Biotech Daily

Tuesday March 20, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 7%, LIVING CELL DOWN 14%**

*** PATRYS PHASE I TRIAL SHOWS PAT-SM6 SAFE, TARGETS TUMORS**

*** HEALTHLINX REACHES SOUTH KOREAN OVPLEX SAMPLE TARGET**

*** LIVING CELL SHARE PLAN TO RAISE $3m FOR NTCELL**

*** AUSTRALIAN ETHICAL TAKES MORE THAN 100% PROFIT ON AVITA**

*** CORRECTION: REVA**

*** NOVOGEN, MARSHALL EDWARDS 2-FOR-1 RIGHTS ISSUE**

*** DR ROGER ASTON REPLACES IDT DIRECTOR DR GEOFFREY VAUGHAN**

*** NAOMI HAYDARI REPLACES RESONANCE CFO COLIN MCDONALD**

*** EXPLAINING ACRONYMS: CHESS DEPOSITARY INTERESTS**

MARKET REPORT

The Australian stock market fell 0.37 percent on Tuesday March 20, 2012, with the S&P ASX 200 down 15.8 points to 4275.0 points. Eight of the Biotech Daily Top 40 stocks were up, 19 fell, 11 traded unchanged and two were untraded.

Impedimed was the best, up 3.5 cents or 7.1 percent to 52.5 cents, with 66,000 shares traded, followed by Benitec up 5.6 percent to 1.9 cents with 1.9 million shares traded.

Anteo climbed 3.8 percent; Patrys, Phylogica and Tissue Therapies rose more than two percent; Genetic Technologies and Nanosonics were up more than one percent; with Resmed up 0.7 percent.

Living Cell led the falls, down 1.4 cents or 14 percent to 8.6 cents with one million shares traded.

Circadian lost 6.7 percent; Psivida was down 5.2 percent; Antisense fell 4.35 percent; Allied Health, Bioniche, Clinuvel, Neuren and Reva were down more than three percent; Bionomics, Ellex and Sunshine Heart shed more than two percent; Cochlear, Heartware, Sirtex and Starpharma were down more than one percent; with Acrux, Biota, CSL, Mesoblast and Pharmaxis down by less than one percent.

PATRYS

Patrys says that data from its nine-patient, phase I, melanoma trial shows “uniform evidence for PAT-SM6’s safety … [and] supporting its ability to specifically target melanoma tumors”.

Patrys chief executive officer Dr Marie Roskrow told Biotech Daily that although the trial was not designed to show efficacy, there was evidence of apoptosis in the tumor samples and evidence in the same samples of SM6.

Patrys said the primary objective was to establish safety and tolerability and no significant safety issues were observed or reported for any patients treated with PAT-SM6 during infusion, immediately following dosing, or during the month-long follow up period.

The company said that all patients completed the trial without incident and were eligible for assessment.

Patrys said that blood samples collected during the trial confirmed that no patient generated a significant adverse immune response to PAT-SM6, which was an important finding as adverse immune reactions to existing marketed antibodies was known to limit the effectiveness of those treatments.

The company said the provided additional support for the decision to ensure the natural human properties of the antibodies were preserved throughout development, by advancing production through the manufacturing human cell line PER.C6.

Patrys said that additional blood samples were assessed for pharmacokinetic parameters, such as drug half-life, to provide information for the design of dosing regimens for the next PAT-SM6 trial for patients with the blood cancer, multiple myeloma.

The company said that pre-dose and post-dose melanoma tumor samples from the final cohort were also examined.

Patrys said that despite the low dose of PAT-SM6 relative to expected therapeutic dose levels, an increased level of cancer cell death or apoptosis was observed to be widespread in one of the patient’s post-treatment samples, compared to the same patient’s pre-treatment specimen.

Dr Roskrow said the data was “very exciting and provides a glimpse into the promise of Patrys’ unique pipeline which is based on natural human antibodies like PAT-SM6”.

“The safety of PAT-SM6 as demonstrated in this trial and the additional information we have gathered lays the groundwork for our upcoming multi-dose study in patients with multiple myeloma,” Dr Roskrow said

“These data represent a significant milestone for Patrys and strengthens our position as a clinical stage cancer development company,” Dr Roskrow said.

