Biotech Daily

Thursday October 2, 2008

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECHS UP: STARPHARMA UP 15%, CHEMGENEX DOWN 9%**

*** BIOGUIDE: PHOSPHAGENICS' VERY DEEP VITAMIN E PIPELINE**

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MARKET REPORT

The Australian stock market lost 0.8 percent on Thursday October 2, 2008 with the All Ordinaries down 40.4 points to 4,774.1 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, five traded unchanged and eight were untraded.

Starpharma was best, up four cents or 15.38 percent to 30 cents, followed by Neuren up 14.29 percent to eight cents and Prana up 11.36 percent to 49 cents.

Sirtex climbed 9.71 percent; Benitec and Clinuvel were up more than eight percent; Pharmaxis was up 7.8 percent; Arana rose 6.1 percent; Living Cell was up 5.41 percent; Bionomics, Circadian and Heartware were up more than three percent; Cellestis and Progen rose more than two percent; with CSL and Cathrx up more than one percent.

Psivida ostensibly led the falls, down 20 cent or 10 percent to $1.80 with one share traded, followed by Chemgenex down 9.09 percent to 70 cents on modest volumes.

Optiscan lost 8.33 percent; Biota, Cytopia and Polartechnics fell five percent or more; Mesoblast fell 4.27 percent; Viralytics lost 3.85 percent; Phosphagenics and Resmed shed more than two percent; with Antisense and Bone down more than one percent.

MARC SINATRA'S BIOGUIDE: PHOSPHAGENICS

Overview: Phosphagenics is a Melbourne-based company, primarily focused on exploiting the properties of their proprietary phosphorylated vitamin E compounds.

Phosphorylated vitamin E is thought to be the biologically active form of vitamin E and it also demonstrates unique properties when applied to the skin. This has led Phosphagenics to seek multiple applications in a wide range of areas, including nutraceuticals, drug delivery and as enhancers of existing drugs.

Nutraceuticals include food additives, dietary supplements and some cosmetics enhancers.

This raises the question of whether Phosphagenics is trying to do too much and, if so, on which projects should they be focused?

Financials: Market cap: $46 million; cash: $16 million; last half cash burn: $4 million.

Directors: Non-executive chairman, Prof Andrew Vizard; president and chief executive officer, Harry Rosen; executive vice-president, Dr Esra Ogru; non-executive directors Prof John Mills, Jonathan Addison and Michael Ashton.

Phosphagenics' board is quite strong and suits its wide ranging activities.

Products in Development:
1) Phospha E (supplement): Previously sold in the US under the brand name Ester-E by Zila Nutraceuticals, generating $2 million a year in royalties for Phosphagenics. The licence with Zila was not renewed and Phosphagenics looks likely to take this product to market.
2) Phospha E (food additive): Subject of a research agreement with Nestlé. A worldwide licence has been negotiated and is likely to be signed after completion of a phase 2 study for metabolic syndrome due at the end of 2008.
3) Phospha E (cosmetics): A material transfer agreement was signed with a major cosmetics company in 2006. Any commercial outcome should be known in 2009.
4) Oxycodone-TPM: A transdermal system to deliver oxycodone. A phase I trial has been completed. The product may be refined before phase II trials or out-licencing.
5) Morphine–TPM: A patch for the delivery of morphine. Phase Ia and Ib studies have been completed. Its future will become clearer after its current phase IIa trial.
6) Lidocaine-TPM: A system to enhance delivery of lidocaine to the skin. A phase I trial commenced last month.
7) Diclofenac-TPM: A system to enhance the delivery of the non-steroidal anti-inflammatory Diclofenac to the skin. Currently in pre-clinical testing.
8) Insulin–TPM: A transdermal system to deliver insulin. Phase Ia and Ib trials have been completed. Results from its phase II study are due at the end of 2008.
9) Retinoic Acid–TPM: A system to efficiently deliver retinoic acid (vitamin A) to the skin. It has completed a phase I trial.
10) APA-01: An enhanced form of Vitamin E for use with a statin or cholesterol-lowering drug. Preclinical work is complete and the project is available for out-licencing.
11) GTP-0805: An anticancer agent intended for combination use. Preclinical work is complete and the project is available for out-licencing.

