Biotech Daily

Wednesday November 7, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRIMA UP 12.5%, BIONICHE DOWN 11%**

*** BIOTECH DAILY'S 7th BIRTHDAY**

*** SENZ BEGINS PHASE I/II TRIAL OF VAL-1000 FOR ACUTE LEUKAEMIAS**

*** ALLIED WINS $2m ARCOMED INFUSION CONTRACT**

*** NOVOGEN'S MEI DATA SHOWS HIGH MDS RESPONSE RATES**

*** MEDICAL DEVELOPMENTS TO SUPPLY ASTHMA SPACER TO CANADA**

*** PATRYS ENROLS 1st MULTIPLE MYELOMA TRIAL PATIENT**

*** ELLEX TO LAUNCH NEW EYE PRODUCTS AT CHICAGO CONGRESS**

*** BIOTA EARNS $4.2m R&D TAX CREDIT**

*** BRUCE MATHIESON INCREASES TO 8% OF MAYNE**

*** RESONANCE FERRISCAN CLOSER TO REIMBURSEMENT**

*** QRX FACES 20% OPPOSITION ON REMUNERATION, DIRECTOR OPTIONS**

MARKET REPORT

The Australian stock market was up 0.71 percent on Wednesday November 7, 2012 with the S&P ASX 200 up 31.7 points to 4,516.5 points. Eleven of the Biotech Daily Top 40 stocks were up, nine fell, 16 traded unchanged and four were untraded. All three Big Caps were up.

Prima was the best, up 1.5 cents or 12.5 percent to 13.5 cents with 4.6 million shares traded. Allied Health climbed 8.7 percent; Patrys was up 5.6 percent; Nanosonics was up 4.8 percent; Heartware and Mesoblast rose more than two percent; CSL, Resmed and Viralytics were up more than one percent; with Acrux, Alchemia, Cochlear, Sirtex and Starpharma up by less than one percent.

Bioniche led the falls, down five cents or 11.1 percent to 40 cents with 20,000 shares traded. Neuren lost 9.8 percent; Sunshine Heart was down 5.9 percent; Phylogica fell four percent; Prana were down 3.7 percent; Circadian, Reva and Universal Biosensors shed more than one percent; with Pharmaxis down 0.8 percent.

BIOTECH DAILY

Biotech Daily is seven years old today. We have published some 1,750 editions running to more than 10,000 articles and somewhere between two million and five million words.

There have been about 80 corrections over the seven years, with at least 50 sub-editors dispatched to warmer or colder climes and several suitably admonished. There is nothing wrong with admitting to one's mistakes and that's why we have sub-editors.

There have been many changes to the biotechnology industry over the seven years and a detailed analysis will be in the last edition for the year on December 21.

But it is fair to say that we have seen the departure from the ASX of several important companies with interesting technologies, some acquired by larger companies and some running out of funds to continue their programs or acquire new ones.

Gropep was one of the first we saw depart the ASX, followed by Evogenix to Peptech which, as Arana, in turn went to Cephalon, Meditech into Alchemia and then out again as Audeo Oncology, Chemgenex to Cephalon, Peplin to Leo Pharma, Cytopia to YM Biosciences and Cellestis to Qiagen,

It has not all been plain sailing, with the collapse of Ventracor, Polartechnics, Dia-B Tech, Rockeby Biomed, Virax and Tyrian, along with the 10 companies named in Monday's edition, who went mining and never came back (BD: Nov 5, 2012).

Recent additions include Osprey, Reva, GI Dynamics and Bioniche with a few backdoor listing mergers including the ill-fated Hunter Immunology/Probiotec/Bioxyne adventure as well as the more promising CBio/Invion move.

The one clear message is that there is a need for more good companies, with strong responsible boards and serious Australian-developed technologies.

It is hard to believe that Australia's research institutes and universities don't have a wealth of commercializable technologies. The listed biotechnology sector should be alert to them.

There are several companies that have searched pro-actively for good technologies with Biodiem at the forefront, despite its low share price and funding issues. Other companies are also known to be hunting good technologies.

While last week's Ausbiotech conference appeared to be shorter in duration and lower on numbers that previous conferences, Biotech Daily does not believe this indicates any major downturn in the sector.

With the return of President Barack Obama in the US and a hoped-for recovery in Europe, the likelihood is that the global economy will improve and we should expect increased investment in our sector to cope with the needs of a globally ageing population. We need to be ready for it.

David Langsam
Editor

SENZ ONCOLOGY

Senz Oncology says it has treated the first patient in its phase I/II clinical trial of VAL-1000 in patients with acute leukaemias at Melbourne's Alfred Hospital.

Senz said that the single-arm, open-label clinical trial was being conducted by the Alfred's head of leukaemia services and principal investigator Dr Andrew Wei.

The company said that the primary objective was to evaluate the safety and tolerability of VAL-1000 in adult patients with acute leukaemias that were unsuitable for treatment with standard chemotherapy treatments.

Senz said that the trial would also evaluate secondary objectives including assessing patient-related efficacy outcomes, measuring VAL-1000 pharmacokinetics and defining a dose level for testing in subsequent phase II clinical trials.

