Biotech Daily

Thursday December 18, 2008

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECHS DOWN:
POLARTECHNICS UP 18%, STARPHARMA DOWN 12.5%**

*** BIOTECH DAILY'S SUMMER HOLIDAYS EDITORIAL**

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*** POLARTECHNICS SIGNS HEALTHSCOPE CERVISCREEN AGREEMENT**

*** LIVING CELL IN CAPSULE DEAL WITH CENTOCOR**

*** FLUOROTECHNICS EXPECTS 47% REVENUE SHORTFALL**

*** SAFETY MEDICAL RAISES $9.5m FOR WOMEN'S HYGIENE PRODUCTS**

*** ACUVAX: HAWAII BIOTECH'S PHASE I WEST NILE VIRUS DOSING DONE**

*** SPACELABS TAKES 5% OF USCOM**

*** MEDICAL THERAPIES SHARE PLAN RAISES $28.5k**

MARKET REPORT

The Australian stock market was up 0.2 percent on Thursday December 18, 2008 with the All Ordinaries up 6.7 points to 3,521.7 points. Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and eight were untraded.

Polartechnics was best, up three cents or 18.18 percent to 19.5 cents with 1.8 million shares traded, followed by Tyrian up 16.67 percent to 3.5 cents and Circadian up 12.07 percent to 65 cents.

Heartware climbed 7.27 percent; Peplin and Pharmaxis were up more than six percent; Acrux, Avexa and Phylogica were up five percent or more; Living Cell was up 4.76 percent; Cochlear rose 2.47 percent; with Mesoblast and CSL up more than one percent.

Starpharma led the falls, down three cents or 13.04 percent to 20 cents. Cytopia and Optiscan lost more than nine percent; Biota and Cellestis were down more than six percent; Bionomics fell 4.35 percent; Alchemia, Labtech and Novogen were down more than three percent; Clinuvel and Viralytics shed more than two percent; with Arana, Phosphagenics, Resmed and Universal Biosensors down more than one percent.

BIOTECH DAILY SUMMER HOLIDAY EDITORIAL

While black clouds ruled the biotechnology sector in the demise of Apollo Life Sciences and the falls from grace of Agenix, Alchemia, Avexa, Biota, Genetic Technologies, Progen and Ventracor, the silver lining is quite bright.

The initial public offerings of Genera Biosystems and Fluorotechnics raised funds for companies that have serious technologies and strong potential and the other capital raisings this year give lie to the claim that there is no money for biotechnology. If you have the right story, the right compound or device, the right board and the right CEO there is plenty of money around.

For the record:
Peplin $US30.7m ($A46m); October 2008
Fluorotechnics $9m; October 2008
Chemgenex $13m; September 2008
Spinifex $12m; September 2008
Heartware $30m; May 2008
Phosphagenics $9m; May 2008
Genera Biosystems $5m; April 2008

It is important to put our sector in context. While the Biotech Daily Top 40 Index (BDI-40) fell 55.1 percent in the year to December 1, 2008, the All Ordinaries - Australia's top 500 companies by market capitalization - fell 46.5 percent. The Big Caps of CSL, Cochlear and Resmed climbed 2.7 percent.

We don't want to play statistical games, but adding the Big Caps to the BDI-40, the best 43 life sciences companies fell just 6.2 percent for the year. This is little comfort to the Alchemia staff made redundant or those at Apollo and Agenix, but as a sector we have held up against the mainstream. The Global Financial Crisis has left the All Ordinaries with seven companies worth less than $10 million and 16 worth less than $20 million.

Which brings us to specific score cards. That Progen has been unable to find a use for its $70 million in cash is a worry, but not deserving of outright condemnation. Dr Roland Scollay was unable to find an appropriate use for Metabolic's $17 million and following his departure, the company announced a merger with Xceed's Polynovo that resulted in one of several surprising annual general meetings (see Metabolic Polynovo update below). That said, historic US and UK institutions, Babcock & Brown and the Commonwealth Bank make our sector look cautious, balanced and responsible by comparison.

It's easy to speculate on what companies should or should not do, but without access to the confidential documents that describe the inner workings of those companies, we are just dancing in the dark, as Prof Springsteen might say.

Marc Sinatra and I disagree on the merits of returning cash. A post-war baby-boomer, I like money in the bank. Young Marc says it is a waste of resources. Let the shareholders decide. In his analysis of Circadian he says surplus share-holdings and cash should be given back to investors (see If Marc Sinatra Was King Of Circadian; August 22, 2008). Over several discussions, he won me around to this view, but Progen is different. There is a pool of $70 million available to our sector. Marc says let the investors decide and if they go to the 19th Century auto industry or 18th Century coal industry, instead, so be it.

