Biotech Daily

Thursday December 5, 2013

Daily news on ASX-listed biotechnology companies

* **ASX, BIOTECH DOWN: OSPREY UP 7%, PHARMAXIS, TISSUE THERA DOWN 4%**

*** CSL MEETS 2012 R&D TARGETS, $531m BUDGET, PROTEIN FOCUS**

*** CSL LICENCES CSL362 FOR AML TO JANSSEN BIOTECH**

*** BIOTRON: 'BIT225 REDUCES RESERVOIR CELL HIV'**

*** VIRAX REVIEWS ASSETS, OPPORTUNITIES**

*** FMR CEASES, FIDELITY HOLDS 5% OF ACRUX**

*** ACUVAX EX-CEO DR WILLIAM ARDREY FRAUD TRIAL RESET**

MARKET REPORT

The Australian stock market fell 1.44 percent on Thursday December 5, 2013 with the S&P ASX 200 down 75.8 points to 5,198.0 points.

Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and four were untraded. All three Big Caps were down.

Osprey was the best, up five cents or 7.1 percent to 75 cents, with 30,000 shares traded, followed by Anteo up 6.1 percent to 17.5 cents with 25.4 million shares traded.

Phosphagenics, Phylogica and Prana climbed more than four percent; Admedus and Starpharma were up more than three percent; Circadian, GI Dynamics and QRX rose more than two percent; with Acrux up by 0.9 percent.

Both Pharmaxis and Tissue Therapies led the falls, down 4.35 percent to 11 cents and 22 cents, respectively, with 458,931 shares and 240,000 shares traded, respectively, followed by Mesoblast down 4.2 percent to $5.90 with 518,485 shares traded.

Bionomics and Patrys lost more than three percent; Alchemia, Cellmid, Medical Developments, Prima, Resmed and Viralytics shed two percent or more; Clinuvel, Cochlear and Genetic Technologies were down more than one percent; with CSL, Nanosonics and Sirtex down by less than one percent.

CSL

CSL chief scientific officer, Dr Andrew Cuthbertson has told the annual research and development briefing that the company achieved most of the targets set in 2012.

“On the whole we did achieve the things we called out … 12 months ago,” Dr Cuthbertson said.

Dr Cuthbertson described the four parts of CSL’s protein therapeutics program as immunoglobulins, haemophilia products, breakthrough medicines and speciality products and said the company expected to increase research and development spending by 13 percent in the 2013-’14 financial year to $US480 million ($A531.3 million).

“We are determined to remain the world leader in plasma fractionation and at the same time [develop] recombinant technologies,” Dr Cuthbertson said.

Dr Cuthbertson said there were synergies between the two platforms and they could each be used depending on the patient’s needs.

Dr Cuthbertson said CSL’s “strong commitment to innovation” was not just in research and development but across the board including plasma collection.

He said the company aimed to balance its portfolio to include necessary high risk and reward projects such as CSL112.

In November, CSL said its phase IIa trial of CSL112 in patients with stable cardiovascular disease had shown a dramatic and rapid increase in the key indicators of reverse cholesterol transport and that rapid removal of cholesterol following a cardiac arrest might be a new mechanism for stabilizing vulnerable plaque lesions and lowering the high risk of subsequent events (BD: Nov 21, 2013).

“We are investing in the portfolio rather than individual programs and the programs are global,” Dr Cuthbertson said.

He said that there had been progress in clinical activities in all areas with recombinant factors VIII moving to phase III trials, factor VIIa completing a phase I trial and the filing for registration of Zemaira in Europe “in the last few days”.

Dr Cuthbertson said that the Iscomatrix vaccine adjuvant for influenza partnered with Novavax had shown positive data in phase I trials for H5N1 and H7N9 but would not proceed as Novavax had decided to use its own saponin-based adjuvant, which it acquired through purchase of Swedish-based company Isconova.

A CSL spokesperson told Biotech Daily that the company remained “optimistic about the long-term prospects of Iscomatrix”.

