Biotech Daily

Monday June 22, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN; BONE UP 11%, CYTOPIA, PRANA DOWN 11%**

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*** INCITIVE TO ACQUIRE V-PATCH MEDICAL; SIDELINES BROMELAIN**

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*** PATRYS RELEASES 63m ESCROW SHARES**

*** STIRLING CLAIMS WORD-OF-MOUTH RAPID SALES GROWTH**

MARKET REPORT

The Australian stock market climbed 0.48 percent on Monday June 22, 2009 with the S&P ASX 200 index up 18.6 points to 3,918.2 points.

Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and one was untraded.

Bone was best, up two cents or 11.11 percent to 20 cents with 49,399 shares traded, followed by Chemgenex up 9.9 percent to 72 cents with 1.1 million shares traded.

Genetic Technologies climbed 9.1 percent; Novogen was up 4.8 percent; Genera, Impedimed, Nanosonics and Sirtex were up more than three percent; Phylogica and Progen rose more than two percent; with Resmed up one percent.

Cytopia and Prana led the falls, both down 11.11 percent to eight and 16 cents, respectively, on low volumes.

Antisense lost 7.5 percent; Tyrian fell 6.7 percent; Living Cell and Viralytics were both down 5.3 percent; Bionomics, Clinuvel, Optiscan and Psivida fell more than four percent; Pharmaxis, Starpharma and Universal Biosensors were down more than three percent; Biota, Phosphagenics and Polartechnics shed two percent or more; with Alchemia, Heartware and Peplin down more than one percent.

MARC SINATRA'S BIOGUIDE BRIEF: DIA-B TECH, PALLANE

Recently, I attended a lunch meeting on the $15 million capital raising as part of Dia-B Tech's merger with Pallane Medical.

Asked for a comment on the merger, I said, among other criticisms, that the valuation was 'insane', as in insanely high. I then asked the journalist to change 'insane' to 'excessive' before quoting me.

Insane was the correct word and I shouldn't have asked the journalist to change my quote.

Late last Friday, Dia-B Tech published a supplementary prospectus regarding the capital raising.

The first thing to note from the supplementary prospectus is that an independent expert report arrived at a value of $18.5 million to $31.4 million for Pallane, compared to a value of $85.5 million implied by the prospectus and the market capitalization of Dia-B Tech.

The reason for this discrepancy according to the supplementary document is that the report assumed a licencing model, whereas Pallane prefers a go-it-alone model.

It also implies that the report fails to recognize the value to investors of a mechanism whereby the merged entity can, upon shareholder approval, buy-back shares issued to the Pallane-related vendors at a nominal price in the event that certain milestones are missed.

This buy-back plan, however, appears to have fleas since at best it will only lead to existing Dia-B Tech and subscribing shareholders to the capital raising owning more of a company with less value, from missing those milestones.

Theoretically, vendors could vote down any proposal to buy shares back from them, given they will control 85.4 percent of the merged entities voting power according to the IER, although conflict of interest may prevent them from doing so. Regardless, with the vendors holding 85.4 percent of the company, small shareholders will get little say in how the company is run.

Yep, insane was the right word.

Another source of fleas is that the raising doesn't really seem to be underwritten for $12.5 million as has been claimed, since one of the conditions for the merger to proceed is for "not less than $10 million" to be subscribed for under the offer, with a minimum subscription for shares to be issued of $12.5 million.

The rest of the supplementary prospectus is largely confusing waffle combined with standard points.

Although not part of the supplementary prospectus, I decided to update my figures on the share price performance of listed companies which have Dr Michael Wooldridge on their board, since he will be the only existing Dia-B director retained by the merged entity.

In 2007, I found that investing $10,000 in each of four companies (Cogstate, Resonance Health, Dia-B and Australian Pharmaceutical Industries) as per his presence would have turned $40,000 into $21,000, representing an average annual loss of 24 percent.

Two years later, with an additional company in the mix (Prime Retirement Units), $50,000 would have been turned into just over $11,000, with an average annual loss per investment of 42.5 percent, on share price performance, not including dividends.

As I stare at the note on my desk reminding me to apply Advocate on the 15th of each month to my dog to control fleas, I can only wonder whether rather than writing considered opinions, I should be repackaging the generic active ingredient as the core technology of an IPO and/or back-door listing for development and sale as a global debugging, debunking, parasite and irritant-removal suitable for listed, listing and listless biotechnology companies.

Dia-B was unchanged at 1.3 cents.

