Biotech Daily

Wednesday March 28, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PSIVIDA UP 32%, LIVING CELL DOWN 6%**

*** MONASH UNI ADVANCES INNOVATION INTEGRATION COLLABORATION**

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*** IM RADIOLOGY SALE RETURNS $2.4m TO SHAREHOLDERS**

*** NEURO ORTHOPAEDIC ADELAIDE PAIN CONFERENCE**

MARKET REPORT

The Australian stock market was up 0.98 percent on Wednesday March 28, 2012, with the S&P ASX 200 up 42.2 points to 4,343.5 points.

Eighteen of the Biotech Daily Top 40 stocks were up, eight fell, six traded unchanged and eight were untraded.

Psivida was the best, up 52 cents or 31.9 percent to $2.15 with 70,672 shares, following last night's 36.45 percent rise on the Nasdaq to $US2.497 with 872,943 shares traded.

Cellmid climbed 9.1 percent; Alchemia and Biota were up more than eight percent; QRX was up 7.5 percent; Benitec, Ellex, Genera and Starpharma rose more than five percent; Neuren and Prima were up more than four percent; Reva was up 3.3 percent; Avita, Bionomics, Mesoblast and Viralytics rose more than two percent; CSL was up 1.9 percent; with Nanosonics and Pharmaxis up by less than one percent.

Living Cell led the falls, down half a cent or 5.9 percent to eight cents with 18,000 shares traded.

Antisense and Uscom fell five percent or more; Phosphagenics fell 4.1 percent; Tissue Therapies was down 3.5 percent; Resmed was down 1.6 percent; with Acrux, Cochlear, Sirtex and Universal Biosensors down by less than one percent.

MONASH UNIVERSITY INDUSTRY ENGAGEMENT UNIT

A conference organized by Monash University has been told that a deeper and broader integration of academia and industry could “ramp up medical technologies”.

Hosted by Monash University’s Industry Engagement and Commercialisation Unit the conference in Melbourne, entitled ‘Developing a global Medtech pipeline through public private partnerships at Monash’, was told that the Boston Massachusetts-based Centre for the Integration of Medicine and Innovative Technology (CIMIT) was a model of linking institutions.

Monash University’s research and research infrastructure program director Dr David Lester told the conference that CIMIT linked all the major Boston institutions including Harvard and Boston Universities, and was linked to hubs in Manchester England and Singapore.

Dr Lester said the result was more than 500 innovative products, impact on more than 10,000 patents and 700 peer-reviewed publications, with 36 health care companies formed or affected by the collaboration.

Dr Lester said there was no clear unbroken pathway from discovery or invention to commercialization in Australia “especially in applied research”.

“Monash Medtech can bind disparate centres together,” Dr Lester said.

Dr Lester said that CIMIT was moving from being a hub to a global network of hubs.

Dr Lester said that with an open innovation system allowing information sharing and a resource program along with the cooperation of government institutions and industry would drive the innovation industry.

Monash chancellor Dr Alan Finkel told the conference that one study of 35,000 research papers showed that there was an increase of 45 percent in citation rate when collaborators where in the same building, but at the same time, there was evidence that increased international collaboration increased the impact of research and this conundrum needed to be attacked on multiple fronts.

“Universities can foster links between academia and industry,” Dr Finkel said.

The director of the Monash Vision Group Prof Arthur Lowery said that the bionic eye project developing a camera sending signals to a brain implanted electrode “needs a huge team of people in physiology, surgery, patient recruitment, electrical engineering, robotics, electronic engineering, mechanical materials engineering, mathematicians, immunology, management, commercialization, regulatory approval, financial and marketing”.

“What is the bionic eye? An implant that goes into someone’s brain for 20 years,” Prof Lowery said. “But what we are really doing is building a team of academics and industry professionals [fostering] friendships and networks to allow us to go onto the next projects.”

The chief executive officer of Minifab Dr Erol Harvey told the conference that Australia needed to aim to be “successful in a high cost environment” and compete not with cheap manufactured goods, but with technology from Switzerland, Denmark, Sweden and Norway.

Dr Harvey said the Swiss Franc had risen faster than the Australian dollar but exports increased because “people want to buy their products”.

He said living in Australia was “a non-rational decision” made by people who like living here so the answer is “to create an environment that can compete … [with] products and services of high performance, quality and value”.

Dr Harvey said that a company required loyal, knowledgeable employees, strategic alignments with customers, decentralized business structure, focus, depth and integrated innovation.

“If the cluster affects none of these, it is irrelevant. If it affects only one of these it is a distraction, but If it affects two or more then it becomes key to our process,” Dr Harvey said. Dr Harvey said the challenge was to recruit and motivate the leadership team.

The head of Monash’s Ritchie Centre for Translational Medicine and a collaborator with Mesoblast Prof Euan Wallace said that the work on stem cell therapies was an example of industry requiring the assistance of research to turn placental cells into neurons, muscle and bone “and we demonstrated we could, opening a pathway to a whole range of regenerative medicine”.

