

Ag & Vet Weekly



Monday March 9 – Friday March 13, 2020

All the news on ASX-listed agriculture and veterinary companies

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MARKET REPORT

The Australian stock market climbed 4.42 percent on Friday March 13, with the ASX200 up 234.7 points to 5539.3 points. Fifteen of the AVW-46 stocks were up, 25 fell, one traded unchanged and five were untraded.

Next Science was the best, up 18 cents or 12.5 percent to \$1.62, with 252,409 shares traded. Costa climbed 11 percent; Bega was up 9.9 percent; Tasfoods increased 7.8 percent; A2 Milk was up six percent; Huon and Murray Cod rose more than four percent; Clover and Nufarm were up more than three percent; Food Revolution rose 2.6 percent; Elders, Select, Synlait and Tassal were up more than one percent; with National Veterinary up 0.6 percent.

Ecofibre led the falls, down 35 cents or 19.3 percent to \$1.46, with 540,424 shares traded. Both Anantara and Cannpal fell 17.4 percent; Wide Open was down 16.7 percent; MGC and THC lost more than 15 percent; Seafarms fell 12.2 percent; both Apiam and Creso fell 9.1 percent; Terragen was down 8.3 percent; Cann Group, Palla and Regeneus lost more than seven percent; Bubs shed 6.9 percent; AP Hemp, Ocean Grown and Roots fell five percent or more; Memphasys fell 4.4 percent; Althea, Auscann, Opyl and Pharmaust shed more than two percent; with Elixinol, Fonterra and Ridley down more than one percent.

DR BOREHAM'S CRUCIBLE: QBIOTICS GROUP

By TIM BOREHAM

Qbiotics is a public unlisted company

CEO: Dr Victoria Gordon

Board: Rick Holliday Smith (chairman), Dr Victoria Gordon, Dr Paul Reddell, Andrew Denver, Graeme Levy, Dr Steve Ogbourne, Neville Mitchell, Dr Susan Foden.

Major holders: Dr Gordon and Dr Reddell, 8% each

Your columnist normally confines his musings to publicly-listed biotechs, but given the current foment readers may be relieved to read about an unlisted one that isn't losing large chunks of its value by the day.

In their heart of hearts - and whether they're public or private - life science companies aspire to develop the blockbuster therapies to rid humans of curses such as cancer, heart ailments, Alzheimer's disease and, of course, coronaviruses.

But for Qbiotics chief executive and microbiologist Dr Victoria Gordon, developing drugs for the human and animal markets is not the awkward mix of motives it is often perceived to be.

"The vet market is not too shoddy, with blockbuster drugs worth \$100 million or more," she says.

Qbiotics is doing more than just dreaming. In January its cancer canine drug tigilanol tiglate was green-lighted by the European Medicines Agency - the company's first regulatory tick of approval.

Branded as Stelfonta, the drug is indicated for all grades of canine mast cell tumors, the most common form of doggie skin cancer.

Bear in mind that one in four dogs will develop cancer, with half of them over the age of 10 dying from the disease.

At the same time, factors such as the rise in single occupant households and increased pet insurance coverage increase the ability and willingness of owners to pay.

And on the human side, tigilanol tiglate (EBC-46) is in phase I testing for a variety of solid cancers, notably the difficult-to-treat head and neck squamous cell carcinoma (HNSCC).

Dr Gordon describes tigilanol tiglate as a new approach to tackling cancer.

"The drug works largely through specific protein kinase C (PKC) activation," she says. "It locally stimulates the immune system resulting in destruction of the tumor mass and the tumor's blood supply, followed by rapid healing of the site with minimal scarring."

Tapping nature's drugstore

Dr Gordon and her forest ecologist husband Dr Paul Reddell stumbled on the therapeutic benefits of tigilanol tiglate while fossicking in rainforest in the Atherton Tablelands of Far North Queensland.

They observed that animals spat out the seed of the blushwood tree, pointing to a non-toxic deterrent preventing the critters from eating and thus destroying the seed.

"We had an idea about how to discover biologically active small molecules from the natural environment more effectively," Dr Gordon says.

To abbreviate a long story of discovery, they isolated EBC-46 and tested it on a range of animals. The molecule proved safe, but also active against tumors. Both were in the employ of the venerable CSIRO at the time, but in 2000 Dr Gordon quit her day job to form Ecobiotics. Dr Reddell later joined and they formed Qbiotics in 2004 (into which Ecobiotics was merged).

On March 15 the company celebrates its 20th birthday. "It's been an interesting and long journey," Dr Gordon says.

