Biotech Daily

Wednesday April 27, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: LIVING CELL UP 4%; PHYLOGICA DOWN 9.5%**

*** IROKO ACQUIRES ICEUTICA FOR NANOTECHNOLOGY DELIVERY**

*** BIONIC EAR INSTITUTE LAUNCHES SIMPLE, CHEAP HEARING AID**

*** AVITA SAYS BURNS STUDY BACKS RECELL**

*** QRX COMPLETES PHASE III COMPARISON TRIAL ENROLMENT**

*** VIRALYTICS LODGES REPLY TO FDA HOLD LETTER**

*** NESTOR TAKES 6.4% OF GENERA**

MARKET REPORT

The Australian stock market fell 0.83 percent on Wednesday April 27, 2011 with the S&P ASX 200 down 40.9 points to 4872.9 points.

Seven of the Biotech Daily Top 40 stocks were up, 22 fell, six traded unchanged and five were untraded. All three Big Caps were down.

Living Cell was best, up 0.5 cents or 4.2 percent to 12.5 cents with 247,200 shares traded.

Phosphagenics climbed 3.45 percent; with Acrux, Optiscan and QRX up more than one percent.

Phylogica led the falls, down 0.7 cents or 9.5 percent to 6.7 cents with 4.8 million shares traded, followed by Antisense down 7.1 percent to 1.3 cents with 25.3 million shares traded.

Patrys and Prana lost more than six percent; Biota was down 5.45 percent; Circadian fell four percent; Cellmid, Sunshine Heart, Viralytics and Virax were down more than three percent; Alchemia, Cathrx, Clinuvel, Nanosonics, Starpharma and Tissue Therapies shed more than two percent; with Cochlear, Impedimed, Mesoblast and Pharmaxis down more than one percent.

ICEUTICA

Philadelphia-based Iroko Pharmaceuticals has acquired the Perth-founded Iceutica for its nanotechnology drug delivery platform technology.

In Melbourne, the chairman of both companies, Osagie Imasogie, and the chief executive officer of Iceutica Matt Callahan told Biotech Daily that they could not disclose the transaction value for the company with three drugs ready to begin phase III trials, but said it was in the range of $20 million to $100 million or a “10 times return on original value”.

Mr Callahan said that Iceutica would become a division of Iroko, which would fund the trials of the three nanotechnology-delivered non-steroidal anti-inflammatory drugs.

Mr Imasogie said Iroko had “more than enough” in cash to fund the trials.

Mr Imasogie said that Iroko had spent $US450 million on assets in four years and was continuing to look for acquisitions.

He said he particularly liked the Australian approach to research and development as it was different to the US.

“It is off the beaten path technology and gives a competitive advantage,” Mr Imasogie said.

“It’s a different way of seeing,” he said.

Mr Imasogie said he was a graduate of the London School of Economics and the University of Pennsylvania and prior to founding Endo Pharmaceuticals was an intellectual property and corporate lawyer.

From a partnership at Price Waterhouse, Mr Imasogie said he was appointed by Du Pont Pharma as vice-president of international sales and marketing.

Mr Imasogie said that Endo was created around a management buy-out of 33 products to become a $US4 billion publicly-traded company, of which he was a co-founder and general counsel.

Mr Callahan said that Iceutica acquired the nanotechnology delivery intellectual property from the University of Western Australia for a “less than five percent equity stake” and rather than licence the platform, created a business that developed specific uses and licenced the resultant drug.

He said the company was created in 2005 with the support of US and Australian investors led by Phoenix IP Ventures based in Philadelphia, Pennsylvania.

Mr Callahan said the reformulation of existing drugs into nano-particles allowed the drug to be safer, faster, consumed without food and use less active ingredient than the original drug, while retaining all its treatment benefits.

He agreed that it was a similar method to Mayne Pharma’s ‘super generic’ development path.

Mr Callahan said the company also had another non-steroidal anti-inflammatory drug in a phase II trial and muscle relaxant in a phase I trial.

He said the chief scientific officer Dr Bill Bosch was formerly with the Ireland-based Elan Corp and had developed a dry-milling process suited for a dry-powder formulation.

“We don’t change the chemical of the drug. We change the size so that it dissolves more rapidly,” Mr Callahan said.

He said that non-steroidal anti-inflammatory drugs required the minimum dose for the shortest possible time and his company’s products were superior to the originals.

Mr Callahan said the platform technology was not suitable for licencing, but was better applied to products which could then be licenced.

Mr Callahan said it was “nearly impossible for Australian companies to take drugs from start to end” and his company created value by delivering on milestones so that investors would continue providing sufficient capital for the next stage of development.

Iceutica is a private company.

BIONIC EAR INSTITUTE, AUSTRALIAN HEARS, DYNAMIC HEARING

Melbourne's Bionic Ear Institute has launched Dynamic Hearing's small, self-managed hearing aid claiming it will be less than half the price of conventional hearing aids.

In a media release the Institute said the hearing aid was produced by Dynamic Hearing a company established by its deputy director Dr Peter Blamey.

The institute said it used adaptive dynamic range optimization (ADRO) technology first developed for the bionic ear and was "so simple to set up that most users can buy one over the internet and fit it themselves".

The Institute said the units cost between $1,000 and $1500 each and users could fine-tune and switch settings to suit the home, work, or noisy recreational environments.

