Biotech Daily

Thursday September 30, 2010

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: BENITEC UP 48%, CHEMGENEX DOWN 12%**

*** CSIRO, BENITEC WIN ALL USPTO GRAHAM PATENT CLAIMS**

*** TISSUE THERAPIES COMPLETES ULCER TRIAL**

*** STARPHARMA, ELI LILLY COLLABORATE ON UNNAMED CONJUGATE**

*** CIRCADIAN, CINCINNATI COLLABORATE ON LUNG DISEASE DIAGNOSTIC**

*** CBIO'S CHAPERONIN-10 MOUSE STUDY 'PROMISING FOR LUPUS'**

*** HEALTHLINX, PROF MICHAEL QUINN SETTLE OUT-OF-COURT**

*** PHYLOGICA UNDERWRITTEN RIGHTS ISSUE RAISES $2.4m**

*** NEURODISCOVERY UNDERWRITTEN RIGHTS ISSUE RAISES $719k**

*** WILSON HTM TAKES 6% OF NANOSONICS**

*** NANOSONICS DIRECTORS' OPTIONS AGM; CO SEC APPOINTMENT**

*** PRIMA BIOMED TO LIST ON NASDAQ**

MARKET REPORT

The Australian stock market fell 1.34 percent on Thursday September 30, 2010, with the ASX200 down 62.1 points to 4582.9 points. Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and seven were untraded.

Benitec was best, up 1.3 cents or 48.15 percent to four cents with 41.6 million shares traded, followed by Uscom up 10.3 percent to 32 cents with 5,000 shares traded. Antisense climbed 7.7 percent; Alchemia and Tissue Therapies were up more than four percent; Acrux, Prima and Virax were up more than three percent; Patrys and Starpharma rose more than two percent; with Biota and Resmed up more than one percent.

Chemgenex led the falls, down 4.5 cents or 11.7 percent to 34 cents with 395,086 shares traded. Genetic Technologies and Living Cell lost more than seven percent; Circadian fell 6.7 percent; Immuron, Nanosonics and Prana were down more than three percent; Clinuvel and Viralytics shed more than two percent; with Cathrx, Cochlear and Phylogica down more than one percent.

BENITEC, CSIRO

Benitec says the US Patent and Trademark Office's board of patent appeals and interferences has reversed all previous rejections in the '099 Graham patent appeal.

Benitec said the rejection of all appealed claims relating to US Patent 6,573,099, known as the '099 Graham patent had been reversed.

Benitec chief executive officer Dr Peter French told Biotech Daily that his company had an exclusive worldwide licence from the patent holder, the Commonwealth Scientific and Industrial Research Organisation.

"We couldn't have gotten a better result," Dr French said.

Benitec said the '099 Graham patent would be returned to the examiner for further action consistent with the decision.

The company said it expected the USPTO to issue a notice of intent to issue ex parte re-examination certificate, which would terminate the re-examination proceeding.

Benitec said that within several weeks after issuance of the Notice, an ex-parte re-examination certificate would be issued, analogous to the re-issuance of the patent certificate.

The company said a January 2010 article in Nature Biotechnology described the patent portfolio as "one of the most critical patent estates for deploying RNAi in animals and plants".

In a media release Dr French, said the decision confirmed Benitec's "pre-eminent patent position in RNA interference".

"This includes Benitec's primary focus in the field of DNA-directed RNA interference (ddRNAi) in humans," Dr French said.

"This provides new impetus for expanding licencing negotiations with all US groups working in this field," Dr French said.

Dr French said the decision supported Benitec's research and development programs including HIV, hepatitis B, hepatitis C and non small-cell lung cancer.

"A further benefit of this decision is that it provides guidance for the examiners in assessing the several related US applications of the '099 Graham patent, in which Benitec and CSIRO intend to pursue subject matter disclosed but unclaimed in the '099 Graham Patent," Dr French said. "Pleasingly, it should bring to a close a protracted and difficult chapter in Benitec's history".

CSIRO's general manager of intellectual property and licencing Jan Bingley said the CSIRO was "extremely pleased with this result".

"All appealed claims were found allowable by the board of appeal for the USPTO, which provides our exclusive licencee Benitec and its sub-licencees with a strong commercial position in the US, in line with the position in other parts of the world," Ms Bingley said.