EBC-46 was chosen as a clinical candidate after a "hard cull" of dozens of other prospects. Dr Gordon says the drug candidates need to be safe (obviously), patentable and "novel". Oh – and there has to be an addressable market.

"We pride ourselves on being a little bit different," Dr Gordon says. "We push our drugs (in testing) and actually try to make them fail."

Only other vets would understand

Stelfonta's approval by the European Medicine Agency was supported by a pivotal study of 123 hounds with mast cell tumors which account for one-fifth of all canine cancers.

Twenty-eight days after a single injection of the drug, 75 percent of the dogs had a complete response. The randomized and blinded trial involved an untreated control group that received rescue therapy after the 28 days. The trials were held at 11 clinics.

According to Qbiotics veterinary oncologist Dr Pam Jones, the current standard of care is surgery - but anaesthesia is dangerous for older dogs and brachycephalic breeds (short-snouted ones such as bulldogs, boxers, pugs and shih tzus).

"Stelfonta is administered by injection directly into the tumor mass," she says. "Generally, a dog undergoing treatment does not need to be sedated or need local or general anaesthesia."

Qbiotics is backed by the French vet drug house Virbac, which has signed on to distribute Stelfonta in the US, Europe and the UK - which just about covers the world of animal care. Dr Gordon is suitably mysterious about the fine print of the deal, but says in effect it's a 50-50 revenue sharing arrangement.

While the European approval covers 27 countries, Virbac is gearing up to launch Stelfonta initially in Britain, France, Spain and Germany. “We’re really happy to be aligned with Verbac; it’s been a good relationship.”

Meanwhile, the company is putting the finishing touches to an application to the US Food and Drug Administration, with a submission also lodged to the Australian Pesticides and Veterinary Medicines Authority last September. Dr Gordon is confident these authorities will not require further trials.

The Brits make for an attractive market, thanks to the legacy of the dog-loving Queen Victoria. But Dr Gordon says there’s also appeal in Russia, China and Japan.

While Dr Gordon believes Stelfonta could “potentially” move beyond that \$100 million a year ‘blockbuster’ threshold, the company will really only know the European potential when it starts selling.

EBC-46 does the trick with human trials

The human trials, we stress, are less advanced, but promising nonetheless. The peer-reviewed journal, The Lancet’s Ebiomedicine, has published the data from the company’s first-in-human trial that tested EBC-46 on patients with a variety of solid tumors.

The 22-patient study was performed at four Australian hospitals, covering nine tumor types including squamous and basal cell carcinomas, melanoma, breast cancers and metastatic colorectal cancer.

“Signs of clinical activity were observed in all nine tumor types, even at the lowest doses,” the company says. “As this was a first-in-human, single dose safety study, the expectation of a strong anti-cancer response was low.”

But voila! The phase I study showed that six patients (27%) had a treatment response, with four patients (18%) showing full tumor destruction.

The company is now recruiting for a phase I/II trial of EBC-46 in patients with head and neck squamous cell carcinoma. The study will enroll up to 40 patients from the Tata Medical Centre in Kolkata and the Tata Memorial Hospital in Mumbai, as well as Australian clinical sites. A combination trial with an existing cancer drug is also planned.

Qbiotics pipeline also includes EBC-1013 for venous leg ulcers and burns and blast wounds in humans, as well as acute and chronic wounds on horses.

Finances and performance

In case you’re wondering - and we certainly are - Qbiotics is eyeing an ASX listing in early 2022. But this timetable is subject to change and the company is not in a hurry - even less so given the bombed-out bourse.

“A problem with Australian biotechs is they are desperate to raise funds and go the listed environment too early. We are now ready to choose to go rather than be pushed.”

To prove that point, Qbiotics has just raised \$17.75 million in a private share placement, valuing the entire company at \$255 million. Along the way, the company has raised \$110 million from a shareholder base that currently numbers 2230 investors, mainly wealthy individuals.

“They have been incredible loyal over the years,” Dr Gordon says. “Some have held for 18 years, so can be truly described as patient investors.”

Dr Gordon and Dr Reddell both hold about eight percent and are the biggest shareholders. The company provides a secondary market, with 19 off-market trades executed in calendar 2020 so far. Mainly involving small volumes, the trades were struck at between 58 cents and 95 cents (the most recent were two trades of 10,000 each on January 20, at 75 cents apiece). Punters can find the details on the company’s website: <https://qbiotics.com/>.

Dr Boreham’s diagnosis:

Naturally, the animal market faces stiffer hurdles than the human one in terms of what customers are willing to pay. Mind you, the bar is being raised all the time given improved pet insurance coverage and the willingness and ability of folk to spend up big on salvaging their canine companion.

