Biotech Daily

Wednesday February 11, 2009

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: BIOTA UP 13%, POLARTECHNICS DOWN 14%**

*** LIVING CELL: PIG CELLS 'CLEAR BENEFIT' IN 5 OF 6 DIABETES PATIENTS**

*** AVEXA REBUTTS CYTOPIA CLAIM IN BIDS FOR PROGEN'S CASH**

*** GSK BOOSTS BIOTA'S JAPAN STOCKS; COMPETITOR RESISTANCE**

*** INTUS TAKES HEALTHLINX OVARIAN CANCER TEST TO UK, IRELAND**

*** AVITA STREAMLINES OPERATIONS, REDUCES ANNUAL COSTS $600k**

*** STEM CELL, SELECT VACCINES ANSWER ASX CASH BURN QUERIES**

*** COMPUMEDICS EXPECTS STRONG H1 RESULTS**

*** BRAIN RESOURCE POSTS 1st H1 PROFIT OF $3.5m**

*** BIO-MELBOURNE WORKSHOPS KEY OPINION LEADERS**

MARKET REPORT

The Australian stock market fell 0.4 percent on Wednesday February 11, 2009 with the S&P ASX 200 down 14.3 points to 3,474.4 points.

Nine of the Biotech Daily Top 40 stocks were up, nine fell, seven traded unchanged and 15 were untraded.

Biota was best, up 5.5 cents or 13.25 percent to 47 cents with 420,049 shares traded, followed by Cellestis up 20 cents or 12.5 percent to $1.80 and Impedimed up seven cents or 10.77 percent to 72 cents.

Pharmaxis climbed 5.13 percent; Avexa, Heartware and Resmed were up more than four percent; Acrux and Arana rose more than two percent; with CSL and Novogen up less than one percent.

Polartechnics led the falls, down two cents or 13.79 percent to 12.5 cents with 230,000 shares traded, followed by Viralytics down 0.4 cents or 10 percent to 3.6 cents.

Phosphagenics lost five percent; Bionomics, Circadian, Clinuvel and Sirtex fell four percent or more; Cochlear and Mesoblast were down more than three percent; with Chemgenex down 2.86 percent.

LIVING CELL TECHNOLOGIES

Living Cell Technologies says five of six type 1 diabetes patients have had long term benefit in its Russian phase I/IIa clinical trial of Diabecell porcine islets of Langerhans.

Living Cell said a seventh patient has received a Diabecell implant and has been followed-up for four weeks.

The results of 36 weeks to 68 weeks follow-up from the first four patients showed that good blood glucose control was maintained, as reflected by a reduction in glycated haemoglobin (% HbA1c) levels from a mean of 8.0% pre-enrolment to 6.8% at the time of clinical review.

Living Cell said the American Diabetes Association target for good blood glucose control was HbA1c below 7.0% and the normal is less than 6.2%.

The company said the level of control was attained despite a reduction of 10 percent to 38 percent in the required daily insulin dose.

Living Cell said it was too early to assess the second implant for the fifth patient but the patient's HbA1c improved markedly from 9.8% before enrolment to 7.2% accompanied with a small reduction in the average daily insulin dose of 6%.

Living Cell chief executive officer Dr Paul Tan said that following treatment five of six patients had "clearly demonstrated a long-term positive biological effect".

Of the seven patients, five have had two low dose (5,000 islet equivalents (IEQs) per kg body weight) implants at least six months apart and two patients have received a single higher dose (10,000 IEQs/kg).

The company said there had been no safety concerns to date and no remarkable adverse events attributed to double implants.

Living Cell medical director Prof Bob Elliott said the patients "clearly benefited from the implants administered at the lowest dose".

"The second implant maintained this benefit," Prof Elliott said.

"Remarkably none of the patients have had problems with clinically relevant episodes of low blood glucose," Prof Elliott said.

"Most people with diabetes cannot attain this degree of blood glucose control shown by these patients without large swings of very low or high blood glucose levels that are often fatal," he said.

Living Cell said the sixth patient declined further follow-up at 20 weeks after the first implant when there was no change in glucose control or insulin dose.

