Biotech Daily

Thursday December 16, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRIMA UP 19%; OPTISCAN DOWN 9%**

*** BIOTECH DAILY EDITORIAL: THE YEAR IN REVIEW**

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*** LBT LOSES DIRECTOR DOUGLAS LEMESSURIER**

*** SOLAGRAN PLACEMENT RAISES $6.6m**

MARKET REPORT

The Australian stock market was up 0.34 percent on Thursday December 16, 2010 with the S&P ASX 200 up 16.2 points to 4784.0 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and three were untraded. All three Big Caps were up.

Prima was best, up two cents or 19.05 percent to 12.5 cents with 9.2 million shares traded. Bionomics and Viralytics were up 6.25 percent; Genera climbed 5.3 percent; Compumedics and Starpharma rose more than four percent; Benitec and Living Cell were up more than three percent; Cellmid and QRX rose more than two percent; with Biota, Circadian, Cochlear, Heartware, Resmed and Tissue Therapies up more than one percent.

Optiscan led the falls, down half a cent or 9.3 percent to 4.9 cents with 10,500 shares traded. Patrys and Genetic Technologies lost five percent or more; Prana fell 3.85 percent; Alchemia, LBT and Sunshine Heart shed more than two percent; with Acrux, Chemgenex, Immuron, Impedimed, Mesoblast and Phylogica down more than one percent.

BIOTECH DAILY EDITORIAL: THE YEAR IN REVIEW

The year after the so-called global financial crisis has seen not a single biotech dead, buried or cremated.

Rockeby finally departed the ASX after a prolonged coma. New Zealand's **Genesis R&D** and **Norwood Abbey** linger in palliative care, while **Fermiscan**, **Select Vaccines**, **Safety Medical** and **OMI** are in intensive care. **Agenix** has been moved to the recovery ward, while **Prima Biomed** has been resuscitated by Martin Rogers and Lucy Turnbull and, pending test results, is considered 100 percent fit for duty.

There have been some great successes and a few almost crippling disasters, among the Biotech Daily Top 40, with Prof Silviu Itescu's **Mesoblast** merger with **Angioblast** and $1.7 billion deal with **Cephalon** the highlight and the **Chemgenex** application to the US Food and Drug Administration, the lowlight.

Biotech Daily unreservedly withdraws its editorial concern on owner-drivers (BD: Sep 19, 2008), following Prof Itescu's unequivocal success in taking his own invention, first to an ASX listing and then winning the ultimate prize - a big pharma deal worth a huge amount of money and still leaving him very much in control.

Acrux has also performed remarkably this year with its **Eli Lilly** deal worth at least $670 million for one application of its platform technology and also reaching the goal of a second FDA approval.

The **Phylogica** $100 million deal with **Medimmune**, while executed in a less than orthodox fashion, is also a notable success. It also proves Biotech Daily's view on market capitalization: size isn't everything. Phylogica's market cap has fallen from $25 million on November 30, 2009 to $14 million on November 30, 2010.

In fact, 23 of the Biotech Daily Top 40 Index (BDI-40) companies have fallen in the 12 months to November 30, 2010, but the total value has increased by 12.4 percent, led by Acrux, **Heartware** and Mesoblast; with **Impedimed**, **Nanosonics**, **Psivida**, **QRX**, **Starpharma** and **Tissue Therapies** all performing exceptionally well.

Biota has tumbled from $546 million to $179 million, with **Cellestis** and **Sirtex** also falling significantly. All three have product in the market and revenue – go figure!

Following equivocal trial results at **Pharmaxis** and serious criticism of its application execution by **Chemgenex**, there have been many in the industry who privately voice concerns over the Byzantine world of the US FDA.

While Biotech Daily will always give a sympathetic hearing to a small Australian caught up with a less than transparent US bureaucracy, not all of them are Julian Assanges fighting the State Department. US companies also complain about the FDA process and there are some that argue that the FDA makes the former Soviet bureaucracy look mean, fit and agile by comparison.

But to be fair, there are several, predominantly device or diagnostic, companies who have told Biotech Daily that they have had no problems at all in their FDA dealings.

Biotech Daily also supports the high bar the FDA places on obesity drug trials. Eat less, exercise more. It isn't too much to ask. And think of how much great scientific effort and research and development expenditure could be spent on serious drugs, rather than wasting time trying to find a remedy for fast food outlets and too many electronic games.

