



Biotech Daily

Wednesday April 6, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX; BIOTECH UP: PHOSPHAGENICS UP 14%; GENERA DOWN 9%**
- * **AUSBIOTECH SURVEY: OPTIMISM DESPITE FUNDS, FEDERAL INERTIA**
- * **CIRCADIAN: 'VGX-100 REDUCES PROSTATE, OVARIAN, LUNG TUMORS'**
- * **CIRCADIAN'S VEGF3 IN IMCLONE PHASE I SOLID TUMOR TRIAL**
- * **PROGEN COMPLETES PHASE I PG11047 SOLID TUMOR ENROLMENT**
- * **NOVOGEN, MARSHALL EDWARDS \$US17m ASSET DEAL EGM**
- * **CATHRX: OPPENHEIMER MAKES LICENCING HEADWAY**
- * **LANDON CLAY, EAST HILL TAKE 6% OF BIOTA**

MARKET REPORT

The Australian stock market climbed 0.26 percent on Wednesday April 6, 2011 with the S&P ASX 200 up 12.8 points to 4912.9 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 14 fell, four traded unchanged and four were untraded.

Phosphagenics was best, up 1.5 cents or 14.3 percent to 12 cents with 1.5 million shares traded, followed by Prima up 11.9 percent to 33 cents with 39.9 million shares traded and Antisense up 11.8 percent to 1.9 cents with 98.6 million shares traded.

Bionomics and Sunshine Heart climbed 10 percent or more; Clinuvel was up 9.2 percent; Cellmid was up 8.3 percent; LBT rose seven percent; Prana was up 4.3 percent; Patrys, Phylogica and Resmed were up more than three percent; Living Cell rose 2.4 percent; with Biota, Circadian, CSL, Impedimed and Pharmaxis up more than one percent.

Genera led the falls, down 2.5 cents or 8.9 percent to 25.5 cents, with 15,000 shares traded followed by Viralytics down 7.8 percent to 4.7 cents with 2.5 million shares traded.

Compumedics lost 4.55 percent; Benitec and Virax fell more than three percent; Nanosonics shed 2.1 percent; with Genetic Technologies, Sirtex and Starpharma down more than one percent.

AUSBIOTECH

Ausbiotech says that “optimism prevails in the biotechnology industry, despite ongoing issues with a lack of funding”.

In a media release the industry organization said that a survey of chief executive officers undertaken with accounting and consulting firm Grant Thornton Australia found that most chief executive officers were positive about the future of the industry, but access to capital remained an issue.

The survey found that 56 percent said 2010 was either a good or an excellent year with 75 percent expecting their business to grow and 67 percent saying they were “confident to extremely confident that the Australian industry will grow during 2011”.

Ausbiotech said that more than half the companies expected to hire more staff this year and while lower than last year, showed strong sentiment and was “in stark contrast to 2009” when not one company was hiring and 48 percent expected to reduce staff levels. Ausbiotech said the survey showed that only 13 percent of respondents said the Australian economic and public policy environment was conducive to increasing the size of a biotechnology company, while 52 percent said the operating environment was working against the industry.

Ausbiotech said the delay associated with the research and development tax credit announced in the 2009-‘10 Federal Budget was identified by 61 percent of respondents as an area of frustration and the most concerning public policy issue at a Federal level.

The industry organization said that 60 percent of respondents said that the passing of the legislation would help their business and that they wanted access to it as soon as possible.

The Tax Laws Amendment (Research and Development) Bill 2010 and the Income Tax Rates Amendment (Research and Development) Bill 2010 were expected to be introduced into the Senate in November, but the Federal Government failed to provide time for it to be debated (BD: Nov 23, 26, 2010).

The survey found that 76 percent of respondents said support from state governments was the most concerning and important state-based issue.

Ausbiotech said the Biotechnology Industry Position Survey 2011 was conducted in February and March and asked the industry’s chief executive officers to comment on sentiment, financing and the policy environment.

