Biotech Daily

Monday February 18, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PHYLOGICA UP 7%, SIRTEX DOWN 8%**

*** FEDERAL GOVERNMENT INNOVATION POLICY**

*** MEDICINES AUSTRALIA WELCOMES TRIALS REFORM, PRECINCTS**

*** GBS VENTURE PARTNERS 'THRILLED' BY FUNDING RE-INVESTMENT**

*** AUSBIOTECH, BIO-MELBOURNE WELCOME INITIATIVES**

*** ACRUX H1 REVENUE UP 9% TO $5m, PROFIT DOWN 58% TO $2m**

*** BIOXYNE PROCEEDS WITH VITALITY ACQUISITION**

*** CALZADA, POLYNOVO REVISE BARDA APPLICATION; TRIAL PROGRESS**

*** ALCHEMIA Q2 FONDAPARINUX ROYALTY UP 90% TO $3m**

*** ACUVAX BIOLIFE ACQUISITION, NAME CHANGE EGM**

*** PERPETUAL TAKES 6% OF RESMED**

*** SOCIAL INVESTMENTS REDUCES TO 5% OF NEURODISCOVERY**

*** ALCHEMIA PROMOTES CFO CHARLES WALKER TO CEO**

MARKET REPORT

The Australian stock market climbed 0.59 percent on Monday February 18, 2013 with the S&P ASX 200 up 29.5 points to 5,063.4 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and three were untraded.

Phylogica was best, up 0.2 cents or 7.4 percent to 2.9 cents. Alchemia, Genetic Technologies and Prima rose more than four percent; Anteo, Medical Developments and Phosphagenics climbed more than three percent; Bionomics, Heartware and Reva rose more than two percent; with Acrux, Anteo, CSL and Psivida up more than one percent.

Sirtex led the falls, down 90 cents or eight percent to $10.35 with 613,183 shares traded. Antisense lost 7.1 percent; Benitec, Patrys and Viralytics fell more than six percent; Circadian fell five percent; Impedimed, Living Cell and Optiscan lost more than four percent; Avita and Clinuvel fell more than three percent; Pharmaxis shed 2.4 percent; with Mesoblast, QRX, Tissue Therapies and Universal Bio down more than one percent.

FEDERAL GOVERNMENT

The Federal Government has announced an 'Industry and Innovation' policy providing venture capital funding, clinical trial reform and the establishment of 'innovation precincts'.
In a series of announcements from Prime Minister Julia Gillard, the Minister for Industry and Innovation Greg Combet, and other ministers, the Government said it would invest $378.6 million under Venture Australia, including a new $350 million round of equity funding through the Innovation Investment Fund to attract private sector investment; changes to tax concessions "to provide clarity and certainty for private sector investors and to facilitate investment by 'angel' syndicates"; and promoting success stories of new Australian firms to global venture capital markets, to showcase the capabilities of Australia's innovative firms and to attract international investment.

