Biotech Daily

Tuesday October 29, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHYLOGICA UP 10.5%, CELLMID DOWN 9%**

*** TGA APPROVES PROGEN PHASE I PG545 SOLID TUMOR TRIAL**

*** NO ADVERSE CARDIAC EVENTS IN REVA 30-DAY REZOLVE2 FOLLOW-UP**

*** ECO QUEST CYNATA AGM SUSPENSION**

*** ALCHEMIA HA-IRINOTECAN FOR LUNG CANCER 'GOOD EARLY DATA'**

*** US PATENT FOR DRAWBRIDGE PHAXAN ANAESTHETIC**

*** XERAYA $13m FOR NUSEP'S PRIME, ALISON COUTTS TAKES CHAIR**

*** SIRTEX SMALL DISSENT AGAINST CEO PERFORMANCE RIGHTS**

*** ALCHEMIA RECEIVES $9m FEDERAL R&D TAX REFUND**

*** PSIVIDA AGM FOR 370k DIRECTOR, CEO OPTIONS**

*** DOMAIN REDUCES TO 5.6% OF GI DYNAMICS**

*** AUSBIOTECH, KOREABIO COLLABORATION**

MARKET REPORT

The Australian stock market retreated 0.48 percent on Tuesday October 29, 2013 with the S&P ASX 200 down 25.9 points to 5,415.5 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and four were untraded.

Phylogica was the best, up 0.2 cents or 10.5 percent to 2.1 cents with 6.4 million shares traded. Circadian climbed 8.9 percent; Antisense was up 7.7 percent; Nanosonics rose 6.25 percent; Neuren and QRX were up more than four percent; Allied Health, Anteo and Atcor were up more than three percent; Bionomics and Universal Biosensors rose more than two percent; Starpharma was up 1.1 percent; with CSL up one cent.

Cellmid led the falls, down 0.4 cents or 8.9 percent to 4.1 cents with 14.5 million shares traded. Genetic Technologies, Phosphagenics and Reva lost six percent or more; Acrux, and Living Cell fell more than four percent; IDT and Tissue Therapies were down more than three percent; Compumedics, Medical Developments, Mesoblast and Osprey shed more than two percent; Prana and Viralytics were down more than one percent; with Benitec, Cochlear, GI Dynamics and Sirtex down by less than one percent.

PROGEN PHARMACEUTICALS

Progen says that it has Australian Therapeutic Goods Administration approval for the first in-human 25-patient trial of intravenous PG545 for solid tumors.

Progen said it developed the PG545 heparan sulfate mimetic with the dual mechanism to inhibit growth factors, or anti-angiogenesis, and the anti-metastatic enzyme heparanase, slowing blood vessel growth in tumors, starving it of nutrients and blocking cancer cells from spreading body.

The company said the phase I study would enrol about 25 advanced cancer patients with non-haematological, malignant solid tumors, excluding primary brain or spinal tumors.

Progen said the primary objective was the determination of the maximum tolerated dose as defined by significant dose limiting toxicity.

The company said that secondary objectives were assessment of the safety and tolerability of PG545 following multiple doses in subjects with advanced solid malignancies; to estimate pharmaco-kinetic parameters of PG545 and explore pharmaco-kinetic and pharmaco-dynamic relationships; and to document any anti-tumor activity observed with PG545.

Progen said it hoped to recruit all patients within 12 months at multiple sites with the first the Linear Clinical Research Unit at the Sir Charles Gairdner Hospital in Perth, Western Australia, with principal investigator the Hospital's head of medical oncology Prof Michael Millward.

The company said the second site would be the Nucleus Network at Melbourne's Alfred Hospital led by Nucleus medical director Dr Jason Lickliter.

Progen was up 1.5 cents or 7.3 percent to 22 cents.

REVA MEDICAL

Reva says that 65 patients of the targeted 125 patients in its Rezolve2 stent trial have had 30-day follow-up with no reported major adverse coronary events.

Reva said the interim results from its Rezolve2 sirolimus-eluting bioresorbable coronary scaffold would be presented today by the Sao Paulo, Brazil-based Institute Dante Pazzanese of Cardiology's Dr Ricardo Costa at the Transcatheter Therapeutics cardiology conference in San Francisco, California.

The company said there were no major coronary events, no incidences of ischemic target revascularization, myocardial infarction, or heart attack, or stent thrombosis.

Reva said the trial began enrolling patients in March 2013 in Australia, Brazil, Europe, and New Zealand to provide data for Conformité Européenne (CE) mark approval.

