Biotech Daily

Monday October 17, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PHARMAXIS UP 9%; ANTISENSE DOWN 11%**

*** VICTORIA UNVEILS $55m BIOTECH SUPPORT PROGRAM**

*** NHMRC GRANTS $674m FOR 1,140 PROJECTS**

*** PHARMAXIS BRONCHITOL EURO-REVIEW TRADING HALT**

*** CLINUVEL HOPEFUL OF EUROPEAN SCENESSE DOSSIER BY YEAR-END**

*** CALZADA'S NOVOSKIN VIABLE IN PIG TRIAL**

*** QRX FOCUS EXPANDS TO PARTNER DEALS; CORRECTION**

*** PATRYS TO RELEASE IGM SCALE-UP DATA**

*** PROGEN: KOREA APPROVES MEDIGEN PI-88 LIVER CANCER TRIAL**

*** HELICON SIGNS DEAL TO ACQUIRE ASPEN MEDISYS WITH SHARES**

*** ITHREE JOINS MEDICAL RESEARCH COMMERCIALISATION FUND**

*** ITL AGM PROPOSES SHARES IN LIEU OF DIRECTORS' PAY**

MARKET REPORT

The Australian stock market climbed 1.66 percent on Monday October 17, 2011 with the S&P ASX 200 up 69.8 points to 4,275.4 points. Fourteen Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and six were untraded. All Big Caps were up.

Pharmaxis was the best, climbing as much as 20.5 cents or 23.8 percent to $1.065, closing up eight cents or 9.3 percent at 94 cents with 1.8 million shares traded. Alchemia climbed 8.8 percent; Cellmid and Mesoblast were up more than five percent; Circadian and QRX rose four percent or more; Genera, Phosphagenics and Reva were up three percent or more; with Anteo, Bionomics, Biota, Cochlear, Resmed and Starpharma up one percent or more.

Antisense led the falls, down 0.1 cents or 11.1 percent to 0.8 cents with two million shares traded. Viralytics lost 6.1 percent; Benitec and Psivida fell five percent or more; Universal Biosensors fell 4.4 percent; Allied Health, Compumedics and LBT shed more than two percent; with Phylogica down 1.8 percent.

VICTORIA GOVERNMENT

Victoria's Minister for Technology Gordon Rich-Phillips has announced a $55 million plan to support Victorian biotechnology.

The Victoria Government media release said the funding was part of the State Government's 'Technology Plan for the Future' and included the previously announced $15 million health market validation program (BD: Oct 4, 2011).

The media release said that the plan covered two key areas capability development and biotechnology-enabled innovation.

The media release said that capability development would support the development of the necessary talent pool, capitalize on Victoria's world-class research and development base, and pursue international trade and investment opportunities, while the biotechnology-enabled innovation would focus on demand-driven product development, uptake programs, demonstration projects and regulatory reform.

Mr Rich-Phillips said the plan reflected "the Coalition's new approach to supporting technology and its commitment to driving productivity growth".

"The statement sets forth the Coalition Government's direction for Victorian biotechnology and the key role of biotechnology in contributing to a competitive, productive and growing Victorian economy," Mr Rich-Phillips said.

"The biotechnology plan will support the sector in overcoming current and future challenges, while promoting biotechnology-enabled innovation more broadly across Victorian industry and generating opportunities from technology convergence," MR Rich-Phillips said.

"For the first time, the Government will establish a number of dedicated programs that will directly support the biotechnology sector and encourage the uptake of biotechnology," Mr Rich-Phillips said.

The media release said that a key component of the biotechnology plan was the $15 million health market validation program (Health MVP) to encourage innovation in Victoria's healthcare system.

The State Government said that the Health MVP was "a competitive grants program that will leverage the power of government-as-customer to support the development of innovative health technology solutions to identified problems facing Victoria's health sector".

The media release said that the program aimed "to support the growth of innovative small to medium enterprises in order to deliver economic benefits for Victoria such as increased jobs, exports, investment and productivity".

The Government said that a Technology Trade and International Partnering Program would provide grants for Victorian companies to attend overseas biotechnology conferences and trade events.

Mr Rich-Phillips said biotechnology was a vitally important Victorian industry and an area of competitive advantage for the state.