To improve consistency, the company said it had narrowed product quality release specifications for all subsequent implants.

Living Cell said that at four weeks of follow-up the seventh patient's HbA1c "improved dramatically" from 8.3% to 4.8% and daily insulin requirement dropped by 60 percent.

"We can expect better outcomes with higher doses," Prof Elliott said.

"The encapsulated cells offer not only an alternative but a physiological replacement therapy to provide new hope and improved lifestyles for people with diabetes," he said.

Dr Tan said the next three patients in Russia were scheduled to receive the 10,000 IEQ/kg dose by April this year before testing the top dose of 15,000 IEQs/kg.

He said steps had been taken to initiate a pivotal trial and a commercialization strategy in Russia.

Living Cell said Diabecell was an encapsulated, porcine insulin-producing, cell product designed for the treatment of type 1 diabetes without the use of immunosuppressive drugs.

Living Cell was unchanged at 9.8 cents.

AVEXA, CYTOPIA, PROGEN

Avexa says Cytopia's February 9, 2009 announcement "contains inaccurate statements about the funding requirements" of the proposed merged Avexa and Progen entity.

In a media release to the ASX entitled 'Response to inaccurate statement by Cytopia regarding funding shortfall' Avexa said the Cytopia announcement (BD: Feb 9, 2009) referred to a "$95 million shortfall".

"This statement is not consistent with any of the documents or commentary released by Avexa and Progen," Avexa said.

"Therefore, any reference to a funding 'shortfall' is inaccurate," Avexa said.

Avexa said it had "consistently stated in all releases to date that the merged entity will have $60 million in cash resources, which should be sufficient to fund the estimated $45 million phase III trial cost of ATC [apricitabine] up to the week 24 data milestone".

"This milestone, which is expected to be reached in the second half of 2010, is a major value inflection point in the development of ATC," Avexa said.

Progen and Avexa announced the proposed merger late last year (BD: Dec 22, 2008) offering Progen's major institutional shareholders a $1.10 per share in a buy-back capped at $20 million.

On January 28, 2009 Cytopia entered the fray with a hostile merger proposal for Progen offering the institutions the same $1.10 buy-back but with no cap.

In an extraordinary general meeting called by a Progen shareholders group led by former EG Capital analyst Alison Coutts and Antisense chairman Bob Moses on January 9, 2009 (BD: Jan 16, 2009) the institutions supported the existing board in votes of about 20 million to 10 million, with about half of Progen's 60 million eligible shares voting.

It is believed Progen's three institutional investors want their funds returned through the buy-back and no longer want to invest in the biotechnology sector.

The Progen Coup group was attempting to keep some of the funds in the sector to create a major anti-cancer company.

Avexa said today that the week 24 data milestone expected in the second half of 2010 could provide the opportunity for a new drug application filing in early 2011, enabling a commercial launch of ATC and could also increase the prospect of finalizing a partnership agreement, if one had not already been secured, with Avexa receiving upfront and milestone payments to fund remaining phase III trial costs.

Avexa chief executive officer Dr Julian Chick said: "There is no shortfall."

"We are steadfast in the belief that the 24 week data milestone is the key value driver for both Avexa and Progen shareholders," Dr Chick said.

Separately, Avexa and Progen said they would host a second series of shareholder fora to be addressed by Dr Chick, Avexa's chief scientific officer Dr Jonathan Coates,Progen's chief executive officer Justus Homburg and Avexa chairman and proposed merged entity chairman Nathan Drona.

The meetings will be held in Sydney on February 23, in Brisbane on February 24 and in Melbourne on February 25.

The companies provided a merger timetable with Progen's shareholder meeting to approve the merger and share buyback on March 11; the Avexa scheme meeting to approve the merger on March 20, 2009 and the Progen share buyback to be conducted in late March with the merger implementation in early April 2009.

There was no mention of a date for the Cytopia requisitioned Progen meeting.

Avexa climbed 0.3 cents or 4.41 percent to 7.1 cents.

Progen was unchanged at 85 cents.