"In this preliminary analysis, the scaffold is performing well and investigators in the trial continue to appreciate the complete visibility of Rezolve2 as well as the ability to expand the scaffold to the desired implant size with a single inflation," Dr Costa said.

Reva chief executive officer Bob Stockman said the early results were "an important step toward CE Marking and eventual commercialization of Reva's first commercial product".

Reva said that Dr Costa would also present the 12-month data on patients enrolled in the original Restore pilot trial.

Reva fell 3.5 cents or six percent to 55 cents.

ECO QUEST

Ecoquest has requested a suspension pending shareholder approval of a change of activities. All annual general meeting resolutions were passed overwhelmingly.

Eco Quest last traded at 2.5 cents.

ALCHEMIA

Alchemia says early data from a phase II trial of hyaluronic acid-irinotecan with carboplatin for small cell lung cancer shows it can be administered safely with signs of efficacy.
Alchemia said that 26 patients had been recruited to the 40-patient investigator-sponsored phase II trial assessing the safety of hyaluronic acid-irinotecan (HA-irinotecan) with carboplatin and the effects of the drug regimen on cancer stem cells.
The company said that there were “early encouraging signs of clinical activity of HA-irinotecan when combined with carboplatin, which would need to be confirmed in larger controlled clinical trials.
Alchemia said that the primary endpoints were safety, measured by the incidence of grade 3 and 4 toxicity, and clinical activity of HA-irinotecan combined with carboplatin when administered as first-line or second-line chemotherapy for patients with advanced small cell lung cancer.
Alchemia said the early analysis of circulating tumor cell data showed close correlation between the number of circulating tumor cells and tumor response and relapse.
Alchemia was unchanged at 60 cents.

DRAWBRIDGE PHARMACEUTICALS

Drawbridge says it has been allowed a US patent entitled ‘Anaesthetic Formulation’ providing coverage until 2031.
The Melbourne-based Drawbridge said that the patent had been granted in the United Kingdom, Australia, New Zealand, Hong Kong, Singapore and South Africa.
Drawbridge chief executive officer Dr Anthony Filippis said that since the company was founded in 2011, it had been building a patent portfolio around its lead drug candidate, Phaxan, for use in anaesthesia and sedation.
“The granting of our patent in these countries not only adds significant value to the company, but allows us to take another step forward in our development efforts to bring Phaxan to patients who need better treatment options in critical care,” Dr Filippis said.
Drawbridge said that Phaxan was “a novel water based formulation of the neuroactive steroid, alphaxalone [had] a wide therapeutic index and rapid onset and offset of action”.
The company said that the anaesthetic agent in Phaxan had been administered in the past as Althesin when formulated in a different excipient, but was withdrawn in 1984 because of problems with the formulation.
Drawbridge said that Phaxan did not have the problems of the Althesin formulation and was superior to the industry gold standard, propofol, in preclinical models.
The company said that Phaxan was alphaxalone formulated in sulfobutyl ether beta cyclodextrin.
Drawbridge said that propofol was seen as the gold standard due to its predictable onset and recovery from anaesthesia and sedation, but had some significant problems including: the lipid based preparation being easily contaminated and supporting bacterial growth, as well as causing falls in blood pressure, depression of breathing, pain on injection and was incompatible with plastic containers and lead to lipid toxicity.
Drawbridge chief medical officer Prof Colin Goodchild said that the case for the use of Phaxan was “compelling”.
“It is water-soluble, much safer with a wider therapeutic index than propofol, showing the same rapid onset and offset of action, but with none of the lipid issues,” Prof Goodchild said. “No other product on the market has that combination”.
Drawbridge is a private company.

NUSEP HOLDINGS

Nusep says Xeraya Capital Labuan will invest up to SGD15 million ($A12.7 million) in Prime Biologics and Alison Coutts will replace chairman John Manusu.

Nusep said that subsidiary Prime Biologics had a non-binding term sheet with Xeraya to invest up to SGD15 million in its therapeutic plasma business, subject to due diligence, approvals and the demerger of Prime Biologics from Nusep.

The company said that Alison Coutts would replace chairman John Manusu at the November 29, 2013 annual general meeting with directors Dr Hari Nair and Clifford Eu retiring as well.

Nusep said that Ms Coutts' appointment was subject to shareholder approval and Mr Manusu and Dr Nair would concentrate on developing Prime Biologics in Singapore.

Mr Manusu told Biotech Daily that he and Dr Nair would run the Prime operation from Sydney and it would undertake plasma separation, returning payment for the Nusep membranes and paying royalties, while Nusep would focus on the sperm separation business and other uses for the separation membrane.

