



# Biotech Daily

Monday January 20, 2020

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: PATRYS UP 10%; ONCOSIL DOWN 11%**
- \* **VALE MESOBLAST'S PROF PETER GHOSH (4.8.1940 – 12.1.2020)**
- \* **AMPLIA PLACEMENT RAISES \$930k**
- \* **EUROPE OKAYS QBIOTICS STELFONTA FOR DOG SKIN CANCER**
- \* **HERAMED TELLS ASX: 'NEWS FOLLOWED 52% SHARE JUMP'**
- \* **HERAMED: MAYO DATA FOR ORION MONITOR, HIRES URI MERHAV**
- \* **G MEDICAL: PRIZMA SMARTPHONE CASE APPROVED IN TAIWAN**
- \* **ROBERT LEDERER, RTL TAKE 11% OF ANATARA**
- \* **ELEANORE GOODRIDGE TAKES 11% OF NYRADA**
- \* **THC TO SELL MGC'S CANNDEO MARIJUANA, 1st PURCHASE FOR \$40k**
- \* **THC REQUESTS 'RECEIPT OF TGA LICENCE' TRADING HALT**
- \* **MTP CONNECT APPOINTS ALEX FOWKES DIRECTOR**

## MARKET REPORT

The Australian stock market was up 0.22 percent on Monday January 20, 2020, with the ASX200 up 15.4 points to 7,079.5 points. Nine of the Biotech Daily Top 40 stocks were up, 21 fell, eight traded unchanged and two were untraded.

Patrys was the best, up 0.2 cents or 10 percent to 2.2 cents, with 1.5 million shares traded. Actinogen climbed 8.8 percent; Mesoblast was up 6.3 percent; Polynovo improved 3.7 percent; Avita and Cyclopharm rose more than two percent; CSL and Orthocell were up more than one percent; with Ellex and Pro Medicus up by less than one percent.

Oncosil led the falls, down two cents or 11.1 percent to 16 cents, with 2.6 million shares traded. LBT lost 8.8 percent; both Osprey and Pharmaxis retreated 6.9 percent; Optiscan was down 5.4 percent; Cynata fell four percent; Volpara was down 3.2 percent; Imugene, Next Science and Paradigm shed more than two percent; Clinuvel, Cochlear, Genetic Signatures, Medical Developments, Opthea, Prescient, Proteomics, Resonance, Starpharma and Telix were down one percent or more; with Compumedics, Nanosonics and Resmed down by less than one percent.

## MESOBLAST

Mesoblast says that arthritis and degenerative disc disease consultant Prof Peter Ghosh died after a brief illness on January 12, 2020, at the age of 79 years.

Mesoblast said that Prof Ghosh had been involved with the company since 2005 and was responsible for the development and execution of its pre-clinical research programs in arthritis and degenerative disc disease, which had progressed to phase II and III human clinical trials.

The company said that Prof Ghosh also developed novel methodologies for the repair of musculo-skeletal tissues, using Mesoblast's mesenchymal stem cells and scaffolds.

Mesoblast said that Prof Ghosh had been engaged in medical research for more than 45 years and was acknowledged as an international authority on musculo-skeletal disorders and diseases, and modalities for their treatments and repair, and was the author or co-author of more than 420 publications and was the inventor or co-inventor of 22 patents, many with Mesoblast chief executive Prof Silviu Itescu.

The company said that from 1974 until 2002, Prof Ghosh was the associate professor and director of the Raymond Purves Research Laboratories in the Department of Surgery at the University of Sydney; and from 1999 until his retirement in 2002, he was the president of the Institute of Bone and Joint Research at Sydney's Royal North Shore Hospital.

Mesoblast said that Prof Ghosh was past president of the Australian and New Zealand Orthopaedic Research Society and the Matrix Biology Society of Australian and New Zealand and was formerly a board member of the Osteoarthritis Research Society International and the Bone and Joint Research Foundation of the University of Sydney.

The company said that Prof Ghosh was an honorary associate professor at the University of Sydney, adjunct professor at the Institute of Medical Engineering and the Richie Institute at Monash University and a visiting professor at Chiang Mai University, Thailand.

Prof Itescu said that Prof Ghosh had made "a tremendous contribution to Mesoblast, especially with his pioneering work in the development of a cell therapy for chronic low back pain".

"Peter was a brilliant and innovative scientist," Prof Itescu said. "His dedication and enthusiasm for his life's work was unmatched and he will be sorely missed by all of us at Mesoblast," Prof Itescu said.

