



Biotech Daily

Wednesday October 22, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: CELLMID UP 8%, LIVING CELL DOWN 12%**
- * **GENETIC SIGNATURES UP TO \$15m FOR MOLECULAR DIAGNOSTICS**
- * **NOVOGEN: 'TRX-E-009-1 KILLS PAEDIATRIC CANCER IN-VITRO'**
- * **PHARMAUST TREATS 2 DOGS IN PPL-1 CANINE CANCER TRIAL**
- * **BPH ENERGY HAS LESS THAN ONE QUARTER CASH**
- * **ORTHOCELL AGM FOR 2.1m DIRECTOR OPTIONS**
- * **PHYLOGICA AGM FOR 6.5m CEO OPTIONS, DIRECTORS' FEES**

MARKET REPORT

The Australian stock market was up 1.14 percent on Wednesday October 22, 2014 with the S&P ASX 200 up 60.9 points to 5,385.9 points.

Eleven of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and seven were untraded.

Cellmid was the best, up 0.2 cents or 8.0 percent to 2.7 cents with 490,000 shares traded.

Clinuvel and Phosphagenics climbed more than seven percent; GI Dynamics and Sirtex were up five percent or more; Biotron was up 4.55 percent; Impedimed was up 3.45 percent; IDT and Prima rose more than two percent; Mesoblast was up 1.9 percent; with Bionomics, Cochlear, CSL and Resmed up by less than one percent.

Living Cell led the falls, down 0.8 cents or 11.6 percent to 6.1 cents with 176,311 shares traded, followed by Acrux down 7.3 percent to \$1.21 with 2.8 million shares traded.

Neuren and Patrys fell more than four percent; Admedus, Alchemia, Optiscan, Starpharma and Uscom lost more than three percent; Pharmaxis shed 2.1 percent; with Nanosonics down 0.5 percent.

GENETIC SIGNATURES

Genetic Signatures hopes to raise up to \$15 million to commercialize its molecular diagnostics for gastric, respiratory, sexually transmitted and other infections.

The Sydney-based Genetic Signatures technology was developed by former Commonwealth Scientific and Industrial Research Organisation head of molecular biology Dr Geoffrey Grigg who was also a founder of Cambridge Antibody Technology and Peptech (later Arana Therapeutics).

Genetic Signatures chief executive officer Dr John Melki told Biotech Daily that the original CSIRO patent had lapsed and all the work on the technology had been undertaken in-house by the company, during the past 13 years, with significant contributions from special adviser and Cambridge Antibody Technology founder Dr Greg Winter and Genetic Signatures chief scientific officer Dr Doug Miller.

Dr Melki said that the company was in the process of preparing a prospectus and hoped to open an initial public offer to list on the ASX.

Dr Melki said that the technology platform was “a molecular diagnostic targeting the DNA or RNA of target pathogens that make us sick”.

He said the company had Australian Therapeutic Goods Administration approval as a manufacturer, approval for its *Clostridium difficile* test, as well as bacterial and protozoan gastroenteritis diagnostics.

Dr Melki said that the lead product the gastroenteritis diagnostic was rapid and accurate, taking four hours to produce a result.

Dr Melki said that the diagnostic was suited for infection control and was “accurate, fast, inexpensive and can work on existing equipments in pathology laboratories”.

He said that the company had total revenue of \$660,000 in 2013-'14, with about \$500,000 coming from sales of the diagnostics to pathology laboratories and hospitals and the remainder from an earlier diagnostic sold to research and development laboratories.

Dr Melki said the company recently appointed a sales and marketing manager and had a distributor in Israel.

Dr Melki said that the diagnostics could accurately detect infections caused by bacteria, viruses and protozoa.

He said that the pipeline included a test for multi-resistant staphylococcus aureus which was being beta-tested in 500 patients, as well as a respiratory infection diagnostic, also in beta-testing.

Dr Melki said that the company was developing a test for meningitis.

He said that the diagnostic to determine the cause of up to 13 sexually transmitted infections included herpes simplex 1 and 2, syphilis, gonorrhea and Chlamydia, among others.

“And we already have customers including pathology labs and hospitals,” Dr Melki said. Genetic Signatures website said that its chairman was Dr Nick Samaras who was formerly with Applied Biosystems and Perkin Elmer and a National Health and Medical Research Council research committee member from 2006 to 2012.

The company said that Peplin and Maple-Brown Abbott founder Dr Christopher Abbott was a co-founder of the company and its “chairman emeritus”.

Genetic Signatures directors include former Los Angeles, California-based National Genetics Institute chief executive officer Mike Aicher, former founding chairman of the Sydney-based Australian Proteome Analysis Facility Phillip Isaacs, and Genetic Signatures co-founder Robert Birrell the company's chief financial officer.

Genetic Signatures is a public unlisted company.

More details are at the company's website: www.geneticsignatures.com.

NOVOGEN

Novogen says that two in-vitro studies show that its super-benzopyran drug-candidate TRX-E-009-1 kills paediatric brain cancer cells and neuro-blastoma cells.

Novogen said the studies examined the effect of TRX-E-009-1 on diffuse intrinsic pontine glioma (DIPG), neuro-blastoma and medullo-blastoma cells, clearing the way for the compound to come into the clinic as a potential treatment of childhood cancers.

The company said the studies found that TRX-E-009-1 was “highly active in-vitro against three-dimensional spheroids of DIPG derived from patient biopsies”.