Significant Product Markets: Nutraceutical sales are marketing driven, quite competitive and dominated by big brands.

Supplemental vitamin E sales in the US were $US400 million in 2006. Sales have been falling since 2000, as papers questioning vitamin E's benefits have surfaced.

The worldwide opioid analgesics market was worth $US7.7 billion in 2007. The long-acting opioid segment was worth $US3.0 billion. A 2008 Datamonitor report found "the topical market represents an opportunity for companies to enter a comparatively underserved market". Fentanyl is the only opioid that is currently delivered transdermally. Sales of the first Fentanyl patch, Duragesic, were $US1.2 billion 2007, despite increasing generic competition.

Worldwide insulin sales were $US7 billion in 2007.

In 2005, Pfizer launched, Exubera, an inhalable form of insulin. Sales were poor and Exubera was discontinued earlier this year. There were product specific issues with Exubera (such as being a cumbersome device as well as safety), but it also appears diabetics aren't too worried by the injections. Several companies have since discontinued new insulin delivery projects.

Phosphagenics puts the US topical retinoids market at $US340 million. Retinoids mainly target the acne market, which is crowded and the subject of much research.

Lidoderm Patch, a leading lidocaine product, had worldwide sales of $US748 million in 2006. Development of topical lidocaine products is focused on dysmenorrhea.

Opinion: Phosphagenics' nutraceutical and drug delivery arms have significant merit.

Earning $2 million a year in royalties, Phospha E clearly has some appeal to consumers, despite the negative image of standard vitamin E. Whether this demand will stay with Phospha E if it is launched under a Phosphagenics brand is another question, given the marketing and brand driven nature of nutraceuticals. Successfully striking a deal with Nestlé could do wonders for the Phospha E brand.

A licencing agreement is needed to validate the drug delivery technology, but it does look good for opioid analgesic delivery where the market need is clear. The retinoic acid and lidocaine products will probably need to demonstrate clear superiority over the market leaders to garner significant sales. Given the fate and fallout from Exubera, the insulin product has a very tough task in front of it.

Phosphagenics is probably doing too much and I would like them to choose a subset of projects and truly back them. In the future, it may be worth splitting the nutraceutical and drug delivery arms into two companies given their different foci. Nonetheless, Phosphagenics has some gems and, as such, I have given it a valuation based on comparables of $0.12 per share.

Phosphagenics closed down 0.2 cents or 2.86 percent at 6.8 cents.

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ARANA, CIRCADIAN

Arana has successfully engineered an improved version of the VEGF-D antibody VGX-200 owned by Circadian subsidiary Vegenics, for the treatment of solid cancers.

Vascular endothelial growth factors (VEGF) are signaling proteins involved in vascular angiogenesis and tumor growth.

In a joint media release Arana and Circadian said that Arana used its Superhumanisation technology to successfully develop humanized versions of Vegenics' VEGF-D lead mouse antibody.

The companies said the purpose of converting a non-human antibody into a human-like antibody was so that it may be safely administered to patients minimizing the risk of rejection of the treatment.

The companies said the potency of the candidates was then further improved using Arana's Evogene optimization technology.

They said the completion of the project triggered a final instalment of research costs to Arana under the terms of the collaboration agreement between the two companies.

In addition, Arana will receive a milestone payment for successfully meeting the improvement criteria set at the outset of the project.

Vegenics is a wholly owned subsidiary of Circadian and will conduct further pre-clinical studies on the series of humanized and improved VEGF-D antibody drug candidates.

Upon designation by Vegenics of a lead drug candidate a further milestone will become payable to Arana, the companies said.

Arana is then eligible to earn further milestone payments as the product advances through subsequent stages of pre-clinical and clinical testing and regulatory approval and a royalty on product sales.

Circadian said Vegenics has "a strong patent portfolio covering drugs directed against VEGF-D".

VEGF-D is closely related to VEGF-A, the target of Genentech's Avastin, a leading cancer therapy with worldwide sales in 2007 in excess of $US6 billion.

Circadian and Vegenics chief executive officer Robert Klupacs said the achievement of this humanization milestone was "an important step in our ongoing development of anti-VEGF-D antibodies as potential therapeutic candidates for the treatment of cancer".

