Biotech Daily

Monday November 30, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH FLAT; BIOTA UP 16%; AVEXA DOWN 17%**

*** FEDERAL GOVERNMENT AXES $14m COMET PROGRAM**

*** WHO OWNS PALLANE MEDICAL?**

*** AVEXA PLACEMENT RAISES $8m; SHARE PLAN TO RAISE $3m**

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MARKET REPORT

The Australian stock market rebounded 2.8 percent on Monday November 30, 2009 with the S&P ASX 200 up 129.2 points to 4,701.3 points. Eleven of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and eight were untraded.

Biota was best on no news, climbing 43 cents or 16.4 percent to $3.05 with 2.9 million shares traded, followed by Uscom up 15.1 percent to 76 cents and Clinuvel up 11.1 percent to 30 cents.

Genetic Technologies climbed 4.2 percent; Cochlear was up 3.2 percent; Benitec, Cellestis, Nanosonics and Viralytics rose more than two percent; with CSL, Cytopia and Mesoblast up more than one percent.

Avexa led the falls, down 3.5 cents or 17.1 percent to 17 cents with 7.5 million shares traded, followed by Alchemia down 6.1 percent to 62 cents with 222,063 shares traded.

Chemgenex lost 5.3 percent; Bionomics and Phosphagenics fell four percent or more; Tissue Therapies was down 3.2 percent; Psivida and Starpharma shed more than two percent; with Antisense and Resmed down more than one percent.

FEDERAL GOVERNMENT

The Federal Labor Government has axed the $14 million a year Commercialising Emerging Technologies (Comet) program.

In a media release entitled 'Commercialization help made simpler' the Minister for Innovation Senator Kim Carr said the Comet program would be "closed to new applications from January 1, 2010".

A spokeswoman for the Department of Innovation Industry Science and Research told Biotech Daily that Comet was worth about $14 million a year.

In May this year the then Shadow Innovation Minister Eric Abetz called on Senator Carr to ensure the continuation of the program (BD: May 11, 2009).

In the run-up to the Federal Budget, Senator Abetz said that in the previous year Senator Carr allowed the $700 million Commercial Ready program to be axed and called on the Government to retain the Comet program.

Senator Abetz quoted Senator Carr saying in 2008 that: "The Comet program is an example of government and industry working in partnership to boost Australia's innovation capacity and performance….In particular, the practice of providing strategic and tailored support to early stage companies significantly enhances their chances of successfully converting new and innovative ideas into successful commercial outcomes".

The May 2009 Federal Budget announced the Commonwealth Commercialisation Institute, later rebadged as Commercialisation Australia, with a maximum total funding of $82 million a year to be divided across all new technologies.

Today's media release from Senator Carr said that Comet would "continue to be available to customers who lodge completed applications prior to closure and customers with ongoing Comet grants".

The media release said the Government would "introduce a new, simpler form of assistance to companies seeking to take their ideas to market from early January 2010".

"Government assistance for commercializing Australian innovation will be simplified through Commercialisation Australia," Senator Carr said.

"This is a radical new approach to government commercialization assistance through a single program, Commercialisation Australia," he said.

"Case managers will guide applicants through commercialisation, helping them to build their skills and knowledge and, depending on their needs, link them to volunteer business mentors and specialist advice," Senator Carr said.

"As Commercialisation Australia comes into operation, the services and assistance it offers will supersede those currently available under the Commercialising Emerging Technologies (Comet) program.

"Commercialisation Australia will become the primary source for Australian Government assistance in helping to get ideas into the market place."

Bio-Melbourne Network chief executive officer Michelle Gallaher said the concern with axing Comet and rolling the activity into Commercialisation Australia was that "the pool of available funding and ability to service the innovation sector will not be enough".

"With the government encouraging companies to innovate and urging Australians to commercialize new ideas, Commercialisation Australia will need to have a large welcome mat to accommodate the influx of newly minted entrepreneurs," Ms Gallaher said.

"I'm all for reducing duplication and making the granting process simpler and any cost saving from increased efficiency and the available Comet funds should be deposited into the account for Commercialision Australia," she said.

"The Government has encouraged our appetite for innovation but my fear is that there is simply not enough to go around," Ms Gallaher said.

