Biotech Daily

Monday August 11, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS UP: SUNSHINE UP 27%, PHOSPHAGENICS DOWN 11%**

*** TISSUE THERAPIES TREATS 1ST VITROGRO PATIENT**

*** BIOTA CHALLENGES COMMON COLD IN PHASE IIa TRIAL**

*** ACRUX REQUESTS 'COMMERCIAL ARRANGEMENT' TRADING HALT**

*** VICTORIA GOVT CLAIMS $1bn INNOVATION SPEND AT IDT LAUNCH**

*** BONE RAISES $1m**

*** INCITIVE MEETING BACKS DIRECTORS, OPTIONS, SHARE ISSUE**

MARKET REPORT

The Australian stock market climbed 0.6 percent on Monday August 11, 2008 with the All Ordinaries up 31.7 points to 5,069.3 points.

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

Sunshine Heart was best for the second trading day in a row, up 1.5 cents or 27.27 percent to seven cents on very small volumes, with Living Cell up four cents or 17.39 percent to 27 cents and Novogen up 13 cents or 11.61 percent to $1.25.

Peplin climbed 6.25 percent; Agenix, CSL, Genetic Technologies and Pharmaxis were up more than five percent; Viralytics was up four percent; Alchemia, Heartware and Prana were up more than three percent; Optiscan rose two percent; with Arana, Bionomics, Clinuvel and Cochlear up more than one percent.

Phosphagenics led the falls, down one cent or 11.11 percent to eight cents on modest volumes, followed by Polartechnics down 8.33 percent to 11 cents.

Mesoblast lost 6.83 percent; Antisense fell 4.29 percent; Psivida was down three percent; with Benitec and Ventracor down more than two percent.

TISSUE THERAPIES

Tissue Therapies has begun the first human trial of its Vitrogro wound care treatment saying it "could revolutionize" the venous, pressure and diabetic ulcer market.

Tissue Therapies' chief executive officer Dr Steven Mercer told Biotech Daily the first patient was an elderly woman with venous ulcers.

Dr Mercer said he expected to hear more about the long-awaited Toronto trial this week.

The trial was originally scheduled for December 2007 but has been delayed with ongoing discussions between the company and the Canadian regulatory agency.

Tissue Therapies chairman Roger Clarke the trial was "the culmination of 10 years of research and development and follows successful preclinical and human skin cell trials conducted in the laboratory".

"We believe Vitrogro has the potential to save both lives and limbs and, based on laboratory research to date, to generate a strong global business for Tissue Therapies," Mr Clarke said.

The inventor of the Vitrogro technology Prof Zee Upton said that non-healing diabetic, pressure and venous ulcers alone caused an amputation every 30 seconds across the world.

"Using Vitrogro could potentially help relieve some of these drastic personal, clinical and financial impacts," Prof Upton said.

"Imagine living with an ulcer and up to four layers of dressings or compression hosiery during the height of summer, with pain, reduced mobility and a reliance on carers and the health system, for potentially up to six months or until your limb is amputated?" Dr Upton said.

"Vitrogro has the potential to significantly reduce healing times and improve patients' quality of life through less pain, regaining mobility and reducing the burden on others," she said.

"Our studies show that Vitrogro will assist in the fast and effective treatment of ulcers by boosting the natural proteins in normal skin that encourage the proliferation and migration of healthy cells," Prof Upton said.

Tissue Therapies said the first human trial of the Vitrogro synthetic protein technology was taking place under the direction of the chief clinical investigator and vascular surgeon at Fremantle Hospital in Western Australia Prof Michael Stacey.

Prof Stacey said the application of Vitrogro was very simple.

"If this is successful, the new product could reduce the treatment time for thousands of patients with chronic wounds and would simultaneously cut treatment costs," Prof Stacey said.

Mr Clarke said the expected positive results were likely to lead to the commercialization of Vitrogro within two years for widespread use on ulcers and burns for a potential market of more than 200 million people annually worldwide.

