Biotech Daily

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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: ASX: 71,794,370 CDIs; Nasdaq 10,968,887 shares equivalent to 54,844,435 CDIs = 126,638,805 CDIs and equivalents (five CDIs equals one US share)

CDI price: $3.80; **Market cap:** $481.2 million

Chief executive officer: James (Jim) Corbett

Board: Lou Panaccio (chair), Mr Corbett, Jeremy Curnock Cook, Prof Suzanne Crowe, Jan Reed. Cary Vance and Robert McNamara, effective from April 1, 2023

Financials (year to December 31, 2022): sales $US34.42 million (up 4%)*****, expenses $US59.1 million (up 10%), loss of $US27.1 million (previous $US25.1 million deficit) Cash of $US18.2 million with $US68.1 million of marketable securities
* Includes BARDA sales of $US370,000 compared with $US7.934 million previously, and a move from June 30 to December 31 reporting; $A1.00 = 67 US cents

Identifiable major holders: Vanguard Group 4.5%, Pura Vida Investments LLC 3.4%, BlackRock Institutional Trust Company 1.85%, Michael Perry 1.4%, Thorney Investments 0.5%.

Avita shareholders: put a ring around July 1, 2023 on your calendars and highlight the month of June as well.

Why? June is when the company expects US Food and Drug Administration approval for use of its Recell spray-on skin device for soft tissue injuries.

July 1 is when the company expects to launch the device for that indication, with a trained US sales force already boosted from 30 to 70 ahead of time.

Avita will also expects approval for a broader skin condition, vitiligo and have its treatment reimbursed and launched in January 2025.

Naturally, biotechnology boardrooms prefer ample wiggle room to allow for the inevitable delays and setbacks.

But Avita's new CEO Jim Corbett is not one for prevaricating. Having been appointed in late September last year, he moved to abolish vague targets in favor of specific statements of intent.

This includes introducing specific quarterly profit guidance - as alien a concept to Australian boardrooms as little green men.

"The prior communication was we would submit for approval in the second half of 2022 and get approval in the second half of 2023," Mr Corbett says.

"If an analyst hears that they say 'what am I going to do with that [guidance]?' Well, you can't do a thing with that, damned honestly."

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.

Mr Corbett replaces Mike Perry, Avita's CEO since 2017. Chief financial officer Mike Holder and chief operating officer Kathy McGee have also left the building.

So far investors have embraced Mr Corbett's straight-shooting approach, with the share price rising about 150 percent since his appointment.

The Avita story, condensed

Recell involves taking a small skin sample from the body and mixing the cells into a liquid spray, for use in 30 minutes.

Strictly speaking, Recell is a "single use, stand-alone battery-operated autologous cell harvesting device, containing enzymatic and buffer solutions, sterile surgical instruments and actuators to achieve the disaggregation and delivery of skin cells".

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

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 became known as Avita Medical in 2008, and following a merger with Visiomed, Clinical Cell Culture listed on the ASX on August 9, 1993.

Avita's 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. In a reverse share split (better known as "a consolidation"), shareholders received one share in US common stock for every 100 held.

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

In September 2018, the 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.

Meanwhile, Recell is approved in Europe and Australia for burns and broader indications, but until the company secures adequate reimbursement it won't sell actively in these markets (ad-hoc surgeon requests are supplied on demand).

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.

No longer a slow-burn story

At his first national sales meeting, Mr Corbett heard about an incident that in his view exemplified the strengths and weaknesses of Avita.

The tale goes that two Avita sales people drove across west Texas for eight hours to supply a hospital with a Recell kit for a crucial surgery.

While this amounted to "uncommon commitment" the action highlighted the lack of sales coverage in a key region.

"It's wonderful that we have those people, but we should be in a place where instead of driving all night they are with the customer on the ground."

Having spent a year on the board as a non-executive director, Mr Corbett had plenty of opportunity to size up what needed to be done. In essence, he says, Avita had an "amazing transformative technology" but for the relatively small burns indication.

For a country with 330 million people there are surprisingly few burns centres in the US - about 150 - and about 300 specialist burns surgeons.

Hard targets for soft tissue

Of the half a million or so Americans who present to hospitals with burns every year, the company estimates a market of 40,000 ‘Recell-eligible’ victims.

