



Biotech Daily

Thursday October 9, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ANALYTICA UP 6.5%, LIVING CELL DOWN 9%**
- * **EX-PHOSPHAGENICS DR ESRA OGRU 'GUILTY', 'WHY?', EXPECT GAOL**
- * **SIRTEX COMPLETES SIRFLOX, RESULTS IN JUNE 2015**
- * **REGENEUS REBUTS ABC-TV 7.30 STEM CELLS REPORT**
- * **J&J PAYS \$US1.75b FOR D3 INVESTMENT ALIOS**
- * **ANALYTICA WINS CE MARK FOR PERICOACH**
- * **VICTORIA LAUNCHES HEART HOSPITAL, MEDICAL TECHNOLOGY, VISION**
- * **AUSTRALIAN PATENT FOR OBJ'S MAGNETIC CLEANING TECHNOLOGY**
- * **DR LARRY MARSHALL REPLACES CSIRO CEO DR MEGAN CLARK**

MARKET REPORT

The Australian stock market climbed 1.06 percent on Thursday October 9, 2014 with the S&P ASX 200 up 55.4 points to 5,296.7 points.

Eleven of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and six were untraded.

Analytica was the best, up 0.2 cents or 6.45 percent to 3.3 cents with 4.8 million shares traded.

Bionomics and Medical Developments climbed more than five percent; IDT, Impedimed, Oncosil, Starpharma and Tissue Therapies were up more than four percent; Prima rose 2.6 percent; Cochlear and Sirtex were up more than one percent; with CSL and Mesoblast up by less than one percent.

Living Cell led the falls, down 0.6 cents or 8.6 percent to 6.4 cents with 197,180 shares traded

Universal Biosensors lost 6.25 percent; GI Dynamics was down 5.7 percent; Avita and Prana fell four percent or more; Anteo and Cellmid were down more than three percent; Benitec and Nanosonics shed more than two percent; Acrux, Neuren and Phosphagenics were down more than one percent; with Alchemia down 0.8 percent.

PHOSPHAGENICS

Phosphagenics former chief executive officer Dr Esra Ogru formally pleaded guilty to seven charges relating to the theft of \$6,146,732.70 from the company.

In the County Court before Justice Felicity Hampel, five charges of dishonestly obtaining a financial advantage by deception for a total of \$5,600,842.70 relating to 180 invoices and a further \$545,889.36 for two counts relating to 37 false credit card claims were read to the court.

After each charge Dr Ogru pleaded 'Guilty' with the volume of her response noticeably lowering to each successive charge.

Dr Ogru's co-accused, Dr Robert Gianello and Dr Woei-Jia Jiang, were also in the court, along with their respective legal teams and family members.

Phosphagenics chief executive officer Harry Rosen was also present.

The prosecutor for the Commonwealth Director of Public Prosecutions Allan Sharp told the Court he would not repeat material previously read to the Court that related to Dr Gianello and Dr Jiang (BD: Aug 20, 21, 2014).

Mr Sharp said that Dr Ogru had used the false invoices as a personal banking system and cited a series of emails in which she asked Dr Gianello to allow her to invoice for \$7,000 and it would be "his turn next month".

Mr Sharp quoted emails from Dr Ogru to Dr Gianello which said: "We work hard and we deserve it. Enjoy it." And another which said: "So go out and spend, spend, spend. Get rid of your mortgage. We are down to \$16,000."

Mr Sharp said that between 2005 and 2007, Dr Ogru paid down her Bendigo Bank mortgage from \$445,000 to \$5,449.17.

Mr Sharp said that Dr Ogru claimed credit card payments for work done for Vital Health Sciences [later Phosphagenics], but one supplier did not have credit card facilities and Dr Ogru had Visa and American Express cards payments of \$316,818.14 per year but only \$9,000 related to Phosphagenics.

Mr Sharp said that \$3.8 million had been reimbursed to Phosphagenics and said he anticipated that \$5.2 million would be recouped.