Which brings us to the year that saw **Chemgenex** devalued from $5.50 a share to $2.90 a share and not much enthusiasm that the board and management will extract even half of the latter figure from Cephalon.

Compare the Chemgenex deal with Cephalon's **Arana** and Mesoblast deals. Cephalon buys 10 percent of Chemgenex for 50 cents and a further 20 percent for 70 cents. Why would they offer $2.90 for the rest? The investors who can give Cephalon a majority in Chemgenex, Alta Partners and GBS Venture Partners, bought shares at a range of prices, but probably average around 40 cents (like Biotech Daily's editor and analyst). What will they want from Cephalon for control of a company that could have been great?

It begs the question of how this happened and that takes us back to the FDA. Chemgenex failed to take bone marrow aspirations of at least two patients as per the FDA-approved trial protocol – and that's just one of many criticisms leveled at the company by either the FDA or the Oncologic Drugs Advisory Committee. It appears the process is back on track with a healthier attitude to the regulator, but a year has been lost in the process, along with a halving of market capitalization. So Cephalon picks up low-hanging fruit, instead of paying a significant premium to the market price, like it did with Arana and Mesoblast.

Novogen has had to admit its phase III trial results were less than glowing, but this has been the trigger for a reorganization, taking the anti-cancer compounds to US subsidiary **Marshall Edwards** and leaving Novogen to concentrate on over-the-counter consumer health products.

Finally in mergers and capital raisings, **Broadvector** couldn't raise its $5 million minimum, **Bioniche** is hoping for up to $30 million, while **Reva** has been oversubscribed to $85 million. Clean story plus good board and management equals investor confidence.

On the political front, the **Federal Government** has failed to provide its R&D Tax Concession, leaving us dependent on **Commercialisation Australia** and innovation investment funds and in need of a real funding mechanism for phase II and III trials. **Victoria** has lost its champion of biotech, **John Brumby**, but there is hope that the new **Innovation Minister Louise Asher**, will pick up the baton and build on the Brumby infrastructure successes.

Biotech Daily's last formal edition for 2010 will be published tomorrow and we return on January 17, 2011. Any major breaking news over the summer holiday period will be reported as a news flash with details in the January 17 catch-up edition. There will be a 5.3 percent subscription price increase to a base rate of $790 in the New Year.

We wish all our readers a very relaxing Summer holiday break, Merry Christmas, a sunny Summer Solstice and a brilliant biotech New Year in 2011.

David Langsam, Editor
Marc Sinatra, Analyst

REVA MEDICAL

The San Diego-based Reva Medical ASX initial public offering is said to have closed heavily oversubscribed and expects to raise $85 million.

Sources close to the offer told Biotech Daily that the company had hoped to raise $70 million and had allowed a further $15 million for oversubscriptions, all of which had been taken up.

Reva is developing the Rezolve bio-resorbable drug-eluting stent designed to restore blood flow to the coronial arteries and the funds are expected to take the company to a 50-patient Conformité Européenne (CE) mark pilot trial by July 2011.

Reva's director of corporate development Cheryl Liberatore told Biotech Daily that the company hoped to have CE mark approval in 2013, prior to taking the technology to the US Food and Drug Administration.

Ms Liberatore said the trial of 50 patients with denovo coronary lesions would be a pilot safety trial to be conducted in Brazil and Europe, including a centre in Germany and would be followed up with imaging at 12 months.

Ms Liberatore said the pivotal CE mark trial would involve "several hundred" patients and centres were likely to include Australia and New Zealand.

Ms Liberatore said that Reva had a pipeline beyond the stent including "other polymer related technology" which had not been detailed publicly.

According to the Reva Prospectus the company has 24,973,324 shares on offer equivalent to 249,733,240 Chess Depository Instruments (CDIs) and was offering a further 63,636,370 CDIs at $1.10 each, with the right to offer a further 13,636,360 CDIs.

The company expected the post-IPO market capitalization to be $US344,706,571, but the oversubscriptions would take the total to $359,706,667.

The Reva prospectus said that the company had an operational cash burn of $US12,569,000 for the year to December 31, 2009 and an unaudited burn of $US6,930,000 for the nine months to September 30, 2010, with cash and cash equivalents of $US6,147,000 at September 30, 2010.

Reva's co-founder, chairman and chief executive officer Bob Stockman, has been chairman since 1999 and CEO since August 2010 and is also a director of Heartware as well as president and CEO of US merchant bank Group Outcome LLC.