Novogen chief scientific officer Dr David Brown said that DIPG cells were “highly resistant to standard chemotherapies, so the ability of TRX-E-009-1 to impact the viability of these cells is particularly exciting”.

“Importantly, the drug was relatively inactive against normal cells in the study, indicating that it has a good safety margin, an important factor in the treatment of children,” Dr Brown said.

Novogen said that US researchers found that TRX-E-009-1 was “highly active against a panel of neuro-blastoma cell lines, irrespective of the type of mutations present, but more importantly including those mutations most commonly encountered in the clinic”.

The company said that TRX-E-009-1 was a super-benzopyran drug-candidate that showed broad anti-cancer activity in the laboratory against a wide range cancer cell types, was designed to cross the blood-brain barrier and had been selected for its ability to kill cancer cells of neural, or nervous system, origin.

Novogen said that TRX-E-009-1 was delivered in a construct to optimize bioavailability and the entire construct was known as Trilexium, which was being developed as a treatment for both primary and secondary brain cancer in adults.

Novogen said that US studies showed that TRX-E-009-1 was highly cytotoxic to glioblastoma multiforme, stem-like cells derived from patients whose cancers failed to respond to standard chemotherapy.

The company said that TRX-E-009-1 was the first drug to show any significant activity against a library of these highly chemo-resistant cancer cells and it was planning to take Trilexium into a phase I Australian trial for glioblastoma multiforme in late 2015.

Novogen said it questioned whether Trilexium would be equally active against neural cancers such as brain cancer and neuro-blastoma in children.

The company said that paediatric brain cancers involved different parts of the brain and different cell types to adults and neuro-blastoma only occurred in children, so the studies looked at the effect of TRX-E-009-1 on DIPG, neuroblastoma and medulloblastoma cells.

Novogen chief executive officer Dr Graham Kelly said that “children’s cancer is an area notoriously neglected by pharmaceutical companies”.

“Only one drug has been developed specifically with children’s cancers in mind, and children with brain cancer and neuro-blastoma are being treated with drugs developed for adults, with the children then at risk of bearing the results of toxic side-effects for the rest of their lives,” Dr Kelly said.

“The crucial first step was evidence that TRX-E-009-1 was active against paediatric neural cancer cells,” Dr Kelly said.

“These two studies reported here today have provided that evidence,” Dr Kelly said.

“The fact that DIPG is a rare tumor of the brainstem with only 300 to 350 cases reported annually in the world is not the point,” Dr Kelly said.

“The importance lies in the fact that here is a paediatric neural cancer that is highly insensitive to chemotherapy, and yet has proven to be sensitive to TRX-E-009-1.

Novogen was unchanged at 12 cents.

PHARMAUST

Pharmaust says it has begun treatment of two dogs using a soft gel formulation in its home-based, dose-ranging trial of PPL-1 in up to 36 dogs for canine cancers.

Pharmaust hoped to start the trial earlier this year but issues with the palatability of the liquid form causing vomiting delayed the study (BD: Sep 9, 2014).

Pharmaust executive chairman Dr Roger Aston said the company had a research and option agreement with a company marketing animal health products for the veterinary applications of PPL-1, which was also being trailed for human cancers (BD: Oct 21, 2014). Pharmaust was unchanged at 0.9 cents with 3.5 million shares traded.

ORTHOCELL

Orthocell will vote to grant directors 2,100,000 options under the company's employee option plan.

Orthocell said that the annual general meeting would vote to approve the grant of 750,000 options to chief executive officer Paul Anderson, 400,000 options to executive chairman Dr Stewart Washer, 400,000 options to director Matthew Callahan, 250,000 options to chief financial officer Nicole Telford, with 150,000 options each to directors Prof Lars Lidgren and Qi Xiao Zhou.

The company said the options would be exercisable at a 45 percent premium to the one-week volume weighted average price to the date of grant within three years.

Orthocell's notice of meeting said shareholders would vote on the election of directors Mr Callahan and Prof Lidgren, the employee option plan and 10 percent placement facility. The meeting will be held at Building 191, Murdoch University, South Street, Murdoch, Western Australia on November 24, 2014 at 10am (AWST).

Orthocell was untraded at 35 cents.

PHYLOGICA

Phylogica will vote to grant chief executive officer Dr Richard Hopkins 6,500,000 conditional options and to increase the remuneration pool for directors to \$300,000.

Phylogica said Dr Hopkins options would be exercisable at 2.5 cents by September 23, 2017, with 3,700,000 options not vesting until February 28, 2015 and the balance when the share price exceeded six cents on a five-day volume weighted average price.

The company said the meeting would vote on the increase in the directors remuneration pool from \$200,000 to \$300,000, along with the reelection of chairman Dr Doug Wilson and directors Dr Bernard Hockings and Jeremy Curnock Cook.

The meeting will be held at the Seminar Room, Telethon Kids Institute, 100 Roberts Road, Subiaco, Western Australia on November 27, 2014 at 2pm (AWST).

Phylogica was unchanged at 1.5 cents with 9.1 million shares traded.

BPH ENERGY

BPH says its net operating cash burn for the three months to September 30, 2014 was \$139,000 with cash at the end of the quarter of \$70,000.

BPH has investments in Molecular Discovery Systems and Cortical Dynamics.

BPH was untraded at 0.8 cents.