"Biotechnology is one of the most transforming technologies of our time, with the potential to unlock solutions to global issues impacting on Australia today and the challenges of future generations," Mr Rich-Phillips said.

"Our vision for the future is to bring together the transformative power of the major technology platforms - biotechnology, [information and communications technology and small technologies - to unleash greater innovation and wider economic benefits," Mr Rich-Phillips said.

"It is this approach which will not only propel results for our biotechnology sector, but also enable growth, productivity and competitiveness in other industries," Mr Rich-Phillips said.

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

Through the National Health and Medical Research Council, the Federal Government has providing $673.7 million for 1,140 grants.

The Minister for Mental Health and Ageing Mark Butler announced the largest investment in grants for health and medical research in Australian history.

In April, researchers were concerned the Federal Government would cut funding to the NHMRC, but following a campaign led by the Walter and Eliza Hall Institute the May Federal Budget increased funding (BD: Apr 8, May 11, 2011).

The Minister's media release said the investment in research, through the National Health and Medical Research Council, "will ensure that Australia continues to expand the frontiers of health and medical research".

"These grants support our research community to continue to make cutting edge discoveries that improve the diagnosis, treatment and cure of illnesses that touch all Australians," Mr Butler said.

"Health and medical research is an area where Australia shines," Mr Butler said.

"We are renowned internationally for our outstanding contribution to health, including the development of a rotavirus vaccine to protect children against this gastro killer, the first humid cribs for premature babies and more recently, the cervical cancer vaccine," Mr Butler said.

"The grants announced today will ensure that young researchers have a solid foundation for their future career, experienced researchers can continue to run innovative research projects and clinicians can integrate their clinical skills into research practice," Mr Butler said.

"The Gillard Labor Government is committed to supporting Australia's role as the clever country, a prosperous country that contributes to tackling the health challenges of our time, both at home and internationally," Mr Butler said. "That's why the Government continues to fund health and medical research at record levels."

The media release said that Victoria would receive the highest amount of funding, with $278.2 million for 472 grants, while the University of Sydney would receive the greatest amount of funding, with $87.8 million for 149 grants and the Murdoch Children's Research Institute in Victoria, was the independent medical research institute receiving the greatest amount of funding, with $29.2 million for 39 grants.

For more detail on the grants go to: http://www.nhmrc.gov.au.

PHARMAXIS

Pharmaxis has requested a trading halt and has flagged a voluntary suspension relating to its Bronchitol re-examination for European marketing approval.

Pharmaxis said the re-examination by the European Committee for Medicinal Products for Human Use would be held in London from October 17 to 20, 2011.

Pharmaxis said it would be provided "with some incomplete information concerning the outcome of the re-examination during the course of the week, [but did] not expect to receive definitive notification of the outcome of the re-examination until the evening of Friday October 21, 2011 (Australian time) when the CHMP releases notes of the meeting on its website".

Pharmaxis said it requested the trading halt "to manage its continuous disclosure obligations" and intended to request a voluntary suspension of trading in its shares for two days commencing on October 20, 2011.

Pharmaxis climbed as much as 20.5 cents or 23.8 percent to $1.065, closing up eight cents or 9.3 percent at 94 cents with 1.8 million shares traded.

CLINUVEL

Clinuvel chief executive officer Dr Philippe Wolgen says he expects to complete thets European application on Scenesse for erythropoietic protoporphyria by the end of 2011.
In a shareholder update, Dr Wolgen said the company intended to file a marketing authorisation application with the European Medicines Agency “before the end of 2011”.
Dr Wolgen said that the analyses of results of US phase II and European phase III erythropoietic protoporphyria studies were drawing to a close and “while this process has taken our teams longer than anticipated, I wholeheartedly support the desire to ensure certainty and accuracy in the data analyzed and published”.
Dr Wolgen said the data formed part of the pivotal data for the European Medicines Agency marketing authorization application.
“Preparing a European dossier in 2011 has been our primary goal and I am confident we are going to meet this objective, subject to the safety and efficacy results from our latest studies,” Dr Wolgen said. “Drug safety … is the dominant factor during the review.”
“Commercial concerns, speed of approval and public demand, while important corporate concerns, do not play a role in this process, and are of no interest to the EMA’s Committee for Medicinal Products for Human Use,” Dr Wolgen said.
“In developing a first line therapy, a company has a clear and higher obligation of submitting evidence of drug safety,” Dr Wolgen said. “The Clinuvel teams have been vigilant about this aspect since the start of the program in 2006 and we are very focused in our efforts to be prepared accordingly and in a disciplined matter.”
Dr Wolgen said the company was “making significant progress on a number of other fronts” including the recruitment of all sites for the vitiligo pilot program across the US and Europe as an adjunct re-pigmentary agent to an existing therapy.
Clinuvel was up one cent or 0.7 percent to $1.51.

