Biotech Daily

Thursday June 18, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN; AVEXA UP 14%, PHYLOGICA DOWN 17%**

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MARKET REPORT

The Australian stock market fell 0.31 percent on Thursday June 18, 2009 with the S&P ASX 200 index down 12.0 points to 3,892.1 points. Ten of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and six were untraded.

Avexa was best, up 1.5 cents or 13.64 percent to 12.5 cents with 5.4 million shares traded on no news, followed by Circadian up 10.3 percent to 75 cents.

Antisense and Benitec climbed more than seven percent; Tissue Therapies was up 6.25 percent; Living Cell and Phosphagenics were up more than three percent; CSL, Resmed and Viralytics rose more than two percent; with Mesoblast and Psivida up more than one percent.

Phylogica led the falls, down one cent or 16.7 percent to five cents with 200,000 shares traded. Clinuvel, Nanosonics, Novogen and Polartechnics fell more than four percent; Starpharma was down three percent; Bionomics and Prana shed more than two percent; Biota, Chemgenex, Heartware and Sirtex were down more than one percent; with Cellestis, Cochlear and Universal Biosensors down by less than one percent.

EDITORIAL: BIOTECHS, THE LAW AND MATTERS OF PRINCIPLE

Anyone with any significant exposure to the law and especially commercial law will know that we have the best legal system money can buy.

That is, whoever can afford to keep appealing to the higher courts is likely to win the poker game – unless both go all the way to the Full Bench of the High Court or in the UK the Law Lords, in which case, anything can happen and generally does.

Fighting a matter of law or using the legal system to achieve a commercial end is very different to fighting 'a matter of principle'.

In matters of principle, human emotions become entangled with probable legal outcomes. Decisions are not objective. People say silly things like: "I'm going to teach them a lesson" or "They can't be allowed to get away with that". But one can only use the legal system to teach other people lessons or prevent them doing things if one has a reservoir of cash.

A family law barrister once told Biotech Daily that his hardest task was explaining to litigants that unless they were fighting over $2 million it wasn't worth coming to him, because $200,000 would go in legal costs. In some cases it is cheaper to give the other side 80 percent rather than go to court for a 50-50 split.

Yesterday's publication of the New South Wales Supreme Court judgment against Fermiscan, in favor of inventor Prof Veronica James is merely the most recent of legal actions that never should have begun. Justice Robert McDougall's judgment is a damning indictment of Fermiscan's decision-making.

http://www.lawlink.nsw.gov.au/scjudgments/2009nswsc.nsf/6ccf7431c546464bca2570e6001a45d2/399a75edcecdcf26ca2575d6007a8f5d?OpenDocument.

One claim against the inventor of their technology was that she disparaged the company. The judgment says Prof James did point to criticisms of the x-ray diffraction test of hair to detect breast cancer, but she did so by relying on Fermiscan's own published documents.

That Fermiscan managed to have Prof James agree to a $700,000 penalty should she ever disparage the company in settlement of a previous Federal Court case is breath-taking. Justice McDougall said this penalty was not enforceable.

Justice McDougall also dismissed the Fermiscan claim that Prof James patents on detecting cancer from skin and nail was merely "an improvement" on the earlier hair test, citing that most authoritative document, the Australian Oxford Dictionary.

The proof that this legal action has been counter-productive is that all of Fermiscan's documentation and criticisms of its own technology are now in the public realm.

Fermiscan will appeal the decision, scheduled for August 5, 2009, meaning they believe that there has been a technical error by Justice McDougall in arriving at his judgment.

But Fermiscan is not alone in this pursuit of principle.

Biotech Daily has reported on the reciprocal case of the inventor taking on the company as Sirtex former chairman Dr Bruce Gray uses his 30 percent holding to call meetings to oust the Sirtex board. It is Biotech Daily's view that Dr Gray would find it far more profitable to leave the board and management to get on with work, rather than providing never-ending distractions, which cannot possibly assist in improving Sirtex's share price.

Finally, Biotech Daily mentions in passing only that Biota investors were short-changed by $55 million when, acting on a matter of principle, that company's previous board knocked back an offer of $75 million from Glaxosmithkline to settle the Relenza matter, later accepting $20 million, which was insufficient to cover legal costs.

As one respected litigator said of an English case she had just been given, rubbing her hands together with a glint in her eye mocking an avaricious shopkeeper: "Oooh goody, a matter of principle."

