Biotech Daily

Friday December 20, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.25 percent on Friday December 20, 2019, with the ASX200 down 16.8 points to 6,816.3 points. Sixteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and three were untraded.

Alterity (Prana) was the best, up 0.4 cents or 20 percent to 2.4 cents, with 600,000 shares traded. Imugene climbed 14.8 percent; Osprey improved 7.1 percent; Cyclopharm was up 6.8 percent; Opthea and Resonance were up more than four percent; Actinogen, Oncosil and Pharmaxis were up more than three percent; Avita, Genetic Signatures and Kazia rose more than two percent; Medical Developments was up 1.9 percent; with Cochlear, Compumedics, Next Science and Telix up by less than one percent.

Immutep led the falls, down one cent or 4.1 percent to 23.5 cents with 396,053 shares traded. Impedimed, Optiscan and Starpharma lost more than two percent; Cynata, Nanosonics, Neuren, Paradigm, Polynovo, Prescient and Volpara were down more than one percent; with CSL, Pro Medicus and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: AVITA MEDICAL

By Tim BOREHAM

ASX code: AVH; **Nasdaq code:** RCEL (American Depositary Shares)

Market cap: $1.38 billion; **Share price:** 65 cents; **Shares on issue:** 2,117,474,277

Chief executive officer: Dr Mike Perry

Board: Lou Panaccio (chairman), Dr Perry, Jeremy Curnock Cook, Louis Drapeau, Damien McDonald, Prof Suzanne Crowe

Financials (September quarter 2019): revenue $4.06 million, cash burn $7.03 million, end of quarter cash***** $22.65 million, estimated current quarter cash outflows $12.95million.

***** Ahead of institutional placement that raised $120 million.

Identifiable major holders: Redmile Group/Jeremy C Green 10.7%, Blackcrane 7.8%, Karst Peak Capital 7%

At every investor presentation - and he's fronted a few - Avita chief executive Dr Mike Perry includes a before-and-after picture of the visage of a 12-year-old girl who suffered burns to two-thirds of her body when her family's Jeep crashed and exploded.

Two years later, the burns are barely discernible after the girl was treated with Recell, Avita's spray-on skin product developed by Perth burns surgeon Prof Fiona Woods and famously used on the Bali terror bombing victims in 2002.

"You would normally be in hospital for three to four months and be fully scarred and disfigured for life," Dr Perry says. "Instead she was discharged after 23 days because the donor site is smaller".

"This is an amazing outcome."

Australian burns technology aids volcano victims

Almost two decades on from the Bali incident that forged Recell's reputation, burns treatment technology again has been cast into the limelight with New Zealand's White Island volcanic eruption, which inflicted serious wounds on about 30 tourists.

Dr Perry said the company had offered Recell to the Australian and NZ hospitals treating the patients, with two US burns surgeons on standby. "They said it was not required at this point while the patients are being stabilized," Dr Perry said.

In such situations deeper wounds might need a lattice-based product, along the lines developed by ASX counterpart Polynovo.

Polynovo reports that it has supplied its lattice repair product Novosorb Biodegradable Temporising Matrix (BTM) to three NZ and two Australian hospitals. “There are further surgeries scheduled for the week ahead and we will continue to work closely with the hospital teams,” the company says.

Both Avita and Polynovo were reluctant to discuss their involvement as they did want to be seen to be benefiting from the tragedy.

Slow journey to top 200 status

Known as Clinical Cell Cultures up to June 2008, Avita has been a slow burn development-wise. In fact, the company looked to be going nowhere before the US Food and Drug Administration granted approval for burns indications in September 2018.

The company has been selling to US burns centres since January this year.

Since then the shares have risen seven-fold, culminating in a monster $120 million capital raising (by way of an institutional placement) in November. A week earlier, the stock was promoted from the S&P/ASX300 index to the ranks of the top 200 stocks.

Dr Perry admits he felt like a rock star when he attended the American Burns Association annual get-together last April. “It felt like a Recell meeting, everyone was talking about us and it was a delight to be there.”

As the market finally wakes up to Avita’s potential, the company is turning to other indications including paediatric scalds, diabetic and venous ulcer wounds and vitiligo.

Restoring the ‘glossy finish’

The Recell process involves cutting skin !!!!! 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, the grafts - rather than the burns - create the most pain.

Dr Perry estimates that 53,000 patients are treated in-house, 75 percent of them at one of 132 burns centres across the US (not a huge number given the country’s size and population).
Recell is effective for second or third-degree burns (partial thickness of skin burns), but if the burn is fourth degree (full thickness), a reconstruction is usually required.

Using a smash repair analogy, Dr Perry says Recell produces the glossy finish rather than removing the deep dents.