Dr Gordon said the company has been careful to ensure the pricing is no higher than the standard-of-care of surgery, which sounds like a sage strategy.

Qbiotics’ endeavors are supported by a high-calibre board: chairman Rick Holliday-Smith also helms Cochlear and the ASX Ltd, while Prof Bruce Robinson chairs the National Health and Medical Research Council.

Neville Mitchell was Cochlear’s chief finance officer, while Andrew Denver is the former executive chairman of Universal Biosensors and a current director of Cochlear. Dr Sue Foden has an extensive background in drug development and commercialization.

Dr Gordon has been a director of Biopharmaceuticals Australia, a member of the Queensland Government’s Biotechnology Advisory Council and chair of the Australian Rainforest Foundation. In 2004 Queensland premier Peter Beattie awarded her a gong for services to the biotechnology industry.

While there is no recipe for assured success in bioscience, the boardroom oomph means Qbiotics has an enhanced chance of cracking the market - whether it is a two-legged or four-legged curative.

Disclosure: Dr Boreham is not a qualified medical practitioner or veterinarian and does not possess a doctorate of any sort. But he can distinguish both ends of a dog - the waggy bit and the slobbery bit.

SYNLAIT MILK

Synlait says it has approval to acquire the Christchurch-based Dairyworks New Zealand for \$NZ112 million (\$A104.6 million) on April 1, 2020 (AVW: Oct 25, 2019).

Synlait said the New Zealand Overseas Investment Office approved the acquisition.

The company said Dairyworks processed, packaged and marketed dairy products, including cheese, butter, ice cream and milk powder, in New Zealand and Australia.

Synlait chief executive officer Leo Clements said the acquisition would provide the company "with instant scale in the sector, new growth opportunities, and a diversified earnings base for our shareholders".

"Dairyworks gives Synlait the opportunity to extract more value from our milk pool and ... strong synergies with our recent Talbot Forest acquisition," Mr Clements said.

"We'll now be closer to the consumer and own more of the value chain," Mr Clements said.

Synlait said it expected the acquisition to contribute about \$NZ4 of million earnings before interest, tax, depreciation or amortization (EBITDA) for the year to July 2020.

Synlait was up five cents or 1.0 percent to \$5.00.

SYNLAIT MILK

Synlait says it will pay \$NZ25.7 million (\$A25.0 million) for 582-hectares of farmland adjacent to its Dunsandel, Canterbury, New Zealand milk facility.

Synlait said the land would enable it to pursue strategic supply chain and sustainability initiatives to support the long-term operation and expansion of the Dunsandel facility.

The company said the purchase would support the Dunsandel long-term operation and expansion with greater control over water rights and certainty over access to water and disposal of its factory processing water.

Synlait said that it would develop a rail siding adjoining Dry Store 4 providing for containerized goods to be transported by rail between Dunsandel and Lyttelton,

"significantly reducing Synlait's environmental footprint by removing approximately 16,000 truck movements annually".

The company said it would provide opportunities "to evaluate and trial sustainable farming practices and carry out on-farm research".

Synlait chief executive officer Leon Clement said: "Our purpose at Synlait is doing milk differently for a healthier world and this land provides a unique opportunity to pursue on-farm sustainability initiatives and reduce our environmental footprint whilst creating further supply chain efficiencies in our business".

A2 MILK

A2 Milk says Canada's Agrifoods Cooperative will produce, distribute, sell and market A2 branded liquid milk in Canada through an exclusive licencing agreement.

A2 Milk said it would give the Abbotsford, British Columbia-based Agrifoods access to its intellectual property, marketing assets and proprietary systems, and would work with Agrifoods and local Canadian dairy farmers to source milk locally.

The company said it expected that "a range of liquid milk products [would] be launched later this calendar year".

A spokesman for the company told Ag & Vet Weekly that the commercial terms of the agreement were confidential.

A2 Milk was up 89 cents or 6.0 percent to \$15.71 with 13.1 million shares traded.

WATTLE HEALTH AUSTRALIA

Wattle Health says Mason Dairy Holdings has terminated its share purchase agreement for the partial acquisition of the Blend & Pack packaging and canning facility.

In January, Wattle Health said the Hong Kong-based Mason Group had agreed to an amended \$US55 million (\$A79.9 million) deal to buy 80 percent of Blend & Pack, instead of 75 percent (AVW: Jan 20, 2020).

