



Biotech Daily

Tuesday September 3, 2013

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market climbed 0.16 percent on Tuesday September 3, 2013 with the S&P ASX 200 up 8.3 points to 5,196.6 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and two were untraded.

Both Alchemia and Prana were up 9.3 percent, to 47 cents and 59 cents, respectively, with 1.8 million shares and 1.6 million shares traded, respectively.

Viralytics climbed 7.9 percent to 34 cents; Optiscan was up 6.15 percent; both Allied Health and GI Dynamics were up five percent; Anteo, Benitec and Starpharma were up more than three percent; Neuren and Phosphagenics rose more than two percent; Genetic Technologies, Nanosonics, Prima and Universal Biosensors up more than one percent; with Cochlear up 0.16 percent.

Uscom led the falls, down two cents or 10 percent to 18 cents with 1,748 shares traded.

IDT, Living Cell and Phylogica lost more than six percent; Reva fell 4.8 percent; Pharmaxis and QRX were down more than three percent; Acrux, Bionomics and Impedimed shed more than two percent; CSL and Mesoblast were down more than one percent; with Heartware, Medical Developments, Resmed and Sirtex down by less than one percent.

BIOTECH DAILY ELECTION EDITORIAL

The problem for innovation in general and biotechnology in particular is that none of the major Federal parties understand the subject area like the previous Victoria and Queensland Governments.

The acumen, zeal and commitment of Victoria's John Brumby and Steve Bracks and Queensland's Peter Beattie and Anna Bligh, translated to the national stage with a commensurate increase in funding, would transform the country and make us truly a world leader in innovation.

Not one of the major parties has mentioned funding for phase III drug registration trials, which cost tens of millions of dollars. To labor the same point again: One single Collins Class submarine which is incapable of submerging (about \$1 billion), invested wisely, would pay for several phase III trials per year and with the right contract requiring equity or pay-back, just one success a year could make that fund perpetually self-funding.

That said, the biotechnology, research and development and commercialization policies of all three major contestants appear to do no harm.

The Australian Greens

The Australian Greens have promised to inject \$2 billion over seven years to increase research and development spending to three percent of gross domestic product and the proposals include returning previous cuts and increasing a number of specific programs (BD: Aug 20, 2013).

The Greens say the proposals have been costed by the Parliamentary Budget Office and would be funded from announced revenue measures, including the abolition of fossil fuel subsidies.

Biotech Daily joins Walter and Eliza Hall Institute director Prof Doug Hilton and the Australian Academy of Science's former secretary for science Prof Robert Williamson in welcoming the Greens proposals and acknowledges that the Greens Deputy Leader and Member for Melbourne Adam Bandt understands that he is also 'the Member for Biotech'.

Apart from the absence of funding for phase III drug trials the Greens policies are good.

The Australian Labor Party

The Australian Labor Party has committed itself to a continuation of present levels of funding for the major pillars of innovation research and development and commercialization: the 45 percent Research and Development Tax Credit, Australian Research Council, National Health and Medical Research Council, Innovation Investment Funds and Commercialisation Australia.

On August 20, the Labor Party announced a \$250 million Medical Research Innovation Fund to assist commercialize medical treatments and healthcare technologies. With \$125

million from the Government, it requires private sector matching and is aimed at “early stage development of innovative biotechnology ventures” hopefully closing a gap recently identified by GBS Venture Partners, which was forced to reject a \$30 million IIF grant because it saw \$50 million as the minimum required to provide for risk-spreading.

Apart from the absence of funding for phase III drug trials the Labor promises on innovation are good.

Biotech Daily would be more convinced that those promises would be kept if we knew in advance that the Labor candidate for Forde, former Queensland premier Peter Beattie would be the Minister for Innovation in a returned Labor Government.

If Labor confirmed that Mr Beattie would have a leading role in innovation, that would be a big plus for our sector. Mr Beattie told Biotech Daily that no matter what role he had, he would champion biotechnology and innovation (BD: Aug 22, 2013).

[The Liberal National Party Coalition](#)

Like Labor, the Liberal National Party Coalition has committed to present levels of funding for the Australian Research Council and the National Health and Medical Research Council.

Requests to Liberal Party officials to confirm the same for the 45 percent Research and Development Tax Credit, Innovation Investment Funds and Commercialisation Australia were unanswered at the time of publication.

The Coalition policy on manufacturing includes a review of the Research and Development Tax Credit, widening it to large companies, for whom it is less critical. It is not dissimilar to the Paid Parental Leave program and Education policies, in that rather than funding needs, through means-testing, it is regressive. The policy includes reversing previous changes to definitions, one of which was to exclude roads to mines as “research and development”. No one from the Liberal Party was available to clarify this at the time of publication.

