Biotech Daily

Friday May 2, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PATRYS UP 12%, ANALYTICA DOWN 6%**

*** FEDERAL AUDIT COMMISSION HITS CRCs, IIF, R&D TAX INCENTIVE - BIOTECH DAILY COMMENT**

*** SHIRE BUYS MRCF-BACKED FIBROTECH FOR $81m, MILESTONES**

*** GI DYNAMICS EXPECTS PLACEMENT TO RAISE $34m**

*** CLARITY RAISES $1.1m FOR PERSONALIZED MEDICINE IMAGING**

*** NOVOGEN, GENEA WORK ON STEM CELLS FOR DEGENERATION**

*** ALLAN GRAY TAKES 18.55% OF ACRUX**

*** HUNTER HALL TAKES 7% OF ALCHEMIA**

*** HEARTWARE WARNS ON BATTERY LIFE; Q1 REVENUE UP 35% TO $72m**

*** QRX COO DR EDWARD RUDNIC REPLACES CEO DR JOHN HOLADAY**

MARKET REPORT

The Australian stock market rose 0.17 percent on Friday May 2, 2014 with the S&P ASX 200 up 9.3 points to 5,458.1 points. Twelve of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and four were untraded.

Patrys was the best, up 0.4 cents or 11.8 percent to 3.8 cents with 3.3 million shares traded.

Living Cell climbed 8.3 percent; Benitec and Biotron rose more than five percent; Atcor was up 4.35 percent; Medical Developments and Prima were up more than two percent; IDT, Neuren and Tissue Therapies were up more than one percent; with Cochlear, CSL, GI Dynamics and Mesoblast up by less than one percent.

Analytica led the falls, down 0.2 cents or 6.45 percent to 2.9 cents with 2.8 million shares traded.

Pharmaxis and Starpharma lost five percent or more; Acrux and Oncosil fell more than four percent; Antisense was down 3.6 percent; Anteo and Prana shed more than two percent; Alchemia, Bionomics, Nanosonics, Sirtex and Universal Biosensors were down more than one percent; with Resmed down 0.6 percent.

FEDERAL GOVERNMENT

The Commission of Audit says the R&D Tax Credit "skews" investment and recommends abolition of the Innovation Investment Fund and Cooperative Research Centres.

The National Commission of Audit recommendations on research and development are at: http://www.ncoa.gov.au/report/phase-one/part-b/8-2-research-and-development.html

"Aligning the Australian Research Council and National Health and Medical Research Centre grant processes, but keeping the entities separate, would reduce administrative costs to the Commonwealth and should also decrease the cost to researchers of applying for grants," the Commission recommended.

"A significant amount of firm and sector-specific research is supported by measures such as the Research and Development tax concession," the Commission said. "Specific grant programs in addition to this support have the potential to skew investment decisions".

"Cooperative Research Centres should be abolished, with funding rolled into the Australian Research Council Linkages program," the Commission said.

"As part of this transition, consideration should be given to allowing longer funding periods for Australian Research Council grants," the Commission said.

The Commission recommended the Collaborative Research Network program be abolished.

"Given that the evidence base shows that industry clusters created deliberately by Government rarely become independent of Government funding, Government should pull back from this area, abolishing the current Industry Innovation Precincts program, including the associated Industry Collaboration Fund," the Commission said.

"The Commission considers that sector-specific grants, such as those through the Australian Renewable Energy Agency, National Low Emissions Coal initiative, Carbon Capture and Storage Flagships and the Innovation Investment Fund should be abolished," the Commission said.

"A reduction in duplication of administrative support and processes could be achieved by better aligning research programs to the Government's policy priorities, targeting those areas with high spillovers and consolidating ... other programs," the Commission said.

Last year, Federal Liberal MP Kelly O'Dwyer said that if the Coalition won the election, research and development funding would be protected at current levels (BD: Mar 5, 2013)

Ms O'Dwyer told Biotech Daily at that time that the commitment was for all funding including National Health and Medical Research Council grants, Australian Research Council grants and Linkage programs, Innovation Investment Funds and Commercialisation Australia.