Nusep said that subject to shareholder approval, shareholders would own a pro-rata shareholding in Prime Biologics post the demerger, expected by April 2014.

The company said that Dr Nair would continue to assist the board with scientific innovation and research under a consultancy agreement.

Mr Manusu said the board would compose Ms Coutts. Managing director Prakash Patel and director Andrew Goodall, but the company would appoint new directors.

Nusep said that Ms Coutts had experience across a number of industry sectors and disciplines, including engineering project management with Bechtel Corp, strategy consulting, management training and organizational structuring with Boston Consulting Group and executive search with Egon Zehnder.

The company said that Ms Coutts was formerly chair of the Commonwealth Scientific and Industrial Research Organisation's Health Sector Advisory Council and a founder and director of Eg Capital and continues as a director of Datadot Technology.

Ms Coutts holds a Bachelor of Engineering and a Master of Business Administration from the University of Melbourne.

Nusep was unchanged at five cents.

SIRTEX MEDICAL

The Sirtex annual general meeting passed all resolutions but with 5.5 percent opposition against the issue of 115,000 'performance rights' to chief executive officer Gilman Wong.

Sirtex said the issue of the performance rights at no cost and exercisable as shares at no cost to Mr Wong was supported by 31,699,910 proxy votes (94.5%) with 1,833,464 proxy votes against (5.5%).

Renewed approval of the executive performance rights plan, the re-election of director Dr John Eady and the remuneration report were passed overwhelmingly.

The company's most recent Appendix 3B said that Sirtex had 56,108,439 shares on issue meaning that the opposition to Mr Wong's rights was 3.3 percent of the company's total shares on issue, not sufficient to requisition extraordinary general meetings.

Previous Sirtex meetings have been dogged by opposition from founder and former chief executive officer Dr Bruce Gray, who held 10,090,604 shares or 18.1 percent of the company a year ago (BD: Oct 23, 2013).

In August, Dr Gray sold most of his holding in the company with a crossing organized by Macquarie Bank returning $87,261,768 for 7,271,714 shares (BD: Aug 7, 12, 2013).

Sirtex fell 12 cents or 0.96 percent to $12.32 with 188,070 shares traded.

ALCHEMIA

Alchemia says it has received $8.8 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Alchemia said the rebate related to research and development expenditure in Australia and off-shore for the year to June 30, 2013

PSIVIDA

Psivida will vote to grant chief executive officer Dr Paul Ashton 185,400 options and 185,000 options to chairman David Mazzo and four directors.
Psivida said that it proposed to issue Dr Ashton 185,400 options vested in four tranches over four years and exercisable at the closing price on July 23, 2103 of $US3.51 ($A3.69) within 10 years.
The company said it proposed to issue Mr Mazzo 45,000 options, and directors Douglas Godshall, Paul Hopper, Michael Rogers and Peter Savas 35,000 options each, vesting on July 23, 2014 and exercisable at $US3.51 within 10 years.
The company's notice of meeting said it would also seek shareholder approval for an advisory vote on executive compensation required under US law, as well as an advisory vote on the frequency of the 'say-on-pay' vote and the re-election of directors and
The meeting will be held at the Waltham Westin Hotel, 70 Third Avenue, Waltham, Massachusetts on December 18, 2013 at 10am (USEST).
Psivida was untraded at $2.68.

GI DYNAMICS

GI Dynamics says that Domain Partners V and DP V Associates reduced their holding from 26,746,375 Chess depositary interests (CDIs) (6.68%) to 22,267,685 CDIs (5.56%).
GI Dynamics did not provide details of the share sales.
GI Dynamics fell half a cent or 0.6 percent to 82.5 cents.

AUSBIOTECH

Ausbiotech says it expects to sign a collaboration agreement with the Korea Biotechnology Industry Organization at its conference on November 1, 2013.
Ausbiotech said that a memorandum of understanding between the two industry organizations would recognize the role that biotechnology played in economic and social development and the benefits of a strategic partnership between Australia and Korea.
Ausbiotech said that the agreement would be signed at the Brisbane conference by chief executive officer Dr Anna Lavelle and Korea Biotechnology Industry Organization president Dr Eun-Hee Bae to promote collaboration and cooperation in biotechnology.
Ausbiotech said the agreement would promote cooperation, promote the exchange of views in supporting the formulation and application of biotechnology policy by Government and facilitate interaction between officials, scientists and technologists.
The industry organization said the agreement supported increased interaction through access to visitor office facilities in Seoul and Melbourne to support Koreabio and Ausbiotech members and the two organizations would identify projects that could attract funding to support collaboration.