Biotech Daily welcomes the Coalition’s \$50 million commitment for transition funds and \$50 million for export programs and would like to see more detail on how these funds would be spent. With transition grants of up to \$10 million there won’t be many of them.

The promises of \$42 million for the Australian Institute of Tropical Health and Medicine and \$35 million for type 1 diabetes research are also welcome, but the scale needs to be compared to the \$50 million Living Cell and Otsuka joint venture (BD: Oct 19, 2011).

Although the Coalition criticizes ‘reviews’, a major plank of its policy is another White Paper review into funding innovation. This will take a very long time to reach the logical conclusion of a \$1 billion phase III drug trials fund (see above).

Finally, the Coalition focus on cutting the Corporate Tax rate, while welcome by some, along with the promise to remove the Carbon and Mining Taxes, means that there will be less available for Government investment and seed funding.

The promised savings of \$1 billion from cutting alleged waste and what the Coalition calls red and green tape does not bode well for a sector closely involved with Government funding and requiring strict regulations relating to drugs, devices and diagnostics for human use. Promises to expedite drug trials and approvals, while superficially welcome, need to ensure that integrity is not compromised.

That said, reform of Australia's regulatory framework (or lack thereof) is well overdue, as outlined last month by Cochlear's Dr Chris Roberts (BD: Aug 6, 2013).

Decision-making by the Therapeutic Goods Administration appears to be idiosyncratic, with approvals granted to large and/or foreign companies, while making life impossible for local and/or smaller companies. A TGA-approved CSL vaccine subsequently had paediatric safety issues, while the TGA demanded that Acrux run a further trial for its FDA-approved generic hormone in an alcohol and sunscreen base, despite being on sale in the US for four years.

The Coalition's policies appear to do no harm, but require greater detail. Previous policies accusing climate and reproductive science of being 'political' also remain a concern.

The Opposition spokesperson on Innovation, Sophie Mirabella, has been noticeably absent since she replaced Senator Eric Abetz in the role, let alone through the election period.

Biotech Daily has attempted to contact the Member for Kooyong, Joshua Frydenberg who was said to be involved in developing Coalition innovation policies, but he has not returned telephone calls.

Biotech Daily is concerned that the Coalition's policies lack detail.

Biotech Daily is also concerned that following the election whichever Party forms Government will declare that the Budget has again changed and cuts are required.

The written promise from Opposition Leader Tony Abbott, restated by the Member for Higgins Kelly O'Dwyer at a Bio-Melbourne Breakfast earlier this year that the ARC and NHMRC budgets will not be cut, is encouraging.

The Greens Adam Bandt made the same pledge at the same meeting.

Biotech Daily supports whichever political party is prepared to take innovation seriously and pay more than mere lip-service to investing in future technologies. A \$1 billion phase III drug trials fund would be convincing.

David Langsam
Editor

ALLIED HEALTHCARE GROUP

Allied Health says the first two of five cohorts have been dosed in its 20-patient, phase I, herpes simplex virus 2 DNA vaccine study, with no safety issues raised.

Allied said that the therapeutic vaccine developed by 50 percent subsidiary Coridon, led by Prof Ian Frazer, targeted herpes simplex virus 2, commonly associated with genital herpes, and was designed to both prevent transmission of the virus, as well as treat those who have already been exposed.

Allied chief executive officer Lee Rodne said the study was “progressing well, with the first participants being dosed and no safety issues reported”.

“There is no curative treatment for herpes and there is a major unmet medical need, meaning our herpes therapeutic vaccine has huge market potential,” Mr Rodne said.

Allied said that the trial was being run by Q-Pharm Pty Ltd at the Royal Brisbane and Women’s Hospital and was exploring five doses of the herpes virus 2 vaccine.

Allied said that the trial of 20 healthy, HSV-free volunteers was expected to conclude at the end of September, with interim results by the end of 2013.

Prof Frazer said that the Brisbane study would “provide important information as to the effective dose and to demonstrate that our vaccine approach works”.

Allied said that there was no cure for herpes simplex virus 2 (HSV-2) and the infection was life-long, with current therapy involving antiviral drugs which could reduce, but not eliminate, outbreaks and viral shedding; and could reduce but not prevent the spread of the virus.

The company said the US Center for Disease Control estimated that 16 percent of all people between the ages of 15 and 49 were infected with HSV-2.

Allied chief operating officer Dr Julian Chick told Biotech Daily that the vaccine was being trialed intradermally, into the surface layer of skin and not subcutaneously or intramuscular.

Dr Chick said that the company was continuing to recruit healthy volunteers to the trial and people interested in participating should contact Q-Pharm by telephone on 1300 774 276 or email volunteers@qpharm.com.au.

Allied climbed as much as 2.5 cents or 25 percent to 12.5 cents, before closing up half a cent or five percent at 10.5 cents, with 55.1 million shares traded.