"Venture capital has a pivotal role in translating new ideas into innovative products, processes and services. It supports the growth of competitive new firms," Mr Combet said.
"A new round of equity funding through the IIF program would stimulate another $350 million in private sector investment in the venture capital market and provide management expertise to grow start-ups," Mr Combet said.
"Changes to venture capital tax concessions will provide incentives to private investment in start-ups and help Australia to be a competitive destination for investment capital," Mr Combet said.
The Government said it would return profits from successful joint ventures under IIF funding to the Revolving Fund to ensure it was re-committed to future equity funds.
The Government said that the research and development tax incentives would be removed from about 20 very large businesses with turnovers of $20 billion or more but they could claim their expenditure under general tax law provisions.
Health Minister Tanya Plibersek announced a package to support clinical trials saying that impediments included the high Australian dollar, rising and varying costs between clinical trial sites and jurisdictions, delays in approving trials and difficulty recruiting patients.
A Government media release said that initiatives would expedite the remaining Clinical Trials Action Group recommendations, including: creating standardized costs for items used by both the research and industrial clinical trials community to help budget and negotiate with hospitals to establish trials; incorporating clinical research needs into the Australian e-Health system to guide effective trials; developing a conceptual design to enable clinical trials to link, on-site and remotely, with medical records of participants; a pilot project to develop a national interactive Clinical Trials Portal to improve clinical trials management and enable greater participation and engagement in clinical trials; education and training of staff and researchers to improve clinical trial conduct and timeliness of approvals; and enhancing the ability of the National Health and Medical Research Council to work with States, Territories and stakeholders on a nationally consistent approach to clinical trials.
Mr Combet said the reforms would increase the number of clinical trials conducted in Australia by improving the competitiveness of the pharmaceuticals sector.
The Government said it would commit $504.5 million to establish up to 10 Industry Innovation Precincts to drive productivity, improve connections between business and the research sector and mobilize industry to compete more successfully in global markets.
The precincts would collaborate on identifying new business opportunities, deploying new technology, research and development and carrying out industry-led research projects.
The media release said that the first precinct, manufacturing, would be based in South East Melbourne and Adelaide and the second would be a food precinct in Melbourne.
The Government said that Industry Innovation Precincts would be able to bid for funds from an Industry Collaboration Fund which would build to $50 million a year.

MEDICINES AUSTRALIA

Medicines Australia chief executive Dr Brendan Shaw welcomed the Government's industry and innovation statement.

"The Government's positive engagement in this vitally important area of public policy for Australia's future through the Prime Minister's Manufacturing Taskforce, the Clinical Trials Action Group and the McKeon Strategic Review of Health and Medical Research is to be applauded," Dr Shaw said.

"Innovation by Australian businesses leads to greater productivity, stimulates employment and makes us a more competitive nation in the global economy," Dr Shaw said.

"The Government's further commitment to implement clinical trial reforms that were recommended by the Clinical Trial Action Group is especially welcome," Dr Shaw said.

"Medicines Australia, has been strongly advocating for these reforms since the Action Group reported to Government in March 2011," Dr Shaw said.

"Clinical trial reform has a had a long and rather torturous history - two steps forward, one step back - so it is satisfying to see the Government commit real financial resources to getting this work done," Dr Shaw said.

"Given the disappointments of the past, this is great news and we are very keen to work with the Government to ensure this important area of microeconomic reform is implemented as soon as possible," Dr Shaw said.

Dr Shaw also applauded the proposed establishment of 10 Innovation Precincts which he said would "provide opportunities for Australia's biotech and medicines companies to connect and collaborate with other businesses to create synergies and efficiencies".

"The Innovation Precinct concept is a real opportunity for Australia to capitalize on opportunities for collaboration," Dr Shaw said. "In an environment where the pharmaceuticals industry has faced over 300 job losses in the last quarter of 2012, we welcome initiatives that will help reverse this trend."

"Medicines Australia and our member companies look forward to working with the Government to finalise and implement clinical trial reforms in a timely manner and to create opportunities for Australia's medicines industry to build on its success in driving innovation in partnership with the Australian research sector," Dr Shaw said.

GBS VENTURE PARTNERS

GBS Venture Partners managing director Dr Brigitte Smith told Biotech Daily that her company was "thrilled with [the announcements] and the Government's Venture Capital review".

"The commitment to $350 million to a renewed IIF program is terrific, as it will allow the Government to continue to run this globally best-in-class program to foster the Australian venture capital industry," Dr Smith said.

"While it is largely unchanged from the current program, there are a few smart tweaks - any money returned to the program stays in the program," Dr Smith said.

"This was not previously the case, so when the profits from our first IIF fund were returned to Government they were removed from the program," Dr Smith said.

"This change will help make the IIF program self sustaining," Dr Smith said.

"The Venture Capital Review makes the clear point that there's not a lot of point in Governments trying to attract foreign venture capital firms to Australia, foreign firms want a local partner if they're to invest in Australian companies," Dr Smith said.

"This has been our experience and companies we've backed have raised $5 for every $1 we've invested to date, much of it from off-shore venture capital syndicate partners," Dr Smith said.