"Consistent with our strategy this humanized VEGF-D antibody expands our cancer drug development program, which includes our existing human VEGF-C cancer drug candidate VGX-100," Mr Klupacs said.

Arana chief executive officer Dr John Chiplin said the project was the fourth product his company had "significantly improved and delivered back to a collaboration partner using our proprietary technologies which improve antibody and protein products".

"This represents an impressive 100 percent track record of success and we look to continue to build on this as we move forward with other partners," Dr Chiplin said.

Arana said it had successfully engineered products from the biopharmaceutical pipelines of both CSL and Glaxosmithkline.

Arana also has an ongoing alliance with US-based Aveo Pharmaceuticals Inc for the use of Arana's Superhumanisation technology for the internal development of several Aveo drug products.

Arana climbed five cents or 6.1 percent to 87 cents.

Circadian climbed three cents or 3.75 percent to 83 cents.

PSIVIDA

Psivida says interim six-month safety and efficacy results from the first human pharmacokinetic study of Medidur for diabetic macular oedema are “very encouraging”.

The study was conducted with licencing and development partner Alimera Sciences.

The company said Medidur FA would be marketed under the trade name Iluvien, if approved by the US Food and Drug Administration.

Psivida said the 36-month, open label phase II study, was running concurrently with the pivotal phase III fluocinolone acetonide in diabetic macular oedema study and was designed to assess systemic exposure of the corticosteroid, fluocinolone acetonide after administration of Iluvien in diabetic macular oedema patients.

The study was also designed to provide information on the safety and efficacy of Iluvien in a diabetic macular oedema population.

A total of 37 subjects were enrolled in the study, 20 patients received a low-dose Iluvien, which delivered a 0.23µg per day dose and 17 patients received a higher-dose Iluvien of 0.45µg per day.

The six-month data showed 25 percent of the low dose patients and 41 percent of the higher dose patients had an improvement in best corrected visual acuity (BCVA) of 10 or more letters on an eye chart compared with their baseline vision, while 18 percent of the higher dose patients had an improvement in BCVA of 15 or more letters.

The percentage of low dose patients that had an improvement in BCVA of 15 or more letters from baseline decreased from the 20 percent seen at the three-month readout due to one patient having developed a cataract and one patient having developed an epiretinal membrane involving the macula prior to the readout.

Psivida said the development of cataracts and epiretinal membranes in a diabetic population were not unusual and are commonly addressed with surgical intervention.

Psivida said 12 percent of patients in the higher dose group and no patients in the low dose had a recorded intraocular pressure of above 30mmHg during the six months.

This was unchanged from the three month read-out.

At six months, two patients in each group had experienced an adverse event related to cataract formation and one additional patient in each group underwent cataract extraction.

Iluvien is an intravitreal insert for the treatment of diabetic macular oedema, one of the leading causes of blindness in people under 65 years of age.

Each insert is designed to provide a therapeutic effect for up to 36 months for the low dose and up to 24 months for the higher dose.

The early readout and comparison with Bausch & Lomb’s Retisert, also developed by Psivida, provides further insight into the dose-response of Iluvien. Retisert releases the same drug as Iluvien but at a higher dose and faster rate (initially 0.6 µg per day).

In a similarly sized clinical trial of Retisert in diabetic macular oedema at six months, 27 percent of patients receiving Retisert had gained 10 or more letters of BCVA and 15 percent gained more than 15 letters.

Iluvien was designed with the hypothesis that by better device design it would be possible to achieve similar efficacy in diabetic macular oedema to Retisert, while reducing side effects and improving ease of administration.

Psivida managing director Dr Paul Ashton said the “very encouraging six-month readout from the Iluvien PK study indicates continued improvement of visual acuity”.

Dr Ashton said the study supported the hypothesis that Iluvien could have an impact on diabetic macular oedema while minimizing side effects associated with corticosteroids.

Data from the study is being evaluated on an ongoing basis.

The last patient was enrolled in this study at the end of February 2008.

Psivida fell 20 cents or 10 percent to $1.80 with one share traded.