The company's non-executive directors are Brian Dovey, Gordon Nye, Robert Thomas, Anne Keating and James Schiro.

The prospectus said former Dura Pharmaceuticals executive Dr Robert Schultz was Reva's president and chief operating officer.

Reva said the vice-president of biomaterials product development was Dr Donald Brandom who holds a Bachelor of Science in chemistry from the University of California in Davis and a Ph D in materials engineering science from Virginia Tech.

The prospectus is available at:https://www.inteqrevaoffer.com.au/Pages/Default.aspx and further details are at the Reva website: http://www.teamreva.com/.

Reva is a public unlisted company.

HEARTWARE INTERNATIONAL

Heartware has raised $US143,750,000 ($A145,693,000) through the issue of convertible notes and Apple Tree Partners LLC has sold sell one million shares at $US81.31 each.

Heartware previously said that existing shareholder Apple Tree Partners LP, intended to offer 1,000,000 shares of common stock (BD: Dec 10, 14, 2010).

Heartware was up three cents or 1.2 percent to $2.45.

PHARMAXIS

Pharmaxis says the open label part of its second phase III trial of Bronchitol for cystic fibrosis has shown significant improvement over control patients and standard of care.

Pharmaxis said the trial was an extension of the trial that did not meet its primary endpoint, while demonstrating significant improvements in lung function.

Today, Pharmaxis said that in this part of the trial, all participants were treated with Bronchitol, including those that were in the control arm for the first six months.

The company said that lung function change measured by forced expiratory volume over one second (FEV1) for those participants treated with Bronchitol for six months was 8.2 percent (p=0.001 versus baseline) and this was maintained to 12 months.

Pharmaxos said that subjects who were switched from control to Bronchitol at the end of the first six months had a 6.3% improvement in lung function relative to baseline at the end of 12 months (p=0.031).

The company said the withdrawal rate in the open label phase was seven percent.

Pharmaxis chief executive officer Dr Alan Robertson told Biotech Daily that the results showed the life extending value of Bronchitol.

“With the best treatments available in terms of medicine and physiotherapy, lung function in these patients normally declines by one to two percent a year,” Dr Robertson said.

In a media release Dr Robertson said the result “confirms the robust clinical response and good safety profile we have demonstrated with Bronchitol over a number of clinical trials”.

“Cystic fibrosis is a disease that leads to slow decline in lung performance over time and, in this trial, Bronchitol was again able to improve lung function at commencement of treatment, at week 26, and maintain that improvement over 52 weeks for patients who were already receiving best standard of care,” Dr Robertson said.

“The repeated demonstration of sustained benefit in this second trial with Bronchitol holds out the promise that long term use of Bronchitol can change the course of the disease,” Dr Robertson said.

Pharmaxis said the trial objective was to determine the safety of Bronchitol in patients with cystic fibrosis following 12 months treatment and to assess the long term effects on lung function.

The company said the trial was conducted in two phases, with the first six months controlled and blinded and designed to assess efficacy and safety, while the second six months was open label, unblinded and not controlled.

Patients initially randomized to the control group were switched to receive Bronchitol during the subsequent six month open phase, Pharmaxis said.

A total of 260 subjects (Bronchitol=153, placebo=107) participated in the open label phase and of these, 242 subjects (93%) completed the six month phase.

For the subjects that entered the open label phase, the average age was 19.6 years and the mean lung function on entry was 64.6 percent of the predicted normal FEV1.

In all subjects in the open label phase, the most commonly reported adverse events were haemoptysis (5.7%), headache (4.2%) and cough (8.8%).

Pharmaxis said haemoptysis and cough were “common clinical features of cystic fibrosis”.

The trial was conducted in 53 centres in the US, Argentina, Canada and Europe.

Pharmaxis said that additional data from the trial including other lung function parameters and effects on exacerbation would be presented at a forthcoming scientific meeting.

The company said Bronchitol was designed to hydrate the airway surface of the lungs, and promote normal lung mucus clearance and the drug had orphan drug designation and fast track status from the US Food and Drug Administration and orphan drug designation from the European Medicines Agency.

Pharmaxis was unchanged at $2.82.

