Biotech Daily

Wednesday October 15, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PATRYS UP 5%, BIOTRON DOWN 17%**

*** FEDERAL ACTION PLAN: TGA TO ACCEPT 'TRUSTED' REGULATION**

*** COMMENT: COCHLEAR, MEDICINES AUSTRALIA, BIOTECH DAILY**
- AUSBIOTECH WELCOMES TAX, REGULATORY CHANGES

*** BIOTRON 2-FOR-9 RIGHTS ISSUE FOR $4m**

*** IMMURON READY FOR TWO PHASE II IMM-124E FATTY LIVER TRIALS**

*** CSL 11% OPPOSE CEO PAUL PERREAULT $3m 'PERFORMANCE' STOCK**

*** AUSPHERIX, DOMAINEX WORK ON ANTIBIOTIC-RESISTANT INFECTIONS**

*** ANTISENSE RECEIVES $1.14m FEDERAL R&D TAX REFUND**

*** VIRAX REQUESTS 'MATERIAL TRANSACTION' TRADING HALT**

*** HUNTER HALL TAKES 8% OF GI DYNAMICS**

*** UBS AG 'RETURNS' 2.6m ACRUX SHARES TO 8%**

MARKET REPORT

The Australian stock market climbed 0.73 percent on Wednesday October 15, 2014 with the S&P ASX 200 up 38.2 points to 5,245.6 points. Six of the Biotech Daily Top 40 stocks were up, 21 fell, eight traded unchanged and five were untraded.

Patrys was the best, up 0.1 cents or 5.3 percent to two cents with 205,000 shares traded. Antisense climbed five percent; Benitec was up 4.6 percent; Anteo, Atcor and Cochlear were up more than three percent; with CSL and Sirtex up more than one percent.

Biotron led the falls, down 2.5 cents or 16.7 percent to 12.5 cents with 16.9 million shares traded, followed by Genetic Technologies down 11.1 percent to a new low of 1.6 cents with 2.4 million shares traded.

Prana lost 8.7 percent; Optiscan fell 6.1 percent; Osprey fell 5.2 percent; Admedus, Analytica and Phosphagenics were down more than three percent; Impedimed, Prima and Starpharma shed more than two percent; Acrux, Bionomics, Clinuvel, Mesoblast, Nanosonics, Neuren, Pharmaxis, Resmed, Tissue Therapies and Viralytics were down more than one percent; with Alchemia down 0.8 percent.

FEDERAL GOVERNMENT

The Federal Government says Australia will not regulate a system, service or product approved by a trusted international standard without good reason.

In yesterday's launch of the 'Industry Innovation and Competitiveness Agenda - An action plan for a stronger Australia', the Federal Government said it would "adopt the principle that if a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements unless it can be demonstrated that there is good reason to do so".

"All Commonwealth Government regulatory standards and risk assessment processes will be reviewed against this principle," the Innovation and Competitiveness Agenda said.

"As a first step, the Government will enable Australian manufacturers of medical devices to register routine medical devices using conformity assessment certification from European notified bodies," the Agenda said.

"The regulation of industrial chemicals is another early priority for reform," the Agenda said.

The Department of Prime Minister and Cabinet said the Government was "removing regulation that duplicates trusted overseas processes, except in cases where unique Australian regulations can be justified".

The Government said that adoption of the principle that approval under a trusted international standard, would be sufficient unless there was a demonstrable reason not to would "reduce costs and delays for businesses, increase the supply of products into the Australian market and allow regulatory authorities to focus on higher priorities".

"As a first step, the Therapeutic Goods Administration will enable Australian manufacturers to register routine medical devices using conformity assessment certification from European notified bodies," the Government said. "Similarly, the National Industrial Chemicals Notification and Assessment Scheme will better utilise and increase its acceptance of international risk assessment materials from trusted overseas regulators."

"To ensure a thorough review of all regulations, ministers will be asked to write to regulators in their portfolio and key business and other stakeholders seeking their views on each of their standards and risk assessment processes against this principle," the Federal Government said.

"Separately, stakeholders can submit examples of unnecessary divergence from international standards at www.cuttingredtape.gov.au," the Government said.

The Federal Government said that Australia's chemicals regulatory arrangements were complex, involving about 140 pieces of legislation, multiple agencies and numerous regulatory decision makers at all government levels.

The Government said it intended to remove regulatory barriers to the introduction of lower-risk industrial chemicals already approved overseas, while allowing resources to be devoted to assessing higher risk industrial chemicals.

Yesterday, the Federal Government said the Agenda included $188.5 million for five Industry Growth Centres, one of which would be for medical technologies and pharmaceuticals, to assist businesses link with medical device and materials researchers to develop new biomedical devices and platform technologies (BD: Oct 14, 2014).