Ms O'Dwyer referred to a statement by Opposition Leader Tony Abbott and Opposition Health spokesman Peter Dutton that was released on January 31, 2013.

"While Budget conditions are tough and the Coalition is committed to returning the Budget to surplus, we also recognize that funding of medical research needs to be consistent and ongoing to ensure Australia does not hollow out its capabilities," Mr Abbott said. "Our commitment to protecting the funding of medical research is in contrast to Labor's previous attempt to cut medical research funding and its current cuts to health funding."

Today, a spokesman for Ms O'Dwyer told Biotech Daily that "the Commission of Audit was a report to the Government not a report by the Government. Full Government policy will be released in the Budget".

Biotech Daily Comment

The recommendations do not call for savage cuts to research and development, but it is clear that the ideologically-motivated authors do not understand the importance of retaining the R&D Tax Credit or expanding, rather than abolishing, the IIF program.

FIBROTECH

The Melbourne-based Fibrotech says Shire Plc will pay $US75 million ($A80.9 million) as an upfront fee to acquire the company, primarily for its FT011 oral anti-fibrotic drug.

Supported by the Medical Research Commercialisation Fund, Fibrotech said that Shire would also make payments for development and regulatory milestones and undertake the further development of FT011, which had completed a phase Ia study in healthy volunteers and was currently in a phase Ib study in patients with diabetic nephropathy (BD: Mar 4,2014).

Fibrotech said that subject to successful completion of the trial, the first phase II study was expected to enroll focal segmental glomerulosclerosis patients next year.

The company said that focal segmental glomerulosclerosis was a rare disease that affected the kidney's filtering system causing serious fibrosis, or scarring.

Fibrotech said that 85 percent of cases were idiopathic and most of the patients progressed to end-stage renal disease.

The company said that in addition to the lead compound FT011, Shire would acquire its library of novel molecules including FT061, which was in pre-clinical development and had a similar mode of action to FT011.

Fibrotech said that FT061 was an oral small molecule with the potential to address both the inflammatory and pro-fibrotic components of fibrosis.

The company said the acquisition was subject to customary conditions, including approval of Australia's Foreign Investment Review Board.

Shires head of research and development Dr Phil Vickers said the acquisition was "a strategic step in expanding Shire's pipeline with a novel, clinical stage anti-fibrotic agent that strengthens our growing and innovative portfolio targeting renal and fibrotic diseases".

"There have been significant advances in the scientific understanding of fibrosis and the use of biomarkers to support clinical development, which makes now a good time to invest in these promising assets targeting a novel mechanism of action," Dr Vickers said

Brandon Capital founding partner and Medical Research Commercialisation Fund principal executive Dr Chris Nave said that Fibrotech was the Fund's first investment, "so this deal represents a significant validation of our approach to commercialize the very best discoveries from Australia's leading medical research institutes".

"To get such an impressive return on our investment speaks to the quality of the science at the University of Melbourne, St Vincent's Institute of Medical Research and Bio21 Institute," Dr Nave said.

Fibrotech said that it had been supported by Uniseed, a venture fund operating at the University of Melbourne, the University of Queensland and the University of New South Wales with capital provided by Australian Super.

Uniseed chief executive officer Dr Peter Devine said the deal was "an endorsement of the Uniseed concept to facilitate commericalization of university intellectual property".

"Having supported Fibrotech since its inception, Uniseed is proud to be associated with such a significant partnership," Dr Devine said.

Fibrotech chief executive officer Prof Darren Kelly said his team were "very excited about this acquisition as Shire are strategically aligned with our commitment to renal and fibrotic conditions, including rare diseases, areas of high unmet medical need".

"This acquisition will have significant benefit to the Australian biotechnology sector and highlights the importance of commercialization and collaboration between academia and industry," Prof Kelly said.

Fibrotech is a private company, funded by the Medical Research Commercialization Fund which is managed by Brandon Capital.

