Biotech Daily

Tuesday April 14, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP; LABTECH UP 15%, LIVING CELL DOWN 23%**

*** EDITORIAL: WHY IS THERE GOOD NEWS?**

*** PEPLIN GEL TO BE 'STANDARD OF CARE'; CAPITAL RAISING MOOTED**

*** JAPAN APPROVES CELLESTIS' TB TEST IN A TUBE**

*** US PANEL GIVES VIVUS 30 DAYS TO SET ACRUX PHASE III TRIAL**

*** TISSUE THERAPIES LOSES DIRECTOR PROF DAVID GARDINER**

*** PHYLOGICA, AEGIS COLLABORATE ON INTRANASAL PHYLOMERS**

MARKET REPORT

The Australian stock market climbed 2.21 percent on Tuesday April 14, 2009 with the S&P ASX 200 up 81.3 points to 3,752.9 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, five traded unchanged and six were untraded.

Labtech was best, up two cents or 14.8 percent to 15.5 cents with 151,500 shares traded followed by Cathrx up 13.2 percent to 60 cents and Cellestis up 12.7 percent to $2.66.

Chemgenex climbed 9.52 percent; Nanosonics was up 4.2 percent; Biota, Mesoblast, Progen and Tissue Therapies were up more than three percent; Clinuvel, Genera and Viralytics rose more than two percent; Alchemia, Cochlear and Heartware were up more than one percent; with Arana and Sirtex up by less than one percent.

Living Cell led the falls, down 3.5 cents or 22.6 percent to 12 cents with 430,310 shares traded, followed by Bone down 20 percent to 20 cents, Benitec down 16.1 percent to 2.6 cents and Antisense down 12.1 percent to 2.9 cents.

Cytopia lost 10 percent; Pharmaxis fell 8.4 percent; Novogen fell 4.5 percent; Peplin and Phosphagenics were down more than three percent; Genetic Technologies and Prana shed more than two percent; Avexa lost 1.3 percent; with Circadian, CSL and Resmed down less that half a percent.

BIOTECH DAILY EDITORIAL

The increase in institutional investment in biotechnology stocks through capital raisings of the past months and the strong rise in share prices are primarily because serious investors can see well-managed, grossly-undervalued companies.

While some talk about leading indicators, including “high beta” stocks, falling first and recovering first, underlying this formulaic representation of volatility and correlation is that in times of stress these stocks become undervalued. While statistics can explain events, I don't think GBS Venture Partners, Acorn Capital and Starfish Ventures sit around looking at charts and say 'Let's invest in something biotech.'

What is really happening is that in the past three or four years, a large number of companies have moved from juvenile or nascent to maturing, as evidenced by the number of companies with product in the market (Acrux, Biota, Cellestis, Labtech, Nanosonics, Pharmaxis, Polartechnics, Sirtex, Starpharma) or are near, or at, the end of the regulatory process (Alchemia, Avexa, Avita, Clinuvel, Medical Developments, Peplin) not to mention another large group of companies that are about half-way there with phase II trials.

The key is that they were undervalued prior to the 2008-'09 market correction.

I have previously said biotechs are not for the faint-hearted and the money coming into the sector is not from the so-called mums and dads investors, but from very serious, well-credentialed, professional investors and equally serious day-traders and month-traders. How could you not buy Biota at 33 cents? Peplin and Chemgenex have been woefully underpriced along with the rest of the sector, but that doesn't mean anything labeled 'biotech' is a smart bet. It means that for the canny speculator there is significant high-risk potential.

The Biotech Daily Top 20 Index (BDI-20) was up 20 percent in the month of March with two companies leaping more than 100 percent; two more doing better than 50 percent; and four up by more than 40 percent.

Over the four months from November, the BDI-20 was up 30%. Biotech companies have raised more than $60 million since January and $200 million in the past 12 months with biotech-focused institutions raising a further $200 million and another $100 million expected from one institution “soon”. Major institutions like AMP and ABN Amro Morgans are back in the action and buying biotech stocks as well as investing in capital raisings.