Marc Sinatra
Analyst

INCITIVE

Incitive has changed direction from its bromelain pineapple stem-based cancer drug focus to developing and marketing a mobile cardiac monitoring system.

Incitive executive chairman Mel Bridges said the company would acquire 100 percent of the shares in V-Patch Medical Systems and its related entities through the issue of up to 495,000,000 'performance shares' and up to 400,000,000 options to buy shares at one cent, subject to shareholder approval and the satisfaction of certain milestones.

V-Patch shareholders and interested parties will hold between 51 percent and 64 percent of Incitive, dependent on meeting the performance milestones.

Incitive said it would raise between $1 million and $2 million in new equity at one cent a share, subject to approval by shareholders "to further capitalize the company and continue the international distribution of the V-Patch technology".

The company said V-Patch's core business was the development of a non-invasive, non-obtrusive wireless-based telemetry system for collecting human vital signs, initially focused on cardiac (heart) monitoring in real time.

Because it was wireless and light-weight, the V-Patch would allow more patients to be monitored in a mobile situation within the hospital without hard-wired monitoring and would also allow monitoring of patients outside hospital, lowering costs and speeding recovery times, the company said.

Incitive said the V-Patch had Conformitée Européenne (CE) Mark approval with an intention to file for US Food and Drug Administration approval by July 2010.

Mr Bridges told Biotech Daily that V-Patch had existing orders from Europe.

Incitive said there were 21 patents employed in the technology and protection was secure in Australia and overseas, creating substantial barriers to entry for competitors.

Mr Bridges said the V-Patch acquisition would "position Incitive in an income earning position as early as the last quarter of 2009 and importantly position the company to be cash flow positive in a faster timeframe".

"The V-Patch acquisition, on the back of the recently announced licence deal to Peptech for the animal health rights, positions Incitive as a growth technology stock," he said.

Mr Bridges said the bromelain cancer drug program would continue, but would be "separately funded" apart from the Incitive V-Patch program.

Incitive said V-Patch managing director and co-founder Peter Taylor would be the Incitive chief executive officer and managing director following the acquisition.

Mr Bridges will remain the independent chairman together with Winton Willesee as an independent director. V-Patch will nominate up to two additional directors.

Incitive said V-Patch had designed, developed and manufactured a set of miniaturized, wearable, non-invasive and non-obtrusive biosensors comprising disposable patches and non-disposable, wearable, smart-analysis modules with wireless connection to mobile telephone networks directly interfacing with the internet.

Incitive said the device gave physicians the ability to remotely monitor and analyze a patients' electrocardiograph, which would be transmitted via the Vodafone mobile telephone network, to the doctor via the internet and the doctor would be advised of the event by email or SMS text, allowing freedom for both patient and doctor.

Incitive said the system had been tested operationally across diverse telephony/data networks in the UK, Europe, Turkey, China and Brazil.

Incitive said the market for the technology included the $US1.7 billion cardiac monitor market, which continued to grow due to the obesity pandemic.

The company said the V-Patch was the most advanced in innovation, telemetry and size and could be used for other forms of mobile ambulatory telemetry, for intra-hospital use.

Incitive jumped 0.3 cents or 42.9 percent to one cent with 1.8 million shares traded.

VENTRACOR

Ventracor's administrators Ferrier Hodgson have failed to sell the assets of the company as expected (BD: Jun 16, 2009).

It is believed that Ferrier Hodgson will proceed to liquidation of Ventracor's assets.

Last week Ferrier Hodgson said it had a deed of company arrangement to sell the assets of the company to Siqro which is widely believed to be related to the US-based cardiac technology company Orqis.

A Ventracor employee at the meeting told Biotech Daily that Ferrier Hodgson's administrators said there were no other funding options available.

Biotech Daily has attempted to speak with Ferrier Hodgson's administrators and media representatives but there has been no response to recent inquiries.

Ferrier Hodgson has made occasional announcements about Ventracor on its website, but little detail has been provided to shareholders via the ASX website posting system.

Ventracor is in a suspension and last traded at 8.3 cents.

ACRUX

Acrux has signed its first licencing deal for Europe with an agreement to by Vifor Pharam to distribute Ellavie for menopause in Switzerland.

Acrux chief executive officer Dr Richard Treagus said that his company began the European Union regulatory process in December filing for approval in Sweden.

Dr Treagus said he expected European Medicines Agency approval by the end of 2009 and Ellavie on the market in the EU in 2010.

Dr Treagus said Switzerland had its own independent regulatory system and although the company has signed a distribution agreement with Vifor, a segment of the Swiss-based Galenica Group, the company would begin its regulatory application for Switzerland.

