Biotech Daily

Wednesday October 7, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: AVITA UP 17%; POLYNOVO DOWN 7%**

*** HIGH COURT RULES ISOLATED BRCA GENE NOT PATENTABLE**
- MEDICINES AUSTRALIA CONCERN OVER IP IMPACT

*** CEO DR ANNA LAVELLE OPENS AUSBIOTECH CONFERENCE**
- VICTORIA TO BUILD ON SUCCESS
- PROF ALAN TROUNSON: 'AUSTRALIA LAGS ON STEM CELLS'
- PROF MAREE SMITH, ELLUME, SPINIFEX WIN J&J INNOVATION GONGS

*** LBT APAS TRIAL 'FAR EXCEEDS EXPECTATIONS'**

*** CE MARK FOR AVITA REGENERCELL, RENOVACELL**

*** AUSTRALIAN ETHICAL REDUCES, DILUTED TO 10% IN AVITA**

*** NY LAGODA, FATIMA DICKEY, RICHARD BAYLES TAKE 6% OF CLINUVEL**

*** WEHI, MRCF CATALYZING COMMERCIALIZATION SYMPOSIUM**

*** ACTINOGEN ALZHEIMER'S INVESTOR SYMPOSIUM**

MARKET REPORT

The Australian stock market was up 0.59 percent on Wednesday October 7, 2015, with the ASX200 up 30.5 points to 5,197.9 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and two were untraded.

Avita was the best, up 1.6 cents or 17.0 percent to 11 cents with four million shares traded, followed by Cellmid up 10 percent to 3.3 cents with 1.7 million shares traded.

Acrux climbed 7.8 percent; Psivida was up 4.2 percent; Oncosil and Uscom were up more than three percent; Optiscan and Pro Medicus rose more than two percent; Actinogen, Anteo, Impedimed and Orthocell were up more than one percent; with Clinuvel, Cochlear CSL, Mesoblast and Nanosonics up by less than one percent.

Polynovo led the falls, down one cent or 6.9 percent to 13.5 cents with 347,478 shares traded. Atcor and Universal Biosensors lost more than six percent; Ellex and Genetic Technologies fell five percent or more; Biotron, Osprey and Prana were down more than three percent; IDT and Reva shed more than two percent; Admedus, Bionomics, Medical Developments, Prima, Sirtex, Starpharma and Viralytics were down one percent or more; with Resmed down 0.9 percent.

HIGH COURT OF AUSTRALIA, GENETIC TECHNOLOGIES

The full bench of the High Court has unanimously allowed an appeal finding that an isolated nucleic acid, coding for a BRCA1 protein, was not a patentable invention.

The decision overturns last year's Federal Court of Australia decision to dismiss an appeal against a previous decision supporting Myriad Genetics right to patent biological materials (BD: Sep 5, 2014).

The High Court decision is final and cannot be appealed further.

In 2013 in the Federal Court, Judge John Nicholas dismissed the application brought by Yvonne D'Arcy, Cancer Voices Australia and others against Myriad, Genetic Technologies and others, alleging the BRCA1 patent held by Myriad and Genetic Technologies, Patent 686,004, was invalid, with Justice Nichols saying that isolating DNA and RNA was a manner of manufacture (BD: Feb 21, 2012; Feb 15, 2013).

In 2014, Genetic Technologies then chief executive officer Alison Mew told Biotech Daily the BRCA patents protected the intellectual property in Australia until December 2015, but her company had amended the Myriad licence to a distribution agreement.

Today, the High Court "held that an isolated nucleic acid, coding for a BRCA1 protein, with specific variations from the norm that are indicative of susceptibility to breast cancer and ovarian cancer, was not a 'patentable invention' within the meaning of Section 18(1)(a) of the [Commonwealth] Patents Act 1990".

"The term 'nucleic acid' includes two kinds of molecules, deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), which are found inside a human cell," the High Court said.

"A gene is a functional unit of DNA which encodes a particular protein produced by the cell," the Court said. "The protein produced depends on the sequence of nucleotides."

"The BRCA1 gene codes for the production of a protein called BRCA1.

"The first respondent filed a patent which contained 30 claims.

"Relevantly, claims 1 to 3 concerned a nucleic acid coding for a BRCA1 protein, and with one or more specified variations from the norm in its nucleotide sequence, isolated from its cellular environment.

"Those specified variations, characterised as mutations or polymorphisms, are indicative of susceptibility to breast cancer and ovarian cancer," the High Court ruled.

The Court said that the Act required, for an invention to be patentable, it must be "a manner of manufacture" within the meaning of Section 6 of the Statute of Monopolies.