The answer is simple really. If you have a matter of principle, don't go to court.

David Langsam, Editor

CLINUVEL PHARMACEUTICALS

Clinuvel says the European Medicines Agency has granted orphan medicinal product status to its photo-protective drug afamelanotide for the treatment of solar urticaria.

The European Medicines Agency (EMEA) granted Clinuvel its first orphan medicinal product designation for afamelanotide in March 2008 for the treatment of erythropoietic protoporphyria, which is in phase III clinical trials.

Clinuvel said solar urticaria was a skin disorder marked by an acute allergic response following ultra-violet or sun exposure, with potentially systemic symptoms including anaphylaxis, breathing difficulty, nausea and headaches.

Immediate localized reactions vary from characteristic wheal formation and erupting flares on exposed skin sites to swelling of soft tissues.

Clinuvel said solar urticaria patients typically avoid ultra-violet and visible light sources and to prevent an outbreak of symptoms, they tend to live indoors in social isolation.

The company said about three per 100,000 people suffered from solar urticaria worldwide.

Clinuvel said preliminary studies indicated that afamelanotide might be able to provide photo-protection to solar urticaria patients and prevent the onset of symptoms.

The company said an analysis of results from a phase II clinical trial of afamelanotide in solar urticaria was expected soon.

If the data warrant, Clinuvel will consider conducting further clinical trials to determine the ability of afamelanotide to satisfy this unmet medical need.

Clinuvel said the European Medicines Agency orphan medicinal products were intended for prevention or treatment of life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the European Union.

The company said orphan designation provided regulatory benefits and access to assistance from the European Medicines Agency to facilitate registration including protocol assistance including scientific advice during the product development phase; fee reductions including 100 percent protocol assistance, pre-authorization inspections, marketing authorization application and reduction for post-authorization activities in the first year after granting of marketing authorisation; access to the European Medicines Agency's centralized approval procedures covering 27 member states; and access to European Commission-funded research projects.

Orphan designation grants Clinuvel 10 years' market exclusivity for afamelanotide for the treatment of solar urticaria in the EU, following approval.

Clinuvel's chief executive officer Dr Philippe Wolgen said the second orphan designation "consolidates the position of afamelanotide as a systemic photo-protectant for a range of diseases".

"In 2006, we started the program on identified disease symptoms that are caused by UV and light," Dr Wolgen said.

"In using afamelanotide as a photoprotective drug in these indications, we established the beneficial use in the most severe diseases," Dr Wolgen said.

"It is rewarding to treat patients who have never been able to find medicinal answers to their diseases," he said.

"Regulators acknowledge that there is a clinical demand for medicinal photo-protection in severe diseases and the path chosen to bring the drug to market is well mapped out," Dr Wolgen said.

Clinuvel fell 1.5 cents or 4.7 percent to 30.5 cents.

ANTISENSE THERAPEUTICS

Antisense says studies in mice of ATL1101 for prostate cancer showed it “significantly enhanced the tumor-suppressive effect of the cancer drug paclitaxel”.
Antisense said paclitaxel was one of a class of drugs known as taxanes.
Along with androgen (a male hormone) blockade, taxane chemotherapy is an important treatment option in the most dangerous form of the disease, castration-resistant prostate cancer.
The compant said that in the mouse model of prostate cancer, tumor volume was halved after five weeks of paclitaxel and ATL1101 combination treatment, compared with control paclitaxel-treated mice.
In cell culture experiments, the amount of paclitaxel required to induce tumor cell apoptosis (or cell death) was significantly reduced when used in combination with ATL1101.
Antisense said the ability to sensitize tumor cells to the cytotoxic effects of paclitaxel showed ATL1101’s potential as a chemo-sensitizing agent to be used in combination with existing prostate treatments to improve the outcomes for patients.
The company said ATL1101 was a second generation antisense inhibitor of the insulin-like growth factor-I receptor (IGF-IR) which suppressed the growth of human prostate tumors in an animal model of prostate cancer, and slowed down transition to castration-resistant prostate cancer when used as a single agent.
Antisense said drugs targeting IGF-IR are being developed by a number of the major pharmaceutical companies for a variety of cancer indications, indicating the importance of the IGF-IR target in cancer.
Antisense research collaborator in the study was University of British Columbia urology sciences professor Prof Martin Gleave who said that resistance of tumor cells to the effects of existing treatment was a major challenge in the management of prostate cancer.
“Tumor cells build resistance to chemotherapy treatment via survival mechanisms that include IGF-I signaling,” Prof Leave said.
“In our prostate cancer model we have shown that ATL1101, which is an IGF-I receptor blocker, can inhibit this mechanism and restore sensitivity to chemotherapy,” Prof Gleave said.
Antisense said it was “in dialogue with various parties” on the development of ATL1101 in prostate cancer, aiming to build on ATL1101’s pre-clinical pharmacology data package, completed mouse toxicology study, established drug manufacturing process and intellectual property protection.
Antisense was up 0.3 cents or 7.5 percent to 4.3 cents.