I don't think it is because the algorithm is in Aquarius, but because the fundamentals of the stocks scream out for investors to make money, despite the antipathy of the Federal Labor Government and some finance commentators.

One could make a serious argument that the strength of the sector reflects the life sciences’ long lead-times, supported more than a decade ago by the Federal Labor initiation and Federal Coalition continuance of the Commercial Ready Grants system.

David Langsam
Editor

PEPLIN

Peplin's chairman and chief executive officer Tom Wiggans is in Australia to see existing and new investors, despite having sufficient cash for all its programs.

Peplin has completed a phase II trial of its PEP005 topical gel (ingenol mebutate) for actinic keratosis on the head and neck (BD: Mar 6, 2009) and is due to report on its phase III trial of PEP005 for non-head locations by July 2009, with results from a phase III trial for head and neck actinic keratosis by the end of 2009.

"We have enough money to complete our development program," Mr Wiggans said.

"We have to put some more money in the bank, but not until after the first part of the phase III data," he said.

Asked whether he wanted Peplin to retain all rights to the topical anti-cancer agent or licence it out nearer to registration, Mr Wiggans said the 'A-strategy' was for Peplin to launch the PEP005 Gel in the US and have a non-US partner for other jurisdictions.

"We have very supportive shareholders and investors with very deep pockets," he said.

"Australian biotech needs some success" to put the country on the international map as a significant creator of technologies.

"It's also good to have some shareholders make some money from Australian biotechs," Mr Wiggans said.

He said about one third of Peplin's share register was based in the US and despite the market capitalization quoted by the ASX at $102 million, it was more like $180 million.

Mr Wiggans said that while he was hoping to see equal efficacy and safety data for PEP005 when compared with existing treatments, the difference was in the time for treatment.

He said PEP005 required two or three treatments over two or three days, while existing treatments took two to three months and had a poor rate of compliance often due to the skin looking worse for a long period of time as the treatment acted on the precancerous lesions, a problem less likely with a gel applied for two or three days.

"Our topical therapy, if approved, will become the standard of care," Mr Wiggans said.

Peplin fell two cents or 3.33 percent to 58 cents.

CELLESTIS

Cellestis says Japan has given regulatory approval for its diagnostic for tuberculosis infection, Quantiferon-TB Gold In-Tube.

Cellestis said the approval was granted after detailed examination of performance and quality data by the regulatory authorities in Japan.

Cellestis said it would market the In-Tube test through its distribution partner, Japan BCG Laboratory.

Cellestis said there was "significant assistance provided by Japan BCG Laboratory" as well as commitment by its own staff in achieving the milestone.

The company said Quantiferon-TB Gold In-Tube replaced the original version of Quantiferon-TB Gold and provided the same specificity and accuracy advantages.

The In-Tube format was easier, safer and simpler, allowing wider adoption and less cost for customers, the company said.

Cellestis chief executive officer Dr Tony Radford said that with the BCG vaccination being almost universal in Japan, "the old tuberculin skin test has virtually no utility for the diagnosis of TB infection due to its high rate of false positive results".

"With the approval of the QFT In-Tube test, the logistic and cost benefits of testing for TB with QFT are further enhanced," Dr Radford said.

Cellestis climbed 30 cents or 12.7 percent to $2.66.

ACRUX

Acrux says California's Judicial Arbitration and Mediation Service has ruled that Vivus must set a date to begin a phase III trial of Acrux's testosterone spray for women.

Prior to listing on the ASX, in February 2004, Acrux licenced the rights to Vivus for its testosterone metered dose transdermal spray to treat decreased libido in women.

Acrux chairman Ross Dobinson told Biotech Daily that the testosterone spray had completed its phase II trials in 2005, but due to negotiations with the US Food and Drug Administration there had been "no finite time-frame" on when Vivus would begin its phase III trial.