Appearing for Dr Ogru, David Grace QC told the Court that his plea in mitigation would explain the documents, family background and matters relating to 'Baby A' formerly described as 'Baby Z'.

"I do not contend there should be a sentence, other than a sentence of imprisonment," Mr Grace said, adding there were "exceptional circumstances for mercy due to the child's needs".

Mr Grace referred to documents including 14 co-authored publications, 18 co-authored patents, a media release from Victoria Minister for Technology Gordon Rich-Phillips as well as emails from the Women In Science Network and the Turkish Australia Society, a consultant psychiatrist and medical reports including a discharge summary from the Royal Children's Hospital which noted the six-year old Baby A's weight of 9.7kg on admission.

Mr Grace said that one document related to \$418,000 to extend the family home to allow for the better provision of treatment and services and the free access of a wheelchair and part of the embezzled funds went to that work.

Mr Grace said that Dr Ogru's husband Vedat Isikgel had set out in detail what occurs to support Baby A on a daily basis.

Mr Grace said that his client was two years old when her family migrated to Australia from Turkey for a better life, she was educated at Princes Hill Secondary College completing Year 12 in 1995 and enrolled in a Bachelor of Science degree at Monash University and went on to complete a Doctorate of Philosophy with first class honors in 2002.

Mr Grace said that Dr Gianello was one of her doctoral supervisors and she also had close contact with Dr Jiang at that time.

Mr Grace said Dr Ogru married Mr Isikdel in 1998 and following the birth of Baby A on May 1, 2008 he had to give up his work as a qualified agricultural engineer and was "occupied full-time in normal work hours [until] his wife, my client, would take over".

Mr Grace said that there was no cure for Baby A's illness, which was caused by a missing gene and the only hope was the possibility of a future development using cord-blood stem cells, "but the prospects are not good".

"The child has daily drugs, without which she would die. The whole lives of my client and her husband are directed to the care of this child," Mr Grace said.

He said that "frantic efforts" were made by Dr Ogru, Dr Gianello and Dr Jiang to find a therapy, resulting in the discovery of cPMP in Cologne, Germany, which had been trialled in animals, but not humans and had no toxicology studies.

Monash Medical Centre gave ethics approval and the Family Court approved the use of cPMP in June 2008, which was given to Baby A every day through an intra-venous line in her chest into a main artery in a sterile condition, Mr Grace said.

Mr Grace said cPMP was not manufactured in Australia and importation was "quite an expense" and embezzled funds from Phosphagenics were spent on the drug.

Mr Grace said that Baby A was the first to be treated and was the longest surviving of seven children who had been treated with cPMP all of whom were surviving.

"It is no longer a fatal disease if treated early," Mr Grace said, attributing the development to the tenacity and determination of his client and the others involved.

Mr Grace said that Dr Ogru had worked with a number of support and community organizations and drew a distinction between the events before and after May 1, 2008.

"Prior, greed. Post, greed and need. We can't shrink from those categorizations. The evidence is clear," Mr Grace said.

Mr Grace said that Dr Ogru's gross income increased from \$125,000 in 2005 to \$249,000 in 2007 and varying from \$206,000 to \$268,000 until 2012, and following her termination from Phosphagenics in 2013, Dr Ogru had not worked in Australia, but had worked for a Singapore company on the equivalent of \$130,000.

'Why Did She Do It?'

Mr Grace said his client had achieved a great deal in biotechnology, was the principal author on 10 patents, co-authored 18 patents in total and "her expertise is exceptional".

Justice Hampel interrupted Mr Grace and asked: "Why did she do it?"

"Because there was opportunity. She felt she deserved more in remuneration and wanted a better lifestyle quickly," Mr Grace said.

"There's a flavor of just milking them," Justice Hampel said.

"There can be no argument," Mr Grace said.

Mr Grace said that in 2007 Dr Ogru went to New York with Mr Rosen to list Phosphagenics on the second board of the stock exchange.