We think Bob Moses' plan to create a single strong company targeting cancer is a great idea. Mr Moses and Progen chairman Dr Mal Eutick should be locked in a very small room until they have a deal. The sector clearly requires mergers, a proposal everyone agrees to as long as it's not in their listed company. And would someone please give Ventracor $10 million to complete registration? Any failure of a leading company hurts the whole industry.

Yesterday, Biota's share price jumped 11.4 percent on the news that director Barbara Gibson had resigned two weeks early. One can only wonder how high the share price will go when chairman John Grant finally understands the meaning of "taking responsibility" for the board's inept handling of the Glaxosmithkline case. Asked to take responsibility for refusing a $75 million offer and then being forced to accept $20 million, he simply refused to understand that shareholders at the meeting wanted his resignation. He said the idea was bizarre. That both Biotech Daily's editor and Bioshares' editor David Blake are Biota shareholders calling for his resignation didn't seem to compute. He should go and go now.

Biota's board has put the issue of director's competence and the proper composition of a company's board in the spotlight. We have some truly awful boards misdirecting competent chief executive officers and, until last month, Genetic Technologies had a truly excellent board, dismissed at the whim of majority shareholder, Dr Mervyn Jacobson. Biotech Daily is considering the implications of the Biota, Genetic Technologies and Progen issues and will publish an editorial on boards and directors early in 2009.

Again, some of Australia's biggest companies are worse. Can anyone explain why Kerry Packer's son and a soldier are running our airline and whether these brave decisions by the former Howard Government have anything to do with Qantas's industrial problems and an increasing rate of aircraft incidents and accidents? Then there's always Telstra and the Australian Wheat Board.

Despite problems at the board level, Biotech Daily believes both Biota and Genetic Technologies can be great companies. They will take very different remedies, but it is fair to say the shareholders who wield power are to blame for the problems downstream.

Agenix may return to form, but it has been a disastrous year for the company once focused on Thromboview for deep vein thrombosis and pulmonary embolisms. The main game is now China's hepatitis B market - if all the pieces of the China deal can be put back together again. And then there's the matter of the missing $4 million, which led to a court appearance by former chief executive officer Neil Leggett, but apparently no charges have been laid relating to the matter. We wish the new board good luck.

Avexa and Ventracor are two diverse companies in the same boat, HMAS Cashstrapped. The problem is running out of cash as their respective drug and device near FDA registration, but it raises the question of why no major player is interested in either technology. How can they have come so far, have done most things right, only to fall at the final hurdle? This is the high risk element of our sector.

Finally, there is the question of industry representation and government subsidies. Why is it that the motor vehicle lobby takes up several pages of newspapers for a week as it harasses Innovation Minister Senator Kim Carr and Treasury and we merit a paragraph a fortnight? We are roughly the same size industries in contribution to GDP and workers.

The data below has been collected by Biotech Daily and is accurate but not definitive. That Ausbiotech has 20 staff including many researchers and does not even know the size of its own sector is nothing less than breath-taking.

Senator Carr's office says the automotive sector is worth $8 billion a year to GDP – whatever that means – with exports of $5.6 billion a year, a figure confirmed by the Federal Chamber of Automotive Industries. There are about one million new cars registered each year providing $25-30 billion a year in sales

Medicines Australia says that in the year to June 2008 the total market for prescription and over-the-counter drugs was worth $8.73 billion. This does not include devices, over-the-counter diagnostics, herbal remedies, food additives and the animal health market. In terms of revenue, CSL earned $3.8 billion followed by Cochlear ($602m) and Resmed ($1.3bn). That $5.16 billion was augmented by $223.1 million from Biota ($45m), Arana ($39.5m), Sirtex ($38m), IDT ($31.5m), Cellestis ($19.6m), Ventracor ($17.3m), Genetic Technologies ($15.7m), Pharmaxis ($9.5m) and Acrux ($7m). Blackmores earned $179 million. To give perspective, BHP and RIO had combined revenue of $136.8 billion.

In terms of value and employees, compare the unlisted Australian branches of GSK, Merck and Pfizer with Ford, GM, Mitsubishi and Toyota. All are foreign-based, privately owned and don't have to report financial data publicly.

Then compare the research staff at the major institutions and universities working directly on life sciences and compare them to all the car mechanics, sales staff and ancillary industries and I'm sure the numbers are in the same order of magnitude. It is possible that we are actually bigger. And while people can choose not to buy another car, they can't choose not to take a $30,000 a year anti-cancer drug.