"While Tissue Therapies plans to focus on the application of Vitrogro on the chronic ulcer market, it also intends to continue with its burns application work," Mr Clarke said.

Vitrogro's protein formulation allows the skin to heal itself by substantially accelerating cell growth, cell migration and protein production; the essential elements of tissue repair and wound healing, the company said.

Mr Clarke said the human trial coincided with a capital-raising to fund the large scale manufacturing of the Vitrogro to maximize future sales, provide additional working capital and fund further wound care product development (see Biotech Daily; July 21, 2008).

Tissue Therapies was up 0.3 cents or 3.09 percent to 10 cents.

BIOTA

Biota has begun dosing in the first phase IIa challenge study of BTA798, an orally delivered inhibitor of human rhinovirus.

Biota said human rhinovirus (HRV) was the major cause of the common cold and was associated with clinical complications for patients with asthma, cystic fibrosis, chronic obstructive pulmonary disease or a compromised immune function.

The company said the aim of the phase IIa study was to evaluate BTA798 for the prevention of human rhinovirus infection in 200 healthy volunteers, dosed with either placebo or one of three strengths of BTA798 before being exposed to an experimental rhinovirus infection.

Biota said the double-blind study would be conducted in a controlled quarantine facility in the United Kingdom and would monitor the clinical endpoints of viral count and cold symptom improvement.

Drug safety and pharmacokinetics will also be monitored to provide further data on BTA798.

Biota said the results of this and subsequent phase IIa studies would assist in selecting doses for treatment and prevention of human rhinovirus infection in later clinical studies.

Dosing is expected to be completed by January 2009, subject to adequate enrolment rates with volunteers with full results expected by the end of April 2009.

Biota said challenge studies with antiviral drugs exposed volunteers to both an induced infection and the drug under study.

Challenge studies may examine the efficacy of the drug to either treat the infection (therapy) or prevent the infection (prophylaxis) and the effectiveness of the drug usually is measured by comparison to a placebo.

Therapeutic challenge studies require the infection to be established before drug treatment and prophylactic challenge studies require the commencement of drug treatment before exposure to the induced infection.

Volunteers included in challenge studies must be both healthy and potentially susceptible to the induced infection.

Biota's initial trial is a prophylaxis study with volunteers exposed to human rhinovirus infection by intranasal inoculation.

Biota said rhinoviruses can cause up to 50 percent of all adult colds and were the predominant cold virus in children.

In otherwise healthy individuals, rhinovirus infections were a minor inconvenience, but 75 percent of colds suffered by US children under five years of age were medically attended.

The company said that human rhinovirus was a major cause of hospitalization and respiratory distress in individuals with chronic underlying respiratory conditions, including asthma and chronic obstructive pulmonary disease (COPD) sufferers.

Biota fell half a cent or 0.67 percent to 74 cents.

ACRUX

Acrux has requested a trading halt pending an announcement regarding " a commercial arrangement which is likely to have a material effect" on its share price.

Acrux said the arrangement "had not yet been finalized".

Trading will resume on August 13, 2008 or on an earlier announcement.

Acrux last traded at $1.24.

VICTORIA GOVERNMENT

Victoria's Premier John Brumby says the State Government has committed $1 billion to innovation programs this year, while opening IDT's new pharmaceutical facility in Boronia.

In a media release Mr Brumby said the Government had "injected another $300 million into innovation programs throughout Victoria, bringing the total committed to innovation this year to more than $1 billion".

"By injecting $1 billion into Victoria's innovation program I want to make this state a national leader in the field, providing benefits for the health, sustainability and productivity of all Victorians," Mr Brumby said.

Mr Brumby used the Institute of Drug Technology's $20 million facility opening to launch "the Victorian Government 2008 Innovation Statement - Innovation: Victoria's Future".

The $300 million was described as "new funding" but at least $50 million was announced in June as a matching grant for the Victorian Life Sciences Computation initiative at the University of Melbourne (see Biotech Daily; June 18, 2008).