Justice Hampel said that Dr Ogru was raising money for her own pocket.

Mr Grace said that as head of research and development at Vital Life Sciences, Dr Ogru thought it was fair enough that Dr Gianello was paid for his after hours work, but she didn't tell the company.

"Then the treadmill started getting faster and she thought 'We can all profit from this'," Mr Grace said.

Mr Grace said the money was used for payment of her mortgage and lifestyle.

"A couple of million dollars for jewellery," Justice Hampel said.

Mr Grace said that the funds also paid for travel for the Cologne researchers to come to Australia and stay in hotels.

He said that the money was Phosphagenics money, with the jewellery and house in one category and the drugs for Baby A in another category.

The matter was adjourned for sentencing on November 5, 2014.

Phosphagenics fell 0.1 cents or 1.3 percent to 7.7 cents.

SIRTEX MEDICAL

Sirtex says it has completed its 500-patient trial comparing its SIR-Spheres with standard-of-care to standard-of-care alone and expects to publish results in June 2015.

Sirtex previously said that the trial compared Oxaliplatin, Leucovorin and 5-Fluorouracil (Folfox) against Oxaliplatin, Leucovorin and 5-Fluorouracil with the administration of Sirtex Yttrium-active microspheres in patients with inoperable liver metastases from primary colorectal cancer, or bowel cancer.

The company said that the primary endpoint was progression-free survival, a measure of the remission effect of the treatment, that is the time from randomization until tumor progression, with secondary endpoints including overall survival, tumor response rate, quality of life and surgical resection rate.

Sirtex said that a reconciliation of data was expected to be completed by March 2015, when the Sirflox study would be locked and analyzed.

The company said that the study results and preliminary analysis would need to be verified and validated and that peer review, through publication in a medical journal or presentation at a scientific conference was an essential part of the verification and validation process.

Sirtex said it expected the final results and related detailed analysis of the Sirflox study would be presented at the American Society of Clinical Oncology meeting in Chicago in June 2015.

The company said that the Sirflox international multi-centre randomized controlled trial was carried out in Australia, New Zealand, the US, Europe and Israel, and was led by Royal Melbourne Hospital oncologist Prof Peter Gibbs and the Perth, Western Australia-based Sir Charles Gairdner Hospital's Professor Guy van Hazel.

Sirtex said that if the results were positive, SIR-Spheres might be elevated to a first-line therapy for patients with colorectal liver metastases, providing important clinical benefits to patients and leading to a material change in Sirtex's business.

The company said that if the results were not positive, SIR-Spheres would remain a salvage therapy for the foreseeable future.

Sirtex said its Foxfire study was scheduled to complete recruitment by April 2015 and due to a high level of interest in the study at participating hospitals, patient recruitment accelerated during 2014 and was well ahead of schedule with the total number of patients higher than originally planned.

The company said that the Foxfire study aimed to evaluate whether a first-line treatment strategy of using the current standard-of-care chemotherapy plus SIR-Spheres microspheres was more effective than chemotherapy alone, in patients with inoperable liver metastases from primary colorectal cancer.

Sirtex said that the Foxfire primary endpoint was overall survival, a measure of the effect of the treatment on the duration of survival, the time interval from randomization to death.

The company said that the French 400-patient Sarah trial was comparing SIR-Spheres head-to-head with sorafenib for primary hepatocellular carcinoma or liver cancer and was scheduled to complete recruitment by the end of 2014 and was well ahead of schedule.

Sirtex said that an interim analysis undertaken by the principal investigator and study statistician demonstrated a higher rate of treatment cross-over than assumed in the original design of the Sarah study.

The company said that the treatment cross-over "necessitated the recruitment of an additional 60 patients onto the study" but patient recruitment would be completed this year, as scheduled.

Sirtex said the Sarah study primary endpoint was overall survival.

Sirtex was up 39 cents or 1.8 percent to \$22.27 with 226,858 shares traded.