The media release said Dr Blamey invented one of the hearing aid's core technologies and said it was "the culmination of nearly 12 years of research and development supported at key stages by the Australian Government".

"In 1998 we created digital technology for the bionic ear that allows the user to boost or reduce key frequencies so that all the important sound frequencies for hearing are at a comfortable level," Dr Blamey said.

"We realised that this technology … could help not only people who are deaf, but anyone with hearing loss and we created a company, Dynamic Hearing, to commercialize it," Dr Blamey said.

The media release audiologist Elaine Saunders co-founded Australian Hears with Dr Blamey and the company created a new business model for hearing aids, to make the technology more easily available.

"We have a generation of middle-aged Australians whose quality of life has already been affected by hearing loss due to loud music or occupational noise," Ms Saunders said.

The Institute said the hearing aid was easy to purchase online and came already adjusted, based on a hearing test or by six questions answered online.

A spokesman for Australia Hears said the hearing aid options included being placed in the ear canal or worn externally around the outer ear.

More information is at: http://www.australiahears.com.au.

AVITA MEDICAL

Avita says a pilot clinical study of four patients with deep dermal flame burns to their legs "healed quickly" following treatment with its Recell would treatment.

Avita said Recell was used in combination with a biological dressing and the patients "were able to return to work and activities of daily living with relative ease".

The company said the study entitled 'Biobrane and Recell for the Treatment of Deep Dermal Burns to the Leg - A Comparative Pilot Study' was presented at the British Burns Association meeting in March by principal investigator Dr Jeremy M Rawlins of the Yorkshire Regional Burn Centre and Department of Plastic Surgery.

Avita did not provide the data from the presentation.

"This comparative pilot study using Recell and a biological wound dressing in combination has shown a number of benefits compared to standard skin grafting techniques," said Dr Rawlins.

"In the Recell and biological dressing group early, surgical intervention allowed better dermal salvage with the use of the cell based therapy and biological dressing," Dr Rawlins said.

"These techniques result in less pain for the patient, a smaller donor site, faster wound healing and better scar outcomes," Dr Rawlins said.

Avita was unchanged at 13.5 cents with one million shares traded.

QRX PHARMA

QRX says it has completed enrolment in its phase III trial comparing Moxduo immediate release (IR) to equi-analgesic doses of morphine or oxycodone.
QRX said the tolerability and safety profile trial, known as study 022, would evaluate the incidence of opioid-related adverse events, including changes in respiratory function, moderate to severe nausea, vomiting and dizziness in patients with moderate to severe postoperative pain following bunionectomy surgery.
The company said the trial enrolled 375 patients with 125 patients in each treatment group at five US clinical research sites.
QRX said it expected to release top-line data in June 2011.
QRX chief executive officer Dr John Holaday said the trial was “a major milestone” as it is the first comparison of Moxduo IR which was a combination of 12mg morphine and 8mg oxycodone to separate equi-analgesic doses of morphine and oxycodone.
“With patient enrolment complete, we are optimistic that the pending results will confirm the significant tolerability and safety advantages of Moxduo IR over these two widely prescribed opioids,” Dr Holaday said.
QRX said a prior comparator study in patients experiencing acute postoperative bunionectomy pain demonstrated the potential side effect and safety benefits of MoxDuo IR (6mg/4mg) when compared to equi-analgesic doses of morphine (12mg) or oxycodone (8mg).
The company said that the occurrence rate of moderate to severe adverse events including nausea, vomiting and dizziness was reduced by 50 to 75 percent in Moxduo IR treated subjects compared to patients receiving morphine or oxycodone alone at the same 12mg morphine equivalent dose.
QRX said the phase III study 022 was similarly designed, but compared Moxduo IR (12mg/8 mg) with equi-analgesic doses of morphine (24mg) and oxycodone (16mg).
The company said that it designed the trial to include about 40 percent of the enrolled subjects aged 60 years or older, providing evaluation of the tolerability of the three treatments in this age group.
QRX said the trial results would form part of its European Marketing Authorisation Application scheduled for submission by April 2012 and said the results, when published in medical literature, could be a component of the promotional package following the projected commercial launch of Moxduo IR in the US in 2012 and in Europe in 2013.
QRX was up two cents or one percent to $2.00.

VIRALYTICS

Viralytics says it has lodged a reply to the questions raised by the US Food and Drug Administration following the initial review of its investigational new drug application.
Viralytics said the reply was known as a ‘Complete response to clinical hold letter’ would be reviewed by the FDA, which had 30 days from the date of lodgment to either remove the current clinical hold, allowing the company to proceed with its planned phase II intra-tumoral 54 patient melanoma trial or ask Viralytics further questions or require clarification and/or request additional information.
The company said that if the FDA was not fully satisfied with the information supplied or further questions were raised by the additional information Viralytics supplied, the FDA may ask additional questions while maintaining the clinical hold.
Viralytics fell 0.2 cents or 3.9 percent to 4.9 cents.

GENERA BIOSYSTEMS

Nestor Investment Management has increased its substantial shareholding in Genera from 3,378,507 shares (5.39%) to 4,516,865 shares (6.44%).

The substantial shareholder notice from the Grand Duchy of Luxembourg said Nestor Investment Management acquired 600,000 shares for Nestor Australien Fonds on April 6, 2011 for $200,622 or 33.4 cents a share.

Genera was unchanged at 25 cents.