Biotech Daily

Friday December 6, 2024

*Daily news on ASX-listed biotechnology companies*

# Dr Boreham's Crucible: Avita Medical

**By TIM BOREHAM**

**ASX code:** AVH (Chess depositary instruments); **Nasdaq code:** RCEL (US shares)

**Shares on issue:** 131,088,145 (CDIs and equivalents)

**CDI price:** $3.86

**Market cap:** $506.0 million

**Chief executive officer:** James (Jim) Corbett

**Board:** Lou Panaccio (chair), Mr Corbett, Jeremy Curnock Cook, Prof Suzanne Crowe, Jan Reed, Robert McNamara, Cary Vance

**Financials (September quarter 2024):** revenue $US19.5 million (up 44%), loss of $16.2 million (previously an $US8.7 million deficit), cash and equivalents of $US44.4 million (down 50%). ($US1.00 equals $A1.56
)
**Identifiable major holders:** Vanguard Group 4.5%, Pura Vida Investments 3.4%, Black Rock Institutional Trust Company 1.85%, Michael Perry 1.4%, Thorney Investments 0.5%.

When it comes to medical devices, improving the lives of clinicians is just as important as improving the lives of patients. If both these aims can be achieved, that's the sweet spot.

In the case of Avita, the company's approved spray-on skin burns treatment Recell has the runs on the board. To date, 400 to 500 US burns surgeons are using Recell, with indications expanded to traumatic and surgical wounds and vitiligo.

Avita CEO Jim Corbett notes an American Burns Association appraisal that showed patients left hospital 30 percent faster.

He cites the experience of one patient with 85 percent total body surface area (TBSA) wounds.

“The doctor said she would be lucky if she were in [the intensive care unit] for a year and then die. She walked out at six months.”

(The patient now advocates for Recell under the auspices of the Burns Survivor foundation).

Management’s priority is now making Recell easier to prepare and apply, with an automated 2.0 device called Recell Go that eliminates about 90 percent of the training requirements.

“It’s a better use of [surgeons’] time to be doing something for the patient, other than scraping skin,” Mr Corbett says. “It is going to make substantial changes to the business.”

Specifically, he expects Avita’s share of the burns market to double, while it also makes the full-thickness burns indication expansion easier to obtain.

**A slow-burn story**

A battery-operated autologous cell harvesting device, Recell involves taking a small skin sample from the body and mixing the cells into a liquid spray, for use in 30 minutes.

Recell competes in the main with traditional skin grafts, but the one Recell kit can cover 80 times the area of a graft.

Avita’s Recell technology evolved from the pioneering work done by legendary Perth burns surgeon and Australian of the Year, Prof Fiona Wood.

Recell was famously used on Bali burns victims after the 2002 terrorist attack.

Originally known as Clinical Cell Culture, Avita was founded in 1992 and merged with Visiomed to become Avita in 2008. Its American depositary shares traded on the over-the-counter exchange, and then on the Nasdaq from October 2019.

Avita was headquartered in Perth, but a corporate rejig in 2020 saw the company migrate to the US.

Recell was approved in Europe and launched there in 2005, and was available in Australia a year later. It is also approved in Japan.

In September 2018, the US Food and Drug Administration (FDA) approved Recell as a class-three device, to treat second and third-degree thermal burns in adults.

In June 2021, the FDA expanded this indication to paediatric third-degree burns, which account for about one-quarter of all US burns injuries. Recell was then approved for wounds and full-thickness skin defects.

In 2019, Avita forged an alliance with M3 Group subsidiary Cosmotec to market and distribute Recell in Japan, the second biggest healthcare market. Cosmotec launched the product there in September 2022.

These days, Avita is based in California's orange capital of Valencia.

An Avita director since June 2021, Mr Corbett replaced Mike Perry as CEO in September 2022. Brought up in St Louis, Missouri, Mr Corbett was CEO of the Nasdaq-listed Micro Therapeutics Inc, Ev3 Inc and Alphatec Spine.

He also helmed three private biotechs and has had roles at Baxter, Scimed Life Systems and Boston Scientific.

**It's Go time**

Recell Go consists of a battery-powered processing device and a single-use cartridge (containing the requisite enzymes and other goodies).

The automated device scrapes the skin samples and mixes them with the liquid ingredients.

About the size of a blender, Recell Go ameliorates the need for sales agents to spend many hours training nurses and clinicians on how to prepare the kits.

In late May this year, the FDA approved Recell Go and the product was launched in June.

"It's Go time for a new era in wound care," Mr Corbett said at the time.

Yes - he did say that.

"By streamlining processes and enhancing operational efficiency with Recell Go, clinicians can now treat a greater number of patients and more broadly experience the proven benefits of Recell technology."

Mr Corbett said the device will reduce training time from about 50 minutes to five minutes and make Avita's sales force 50 to 70 percent more productive.

In June this year, the first burns patient was treated with Recell Go, at the clunkily-monikered Joseph M Still Burn Center at Doctors Hospital of Augusta, Georgia.