Prof Wallace said the Victorian Consortium for Cell-based Therapies included universities, research institutes, health partners and industry, such as the Monash Institute of medical Research, Melbourne’s St Vincent’s Institute, the Burnet Institute, Southern Health and the Australian Red Cross.

Leica Microsystems innovation manager Luke Restorick told the conference that his company specialized in cancer diagnostics and had developed high cost and high quality advanced staining systems, as well as reagents and equipment for histopathology laboratories and research sample preparation and had benefited from academic and industry partnerships.

“We can give guidance on the regulatory environment to academic and funding bodies and a commercial perspective on the path to market,” Mr Restorick said.

Mr Restorick said the company fostered the entrepreneurial spirit and combined thinkers and doers under one roof to create “an ivory castle with a factory floor”.

Monash Faculty of Medicine Nursing and Health Sciences research translation director Prof John Morrison told Biotech Daily that the meeting was intended “to get people talking about open innovation, collaboration, funding and leveraging international networks”.

David Langsam
Editor

BIOTA

Biota's phase IIb study of the BTA798 oral antiviral for naturally acquired human rhinovirus infection in asthmatics had a statistically significant reduction in cold symptoms.

Biota said that "the successful completion of the phase II study delivers a major milestone in the development of BTA798 and establishes the basis for the further development of the product" and it would begin work on the design of phase III studies of BTA798 or vapendavir, with detailed findings from the phase II trial provided to potential commercial partners over the next few months.

Biota chief executive officer Peter Cook said the outcome of the phase II human rhinovirus (HRV) study was extremely positive.

"This trial not only represents a valuable step in the successful delivery of one of Biota's key programs but it is also a unique accomplishment in the field of antiviral development," Mr Cook said.

"While the clinical link between HRV infection and loss of asthma control is now widely accepted, Biota is the first company to evaluate the use of an antiviral to treat the infection in asthmatics," Mr Cook said.

"This has the potential to be of considerable benefit to sufferers through better control of their asthma," Mr Cook said.

Biota chief financial officer Damian Lismore told Biotech Daily that the trial cost $18 to $19 million compared to the estimated $25 million.

Mr Lismore said that the phase III trial would cost "up to $300 million" which was why Biota was looking to partner the drug.

Mr Lismore said that BTA798 was "not a specialized drug" and was "more suited to a big pharma" to develop.

Biota said the multicenter, randomized, double-blind, placebo-controlled trial in asthmatic adults with symptomatic, naturally acquired human rhinovirus infection was conducted over two consecutive seasons in 48 centres in the US.

The company said that subjects received 400mg of BTA798 or placebo twice daily for six days, with 300 subjects enrolled of which, 93 were confirmed HRV A, B or C infected and 85 fully complied with the study protocol.

Biota said the primary endpoint used the Wisconsin Upper Respiratory Symptom Survey to assess cold symptoms for 14 days, with high scores a predictor of deterioration in asthma control. Other measures were lung function, asthma control and virology.

Biota said that the primary efficacy parameter was the mean daily difference in WURSS-severity score over days two to four, the anticipated peak of the infection.

The company said that BTA798 treatment resulted in a statistically significant reduction in the severity of cold symptoms when compared to placebo ($p = 0.028$) and the WURSS scores also showed a statistically significant improvement in mean daily difference over the longer period of days two to 14 ($p = 0.001$).

Biota said that BTA798 appeared to be effective in all HRV types and treated subjects improved earlier with peak symptoms at 1.7 days compared to 2.5 days ($p = 0.036$).

The company said that lung function evening peak expiratory flow was significantly higher in the treated group on day 5 ($p = 0.023$) and there was a reduction in the use of asthma reliever medication showing a positive trend toward improvement in the BTA798 group as early as day three and reached statistical significance on day 13 ($p = 0.045$).

Protocol compliant BTA798 treated subjects showed a statistically significant lower incidence of virus infection (74.4%) compared to placebo (91.4%) on day three, as measured by PCR of nasal swabs ($p = 0.025$).

There were no serious adverse events and generally BTA798 was well tolerated.

Biota was up seven cents or 8.1 percent to 93 cents.