Last month, the company said its two-for-one rights offer at 30 cents a share raised \$9,316,105 of up to \$39.7 million, with Xuan Khoa Pham subscribing for up to the lower of \$25 million in shortfall shares or the number of shares equivalent to 19.9 percent of the company at February 24, 2020 (AVW: Feb 21, 28, 2020).

On March 11, Wattle said it was unable to settle with the Mason Group under the revised share agreement before the February 29, 2020 sunset date.

The company said that “due to difficulties caused primarily by the global Covid-19 crisis ... [Mr Pham] faced significant challenges in transferring funds, including being unable to undertake necessary travel to provide signatories”.

Wattle Health said Mr Pham requested an extension to transfer the funds, but no agreement had been reached with Mason to accommodate a delay.

The company said it was working with all parties to achieve a commercial outcome.

Wattle Health was untraded at 48.7 cents.

CANNPAL ANIMAL THERAPEUTICS

Cannpal says it has a US Food and Drug Administration investigational new animal drug (INAD) file for its marijuana-based CPAT-01 for osteoarthritis-related symptoms in dogs.

Cannpal said the INAD was established through the FDA’s Centre for Veterinary Medicine, following a request on January 14, 2020.

The company said that CPAT-01 was derived from natural tetrahydrocannabinol (THC) and cannabidiol (CBD) extracts to reduce osteoarthritis symptoms “with an initial focus on pain and inflammation”.

Cannpal said the INAD file contained correspondence and submissions that could be used to support a new animal drug application (NADA) and allow Cannpal to request a pre-submission conference with the FDA and Centre for Veterinary Medicine

The company said the pre-submission conference would discuss the development plan and regulatory pathway for CPAT-01, and was it expected by October 2020.

Cannpal said the INAD file allowed the company to submit a notice of claimed investigational exemption (NCIE) with the FDA, for the shipment of product to study investigators in the US for future animal studies.

The company said it had received a fee waiver under the “significant barrier to innovation provision” of the FDA’s Animal Drug User Fee Act (ADUFA), which would waive the current annual INAD file sponsor fee of \$220,000

Cannpal said that under the provision, a waiver or reduction of fees would be given for innovative products if the fee would reduce the company’s ability to develop, manufacture or market the product and would need to be renewed yearly.

Cannpal managing director Layton Mills said “the establishment of our INAD file is a significant regulatory milestone for Cannpal, and an important step on the pathway to the potential authorization of an animal health drug”.

“We have made significant progress on the development of CPAT-01, and are excited to be able to discuss the regulatory pathway with the FDA-CVM at the upcoming pre-submission conference,” Mr Mills said.

Cannpal was down two cents or 17.4 percent to 9.5 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has dosed the first of 50 patients in its phase II trial of marijuana-derived Cognicann for dementia and Alzheimer's disease.

MGC said the randomized, double blind, crossover, placebo-controlled trial at Perth's University of Notre Dame Australia would involve patients aged 65 and older to confirm the clinical efficacy of Cognicann and determine the therapeutic individual dose response. The company said that participants would be "involved for 18 weeks" but did not describe the dosing regimen.

MGC said it expected the results by October 2021.

The company said that Cognicann was "the only dementia targeting phytocannabinoid-derived product available for prescription in Australia, putting the company in a unique position to access a large patient population in Australia and key international markets via early access schemes".

MGC was down 0.3 cents or 15.8 percent to 1.6 cents with 9.2 million shares traded.

THE FOOD REVOLUTION GROUP

Food Revolution says it has made its first delivery of hand sanitizers with orders of more than \$2.4 million and will start producing ethanol-based disinfectant.

Food Revolution said its hand sanitizer was "in high demand due to the global outbreak of coronavirus" and had sent the first delivery to "high priority clients" including hospitals, schools and pharmacies, with deliveries to supermarkets "scheduled for later this month".

The company said it would begin production of an all-purpose disinfectant under the Sanicare brand at its Melbourne-based factory.

Food Revolution said "the anti-bacterial properties of this ethanol-based product mean it is effective for disinfecting surfaces such as wood, plastic and glass".

"The denatured component of ethanol means it prevents bacteria growing and kills the present bacteria," the company said.

Food Revolution chairman Dr Norman Li said that the disinfectant was "the next product needed for widespread distribution to help combat the coronavirus epidemic".

"[We have] the capacity to produce this product in large quantities and we expect a big demand for this product given recent enquiries from our customers," Dr Li said.

Sudden acute respiratory syndrome-coronavirus-2 (Sars-CoV-2) is a virus, not a bacterium, but it is probable that a concentrated alcohol-based product would kill the virus.