He said Ellavie should be available in Switzerland in 2011.

Acrux said in a media release to the ASX that its Ellavie transdermal estradiol spray is marketed in the US as Evamist.

The agreement with Vifor is a marketing and distribution agreement for Switzerland, alone, but it is Acrux's first distribution agreement for Ellavie in Europe.

Acrux said it would receive undisclosed fees on signing, on confirmation of Swiss marketing authorization and on the first three anniversaries of market launch.

The company said it would receive an ongoing distribution fee based on net sales of Ellavie.

Vifor Pharma is responsible for obtaining marketing authorization in Switzerland, using the product dossier previously approved by the US Food and Drug Administration.

The hand-held transdermal spray intended to reduce the symptoms that affect quality of life for menopausal women is under evaluation by the regulatory authorities in Australia and Sweden.

Dr Treagus said in the media release that Vifor Pharma was "a strong partner for Acrux in Switzerland, leveraging its existing women's health franchise".

"Whilst the Swiss pharmaceutical market is relatively small, sales of hormone replacement products represent a higher proportion than in many other countries," Dr Treagus said.

"Vifor Pharma's established market position and expertise will be valuable towards achieving rapid commercialization," Dr Treagus said.

Acrux was unchanged at $1.24.

HALCYGEN PHARMACEUTICALS

Halcygen says the Swedish Medical Products Agency has required a pharmacokinetic study for the European registration of its SUBA-Itraconazole anti-fungal drug.

Halcygen said that as the 'reference member state' for registration purposes, the Swedish Agency reviewed its US pharmacokinetic studies and "guided Halcygen to undertake a single pharmacokinetic study in the European Union, with the aim of demonstrating that SUBA-Itraconazole performs in a similar manner against EU registered Sporanox as it does with US-derived Sporanox.

Halcygen's chairman Dr Roger Aston told Biotech Daily that all Sporanox was manufactured in Belgium.

Dr Aston said the additional trial would require about 36 patients and take three months for dosing and further three months for data analyses, with a further six months to prepare the application.

He said the application should be completed by mid to late 2010, with SUBA-Itraconazole registered and available in the EU market in 2011.

Halcygen said in its media release to the ASX that it did not expect there would be any difference between EU and US purchased Sporanox, it was a regulatory requirement that comparative bioavailability was demonstrated against the 'locally-sourced' drug.

The company said the Swedish Agency said that in the event that different results were obtained from what was observed in the US studies, they would look at the results of Halcygen's clinical safety and efficacy study currently recruiting in the US for registration purposes.

Halcygen said it had undertaken a total of nine pharmacokinetic studies in Australia and the US which demonstrated that the company's half dose formulation of Itraconazole was comparable to Sporanox (itraconazole) in terms of blood levels.

The company said SUBA-Itraconazole showed lower inter-patient variability compared to Sporanox, resulting in more predictable blood levels.

Halcygen was up 1.5 cents or 7.14 percent to 22.5 cents cents.

KARMELSONIX

Karmelsonix says it has launched its Pulmotrack-3010-Cough Counter in the US.

Karmelsonix said the launch was at the Second American Cough Conference in Jersey City, New Jersey, June 12 and 13, 2009

The company said the technology was under review by the regulatory authorities in Europe and the US, awaiting Conformitée Européenne (CE) mark clearance and US Food and Drug Administration approval.

Karmelsonix said the device was an additional component to the Pulmotrack, Wholter and WIM-GER respiratory diagnostic devices.

Karmelsonix fell 0.1 cents or 2.22 percent to 4.4 cents.

PATRYS

Patrys says 63,345,205 shares held in voluntary escrow will be released on July 13, 2009.

The company's total share issue is 164,151,875 shares with a further 11,300,000 shares to come out of escrow on December 3, 2009.

Patrys said 750,000 options exercisable at 45 cents expiring on July 12, 2012 would also be released from escrow.

Patrys was untraded at 12 cents.

STIRLING PRODUCTS

Stirling says it has had a rapid growth in sales in Mongolia “as news of the effectiveness of the company’s phytopharmaceutical products spreads through word of mouth”.

Stirling said 377 sales agents had been appointed and will be addressed at a meeting in Ulaan Bataar this evening by the company’s managing director, Peter Boonen.

The company said gross sales were increasing rapidly and last week were $US33,000 with the main demand being for Cholonorm for the reduction of low density lipoprotein cholesterol, Diabetin for the reduction of blood sugar and Immunoxel an immune booster and influenza prevention.

Stirling was unchanged at 2.1 cents.