The company said that about 900 patients a year were diagnosed with acute myeloid leukaemia in Australia and the majority would relapse, especially those over the age of 60 years and with poor risk cytogenetic and molecular characteristics.

Senz said that patients falling into those categories had limited treatment options once standard approaches have been exhausted.

Senz executive director Dr Anthony Filippis said the trial was the first time that VAL-1000 had been tested clinically for the treatment of acute leukaemias and if shown to be safe and efficacious "it could provide a completely new treatment option for patients".

Senz is a private company.

NOVOGEN

Novogen's says US subsidiary MEI Pharma's Pracinostat with 5-azacitidine has shown "high rates of clinical and cytogenetic response in high-risk myelodysplastic syndrome".

Novogen said the preliminary data from a pilot phase II trial of MEI's oral histone deacetylase-inhibitor Pracinostat in combination with azacitidinein patients with advanced myelodysplastic syndrome had been accepted for poster presentation at the American Society of Hematology meeting in Atlanta, Georgia, on December 10, 2012.

The company said that an abstract of the presentation, entitled 'Very high rates of clinical and cytogenetic response with the combination of the histone deacetylase inhibitor Pracinostat (SB939) and 5-azacitidine in high-risk myelodysplastic syndrome' was available online at www.hematology.org.

MEI chief executive officer Dr Daniel Gold said that the company was "very encouraged not only by the response rates reported to date, but also by the rapid appearance of the responses with the combination of Pracinostat and azacitidine"

"These data are particularly compelling given that most patients in the study had treatment-related [myelodysplastic syndrome] and expressed high-risk cytogenetic abnormalities, both of which carry a poor prognosis," Dr Gold said.

Dr Gold said that he expected to begin a randomized phase II trial of Pracinostat in combination with azacitidine in patients with myelodysplastic syndrome by July 2013.

The company said that Pracinostat had shown evidence of single-agent activity in multiple clinical trials, including advanced haematologic malignancies such as myelodysplastic syndrome, acute myeloid leukemia and myelofibrosis.

MEI said that Pracinostat had demonstrated pre-clinical activity in haematologic disorders and solid tumors when used alone or in combination with a range of therapies.

The company said that Pracinostat had been generally well tolerated in clinical testing of more than 150 patients, with readily manageable side effects often associated with drugs of this class, with the most common adverse event, fatigue.

Novogen was up 7.5 cents or 83.3 percent to 16.5 cents with 1.2 million shares traded.

ALLIED HEALTHCARE GROUP

Allied Health says that it has a $2 million five-year contract to supply the Swiss-made Arcomed infusion management system to Mater Health Service North Queensland.

Allied managing director Lee Rodne said the contract was “the latest in a period of strong sales growth and it validated efforts to bring the technology to Australia”.

Mr Rodne said the device was “the latest in infusion management technology, which is designed to improve both hospital efficiency and clinical outcomes for patients by using data management to ensure patients receive the correct medication at the correct time”.

“This five year supply contract also signals a growing recognition of Allied as a leading provider of innovative medical products and technologies, to Australian and New Zealand hospitals and healthcare facilities,” Mr Rodne said.

Allied Health (then Allied Medical) acquired Biomd and its Cardiocel cardiac patch technology in 2011, and Mr Rodne said at that time that the company had an existing health care distribution network, as well as a significant stake in Coridon for its DNA vaccine assets (BD: May 19, Jun 29, 2011).

Today, Allied Health said it had the sole licence to distribute Arcomed’s technology platform in Australia and the Mater was the first facility to introduce the infusion platform since it became available in Australia earlier this year.

The company said it was also preparing for the launch of Cardiocel and said it expected the global launch of Cardiocel “to significantly increase revenue for the company once approved”.

Allied Health said that it generated about $7 million in sales annually from its range of cardiology and infusion products.

“We plan to introduce a string of new technologies that will further expand revenue from the sales and marketing division in coming years as we bring new products to market,” Mr Rodne said.

Allied Health was up 0.2 cents or 8.7 percent to 2.5 cents with 2.2 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has won a tender to supply its Reusable Space Chamber to hospitals in Canada through Canadian business partner Carestream Medical.

Medical Developments said that Carestream submitted its space chamber for evaluation as part of a larger tender and was awarded an exclusive five-year contract with an option to extend for a further year.

The company said that Carestream advised that it expected to supply the space chamber to up to 70 percent of hospitals in Canada.

Carestream chief executive officer Mo Shariff said the space chambers were “an important part of the range of products we will be supplying the Canadian Government”.

“We expect to start delivering the Reusable Space Chamber into the Canadian hospital system early in the New Year and are expecting to achieve volumes of 150,000 to 300,000 annually,” Mr Shariff said.

Medical Developments did not disclose the value of the contract.

Medical Developments chief executive officer John Sharman said that winning the tender was “a significant achievement … and provides further validation of our world class range of asthma medical devices”.

“We have enjoyed a 10-year relationship with Carestream and the roll out of this new business in the New Year will likely generate significant additional revenue and profit for our business,” Mr Sharman said.

Medical Developments was unchanged at $1.83.