Dr Cuthbertson said that among new product registrations were Privigen for chronic inflammatory demyelinating polyneuropathy, Hizentra in Japan and broadening of the label fro bi-weekly dosing, which was important for patient flexibility, to other labels, as well as Voncento in Europe, factor XIII in Japan, Kcentra for bleeding in the US and Berinert for short-term prophylaxis in Europe.

CSL research senior vice-president Dr Andrew Nash told the research and development teleconference that 130 of 1000 CSL scientists were involved in protein science research with about two thirds based at the Bio21 facility in Parkville.

Dr Nash said that Bio21 was close to the University of Melbourne, the Walter and Eliza Hall Institute for Medical Research and hospitals.

Dr Nash said that Parkville was “the key medical precinct in Australia” and Bio21 had technical expertise in protein engineering, molecular biology, cell biology, disease models, genomics and bio-informatics.

“CSL is focused on protein based science,” Dr Nash said.

CSL fell 53 cents or 0.8 percent to $67.79 with 1.4 million shares traded.

CSL, JANSSEN BIOTECH

CSL says it has granted Johnson & Johnson subsidiary Janssen Biotech a licence to monoclonal antibody CSL362 for haematological cancers and autoimmune diseases.

CSL said that CSL362 was in a phase I clinical trial for acute myeloid leukaemia patients who achieved remission after chemotherapy and were at high risk of relapse.

The company said that acute myeloid leukaemia was a fast growing cancer of the blood and bone marrow and a significant unmet medical need with no recent advances.

CSL said that it would receive a licence fee and be entitled to development, regulatory and sales based milestone payments, as well as royalties on sales.

CSL said it would be responsible for the completion of the phase I acute myeloid leukaemia trial and Janssen would be responsible for all further development and commercialization in acute myeloid leukaemia and other indications and the two companies would work collaboratively on research programs primarily to support the use of CSL362 in other indications.

CSL said that laboratory studies showed that CSL362 specifically targeted acute myeloid leukaemia cells and recruited and activated killer cells from the body's innate immune system to attack the cancer cells.

The company said it was hoped that the natural killer or NK cells would eliminate residual acute myeloid leukaemia cells, preventing relapse of the disease and the target to which CSL362 was bound on acute myeloid leukaemia cells, CD123, was also expressed on other haematological cancers and on rare blood cell populations thought to mediate autoimmune diseases such as lupus.

CSL said that CSL362 was engineered by its scientists using a unique antibody developed by Adelaide Centre for Cancer Biology's Prof Angel Lopez, which was able to recognize acute myeloid leukaemia preferentially, but was not suitable for use in humans and lacked the ability to recruit and activate the body's natural killer cells.

The company said it engineered the antibody to ensure that it was suitable for humans and enhanced its ability to recruit natural killer cells to kill acute myeloid leukaemia cells.

Janssen Australia and New Zealand managing director Chris Hourigan said that "CSL had "taken the all-important first steps with CSL362".

"We look forward to playing our part in further developing this important therapy and hopefully making it available to patients," Mr Hourigan said.

"The agreement with CSL is another example of Janssen Australia boosting Australia's life science bio-economy as part of its quest to address unmet global healthcare needs," Mr Hourigan said.

Janssen said that during the past two years it had entered into "a dozen early stage research and development agreements with Australian biotechnology companies … institutes and universities, including a research collaboration and worldwide licensing agreement with Dendright, a Queensland-based biotechnology company developing a vaccine against rheumatoid arthritis".

CSL said that the clinical trial was being conducted in Australia and the US with the Australian arm led by Royal Melbourne Hospital haematologist Prof Andrew Roberts.

"Acute myeloid leukaemia is a very aggressive type of cancer and has very poor survival rates," Prof Roberts said.

"Although we can induce remission with chemotherapies there is a high likelihood of relapse, at which point the outcome is often very poor," Prof Roberts said.

"CSL's investigational antibody therapy offers a novel treatment approach because it is designed to recruit the body's immune system to help keep the leukaemia in remission," Prof Roberts said.

