerve trial results.

Orthocell shares plumbed a record low of 20 cents in March 2020, having peaked at 80 cents in August 2015.

Dr Boreham’s diagnosis:

Putting a human slant on it, Orthocell cites the experience of Damien Hall, a nerve trial participant who seriously injured his hand in a skate-boarding mishap.

Mr Hall has now returned to his favorite pursuit of rock climbing and the company has the pictures to prove it.

Of course, Orthocell is not exactly an orphan in the regeneration game.

The closest comparison is to ASX-listed Perth and Singapore counterpart, Osteopore, which is using three-dimensional printing technology to produce bio-resorbable implants for bone replacement.

Orthocell's preferred exemplar is Polynovo, given the latter also uses lattice-type devices for procedures such as wound repair and hernias.

These days Polynovo's worth a hefty $1 billion, but at a similar point of development to Orthocell it was valued at Orthocell's current $100 million.

While the older Ortho-ATI and Ortho-ACI have clear market positions, Celgro is the company's "genuine platform technology".

Just over a year ago Mr Anderson said Celgro would be the "game changer and the company maker".

That sounds about right, given nerve repair is a "massive indication" worth $US7.5 billion a year, with two million nerve repair procedures done annually.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he has a full set of teeth and his rotator cuffs are fine, so thanks for asking.