

Biotech Daily

Wednesday April 4, 2012

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH DOWN: GENERA UP 6%, OPTISCAN DOWN 13%
- * REPORT BACKS CYCLOPHARM'S MAJOR CLAIM AGAINST ANSTO
- * PROGEN DATA SHOWS PG545 MAY HAVE CANCER EFFICACY
- * PHOSPHAGENICS LICENCES INDIAS INTAS FOR THREE COSMETICS
- * ALLAN GRAY (FORMERLY ORBIS) TAKES 20% OF IMPEDIMED
- * PROBIOMICS (BIOXYNE) RELISTS UP 0.5c
- * REVA COMPLETES \$US24m SHARE TRANSFER
- * ALLIED LOSES BIOMD FOUNDER ROBERT TOWNER
- * CLARIFICATION: DR ROSS MACDONALD, ISONEA
- * GI DYNAMICS EXPANDS COMMERCIAL TEAM

MARKET REPORT

The Australian stock market slipped 0.07 percent on Wednesday April 4, 2012 with the S&P ASX 200 down 3.1 points to 4,333.9 points. Nine of the Biotech Daily Top 40 stocks were up, 15 fell, 12 traded unchanged and four were untraded. All three Big Caps climbed.

Genera was the best, up one cent or 5.6 percent to 19 cents with 148,534 shares traded, followed by Genetic Technologies up 4.2 percent to 10 cents, with 11.3 million shares traded.

Tissue Therapies climbed 3.1 percent; Heartware, Pharmaxis, Prima, Resmed and Viralytics rose more than two percent; Cochlear, CSL and Reva were up more than one percent; with Alchemia up 0.9 percent.

Optiscan led the falls, down two cents or 12.9 percent to 13.5 cents, with 123,722 shares traded.

Avita and Sunshine Heart lost more than nine percent; Bionomics and Patrys were down three percent or more; Anteo, Impedimed, Nanosonics, Phosphagenics and Psivida shed two percent or more; Sirtex, Starpharma and Universal Biosensors were down more than one percent; with Acrux and Biota down by less than one percent.

CYCLOPHARM

The Australian Government Productivity Commission has found Cyclopharm competitor Petnet Australia has breached competitive neutrality policy.

The Productivity Commission Competitive Neutrality Complaints Office report found that some allegations were not substantiated, but that the Petnet division of the Australian Nuclear Science and Technology Organisation (ANSTO), needed to change its business model to achieve a commercial rate of return reflecting risk and the investment in Petnet. Cyclopharm said that it complained to the Productivity Commission that Petnet had an unfair advantage in the positron emission tomography market in August 2011. Cyclopharm said that its subsidiary Cyclopet, marketed the nuclear pharmaceutical F-18 fluoro-deoxy- glucose (FDG) from its facility at Lucas Heights, New South Wales.

The company said that FDG was used in positron emission tomography (PET) by doctors to improve diagnosis, primarily cancers, by enabling high quality imaging of both function and disease states in specific tissues and organs.

Cyclopharm alleged that Petnet was in breach of three of the five requirements to ensure competitive neutrality in relation to a contract awarded in May 2011 to Petnet as the exclusive external supplier of NSW Health's FDG radiopharmaceutical needs.

The Productivity Commission report said that "ANSTO's process for selecting a commercial partner to re-enter the PET radiopharmaceuticals market is not a breach of competitive neutrality policy" and its "approach to apportioning and charging centrally provided services satisfies the requirements of competitive neutrality policy".

But the report also found that "revenue and expenditure forecasts over 10 and 15 years demonstrate that Petnet Australia's commercial operations are unlikely to achieve a commercial rate of return on the equity invested over either time period".

"This represents an ex ante breach of competitive neutrality policy," the report said. The report said that ANSTO's pricing of individual services in particular market segments, in itself, was not a breach of competitive neutrality policy.

The report recommended that ANSTO "would need to adjust Petnet Australia's business model such that it can be expected to achieve a commercial rate of return that reflects its risk profile and the full investment in Petnet Australia".

A second recommendation said that "the cost disadvantage resulting from the more stringent regulations applying to Petnet Australia should be neutralized in its cost base". A Productivity Commission spokesman said the second recommendation referred to Table 2.2 which implied a greater cost of compliance by ANSTO over Cyclopharm of \$16,072. The report said that Petnet aimed for a 10 year payback period but it "fails in this test by demonstrating a negative rate of return over a 10 year period" with accumulated losses expected to be \$4.8 million.

The report said that a positive return on investment was unattainable in either the period stated or as the guidelines dictate and the only possible way stated and required returns could be achieved is if all competition, including both Royal Prince Alfred Hospital and Cyclopet were eliminated from the market.

Cyclopharm managing director James McBrayer said the report validated his company's allegations and that ANSTO's behavior had serious implications for fairness and equity when Government and private businesses were tendering for Government contracts. Mr McBrayer said he wanted the Federal Minister for Science and Research, Senator Chris Evans to conduct a review of ANSTO's governance, board representation, management practices and general operations and hoped the NSW Health Minister Jillian Skinner would cancel the contract awarded in May 2011 to Petnet.

The report is at: http://www.pc.gov.au/agcnco/publications.

Cyclopharm was untraded 3.6 cents.

PROGEN

Progen says that new preclinical and clinical data on PG545 shows that it has potential efficacy for cancer, despite the closure of the compound's phase la trial.

Last year, the trial was halted due to injection site reactions and the company later announced that it would develop an intravenous alternative to the sub-cutaneous formulation (BD: Sep 20, 2011; Jan 22, 2012).

