

Biotech Daily

Wednesday July 31, 2013

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH UP: BIONOMICS UP 21%, USCOM DOWN 10%
- * BIONOMICS 'UP TO \$190m' MERCK LICENCE FOR PAIN COMPOUND
- * BIOTRON ENROLS ALL 12 PHASE II HEP C/HIV PATIENTS
- * EGM TO REVIVE VIRAX, ELECT DR WAYNE MILLEN DIRECTOR
- * BENITEC SHARE PLAN \$2.8m TAKES TOTAL TO \$10.7m
- * DAVIES COLLISON CAVE US INTELLECTUAL PROPERTY SEMINAR

MARKET REPORT

The Australian stock market was flat for the third day, up 0.1 percent on Wednesday July 31, 2013 with the S&P ASX 200 up 4.8 points to 5,052.0 points.

Seventeen Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and three were untraded.

Bionomics was the best, up 9.5 cents or 20.9 percent to 55 cents with three million shares traded.

Both Avita and Living Cell climbed eight percent; Patrys was up 7.9 percent; Prima was up five percent; Alchemia was up 4.2 percent; Impedimed was up 3.45 percent; Mesoblast, Nanosonics, Psivida and Sirtex rose more than two percent; Anteo, Heartware, QRX, Resmed and Starpharma were up more than one percent; with Acrux, Clinuvel and CSL up by less than one percent.

Yesterday's equal best, Uscom, led the falls, down two cents or 10 percent to 18 cents with 2,324 shares traded.

Neuren lost 8.6 percent; Prana was down five percent; GI Dynamics, Optiscan and Viralytics fell four percent or more; Cellmid was down 3.45 percent; Benitec, Medical Developments and Tissue Therapies shed more than two percent; both Allied Health and Osprey lost 1.85 percent; with Cochlear and Reva down by less than one percent.

BIONOMICS

Bionomics says it will licence a compound to the US-based Merck Inc to discover and develop small molecule candidates for chronic pain, including neuropathic pain.

Bionomics said that the two-year agreement with Merck Inc, known as Merck Sharp and Dohme outside the US and Canada, provided option exercise fees and development and regulatory milestone payments to Bionomics of up to \$US172 million (\$A190.4 million).

The company did not mention an upfront fee, but said it could also be eligible for undisclosed royalties on net sales of products from the collaboration.

Bionomics chief executive officer Dr Deborah Rathjen was not available for clarification. Bionomics said it retained the right to develop and commercialize certain compounds for which Merck did not exercise its option.

Dr Rathjen said the company was "very excited to be working with Merck to define new therapies for chronic and neuropathic pain".

The company said it would use its lonx drug discovery platform and Multicore chemistry to identify potential drug candidates.

The company said that the global pain treatment market was \$US22 billion in 2010, contracting to \$US18.7 billion by 2016 with patent expiries, but the neuropathic pain market was expected to grow from \$US2.4 billion in 2010 to \$US3.6 billion by 2020. Bionomics was up 9.5 cents or 20.9 percent to 55 cents with three million shares traded.

BIOTRON

Biotron says it has completed enrolment of all 12 patients in its phase II clinical trial of BIT225 in patients co-infected with both hepatitis C virus and HIV.

Biotron said that the trial was designed to generate the first efficacy data in this specific population and extend existing BIT225 hepatitis C efficacy data to additional genotypes. The company said that to date, clinical trials of BIT225 in hepatitis C patients had concentrated on the most common genotype, genotype 1, but the trial included patients infected with genotypes 1, 2 and 3.

Biotron said that the patients would receive 28 days treatment with BIT225 (300mg twice daily) in combination with current anti-hepatitis C standard of care therapies, interferon and ribavirin and at the conclusion of BIT225 treatment, the patients would continue to receive interferon and ribavirin alone as per standard treatment guidelines.

The company said that all patients were on antiretroviral drugs at the time of enrolment, and will continue to receive those drugs throughout the trial.