AUSBIOTECH

Ausbiotech commended the Government on a comprehensive top-level policy and was "pleased to see the positioning of innovation as central to jobs, productivity and a thriving economy - where it belongs".

Ausbiotech chief executive officer Dr Anna Lavelle said it was "good to see the Government has been listening to the concerns of industry and notes that the policy responds to many of the initiatives that have been well-articulated … for some years".

"While the statement is very welcome, I look forward to clarifying the details of many of the policy planks and hope that the positive elements of the policy can enjoy an expedited and rapid implementation after the election is decided," Dr Lavelle said.

Ausbiotech applauded the continuation of the Innovation Investment Fund and said the program had been critical to the industry and that access to capital, at the right price, was a bottleneck to innovation, as Australia had "substantially more innovation than capital".

"It is fantastic to see that IIF money generated by the sector and returned to the Government will be reinvested to support new innovative enterprises," Dr Lavelle said.

Ausbiotech said it supported innovation clusters "however they don't always succeed".

"There needs to be a level of sophistication that takes account of natural synergies, linkages and attributes of the contributors," the industry organization said.

Ausbiotech said it looked forward to more details about how they would be developed.

Ausbiotech said that Australia had been a destination of choice for clinical trials, but "our competitive advantage has declined over the last five years with … rising and varying costs between clinical trial sites and jurisdictions, delays in approving trials and difficulty recruiting patients … some of the causes".

Ausbiotech said it applauds the Government's support for clinical trials, while noting that the implementation of recommendations was "well overdue".

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says the innovation precincts confirmed Victoria's approach to biotechnology for the past 13 years and that an industry-specific dedicated, geographically based network was "the best way to accelerate interactions between academia, industry and investors".

The Bio-Melbourne Network chief executive officer Michelle Gallaher said the Newtwork was the centre of Melbourne's successful biotechnology Industry hub, with a market capitalization of more than $24 billion, the network linked about 190 organizations from industry, academia, manufacturing, investors and government.

"I hope the policy supports ongoing networks like ours that have proven to be very successful," Ms Gallaher said. "An injection of funding into the Bio-Melbourne Network would enable us to expand our services to so many more organizations."

Ms Gallaher said that the online innovation network that the policy was proposing to develop was already up and running through the Bio-Melbourne Network - the Victorian Bio-Portal, which linked more than 500 organizations in Melbourne's biotechnology and life sciences sector in an online forum hosted on the Bio-Melbourne Network web site.

"The site receives more than 1200 unique visitors a month, about 22 percent of those visitors are from overseas," Ms Gallaher said. "It is the only one of its kind in the world".

"Understanding the pressure on Government to minimize the damage from the underperforming mining tax, I'm relieved that the big end of town will lose the R&D tax credit instead of the little guys in biotech," Ms Gallaher said.

"The Victorian biotech sector has been a significant beneficiary of the R&D tax incentive and it has most certainly been a game changer for the industry," Ms Gallaher said.

ACRUX

Acrux says revenue for the six months to December 31, 2012, was up 8.8 percent to $5,131,000 with the net profit after tax down 57.9 percent to $2,144,000.
Acrux said that revenue from royalties on its Axiron testosterone replacement product increased from $2.3 million in the six months to December 31, 2011 to $4.2 million for the six months to December 31, 2012, but at the same time other revenue fell from $1.6 million to $300,000.
The company said that an income tax expense of $400,000 was incurred in the six months to December 31, 2012 compared to a $3.4 million tax benefit in the previous corresponding period.
The company said that net tangible asset per share fell 31.25 percent to 11 cents and diluted earnings per share was down 66.7 percent to 1.0 cents.
Acrux said that cash and cash equivalents at December 31, 2012 was $19.0 million compared to $30.0 million at June 30, 2012.
Acrux was up four cents or 1.05 percent to $3.86 with 338,728 shares traded.