Recell Go applies to burns covering up to 10 percent of the body, or up to 1,920 square centimetres. The company expects FDA approval for a variant, Recell Go Mini, for burns up to 2.5 percent of the body or up to 480 square centimetres.

## Bringing it home

While Recell is approved locally the company hasn't been selling actively, for want of decent reimbursement.

But in November the company entered an exclusive distribution agreement with Revolution Surgical Pty Ltd, covering Australia and New Zealand.

The deal includes Recell Go, pending regulatory approval. Mr Corbett says the deal "reintroduces Avita to its place of origin" a reference to Prof Wood's ground-breaking work

## Layer upon layer

In July 2024 Avita entered a five-year partnership with Regenity Biosciences to develop a collagen-based dermal matrix called Cohealyx (so called because of the collagen's helical structure). The idea is that the matrix goes on the bed of the wound and Recell goes on top. The matrix promotes the growth of cell fibre tissue and re-vascularation (in other words: healing).

Under the deal, Regenity will make the scaffold and it will be sold by Avita's sales team under the Avita moniker. The revenue is shared equally in the first two years; thereafter Avita pockets 60 percent.

Avita also holds the exclusive US rights to market, sell and distribute Permeaderm, a biosynthetic wound dressing that goes on top.

Mr Corbett says Permeaderm has "microporous variability" meaning it can be stretched to make it bigger or smaller while ensuring the pus exits the wound (a good thing).

In animal models, the company tested 18 formulations from 10 different companies.

"In our pre-clinical data, we got graft-ready somewhere between five and seven days faster than the closest [product]," Mr Corbett says. "We don't have human data but it is a validated porcine model."

The company estimates per patient revenue from the combined devices at $US28,000 to $US55,000 per procedure.

## Tackling the 'Michael Jackson disease'

Meanwhile, Avita is working on a Recell cartridge to treat vitiligo, the genetic disorder that results in loss of pigmentation and skin turning white (the late Michael Jackson was a famous sufferer).

The FDA approved Recell for vitiligo last year, but management did not feel the data from a previous 23-patient trial was strong enough and carried out a 109-patient post-market study called Tone.

The six-month data is yet to be released - it should be published in early 2025 - but Mr Corbett says the results showed 80 percent better re-pigmentation than the earlier data presented to the FDA. A health economics study also shows it is cheaper, which will be handy for reimbursement options.

Current therapies include phototherapy or melanocyte transplants, which are either ineffective, long and/or expensive.

In the US, 50,000 vitiligo patients are currently seeking therapy, of a total affected populace of three million to 6.5 million. There are about 70 million vitiligo sufferers, globally.

**Finances and performance**

Avita posted September (third) quarter revenue of $US19.5 million, 44 percent higher than previously.

The loss came in at $US16.2 million, compared with a $US8.7 million deficit previously and attributable mainly to increased sales and marketing costs.

Management has guided to current (December) quarter revenue of $US23.2 million at the midpoint, 65 percent higher year-on-year.

Full year (calendar 2024) guidance is for revenue of $US68 million to $US70 million, 37 to 41 percent higher.

Management has also guided to cash flow breakeven and profitability under Generally Accepted Accounting Principles (GAAP) by the end of the September quarter 2025. Put that one in your diary folks!

At the end of September, the company had net cash and equivalents of $US44.4 million, 50 percent lower.

Avita’s development is being funded substantially by a $40 million loan from healthcare investor Orbimed.

Mr Corbett says the company could have raised equity, but given the “undervalued” shares it would have diluted shareholders by an unacceptable 15 percent.

In November, the company agreed to forego an extra $US50 million available from Orbimed, in return for Orbimed dropping a revenue-related covenant requirement.

Over the last 12 months, Avita’s ASX-listed shares have traded between $5.51 (February 2, 2024) and $2.37 (July 5 2024). The stock peaked at $16.30 in February 2020.

**Dr Boreham's diagnosis:**

Mr Corbett says more than 75 percent of Avita's Recell customer base has transitioned to Recell Go.

With the anticipated launch of Cohealyx in 2025 "we are positioned to address a broad continuum of wound care needs".

In March 2023, Mr Corbett attributed the company's lowly share price to its own performance - rather than the overall market - and "how we express ourselves to investors".

He said investors would "kill' him if his definitive deadlines and targets were not met.

It now looks like Mr Corbett will spare being slayed - metaphorically speaking, of course - because the shares have lifted 50 percent over the last six months.

"The sun is coming up and we can see it," he says.

The company cites a total addressable market in the US as 127,000 annual procedures, including 120,000 traumatic wounds and 900 surgical procedures.

Expanding indications would take the tally to 271,500, including 136,000 cancer excisions (Avita's material also mentions 1,500 gunshot wounds, which surely is an underestimate).

So, there's clearly a large addressable market. All Avita needs to do now is to execute its commercial rollout and demonstrate consistent profitability - something it has struggled with in the past.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is still snoozing when the sun comes up, so can't see it.***