He said there had been "inactivity" and Acrux needed to take action to ensure the product's progress.

In a media release to the ASX Acrux said it had received an interim ruling from the Mediation Service's independent arbitration panel requiring Acrux and Vivus to meet within 30 days and agree to a new "outside date" by which Vivus must start the first phase III study of the testosterone spray, to be marketed in the US as Luramist.

Acrux reported the panel saying that if agreement could not be reached, the panel would hear both sides' positions and set a new outside date and a final arbitration ruling would include the new outside date.

Acrux said the dispute was between its wholly-owned subsidiary Fempharm and Vivus, the US licencee of Luramist.

In the media release Mr Dobinson said the binding arbitration ruling provided "a clear and unambiguous framework within which the parties are required to cooperate".

"Importantly, the panel found that the prior regulatory environment that made it commercially reasonable for Vivus to proceed as it did with respect to the development of Luramist no longer exists and there is no reason for further delay by Vivus," Mr Dobinson said.

"Accordingly, the award requires the parties to set a date by which the first phase III study for Luramist is now to commence," Mr Dobinson said.

The panel also ruled that Acrux and Vivus would meet within 30 days to enable Vivus to consider any documents and information such as know-how, that had been generated by Acrux and that may be useful for the development of Luramist and the two companies should appoint a joint development committee.

Acrux reported the panel saying Vivus was not in breach of the licence agreement and had used diligent, commercially reasonable efforts to develop Luramist.

The panel was reported saying that Acrux had not interfered with Vivus's prospective advantage or breached the implied covenant of good faith and fair dealing.

Acrux and Vivus were required to report back to the panel on the outcomes of their meeting within 35 days of the interim ruling.

Acrux was unchanged at 63 cents.

TISSUE THERAPIES

Tissue Therapies says Prof David Gardiner has resigned as a director.

Tissue Therapies' chairman Roger Clarke said Prof Gardiner had been a director since 2002 and he "made a substantial contribution" to the company.

Mr Clarke said Prof Gardiner's departure was "a loss to Tissue Therapies" and the company would seek a suitable replacement as soon as is practical.

Tissue Therapies was up half a cent or 3.12 percent to 16.5 cents.

PHYLOGICA

Phylogica will collaborate with Aegis Therapeutics to use Aegis' proprietary Intravail transmucosal delivery formulations to deliver Phylomer peptide drugs.

Phylogica's chief scientific officer and corporate development vice president Dr Paul Watt said the synergy between his company's Phylomer peptides and the San Diego-based Aegis Intravail delivery platform was "so compelling".

"Phylomer peptides are of an ideal size to deliver as a nasal spray using the Intravail formulation, since they are much smaller than proteins such as antibodies, which are delivered far less efficiently by means other than injection," Dr Watt said.

"Peptides of the size of many of our Phylomers have been delivered with bio-availabilities of 80 percent," he said.

"This is very impressive and suggests that intranasal delivery of Phylomers may be highly feasible," Dr Watt said.

Aegis chief executive officer Dr Ed Maggio said intranasal delivery was "the most validated non-injectable means of delivering peptides with several peptides including calcitonin, desmopressin, and nafarelin approved and marketed for years".

"Intranasal formulations have been shown to increase market share by more than 30-fold over the corresponding injectable formulations, because patients overwhelmingly prefer to avoid injections if possible in favor of other delivery approaches," Dr Maggio said.

"Peptide therapeutics are among the most potent and safe drugs ever developed," Dr Maggio said.

"Phylomer technology, for the first time, can harness the nearly unlimited structural diversity found in thousands of naturally occurring protein-folds to greatly expand the prospects of novel, safe, and effective peptide therapeutics in virtually any disease category."

The companies have agreed to offer their services together to parties such as pharmaceutical companies, who may be seeking a patient-friendly intranasal Phylomer peptide developed against their target of interest.

Phylogica was untraded at seven cents.