Cytopia was untraded at 11 cents.

BIOTA

Glaxosmithkline KK of Tokyo will import an additional two million Relenza packs "to maintain a stable supply".

Biota earns a seven percent royalty on all sales of Relenza. The packs are worth about $25 each when sold and Glaxosmithkline is importing the packs for future sales.

Glaxosmithkline said 400,000 packs would be available in February, 600,000 packs in March and one million packs in April.

The company said the decision was "based on this season's epidemic situation" and had originally prepared for the influenza season with three million packs of Relenza (zanamivir hydrate).

Glaxosmithkline said the quantity was equivalent to meeting the requirement for half the prescriptions of anti-influenza virus drugs in an average year.

"However, due to reports that most of the prevailing A/H1N1 influenza virus, which accounts for about half of the current epidemic, are resistant to another anti-influenza virus drug this year, attention and demand for Relenza has increased dramatically," Glaxosmithkline said.

The other anti-influenza virus drug is believed to be Relenza's main competitor Tamiflu (oseltamivir) which is marketed by Roche.

Glaxosmithkline said there was enough Relenza in distribution in the market, but in order to prevent stock accumulation, it was controlling its shipment.

Biota climbed 5.5 cents or 13.25 percent to 47 cents.

HEALTHLINX

Healthlinx says Intus Healthcare will distribute its Ovplex ovarian cancer diagnostic to the United Kingdom and Republic of Ireland.

Healthlinx said Ovplex was "the most accurate commercially-available, early stage ovarian cancer diagnostic with 92 percent diagnostic efficiency" and was based on a blood test women can request from their doctors.

Healthlinx said the Intus Healthcare agreement was a three-year deal and the first time the Ovplex diagnostic would be available outside Australia

The company said the exclusive distribution depended on Intus surpassing minimum sales targets with sales expected to begin in the second half of 2009.

Healthlinx managing director Nick Gatsios said that with the advantages of early detection of ovarian cancer, Ovplex had "the potential to save hundreds of lives".

Ovplex was released by ARL Pathology in the Australian market in October 2008 and uses five protein biomarkers detected in blood.

Healthlinx chairman Dr Greg Rice, who helped develop the technology, said Ovplex was "a new generation multi-marker blood test that delivers superior diagnostic efficiency and out performs any other commercially-available ovarian cancer test".

More than 240,000 cases of ovarian cancer are diagnosed globally each year and more than 130,000 women die from the disease.

"The reason why it is the most lethal of the reproductive tract cancers is that 75 percent of women with ovarian cancer are not diagnosed until late stage disease," Dr Rice said.

"Their chances of surviving five years are probably only 20-30 percent, but if the disease is diagnosed at [an] early stage where it is contained within the ovary, the chance of surviving five years rises to 80 percent," Dr Rice said.

"That is why it is so important to try [to] develop better tests for diagnosing ovarian cancer, particularly early stage disease. That is where we can really make a difference," he said

Healthlinx was untraded at six cents.

AVITA MEDICAL

Avita (formerly Visiomed and Clinical Cell) says changes to its operations and manufacturing processes have resulted in cost savings of up to $600,000 a year.

Avita said that during the past six months the company has conducted a review of its operations processes and has streamlined manufacturing process, increased product reliability, reduced waste and decreased production costs with concomitant increased margins.

In November 2008 Avita revised its spacer manufacturing process including the relocation of manufacturing to a new facility in Malaysia which will allow high volume, low cost production at a cost reduction of approximately 35 percent compared to the current manufactured product.

Tool qualification and validation processes are underway in preparation for initial production runs anticipated in March.

One-off costs associated with the manufacturing transfer are reflected in the December 31, 2008 Appendix 4C quarterly statement and include costs related to the shipment and qualification of tools, an initial outlay for increased inventory as a safety net and the advance purchase of raw materials.

Avita operations vice-president William Marshall said production would begin by late March “ahead of the southern hemisphere autumn and winter asthma season”.

Critical revisions to the Recell wound treatment manufacturing process have been implemented and are expected to save more than $500,000 over the next 12 months.