Biotech Daily asked Innovation Minister Gavin Jennings's media officer for specific details of the spending and was referred to www.business.vic.gov.au/innovationstatement but most of the "fact sheets" did not elaborate further.

The State Government said it would provide $145 million for 'Victoria's Science Agenda', which included an investment fund and the Strategic Projects Fund "to develop research facilities, platform technologies and skills and boost private and public sector research and development investment".

Small and medium-sized enterprizes

The Government said $40 million would go to "the Boosting Highly Innovative SMEs (BHIS) program, the first initiative of its kind in Australia, supporting small to medium enterprises to commercialize new knowledge through targeting Government challenges in areas that require new solutions, especially where there is likely to be flow-on demand locally or internationally".

The relevant "fact sheet" said the BHIS initiative would include two main components.

A $12 million Technology Commercialization Program would support the establishment and development of fast growth, technology SMEs by reducing the time and resources needed to bring technology to global markets.

A $28 million Market Validation Program would develop a Small Business Innovation Research Fund model "utilizing Victorian Government technology demand as a driver for technology SME development and commercialization".

Innovation Minister Gavin Jennings said a $20 million "Biotechnology Bridges" initiative would "lead to major improvements in health outcomes and will impact on some of the biggest challenges facing our health system and quality of life, such as cancer, cardiovascular disease, neurological disease and diabetes".

The "fact sheet" at the Government website said the $20 million for the Biotechnology Bridges would be spent on "streamlining ethical review of multi-site clinical trials by creating a single approval mechanism"; attracting international investment in clinical development to Victoria; and creating a Clinical and Research Data Linkage Unit.

The Government said Biotechnology Bridges would contribute to key areas of the 2007 Biotechnology Strategic Development Plan, which was being implemented through a partnership between government, industry bodies, industry and the research sector.

"It aims to deliver a competitive business environment, access to appropriate research and development infrastructure, a skilled workforce, cross-sector connections and initiatives, including responses to climate change and international collaborative projects," the Government said.

INSTITUTE OF DRUG TECHNOLOGY

The Institute of Drug Technology (IDT) manufacturing facility will produce active pharmaceutical ingredients for anticancer drugs, hormone therapy, and antibiotics.
Mr Brumby said the IDT venue was “very appropriate … because it is the type of enterprise that the Statement is focused on building-up”.
In a media release to the ASX, the Institute of Drug Technology said the “state of the art” containment facility was designed to exclusively manufacture a highly potent antibiotic for supply to Pfizer Inc.
IDT said it signed “a substantial contract” with Pfizer Australia in 2004 to develop and manufacture the drug for use in clinical trials.
The company said the $20 million active pharmaceutical ingredient facility “further strengthens the long term relationship between Pfizer Australia and IDT”.
The Institute of Drug Technology climbed five cents or 2.86 percent to $1.80.

BONE MEDICAL

Bone Medical says it has raised $1.04 million through a private placement with strategic investors at 25 cents a share.
Bone said the funds were for working capital and to support the commercialization of its biopharmaceutical projects.
The company said the total capital raised includes the contribution from Proxima Concepts through a conversion of outstanding obligations of $250,000 and participation by chairman Mr Leif Helth Jensen of $50,000.
Both share allotments will be the subject of a notice of meeting to obtain approval from shareholders.
Bone was untraded at 26 cents.

INCITIVE

Incitive shareholders have overwhelmingly supported the reelection of and issue of options to directors and ratified a placement of 10,600,000 shares,
Dr Tracie Ramsdale and JJ (Kim) Wright were reelected and each will receive 50,000 options.
The issue of 10,600,000 shares to Cygnet Capital at five cents a share was also approved.
All votes were supported by 8,355,116 proxy votes with the election of directors unopposed, but 10,000 proxy votes opposed the granting of options and the share issue.
Incitive was untraded at four cents.