REGENEUS

Regeneus says it was not given the opportunity to respond properly to claims made on the ABC-TV 7.30 Report on Monday October 6 (BD: Oct 7, 2014).

The 7.30 program said that a complaint had been filed to the ASX relating to a Regeneus announcement in August that the Australian Football League had approved its fat-derived Hiqcell treatment and it was misleading (BD: Aug 27, 2014).

Today, Regeneus said that “at the time of the interview, it was not aware of any complaint being made to the ASX and was only made aware of a complaint being lodged following the interview, when it made an enquiry to the ASX”.

The company said that the ABC reporter did not inform Regeneus or co-founder Prof Ben Herbert of the complaint, or its nature, prior to the interview and, to date, had not seen the complaint letter.

Regeneus said that the 7.30 Report complaint letter stated the announcement was “misleading because the control ... group in that trial also achieved the same reduction in pain and slowing of cartilage degeneration ... and a reasonable person would draw the conclusion that the company's product had been shown to be clinically efficacious when rigorously tested ...there are no data we are aware of that support that conclusion”.

Regeneus said it did not consider the ASX announcement was misleading.

The company said the double-blind clinical study demonstrated that Hiqcell was safe, reduced pain and halted cartilage degradation, with statistically significant differences between the Hiqcell group and placebo group in biomarkers related to inflammation and cartilage degradation.

Regeneus said the placebo group also demonstrated a reduction in pain, which was common in osteoarthritis trials.

The company said that the August 5, 2013 prospectus disclosed that both the treatment group and the placebo group showed a reduction in pain scores.

Regeneus said its biomarkers announcement on October 8, 2013 said that Hiqcell stabilized levels of CTX-II in urine, a cartilage-specific breakdown molecule that increased in patients with osteoarthritis, with patients on placebo showing a significant increase in CTX-II, while Hiqcell patients showed no increase.

The company said the purpose of a recent ASX announcement was not to repeat the findings in detail but disclose that the AFL had approved the use of Hiqcell on a case-by-case basis as not in breach of its Prohibited Treatments List (BD: Aug 27, 2014).

Regeneus said it chose not to include a further description of the placebo pain results, as the placebo effect was complex and “not easily communicated with a few sentences”.

Regeneus said it was committed to publishing the results of its clinical trials and a final manuscript fully describing the study had been prepared and was expected to be submitted to the peer review journal Osteoarthritis and Cartilage.

Regeneus said it did not consider the August 27, 2014 ASX release on AFL approval misleading.

The company said that while it was not expressly mentioned in the story, the way it was compiled may have left the viewer under the impression that Hiqcell was the reason for former AFL player Clint Bartram's treatment failure.

Regeneus said Mr Bartram was not treated using Hiqcell, nor was NRL player Trent Hodkinson.

The company said that the ABC report inferred that Regeneus had taken shortcuts in the evaluation of safety and efficacy.

Regeneus said that Hiqcell had been used to treat more than 550 patients in Australia since 2011 including “a world-first double blind clinical study”.

Regeneus was up 0.5 cents or 3.6 percent to 14.5 cents with 2.3 million shares traded.

D3 MEDICAL

D3 says that Johnson & Johnson will pay \$US1.75 billion for the South San Francisco, California based Alios Biopharma developing therapeutics for viral diseases.

D3 said that the amount would be paid in cash on closing of the transaction in which Alios would join the Johnson & Johnson's Janssen Pharmaceutical Companies.

The transaction has been approved by the boards of directors of both companies.

Alios chief executive officer Dr Lawrence Blatt said the company's portfolio targetted "a diverse range of viral infections, including respiratory syncytial virus, which complements ongoing efforts by Janssen to develop innovative treatments for important and life-threatening infections".

"We engaged D3 to help us challenge conventional pediatric development paradigms for our RSV program," Dr Blatt said.

D3 Medicine said it collaborated with Alios on the development of AL-8176, a phase II treatment for respiratory syncytial virus, with results presented at ID Week in Philadelphia this week.