PATRYS

Patrys says it has enrolled the first patient in its phase I/IIa PAT-SM6 multiple myeloma trial.
Patrys said the trial was an open-label, multi-dose escalation trial in relapsed and multi-resistant patients with multiple myeloma who had failed all currently marketed drugs and had a very poor prognosis.
The company said that multiple myeloma was a cancer of the plasma cells in bone marrow.
Patrys said that the trial was being conducted at Germany's University Hospital of Würzburg.
The company said that initially, 12 patients would be enrolled in four dosing groups to receive a minimum of two cycles of treatment.
Patrys said that if a patient showed a partial response to treatment with PAT-SM6 an additional cycle of treatment would be offered.
The company said that the primary objective of the study was to evaluate the safety and tolerability of escalating doses of PAT-SM6 and the secondary objective was to measure efficacy as determined by a series of well-established laboratory assays.
Patrys said that as the trial was an open-label study, data would be released on an ongoing basis, with initial data expected to be available by April 2013.
Patrys was up 0.2 cents or 5.6 percent to 3.8 cents.

ELLEX MEDICAL LASERS

Ellex says it will launch a suite of new ophthalmic products at the American Academy of Ophthalmology congress in Chicago, Illinois, November 10-13, 2012.
Ellex chief executive officer Tom Spurling said that about 16,000 medical professionals would attend the congress.
Ellex said it would launch an upgrade to its Eye Cubed ultrasound to provide an interface for images with electronic medical records systems; a new multi-wavelength photo-coagulator for specialized treatment of retinal disease; a new pattern scanning photo-coagulator for high-speed treatment of retinal disease; and a new laser for the treatment of vitreous 'floaters', a common, but difficult to treat ailment.
Ellex was unchanged at 20 cents.

BIOTA BIOPHARMACEUTICALS

Biota says that it has received $4.2 million Australian research and development tax credit.
Biota is due to list on the Nasdaq replacing takeover target Nabi on Friday night November 9, 2012, Australian time.

MAYNE PHARMA

Mayne director Bruce Mathieson has increased his shareholding from 13,411,622 shares (5.94%) to 26,823,244 shares (7.67%).
In his substantial shareholder notice, gambling machine operator Mr Mathieson said he acquired 13,411,622 shares for $2,682,324 or 20 cents a share on November 7, 2012 as part of the company's $65 million equity capital raising (BD: Oct 4, 2012).
Mayne fell one cent or 3.6 percent to 26.5 cents.

RESONANCE HEALTH

Resonance says two US customers have received a positive response for Ferriscan liver scan reimbursement from two of the largest insurance payers in the US.
Resonance said that Blue Cross Blue Shield Massachusetts and Kaiser Permanente had advised that coverage could be provided for the Ferriscan test when a patient's clinical circumstances required it and that prior authorization was required to confirm whether the proposed service was medically necessary.
Resonance said the confirmation was "a significant step forward and may help set a precedent in other states and with other payers" and said it had verbal confirmation from four US hospitals that they were receiving reimbursement from payers for Ferriscan costs.
Resonance said it had been actively establishing new US Ferriscan service providers.
The company said that a medical service must be widely available to gain reimbursement and the number of US Ferriscan centres increased from 10 in 2010 to 40 in 2012.
Resonance said that published clinical guidelines and patient advocacy societies were supporting the need for patients to have access to Ferriscan, including the 2012 Thalassemia Standards of Care Guidelines in California which said that magnetic resonance imaging (MRI) provided "an expedient and non-invasive way to directly measure [liver iron concentration] …... a Ferriscan is a commercially available and validated system for quantitative MRI measurements of iron".
The company said that an application had been made to the American Medical Association for a current procedural terminology (CPT) code for Ferriscan and while a unique CPT code was not mandatory it streamlined coverage and payment processes.
Resonance was up 0.2 cents or 13.3 percent to 1.7 cents.

QRX PHARMA

QRX came close to a first strike on its remuneration report with 19.8 percent opposition, while 10 percent of votes cast opposed the granting of options to directors.
The remuneration report was opposed by 6,835,530 votes (19.8%) and supported by 27,689,696 votes (80.2%).
In the first annual general meeting since the refusal of the US Food and Drug Administration (FDA) to approve its Moxduo dual opioid analgesic (BD: Jun 27, 2012) QRX shareholders were asked to issue chief executive officer Dr John Holaday 300,000 options and 75,000 options each to chairman Dr Peter Farrell and directors Peter Campbell, Dr Gary Pace and Michael Quinn, saying they had not had a fee increase since May 2007 and the options were a reward for past performance, a long term incentive, a retention mechanism and compensation for no increase in fees (BD: Oct 5, 2010).
All director options were supported by more than 31 million votes and opposed by more than 2.9 million votes, except for the issue of options to Mr Quinn which was supported by 26,453,057 votes (90.0%) and opposed by 2,946,313 votes (10%).
Mr Campbell was elected overwhelmingly.
QRX's most recent Appendix 3B share issue announcement said there were 144,577,206 shares on issue, meaning that the strongest opposition came from 4.7 percent of all shares on issue, which is not sufficient to requisition extraordinary general meetings.
QRX was unchanged at 72 cents.