# Biotech Daily

Tuesday September 9, 2014

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: IMPEDIMED UP 11%, PRANA DOWN 14%**

*** VIRAX TO REACTIVATE GGTI-2418 FDA IND FOR BREAST CANCER**

*** AVEXA MANUFACTURES SPECIAL ACCESS ATC FOR HIV**

*** REGENEUS PLAN RAISES $3m, TAKES TOTAL TO $6m**

*** PHARMAUST BEGINS PPL-1 DOG CANCER TRIAL**

*** ISONEA PLEADS SCHULTZ TO 31% FALL QUERY, CASHED-UP**

*** GENETIC TECHNOLOGIES REQUESTS CAPITAL RAISING TRADING HALT**

*** RON DEWHURST, KROY WEN (BACK) TAKE 6% OF RHINOMED**

*** ONCOSIL CHANGES: ROGER ASTON, NEIL FRAZER, MARTIN ROGERS**

## MARKET REPORT

The Australian stock market climbed 0.55 percent on Tuesday September 9, 2014 with the S&P ASX 200 up 30.9 points to 5,607.9 points.

Seventeen of the Biotech Daily Top 40 stocks were up, nine fell, 11 traded unchanged and three were untraded. All three Big Caps were up.

Impedimed was the best, up five cents or 11.4 percent to 49 cents with 533,513 shares traded.

Living Cell climbed 9.1 percent; Acrux was up 7.5 percent; Nanosonics, Pharmaxis, Tissue Therapies and Universal Biosensors rose five percent or more; Compumedics climbed 4.55 percent; Antisense and GI Dynamics were up three percent or more; Analytica and Mesoblast rose more than two percent; CSL, Phosphagenics, Sirtex, Starpharma and Viralytics were up more than one percent; with Bionomics, Cochlear and Resmed up by less than one percent.

Prana led the falls, down four cents or 13.8 percent to 25 cents with 1.5 million shares traded.

Anteo lost 7.1 percent; Circadian and Ellex fell more than five percent; Oncosil was down 3.7 percent; Benitec, Clinuvel and Psivida shed more than one percent; with Alchemia down 0.8 percent.

## VIRAX HOLDINGS

Virax says it plans to request an investigational new drug application reactivation and a US Food and Drug Administration meeting to discuss the GGTI-2418 program.
Virax said the plan to request the application reactivation followed a technical assessment by Ground Zero Pharmaceuticals on the cancer immunotherapeutic GGTI-2418 and would prepare the way for a phase Ib/II breast cancer trial in 2015.
The company said that if the application and FDA meeting were granted, the meeting could be held 30 days post-request.
Virax said that GGTI-2418 was a first-in-class cancer immunotherapeutic with the ability to block the cancer growth enzyme GGTI-2418 and also blocked the Ral and Rho circuits in cancer cells which acted as oncogenic survival pathways leading to apoptosis, or death, of cancer cells.
The company said that GGTI-2418 had been in phase I clinical trials at Pennsylvania State University and Indiana University which established a favorable safety profile.
Virax said that four of nine patients had stable disease of their advanced stage and treatment-refractory solid tumors.
The company said GGTI-2418 came from a collaboration between Yale University and the Moffitt Cancer Centre and had caused breast tumor regression in mouse models.
Virax managing director Dr Robert Crombie said that re-opening the investigational new drug application was “a critical step toward next stage clinical trials”.
Virax said it was also pursuing development of GGTI-2418 as a treatment for multiple myeloma, or bone marrow cancer.
Virax climbed 0.1 cents or 20 percent to 0.6 cents with 10.1 million shares traded.

## AVEXA

Avexa says that the manufacture of Apricitabine or ATC for its HIV early access and named patient scheme has been completed on schedule (BD: Jun 25, 2014).
Avexa said that the product was ready for shipment to Link Healthcare’s facility in Singapore when regulatory paperwork was completed.
The company said Link’s Singapore facility would act as the hub for world-wide distribution of ATC through the early access and named patient schemes, expected to be operational by the end of 2014.
Avexa interim chief executive officer and chief scientific officer Dr Jonathan Coates said the manufacture was “a significant milestone for Avexa and ATC”.
“Patients who are running out of options for HIV treatment, will now have access to a new agent that has activity against drug-resistant HIV and which has been demonstrated to be well tolerated,” Dr Coates said.
Avexa was up 0.1 cents or 6.25 percent to 1.7 cents.

## REGENEUS

Regeneus says its oversubscribed share plan at 26 cents a share has raised $3 million, taking its total capital raising to $6 million (BD: Aug 6, 2014).
Regeneus said it would accept the oversubscriptions “in recognition of the strong show of support by shareholders”.
The company said that the funds raised together with the Federal Government R&D Tax Incentive for the tear to June 30, 2014 of $3.7 million as well as sales revenues meant it had sufficient funds to accelerate its product development initiatives.
Regeneus was up one cent or 3.6 percent to 29 cents.

## PHARMAUST

Pharmaust says it will begin a dose-ranging trial of cancer drug PPL-1 in up to 36 dogs for canine cancers, originally planned for early this year.

Last year, Pharmaust said it planned to begin the trial by April 2014 (BD: Dec 19, 2013).