D3 is a private company.

ANALYTICA

Analytica says that its intra-vaginal Pericoach pelvic floor monitoring and training system has received Conformité Européenne (CE) mark clearance.

Analytica said the "major milestone" allowed it to market the Pericoach system in Europe.

The company said that sales in each European country required additional "minor procedural clearances and fees" and it would pursue the additional approvals with each European national authority according to the company's commercial priorities.

Analytica said that CE certification was recognized by many non-European medical device regulatory jurisdictions and the certification would expedite clearances when Analytica targetted those countries.

Analytica was up 0.2 cents or 6.45 percent to 3.3 cents.

VICTORIA GOVERNMENT

The Victoria Government made three health, medical research and biotechnology related announcements in separate launches, ahead of the November 29, 2014 State Election.

The Victoria Premier Dr Dennis Napthine and the Minister for Health David Davis officially announced what they said was "Australia's first dedicated cardiac hospital"- Monash Heart in the South-Eastern suburbs.

A media release said the Coalition Government would commit \$70 million to the new Monash Heart Hospital, with Monash Health committing \$50 million.

The Minister for Technology Gordon Rich-Phillips launched Victoria's \$18.8 million Medical Technology Strategy in North Altona in the Western suburbs.

Mr Rich-Phillips said that Victoria's Medical Technology Strategy was "Victoria's first focused and coordinated plan to expand the state's medical technology industry and boost its exports".

"This strategy aims to increase the number of medtech companies operating in Victoria, reduce our medtech imports and increase our exports, while also generating more highly skilled jobs for Victorians and contributing to our quality of life," Mr Rich-Phillips said.

The Minister for Health David Davis was expected "to make a significant pre-election announcement at Vision 2020 World Sight Day celebration" in Preston in the Northern suburbs, but no details were available at the time of publication.

OBJ

OBJ says that the Australian Patent Office has allowed wholly-owned subsidiary International Scientific Pty Ltd a patent entitled 'Delivery of Fabric Care Products'.

OBJ said that the patent application described the use of its magnetic micro-array technology to enhance the delivery and penetration of cleaning and conditioning agents into fabrics and the patent was expected to be granted within three months.

The company said the technology was designed "to use diamagnetic repulsion and micro-fluidic flow enhancement as a means of increasing the efficacy of washing and cleaning processes in both household and industrial applications".

OBJ said the fabric care program was part of its non-skin research and development program which included surface penetration, hygiene and hair care research.

The company said that International Scientific held more than 22 granted and filed patent applications covering powered magnetic delivery or 'Dermaportation', magnetic microarray technology, magnetic microarrays in motion and a range of sector and industry specific use patents covering magnetic microarrays in specific commercial applications and with special groups and classes of molecules and agents.

OBJ said that the allowance of the fabric care patent supported the wider use of its magnetic micro-array enhanced delivery technology into homecare and industrial areas.

OBJ fell 1.5 cents or 12.5 percent to 10.5 cents with 19.1 million shares traded.

THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

Southern Cross Ventures managing director Dr Larry Marshall has been appointed as the Commonwealth Scientific and Industrial Research Organisation's chief executive.

CSIRO chairman Simon McKeon said that Dr Marshall had "an impeccable record as a scientist, a technology innovator and business leader".

"His wealth of experience in developing and applying science and technology makes him an excellent fit," Mr McKeon said.

In a media release Mr McKeon thanked current chief executive Dr Megan Clark for her leadership of CSIRO for the past six years and said she would leave the Organisation at the end of December this year and Dr Marshall would join CSIRO in January 2015.

CSIRO said that Dr Marshall held a Doctorate of Philosophy in physics from Sydney's Macquarie University and began his career in the Defence Science and Technology Organisation.

CSIRO said that Dr Marshall had 25 years experience as a technology entrepreneur and held 20 patents protecting commercial products and founded six US companies in biotechnology, photonics, telecommunications and semiconductors.