Benitec said that of the 23 claims of the '099 Graham patent, claims four and five were the most important, with claim four describing a double stranded genetic construct (dsRNA) for reducing expression of a target gene in an animal cell, comprising: two identical copies of a structural gene sequence, one in the sense orientation and the other in the antisense orientation, each under the control of a separate promoter operable in animal cells and the sequences being substantially identical to a region in the target gene.

The company said that claim five described a double stranded genetic construct (dsRNA) for reducing expression of a target gene in an animal cell, comprising: a promoter sequence operable in animal cells; two identical copies of a structural gene sequence, one in inverted orientation to the other and the sequences being substantially identical to a region in the target gene, with a stuffer fragment, which is a length of double stranded DNA coding for a hairpin loop in the dsRNA.

Benitec was up 1.3 cents or 48.15 percent to four cents with 41.6 million shares traded.

TISSUE THERAPIES

Tissue Therapies says the final three patients in its 30-patient Australian trial of its Vitrogro wound treatment of chronic venous leg ulcers have had "excellent results".

Tissue Therapies said the patients had venous ulcers prior to Vitrogro treatment for one, four and eight months respectively with healing achieved with six Vitrogro treatments over 24 days of 57 percent, 46 percent and 90 percent, respectively.

The company said the Australian venous ulcer trial had treated a total of 30 patients with five patients experiencing complete healing and with average venous ulcer healing of 43 percent ($p < 0.0001$).

Tissue Therapies said the average patient age was 71 years and the average duration of venous ulcer prior to Vitrogro treatment was 11 months with an average nine months of the ulcers being unresponsive to compression therapy, the current best practice treatment.

Tissue Therapies chief executive officer Dr Steven Mercer said Vitrogro "consistently produced excellent results across both the Australian and Canadian human trials" (BD: Nov 18, 2009).

"The human data is even better than we expected from more than 8 years of our published scientific work with live human skin," Dr Mercer said.

"When 20 weeks of conventional treatment leaves up to 50 percent of diabetic and venous ulcers unhealed, the results achieved with only six treatments of Vitrogro over 24 days are remarkable," Dr Mercer said.

"The clinical data from 40 patients gives us even more confidence in the ability of Vitrogro to fundamentally improve the treatment of chronic wounds with accelerated healing that is safe and predictable and with a cost effectiveness that has not previously been available."

The company said the trial results marked the conclusion of the Australian venous ulcer trial conducted by Western Australia Vascular Research Laboratory's Prof Michael Stacey.

Tissue Therapies said Prof Stacey's group had begun participation as one of the sites in the European Union multi-centre trial of commercial scale Vitrogro (BD: Jan 17, 20, 2010).

Tissue Therapies was up one cent or 4.4 percent to 23.5 cents.

STARPHARMA

Starpharma and Eli Lilly have signed a collaborative research agreement for one of Starpharma's dendrimer-drug conjugates.

Starpharma said Eli Lilly would receive an option on the conjugate - the combination of the dendrimer delivery system and a drug molecule.

Starpharma said it would receive research fees and conduct studies in animal models to advance the compound but the identity of the conjugate could not be disclosed due to confidentiality restrictions.

The agreement followes two previous agreements between the companies.

In February 2010, Starpharma said its dendrimer drug delivery technology would be applied to enhance compounds in Lilly's human pharmaceutical portfolio and in May 2009 Starpharma and Lilly's animal health division Elanco signed an agreement to develop animal health products with enhanced properties (BD: May 11, 2009; Feb 1, 2010).

Starpharma chief executive officer Dr Jackie Fairley said the company was "delighted that Lilly has chosen to expand the scope of its partnership with us once again".

"The agreement follows on from an initial evaluation in animal models of this conjugate by Lilly," Dr Fairley said. "Starpharma now looks forward to developing the compound as rapidly as possible with Lilly."

Starpharma was up 1.5 cents or 2.75 percent to 56 cents.

CIRCADIAN TECHNOLOGIES

Circadian has partnered with the Cincinnati Children's Hospital Medical Centre to develop and market a blood test to diagnose the lung disease lymphangioleiomyomatosis (LAM).

Circadian said that lymphangioleiomyomatosis was a rare but serious lung disease that affected women, usually in their child bearing years.

The company said the diagnostic was being developed following the discovery that high levels of vascular endothelial growth factor-D (VEGF-D) holds the key to detecting the disease.

