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 (American depositary shares)

Market cap: $574.5 million

Share price: AVH $4.61; RCEL $US17.32

Shares on issue: ASX 68,499,335 CDIs; Nasdaq 11,225,251 US shares
(Five CDIs equal one US share implying 124,625,590 CDI equivalents or 24,925,118 US common share equivalents)

Chief executive officer: Dr Mike Perry

Board: Lou Panaccio (chairman), Dr Perry, Jeremy Curnock Cook, Louis Drapeau, Prof Suzanne Crowe, James Corbett, Jan Stern Reed

Financials (year to June 30 2021): sales $US29.23 million (up 105%), loss of $US26.47 million (previous $US42 million deficit), cash holdings $US110.9 million (up 50 percent)

Identifiable major holders (CDI holders): Redmile Group/Jeremy C Green 6.7%, Vanguard Group 4.9%, Montgomery Investment Management 4.5%, Pura Vida Investments LLC 3.2%, Farallon Capital Management LLC 3.2%.

Is the burns care outfit on the cusp of discovering the elixir of youth?

Not quite, but the work Avita is carrying out with the Houston Methodist Research Institute (HMRI) could be bigger than Texas.

In partnership with the god-fearing academic medical centre, Avita is exploring a novel skin rejuvenation approach that would reverse the ageing of cells.

HMRI has the relevant patented technology that involves genetically-modifying cells to deliver the anti-ageing enzyme telomerase.

The Institute has already demonstrated reversal in progeria (accelerated ageing) in young patients.

Avita notes a $US16 billion ($A22 million) market for aesthetic procedures in the US alone, with 10 million injectable cosmetic procedures performed in 2019.

“Consumers are seeking a natural, more youthful appearance and there is a ‘white space’ in the market for a minimally invasive procedure that provides meaningful results,” Avita says in its US regulatory filing.

Avita chief executive Dr Mike Perry describes the prospect of personalized skin care as “very promising” and a multi-billion-dollar market opportunity.

The rejuvenation work is one of several sidelines Avita is working on to expand its ‘spray on skin’ technology beyond burns, with a string of announcements expected in coming months.

Who Wood have thought?

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 tested on Bali burns victims after the 2002 terrorist attack.

Then known as Clinical Cell Cultures, the company was founded in 1992 and listed on the ASX in August 1993.

The Avita name was adopted in 2008. Initially, Avita’s American Depositary Shares traded on the over-the-counter exchange, and then on the Nasdaq from October 2019.

Recognizing the importance of the US market, in June last year the company redomiciled to Bidenland.

Over time, Avita has had a revolving door of CEOs, including a former war correspondent (Adam Kelliher).

The incumbent, Dr Perry, is a former Novartis executive who joined the Avita board in 2017.

In September 2018, the US Food and Drug Administration granted approval to use Recell for burns and the company started selling there in January 2019.

Progress to date

Recell involves taking a biopsy on any part of the body and mixing the cells into a liquid spray. It's ready for use in 30 minutes and can cover 80 times the area of a skin graft with the same amount of material.

Because the nerves are usually damaged in the biopsy, the grafts - rather than the burns - create the most pain.

Avita thus far has treated 10,000 patients, 4,000 of them in the US. Clinical studies have involved more than 2,000 patients.

"We have been very pleased with the adoption of Recell in the US, we have realized in in excess of $US42 million since approval," Dr Perry says.

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 (surgeon requests are supplied on demand).

This year, Avita won FDA assent to treat paediatric burns, which is a significant expansion given 25 percent of burns patients are kids.

The US burns fraternity is cosier than a White House situation room, with 75 percent of the circa 53,000 in-house patients treated at one of 137 burns centres, by one of 300 burns surgeons.

Of these medicos, about 80 percent are certified (they have completed at least one procedure).

The company says just under 500,000 Americans seek treatment for burns. Of these, an estimated 25,000 patients are "Recell eligible" - a $US260 million a year market.

Meanwhile, Avita has applied to the FDA to extend the use of Recell from burns to soft tissue trauma, such as motor accident injuries and even the gruesome wounds inflicted by flesh-eating bacteria.

The company estimates that 4.5 million US patients present to hospitals with open wounds each year. Of these, 65,000 would be eligible for Recell - a potential market of $US450 million a year.

The company is currently recruiting for the pivotal trial, with 43 patients of the targeted 65 enrolled across 17 sites.

BARDA be prepared for the worst

Avita is backed by the Biomedical Advanced Research and Development Authority (BARDA), the US agency that stockpiles medicine and medical equipment for use in a disaster.

BARDA has committed to up to $US80 million of funding for Avita's burns trials and also plans to stockpile the product.