BIOXYNE (FORMERLY HUNTER IMMUNOLOGY)

Bioxyne says it has a non-binding agreement to acquire Vitality Pty Ltd, with major shareholder Phillip Asset Management proposing to invest up to $2.5 million.
Bioxyne said that Vitality was established in January 2012 by former Chemgenex executives Dr Greg Collier and Dr James Campbell as a sales and distribution business, focusing on high value medical devices (BD: Feb 20, 2012).
The company said that Vitality was focused on chronic heart failure and diabetes markets in Australia and Asia and had distribution agreements for the Optimizer III and Diamond devices.
Bioxyne said that Optimizer III was based on the discovery that cardiac contractility modulation could be used to treat chronic, medically refractory congestive heart failure and three independent randomized trials had shown significant impact on a patient's exercise tolerance and quality of life.
The company said that Optimizer III received Conformité Européenne (CE) mark approval in 2007 for patients with normal coordinated cardiac contraction and reimbursement had been approved in Germany and the US.
Bioxyne said that the diabetes improvement and metabolic normalization device (Diamond) was developed by Metacure for the treatment of type 2 diabetes and was granted CE mark approval in 2007, approved by the Australian Therapeutic Goods Administration TGA in April 2012 and was ready to be launched commercially in Australia.
The company said that Diamond was an implantable gastric stimulator that detected food intake to the stomach and electrically stimulates the antral stomach muscles to increase stomach contractility, believed to result in the activation of neuro-hormonal activity regulating glucose, insulin, glucagon, satiety and blood pressure similar to those activated by GLP-1 and other gastrointestinal hormones.
Bioxyne said that clinical studies found that HbA1c, a key indicator of type 2 diabetes, was reduced in 92 percent of the tested patients with 43 percent of the patient group experiencing a reduction in HbA1c of more than 1.0 percent, with a maximum HbA1c reduction of 3.0 percent.
The company said that it was significant that the HbA1c level in 40 percent of patients was reduced to less than or equal to 7.0 percent, a threshold level.
Bioxyne was in a trading halt for the $2.5 million raising and last traded at 2.5 cents.

CALZADA

Calzada says the US Biomedical Advanced Research and Development Authority has advised it to concentrate on its biodegradable temporizing matrix for deep burns.

Calzada said that its wholly-owned subsidiary Polynovo was a partner in the Novoskin joint venture with Royal Adelaide Hospital specialist Prof John Greenwood.

The company said that Novoskin had applied to BARDA for funding for both the biodegradable temporizing matrix (BTM) and its cultured composite skin product.

Calzada said that BARDA had invited Novoskin to apply for a contract to develop products for medical countermeasures to a mass burns incident, but in a teleconference, BARDA encouraged Novoskin to file a revised contract application focusing solely on the use of the biodegradable temporizing matrix for full thickness or third degree burns.

The company said that a BARDA contract would allow Novoskin to accelerate the development of the BTM treatment for third degree burn wounds and undergo the pre-market approval clinical trials required for US regulatory approval.

Calzada said that the clinical trial evaluating BTM in surgical wound repair or free-flap donor sites, had treated five of 10 patients.

Last year, Calzada said that in two patients the trial had shown that Novosorb was effective in treating full thickness wounds with the biodegradable temporizing matrix wound repair material performing in humans as intended, consistent with the results obtained in earlier pre-clinical studies in pigs (BD: Oct 16, 2012).

The company said at that time that the Novosorb BTM had been implanted, successfully integrated into a wound and closed with skin grafts in two patients.

Today, Prof. Greenwood said the BTM material “appears to be exactly fulfilling its designed role, integrating into the wounds by filling with dermal tissue, then allowing seal delamination followed by skin grafting with successful graft take”.

“The resultant tissue quickly, within six weeks, becomes robust, pliable and mobile from a functional perspective and extremely good in its appearance, being flat but flush with the surrounding wound edges,” Prof Greenwood said.

“These early results have encouraged the plastic surgeons involved to allow its use on the most commonly used free flap - radial forearm flap - procedures, which should markedly increase the number of patients suitable for recruitment,” Prof Greenwood said.

Calzada said that on completion of the BTM trial, Polynovo would prepare a 510(k) pre-market notification submission for the US Food and Drug Administration for indications including second degree burns, surgical wounds, partial and full thickness wounds and other traumatic wounds.