Circadian said it owned the intellectual property rights to VEGF-D and the test was expected to be available in the US from early 2011.

Circadian said it would work with the Cincinnati Children's Hospital Medical Centre and other groups to make the test available in other global markets.

The company said lymphangioleiomyomatosis caused shortness of breath and lung collapse and occurred when an unusual type of cell invaded the lungs and caused tissue destruction by creating holes or cysts in the lung.

Circadian said lymphangioleiomyomatosis could be fatal and the only known treatment was a lung transplant.

The company said lymphangioleiomyomatosis had been difficult and expensive to diagnose, usually requiring a biopsy or high resolution computed tomography scan.

Due to low awareness, the early symptoms were often mistaken for other respiratory conditions such as asthma, bronchitis or emphysema.

Circadian said that although a small number of patients had been diagnosed with the disease, the recent discovery of a link between it and the genetic abnormality, tuberous sclerosis complex (TSC), had led scientists to estimate that more than 250,000 women worldwide were unaware they had lymphangioleiomyomatosis.

Circadian said its simple blood-based diagnostic test might eliminate the need for a surgical lung biopsy, significantly improving the quality of life in women who may be suspected sufferers.

The test would also be helpful in screening for lymphangioleiomyomatosis in women with tuberous sclerosis complex, a genetic disorder that causes tumors to form in many different organs.

Circadian chief executive officer Robert Klupacs said he was proud to be working with the Cincinnati Medical Centre team to make a test available that offered a straightforward and accurate identification of lymphangioleiomyomatosis.

"This test will be able to reduce and hopefully remove the need for surgical intervention for accurate diagnosis of LAM which we believe will have a huge impact on the quality of life for women who may have this terrible disease," Mr Klupacs said.

"The development of this test adds to the portfolio of diagnostics in development by Circadian and our partners," Mr Klupacs said.

"Diagnostics is an important part of Circadian's business that is progressing in parallel to our drug development activity, as a source of early potential revenue and to complement our product portfolio," Mr Klupacs said.

Circadian said the findings of the diagnostic link between lymphangioleiomyomatosis and VEGF-D were made by a research team at the University of Cincinnati and the Medical Centre led by Dr Lisa Young and Dr Frank McCormack and were published in the August 2010 edition of the journal Chest.

Dr Frank McCormack said the findings were the result of a team effort by clinicians around the world to collect blood samples and clinical data from patients with very rare lung diseases.

Circadian fell four cents or 6.7 percent to 56 cents.

CBIO

CBio says it has completed pre-clinical studies showing potential for its Chaperonin 10 in treating systemic lupus erythematosus.
CBio said the University of Munich mouse study showed "significant potential for the treatment of [systemic lupus erythematosus] and strengthen the company's view that its lead compound XToll has utility beyond a single indication".
The company said lupus was a chronic inflammatory disease that can affect various parts of the body, especially the skin, joints, blood, and kidneys.
CBio said systemic lupus erythematosus was the most serious form of the disease which mostly affected young females and was treated with non-specific immuno-suppressants such as steroids or cytotoxic drugs that caused serious toxicities in patients.
The company said XToll was a potential new-generation drug therapy which could provide safer and more effective treatment of autoimmune diseases.
CBio managing director Jason Yeates said the study was an important link in CBio's drug development pipeline and "XToll could potentially be developed to treat a range of autoimmune diseases".
The company said XToll was a biologically active, modified variant of the naturally occurring protein, Chaperonin 10, with phase I and early phase II studies of XToll completed in rheumatoid arthritis, psoriasis and multiple sclerosis.
CBio said an abstract detailing the lupus study had been accepted by the meeting of the American College of Rheumatologists to be held in Atlanta in November, 2010.
CBio said a detailed phase IIa trial of XToll for moderate to severe rheumatoid arthritis, was fully recruited and due to be completed early in 2011.
CBio fell half a cent or 2.8 percent to 17.5 cents.