CYCLOPHARM

Cyclopharm says it has sold the first commercial doses of the radiopharmaceutical compound F18 flurodeoxyglucose (FDG) for use in positron emission tomography.
Earlier this month, Cyclopharm said that wholly-owned subsidiary Cyclopet had been granted good manufacturing process (GMP) approval by the Australian Therapeutic Goods Administration for the cyclotron production and research facility located at Macquarie University Hospital (BD: Dec 6, 2010).
Cyclopharm said that its medical imaging joint venture with Alfred Health Solutions, Macquarie Medical Imaging, purchased the first commercial doses of FDG for use at Macquarie University Hospital.
Cyclopharm said the first patient injected with the product confirmed the presence and location of squamous cell carcinoma, a cancer that could present in different organs, including skin, lips, mouth, esophagus, urinary bladder, prostate, lungs, vagina and cervix.
Cyclopharm said Cyclopet's products and research would "play a major role in early diagnosis and therapeutic management of these cancer patients".
Cyclopharm was untraded at 7.7 cents.

BIODIEM

Biodiem has received a royalty of US$248,310 ($A251,782) as the September quarter royalty from the private sales of the Nasovac vaccine for H1N1 influenza in India.
Biodiem said the payments for private market sales came from agreements with Nobilon, the World Health Organisation and the Serum Institute of India to supply Nasovac in India (BD: Oct 28, 2009; Jul 12, 2010).
Biodiem said Nasovac was based on its live attenuated influenza vaccine technology and was launched in India in July 2010, the first approval for marketing of the vaccine outside Russia and the Confederation of Independent States.
The company said the Serum Institute of India held a sub-licence from the WHO for the public market under the pandemic influenza program.
Biodiem chief executive officer Julie Phillips said the company was "delighted to receive our first royalty payment under this agreement between Nobilon and the World Health Organisation related to the use of the LAIV technology in India".
Biodiem fell half a cent or 3.7 percent to 13 cents.

BENITEC, CSIRO

Benitec says it has developed a strategy to "maximize the benefits" of its '099 Graham patent entitled 'Control of Gene Expression'.
Benitec said that following the re-examination decision (BD: Sep 30, 2010) on the RNA interference patent it had reviewed the claim scope of the pending US applications.
The company said that as a first step the Commonwealth Scientific and Industrial Research Organisation had temporarily withdrawn the patent application 'Synthetic Genes and Genetic Constructs comprising the same' to the US Patent and Trademark Office to file a supplementary information disclosure statement.
Benitec said that with the CSIRO it would amend the claims and the application could then proceed to allowance and grant.
Benitec said the "minor formality" delayed the formal grant of the patent, but the process had no adverse impact on the company's research and commercial objectives or on any other US patent application and was likely to be advantageous.
Benitec was up 0.1 cents or 3.85 percent to 2.7 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says earnings before interest and tax for the six months to December 31, 2010 is expected to be $1,100,000, up from the previous guidance of $630,000 and H1FY10 of $484,000.

Medical Development's chairman David Williams said the guidance was an estimate "only for the purpose of ensuring an informed market".

Medical Developments said any guidance on earnings before interest and tax for the year to June 30, was "premature and given the nature of the company's markets, very difficult to forecast reasonably".

The company said caution was urged "in extrapolating the … guidance to full year results and note that recent history suggests the second half year may not be as strong as the first".

Medical Developments said it had entered into contract negotiations with an unnamed European based contract research organization for a methoxyflurane (Penthrane delivered via the Penthrox inhaler) for acute pain pivotal clinical trial.

The company said the trial would be a randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of methoxyflurane to treat acute pain associated with trauma in patients presenting to emergency departments.

Medical Developments said the trial data would be used for European Union marketing authorization for Penthrox.

The company said it expected to fund the trial and the marketing authorization application from its cash reserves.

Medical Developments was up 2.5 cents or 7.35 percent to 36.5 cents.

BIOTA

Hunter Hall Investment Management has increased its substantial shareholding in Biota from 23,639,738 shares (13.14%) to 25,556,011 shares (14.14%).

Biota was up 1.5 cents or 1.55 percent to 98 cents.

LBT INNOVATIONS

LBT says founding chairman Douglas Peter Le Messurier will resign as a director, effective from February 1, 2011.

LBT said Mr Le Messurier was a founding shareholder and was the chairman prior to Bob Finder being appointed in April 2007.

LBT fell 0.2 cents or 2.6 percent to 7.4 cents.

SOLAGRAN

Solagran says it has raised $6.6 million through the placement of 44.2 million shares at 15 cents a share.

Solagran says the funds would repay $US2.2 million in debt facilities and be used for working capital.

Solagran was up one cent or 7.4 percent to 14.5 cents.