In contrast, about 4.5 million Americans seek treatment for open wounds each year - anything from motor accidents to flesh-eating bacteria to gunshot wounds (we are talking about the US, after all).

Currently, Recell addresses a market of 25,000 burns patients, but soft tissue would expand this to 150,000 potential subjects.

In November last year, the FDA granted Recell breakthrough device designation and a month later the company lodged its pre-market approval application (PMA) application.

Under the breakthrough device/fast track protocol, the FDA has 180 days to approve or reject an application - hence Mr Corbett’s comfort in setting a June 2023 deadline.

The FDA application was supported by last August’s top-line results of a US pivotal trial, showing the study met the two primary endpoints of “statistically significant donor skin spacing and statistically non-inferior healing rates”.

Avita estimates a total addressable market in the US of $US1 billion per annum.

Vitiligo

In December, Avita filed a PMA request with the FDA for vitiligo, the genetic disorder that results in loss of pigmentation and skin turning white. Deceased musician Michael Jackson was a prominent sufferer and he could never Beat It.

The company expects FDA approval by June 2023 and reimbursement by January 2025.

Vitiligo is caused by the malfunction of pigment producing cells, called melanocytes.

Current therapies include phototherapy or melanocyte transplants, which are either ineffective, long and/or expensive. The Avita treatment is a “one and done” procedure for most patients.

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

There are about 70 million vitiligo sufferers, globally.

Avita is running a single-arm, pivotal trial across 15 sites, involving 23 patients. Top-line results suggest the trial is on track to meet the primary endpoint of “a “super superior response rate”.

Finances and performance

Avita's revenue crept up four percent to $US34.42 million in the year to December 31, 2022, with a steady loss of around $US26 million.

The increase would have been more impressive if not for the previous period's income contribution from the Biomedical Advanced Research and Development Authority (BARDA), which came in at $US7.934 million previously - compared with $US370,000 in the December 2022 stanza.

December quarter sales ticked up a more impressive 37 percent to $US9.45 million, with the loss narrowing to $US5.4 million from $US8.5 million.

BARDA, by the way, is the US agency that stockpiles medicine and medical equipment for use in a mass disaster.

BARDA has committed to up-to $US80 million of funding for Avita's burns trials and also plans to stockpile the product. The agency has also stumped-up to fund an economic study.

While Avita's losses are chunky the company has a cash balance of $US86 million, enough to keep the coyotes from the door.

Management's boldly specific revenue guidance of $US10 million to $US11 million for the current (March) quarter is about 20 percent higher than what the market expected initially.

Over the last 12 months, Avita's ASX-listed shares have traded between $4.42 (early June 2021) and $7.67 (mid-October 2020).

The stock peaked at $16.30 in February 2020.

Automate or perish

The expanded Recell indications aside, management is prioritizing the commercialization of an automated device to scrape the skin samples and mix them with the liquid ingredients.

About the size of a blender, the device will ameliorate the need for sales agents to spend many hours training nurses and clinicians on how to prepare the Recell kits. He says the yet-to-be named device will reduce training time from about 50 minutes to five minutes and make Avita's sales force 50 to 70 percent more productive.

When Mr Corbett said he wanted the product on market by January 2024, he was told internally that it couldn't be done for regulatory reasons. But on further probing he received the Obama-esque response of 'Yes We Can'.

So, the January 2024 deadline is what Mr Corbett dubs a "binary deliverable".

Dr Boreham's diagnosis:

Mr Corbett notes that when he took on the top job, Avita shares were near an all-time low - at a time when the biotech sector was being hammered.

"But it wasn't about the market," he says. "It was about the company's own performance and how we express ourselves to investors."

Refreshingly, Mr Corbett has left investors in no doubt as to how his success should be measured. But when it comes to revenue guidance, constantly beating the numbers would be just as bad as falling short because broking analysts would then raise the bar.

"Setting guidance isn't an exercise in sandbagging. It's an exercise in credibility and very different to what has been done before," he says.

Still, Mr Corbett is aware he will join Avita's conga-line of fallen CEOs if the definitive deadlines and targets are not met.

"Investors will kill me if I don't achieve them," he says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He prefers his deadlines to be flexible and his key performance indicators to be as vague as all hell.