PALLANE MEDICAL

The managing director of Glamsmile, Peter King, says he owns the registered business 'Pallane Medical' and not the directors who control the ASX-listed Pallane Medical.
Mr King told Biotech Daily that he is the chief executive officer of Pallane Medical and has nothing to do with the group that has taken over Dia-B Tech and renamed it Pallane Medical.
Glamsmile is a Caulfield Victoria based company involved in dental cosmetic treatments.
The www.pallanemedical.com website describes the rapid virus diagnostic system Rapid Enhanced Tissue Culture Immunoflourescence (Retcif) which was at the core of the May backdoor listing into Dia-B.
Recent announcements by the ASX-listed Pallane have focused on the diabetes treatments of the former Dia-B Tech.
The new board of the ASX-listed entity Pallane Medical includes as executive chairman the Singapore-based former Agenix chairman Ravindran (Ravi) Govindan and directors, Peter Stafford, Joanna Broeders and Santino (Sam) Di-Giacomo.
Mr King said there had been a problem relating to legal filings that allowed the Pallane name to go to the Australian Securities and Investments Commission as a name change for Dia-B Tech.
"We have nothing to do with them," Mr King said.
"We just want to make sure they don't use our name," Mr King said.
Mr King said his group held the intellectual property to the rapid virus test kits that were the main asset of Pallane Medical as it attempted its backdoor listing into Dia-B with the financial assistance of Winteray (BD: May 28, 29, 2009).
But Winteray was unable to fund the $12 million underwriting and the deal appeared to unravel (BD: Jul 28, 29; Aug 11, 13, 2009).
In October Dia B said Trafalgar Capital would take control of the company.
Chairman Dr Michael Wooldridge, director Neil Hewitt and chief executive officer Ken Smith resigned as directors and were replaced by the current board with Wojtek Randla as company secretary, who was later replaced in that role by Mr Di-Giacomo.
The directors said they would pursue Dia-B's claims against Winteray (BD: Oct 4, 2009).
Mr King and the wife of one of the Winteray principals share an accountant in common.
In October Pallane's new management announced it had secured a $30 million equity draw down facility from Fortrend Securities, but last week the company said it could not begin to access that facility for at least a further 12 months.
Biotech Daily attempted to contact a director of the ASX-listed Pallane Medical, Peter Stafford, but at the time of publication had no reply.
Pallane inherited its suspension from Dia-B and has not yet traded shares.

AVEXA

Avexa has raised $8 million through a placement and hopes to raise $3 million from a share purchase plan, with all new shares priced at 14 cents each.
Avexa said the funds would strengthen its balance sheet and provide working capital.
Avexa said it raised $8 million through a placement to institutional and sophisticated investors.
Avexa said RBS Morgans and Blueprint Life Science Group were corporate advisors for the transaction.
The record date for the share plan is December 1, 2009, the plan on December 7 and closes on December 18, 2009.
Avexa fell 3.5 cents or 17.1 percent to 17 cents with 7.5 million shares traded.

QRX PHARMA

QRX has begun registration for a pivotal phase III trial comparing efficacy and safety of Moxduo Immediate Release against component doses of morphine and oxycodone.
QRX chief financial officer Chris Campbell told Biotech Daily the trial of 522 patients would assess the company's morphine and oxycodone combination drug for the treatment of moderate to severe post-operative pain following bunionectomy surgery.
Mr Campbell said the company successfully completed a US phase III 256-patient dose ranging trial in November 2007 for bunionectomy.
Mr Campbell said that the new bunionectomy trial was expected to complete dosing by July 2010.
He said a further trial of Moxduo for total knee replacement was also required by the US Food and Drug Administration and was scheduled to begin by April 2010.
In a media release QRX said "no additional pharmacology, toxicology or long-term clinical safety studies will be required for regulatory submission and market approval".
QRS chief executive officer Dr John Holaday said Moxduo IR was superior in terms of tolerability compared to equi-analgesic doses of morphine, oxycodone and Percocet for the management of acute post-operative pain.
"These studies demonstrated that Moxduo IR provides significant pain relief and fewer side effects [such as] nausea, vomiting, dizziness and constipation," Dr Holaday said.
"We are now addressing a regulatory requirement for new drug application approval of Moxduo IR, that is, demonstration that it is superior in efficacy to its individual components," Dr Holaday said.
QRX said that a double-blind study with about 35 patients per group, completed earlier this year in patients with pain following bunionectomy surgery, "demonstrated the superiority of Moxduo" combining 12mg morphine and 8mg of oxycodone relative to 12mg morphine and to 8mg oxycodone.
QRX said the phase III registration study would to replicate the differences in a larger trial, one with sufficient statistical power to achieve significance on the primary and secondary endpoints.
If successful, this trial will satisfy the FDA combination rule requirement and would also serve as a registration study.
The double-blind, randomized and repeat fixed-dose study compares Moxduo IR's reduction in pain intensity (primary endpoint) to component doses of oxycodone and morphine in patients experiencing moderate to severe post-operative pain over 48 hours.
The primary endpoint for evaluating the efficacy of Moxduo IR 12mg/8mg versus its milligram components of morphine 12mg and oxycodone 8mg administered every six hours is the difference in pain intensity scores for each patient group over the 48-hour treatment period (SPID48 calculated from the 10-point Numerical Pain Rating Scale).
Secondary endpoints include efficacy relating the patient's global assessment of effect, that is the extent of overall pain relief, as well as amount of supplemental analgesia (acetaminophen) used throughout the treatment period; and safety as measured by incidence and intensity of opioid-related adverse effects.
QRX fell one cent or 1.3 percent to 77 cents.