Patrys said that in addition to the completed phase I trial, it had completed an additional multi-dose animal toxicology study to further support human trials and the pool of data on PAT-SM6.

The company said that no adverse effects were observed in non-human primates, despite the very high doses administered.

Patrys said that the doses were many times the expected maximum therapeutic dose that would be used to treat humans and created a significant safety margin for dosing in future trials.

The company said that PAT-SM6 was a natural human antibody that had shown promise as a potential treatment for multiple types of cancer including solid tumors such as melanoma and multiple myeloma.

Patrys said it was the first reported clinical product to target the GRP78 protein on the surface of cancer cells, which played “a number of key roles in cancer cell survival, growth and metastasis”.

Patrys was up 0.1 cents or 2.8 percent to 3.7 cents with two million shares traded.

HEALTHLINX

Healthlinx says it has recruited its minimum 220 patient samples for a pivotal Korean Food and Drug Administration study for approval for Ovplex.
Healthlinx said the samples had been sent to Seoul Clinical Laboratories its commercial partner for South Korea for storage and coding prior to the study commencing.
The company said that measurement of the Ovplex markers was expected to take place over the next four weeks and data would be analyzed in a double-blind case history prior to the sample code being released by Mosaic Medical which was acting as trial coordinators, with full data analysis and reporting expected within three weeks of receiving the decoded data set.
Healthlinx said that the trial outcomes would be reviewed by the principal investigator Samsung Medical Center's Prof Byoung-Gie Kim, followed by a formal submission to the Korean Food and Drug Administration.
The company said that Seoul Clinical Laboratories was co-funding the study and on successful completion, would obtain an exclusive licence to distribute Ovplex in South Korea.
Healthlinx managing director Nick Gatsios said that the study was "a critical element in value creation for the company and its assets and, upon a successful outcome, Ovplex will have entered a sixth jurisdiction with full regulatory registration".
He said Seoul Clinical Laboratories would work towards obtaining Health Industry Representatives Association registration to allow the product to obtain reimbursement from government and insurance companies.
Healthlinx said that the South Korean market for ovarian cancer diagnostics was about 250,000 tests a year, with the disease experiencing a 15 percent annual growth.
Healthlinx was unchanged at 0.9 cents with 2.8 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell hopes to raise $3 million through the issue of shares at a 15 percent discount to the five-day volume weighted average price before the closing date of April 23, 2012.
Living Cell said shareholders eligible at the record date of March 19, 2012 would be able to apply for parcels of shares from $1,000 to $15,000.
Living Cell head of finance and administration John Cowan told Biotech Daily that the company hoped to raise $3 million, but more would be welcome.
The company said the capital raised in the plan would be used to conduct clinical trials with NTCell in Parkinson's disease, to perform further research and development on NTCell in other neurodegenerative diseases and for operating expenses.
Living Cell fell 1.4 cents or 14 percent to 8.6 cents with one million shares traded.

AVITA MEDICAL

Australian Ethical Smaller Companies Trust has reduced its share-holding in Avita from 36,088,191 shares (15.15%) to 33,666,080 shares (14.13%).
Australian Ethical said the 2,422,111 shares were sold for $529,257 or an average price of 21.85 cents a share.
Australian Ethical acquired 2,394,085 Avita shares in December at about 10.5 cents a share and acquired 2,394,085 shares in November at an average price of 9.8 cents a share (BD: Nov 3, 2011, Jan 22, 2012).
Avita was unchanged at 23 cents.

REVA MEDICAL

Last night's edition reported that Elliott Management had agreements to buy $US24 million ($A22.64 million) of Reva's Australian and US shares from existing shareholders.
Today, Reva executive chairman Bob Stockman told Biotech Daily that Elliott was the lead investor in a group of buyers that included Medtronic, already a major shareholder in Reva and the group as a whole would have about 13.8 percent of Reva's stock.
Mr Stockman clarified the announcement saying that Elliott, and other shareholders including Medtronic, participated in the transaction independently of each other.
The transaction was expected to close by March 23, 2012.
Mr Stockman confirmed that the total number of shares in the transaction will be about 13.8 percent of Reva, but they will not all be held by Elliott and any associated entities.
Reva had about one million shares traded and not 6.1 million as reported.
The errors were made by the recently departed sub-editor, whose mathematical computations were accurate, but failed to understand an announcement written by lawyers, compounding the errors with poor transcription skills.
Reva fell 2.5 cents or 3.8 percent to 64 cents.