Deeper wounds might need a lattice-based product, such as Polynovo’s.

Dr Perry by the way is a former Novartis executive who came on board in mid-2017, replacing former war correspondent Adam Kelliher.

All of the company's key 'Cs' – CEO, CFO (chief financial officer) and COO (chief operating officer) have been replaced. In November the CFO role turned over again with the appointment of former Heartware CEO David McIntyre.

The economics of Recell

The company 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 ($117 million) of funding for Avita's burns trials and also plans to stockpile the product for a disaster.

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. (Burns are measured by percentage, using the Wallace Rule of Nines, for head, chest, back, abdomen, lower back, arms and front and back of legs.)

The key to the savings is reducing hospital stays by 30 percent and the number of surgeries by 30 to 40 percent.

"It's a better standard of care and we are saving the health care system," Dr Perry says. "That's because these donor sites are small and (grafts) are the main source of pain that keeps patients in hospitals longer."

What's next?

Avita cites a $US200 million total addressable market for burns in the US, but it's eyeing other indications to take the opportunities to well over $US2 billion.

One area is outpatient burns treatment. While the company is approved for this indication, it is not currently pursuing it because the kit requires two sets of hands.

"It's perfect for the operating theatre but not the emergency room," Dr Perry says. "We are in the process of creating that single-person, fully sterilized kit. We are working with [design house] Planet Innovation in Melbourne and we will be ready for submission by end of calendar 2020 or early 2021."

The company plans to launch Brisbane-based trials for paediatric scalds, which in itself is a $US230 million a year market.

Then there are trials for soft tissue repair after trauma such as bike accidents and gunshot wounds, as well as surgical wounds (such as those resulting from removing a tumor).

Combined, these are a $US750 million market.

‘White leprosy’

But wait, there’s more: 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.

“We have treated 1,000 patients in China, we know it works,” Dr Perry says.

The company cites an addressable market of $US750 million to $US1 billion.

In the US, Dr Perry says, 150,000 vitiligo patients are currently seeking therapy, but there are 6.5 million sufferers in all. “The reason there’s so few (seeking treatment) is that there’s nothing on the market currently to restore pigment to its original color and texture,” he says. (Clinuvel is working on it.)

In the genes

Actually, there’s even more!

In late November, Avita signed a collaboration deal with an esteemed US campus to further a spray-on treatment of genetically modified cells for epidermolysis bullosa.

A nasty rare disease, epidermolysis bullosa results from gene mutation and causes skin blistering, chronic wounds and even cancers.

The tie up is with the Gates Center for Regenerative Medicine at the University of Colorado School of Medicine.

“It’s the same process (as Recell); it’s just an additional step,” Dr Perry says.

Finances and performance

The Recell kits sell for $US7,500 each, with each unit covering 10 percent of the body. So, a poor soul with 30 percent burns would cost $US22,500 to treat.

Avita cites US sales of $10.8 million to the end of September, with September quarter sales of $4.6 million. This compares with sales of $2.9 million in the fourth (June) quarter and $1.1 million in the December 2018 quarter (when the company had not started selling in earnest).

Burns are seasonal in nature. Americans, for instance, are vulnerable to burns on July 4, when they’re lighting crackers after too many Budweisers.

Dr Perry says there are three main causes of burns: industrial accidents, domestic mishaps and “something beginning with ‘watch this!!’”

Avita shares have traded as low as 4.7 cents (mid-November 2017) and as high 71 cents (mid-November 2019).

Where to invade next

Recell is approved in Europe, Australia and China, but you're not mistaken if you get the impression that the company is US-centric.

Because of the vagaries of reimbursement, Avita is not yet marketing in Europe.

"We are providing to European (burns) centres and keeping our licences current, but we are not actively selling," Dr Perry says.

"But we will re-launch in Europe when we add trauma (wounds) and vitiligo."

China makes for a tempting opportunity, but there are problems. "It's hard work and risky because they will figure out a way to reverse engineer your product and they don't care about patents."

The company has a marketing distribution agreement with Japanese company Cosmotec, which is seeking approval from the country's medical gatekeeper.

Dr Boreham's diagnosis:

Avita's 2020 'to do' list involves plugging away at increasing its US burns business and furthering the trials for paediatric scalds, soft tissue wounds and vitiligo.

Beyond the aforementioned programs, Avita has its eye on the facial rejuvenation market, which could be worth many times that of all the other indications combined.

Move over Botox!

"We are working on an exclusive licence but I can't say too much," Dr Perry says.

"If we capture even just five percent of this market, we are looking at well over half a billion dollars."

"And if we got to phase II without being acquired, I would be very surprised."