METABOLIC, CALZADA

The biotechnology company formerly known as Metabolic will be known as Calzada from the opening of the ASX tomorrow, December 1, 2009.
Metabolic fell 0.1 cents or 3.2 percent to three cents.

FEDERAL GOVERNMENT – CLINICAL TRIALS

The Federal Government's Clinical Trials Action Group says wants to know how Australia "can enhance its position as a preferred destination for clinical trials".

Public submissions are being sought following the release of discussion papers by the Parliamentary Secretary for Innovation and Industry Richard Marles and the Parliamentary Secretary for Health Mark Butlerm who co-chair the Action Group.

"Pharmaceutical clinical trials are worth $450 million each year to Australia," Mr Marles said. "They keep Australia and our highly-skilled, clinical experts at the cutting edge of medical breakthroughs and have additional benefits for our science industries."

Other members of the Action Group, established by Science Minister Kim Carr and Health Minister Nicola Roxon on October 27, 2009, include the Australian Government's chief medical officer Prof Jim Bishop, the National Health and Medical Research Council's Dr Tim Dyke and Novartis Pharmaceuticals' Mitch Kirkman.

The Federal Government said it wanted submissions on: developing a clinical trials roadmap; performance measures for clinical trials; ensuring a rapid uptake of streamlined ethics, scientific and governance processes; strategies to improve recruitment; and developing an information and communications technology strategic plan for clinical trials.

For further information on the consultation process and discussion papers, go to www.innovation.gov.au/clinicaltrials.

Submissions can be sent to pharmaceutical@innovation.gov.au by January 15, 2010.

HEALTHLINX

Healthlinx has placed $1.1 million in shares through Stonebridge Securities.

Healthlinx said the funding would support the commercial roll out of its Ovplex ovarian cancer test over the next 12 months and follows $7.2 million in funding from the New York based Springtree and a $750,000 Victorian government grant.

Healthlinx managing director Nick Gatsios said the company was "pleased to attract the support of another major funding provider who can see the company's vision of providing the Ovplex panel, the most accurate woman's ovarian cancer test to the global market."

"The investor community has recognized that the Healthlinx management team have been meeting their milestones and we are delighted with their overwhelming support for the capital raising," Mr Gatsios said.

"Healthlinx is now in a strong position to execute the roll out of Ovplex over the coming months," he said.

Healthlinx was up 0.4 cents or five percent to 8.4 cents,

CLINUVEL PHARMACEUTICALS

Clinuvel says it has received European Medicines Agency status of small and medium enterprise, providing incentives for its filing and commercialization of afamelanotide.

Clinuvel said the status was granted to assist eligible companies during the pre-marketing authorization period, scientific advice, marketing authorization application and inspection procedures.

Clinuvel said it intended to file for registration of afamelanotide in Europe, Norway, Iceland and Liechtenstein ahead of other global markets in 2010.

Clinuvel chief executive officer Dr Philippe Wolgen said the small and medium sized enterprise status provided a benefit from a 90 percent fee reduction during the centralized procedure and good manufacturing practice inspection fees of final product.

Clinuvel was up three cents or 11.1 percent to 30 cents.

ACUVAX

Acuvax says that while all resolutions were carried on a show of hands, the proxy votes divided on the remuneration report and share issues.

The greatest division was on the remuneration report which was passed by 596,112 proxy votes (57.7%) to 436,993 proxy votes (42.3%).

Resolutions relating to share issues were passed by about 90 percent to 10 percnet of proxy votes with the exception of the issue of shares to Panstyn Investments which was opposed by 141,382 proxy votes (29.8%) with 333,234 proxy votes (70.2%) in favor.

The re-election of directors Dr William Ardrey and Dr Yvonne Foong were approved overwhelmingly.

Acuvax was untraded at two cents.

MESOBLAST

All Mesoblast resolutions were passed, but up to 16.5 percent of proxy votes opposed the remuneration report and the issue of options to director Brian Jamieson.

Mr Jamieson's options were opposed by 7,464,574 proxy votes (16.5%), with 37,769,862 proxy votes (83.5%) in favor.

The remuneration report was passed by a similar margin, while the reelection of director Donal O'Dwyer and a prior issue of shares were passed overwhelmingly.

Mesoblast was up two cents or 1.4 percent to $1.45.