BIOTRON

Biotron says BIT225 can reduce virus burden in monocyte reservoirs and “has a potential role in the eradication strategy of HIV-1”.
Biotron said that data analysis showed that BIT225 had the potential to be included in future HIV elimination or cure strategies and could provide a way to halt the ongoing cycle of infection and re-infection with virus from the cells.
The company said that targeting virus reservoirs was the holy grail of HIV research.
Biotron said the study, entitled ‘A Phase IIa Study of the Safety, Pharmacokinetics and Antiviral Activity of BIT225 in Patients with HIV-1 Infection’ was co-authored by chief executive officer Dr Michelle Miller and presented by senior virologist Dr John Wilkinson at the Workshop on HIV Persistence During Therapy, this week in Miami, Florida.
The paper concluded that “treatment with BIT225 reduced the virus burden in monocyte reservoirs, particularly for those individuals with high viral loads [and] by targeting these cells and preventing re-seeding of the myeloid reservoirs, BIT225 has a potential role in the eradication strategy of HIV-1”.
The study said that the randomized, placebo-controlled, parallel, double-blind study of BIT225 in patients with HIV-1 infection who were antiretroviral therapy naïve dosed 14 patients with 400mg BIT225 and seven received placebo.
Biotron said that BIT225 stopped the production of new virus in reservoir cells and reduced the quantity of virus in these cells.
Dr Miller said the results show that BIT225 was “able to clear out underlying virus pools from these reservoir cells”.
“The data support and extend the previously reported encouraging results achieved with BIT225 in HIV infected patients,” Dr Miller said.
“This drug is a novel compound which is the first in a new class of antiviral drugs that may provide a new approach to the treatment of HIV,” Dr Miller said.
Biotron said the trial was performed at Siriraj Hospital in Bangkok, Thailand and was designed to demonstrate that BIT225 was able to target and reduce virus in monocyte lineage cells, which during HIV infection became infected with the virus and were “the seeds of hidden HIV pools in patients, setting up long-lived reservoir cell populations in various sites in the body”.
Biotron said that BIT225 was also in development for hepatitis C virus.
Biotron fell 0.2 cents or 2.35 percent to 8.3 cents.

VIRAX HOLDINGS

Virax says that following its capital raising and reinstatement to the ASX it has engaged an independent expert to prepare a comprehensive report on the company.
Virax said that the expert would examine its intellectual property for the purposes of further developing its existing licencing arrangements and patents to expand on its existing asset base by sourcing synergistic licencing and collaborative opportunities.
The company said it expected the report “early in the new year”.
Virax said it was confident that it could build on the experience with its Co-X-Gene technology and generate further licensing opportunities such as that executed with France’s Transgene for use in two of its immunotherapeutic products TG4001 for human papillomavirus TG4010 for non-small cell lung cancer.
The company said it had been approached by third parties to explore opportunities for collaboration.
Virax fell 0.05 cents or 3.7 percent to 1.3 cents.

ACRUX

Fidelity Investments Singapore says it has increased its substantial holding in Acrux from 8,636,252 shares (5.19%) to 8,936,097 shares (5.37%).
Fidelity said that associated company FMR no longer had a substantial holding in Acrux.
Last year, the Hong Kong branch of the US-based FMR Corp and Fidelity Investments said they became substantial in Acrux with 8,636,252 shares or 5.19 percent of the company, acquiring the shares between May 14 and September 13, 2012 at prices ranging from $US3.19 to $US4.78 (BD: Sep 18, 2012).
The FMR and Fidelity group has previously invested in Cochlear, CSL and Heartware.
Acrux was up two cents or 0.9 percent to $2.35 with 555,503 shares traded.

ACUVAX

Former Acuvax chief executive officer Dr William Ardrey will go to trial on 19 counts of fraud, at the Perth District Court on July 21, 2013.
An officer of the Perth District Court told Biotech Daily that the trial had been set to run from July 21 to August 15, 2014.
Earlier this year a trial date was set for November 18, 2013 but procedural hearings have led to the delay (BD: Feb 28, Apr 20, Jul 20, Nov 30, 2012; Feb 25, Aug 7, 2013).
Last year, Western Australia Police told Biotech Daily that Dr Ardrey had been granted bail with undisclosed conditions.
Western Australia Police said the complainant in the matter was Phoenix Eagle a company described as a small biotechnology company involved in therapeutic cosmetics.
Acuvax was untraded at 0.1 cents.