## AMPLIA THERAPEUTICS

Amplia says it has raised \$930,482 through a placement at seven cents a share, including a cornerstone investment by Platinum International Healthcare Fund.

Amplia said the placement to new and existing professional and sophisticated investors and was a 12.5 percent discount to the last traded price on January 15, 2020, and the funds would help it begin clinical trials of AMP945 for fibrotic disease in 2020.

Amplia said Taylor Collison was the lead manager to the placement.

Amplia was untraded at eight cents.

## QBIOTICS GROUP

Qbiotics says the European Medicines Agency has registered its small molecule, tigilanol tiglate, or Stelfonta, as a veterinary cancer drug for mast cell tumors in dogs.

In 2018, Qbiotics said its 22-patient, first-in-human phase I/IIa trial of tigilanol tiglate, or EBC-46, for solid tumors achieved a complete response in two patients.

The company told Biotech Daily at that time that the open-labelled trial of its tropical rainforest-derived compound enrolled 22 patients with 29 tumors and tigilanol tiglate was administered as a bolus injection on day-1 with escalating doses beginning at 0.06 milligram per metre squared of body surface (BD: Nov 13, 2018).

Today, Qbiotics said that tigilanol tiglate, to be marketed as Stelfonta, was indicated in Europe for the treatment of non-resectable, non-metastatic, subcutaneous mast cell tumors located at, or distal to, the elbow or the hock, and non-resectable, non-metastatic cutaneous mast cell tumors in dogs.

The company said tigilanol tiglate was approved for tumors less than or equal to 8.0 cubic centimetres in volume and must be accessible to intra-tumoral injection.

Qbiotics said mast cell tumors were the second most frequent cancer diagnosed in dogs and the most common skin cancer, accounting for up to 21 percent of skin cancer cases.

Qbiotics veterinary oncologist Dr Pam Jones said the approval was “an exciting additional treatment option for [mast cell tumors] where surgical removal of the tumor mass is currently the standard of care”.

“There are some challenges associated with surgery, as in some cases the tumor isn’t always easily accessible, and anaesthesia carries inherent risks, especially for older dogs and brachycephalic breeds,” Dr Jones said. “Stelfonta is administered by injection directly into the tumor mass [so] generally, dogs undergoing treatment do not need to be sedated, or need local or general anaesthesia.”

Qbiotics said that up to 25 percent of dogs developed cancer at some time in their lives and cancer was the leading cause of death in dogs, with about 50 percent of dogs over the age of 10 years dying of the disease.

Qbiotics managing-director Dr Victoria Gordon said that there were “only a very small number of registered treatments for cancer in companion animals, providing a significant opportunity for new treatments in this growing market”.

“Tigilanol tiglate is a new approach to the problem of cancer,” Dr Gordon said.

“The drug works largely through specific protein kinase C activation, in which 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,” Dr Gordon said.

Qbiotics said the approval was based on a data package supporting the safety and efficacy of Stelfonta, including an intended-to-treat 123-dog (81 and 42), pivotal, multi-centre, randomized, blinded study, with 80 dogs treated and 38 untreated control dogs.

The company said that at 28 days post-treatment 60 dogs (75%) achieved a complete response, with the tumor completely destroyed, after a single intra-tumoral injection of Stelfonta compared to two complete responses in the untreated controls ( $p = 0.0001$ ).

Qbiotics said all dogs were treated with corticosteroids and Stelfonta was “very well tolerated and animals had a good quality of life during and after treatment”.

Dr Gordon said Qbiotics and partner, the Carros, France-based Virbac, were preparing for the launch of Stelfonta in the UK, France, Spain and Germany, and later in the US, subject to US Food and Drug Administration approval.

Qbiotics said the approval was the first registration of tigilanol tiglate, which was under review by the US FDA Center for Veterinary Medicine and the Australian Pesticides and Veterinary Medicines Authority.

Qbiotics is a public unlisted company.

## HERAMED

Heramed has told the ASX it was first aware of US approval of its foetal heart rate monitor on November 15, 2019 the day after its share price rose 51.7 percent.

In November, Heramed said in response to an ASX query regarding the share price rise that an article it “commissioned” was released on the Next Tech Stock website with a “typographical error” that incorrectly referred to the company as being a “\$13 billion capped Aussie junior” (BD: Nov 14, 2019).

The following day, Friday November 15, the company requested a trading halt “pending a response to a follow up by the ASX on the price and volume query” and the following Monday said its foetal ultrasonic heart rate monitor had US Food and Drug Administration (FDA) 510(k) clearance (BD: Nov 15, 18, 2019).