We strongly believe that when the accurate detailed data is collated that we shall see we are punching 90 percent below our weight. Our industry deserves far better representation to demand that the Federal Government fund our 21st and 22nd Century technologies better than smoothing the pillow of the infernal combustion engine whose power train loses 90 percent of its fossil fuel-derived energy before it hits the wheels.

Biotech Daily takes the optimistic view that companies like Alchemia, Acrux, Biota, Chemgenex, Peplin, Pharmaxis, Sirtex and many others are strong and deeply undervalued and that with the inauguration of President Barrack Obama the world will be a far better place in 2009. For anyone with cash, it's time to go bargain-hunting.

Tomorrow is the final edition for the year and we return on Monday January 19, 2009 looking forward to a brave new biotechnology world.

Happy summer holidays to all our subscribers and all our readers and may you enjoy Chanukah, Christmas, the Summer Solstice and time away from the desk for whichever reason or deity you choose.

David Langsam, editor
Marc Sinatra, analyst

MARC SINATRA'S BIO-GUIDE BRIEF: A NEW YEAR'S RESOLUTION FOR BIOTECH

I have a very simple rule when it comes to investing in initial public offerings (IPOs) of biotech companies: Don't.

They are almost always over-valued and I can get on cheaper later. Cellestis and Pharmaxis are the only companies that investors would have done well long-term to get on at the IPO, excluding the big caps.

Another rule I have is don't buy anything that hasn't been listed for at least a year.

The reasons for this rule are multi-fold, but a lot of it comes down to the fact that biotech prospectuses are often highly polished to support optimistic valuations and it takes a while for a true picture of the company to emerge.

A supplementary prospectus lodged by Cellscreen Direct regarding its current IPO highlights why I have these rules.

In the original prospectus, the market for HPV testing is put at $4 billion dollars. It turns out that the market is really about $200 million, as acknowledged in the supplementary prospectus.

If the company is basing its IPO price on the former market size, it has been well and truly overvalued. The supplementary prospectus also makes it clear that the product cannot be distributed straight to Australian consumers as the company seems to imply.

All of a sudden, Cellscreen Direct's marketing strategy looks shaky. If you read the full 84 page prospectus carefully, you can pick up on these issues, but you do have to fight your way through the spin.

Then, of course, you have to figure out what the prospectus doesn't tell you.

Drawing on personal experience, I can say that there are other issues with the company's marketing strategy, such as the fact that doctors don't like receiving test results for a patient they may not have seen in years and the likelihood that they will not take such results at face value.

The problem for the biotech industry is that poor post-IPO performance drives investors from the sector and, eventually, the industry will have to improve their quality to attract investors back, but this will take time and there will be casualties.

The sooner the industry realizes this and starts to behave accordingly the better it will be for all.

So, I hope the industry's New Year's resolution will be to follow the old adage and leave something on the table for the next person. That means valuing the company at a fair price that leaves some upside. Everybody wins that way.

Marc Sinatra

METABOLIC, XCEED

Metabolic has invested $3.5 million for 60 percent ownership of Polynovo Biomaterials.

In November an agreed acquisition of Polynovo by Metabolic collapsed at the Metabolic annual general meeting when major shareholders unexpectedly voted against merger resolutions (see Biotech Daily; November 27, 2008).

Metabolic said in a media release today that it had reached agreement with Polynovo's shareholders, Xceed Capital and the Commonwealth Scientific and Industrial Research Organisation to exchange $3.5 million for 20,750,000 Polynovo Series A shares.

The company said the Series A shares had similar rights to ordinary shares except for priority in the event of the winding up of Polynovo.

The conversion of Metabolic's existing loan to Polynovo of $1.25 million (with accrued interest) is included within the $3.5 million.

Following the Metabolic investment, Xceed and CSIRO, will own 25.5 per cent and 14.5 percent of Polynovo, respectively.

Metabolic has also been granted five options enabling it to invest up to a further $5 million for more Polynovo Series A shares at the same price as the initial investment.

Each option entitles Metabolic to subscribe for 5,928,571 Series A shares on payment of an exercise price of $1 million at any time on or before the expiry date of June 30, 2013.

Metabolic chairman Rob Stewart said his company's board "remains of the view that Polynovo represents an exciting technology with great potential".

"It also considers that this restructured investment reduces the risk for Metabolic shareholders and enables Metabolic to make further investments in Polynovo as and when the technology is further validated," Mr Stewart said.

The Metabolic nominated directors are Rob Stewart, Franklyn Brazil and Paul Lappin. The other directors are expected to be CSIRO's Bruce Rathie and Xceed's Dr Stewart Washer.

Dr Ian Griffiths will continue in his role as Polynovo's chief executive officer.