CALZADA

Calzada says that testing Novoskin’s cultured composite skin on pigs has demonstrated the creation of a viable form of skin.
Novoskin is 80 percent owned by Calzada’s Polynovo and 20 percent by the director of the adult burn service at the Royal Adelaide Hospital Prof John Greenwood
Calzada said that cultured composite skin (CCS) was part of Novoskin’s two stage treatment for full thickness burns which was intended to end the need for skin grafts.
The company said that its biodegradable temporizing matrix (BTM) was the first stage with successful results announced in March and the first human clinical trial due to begin later this year at the Royal Adelaide Hospital (BD: Mar 3, Jul 4, 2011).
Calzada said that cultured composite skin was a bi-layer synthetic skin using the patient’s own cells and a Novosorb scaffold.
The company said that Prof Greenwood’s team produced cultured composite skin and implanted it into the pig to create a viable form of skin in a clinically relevant timeframe.
Polynovo chief executive officer Laurent Fossaert said that producing tissues in bioreactors was “a well established process, however problems frequently occur [when] those bioengineered tissues are implanted in vivo”.
“In this preliminary study we showed that CCS is viable after implantation and does not require an external source of nutrition,” Mr Fossaert said.
“This is a very important proof of concept result for our CCS product,” Mr Fossaert said.
“Importantly it also opens the potential to utilise this technology in many other tissue engineering opportunities,” Mr Fossaert said.
Calzada was up 1.1 cents or 19.6 percent to 6.7 cents.

QRX PHARMA

QRX chief executive officer Dr John Holaday says his company has an increasing focus on a partnership to distribute its Moxduo combined opiate pain relief drug.

Speaking to Biotech Daily in Melbourne, on his way to the Ausbiotech conference in Adelaide, Dr Holaday said that along with supervising ongoing trials of the Moxduo combined morphine and oxycodone formulation for US registration and European marketing authority, QRX was in talks with a range of potential distribution companies.

Dr Holaday said there were many different ways of bringing Moxduo to market through generic pharmaceutical companies, specialist pain relief companies, smaller pharmaceutical companies or even pharmacy chains.

Dr Holaday said QRX would be looking for a partnership that included an up-front payment, equity participation in QRX and sales milestones.

He said that along with the ongoing US Food and Drug Administration new drug application for Moxduo immediate release (IR), the company hoped to file a marketing approval application to the European Medicines Authority in 2012, but needed to undertake a 20 to 30 patient paediatric study which was “ready to go”.

Dr Holaday said the company was also preparing for trials of controlled release Moxduo formulations as well as for other routes of delivery.

QRX climbed six cents or 4.5 percent to $1.385.

CORRECTION: QRX PHARMA

The October 14, 2011 edition reported that QRX shareholders would vote to issue 250,000 options to chief executive officer Dr John Holaday exercisable at “the share price on the date of the grant of the options” but did not specify when the options would expire.

The annual general meeting notice was filed after the market closed and the Friday sub-editor failed to read the “seven year” term on the ninth page of a 12-page announcement.

The sub-editor has been disciplined appropriately but painlessly.

PATRYS

Patrys says it has “overcome the challenges of producing IgMs, which are more complex and six times larger than the more commonly produced IgGs”.

Patrys said data from the scale-up and manufacture of its lead immunoglobulin M (IgM) antibody candidate PAT-SM6 would be published in the December 2011 issue of the journal Bioprocess International.