The company has begun screening up to 15 human patients in a phase I/II trial of PPL-1 for cancer at the Royal Adelaide Hospital (BD: Apr 15, Jun 23, 2014).

Today, Pharmaust said that the palatability of PPL-1 in dogs was not suitable for home administration by the dog owner and in collaboration with the principal investigator Dr Angela Frimberger the company had developed a gel capsule containing PPL-1 suitable for the clinical trial.

The company said that four dogs with untreatable progressive cancers, one melanoma, two with soft tissue sarcomas and one chemo-resistant lymphoma, had received PPL-1 either as liquid or soft-gel formulation on a compassionate use basis.

Pharmaust said that no adverse events or toxicities were observed although the unpleasant taste of the drug in liquid form did caused vomiting in some dogs.

The company said that with the New South Wales-based Veterinary Oncology Consultants Pty Ltd at the Animal Referral Hospital it would conduct a phase I/II clinical trial to test the safety and efficacy of PPL-1 for treating naturally-occurring superficial soft tissue sarcomas, chemo-resistant lymphomas and metastatic melanomas.

Pharmaust said that the dogs admitted to the trial would be treated with the drug by their owners at their homes.

The company said that to determine the safest and most effective dose, the trial design would incorporate incremental increases in drug dose to different groups of dogs, with groups administered higher doses after safety and efficacy of the lower dose had been established.

Pharmaust said that tumor size would be measured before and after treatment using callipers and X-ray computed tomography scan.

Pharmaust executive chairman Dr Roger Aston said that the delay on drug palatability in dogs was unavoidable, but it enabled the company to successfully develop a drug presentation of PPL-1 which was essentially tasteless making future trials easier to conduct.

Pharmaust said that the US pet market included about 77.5 million dogs and 93.6 million cats, with about 60 percent of dogs over the age of six years developing some form of cancer, with US pet market sales about $US14 billion and cancer therapies $550 million.

Pharmaust said that PPL-1 was approved in Australia, New Zealand, Europe for veterinary use by its pharmaceutical company partner.

“We believe that if successful in this trial, PPL-1 will be able to be approved quickly for the treatment of dog cancers following a further pivotal study,” Dr Aston said.

Pharmaust was up 0.1 cents or 10 percent to 1.1 cents with 2,000,000 shares traded.

## ISONEA

Isonea has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company’s share price fell 4.5 cents or 31.0 percent from 14.5 cents on September 5, to 10 cents on September 10, 2014, and noted an increase in trading volume.

Isonea said it had $8.21 million in cash, $1.5 million “of standard current trade creditors and no other short or long term debt” and a cash burn of less than $500,000 a month.

Isonea closed up one cent or 8.7 percent at 12.5 cents with 1.9 million shares traded.

## GENETIC TECHNOLOGIES

Genetic Technologies has requested a trading halt “pending an announcement ... in relation to a proposed capital raising”.
Trading will resume on September 11, 2014 or on an earlier announcement.
Genetic Technologies last traded at 2.5 cents.

## RHINOMED

A substantial shareholder notice from Kroy Wen Pty Ltd says the company has become substantial in Rhinomed with the acquisition of 29,000,000 shares (5.87%).
The notice, signed by Kroy Wen director and former Legg Mason funds manager Ronald Dewhurst, gave the address as 7 Landale Road, Toorak, Victoria.
The property at 7 Landale Road was sold by Mr Dewhurst for $17 million in October 2012 to former Ascent Pharmahealth chief executive officer Dennis Bastas.
Several ASX Appendix 3Y Director’s Interest Notices for Mr Dewhurst link Kroy Wen (“New York” backwards) to the Dewhurst Superannuation Fund.
Kroy Wen said the shares were bought for $1,015,000 or 3.5 cents a share.
Rhinomed fell 0.1 cents or 2.7 percent to 3.6 cents.

## ONCOSIL MEDICAL

Oncosil says that Dr Roger Aston will replaced Martin Rogers as chairman with chief executive officer Dr Neil Frazer appointed as chief medical officer.
Oncosil said that Dr Aston would be the company’s executive chairman, with Dr Frazer remaining an executive director and Mr Rogers would be a non-executive director.
The company said that the restructure was part of Oncosil’s plans as it advanced the pivotal clinical trial of its localised radiation therapy treatment for pancreatic cancer with the US Food and Drug Administration, as well asConformité Européenne (CE) mark commercialization.
Oncosil said that Dr Aston was previously the chief executive officer of Pitney Pharmaceuticals, Psimedica, Psioncology, Peptech, Cambridge Antibody Technology and Mayne Pharma Group and had experience with the FDA and European Union in product registration, clinical trials, global licensing agreements, plus capital raising and other corporate activity.
The company said that Dr Aston would relinquish two of his current board positions.
Oncosil said that Dr Frazer would transfer 2,000,000 loan funded shares to Dr Aston.
The company said that Dr would be responsible for building and managing the doctor-to-doctor relationships to implement the Oncosil pivotal clinical trial with the FDA and would be responsible for doctor interactions as part of the CE mark application in Europe.
Oncosil said that Dr Frazer would relocate to the US but would continue to support global medical interactions.
The company said it had begun a search for a new chief executive officer and Dr Frazer would continue as chief executive officer until a replacement was found.
Oncosil fell half a cent or 3.7 percent to 13 cents with 1.7 million shares traded.