Food Revolution rose 0.2 cents or 2.6 percent to 7.8 cents with 4.9 million shares traded.

CRESO PHARMA

Last Friday, after the market closed, L1 Capital Global Opportunities Master Fund said it became a substantial shareholder in Creso with 11,390,976 shares (5.48%).

The Melbourne and Cayman Islands-based L1 Capital did not disclose the date(s) or price(s) paid for the shares.

Last month, Creso said it had a convertible note agreement with L1 Capital for up to \$17,482,500 (BD: Feb 5, 2020).

On Wednesday March 11, L1 said it ceased to be a substantial shareholder in Creso.

L1 Capital said that it disposed of 1,764,351 shares on February 26, 2020, reducing its total holding to 9,626,625 shares.

According to Creso's most recent Appendix 2A, the company has 207,809,368 shares on issue and Ag & Vet Weekly calculates that L1 retains 4.63 percent of Creso.

Creso was down 0.6 cents or 9.1 percent to six cents.

CANN GLOBAL

Cann Global has requested a trading halt pending “the release to the market of an announcement regarding institutional investment into the company”.

Trading will resume on March 17, 2020 or on an earlier announcement.

Cann Global last traded at 0.8 cents.

RIDLEY CORPORATION

Ridley says chairman Dr Gary Weiss will retire from the board, effective from June 30, 2020, after 10 years as a non-executive director and five years as chairman.

Ridley said a search for a non-executive director was underway and it expected to announced Dr Weiss’ successor closer to June 30, 2020.

Ridley fell one cent or 1.2 percent to 84 cents.

MEMPHASYS

Memphasys says it has appointed Paul Wright as a non-executive director, replacing Marjan Mikel.

Memphasys said Mr Wright had more than 30 years’ experience as an executive and was a non-executive director of Hydrix and an advisory board member of Waterwerx.

The company said Mr Wright was previously the chief executive officer of Universal Biosensors, Invetech and Vision Biosystems

Memphasys said Mr Wright held a Masters of Engineering from Cambridge University.

The company said Mr Mikel resigned following his appointment as chief executive officer of Respiro.

Memphasys was down 0.2 cents or 4.4 percent to 4.3 cents with 1.1 million shares traded.

SYNLAIT MILK

Synlait says it has appointed chief financial officer Angela Dixon, effective from June 15, 2020, replacing Nigel Greenwood.

Synlait said Ms Dixon had 20 years’ experience in the finance, professional services and insurance sectors in New Zealand and the UK and was the chief financial and information officer at Public Trust.

The company said Ms Dixon previously worked for Auckland International Airport, Telewest Communications, Royal Sun Alliance, Price Waterhouse Coopers.

AUSCANN GROUP HOLDINGS

Auscann says it has appointed Dr Marc Russo as chief medical advisor, replacing Dr Danial Schechter.

Auscann said Dr Russo was a pain medicine specialist, had established the Broadmeadow, New South Wales-based Hunter Pain Clinic and was deputy chair of the NSW Regional Committee of the Australian and New Zealand College of Anaesthetists’ Faculty of Pain Medicine.

Auscann was down 0.5 cents or 2.8 percent to 17.5 cents with 4.1 million shares traded.

AUSTRALIAN PRIMARY HEMP

AP Hemp says that Neale Joseph has replaced chief executive officer Charles Mann, effective immediately, starting on \$225,000 a year.

AP Hemp said that Mr Mann had founded the company with chief operating officer James Hood and would resign from the company “to pursue other opportunities”.

The company said Mr Mann would “provide consulting services to the company following the conclusion of his employment”.

AP Hemp said Mr Joseph joined the company in January as head of product, and had previously held senior executive roles at Pure Beauty Australia, Motorola Solutions, David Jones, Dulux, and Simplot.

The company said Mr Joseph would start on \$225,000 a year excluding superannuation, with a short-term incentive of rights over up-to 1,000,000 AP Hemp shares based on the achievement of milestones by May 12, 2021, and long term incentives equity rights as determined by the board of directors.

AP Hemp fell half a cent or 5.6 percent to 8.5 cents.

CRESO PHARMA

Creso says it has appointed Jack Yu, replacing Bill Fleming as managing director and Isaac Allen as vice president of its subsidiary Mernova Medical, effective from today.

Creso said Mr Yu was previously production manager for Canada’s Canopy Growth Corp, interim cultivation manager of Canopy’s facilities, master grower for Medreleaf Corp and consulted for Health Canada.

The company said Mr Allen was previously national operations process improvement manager at Canopy and was the founder and chief executive officer of an insurance technology start-up company.