Metabolic said Polynovo had several "high potential projects", including licencing arrangements with Medtronic, Biomet and Smith & Nephew plc.

Polynovo develops the Novosorb family of biodegradable polymers for use in medical devices, with potential applications in orthopaedics, orthodontics, drug delivery, wound care, tissue engineering, nerve regeneration and cartilage repair.

Options will be issued to Polynovo employees in Metabolic pursuant to the terms of the Metabolic employee option plan.

Following its $3.5 million investment, Metabolic said it would have about $12 million in cash and cash equivalents and said it would "continue exploring opportunities in the current market which present the greatest potential to create significant value for shareholders".

In its media release to the ASX, Xceed set out Polynovo's recent financial history and said it had invested a total of $10.1 million into Polynovo since 2004 which had an impaired value of $7.2 million at June 30, 2008 in the books of Xceed.

Xceed said it was "likely that further impairment of its carrying value of the investment in Polynovo would be brought to account by Xceed as a result of the Metabolic investment".

The company said Peter Francis and Dr Ian Griffiths resigned as directors of Xceed and Polynovo on execution of the revised investment agreement.

Xceed will continue to look to optimize its investment in wholly owned subsidiary Boron Molecular, which is unaffected by the Polynovo deal.

The company said it would "actively consider alternative investment opportunities to seek to recover value for Xceed shareholders".

Metabolic was up half a cent or 20 percent to three cents.

Xceed was untraded at 5.5 cents.

POLARTECHNICS

Polartechnics self-sampling Cerviscreen test for sexually transmitted diseases will be distributed by Healthscope subsidiary, Gribbles Pathology.

Polartechnics said it would sell Cerviscreen to Gribbles which would distribute the tests to its client network.

The company did not disclose any cash value for the three year deal.

Polartechnics said Gribbles was “at the forefront of molecular diagnostics, the fastest growing area in pathology markets” and comprised 43 National Association of Testing Authorities-accredited laboratories servicing more than 40 affiliated medical centres.

Gribbles will perform the pathology analysis for the product and undertake an in vitro study for regulatory submissions to the Australian Therapeutic Goods Administration and the Conformitée Européenne (CE) Mark to allow direct sales to consumers.

Polartechnics has developed Cerviscreen in line with international government policies to reduce the prevalence of sexually transmitted infections.

The company said there were more than 340 million new cases of curable sexually transmitted infections (STIs) in men and women between 15 and 49 years a year, including chlamydia, gonorrhoea and trichomoniasis, all of which can be sampled by Cerviscreen for analysis.

Polartechnics chairman Rob Hunter said that many women “prefer the privacy of self-sampling compared to the uncomfortable and invasive current cervical sampling techniques, which require pelvic examination by a doctor”.

“Cerviscreen can be used by a woman in a medical clinic or in the privacy of her own home,” Mr Hunter said.

Mr Hunter said the Gribbles agreement was “further validation of the market preference for Polartechnics products in this growing sector”.

“These agreements tie in with our global strategy for Cerviscreen that will launch in 2009, and which we expect to generate about $46 million in sales over the next three years,” Mr Hunter said.

Polartechnics said it had confirmed initial orders from its Chinese distributor for 100,000 units of Cerviscreen in March 2009 with mutually agreed forecast sales to rise to 10 million units a year over the next three years. Cerviscreen will be sold through their network of over 2,000 pharmacies in China, the company said.

Polartechnics was up three cents or 18.18 percent to 19.5 cents with 1.8 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell has a research agreement with Centocor Research & Development Inc to provide access to Living Cell’s encapsulation technology.

Living Cell provided no details of the agreement with the Pennsylvania-based Centocor.

The company said alginate capsules consisted of three layers with nano-scale pores, designed to prevent the host’s immune system from detecting the foreign cells, while at the same time allowing nutrients to reach the cells and cell secretions to exit, ensuring long term survival.

Living Cell’s chief operating officer Dr Paul Tan said the encapsulation technology was “a critical factor for the effectiveness of Diabecell”.

“We have always known that this technology has much wider application and value,” Dr Tan said.

“The arrangement with Centocor has the potential for ongoing collaboration and future licencing opportunities,” he said.

Living Cell was up half a cent or 4.76 percent to 11 cents.