HEALTHLINX

Healthlinx says it has settled its legal dispute with former principal investigator and scientific advisor Prof Michael Quinn.
Healthlinx chief executive officer Nick Gatsios told Biotech Daily the matter was settled out-of-court in a confidential agreement and he could not discuss the details.
In July, an article in Melbourne's The Age newspaper quoted Prof Quinn and others making a series of allegations about the Ovplex test (BD: Jul 5, 2010).
Earlier this month, Healthlinx began legal proceedings against Prof Quinn claiming misleading or deceptive conduct.
Court documents said Prof Quinn undertook that until a hearing set for today, he would not republish statements to the effect that Healthlinx was not the owner of the intellectual property in Ovplex; that Prof Quinn, the Women's Cancer Foundation and/or the Ovarian Cancer Institute were entitled to an interest in the intellectual property rights in Ovplex; that the test was based on flimsy evidence; and were disparaging of the effectiveness of Ovplex as a diagnostic panel for use in the detection of ovarian cancer generally and when compared with CA125 (BD: Sep 10, 2010).
Mr Gatsios rejected Prof Quinn's allegations about the Ovplex ovarian cancer test.
Mr Gatsios said Healthlinx controlled the intellectual property around the Ovplex test.
He said that the five biomarker Ovplex test included the existing standard of the CA-125 test reported separately, as well as part of an index with the other biomarkers.
Mr Gatsios said the test was therefore at least equal to CA-125 if not better and earlier studies had shown the Ovplex test was superior to the CA-125 test, alone.
Mr Gatsios said the court proceedings had been terminated.
Healthlinx was untraded at 8.3 cents.

PHYLOGICA

Phylogica says its fully-underwritten rights issue has raised $1,318,840 from the issue of 26,376,797 shares at five cents a share.

Phylogica hoped to raise up to $2,400.000 through the issue of up to 48,000,000 shares and said it had placed the 21,623,203 shortfall shares with Patersons Securities.

Phylogica fell 0.1 cents or 1.9 percent to 5.1 cents.

NEURODISCOVERY

Neurodiscovery says its fully-underwritten rights issue has raised $291,023 from the issue of 11,640,920 shares at 2.5 cents a share.

Neurodiscovery hoped to raise up to $718,577 through the issue of up to 28,743,091 shares and today said it had placed the 17,102,171 shortfall shares with Cunningham Peterson Sharbanee Securities.

The company said the 28,743,091 shares would be allotted on or before October 5, 2010.

Neurodiscovery was unchanged at three cents.

NANOSONICS

Wilson HTM Investment Group and associates have become substantial shareholders in Nanosonics with the acquisition of 13,238,070 shares or 5.84 percent of the company.

Wilson HTM said the shares were acquired by a number of individual holders with one parcel of 2,976,843 shares bought for $1,744,445 or cents a share between May 27, 2010 and September 27, 2010.

Nanosonics fell 2.5 cents or 3.1 percent to 79 cents.

NANOSONICS

Nanosonics annual general meeting will vote to issues 1,000,000 options each to chief executive officer David Radford and executive director Dr Ron Weinberger.

The meeting will also vote on four resolutions relating to the company's employee share option plan, the general share option plan, the deferred employee share plan and the exempt employee share plan.

Nanosonics notice of meeting said the options to be issued to Mr Radford and Dr Weinberger would be over three years, at the board's discretion and at an exercise price equal to the five-day volume weighted average last sale price (VWAP)

The Nanosonics meeting will also vote on the re-election of Mr Radford and Dr Weinberger and the election of director Richard England.

The meeting will be held at the New South Wales Trade & Investment Centre, Level 47, MLC Centre, 19 Martin Place, Sydney, on November 3, 2010 at 4.15pm.

Separately, Nanosonics said it had appointed Robert Waring as its company secretary, effective from October 1, 2010.

Nanosonics said Mr Waring was a former company secretary including at the time of the initial public offer in May 2007.

Nanosonics said Mr Waring was a director of the companies in the Spencer Hamilton Group, which provides secretarial and corporate advisory services to a range of listed and unlisted companies.

PRIMA BIOMED

Prima says it plans to list on the Nasdaq Global Market in the US with one Nasdaq share equivalent to 30 ASX-listed shares.

Prima said it was lodging the requisite form with the US Securities Exchange Commission and expects a response in 60 to 90 days.

The company said the proposed listing would be a Level II American Depository Receipt compliance listing, managed by the Bank of New York Mellon and US broking house National Securities Corporation.

Prima said listing would provide a listed structure that would better meet the needs of the company's Australian and US investors and provide increased liquidity.

Prima was up 0.3 cents or 3.1 percent to 10 cents with 12.2 million shares traded.