Ausbiotech chief executive officer Dr Anna Lavelle said the annual survey “showed that sentiment for continued success remains optimistic, but highlights the difficulty biotech companies are having in accessing funds and the need for the R&D Tax Credit to provide a fresh flow of capital with the 45 percent refundable component”.

Grant Thornton Australia head of life sciences Michael Cunningham said the delays experienced with the R&D Tax Credit affected businesses throughout the biotechnology industry, particularly those still in the pre-revenue phase.

“Adequate funding can be the difference between thriving and starving for Australian biotechnology businesses,” Mr Cunningham said.

“We believe it is essential that this industry be supported and understood and this survey is an important step in gaining that understanding and laying a foundation to secure greater support,” Mr Cunningham said.

The survey also found that most companies had expansionary employment strategies, with 52 percent of companies intending to hire more staff this year.

The survey found that 58 percent of respondents were considering or would raise capital during the current year.

Ausbiotech said that “the overwhelming majority of listed respondents indicated their current share price undervalues their company”.

CIRCADIAN TECHNOLOGIES

Circadian says its lead anti-cancer therapeutic, VGX-100 significantly reduces tumor burden in prostate, ovarian and lung cancer in mouse models.

Circadian said the data was presented in a poster entitled 'The novel therapeutic monoclonal antibody VGX-100 neutralises VEGF-C and inhibits tumor growth and metastasis in subcutaneous and orthotopic models of human cancer' at the American Association for Cancer Research meeting in Orlando, Florida.

The poster was included at the bottom of the ASX media release and is available on the company's website: www.circadian.com.au.

Circadian said that the data indicated that, if clinically validated, VGX-100, a fully human monoclonal antibody targeting the VEGF-C growth factor, had the potential to be a useful new treatment for some types of cancer.

The company said VGX-100 inhibited the development of blood vessels required for tumor growth and could inhibit cancer spread or metastasis by suppressing the development of both blood and lymphatic vessels.

Circadian said that adding VGX-100 to bevacizumab (Avastin) and docetaxel therapy reduced tumor burden in prostate, ovarian and lung cancer models.

The company said that in an orthotopic mouse model of human prostate cancer in which tumors were inoculated directly into the prostate, VGX-100 alone significantly inhibited primary tumor growth by 59 percent compared to a control antibody and significantly reduced the incidence of metastasis to local lymph nodes by 55 percent.

Circadian's head of preclinical research and development and the poster's senior author Dr Megan Baldwin said the data "further demonstrates that blocking the VEGF-C pathway by VGX-100 can inhibit tumor growth in mouse models of cancer".

"Moreover, our data indicates that VGX-100 can act either by itself or in combination with approved drugs to slow the growth of several different tumor types including prostate, ovarian, lung, pancreatic, and glioblastoma," Dr Baldwin said.

"The observed effects on inhibiting the effects of metastatic spread in the prostate cancer model are especially exciting," Dr Baldwin said.

Circadian said it intended to file an investigational new drug application with the US Food and Drug Administration by October 2011 to begin human clinical trials of VGX-100, subject to completing the VGX-100 animal safety and toxicology studies.

Circadian was up one cent or 1.4 percent to 71 cents.

CIRCADIAN TECHNOLOGIES

Circadian says Eli Lilly division Imclone Systems has begun its first phase I clinical trial of IMC-3C5 a vascular endothelial growth factor compound licenced from Circadian.

Circadian said IMC-3C5 was a fully-human immunoglobulin G1 (IgG1) monoclonal antibody being developed by Imclone as a treatment for cancer.

The company said Imclone had exclusive rights from Circadian's Vegenics subsidiary to develop the vascular endothelial growth factor 3 (VEGFR-3) antibody in return for annual licence fees and royalties on potential future product sales.

Circadian said the phase I study would examine the safety and tolerability of escalating doses of IMC-3C5 in patients with advanced solid tumors that are refractory to standard therapy or for which no standard therapy is available.

The company said Imclone and Vegenics scientists discovered that VEGFR-3 played a role in directing the formation of blood supply to tumors as well as to the neonatal retina, that is it had a role in mediating the signals that control blood vessel sprouting, which was crucial to angiogenesis.