BARDA also kindly stumped-up to fund an economic study, which showed that Recell would save healthcare dollars for any patients with bodily burns of 10 percent or greater.

(ASX peer Polynovo also has a BARDA burns contract.)

Bad skin can Beat It

Avita is in early-stage work with vitiligo, the genetic disorder that results in loss of pigmentation and skin turning white. It's also known as white leprosy or the Michael Jackson disease.

The affliction 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. (The ASX-listed Clinuvel has also turned its Scenesse attention to vitiligo.)

"In essence we provide a lab in a box via the Recell system to re-pigment patients and restore original skin texture," Dr Perry says.

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

There are about 70 million vitiligo sufferers globally. The company estimates a total assessable vitiligo market of $US5 billion and a serviceable market of $US750 million across 1.3 million sufferers.

Avita currently has a clinical trial running across 15 sites, involving 23 patients. This patient cohort was reduced from 84 by focusing on one donor skin concentration, rather than three.

Meanwhile, Avita is also exploring a spray-on gene cell therapy for epidermolysis bullosa, in partnership with the Gates Center of Regenerative Medicine in Colorado.

A nasty rare genetic disease, epidermolysis bullosa causes the top dermis not to be connected properly to the bottom one, resulting in skin blistering, chronic wounds and even cancers.

There are no FDA-approved treatments, only palliative ones at a cost of $US300,000 to $US500,000 per patient.

The research involves "gene editing for precise correction of the disorder and cell banking of the corrected cells".

Japan beckons

Avita has a marketing distribution agreement with Japanese company Cosmotec, a subsidiary of the giant M3 Group, which is seeking approval for Recell from the country's medical gatekeeper.

Consent is expected by the end of this year, with commercialization expected next year.

Dr Perry sizes up Japan as a $US60 million a year market, across 6,000 eligible burns patients. But there's a further 22,000 soft trauma patients and two million vitiligo patients.

Cosmotec funds the commercialization, with Avita pocketing a 40 percent revenue share.

Finances and performance

Avita more than doubled Avita commercial revenue in the 12 months to June 2021, to $US29.2 million. Of this amount, $US21.5 million derived from commercial sales and $US7.5 million from BARDA inventory requests.

Total revenue including the BARDA contract was up 72 percent to $US31.3 million. Avita's June quarter revenue increased 165 percent year-on-year, to $US10.3 million.

Chief finance officer Mike Holder notes the Recell achieved a gross margin of 80 percent, which is "exceptional" for a medical device.

The company almost halved its loss to a still-chunky deficit of $US26 million.

Avita has racked up $US42 million from sales since 2018, as well as $US7.6 million from holding inventory on behalf of BARDA. The Recell kits sell for $US7,500 each, with each unit covering 10 percent of the body.

The company has $US111 million of cash, having raised $US69 million in March 2021 by issuing just over 3.2 million US shares.

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

Pay attention guys

Shareholders should avoid the temptation to nap as they might miss out on a number of events in coming months.

There's the expected Japanese approval for burns and, possibly, soft tissue repair.

With epidermolysis bullosa, by the end of this year the company expects to deliver initial proof of concept results for delivering genetically modified skin cells in suspension.

With rejuvenation, Avita expects to unveil some proof-of-concept (mice) results this side of Christmas.

The last patient in the vitiligo trial is expected to be enrolled by the end of the year, with a commercial launch slated for late 2023.

Meanwhile, the last patient for the soft tissue trauma trial is expected to be enrolled in the second half of 2022, with commercial lift-off in 2024.

Avita is also awaiting FDA approval of a Recell device that is easier to use in out-patient applications, with this assent expected in the first half of 2022.

And if that's not enough, Avita is also developing an automated Recell iteration, for use in dermatology practices and by plastic surgeons.

Pop it all in the diary, folks!

Dr Boreham's diagnosis:

One positive fallout from the pandemic is that the travel and recreational restrictions resulted in a plunge in burns-related hospital admissions. In normal years, Avita's US addressable markets for burns, soft trauma and vitiligo amounts to about $US1.5 billion.

As we said, the rejuvenation market could be worth many billions more but we stress the anti-ageing stuff is at a youthful stage.

We would like to able to say that investors have rewarded Avita for growing its burns revenues and pursuing so many near-term expansions - but they haven't. The shares have lost about 30 percent of their value over the last year and in September they were booted from the S&P/ASX 300 index.

How rude!

Still, it's not the first time that the market has ascribed a lesser value to a de-risked revenue-producing biotech, than one with only 'blue sky' promises.

We dare say it won't be the last time. But if Avita achieves only some of what it expects, the valuation should look after itself.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he knows the elixir of youth does not come in a beer can or wine bottle.