Calzada said the 510(k) clearance would allow BTM to be sold in the US for full thickness wound treatments with the exclusion of third degree burns and a pre-market approval was required to market a product indicated for third degree burns, requiring an FDA-sanctioned clinical trial.

Calzada said that the Royal Adelaide Hospital human research ethics committee has requested design clarifications and amendments to some of the study documentation for Dr Greenwood’s November 2012 application for a clinical trial for severe burns.

The company said the Committee also asked Dr Greenwood to justify the commencement of a new study while the topical negative pressure and the free flap clinical trials were both ongoing.

Calzada said that the topical negative pressure clinical trial was nearing completion and Polynovo should be in a position to report on the status of the severe burns study application in the near future.

Calzada fell 0.3 cents or 7.0 percent to four cents.

ALCHEMIA

Alchemia says its quarterly profit share on sales of fondaparinux is up 90 percent to $US3.4 million ($A3.3 million) compared to the previous quarter.

Alchemia's newly appointed chief executive officer Charles Walker (see below) told Biotech Daily that along with increased sales and an increase in market share of its generic anti-coagulant product, the cost of goods had also improved with significant reductions in manufacturing costs.

In a media release, Alchemia said that total net sales were $US12.3 million, of which the funds owing to Alchemia would be $US2.9 million following the contribution of $US500,000 by Alchemia to the agreed activities to improve yields and cost of goods.

The company said that Dr Reddy's average market share for the three months ending December 31, 2012 was 25 percent, compared with 22 percent for the quarter ending September 30, 2012.

Mr Walker said it was "pleasing to see a significant improvement in profits this quarter compared with the last quarter".

"This is mainly a result of the joint investment in process improvement and reduction in the cost of the [active pharmaceutical ingredient]," Mr Walker said.

Alchemia was up 1.5 cents or 4.7 percent to 33.5 cents.

ACUVAX

Acuvax shareholders will vote to approve the acquisition of and change the company's name to Biolife Science (BD: Dec 20, 2012, Feb 12, 2013).

Acuvax said resolutions related to the back-door listing included a placement of 25,000,000 shares at 20 cents each to raise $5,000,000 as well as the issue of 20,000,000 shares to Biolife vendors along with two classes of 10,000,000 performance shares and a one-for-200 share consolidation.

The meeting will be held at Suite 2, 16 Ord Street, West Perth, on March 22, 2013 at 10am (AWST).

Acuvax was untraded at 0.1 cents.

RESMED

Perpetual and its subsidies have increased their substantial shareholding in the company from 80,918,517 shares (5.02%) to 99,130,394 shares (6.37%).

The substantial shareholder said that the shares were acquired between February 1 and 14, 2013 at prices ranging from $4.18 to $4.31.

Resmed was up one cent or 0.2 percent to $4.18 with 3.7 million shares traded.

NEURODISCOVERY

The Claremont, Western Australia-based Social Investments has reduced its substantial holding in Neurodiscovery from 6,838,377 shares (7.05%) to 5,000,000 shares (5.15%).

Social Investments said it sold one million shares for $35,575 or 0.36 cents a share

Neurodiscovery was up 0.3 cents or 9.4 percent to 3.5 cents.

ALCHEMIA

Alchemia has promoted chief financial officer Charles Walker to chief executive officer, with Mel Bridges returning to his non-executive chairman role, effective immediately.

Alchemia said that Mr Walker had been the chief financial officer for the last two years and had 20 years life science industry experience.

The company said that Mr Walker trained as a pharmacologist in the UK before embarking on a career in the pharmaceutical industry and had spent more than 10 years in corporate finance advising technology companies and executing more than 40 successful corporate transactions including initial public offers, mergers and acquisitions and fundraisings.

Alchemia said that Mr Walker had co-founded a successful life sciences investment banking firm in the UK which was sold to Nomura International plc in 2005 realizing significant returns for investors.

The company said that Mr Walker held a Bachelor of Science in Pharmacology from the University of Bristol and a Masters of Business Administration from the University of Warwick.