PROGEN PHARMACEUTICALS

Progen says it has completed enrolment in its 172-patient seven arm phase I combination trial of PG11047 for solid tumors.

Progen said the study was an open-label, multi-centre, dose escalation study to determine the maximum tolerated dose, dose limiting toxicity, safety and pharmacokinetics of PG11047 when used in individual combinations with gemcitabine, docetaxel, bevacizumab, erlotinib, cisplatin, 5- fluorouracil or sunitinib in patients with advanced solid tumors or lymphoma.

Progen said the primary objective was to determine the maximum tolerated dose and dose limiting toxicity of PG11047 when used in combination with other approved anti-cancer products and also to establish the recommended dose for future studies and the secondary objective was to establish the pharmacokinetics of PG11047 when used in each of the combinations and to observe patients for any evidence of anti-tumor activity. Progen said the clinical study report was expected by October 2011.

The company said PG11047 was a novel, conformationally restricted analog of the natural polyamine, spermine, that lowered cellular endogenous polyamine levels and competitively inhibited natural polyamine functions leading to cancer cell growth inhibition. Progen said collaboration with academic partners provided the opportunity to develop this drug in the epigenetic space.

The company said it had demonstrated that PG11047 worked synergistically in combination with the histone deacetylase (HDAC) inhibitor entinostat (MS-275); and with vidaza (5-Azacytidine), a DNA methyltransferase inhibitor.

Progen said it had previously announced that it was planning to divest the cell proliferation and epigenetic assets including PG11047 that it acquired in February 2008 as they were not part of its core program or focus (BD: Feb 4, 7, 2008; Oct 29, 2010).

Progen fell half a cent or 1.5 percent to 33 cents.

NOVOGEN, MARSHALL EDWARDS

Novogen shareholders will vote on the transfer of isoflavone-related assets to 65 percent US subsidiary Marshall Edwards, for convertible notes potentially worth \$US16,991,040.

Novogen shareholders will also vote on the issue of 375,000 options each to directors William Rueckert, Peter White, Ross Youngman and Peter Scutt.

Mr Rueckert is a former Marshall Edwards director and is standing for reelection at the Marshall Edwards annual general meeting in New York on April 13, 2011.

Novogen said each of the 1,000 shares of series A convertible preferred stock would be convertible into 4,872 shares of common Marshall Edwards stock note. At last night's closing price of \$US1.76 a share, the 4,872,000 shares would be worth \$US8,574,720.

The notice said that on the earlier of Marshall Edwards achieving a statistically significant phase II trial result involving any of the isoflavone-related assets or a first patient was enrolled in a phase III trial involving the assets, the notes would convert at 9,654 shares each, implying a current value of \$US16,991,040.

The notice also said that Marshall Edwards would have the option to purchase in a single transaction all unconverted notes for \$US12,000,000 in cash.

Novogen said the director options would vest in two tranches and be exercisable by January 26, 2015 and at 10 percent above the 10-day volume-weighted, average price to the date of the meeting.

The Novogen meeting will be held at the Education and Conference Centre, Macquarie Hospital, Wicks Road, North Ryde, New South Wales on May 6, 2011, at 2pm (AEST).

Novogen was up eight cents or 30.8 percent to 34 cents.

CATHRX

Cathrx says that following the appointment of the New York-based investment bank Oppenheimer & Co it is engaged in “meetings with multiple potential partners”. Cathrx said it contracted Oppenheimer to identify strategic transactions for its cardiac catheter platform technologies and licencing talks were underway (BD: Jan 16, 2011). Cathrx said discussions were likely to continue for some months. Cathrx was untraded at 20 cents.

BIOTA

Landon Clay, East Hill Holding Co and associates have increased their substantial shareholding in Biota from 8,150,481 shares (5.06%) to 11,138,837 shares (6.14%). First Cape said most of the shares were bought at prices between 80 cents and \$1.12 with the last acquisition of 200,000 shares at \$1.49 on April 4, 2011. Biota was up 1.5 cents or 1.1 percent to \$1.385.