The Federal Government said it would invest $12 million to improve the focus on science, technology, engineering and mathematics subjects in primary and secondary schools; change the taxation treatment of employee share schemes to encourage start-ups to attract and retain employees; reverse changes made in 2009 to taxing options; and reform the 457 visa program for skilled migrants.

COCHLEAR

Cochlear chief executive officer Dr Chris Roberts told Biotech Daily that he welcomed Prime Minister Tony Abbott's Industry Innovation and Competitiveness Agenda.

"The Government's Action agenda contains some important changes to how medical systems will be regulated in Australia," Dr Roberts said.

"It adopts the principle that if a system or product is approved under a trusted international standard or risk assessment, then Australian regulators will also approve it unless there is a good reason not to do so," Dr Roberts said.

"This is a huge win for an export company like Cochlear that sells devices into dozens of countries around the world that require country of origin approval," Dr Roberts said.

In a Cochlear media release, Dr Roberts said that the Industry Innovation and Competitiveness Agenda would enhance his company's international competitiveness, cut red tape and improve export opportunities.

"The Agenda shows the Australian Government appreciates that business is critical to strong economic growth," Dr Roberts said.

"The government understands the benefits of linking science with industry, and delivering a highly-skilled workforce, Dr Roberts said.

"Changes to employee share schemes and 457 visa rules are also important in encouraging a smart Australia," Dr Roberts said.

"Today's Agenda will help grow our export capacity and streamline market access," Dr Roberts said.

"It means Cochlear is better placed to export its products, create jobs and improve health outcomes," Dr Roberts said.

Cochlear was up $2.17 or 3.1 percent to $71.29 with 450,796 shares traded.

MEDICINES AUSTRALIA

Medicines Australia chairman Dr Martin Cross also welcomed the Industry Innovation and Competitiveness Agenda and the announcement of five industry growth centres.

"Australia is uniquely placed to harness our competitive advantages, particularly in the medical technologies, pharmaceuticals and advanced manufacturing sectors," Dr Cross said.

"I am particularly encouraged by the Government's commitment to support growth in Australia's medical technologies, pharmaceuticals and advanced manufacturing sectors, when the global market for medicines and vaccines is projected to double over the next 10 years," Dr Cross said.

"We are not only conveniently located but we also have a world-class medical research infrastructure and a well-established reputation in the region for manufacturing safe, high-quality medicines and vaccines," Dr Cross said.

"With the right policies in place, like those announced by the Government today, Australia could double its exports of medicines and vaccines products by 2024," Dr Cross said.

"We could also double the level of investment Australia attracts in pharmaceutical [research and development] and clinical trials," Dr Cross said.

"Government policies are amongst the strongest influencers of global company and local investment decisions," Dr Cross said.

"We need a stable and business-friendly policy environment in Australia to encourage high-tech industries like the global pharmaceuticals sector to directly invest here for the long term," Dr Cross said.

"Industry is looking forward to working with the Government to contribute tangibly to these centres," Dr Cross said.

BIOTECH DAILY

Biotech Daily has long been a critic of the Australian Therapeutic Goods Administration and understands industry enthusiasm to subvert what has been often described as bizarre and chaotic decision-making, as well as its role in obfuscating real regulation.

While some might be glad to see no Australian regulation, Biotech Daily would rather an Australian regulator combining the clarity of the US Food and Drug Administration and the generally easier approval of the European Medicines Authority, both of which have their own problems.

In broad terms, we support the principle that if a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements, unless it can be demonstrated that there is good reason to do so.

The rapid approval of the CSL influenza vaccine that caused a spate of paediatric febrile convulsions while not approving Acrux's transdermal eostrogen already approved by the FDA and on sale in the US for four years are the two examples that leap to mind when considering the TGA and regulation, along with permitting generally untested non-efficacious, but as-safe-as-water, over-the-counter potions to take up valuable shelf space at pharmacies.

That said, the fact that a drug, device or diagnostic might be approved in Europe or the US and putting the onus of proof on the consumer or a competitor, that the product might not be suitable for Australia, is a concern.

Another concern is the call for "a thorough review of all regulations" with Ministers to write to regulators and stakeholders "seeking their views on each of their standards and risk assessment processes against this principle" and asking any interested party to submit examples of unnecessary divergence from international standards to a "cutting red tape" website. This process could be an extraordinarily long bureaucratic process to allegedly cut red tape. The UK Government under Margaret Thatcher spent some GBP500 million to find GBP15 million of civil service 'wastage'.

Biotech Daily is not certain how the $188.5 million for five Growth Centres, one of which would be for medical technologies and pharmaceuticals, compares to last year's Labor election promise of $47.5 million for 19 Centres for Research Excellence or the other promises to implement $70 million of investments and reforms as its initial response to the McKeon Review, $4.2 million seed funding for four Integrated Health Research Networks, $5.8 million in Partnership Project grants and two NHMRC John Cade fellowships in mental health research (BD: Aug 20, 2013).