Dr Perry can be proud of the corporate facelift he has engineered for Avita - on the proviso that revenue remains modest relative to the company's $1.3 billion market valuation.

"We are a relatively small company with 100 people," he says.

"But we have a pipeline that is extraordinarily de-risked and looks like that of a mid-sized pharma company."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has no burning desire to light a bonfire with petrol; diesel is much safer.

PERRON INSTUTUTE, UNIVERSITY OF WESTERN AUSTRALIA

Perth's Perron Institute and University of Western Australia say the US Food and Drug Administration has approved Serapta's Vyondys-53 for Duchenne muscular dystrophy.
The University of Western Australia said that Vyondys-53 had been developed by Prof Sue Fletcher and Prof Steve Wilton at the Perron Institute and the University, and could treat up to eight percent of Duchenne muscular dystrophy (DMD) patients.
The announcement said that Vyondys-53 received "accelerated approval" based on data showing increased dystrophin in patient muscle after treatment.
A spokesperson for the Perron Institute told Biotech Daily that accelerated approval allowed Vyondys-53 to be prescribed for patients, pending a raft of conditions.
The University said that Vyondys-53 was "an antisense oligomer treatment for patients with a confirmed gene mutation amenable to exon 53 skipping".
The announcement said that Vyondys was the second FDA-approved exon skipping drug developed by Prof Fletcher and Prof Wilton, following the approval Exondys-51 for patients who require exon 51 skipping in 2016.
In a separate announcement, the Cambridge, Massachusetts-based Sarepta Therapeutics said that it was enrolling its "placebo-controlled, post-marketing confirmatory trial to support the Vyondys-53 accelerated approval, titled Essence," which it expected to finish by 2024.

CARTHERICS

Cartherics says it has raised $12 million in subscriptions from current and new investors, founders, board members and senior management.
Cartherics said the funds would be used for clinical trials for ovarian cancer and cutaneous T cell lymphoma blood cancer.
Cartherics chief executive officer Prof Alan Trounson said the company expected to start autologous cell clinical trials at the end of 2020 or start of 2021 "and expect our off-the-shelf product to enter clinical trials in Australia in 2022".
Cartherics is a private company.

CYCLOPHARM

Cyclopharm says it has raised $9.775 million in a placement to Karst Peak at $1.15 a share an 11.7 percent premium to its December 18, 2019 closing price.
The company said Karst Peak would hold 10.9 percent of the company following the placement.
Cyclopharm managing director James McBrayer said, "I am delighted with the support Karst Peak has shown for our growth strategy".
"With this capital we are well funded to initiate the launch of Technegas once approved by the US Food and Drug Administration, with commercial sales targeted to commence in 2020, and to continue progressing our strategic initiatives including the expansion of the use of Technegas beyond the pulmonary embolism market and investing in ongoing research and development activities and product and systems enhancements," Mr McBrayer said.
Cyclopharm said Bell Potter Securities was lead manager to the placement.
Cyclopharm was up seven cents or 6.8 percent to $1.10.

TELIX PHARMACEUTICALS

Telix says that Cancer Australia has provided $500,000 to the collaborator the Victoria Cancer Centre to develop its TLX250 for colorectal cancer.
Telix chief executive officer Dr Christian Behrenbruch told Biotech Daily the value of the grant which was not disclosed in the media release.
The company said the grant would support the development of Girentuximab or TLX250, a monoclonal antibody agent for tumor-related antigen carbonic anhydrase IX, expressed in several cancers including kidney and colorectal cancer.
Telix said the grant was awarded under Cancer Australia's priority-driven collaborative cancer research scheme and it would use it to fund a three-year research project with Prof Frédéric Hollande from the University of Melbourne Centre for Cancer Research and the Victorian Comprehensive Cancer Centre.
The company said the research would "explore whether Girentuximab has potential as a molecularly targeted radiation agent for the imaging and treatment of inoperable, metastatic colorectal cancer".
Telix was up one cent or 0.7 percent to $1.51.

CYCLOPHARM

Cyclopharm says it has a nine-year agreement with Cyclotek to expand positron emission tomography opportunities in New South Wales and Australia.
Cyclopharm said it had a collaboration with Cyclotech and Australian Nuclear Science and Technical Organisation (ANSTO) subsidiary Pettech Solutions, to manufacture new positron emission tomography (PET) diagnostics not otherwise produced in New South Wales and to undertake research and development with Macquarie University.
The company said Cyclotek would access its suspended Macquarie University Hospital-based Cyclopet business and ANSTO's Lucas Heights Pettech business facility.
Cyclopharm said it estimated operational savings of $280,000 a year under the agreements, excluding Cyclotek profit-share payments and would contribute $40,000 a year for nine years for research and receive a material share of the joint venture's profits.
The company said it would have exclusive rights to commercialize the joint venture's intellectual property outside Australia and New Zealand.