Key changes include improved sampling efficiency during the manufacturing process and the extension of shelf life for critical enzymatic formulations.

Avita said that the Recell product had many biologically active components and due to stability issues it previously had a shelf life of 12 months, resulting in costly and wasteful replacement of product. The shelf-life has been extended to 24 months.

Avita chief executive officer Dr William Dolphin said the changes was “yielding optimization of Avita's operations and manufacturing processes and will enable the company to significantly tighten its management of working capital”.

“This will have a very positive impact on our cash position,” Dr Dolphin said.

“By implementing these changes to our operational processes we're able to reduce our costs by $600,000 per annum. We enter the second half of the financial year in a significantly strengthened financial position,” Dr Dolphin said.

Avita was up 0.2 cents or 2.04 percent to 10 cents.

SELECT VACCINES, STEM CELL SCIENCES

Select Vaccines and Stem Cell Sciences have both told the ASX they hope expenditure for the next two quarters will be less than the previous quarter and funds are expected.

Select Vaccines told the ASX that it expects to receive the 2008 tax year IRD Tax offset payment and does not expect to have negative cash flows similar to the last two quarters.

The company said a review of operations would reduce expenditure.

Stem Cell Sciences said it continued “to pursue the cash generating opportunities outlined in its business plan including producing licence fees from its intellectual property and it had received £200,00 ($A440,000).

The company said that, given the current investment climate, it would “deliver better shareholder value by selling substantially all of its operating assets and liabilities”

A further announcement on this is expected to be made shortly.

Select Vaccines was untraded at half a cent.

Stem Cell is in a voluntary suspension and last traded at 15 cents.

COMPUMEDICS

Compumedics chairman David Burton says his company's December 2008 half-yearly report will be the "fifth consecutive profitable [quarterly] reporting period".

Mr Burton said the details of the half-year results to December 31, 2008 would be released in the last week of February.

Mr Burton said that over the past two years the company's earnings improved by $5 million, debt was reduced from $6.5 million to $1.9 million, manufacturing gross margins improved by seven percent and costs were reduced by $5 million.

"The company has also consistently generated positive cash over this period," he said.

He said the company would be strengthened "with the roll-out of two comprehensive and advanced new technological platforms designed to rejuvenate our core sleep diagnostic and [electro-encephalograph] businesses".

Mr Burton said the company was "continuing to focus on strategic investor opportunities and programs and the strengthening of Compumedics' board".

Compumedics was unchanged at 14 cents.

BRAIN RESOURCE

Brain Resource says its net profit after tax for the six months to December 31, 2008 was $3,473,022 compared to the previous period's $539,264 loss.

Brain Resource said revenue increased 48 percent to $3,099,637 and it had $19.3 million in cash at December 31, 2008.

Brain Resource was unchanged at 22.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network's February 24, 2009 half-day workshop will examine whether key opinion leaders are a help or a hindrance for biotechnology companies.

The Network says the workshop will help companies "find out how to identify, engage with and gain maximum value from your relationship with an opinion leader".

The organization said that opinion leaders, generally doctors and pharmacists, had typically been aligned with the pharmaceutical industry but there was "a rapidly growing trend for biotechs engaging in contact with opinion leaders at a much earlier stage of development, seeking their assistance with product development, assessing unmet clinical needs, competitor products and market opportunities".

The Bio-Melbourne Network said biotechnology companies were also enlisting the support of opinion leaders in the political lobbying process and investor relations strategies.

Selecting the right opinion leader is critical. An association with the right expert can be enormously beneficial. Dynamic Hearing chief executive officer Dr Elaine Saunders and Pfizer senior medical director Dr Bill Ketelbey will outline their experience and advice on engaging with opinion leaders.

Biotechnology companies are not bound by the pharmaceutical industry's code of conduct but Medicines Australia's Deborah Monk will outline the code's boundaries as a guideline on the rules of engagement with opinion leaders.

For more information go to www.biomelbourne.org; call Nicole Pitcher on +613 9650 8800 or email npitcher@biomelbourne.org.