Today, Heramed said it began drafting an announcement to disclose the FDA clearance immediately on receiving it at 6.05pm (AEDT) on November 15, 2019, with the announcement was issued at 8.57am on November 18, 2019.

Heramed was up two cents or 11.8 percent to 19 cents with 1.7 million shares traded.

## HERAMED

Heramed says that about 90,000 pregnancy records from the Mayo Clinic will help develop its Orion artificial intelligence (AI) algorithm for pregnancy monitoring.

Heramed said the Rochester, Minnesota-based Mayo Clinic had supplied it with more than 10 years of records, including data on foetal heartbeats and early stages of pregnancy, which would allow the Orion AI algorithm to better monitor pregnancies and potentially identify complications.

The company said it had appointed Uri Merhav, who was “fundamental in creating Heramed’s first foetal heart rate algorithm”, as the chief architect for the Orion AI.

Heramed said Mr Merhav was a former machine-learning engineer at LinkedIn and author of seven machine learning patents, and held a Masters of Science from Israel’s Tel Aviv University.

## G MEDICAL INNOVATIONS

G Medical says the Taiwan Food and Drug Administration has granted regulatory approval for its Prizma smartphone case, which monitors vital health signs.

G Medical said partner the British Virgin Islands-registered First Channel Ltd had until April 4 to provide ancillary product information to collect Prizma’s permit licence.

The company said it would work with First Channel on requirements for distribution and service and it intended to explore additional partnerships within Taiwan.

G Medical was up six cents or 46.15 percent to 19 cents with 6.8 million shares traded.

## ANATARA LIFESCIENCES

The Sydney-based Robert Lederer says he has increased his substantial shareholding in Anantara from 4,977,000 shares (10.07%) to 5,527,000 (11.09%)

Mr Lederer said the shares were held by RTL Group Investments Pty Ltd and his superannuation fund, with 550,000 shares acquired on-market between May 16 and December 20, 2019 as “on market purchases”.

Mr Lederer yet again failed to state the price paid for the shares, as required under the Corporations Act 2001 (BD: Nov 14, 2017; May 16, Dec 12, 2018; May 9, 2019).

Anantara was up 4.5 cents or 15.25 percent to 34 cents.

## [NYRADA](#)

Eleanore Goodridge says she has become a substantial shareholder in Nyrada with 12,424,832 Chess depository instruments (CDIs) or 11.36 percent of the company. The initial substantial shareholder announcement said the Sydney-based Ms Goodridge held half the CDIs through Goodridge Nominees and the balance through the Goodridge Foundation.

Nyrada said the shares were acquired on January 16, 2020, the day of the initial public offer in which the price ranged from 30.5 cents to 22.5 cents, but did not disclose the price paid by Ms Goodridge.

Nyrada fell 1.5 cents or 6.7 percent to 21 cents with 1.65 million shares traded

## [MGC PHARMACEUTICALS, THC GLOBAL GROUP](#)

MGC and THC say THC will sell three of MGC's marijuana formulations in Australia and New Zealand under its Canndeo brand, with the first purchase for EUR25,000 (\$A40,307). A joint announcement said MGC's Slovenian facility would produce and supply three unbranded liquid formulations to THC, including a high cannabidiol (CBD) and low tetrahydrocannabinol (THC) concentration, a balanced CBD and THC concentration and a high THC and low CBD concentration, with the products expected to be available by April 2020.

The companies said all of THC's subsequent purchase orders would be for a minimum of EUR50,000, with no minimum order volume.

MGC was unchanged at 3.8 cents with 7.4 million shares traded.

THC was untraded at 38.5 cents.

## [THC GLOBAL](#)

THC has requested a trading halt regarding "the receipt of a licence to manufacture therapeutic goods from the Australian Therapeutic Goods Administration".

Trading will resume on January 22, 2020 or on an earlier announcement.

## [MTP CONNECT](#)

MTP Connect says it has appointed Alex Fowkes as a non-executive director.

MTP Connect said that was most recently the Singapore-based chief strategy officer for genomic information company Wuxi Nextcode and was previously with Wuxi Apptec.

The company said that Mr Fowkes previously worked for Pfizer Pharmaceuticals for 15 years in management roles including head of Asia research strategy and operations, head of worldwide research and development and head of Australia and New Zealand legal affairs.

MTP Connect said that Mr Fowkes held a Bachelor of Laws from Queensland's Bond University and a Bachelor of Science, Biochemistry, Pharmacology from the University of Queensland.