More importantly Biotech Daily believes our industry would be best served by rapid progress on the proposed $20 billion Medical Research Future Fund, de-coupling it from the controversial $7 Medicare co-payment and providing a significant commercialization component to enable the Australian development of any research discoveries.

David Langsam
Editor

AUSBIOTECH

Ausbiotech says it welcomes the restoration of the tax treatment of employee share schemes use of European certification for routine medical devices.

Ausbiotech chief executive officer Dr Anna Lavelle said her organization had advocated the changes announced in the Federal Government's Industry Innovation and Competitiveness Agenda "for many years".

"We are reassured to see the Government is listening to industry's views about how to give Australian technology start-ups a fair go and for home-grown technology to be more internationally competitive," Dr Lavelle said.

"The reversal of the [employee share scheme], altered in 2009, and the ability for Australian companies to rely on regulatory processes undertaken by European notified bodies are big wins for common sense," Dr Lavelle said.

"Australian companies have for many years been frustrated by an inability to incentivize innovation employees with shares and options, and separately by a need to repeat expensive regulatory processes that do not increase safety but instead results in delays and unnecessary cost," Dr Lavelle said.

Ausbiotech said that biotechnology was at the core of our country's promising sectors with three of eight relevant, medical technologies and pharmaceuticals, food and agribusiness, and advanced manufacturing, and recognized as growth sectors with competitive strength.

Ausbiotech said it "looks forward to further details on the plan to establish five Industry Growth Centres, three of which relate to biotechnology".

The industry organization said it welcomed the focus on the Government's $9.2 billion annual investment in research to get a better commercial return, in particular, strengthening intellectual property and improving tax and research funding arrangements to deliver incentives for the translation of research and for collaboration with industry, and the establishment of the Commonwealth Science Council.

Ausbiotech said it was hopeful that these steps are followed by further actions to support innovation, entrepreneurship and translation of research and looks forward to the Tax White Paper, which it is hoped will include a tax incentive for Australian innovation and manufacturing to be internationally competitive.

BIOTRON

Biotron says it expects to raise $4,058,612 through a fully-underwritten, renounceable two-for-nine rights issue at eight cents a share.

Biotron said that each new share would come with an attaching listed option exercisable at 12 cents by September 30, 2016.

The company said that the eight cent offer price was a 51 percent discount to the one month volume weighted average price of 16.4 cents.

Biotron said the funds would be used to complete the phase II trial of BIT225 for hepatitis C genotypes 1 and 3; for studies to complete applications to the US Food and Drug Administration; drug to drug interaction studies with direct-acting anti-virals to be used with BIT225; modelling pharmacokinetic data from previous trials to determine optimal dose and frequency; in-vitro studies of BIT225 antiviral activity; for commercialization fees and costs; and for working capital.

The company said that there had been "strong demand received from the institutional and sophisticated investors ... [and] the book-build closed significantly oversubscribed".

Biotron said the record date for the rights issue fully-underwritten by Patersons Securities was October 21, the offer would open on October 22 and close on October 31, 2014.

Biotron fell 2.5 cents or 16.7 percent to 12.5 cents with 16.9 million shares traded.

IMMURON

Immuron says it expects to begin two phase II trials of IMM-124E for non-alcoholic steatohepatitis and alcoholic steatohepatitis by the end of this year.

Immuron said that both trials were placebo-controlled, double-blinded, dose-ranging, multicentre studies investigating its bovine colostrum formulation enriched with anti-lipo-poly-saccharide antibodies.

The company said that the six-month 120-patient non-alcoholic steatohepatitis trial had been cleared by the US Food and Drug Administration and it was finalizing preparations.

Immuron said it had engaged data management and clinical monitors and hospital ethics submissions were underway with the first approval expected this month.

Immuron said that specialist diagnostic service providers had been engaged and it expected to complete production and packaging of a trial IMM-124E tablet formulation for this month.

Immuron said that there were more than 25 million non-alcoholic steatohepatitis patients in the US alone and there was no approved treatment.

The company said that following commencement of the trial, it would apply for fast track designation of IMM-124E for non-alcoholic steatohepatitis.

Immuron said that the 66-patient phase II alcoholic steatohepatitis trila was funded by the US National Institutes of Health and IMM-124E was “one of only three candidates selected by the NIH for study in patients with [alcoholic steatohepatitis] from 27 drug candidates”.

The company said that the three trial sites were the Virginia Commonwealth University, Indiana University and the Mayo Clinic and each was sponsoring and managing the trial.

Immuron said that the patients would be randomized to cohorts of 22 patients receiving 2,400mg IMM-124E daily, 22 patients receiving 4,800mg IMM-124E daily and 22 patients receiving the placebo.