GI DYNAMICS

GI Dynamics says it has commitments for a private placement to raise about $34.3 million through the issue of about 66 million CHESS Depositary Interests at 52 cents each.
GI Dynamics said the placement to sophisticated, professional and accredited investors in Australia, Hong Kong and the UK would be used to fund its US pivotal trial, expand commercialization efforts for its Endobarrier obesity and type 2 diabetes therapy and for general working capital purposes.
The company said that Bell Potter Securities was the sole lead manager to the placement.
GI Dynamics was up 0.5 cents or one percent to 52.5 cents with 1.7 million shares traded.

CLARITY PHARMACEUTICALS

The Sydney-based Clarity Pharmaceuticals says it has raised $1.1 million to expand its personalized medicine imaging operations in the US, Europe and Asia.
Clarity executive chairman and member of Sydney Angels investment group Dr Alan Taylor said Sydney Angels led the financing round.
“We initially sought $1 million, but expanded the round by over $100,000 to accommodate the demand from additional investors,” Dr Taylor said.
“The success of this round proves there is an appetite in Australia from smart money looking to back new and innovative Australian startups such as Clarity Pharmaceuticals,” said Dr Taylor.
Dr Taylor told Biotech Daily that the company intended to in-licence late-stage, phase II and phase III antibodies and peptides that had demonstrated partial success, but could benefit from Clarity’s imaging technology.
He said that if a drug had efficacy in 20 percent of the patient population and Clarity could identify that it could target that specific group, the drug would have a much greater chance of being approved by regulators.
”We attach a metal-binding chelator cage to an antibody being developed for an indication, typically cancer, and track where it goes to determine whether it binds to the cancer and show the mechanism of action, allowing us to determine the responding patient population and create better targeted therapies,” Dr Taylor said.
A Clarity media release said the company was founded in 2010 by managing director Dr Matt Harris to commercialize medical diagnostic and imaging technology developed by the Australian Nuclear Science and Technology Organisation and the University of Melbourne.
The company said that pharmaceutical companies used its medical imaging and diagnostic tools as part of their development and testing process for new medicines.
Dr Harris said the company’s imaging technology could be used in developing personalized medicines “a burgeoning area that is dramatically improving treatment outcomes for a range of serious diseases”.
“Our pharmaceutical tagging and tracking technology has the potential to play a major role in personalizing treatment for diseases such as cancer and inflammatory diseases,” Dr Harris said.
Dr Harris said the $1.1 million would be used to advance the personalized medicine business and ramp-up existing services and products, and Clarity had raised a total of $3.5 million, which included investor support and grants from Commercialisation Australia.
“When it comes to investment in medical academia, Australia has an extremely strong record, but we have not yet built the eco-system to commercialise a lot of this research,” Dr Taylor said.
Clarity is a private company.

NOVOGEN

Novogen says it will collaborate with Genea Biocells to accelerate testing of their super-benzopyran drugs for degenerative diseases of the nervous system and muscles.
Novogen said that preliminary research with the Sydney-based Genea found that super-benzopyrans appeared to be effective at promoting the normalization of stem cells associated with some forms of neuro-degeneration and muscular dystrophy, genetic disorders which resulted in progressive deterioration of brain function or muscle strength and function.
The company said that the collaboration would pool resources, with each company retaining its own intellectual property rights and commercial opportunities.
Novogen chief executive officer Dr Graham Kelly said that super-benzopyrans had been shown “to be highly effective at killing cancer stem cells, which were previously considered resistant to anti-cancer therapy ... but in some of our studies, we found in some instances that some of these drugs actually appeared to normalize both the behavior and appearance of the cancer cells”.
“It was that observation that set us on the path to testing their ability to do the same thing with stem cells carrying genetic disorders,” Dr Kelly said.
Novogen said that Genea focused on embryonic stem cells with genetic disorders, with the cells sourced from embryos donated by couples undergoing in-vitro fertilization and pre-implantation genetic diagnosis.
The company said that pre-implantation genetic diagnosis enabled testing of embryos to make sure resultant babies were not affected by a genetic disease.
Novogen said that Genea was using those stem cell lines to test compounds to identify potential clinical development candidates.
Genea general manger Dr Uli Schmidt said that super-benzopyrans were the first drug class “we have seen with the ability to selectively modulate misbehaving stem cells”.
“Effected embryos identified during the [pre-implantation genetic diagnosis] process cannot be used for implantation but can instead be donated by patients to develop stem cell lines carrying the genetic disease,” Dr Schmidt said.
“These disease-specific cell lines can now be used to test the effectiveness of exciting new compounds that are thought to counteract the disease,” Dr Schmidt said.
Novogen was up half a cent or three percent to 17 cents.