FLUOROTECHNICS

Fluorotechnics expects sales revenue for the year ending June 30, 2009 to be about $3.5 million short of the $7.5 million projected in the company's prospectus.
Fluorotechnics said the shortfall was due to a delay in the increase of production capacity restricting the ability to demonstrate or deliver products; slower than expected conversion of a major European customer; and the cancellation of all orders by a major US customer as it is struggling to arrange debt or equity financing.
The company said the increase in the company's production capacity was at a point where it could meet the expected demand for the 2009 financial year.
Fluorotechnics said its processes were scaleable and the company could meet the expected growth in demand for products in 2010.
The company said its revenue projections had been delayed by about three months and it expected sales for the year to June 2010 of $18 million as outlined in the prospectus.
Fluorotechnics said its two-dimensional gels offered high resolution and due to the technical advantages of the gels and their electrophoretical characteristics, they offer much higher protein detection sensitivity.
The gels are plastic backed making them much more convenient to use than the cumbersome plate glass alternative.
The company said it was "encouraged" by the number of new institutions and companies making contact to enquire or buy its products and by proteomics leaders that have converted to Fluorotechnics' products.
Fluorotechnics fell one cent or one percent to 99 cents.

SAFETY MEDICAL

Safety Medical says it has secured $9.5 million in funding to allow for the introduction, marketing and distribution of women's hygiene products in Australia and New Zealand.
Safety Medical said it had been working on the project for 12 months with a joint venture partner to commercialize the range of tampons, pads and liners.
The company said it was entering a" mature market segment with an innovative selling proposition that has been identified which will change the landscape of the category".
Safety Medical said the application "could be readily expanded to encompass other absorbency-based products within the healthcare sector".
Safety Medical is a 50 percent owner of the new company that will trade under the same name as the brand of the new range and would operate from Safety Medical's Salisbury Plain facility in Adelaide.
The company said it had arrangements with a European manufacturer in the sector for production of the new range and had interest from major retailers with an initial planned roll out across Australia in the first three months of 2009 through more than 1000 retail outlets, followed by its introduction in New Zealand by July 2009.
Safety Medical said the women's hygiene sector generated more than $310 million a year in Australian retail sales and was virtually recession-proof.
Safety Medical did not explain how the new range was different from existing products, but said the National Australia Bank had shown "strong support for this joint venture".
The company said it had financing $1.5 million for initial working capital, advertising and launch, coupled with access to a further $8.0 million in trade finance, which would see the company meet the expected demand and gain market penetration quickly and efficiently.
Forecasts for the first year following launch would see sales reaching $15 million growing to $42 million by year three, the company said.
Safety Medical was unchanged at 14.5 cents.

ACUVAX

Acuvax says its affiliate, Hawaii Biotech, has completed the phase I dosing of 24 healthy individuals with its West Nile virus vaccine.

Acuvax chief executive officer and Hawaii Biotech director Dr William Ardrey said the dosing was an important milestone which would "assure investors and the broader market that the trial is progressing well despite the global downturn, with results expected in the next few quarters".

Hawaii Biotech chief executive officer Dr Elliot Parks said preliminary safety results and immunologic data from the 24 subjects treated with three doses of the vaccine would be available early in 2009 with complete results by July 2009.

Hawaii Biotech said it had developed a West Nile sub-unit vaccine designed with high fidelity to the native viral antigen to provide protective immunity. The vaccine is non-replicating and designed to be safer than live-attenuated vaccines, the company said.

Hawaii Biotech said West Nile Virus was carried by birds and spread by mosquitoes and could cause serious, life-altering and even fatal disease.

The disease can be transmitted through mosquito bites, blood transfusion and organ transplant and can be passed through the uterus and by breast-feeding.

The company said there was no existing vaccine for human use.

According to the US Centers for Disease Control and Prevention, cases of West Nile Virus infections in humans have been reported in all US states except Hawaii, Alaska and Maine. West Nile Virus has been reported in Europe, West and central Asia, Oceania, Africa, the Middle East and since 1999, in North America. Since it entered the US, there have been 25,000 cases on record and more than 1,000 deaths.

Acuvax fell 2.2 cents or 44 percent to 2.8 cents.

USCOM

Uscom says it will issue two million shares at 30 cents a share to the US-based OSI Systems the parent company of Spacelabs Healthcare for $600,001.

Uscom said on December 16, 2008 that Spacelabs would distribute its ultrasonic cardiac output monitor in the Americas, Europe, Middle East Africa and India.

Uscom said the allocation was five percent of its issued capital and was accompanied by an option to buy a further two million shares over the next five years at 37.5 cents a share.

The funds will be used to support the global product launch, provide infrastructure to support the distribution agreement with Spacelabs and other general working capital.

Uscom was unchanged at 25 cents.

MEDICAL THERAPIES

Medical Therapies says its share purchase plan closed with applications for 712,500 shares raising $28,500.

The plan offered up to $5,000 worth of shares at four cents a share.

Medical Therapies was untraded at 3.6 cents.