PSIVIDA

Psivida has republished an Alimera Sciences US filing that it expects final European approvals for Iluvien for diabetic macular oedema to be delayed by three to six months.
Psivida and Alimera told the US Securities and Exchange Commission and the ASX that delays had been observed with other drugs approved by the UK Medicines and Healthcare Products Regulatory Agency final assessment report and member country approvals.
Alimera said the new timetable for marketing authorizations was by July and October 2012, compared to previous expectations that the approvals would be concluded by April 2012.
In February, Psivida said the UK Medicines and Healthcare Products Regulatory Agency issued licencee, Alimera Sciences a final assessment report along with the agreement of the concerned member states that Iluvien was approvable (BD: Feb 29, 2012).
Psivida said at that time that the regulatory process would enter the national phase in which the reference member state and each concerned member state including Austria, France, Germany, Italy, Portugal and Spain granted a national licence.
Today, Psivida republished a filing by Alimera saying that “based on recent discussions with European regulatory authorities and Alimera’s regulatory consultants in Europe, Alimera believes that it will take longer than originally anticipated to obtain marketing authorizations for Iluvien from the seven countries in which Alimera filed for such authorization.
Alimera restated that the final assessment report said that each of these countries had reached a consensus that Iluvien was approvable.
Alimera said that although the decentralized procedure members states’ standard operating procedure provided that each country should adopt a national decision within 30 days after final assessment report, “given the amount of time regulatory authorities in these countries have taken recently with respect to other drugs between the issuance of a [report] and the issuance of formal marketing authorizations, Alimera now believes that these authorizations likely will be issued in the second and third quarters of 2012, although one or more countries could take longer”.
Alimera said it did not expect that the projected timing of the formal marketing authorizations would delay the availability of Iluvien in Europe, expected by the end of 2012.
Psivida climbed 52 cents or 31.9 percent to $2.15 with 70,672 shares, following last night’s 36.45 percent rise on the Nasdaq to $US2.497 with 872,943 shares traded.

ALLIED HEALTHCARE GROUP

The Metal Group, Avexa through subsidiary AVI Capital and McRae Technology have had their substantial shareholdings in Allied Health diluted through a placement at 2.8 cents.
In a series of change of substantial shareholder notices filed by Allied Health, the Metal Group – associated with Western Australian miner Andrew Forrest - has increased its substantial holding but been diluted in Allied from 90,647,712 shares (15.94%) to 106,719,141 shares (14.69%).
Avexa through AVI retained 103,500,000 shares and was diluted from 15.76 percent to 14.24 percent.
The Western Australia-based McRae Technology said it increased and was diluted from 74,027,712 shares (13.03%) to 77,779,141 shares (10.70%).
Allied Health was unchanged at 2.9 cents.

ISONEA

Isonea says it has begun a post-market study of the Wheezometer monitoring technology to assess wheeze rate in pediatric patients with a range of asthma symptom severity.
Isonea said that the Wheezometer had been studied, but this was the first large US study of the device in a pediatric population.
The company said the study would include patients who were too young to be tested with spirometry, a traditional measuring technique used in older children and adults.
Isonea said the study was planned for two locations and had begun enrollment in Folsom, California.
Isonea said the trial was registered with the site www.clinicaltrials.gov which said there would be 95 patients in the trial.
Isonea said the Wheezometer used acoustic sensors and signal processing software to establish the presence, frequency and severity of wheeze.
Isonea medical director for Dr Jonathan Freudman said that asthma “impacts more than seven million children in the United States and the number of children expected to be diagnosed with this chronic condition continues to climb at alarming rates”.
“This study is an important milestone for Isonea,” Dr Freudman said.
“In the pediatric asthma population, it is challenging to accurately monitor and manage asthma symptoms in patients using conventional techniques,” Dr Freudman said.
“The Wheezometer has the potential to meet a critical unmet need for better, easy to use monitoring tools for young asthma patients,” Dr Freudman said.
Isonea was unchanged at 0.4 cents with 39.3 million shares traded.

PROBIOMICS, HUNTER IMMUNOLOGY

Probiomics says that Phillip Asset Management, as IB Australia Bioscience Fund, is its single largest shareholder with 31,355,427 shares or 20.92 percent of the company.
Probiomics and Hunter Immunology have merged and expect to relist next week.
Probiomics said Wigram Trading held 14,357,626 shares 9.58 percent; Cherryoak Investments held10,003,059 shares or 6.67 percent; PT Soho Industri Pharmasi held 9,678,085 shares or 6.46 percent; Prof Robert Clancy and Christine Clancy held 9,564,390 shares or 6.38 percent; with the University of Newcastle holding 4,680,000 shares or 3.12 percent.
Probiomics last traded at one cent.

IM MEDICAL

IM Medical says it has completed the sale of its radiology business to Capitol Health and will receive 45,559,021 Capitol Health shares.
IM Medical said the Capitol shares would be distributed on a pro-rata basis to eligible shareholders on the record date of April 5, 2012, as a return of capital of about $2,414,000 or 0.291 cents per IM share.
The company said it had 828,364,092 shares on issue.
IM Medical was up 0.2 cents or 40 percent to 0.7 cents with 2.8 million shares traded.

THE NEURO ORTHOPAEDIC INSTITUTE

The Neuro Orthopaedic Institute will host a conference on the science and treatment of pain in Adelaide from April 26 to 28, 2012.

The Adelaide-based publisher the Neuro Orthopaedic Institute said that the 'Neurodynamics and the Neuromatrix conference' has attracted about 500 medical professionals, including physiotherapists, doctors, psychologists, psychiatrists, anatomists, and occupational therapists.

The Institute said that leaders on pain treatment would deliver workshops and keynote presentations over the weekend on the latest science as well as wider topics such as taste and pain - the way something tastes can change your pain experience and how Latin dance is being used as effective pain therapy.

The Institute said that the conference would be held at the Adelaide Convention Centre and further details were available at http://noi2012.com.