



# Biotech Daily

Friday March 13, 2020

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: COCHLEAR UP 21%; ALTERITY DOWN 20%**
- \* **DR BOREHAM'S CRUCIBLE: QBIOTICS GROUP**
- \* **CARDIEX: ASTRAZENECA, BAYER EXPAND XCEL IN TRIALS \$984k**
- \* **VISIONEERING: CANADA APPROVES NATURALVUE MYOPIA LENSES**
- \* **BOTANIX: 'BTX1801 KILLS MRSA'; SURGICAL INFECTION TRIAL**
- \* **CANN GLOBAL REQUESTS 'INSTITUTIONAL INVESTMENT' TRADING HALT**
- \* **HARBOUR TAKES 8% OF VOLPARA**
- \* **DIRECTOR ANDREW KROGER TAKES 39% OF CRYOSITE**
- \* **ZOLTAN VARGA TAKES 19.99% OF TOTAL BRAIN**
- \* **PAUL WRIGHT REPLACES MEMPHASYS DIRECTOR MARJAN MIKEL**
- \* **IMPEDIMED LOSES DIRECTOR GARY GOETZKE**

## MARKET REPORT

The Australian stock market climbed 4.42 percent on Friday March 13, 2020, with the ASX200 up 234.7 points to 5,539.3 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell and three traded unchanged. All three Big Caps were up.

Cochlear was the best, up \$37.62 or 21.1 percent to \$216.11 with 833,349 shares traded. Next Science was the best of the BDI-40, up 12.5 percent; CSL was up 11.9 percent; Genetic Signatures improved 10.3 percent; Nanosonics and Oncosil climbed more than nine percent; Avita was up 8.3 percent; Prescient rose 6.7 percent; Imugene, Mesoblast and Polynovo improved more than five percent; Telix was up 3.7 percent; with Resmed and Volpara up by less than one percent.

Alterity led the falls, down 0.3 cents or 20 percent to 1.2 cents, with 8,000 shares traded. Actinogen lost 15 percent; Patrys fell 14.3 percent; Compumedics shed 12 percent; both Impedimed and Neuren were down 9.1 percent; Resonance retreated 8.7 percent; Osprey and Uscom were down more than seven percent; Antisense, Opthea, Optiscan and Paradigm were down more than six percent; Amplia, Cyclopharm, Ellex and Orthocell fell five percent or more; LBT lost 4.55 percent; Dimerix, Immutep, Medical Developments and Universal Biosensors were down three percent or more; Clinuvel, Cynata and Pharmaxis shed two percent or more; with Pro Medicus down 1.4 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.***

## CARDIEX

Cardiex says Astrazeneca and Bayer have expanded the use of its Xcel devices and data management services in their clinical trials, increasing the value by \$983,737.

Cardiex said its \$US226,000 (\$A359,042) contract with Astrazeneca had been increased to \$US340,217 (\$A540,496).

The company said the \$US756,000 (\$A1,201,042) Bayer contract had been increased to \$US1,261,000 (\$A2,003,325), including a recent increase of \$US75,426 (\$A119,828).

Cardiex said that its subsidiary Atcor's Xcel central aortic waveform devices for adults monitored haemodynamic data during treatment and drug trials.

The company said it expected further amendments of additional existing trials and new trial contracts in the immediate future.

Cardiex was up 0.3 cents or 18.75 percent to 1.9 cents with 2.4 million shares traded.

## VISIONEERING TECHNOLOGIES

Visioneering says Health Canada has approved a medical device licence to market and sell its Naturalvue multifocal contact lenses for myopia progression.

Visioneering said Canada was the first North American country in which it would sell its lenses for myopia progression.

The company said it would launch sales through its existing US sales force over "the next few weeks".

Visioneering was up 0.3 cents or 10 percent to 3.3 cents.

## BOTANIX PHARMACEUTICALS

Botanix says it expects to start a 60-patient, five-day, double-blind, controlled, phase IIa trial of its synthetic cannabinoid BTX1801 for surgical site infections by July 2020.

Botanix said that a pig skin decolonization study showed that BTX1801 killed methicillin-resistant staphylococcus aureus (MRSA or golden staph) bacteria, the leading cause of surgical site infections, within 10 minutes of exposure and resistance did not develop.

The company said that combined with "previous work showing that MRSA bacteria lack the ability to develop resistance to cannabidiol, makes BTX1801 an ideal candidate for nasal decolonization of staph and MRSA for the prevention of [surgical site infections]".

Botanix said that patients colonized with staphylococcus aureus at admission to an intensive care unit had an up-to 15 times increased risk for developing pneumonia compared with non-colonized patients.

The company said the trial would evaluate safety, tolerability and efficacy of two BTX1801 formulations to decolonize Staphylococcus aureus and MRSA from the noses of healthy adults.

Botanix said that study was intended "to establish proof of efficacy of BTX1801, before moving into a pivotal clinical study involving patients undergoing surgery" for US Food and Drug Administration registration.

Botanix was up 0.2 cents or 2.9 percent to 7.2 cents with 3.5 million shares traded.

## 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.

## [VOLPARA HEALTH TECHNOLOGIES](#)

The Wellington, New Zealand-based Harbour Asset Management says it has increased its holding in Volpara from 13,786,895 shares (6.465%) to 17,390,718 shares (7.960%). Harbour said that between January 3 and December 31, 2019 it bought 4,028,804 shares for \$6,093,110 or \$1.51 a share, between July 23, 2019 and March 3, 2020 it sold 449,063 shares for \$719,919 or \$1.60 a share and on July 3, 2019 it acquired 860 shares for \$1,290 or \$1.50 in a rights issue. Volpara was up half a cent or 0.4 percent to \$1.15 with 1.2 million shares traded.

## [CRYOSITE](#)

Cryosite director Andrew Kroger says he has increased his substantial shareholding in the company from 18,186,450 shares (38.81%) to 18,193,450 shares (38.83%). Mr Kroger said that on March 9, 2020 he acquired 7,000 shares at seven cents a share. Cryosite was untraded at seven cents.

## [TOTAL BRAIN](#)

Zoltan Varga says it has increased its substantial shareholding in Total Brain from 105,500,000 shares (19.86%) to 21,660,179 shares (19.99%). Total Brain said it completed its 10-to-one consolidation on January 24, 2020 . The Hong Kong-based Zoltan Varga said that on May 7, 2019 and January 15, 2020, he acquired 68,787,233 pre-consolidation shares for \$2,996,492.52 or 4.4 cents a share through subscriptions for new shares and on-market purchases. Mr Varga said that on March 9, 2020 he acquired 275,000 post-consolidation shares for \$118,082.68 or 42.9 cents a share. Total Brain was untraded at 35 cents.

## [MEMPHASYS](#)

Memphasys says it has appointed Paul Wright as a non-executive director, replacing Marjan Mikel, who had been appointed Respire chief executive officer (BD: Nov 25, 2019). 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. Memphasys fell 0.2 cents or 4.4 percent to 4.3 cents with 1.1 million shares traded.

## [IMPEDIMED](#)

Impedimed says director Gary Goetzke has resigned "to pursue another business opportunity in Japan". Impedimed said Mr Goetzke had been a director for the company for three and a half years. Impedimed fell 0.6 cents or 9.1 percent to six cents with 3.4 million shares traded.