The High Court said that in the Federal Court the appellant challenged the validity of Claims 1 to 3 on the basis that the invention claimed did not meet the requirement of Section 18(1)(a), with the primary judge dismissing the challenge, holding that the invention fell within the concept of a "manner of manufacture" and the Full Court of the Federal Court dismissed an appeal, holding that "an isolated nucleic acid was chemically, structurally and functionally different from a nucleic acid inside a human cell … [and] the invention was a manner of manufacture because an isolated nucleic acid with the characteristics specified in Claims 1 to 3 resulted in an artificially created state of affairs for economic benefit".

The High Court said that the invention claimed did not fall within the concept of a manner of manufacture and "held that, having regard to the relevant factors, an isolated nucleic acid, coding for the BRCA1 protein, with specified variations, is not a manner of manufacture [and] while the invention claimed might be, in a formal sense, a product of human action, it was the existence of the information stored in the relevant sequences that was an essential element of the invention as claimed.

"A plurality of the Court considered that to attribute patentability to the invention as claimed would involve an extension of the concept of a manner of manufacture which was not appropriate for judicial determination," the High Court said.

MEDICINES AUSTRALIA

Medicines Australia says the High Court decision "potentially will have far ranging effects on other patents and future patents"

Medicines Australia chief executive officer Tim James said: "We will need to consider the implications of this decision for patents held by our member companies, a number of which are researching and developing new biological medicines."

"This could have significant negative impact on access to new and innovative biological medicines in the future," Mr James said. "Coupled with weak data protection being maintained in Australia under the recent [Trans-Pacific Partnership], these decisions are potentially bad news for patients."

Medicines Australia said the High Court decision related to particular claims within a specific patent, but it potentially had "far ranging effects on other patents and future patents held by the companies that discover, research, develop and bring new biological medicines to Australian patients".

AUSBIOTECH

Ausbiotech chief executive officer Dr Anna Lavelle opened the annual industry conference today welcoming Prime Minister Malcolm Turnbull's focus on innovation.

Dr Lavelle said she welcomed both the statement on innovation (BD: Sep 21, 2015) and the appointment of Christopher Pyne as the Minister for Industry, Innovation and Science.

Dr Lavelle said she expected to see "a shift in Federal policy" and said "we have seen bipartisan support for biotechnology and commercialization at the State level".

Dr Lavelle said there was "a lot of good news in life sciences and biotechnology" and noted the recent deals involving Hatchtech, Starpharma and Fibrotech, with the acquisition of Spinafex by Novartis "the biggest [venture capital] exit in Australian history".

"To me, we are in the midst of success and we need good public policy and private capital, Dr Lavelle said.

"Like Prime Minister Turnbull says, 'there's never been a better time to be an Australian' and there's never been a better time to be an innovator in Australia," Dr Lavelle said.

Dr Lavelle said that Ausbiotech had worked hard for fundamental system changes like the tax reform including the Research & Development Tax Incentive which was "really helping small companies in a non-dilutive way".

She said that Ausbiotech was continuing to discuss policy reforms including capital gains taxation breaks for patient long-term investors and intellectual property incentives.

VICTORIA GOVERNMENT

Dr Lavelle said that the lead host for the conference was the Victoria Government and introduced the secretary of the State Department of Department of Economic Development, Jobs, Transport and Resources Richard Bolt.

Mr Bolt told the conference that biotechnology and life sciences was "clearly a sector where things are going right" and the question for the Department was "how do we build on what we have achieved?"

Mr Bolt said that Victoria had a competitive biotechnology industry employing more than 20,000 people and generating more than $10 billion in revenue and was a focus and a priority for the State Government.

Mr Bolt said that the Department had issued discussion papers and received many submissions with many recommending "boldness, long-term vision and practical polices".

Mr Bolt said that the three priorities which would be discussed at the conference were clinical trials, drug discovery and medical technology devices.

PROF ALAN TROUNSON

The founder of the Hudson Institute of Medical Research Prof Alan Trounson told the Ausbiotech conference that Australia lagged on stem cell research.

The Hudson Institute is the result of the merger of the Monash Institute of Medical Research and the Prince Henry's Institute.

In a plenary session, entitled 'Regenerative Medicine: when are therapies going to arrive, Prof Trounson detailed the many companies undertaking a large number of trials of different types of stem cells for many different indications.

Prof Trounson said he wanted to bring a $US1.2 billion fund to Australia for translational research.

"We're a little behind here in Australian in regenerative medicine," Prof Trounson said.