VIRAX HOLDINGS

Virax administrators Grant Thornton says that all resolutions for a new board, capital raising and consolidation were passed overwhelmingly at a meeting on August 30, 2013. The resolutions included the issue of shares at 25,000,000 at 0.001 cents, 100,000,000 options at 0.001 cents exercisable at 0.5 cents and 500,000,000 post-consolidation shares at no less than 0.5 cents each; a one-for-10 consolidation; and the election of directors, executive chairman-elect Dr Wayne Millen, Dr Roland Tode and Dr Brendan de Kauwe; and a new constitution.

Most resolutions were won with 50 million votes in favor and about 20,000 votes against, with the securities issue and consolidation supported by about 50 million votes and opposed by about 1.4 million votes.

Dr Millen said he hoped the shares would emerge from the suspension “towards the end of October, pending regulatory approval”.

In July, Grant Thornton said the funds would be used to pay creditors and ASX relisting fees as well as review the existing business and cover a “review and expenditure on new projects”, but the document did not describe the nature of new projects (BD: Jul 31, 2013). Virax last traded at 0.9 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has a settlement and release agreement with the Detroit, Michigan-based Genesis Genetics Institute relating to its non-coding DNA patents. Genetic Technologies said that last year it filed a law suit against Genesis Genetics Institute in the US District Court for the Eastern District of Michigan, Southern Division, under its assertion program (BD: Oct 15, 2012).

The company said that following the final settlement the legal action would be dismissed. Genetic Technologies said the precise commercial terms of the agreement were covered by formal confidentiality provisions and could not be disclosed.

Genetic Technologies was up 0.1 cents or 1.1 percent to 8.9 cents

PHOSPHAGENICS

Phosphagenics says it will present two posters on its tocopheryl phosphate mixture or TPM technology at the Painweek conference in Las Vegas, September 4-7, 2013.

Phosphagenics said the first poster, entitled 'TPM (Targeted Penetration Matrix) - A Novel Vitamin-E Based Transdermal Drug Delivery Platform', would detail the platform's transdermal properties and its ability "to deliver a wide range of analgesics in various dosage forms without irritation or inflammation".

The company said that the second poster, entitled 'Targeted Penetration Matrix (TPM) Transdermal System Delivers Opioid Molecules Systemically without Treatment Limiting Skin Irritation', would detail the top-line results of its TPM-oxycodone and TPM-oxymorphone phase I clinical trials.

Phosphagenics said that Painweek was the largest pain conference in the US with a principal focus on frontline practitioners in pain management and would attended by more than 1,800 pain specialists.

Phosphagenics was up 0.2 cents or 2.2 percent to 9.2 cents.

IMMURON

Immuron says that non-executive director Dr Elane Zelcer has resigned.

Immuron said that Dr Zelcer was appointed a director in November 2009 and cited "other business interests ... consuming an increasing amount of her time and focus".

Immuron was untraded at 0.5 cents.

PRANA BIOTECHNOLOGY

Prana says its PBT2 for Huntington's and Alzheimer's disease has been named by Elsevier Business Intelligence as one of "the top 10 neuroscience projects to watch".

The company said that the Elsevier top 10 list was selected by "an independent panel ... to highlight compounds which address a large, unmet market, strong science and a diversity of indications".

Prana said that other criteria included the potential for further indications, multi-level partnering opportunities and a strong company behind the compound.

Prana said it would present the latest research on PBT2 at Windhover's Therapeutic Area Partnerships meeting on November 18-20, 2013 in Boston, Massachusetts.

Prana up five cents or 9.3 percent to 59 cents with 1.6 million shares traded.

UNIQUEST, DENDRIGHT PTY LTD

University of Queensland start-up Dendright says it has appointed Helen Roberts as chief executive officer.

Dendright said the appointment followed the recent announcement of its collaboration with Janssen Biotech to support the preclinical development of a novel product for the treatment of rheumatoid arthritis (BD: Aug 12, 2013).

Dendright founding director and chief technology officer Dr Ranjeny Thomas said that Ms Roberts “extensive experience across drug development programs with a therapeutic basis in immune-modulation and her demonstrated leadership and management skills in business and product development, will add tremendous value to the company”.

Dendright said that Ms Roberts had more than 20 years’ experience in drug development and commercialization roles in the pharmaceutical and biotechnology industry, including Implicit Bioscience, Agenix, Merck, Sharp & Dohme and Lederle Laboratories, now part of Pfizer.

Dendright chairman and Uniquet business development manager Dr Craig Belcher said the appointment would lead the company “through its next phase of growth with the Janssen collaboration and reflects the strategic importance of our expansion initiative to establish Dendright as a global leader in tolerizing immunotherapy for the treatment of autoimmune diseases”.

Ms Roberts LinkedIn page said she held a Bachelor of Applied Science from Queensland University of Technology and a Masters of Business Administration from the University of Technology Sydney.