NOVOGEN

Novogen says 57 percent subsidiary Marshall Edwards will offer an $US8 million ($A7.5 million) two-for-one share rights issue at 89 US cents per share of common stock.
Marshall Edwards said that each subscription right entitled holders to half a share and one quarter of a warrant over new shares, meaning that every two new shares would come with one attaching option, exercisable at $US1.19, within five years.
Marshall Edwards said the record date was March 30, the offer opened on April 6 and closed on May 11, 2012.
In February Novogen said it would bid for up to $US4 million worth of shares in the Marshall Edwards rights issue (BD: Feb 22, 2012).
The company said that Marshall Edwards intended to use the proceeds to continue the clinical development of its two lead oncology drug candidates, ME-143 and ME-344.
Novogen was up one cent or 11.1 percent to 10 cents.

IDT AUSTRALIA

IDT says it has appointed former Mayne Pharma chairman and chief executive officer Dr Roger Aston as a non-executive director, effective from today.
IDT said that Dr Aston had experiences and skills in the pharmaceutical industry that would assist the company.
IDT said that prior to Mayne Pharma (originally Halcygen) Dr Aston was the chairman of Ascent Pharmaceuticals and had been the chief executive officer of public listed pharmaceutical and biotech companies and has served as chairman on a number of those companies' boards.
Dr Aston has previously served as Peptech's chief executive officer, was an executive director of Psivida and the executive chairman of Clinuvel in its transition from Epitan.
IDT said that Dr Geoffrey Vaughan would retire as a non-executive director, effective from June 30, 2012, having has served as a director since 1986 except for a four-year period when he was national manager of the Australian Therapeutic Goods Administration.
IDT was unchanged at 33 cents.

RESONANCE HEALTH

Resonance says and Naomi Haydari will replace Colin McDonald as chief financial officer and company secretary, effective immediately.
Resonance was untraded at 1.5 cents.

CHESS DEPOSITARY INTERESTS

Biotech Daily has seen a number of different meanings for the commonly used acronym of 'CDI' in relation to off-shore shares traded on the ASX.
It is no wonder that there is some confusion over what the acronym means when a simple Google search finds one leading ASX reference under the title 'Foreign entity data' describing them as CHESS Depository Instruments (note the second "o" in depository) (CDIs), while an Australian Tax Office document says they are Chess Depositary (note the "a") Instruments, and the first Australian Securities and Investments Commission (ASIC) document in the search describes them as "CHESS Depositary (with an "a") Interests.
An ASX published document entitled 'CHESS – Understanding CHESS Depository [with a second "o"] Interests', discusses them throughout as CHESS Depositary [with an "a"] Interests: http://www.asx.com.au/documents/resources/chess_depository_interest.pdf.
Biotech Daily's Oxford English Dictionary helpfully defines 'depositary' as a person with whom a thing is deposited, as compared to 'depository' which is a storehouse and equals 'depositary'.
According to the ASX document, the Clearing House Electronic Subregister System (CHESS) is an ASX computer system that manages the settlement of transactions and facilitates the paperless transfer of legal title to quoted products.
The ASX document said that the System could not be used directly for the transfer of financial products of issuers domiciled in countries whose laws do not recognize uncertificated holdings or electronic transfer of legal title or foreign financial products.
To overcome this difficulty, the ASX said it had developed a depositary receipt known as a CHESS Depositary Interest (CDI) allowing investors to obtain the economic benefits of foreign financial products without actually holding legal title to those financial products.
The ASX said that CDIs also enabled investors to hold and transfer their interests in foreign financial products electronically via CHESS, which they would be unable to do if they held the foreign financial products directly.
The ASX said that depositary receipts were found in other jurisdictions, for example American depositary receipts (ADRs) in the US, but ASX CDIs were different from other forms of depositary receipts.
Biotech Daily has adopted the house style that Clearing House Electronic Subregister System Depositary Interests shall be described as Chess depositary interests or CDIs.
We hope this clears up the confusion.