



Biotech Daily

Monday September 22, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: GENETIC TECH UP 8%, STARPHARMA DOWN 8.5%**
- * **STARPHARMA PLACEMENT RAISES \$18m, SHARE PLAN FOR \$5m MORE**
- * **PRIMARY PAYS \$2m FOR GENETIC TECHNOLOGIES HERITAGE BUSINESS**
- * **BENITEC, CSIRO APPEAL EURO DECISION ON GRAHAM PATENT**
- * **CLINUVEL PRESENTS SCENESSE TO EUROPE'S CHMP TOMORROW**
- * **PROGEN PROGRESSES TO 3rd PG545 SOLID TUMOR COHORT**
- * **ADVANCED SURGICAL TO DISTRIBUTE SMALL BONES PRODUCTS**
- * **BLUECHIIP CLAIMS MORE SALES, MICRONIC PROJECT ON-TRACK**
- * **OPTISCAN REQUESTS FUNDRAISING TRADING HALT**

MARKET REPORT

The Australian stock market fell 1.29 percent on Monday September 22, 2014 with the S&P ASX 200 down 70.1 points to 5,363.0 points. Seven of the Biotech Daily Top 40 stocks were up, 24 fell, eight traded unchanged and one was untraded.

Genetic Technologies was the best, up 0.2 cents or eight percent to 2.7 cents with 737,000 shares traded.

Antisense climbed 7.7 percent on publication in the journal Neurology of its phase II trial of ATL1102 for multiple sclerosis (BD: Jun 30, 2008); Tissue Therapies was up five percent; Clinuvel climbed 3.2 percent; Circadian rose 2.7 percent; Psivida and Viralytics were up more than one percent; with Cochlear up 0.03 percent.

Starpharma led the falls, down six cents or 8.45 percent to 65 cents with 912,411 shares traded.

Both GI Dynamics and Uscom lost eight percent; Mesoblast and Neuren shed six percent or more; Living Cell, Oncosil and Prima fell four percent or more; Acrux, Admedus, Atcor, Benitec, Ellex, Nanosonics and Universal Biosensors were down more than three percent; Analytica, Phosphagenics, Prana and Sirtex shed more than two percent; Avita, Impedimed, Medical Developments and Osprey were down one percent or more; with Bionomics, CSL and Resmed down by less than one percent.

STARPHARMA

Starpharma says it has raised \$18 million in a placement at 65 cents a share and will raise a further \$5 million through a share purchase plan.

Starpharma said that the share price was an 8.5 percent discount to the 71 cents a share closing price prior to the trading halt.

The company said that the combined \$23 million would “significantly strengthen” its cash balance, which was \$24 million at June 30, 2014 and fund the completion of phase III trials of Vivagel for the prevention of recurrence of bacterial vaginosis; commercialization of Vivagel for symptomatic relief of bacterial vaginosis including regulatory submissions and licences; accelerate dendrimer-docetaxel through phase I and into phase II trials; completion of pre-clinical development for another dendrimer candidate, commercialize agro-chemical products and provide working capital and strengthen the balance sheet to support commercial negotiations.

Starpharma said the record date for the share plan, capped at \$5 million, was September 19, it would open on September 29, 2014, and close on October 21, 2014, with shares available in lots up to \$15,000.

Starpharma said that Bell Potter Securities was the sole lead manager to the placement. Starpharma fell six cents or 8.45 percent to 65 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it will sell its heritage genetics business to Primary Health Care pathology subsidiary Specialist Diagnostics Services for \$2 million.

Genetic Technologies said it had a binding contract of sale with Specialist Diagnostics for the diagnostic and sequencing services encompassing medical, forensic, paternity and animal genomic testing.

The company had revenues of several million dollars a year from the services which included dingo and other animal breed identification DNA testing as well as immigration identification and forensic work for New South Wales Police.

In 2011, Genetic Technologies posted a maiden net profit after tax for the year to June 30, of \$901,341 on revenue of \$18,275,701, of which \$13,680,741 was from licencing fees and \$4,594,960 from genetic testing services (BD: Aug 25, 2011).

Today, Genetic Technologies said that settlement was expected within the next month.

The company previously said it would sell non-core assets and focus on the US molecular diagnostics market and commercialization of Brevagen (BD: Sep 15, 2014).