Progen said the new data would be presented in a poster entitled 'The heparan sulfate mimetic PG545 increases plasma VEGF and FGF-2 in advanced cancer patients, and significantly inhibits tumor growth in preclinical models of ovarian cancer - implications for future therapy' at the American Association of Cancer Research Meeting in Chicago. The company said that PG545 was a dual anti-angiogenic and anti-heparanase agent and despite the premature closure of the PG545 trial, continued investigations reported changes in angiogenic biomarkers (VEGF and FGF-2) in patient blood samples following treatment with PG545.

Progen's lead scientist on the project Dr Edward Hammond said that "understanding the source of VEGF and FGF-2 is now critically important because these preliminary findings represent an opportunity to identify ways to check whether PG545 is modulating its intended pharmacological targets".

Progen preclinical development director Dr Keith Dredge said the information was "particularly critical for future clinical trial planning and for monitoring the potential effectiveness of such agents in the oncology setting".

Progen said that US collaborators identified that PG545 blocked important signals related to the function of growth factors in ovarian tumor cells and that both Progen and its collaborators independently found that PG545 blocks the tumor growth and/or metastatic spread in different mouse models of ovarian cancer.

"These data clearly demonstrate that PG545 administered intravenously, or into the peritoneal cavity, is very effective against ovarian cancer and our collaborators will continue to work on the mechanism of action for this and other aggressive forms of cancer," Dr Dredge said.

Progen said the findings were timely and provided insights on PG545 as it tried to find a suitable partner to take the product back into the clinic.

Progen was unchanged at 19 cents.

PHOSPHAGENICS

Phosphagenics has signed a licencing agreement with India's Intas Pharmaceuticals for the manufacture and sale of three anti-ageing products formulated for the Indian market. Phosphagenics said that Intas would pay an undisclosed royalty and market the products, incorporating Phosphagenics' patented tocopheryl phosphate mixture or TPM technology, through dermatologists and general physicians in India.

Intas said that the company would leverage its existing pharmaceutical marketing and sales infrastructure that covered dermatologists and general physicians, to launch the products.

Phosphagenics chief executive officer Dr Esra Ogru said the Intas agreement was "another milestone in the company's commercial strategy to roll out its personal care products globally".

Phosphagenics fell half a cent or 2.1 percent to 23 cents with four million shares traded.

IMPEDIMED

Allan Gray Australia, formerly known as Orbis Investment Management has increased its holding in Impedimed from 29,408,960 shares (18.79%) to 31,064,002 shares (19.85%). Allan Gray said it acquired the 1,655,687 shares for \$826,540 or an average price of 49.9 cents a share.

The substantial shareholder notice was signed by Simon Marais and Biotech Daily believes that the investment company formerly known as Orbis has changed its name and nothing else.

Impedimed fell one cent or two percent to 49 cents.

BIOXYNE (FORMERLY PROBIOMICS, HUNTER IMMUNOLOGY)

Probiomics opened up two cents to 24 cents following its share consolidation to 22 cents and closed up half a cent at 22.5 cents.

Probiomics' name change to Bioxyne has been recorded by the Australian Securities and Investments Commission, but the company will continue trading under its old name and code until April 11, 2012 (BD: Mar 23, 28, 2012).

REVA MEDICAL

Reva says the remaining \$US6.4 million of the private transfers of \$US24 million (\$A23.3 million) of the its US shares of common stock has been completed (BD: March 19, 2012). Reva was up one cent or 1.5 percent to 69 cents.

ALLIED HEALTHCARE GROUP

Allied Health says that Biomd founder Robert Towner has resigned as a non-executive director.

Mr Towner was a director of Biomd which became the vehicle for Allied's backdoor listing on the ASX, with its Adapt bovine and kangaroo tissue patch technology retained within Allied's Celxcel division.

Allied said its board and management thanked Mr Towner for his support and efforts, particularly during the merger of Biond and Allied.

The company said it would strengthen its board in the near future.

Allied was unchanged at 2.9 cents.

ISONEA (FORMERLY KARMELSONIX)

Last night's edition reported Isonea's appointments of Dr Ross Macdonald and Dr Stewart Washer as directors and Donal O'Dwyer as a special advisor.

Dr Macdonald told Biotech Daily that he was concerned with the use of the past tense in describing his board positions.

Dr Macdonald said that he was continuing as a member of the venture fund Uniseed Management's investment committee as well as a director of Telesso Technologies and Hatchtech.

Biotech Daily apologizes unreservedly for any confusion that may have occurred, but stands by its use of syntactic structures.

No sub-editors were badly hurt in making this clarification.

Isonea was unchanged at 0.4 cents with five million shares traded.

GI DYNAMICS

GI Dynamics says it has appointed three staff to expand its commercial team to promote lead product, the Endobarrier.

GI said that Anthony (Tony) Tremaglio was appointed senior director of marketing, Anthony Switzer manager of commercial development for Australia and Gerd Gottschalk as reimbursement director for Europe.

GI said that Mr Tremaglio had nearly 20 years of product and market management experience and a proven track record in companies ranging from medical device start-ups to Fortune 500 corporations.

The company said that Mr Switzer had more than 20 years of experience in the medical device industry, most recently as business development manager for Joint Research, and was formerly with Smith & Nephew Surgical.

GI said that Mr Gottschalk had about 20 years experience with health insurance companies and medical device manufacturers throughout Germany and Europe and had served as the diabetes reimbursement manager for Medtronic Germany.

GI Dynamics was up seven cents or seven percent to \$1.07.