ACRUX

Allan Gray Australia has increased its substantial holding in Acrux from 28,042,103 shares (16.84%) to 30,894,080 shares (18.55%).
Allan Gray said that between April 17 and 30, 2014 it bought 2,851,977 shares for $3,662,055 or an average price of $1.28 a share.
Acrux fell 4.5 cents or 4.4 percent to 98.5 cents with 6.9 million shares traded.

ALCHEMIA

Hunter Hall Investment Management has become substantial in Alchemia, acquiring 22,326,686 shares or 6.9 percent of the company.
Hunter Hall said it acquired the shares between October 7, 2013 and April 18, 2014, with the two largest purchases on October 10, 2013 of 2,455,350 shares for $1,600,885 or an average price of 65.2 cents and April 28, 2014 of 2,157,280 shares for $1,186,474 or an average price of 55 cents.
Alchemia fell one cent or 1.9 percent to 50.5 cents.

HEARTWARE INTERNATIONAL

Heartware says it has issued a voluntary urgent medical device correction related to all Heartware Ventricular Assist System batteries, product codes 1650 and 1650-DE.
Heartware said that it had observed an increase in complaints related to earlier-than-expected battery depletion and routine battery handling.
The company said that premature or unrecognized deterioration of battery capacity or lapses in recommended power management posed a risk to the patient and, although rare, might result in serious injury or death.
Heartware said that similar to the battery in a mobile cell telephone, Heartware batteries would begin to lose charge over time and if a fully-charged battery lasted less than two hours or if the controller switched back-and-forth between batteries, patients were asked to take the affected battery out of service and replace it with a new one.
The company said that no deaths had been reported to Heartware that were directly related to a faulty battery, but between January 1, 2011 and March 31, 2014, three deaths were reported that were potentially related to power source management.
Heartware said that two deaths occurred after both sources of power were simultaneously disconnected, the third patient had batteries that far exceeded their expected useful life and a fourth death was originally reported as possibly related to power management, but later determined to be more likely related to an accidental disconnection of the driveline.
Separately, Heartware said revenue for the three months to March 31, 2014 was up 35 percent to $US66.5 million ($A71.7 million) compared to the previous corresponding period.
The company said that in the three months to March 31, 2014, 665 Heartware Ventricular Assist Systems were sold globally, a 38 percent increase over the previous corresponding period, with US revenue up 29 percent to $US33.8 million and the rest of the world recording sales of 352 units with revenue up 42 percent to $US32.7 million.
Last night on the Nasdaq, Heartware climbed $US9.47 ($A10.21) or 11.15 percent to $US94.43 ($A101.81) with 677,913 shares traded.

QRX PHARMA

QRX says that Dr John Holaday has resigned as managing director and chief executive officer and will be replaced by chief operating officer Dr Edward Rudnic.
Last week QRX fell 80 percent on the third rejection of its Moxduo dual opioid pain drug by the US Food and Drug Administration (BD: Apr 23, 2014).
Today, QRX said that Dr Rudnic was appointed as chief operating officer in early 2012.
QRX chairman Peter Farrell said the “change in leadership was set by mutual agreement to address the challenges facing the company”.
The company said that Dr Rudnic had more than 30 years senior management and product commercialization experience and founded Advancis Pharmaceuticals, later renamed Middlebrook Pharmaceuticals and previously held senior positions with Shire Pharmaceuticals, Pharmavene, Schering Plough and E R Squibb.
QRX said that Dr Rudnic held a Bachelor of Science, a Masters of Science and a Doctorate of Philosophy in pharmaceutical sciences from the University of Rhode Island.
The company said that a final decision by the FDA would be delivered on or before the May 25, 2014 Prescription Drug User Fee Act date.
QRX was unchanged at 8.9 cents with 1.2 million shares traded.