The company said that the treatment of alcoholic steatohepatitis patients with IMM-124E was based on the same mechanism of action underlying the non-alcoholic steatohepatitis trial, so the alcoholic steatohepatitis trial was expected to add to its body of knowledge relating to its IMM-124E and the treatment of chronic inflammation-driven liver diseases.

Immuron said it had completed production of the trial product for alcoholic steatohepatitis, which was separate from the production of the non-alcoholic steatohepatitis clinical trial product and was awaiting a US import permit, expected later this month and once received, the trial would be able to begin.

Immuron was up 0.1 cents or 14.3 percent to 0.8 cents with 3.3 million shares traded.

CSL

All resolutions at the CSL annual general meeting were passed, but with up to 10.7 percent opposition to the grant of stock to chief executive officer Paul Perreault.

The strongest opposition was to the grant of ‘performance’ options and free rights worth up to $US2,932,500 ($A3,358,560) with 27,625,904 votes against (10.7%) and 230,837,788 votes (89.3%) in favor (BD: Sep 12, 2014).

The remuneration report was opposed by 8.3 million votes with 251.4 million votes in favor the 20 percent increase in the directors’ remuneration pool was opposed by 3.3 million votes with 259.2 million in favor and all other resolutions were passed by wider margins.

CSL’s most recent Appendix 3B said the company had 474,503,048 shares on issue meaning that the largest opposition vote, to Mr Perreault’s options and rights, amounted to 5.8 percent of the company’s total shares on issue, sufficient to requisition extraordinary general meetings.

CSL was up $1.00 or 1.4 percent to $73.50 with 1.4 million shares traded.

AUSPHERIX

The Sydney-based Auspherix says it will collaborate with Cambridge UK-based Domainex on an anti-infective drug discovery program for antibiotic-resistant bacterial infections.
Auspherix said it had in-licenced intellectual property from the University of Technology Sydney's Ithree Institute to develop antibiotics with novel mechanisms of action to treat resistant bacterial disease.
The company said it was established in 2013 as a spin-out from the Ithree institute by its director Prof Ian Charles and senior research fellow Dr Dagmar Alber with funding from Australia's Medical Research Commercialisation Fund (BD: Oct 17, 2011).
Prof Charles said that Domainex was selected as its medicinal chemistry partner "as its scientists are highly-experienced in the development of novel anti-infectives" and the company expected to nominate a clinical candidate "in due course".
Auspherix said that the small-molecule drug leads it identified were being refined with Domainex to deliver effective drug candidates suitable for progression to the clinic.
The company said that in the US, at least two million people a year become infected with bacteria that are resistant to antibiotics and more than 23,000 people die each year as a direct result of these infections.
Auspherix is a private company

ANTISENSE

Antisense says it has received $1.14 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Antisense said the rebate related to research and development expenditure for the year to June 30, 2014.
The company said that the funds meant it would no longer need to draw on its Macquarie Bank facility which would be terminated.
Antisense said it had about $1.09 million in cash.
Antisense was up half a cent or five percent to 10.5 cents.

VIRAX HOLDINGS

Virax has requested a trading halt "pending the release of an announcement in relation to a material transaction".
Trading will resume on October 17, 2014 or on an earlier announcement.
Virax last traded at 0.5 cents.

GI DYNAMICS

Hunter Hall Investment Management has increased its substantial shareholding in GI Dynamics from 30,142,098 shares (6.36%) to 39,882,925 shares (8.42%).
The Sydney-based Hunter Hall said it acquired the shares in 18 trades between August 6 and October 10, 2014, with 8,361,150 shares acquired on October 10 for $2,766,077 or 33.1 cents a share.
GI Dynamics share price fell 19.6 percent last week following a halt to its shipments of its Endobarrier gastric liner for obesity and type 2 diabetes (BD: Oct 7, 2014).
GI Dynamics was unchanged at 31 cents.

ACRUX

The Singapore-based UBS AG and related bodies corporate have reduced their holding in Acrux from 15,938,982 shares (9.57%) to 13,768,982 shares (8.27%).

On Monday, UBS AG increased the substantial shareholding in Acrux from 13,633,853 shares (8.19%) to 15,938,982 shares (9.57%) (BD: Oct 13, 2014).

Today, UBS AG said its London Branch "borrowed" 430,000 Acrux shares for no consideration on October 9 and UBS Securities Australia "returned" 2,600,000 shares on October 10, 2014, also for no consideration.

UBS AG has previously said that the shares were held for Warbont Nominees and various custodians and were held with the "power to control disposal over shares pursuant to stock borrowing and lending activities" (BD: Dec 19, 2012; Nov 21, 2013).

Acrux has been reported as one of the most heavily 'short-sold' stocks in the Australian biotechnology sector.

Acrux fell 1.5 cents or 1.1 percent to $1.40.