He described pluripotent stem cells, induced pluripotent stem cells, limbal stem cells in use for corneal burns, neural stem cells for brain diseases, mesenchymal stem cells from bone marrow, fat and placenta, and haematopoietic stem cells, but described work being done with immune system stem cells as "the hottest area and we are at the very tail of the comet, not in the comet itself".

Prof Trounson said that there were many embryonic stem cell trials underway, "mainly for eye diseases as well as diabetes, heart failure, Parkinson's disease and spinal cord injuries".

He described a 2014 Japan study in a woman aged more than 70 years who had age-related macular oedema and 12 months following the insertion of a scaffold of induced pluripotent stem cells had reported progressive benefit.

Prof Trounson said that a great deal of work had been done in mice and rats but there were phase I and I human trials which had not yet reported results.

He said that Viacyte Inc was using human embryonic stem cells for type 1 diabetes and a subcutaneous capsule of pancreatic progenitor cells had been demonstrated to differentiate in-vivo, reducing blood glucose levels.

"It would be a major benefit even if it was not total control, due to the insulin reduction," Prof Trounson said.

"We invested $US54 million into this and they had other funds as well," Prof Trounson said.

Prof Trounson said that limbal stem cells had been collected from the edge of the eye, to repair damage, had been grown and re-implanted and had "a dramatic change between before and after" the procedure and were available in Europe.

Prof Trounson said that there were 374 mesenchymal stem cells trials on the US National Institutes of health database, excluding those of unknown status.

He said that most were in phase I or II with 6.7 percent reaching phase II and 0.3 percent in phase IV.

"There's a lot of loss in this space," Prof Trounson said.

Prof Trounson said that we don't know the mechanism of action but mesenchymal stem cells appeared to have efficacy for graft versus host disease, lower back pain and as a scaffold for bone repair and suggested the action might be through their anti-inflammatory responses.

Prof Trounson said that gene editing techniques had been shown to have an effect in Sickle cell disease and it was possible to cure HIV/AIDS if the CCR5 receptor could be disrupted.

Prof Trounson said that people with a mutation of the CCR5 gene can have the human immunodeficiency virus (HIV) but would not develop AIDS.

JOHNSON & JOHNSON

The University of Queensland's Prof Maree Smith, Ellume Pty Ltd and Spinifex have won this year's Johnson & Johnson Innovation awards.

Johnson & Johnson Australia and New Zealand managing-director Gavin Fox-Smith presented the awards at the Ausbiotech conference saying the J&J Innovation new ventures director Kathy Connell who could not present the awards as she was overseas.

Mr Fox-Smith said that Prof Smith won the Outstanding Leadership award for her work leading the Centre for Integrated Preclinical Drug Development at the University of Queensland.

Prof Smith said that her group had conducted 600 research and development studies for 200 clients over 10 years and that there was a strong pipeline to come.

"Kathy Connell is a tireless worker for discovery and translation," Prof Smith said.

The Emerging Company award went to Brisbane's Ellume for its "simple, highly sensitive and reliable diagnostics for infectious diseases" and linking the results to optimal therapy.

Ellume managing-director Dr Sean Parsons said that the work done since the company was created in 2010 would benefit "tens of millions of users" and would not have been possible without Federal and Queensland Government grants.

Dr Parsons also paid tribute to investors "placing big bets and being prepared to lose and people placing their careers on the line".

"Kathy [Connell's] enthusiasm is nothing less than a force of nature," Dr Parsons said.

Spinifex Pharmaceuticals won the Company of the Year award and outgoing chief executive officer Dr Tom McCarthy said that Prof Smith's intellectual property was the basis of the Spinifex technology, acquired earlier this year by Novaris (BD: Jun 29, 2015).

Dr McCarthy said the development of a treatment for chronic pain, acquired by Novartis, was the work of a team that included the funding agencies and he paid tribute to the late Dr Andrew Baker who was a director of Spinifex until his death (BD: Mar 19, 2012).

LBT INNOVATIONS

LBT says a pivotal trial of its automated plate assessment system (APAS) showed an overall sensitivity of more than 96 percent and all primary endpoints were exceeded.

LBT said the trial conducted at the Albuquerque, New Mexico-based Tricore Reference Laboratories tested the APAS technology against a panel of three microbiologists.

The company said that the trial formed part of its US Food and Drug Administration 510(k) de novo submission and the trial protocol and targets for the primary and secondary endpoints were set after consultation with the FDA.

LBT said that APAS achieved more than 98 percent sensitivity in its detection of disease-causing bacteria on two of the most widely-used culture media, the blood agar and MacConkey agar, a standard two-plate protocol for culturing urine specimens in US laboratories, in samples from 5,500 patients.