MEDICAL THERAPIES

Gregory Glen Worth has become a substantial shareholder in Medical Therapies with a holding of 13,637,809 shares or 7.27 percent.
The shares are held by Mr Worth of Innisfail Queensland and a related party Talrind Pty Ltd and were acquired for $104,606.28 or 0.77 cents a share.
Medical Therapies chief executive officer Maria Halasz told Biotech Daily that Mr Worth was along term supporter of the company, having bought into the initial public offering in 2005.
Medical Therapies was untraded at 2.5 cents.

NOVOGEN

Novogen says data from its terminated phase III trial of phenoxodiol for ovarian cancer has shown no safety concerns, with efficacy to be analyzed in six months time.

Novogen said its 70 percent subsidiary Marshall Edwards reported that the independent data monitoring committee overseeing the phase III trial convened during the recent Annual Meeting of the American Society of Clinical Oncology, considered the data accumulated to date and reviewed the arrangements for early termination of patient enrolment into the study (BD: Apr 15; May 19, 2009).

Novogen said the independent data monitoring committee reviewed available unblinded data from 117 subjects and noted that, at the time of termination of recruitment, 142 subjects had been randomised to the study.

The company said the committee supported the decision to close the study to accrual, and in a review of the available safety data the committee confirmed that there were no safety concerns with phenoxodiol in these subjects.

Novogen said that consistent with the independent data monitoring committee charter, it would convene an expert committee to review the independent data monitoring committee recommendations including those with respect to the disposition of subjects remaining in the study.

The independent data monitoring committee recommended that the final analyses be completed as soon as possible.

Novogen said a full review of the outstanding tasks indicated that completion of data collection and database lock would require a further six months for analysis of the primary efficacy endpoint of progression free survival.

At that stage, a number of pre-specified subset analyses will also be performed.

Novogen said the independent data monitoring committee was advised that, since the tasks to achieve full study completion and database lock were clearly defined, the previous clinical services agreement had been terminated and a new contract was being established for the final stages of data collection and site close-out, which would be offered as a tender to a number of contract research organizations to ensure the study was completed as quickly and as efficiently as possible.

Novogen said the trial was a multi-centre phase III clinical trial of orally-administered investigational drug phenoxodiol in combination with carboplatin in women with advanced ovarian cancer resistant or refractory to platinum-based drugs, to determine its safety and effectiveness when used in combination with carboplatin .

The trial recruited ovarian cancer patients whose cancer initially responded to chemotherapy, but had since become resistant or refractory to traditional platinum treatments.

The trial was approved by the US Food and Drug Administration under a special protocol assessment program and provided for an analysis of interim results after 95 of the planned 340 recruited patients experienced disease progression.

Novogen said it was expected that analyses after the early termination of recruitment following randomization of 142 patients would yield results from a greater number of progressed patients than was required for the planned interim analysis.

Novogen fell 3.5 cents or 4.7 percent to 71.5 cents.

CATHRX

Wilson HTM Investment Group and associates have increased their substantial shareholding in Cathrx from 2,731,648 shares (6.41%) to 3,847,766 shares (9.03%).

Cathrx was unchanged at 45 cents.

CIRCADIAN TECHNOLOGIES

Circadian has been granted a European patent covering the use of VEGF-D protein and antibodies to VEGF-D in a broad spectrum of indications, including cancer.

Circadian said vascular endothelial growth factor D (VEGF-D) was “a major novel target for cancer and other diseases [and was] closely related to VEGF-A, the target of Genentech’s Avastin” which the company said was a leading cancer therapy with worldwide sales of more than $US6 billion.

Circadian said the European patent was granted to its wholly-owned subsidiary Vegenics, which was granted the VEGF-D patent in the US last year, providing the company with access to the world’s two largest markets.