Genetic Technologies chief executive officer Alison Mew said the “divestiture of the Australian genetics business follows our recently announced restructuring plans, and represents a material milestone in our transformation to becoming a streamlined and focused molecular diagnostics company committed to the commercialization of flagship breast cancer risk test Brevagen”.

“Implementation of the restructure plans continue and are on track for completion over the next quarter,” Ms Mew said.

“The Australian genetics business has been fundamental to the company’s development as a specialized genetic testing service provider and more recently a foundation to enter the molecular diagnostics market via Brevagen,” Ms Mew said.

“However, when the opportunity to divest the Australian genetics business arose, the board elected to do so, focusing the company on its core asset Brevagen, and the imminent release of the next generation of the test, Brevagenplus,” Ms Mew said.

Genetic Technologies was up 0.2 cents or eight percent to 2.7 cents.

BENITEC BIOPHARMA

Benitec says it has filed a notice of appeal against the European Patent Office revocation of the 'Graham' patent 1,555,317.

Benitec said it was supporting the owner of the patent, the Commonwealth Scientific and Industrial Research Organisation, in preparing and filing the appeal.

In May, Benitec said the European Patent Office upheld an opposition to one of the European Graham patents directed to genetic constructs for RNA interference.

The patents relate to the work of Dr Michael Graham at the Commonwealth Scientific and Industrial Research Organisation and cover the use of expressed RNA interference in human therapeutic applications (BD: May 5, 2009; Jan 29, Sep 30, 2010; Feb 17, 2011).

The main patent, US Patent 6,573,099, known as the Graham '099 patent, entitled 'Genetic Constructs for Delaying or Repressing the Expression of a Target Gene', was the subject of a long-running legal action defended by Benitec and the CSIRO in the US and was finalized in 2011 (BD: Mar 22, 2011).

In May, Benitec said the European decision "does not have any relevance to other Graham patents in other jurisdictions, or the other patent families owned or licenced by Benitec" (BD: May 23, 2014).

Benitec said in May that the opposition to the patent, filed in June 2012 by Germany's BASF and the UK's Strawman, later identified as the Belgium-based Galapagos NV, and Benitec had a licencing agreement with Galapagos for the use of its European patent 1,444,346 for human therapeutics and diagnostics, providing rights for the further development of its DNA-directed RNA-interference (ddRNAi) pipeline in Europe.

The company said that the European Patent Office decision was despite the initially favorable opinion from the panel issued prior to the hearing and the submissions presented at the hearing by CSIRO's legal counsel.

The company said in May that the decision was made on the preliminary ground that one claim feature was not clearly and unambiguously disclosed in this particular patent specification, the novelty and inventiveness of the claims were not reviewed and the decision was "inconsistent with most of the rest of the world".

Today, Benitec said that the notice of appeal began the process, to be followed by the statement of appeal to be filed by November 11, 2014.

The company said that the statement would address the features of the main claims that were found unpatentable by the European Patent Office in May 2014.

Benitec said that the particular feature of length limitation to the RNA constructs generated by the ddRNAi delivery model was contested when taking the patent to grant in 2011.

The company said that as well as the Graham appeal, the European Patent Office had issued a summons for oral proceedings to the Waterhouse patent 1,068,311, entitled 'Methods and means for obtaining modified phenotypes' and the hearing with the opposition division was scheduled at The Hague on January 7 and 8, 2015.

Benitec said that the Waterhouse patent was granted on April 27, 2011 and was opposed by BASF SE and Strawman, joint opponents of Carnegie Institution of Washington & University of Massachusetts and the Swiss-based Syngenta Participations AG, covering a distinct inventions in the ddRNAi field.

Benitec intellectual property counsel Sakura Holloway said that the Waterhouse patent provided a broad patent position for ddRNAi with her company and CSIRO having "a high degree of confidence that the outcome of the Waterhouse hearing will be favorable".

"Most of the objections raised to Waterhouse have been successfully overcome in other jurisdictions, in particular the US," Ms Holloway said.

Benitec fell four cents or 3.9 percent to 99 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it will present at the plenary meeting of the Committee for Human Medicinal Products of the European Medicines Agency in London tomorrow.

Clinuvel said that the presentation was part of the EMA review of the marketing authorization application for Scenesse, or afamelanotide 16mg, for the preventative treatment of the orphan disease erythropoietic protoporphyria.

The company said that it filed the application in February 2012.