COGSTATE

Cogstate says it has record clinical sales contracts of $19.1 million for the three months to December 20, 2019 and $26.8 million since July 1, 2019.
Cogstate chief executive officer Brad O'Connor said the six month sales contracts was "a reflection of accelerating demand for the company's scientific solutions and technologies".
"Over the last month especially, we have executed a number of contracts in respect of studies that are planning to begin in the March quarter of 2020," Mr O'Connor said.
"The growth was not altogether unexpected, remembering that at the beginning of this financial year Cogstate provided guidance of 50 percent growth in clinical trials sales contracts from the $18 million of contracts executed during the 2019 financial year".
"That said, the December half-year result exceeds the expectations that we had for the business when we provided our earlier guidance," Mr O'Connor said.
"The result certainly validates the expectation of a strong rebound from what was a very disappointing 2019 financial year," Mr O'Connor said.
Cogstate was up 11 cents or 36.7 percent to 41 cents.

REGENEUS

Regeneus says AGC Asahi Glass has agreed to terminate its manufacturing licence and joint venture agreement.

In 2016, Regeneus said AGC would pay $US16.5 million ($A22.9 million) for exclusive rights to manufacture Progenza in Japan and take a 50 percent interest in Regeneus Japan (BD: Jan 22, 2017).

Today, the company said it had achieved the intent of the original agreement transferring its cell therapy manufacturing know-how to AGC and AGC leading the identification of potential partners in Japan.

Regeneus said AGC elected to convert $US2.5 million of their upfront and milestone payments into equity ownership in the company at a fixed subscription price of 16 cents a share, a 100 percent premium to the December 19, 2019 share price.

The company said that AGC would become the company's largest shareholder with about eight percent.

Regeneus chief executive officer Leo Lee said AGC had been "instrumental in advancing our commercialization discussions in Japan and opened doors for us in the market".

"Our mutual agreement to terminate the joint venture gives Regeneus flexibility to develop a go-to-market model where commercial partners can manufacture, develop and commercialize Progenza OA in Japan," Mr Lee said.

"Additionally, we look forward to AGC becoming our largest shareholder and participating in the growth in Japan and globally," Mr Lee said.

Regeneus was up half a cent or 6.25 percent to 8.5 cents.

ANATARA LIFESCIENCES

Anatara says it has finalized the trial protocol for its pineapple-stem bromelain-derived dietary supplement for irritable bowel syndrome but did not disclose the trial design.

Anatara said its gastrointestinal reprogramming dietary supplement (Garp) was being developed to target both irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD).

The company said it had begun the process of selecting a clinical research organization.

Anatara chief executive officer Steven Lydeamore said, "there is a major unmet medical need and significant market opportunity for an evidence-based dietary supplement for IBS".

"Meeting this milestone keeps Anatara on track to commence this human clinical trial in 2Q 2020," Mr Lydeamore said.

Anatara was up one cent or 4.4 percent to 23.5 cents.

ADALTA

Adalta says it has a loan facility deal with Radium Capital to borrow up to 80 percent of its research and development tax incentive each quarter.

Adalta said it would receive the first $961,000 for the three months to September 30 by December 31, 2019.

The company said early access to these funds would facilitate initial human clinical trials for lead candidate AD-214, which it expected to commence by April 2020.

Adalta fell three cents or 23.1 percent to 10 cents.

RHINOMED

W Whitney George says he has increased his substantial shareholding in Rhinomed from 35,384,852 shares (24.93%) to 44,158,951 shares (26.09%).
The Carlsbad, California-based Mr George said that between June 29 and December 16, 2019 he acquired 8,774,099 shares for $US1,339,035 ($A1,942,786) or 15.3 US cents (22.1 cents) a share.
Rhinomed was up one cent or 5.4 percent to 19.5 cents.

RESPIRI

Respiri says it has cancelled 3,125,000 of 5,000,000 shares issued to supplier Two Bulls, who delivered $150,000 of $400,000 in proposed services.
Last year, Respiri said two development partners, Grey Innovation and Two Bulls, had taken equity in the company through a $3.2 million placement, satisfied by $400,000 worth of services by Two Bulls (BD: Dec 18, 2018).
Today, the company said the other supplier, Grey Innovation, fully satisfied subscription requirements at the time.
Respiri said it also reduced the number of unlisted options on issue by cancelling the 10,000,000 options issued to former chief experience officer Koswani Wall, who resigned last week, as vesting conditions would not be met (BD: Jun 11, 2019).
Respiri was up 0.2 cents or 2.2 percent to 9.3 cents.