The company said the publication would be the second scientific paper published on outcomes from its IgM antibody manufacturing platform.

Patrys said that confirmation of the scalability of its process was “a significant technical advancement” that broadened the versatility of its antibody manufacturing platform.

The company said that in March 2010 it appointed Laureate Biopharmaceutical Services, to scale-up and manufacture PAT-SM6 for preclinical and clinical purposes and in May 2011, the first batch was manufactured and released for use.

Patrys said the batch was being used in the PAT-SM6 melanoma trial underway at the Royal Adelaide Hospital and the Princess Alexandra Hospital, Brisbane.

Patrys head of manufacturing said the company was “excited at the opportunity to share the data from the scale-up and manufacturing of our lead IgM antibody, PAT-SM6”.

“The successful completion of our first 250 litre run was essential to advancing PAT-SM6,” Mr Connor said.

Patrys was unchanged at six cents.

PROGEN

Progen says the Korea Food and Drug Administration has approved Medigen's investigative new drug)IND) application for PI-88 for liver cancer.
Progen said it was the second IND approval for Medigen, following approval by the Taiwan Food Administration in April (BD: Apr 19, Jun 23, 2011).
Progen said the approval "in the strategically important market of Korea" allowed Medigen to open sites and begin patient enrolment for its phase III study in PI-88.
The company said that the number of hepatocellular carcinoma or liver cancer patients registered in South Korea was the third highest in Asia, behind China and Japan.
Progen said the study was designed to confirm the efficacy and safety of PI-88 in the adjuvant treatment of hepatocellular carcinoma after surgical resection and was a randomized, placebo-controlled, multinational trial, with disease-free survival the primary endpoint for efficacy assessment.
Progen was untraded at 15 cents.

HELICON GROUP

Helicon says it has a formal agreement to acquire Aspen Medisys with its nanoparticle thermotherapy platform for solid tumors and other pathologies (BD: May 4, 2011).
Helicon said that pending shareholder approval and due diligence, consideration would be a nominal upfront payment, followed by performance and time-dependant milestone payments to be made in the form of Helicon shares.
The company said the first milestone payment of $1.41 million in scrip, would be made at Helicon's discretion on or before July 1, 2012.
The transaction remains subject to HCG shareholder approval and satisfactory due diligence, as well as to satisfactory completion of several closing conditions.
Helicon was up 0.2 cents or 10 percent to 2.2 cents.

ITHREE, MEDICAL RESEARCH COMMERCIALISATION FUND

The University of Technology Sydney's Ithree unit, headed by Prof Ian Charles has joined the Medical Research Commercialisation Fund.
An Ithree and Medical Research Commercialisation Fund media release said the fund was a collaboration 31 medical research institutes and hospitals with assistance from the State Governments of Victoria, New South Wales, Queensland and Western Australia and is managed by Brandon Capital in Melbourne (BD: Jun 9, 2011).
The media release said Ithree had an inter-disciplinary approach to the diagnosis, treatment and prevention of infectious diseases in humans and animals.
An Ithree officer told Biotech Daily the name referred to "infection immunity and innovation".
Prof Charles said the MRCF had a unique collaborative structure with each partner committing its specific expertise to the process of identifying and securing funding for the most promising innovations within Australia's life science industry.
"Each member institute provides the fund with a first-right-of-review of all their investment opportunities, while investors in the fund provide a dedicated source of investment capital to develop those that show the greatest potential," Prof Charles said.
The media release said that the MRCF had invested in 12 projects, with the funding leveraged through grant funding and co-investment, leading to a total investment of more than $55 million into the projects, of which the MRCF provided $12 million.

ITL (INNOVATING TECHNOLOGIES FOR LIFE)

ITL shareholders will vote to issue shares to three directors in lieu of part or all of their annual remuneration.

TTL said the annual general meeting resolutions referred to remuneration due to chairman Julian Gosse, chief executive officer William Mobbs and director Sanjay Sehgal.

ITL will ask shareholders to approve an executive share plan and re-elect Mr Mobbs.

The meeting will be held at ITL, Unit 1, 63 Wells Road, Chelsea Heights on November 18, 2011 at 2pm (AEDT).

ITL was untraded at 8.5 cents.