Biotech Daily is aware the previous European drug applications including presentations to the Committee for Human Medicinal Products have had a same day response from the Committee (BD: May 25, 2011).

Clinuvel climbed 15 cents or 3.2 percent to \$4.90.

PROGEN PHARMACEUTICALS

Progen says it has assessed the second patient cohort in its 25-patient, phase I trial of intra-venous infused PG545 for solid tumors.

Progen said that with an independent medical monitor and the co-ordinating investigators the safety data from the cohort had been reviewed and the trial would progress to the next dose level.

The company said that each patient in the second cohort received once-weekly 50mg doses of PG545, with no dose limiting toxicities reported, following at least four weeks of treatment, with each of the three patients in the third group receiving 100mg doses of PG545 at once-weekly intervals.

The company said the study, entitled 'An open-label, multi-centre phase I study of the safety and tolerability of IV infused PG545 in patients with advanced solid tumors' was had the primary objective of the determination of the maximum tolerated dose as defined by significant dose limiting toxicity.

Progen said that the secondary objectives were the assessment of the safety and tolerability; the pharmacokinetic parameters of PG545; pharmacokinetic and pharmacodynamic relationships; and to document any anti-tumor activity.

The company said that the trial was being carried out at three sites in Australia.

Progen was up two cents or 8.5 percent to 25.5 cents.

ADVANCED SURGICAL DESIGN AND MANUFACTURE

Advanced Surgical says it has been advised by Stryker South Pacific of its intention not to renew the distribution agreement with Small Bone Innovations.

In 2012, Advanced Surgical said it had a distribution agreement with Small Bones Innovations APAC for a range of products including the Star ankle replacement as well as technologies for elbow wrist hand and foot (BD: Feb 16, 2012).

Today, Advanced Surgical said it held the distribution rights for Australia and New Zealand for Small Bone products, with the contract due to expire on December 31, 2014, but Small Bone announced on June 30 2014 that it had a definitive agreement to sell all their assets to Stryker and it was Stryker's intention to distribute directly in Australia.

Advanced Surgical chief executive officer Tom Milicevic said the company's strategy was "to acquire world class products to grow our business by offering a comprehensive product range and outstanding service to a growing population of orthopaedic surgeons".

"We are currently reviewing a number of opportunities to further enhance our product offering," Mr Milicevic said.

Advanced Surgical was unchanged at 5.5 cents.

BLUECHIIP

Bluechiip says that two companies will trial its bio-tagging systems and Micronic BV has completed the first phase of the co-development program.

Bluechiip said that Taylor-Wharton Australia was part of Minnetonka, Minnesota-based cryogenic tank manufacturing group Taylor-Wharton Cryoscience and it had purchased the readers and consumables to conduct life science trials.

The company said that the Brisbane-based Wesley- St Andrews Research Institute had purchased its tagging system for preparing and monitoring samples for a study.

Bluechiip chief executive officer Dr Jason Chaffey said “the sales and trials to Taylor-Wharton Australia and Wesley-St Andrew’s Research Institute are important validation milestones of the Bluechiip product and we are very pleased to be part of the trials being undertaken”.

Bluechiip said that Micronic had over-moulded and integrated its tag with a laser-etched Micronic 2D barcode and the first prototypes were tested for integrity and cryogenic reliability.

The company said that initial testing indicated that dual identity vials incorporating the electronic Bluechiip tag and Micronic’s 2D barcodes operated as specified after the injection moulding process and initial cryogenic testing.

Bluechiip said that the two companies would verify the results and plan for the next phase which would involve collaboration in sales and marketing of the new product.

In March, Bluechiip signed a co-development agreement with the Lelystad, Netherlands-based Micronic Manufacturing BV, which was part of the same Micronic group as its North American distribution partner Micronic America (BD: Mar 24, 2014).

The company said at that time that the co-development agreement was to develop a dual identity vial for the cryo-preservation market, incorporating both the Bluechiip RF micro-electro mechanical systems (Mems) identification tag and Micronic’s 2D data-matrix code. Bluechiip was up one cent or 9.5 percent to 11.5 cents with 2.7 million shares traded.

OPTISCAN

Optiscan has requested a trading halt pending “an announcement to the market ... concerning fundraising, upon finalization of the arrangements”.

Trading will resume on September 24, 2014 or on an earlier announcement.

Optiscan last traded at 3.5 cents.