LBT said it was seeking FDA clearance for a manual version of the technology, while a robotic plate-handling system was simultaneously developed in Europe.

The company said that the integration of APAS with the robotic plate-handling system to create an automated plate reader to be known as APAS Independence was considered to be relatively straightforward and the final FDA hurdle would be a simpler 510(k) supplement to demonstrate that the culture plates were being correctly sorted.

LBT chief executive officer Lusia Guthrie said the results "far exceeded our expectations and confirm that our ground-breaking technology can match the performance of a highly trained microbiologist".

LBT was up 2.5 cents or 23.8 percent to 13 cents.

AVITA MEDICAL

Avita says it has Conformité Européenne (CE) mark authorization that will allow it to define and target its autologous cell suspension technology for particular indications.
Avita said that the approval followed and expanded the previous CE mark approval of Recell, primarily deployed for treating burns.
The company said that with the new CE mark, Recell would remain focused on acute wounds such as burns, with Regenercell targeting chronic wounds, such as venous leg ulcers and diabetic foot ulcers, and a third presentation, Renovacell aimed at the aesthetic arena, covering conditions linked to pigmentation, as well as scar revision.
Avita said that the three devices would vary in the size of wound they could cover, but would all deploy the same approach, converting a small sample of a patient's skin to create a regenerative epithelial suspension which had been shown to be effective in treating all three condition areas.
Avita chief executive officer Adam Kelliher said that the CE mark approval to introduce Regenercell and Renovacell to Europe would give "greater clarity to medical professionals who use our regenerative medical treatment".
Avita was up 1.6 cents or 17.0 percent to 11 cents with four million shares traded.

AVITA MEDICAL

The Australian Ethical Share Fund says it has decreased and been diluted in Avita from 43,700,257 shares (13.45%) to 42,061,582 shares (9.90%).
Australian Ethical said that it bought shares and sold shares between November 1, 2012 and October 1, 2015 with the single largest transaction the sale of 8,555,000 shares for $773,372 or 9.0 cents a share on September 30, 2015.

CLINUVEL

Lagoda Investment Manager, Fatima Dickey and Richard Bayles have increased their holding in Clinuvel from 2,264,713 shares (5.08%) to 2,717,149 shares (6.10%).
The substantial shareholder noticed said that the shareholders included "various clients of Lagoda", Merrill Edge, Oppenheimer, Fiduciary Trust, US Trust, JP Morgan, State Street, Brown Brothers, Northern Trust, Bank of New York Mellon, Wells Fargo and Fidelity.
The Columbus Circle, New York-based Lagoda said it acquired shares on-market between September 23 and October 2, 2015 at prices ranging from $2.66 to $3.00.
Clinuvel was up one cent or 0.4 percent to $2.80.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH
THE MEDICAL RESEARCH COMMERCIALIZATION FUND

The Walter and Eliza Hall Institute and the Medical Research Commercialization Fund will hold a one-day commercialisation symposium on October 13, 2015.
WEHI and the Brandon Capital-managed MRCF said that the symposium was "focussed on fostering broad discussion and debate on the challenges and opportunities facing our sector".
The 9am to 6.15pm free event will be held at the WEHI Seminar Room, Level 7, 1G Royal Parade Parkville, and will be followed by a networking reception and for more information go to: http://www.wehi.edu.au/catalysing-commercialisation-symposium.

ACTINOGEN MEDICAL

Actinogen says it will hold a symposium to discuss Alzheimer's disease including drug discovery and advances in clinical data driving renewed interest in the sector.

Actinogen said that the Sydney symposium, entitled 'Understanding Alzheimer's – from discovery research to patient treatment' would host experts in Alzheimer's disease to provide a better understanding of the disease, its treatment and the impact on patients.

The company said that Edinburgh University professor of psychiatry of aging and a member of its clinical advisory board Prof Craig Ritchie would presenting developments in treating the disease and the Garvan Institute's Dr Bryce Vissel would discuss research discoveries.

Actinogen said that the symposium would feature speakers from Eli Lilly and Alzheimer's Australia to discuss drug commercialisation and the patient experience, respectively, and Actinogen chief executive officer Dr Bill Ketelbey would discuss the company's lead drug candidate Xanamem.

The company said that the panel discussion would followed by a question and answer session and networking.

Actinogen said that the symposium would be held on Monday, October 12, 2015 from 4:30pm to 7pm (AEDT) at the Sofitel Wentworth Hotel, 61-101 Phillip Street, Sydney.

For further information and to register, email amurphy@buchanwe.com.au or telephone +612 9237 2804.

Actinogen was up 0.1 cents or 1.85 percent to 5.5 cents.