Circadian said it was developing its VGX-200 series of humaniszd VEGF-D antibodies as anti-cancer agents.

Circadian chief executive officer Robert Klupacs said that “stemming from the enormous success of Avastin, the development of antibody drugs targeting angiogenic molecules such as VEGF-D is widely considered one of the most promising strategies in the pharmaceutical industry”.

“This patent adds to our considerable estate of intellectual property covering VEGF family members, in particular building on the US patent granted to us last year covering VEGF-D antibodies,” Mr Klupacs said.

“It is an important protection for our internal therapeutics development programs and represents a major asset for commercial partnerships with other companies seeking to pursue this approach,” he said.

Circadian said Vegenics owned worldwide rights to an extensive intellectual property portfolio covering angiogenesis targets VEGF-D, VEGF-C and the receptor protein VEGFR-3.

Circadian climbed seven cents or 10.3 percent to 75 cents.

VERVA PHARMACEUTICALS

Verva says it has completed a $2 million financing for a phase Ib/IIa clinical proof-of-concept testing of the company’s diabetes therapy VVP808.

Verva said the funds were raised from current investors GBS Venture Partners, Queensland Biocapital Funds and Uniseed, along with new investors Westscheme and MTAA Superannuation Fund.

The company said the investors were issued dividend-bearing Class A preference shares with associated redemption rights and liquidation preferences (BD: May 15, 2009).

Verva chief executive officer Vince Wacher said the company was “very pleased to have completed the financing in this difficult economic climate and we are very gratified by the continued support and enthusiasm of our investors”.

Data from the diabetes trial is expected by late 2010.

Verva said the investment was approved by shareholders at Verva's annual general meeting on May 29, 2009.

Shareholders also confirmed Dr Andrew Baker, Dr Greg Collier, Andrew Macdonald and Dr Ian Nisbet as directors and approved changes to the Verva constitution.

The changes permit holders of 10 percent or more of the voting share capital of Verva to nominate a representative to the board and entitle holders of Series A preference shares to vote at any meeting on an ‘as converted basis’, giving them the same voting rights as the ordinary shareholders.

Verva said VVP808 was a non-thiazolidinedione insulin sensitizer for type 2 diabetes.

Verva is a public unlisted company.

BALNAVES FOUNDATION

The Balnaves Foundation has awarded $200,000 to Children's Cancer Institute Australia for Medical Research staff, Dr Joshua McCarroll and Dr Marcia Munoz.

A media release from the Children's Cancer Institute said New South Wales Minister for Science and Medical Research Jodi McKay presented the awards at Parliament House.

The founder of the Foundation Neil Balnaves said he was "proud to assist talented scientists … pursue such important scientific questions".

"It gives me great pleasure to know the Balnaves Foundation Young Researchers' Fund is identifying promising talent and allowing young scientists to pursue new ideas to combat childhood cancer," Mr Balnaves said.

Dr McCarroll's research focuses on brain cancer, the most common cause of cancer death in children.

"Despite recent advances in surgery and drug treatments, the prognosis of children with brain cancer is dismal," said Dr McCarroll.

"Patients who relapse, often suffer toxic side effects of treatment while their tumors frequently develop drug resistance," Dr McCarroll said.

"I intend to use a relatively new technique, RNA interference, which can switch off genes by using nano-sized particles to carry-in genetic silencers," Dr McCarroll said.

"The difficulty is these nano-particles often have trouble distinguishing between normal cells and cancer cells," he said.

"I believe I have a way of making it easier for the gene silencers to work, by attaching molecules which allow the brain cancer cells to be marked out more clearly," he said.

The media release said that by silencing the genes that regulate cell survival and drug resistance, Dr McCarroll's work had the potential to improve the treatment and long term survival of childhood brain cancer patients as well as other difficult to treat cancers.

Dr Munoz funding will assist he research on neuroblastoma, which accounts for 15 percent of all cancer related deaths in children

She said the long-term survival of children within high-risk neuroblastoma was less than 40 percent, "so there is an urgent need for the development of better treatment therapies".

"Tumors create their own inflammatory environment that helps them to thrive," Dr Munoz said.

"In neuroblastoma, the cancer cells can pump out substances into the surrounding tissue that contribute to this inflammation," she said.

"By better understanding this process, it should be possible to come up with new and improved therapeutic strategies," Dr Munoz said.