AUSBIOTECH

Australia's national biotechnology industry body says Dr Terry Cutler's Review of the National Innovation System "failed to emphasize and fund" the biotechnology industry.
In a detailed formal submission to the Cutler Review of the National Innovation System, Ausbiotech said that human health and diagnostics should be made a "national priority".
Ausbiotech chief executive officer Dr Anna Lavelle said the industry was one of the country's most important innovation sectors.
"Human health and diagnostics are vital to the community and will deliver long term economic gains for Australia," she said.
Dr Lavelle said Ausbiotech welcomed "the focus on innovation demonstrated by commissioning the review."
Dr Lavelle said the Cutler review gave too little focus to driving commercialization and attracting the private investment needed to capitalize on Australia's ability to develop industries of the future.
She said all Australians wanted to see the Government support high-growth, high-value, job-creating, export-oriented industries that also helped solve some of the world's most pressing problems.
"Biotechnology is delivering real solutions to the urgent challenges in health, agriculture, climate, energy and environment. It is an area where Australia has significant global expertise."
Dr Lavelle said Ausbiotech supported a system of tax credits and urged the Government to implement the change in the 2009 budget, but also warned administration requirements could limit the effectiveness of this initiative.
She said Ausbiotech also urged the Government to consider the need for incentives to keep large business conducting research and commercialization activities in Australia.
Dr Lavelle said the grant program recommended by the Cutler Review was under-funded and need to be at least $250 million a year.
"Co-investment is as de-risking for Government as it is for private capital," Dr Lavelle said.
"If the right policy settings are in place to reward patient capital, then a portfolio of innovation investments offers excellent returns to private capital and all of Australia," she said.
Dr Lavelle said a "comprehensive 20 year policy framework was needed to amass the quantum of patient capital needed to develop a sustainable innovation system".
The Federal Government will respond to the recommendations of the Cutler Review before the end of the year in a policy white paper.

PHARMAUST

Pharmaust says Simon Owen has resigned as a director and joint company secretary.
Pharmaust has appointed Sam Michael Wright as a non-executive director.
Mr Wright joined the company as the financial controller for Pharmaust Manufacturing Pty Ltd in September 2006 and was appointed joint company secretary for Pharmaust in August 2007.
Mr Wright will be a non-executive director and company secretary.
Pharmaust climbed 0.3 cents or 13.64 percent to 2.5 cents.

NUSEP

Nusep says John Manusu has been appointed executive chairman and Dr Hari Nair has been appointed managing director.
Nusep said the board approved the appointments as part of the NxGen acquisition (see Biotech Daily October 1, 2008).
Nusep was up 0.7 cents or 12.07 percent to 6.5 cents.

METABOLIC, XCEED, CSIRO, POLYNOVO

Metabolic, Xceed Capital and the CSIRO have completed the share sale agreement for Metabolic's acquisition of Polynovo Biomaterials.
Metabolic chairman Rob Stewart told the ASX that the parties “had set an aggressive timetable for carrying out due diligence and to negotiate the terms of the share sale agreement and unfortunately these matters had taken somewhat longer than expected” (see Biotech Daily July 18 and September 5, 2008).
The final terms reflect those previously advised by Metabolic to the market with the exception that (a) the agreed number of new Metabolic shares to be issued to Xceed and the Commonwealth Scientific and Industrial Research Organisation will be 157,577,919 and 82,951,398 (previously approximately 89 million shares) respectively; Xceed intends to distribute all but approximately 7.4 million of the 158 million Metabolic shares to be issued to it; and the company name of Metabolic is proposed to change to Polynovo.
“We are now in a position to press ahead with all of the other steps necessary to complete this exciting acquisition which we believe has significant potential for value accretion for Metabolic shareholders,” Mr Stewart said.
The transaction is subject to several conditions, including the approval by both Metabolic and Xceed shareholders at general meetings.
The meeting of Metabolic shareholders will be convened as soon as practicable in order to obtain the necessary approvals for the acquisition.
It is expected that the shareholder approvals will be sought at the company’s annual general meeting which is likely to be held in the second half of November 2008.
Metabolic climbed 0.3 cents or 9.38 percent to 3.5 cents.
Xceed was unchanged at 6.3 cents.