Biotron said that in addition to providing the first efficacy data in this specific population, the study would also provide detailed pharmacokinetic information on BIT225 in the presence of the other anti-HIV drugs, with results expected by the end of 2013.

The company said the co-infected group "presents unique medical challenges in terms of current therapeutic protocols" and that hepatitis C was a more serious disease in this population, with co-infected people having three times the risk of cirrhosis, liver failure and death compared to those infected with hepatitis C alone.

The company said that at least one in four people infected with HIV in the US were coinfected with hepatitis C and in some populations the rate was estimated to be 40 percent. Biotron said that a previous phase IIa trial of BIT225 in hepatitis C genotype 1 patients in combination with interferon and ribavirin resulted in 100 percent of patients having virus below the limit of detection after 48 weeks and phase IIa trial of BIT225 in patients with HIV alone demonstrated that BIT225 was able to target the virus in reservoir cells, the 'holy grail' of current HIV research, with no existing therapy working in this manner. Biotron was untraded at 8.3 cents.

VIRAX HOLDINGS

(BD: Feb 14, 24, 2011).

A general meeting will be held to approve a series of capital raisings to revive Virax, currently subject to a deed of company arrangement.

Last year Virax went into voluntary administration appointing Grant Thornton's Laurie Fitzgerald and Stephen Dixon as voluntary administrators (BD: Aug 27, 2012). Virax conducted a 131-patient phase I/II South African trial of VIR210 for HIV with support from mining companies but failed to meet its primary endpoints (BD Aug 16, 2010). Virax licenced its Co-X-Gene technology to Transgene SA of Strasbourg, France for use in Transgene's TG4010 for non-small-cell-lung cancer and TG4001 for pathologies relating to human papillomavirus infection and saw its share price climb 34.8 percent to 15.5 cents on news that Novartis had a \$1 billion option for TG4010 (BD: Mar 11, 2010). In February 2011, Virax licenced TG1042 for nodular basal cell carcinoma from Transgene and in the same month Roche ended its licence with Transgene for TG4001

In May this year Virax said Transgene's TG4001 human papillomavirus therapeutic vaccine using its Co-X-Gene technology had shown to be safe with some, but less-than-expected efficacy, with Transgene saying that despite the strong proof-of-concept it was not planning to take TG4001 into phase III for this indication, outlining alternate clinical development plans (BD: May 14, 2012).

Virax was involved in a deal to merge with 4G Vaccines to develop a cancer immunotherapy but negotiations failed to reach agreement (BD: Mar 1, Jun 15, 2012). Today, Grant Thornton said that the deed of company arrangement was entered with Otsana Pty Ltd trading as Otsana Capital "which embodied a proposal by Otsana for the reconstruction and recapitalization of the company".

Grant Thornton said the proposal included a 10-for-one consolidation; the issue of 25,000,000 post consolidation shares at 0.001 cents to raise \$250 and the issue of 500,000,000 post consolidation shares at not less than 0.5 cents each to raise up to \$2,500,000 and a further 100,000,000 post consolidation unquoted options exercisable at 0.5 cents each within four years of issue at an issue price of 0.001 cents each to raise up to \$1,000, to be issued to any Otsana nominee.

Grant Thornton said that the propsed new directors of Virax would be Dr Wayne Millen, Dr Roland Toder and Dr Brendan de Kauwe.

Grant Thornton said the funds would be used to pay creditors and ASX relisting fees as well as review the existing business and cover a "review and expenditure on new projects", but the document did not describe the nature of any new projects.

The notice of motion said that it was "proposed that the budgeted expenditure on existing projects ... will be aimed towards the reinvigoration of the VIR201 HIV/AIDS trials in South Africa as well as a review of the Anutech and Transgene SA licence agreements to determine whether there is any scope for additional partners to assist with the development of the Co-X-Gene Technology".

Dr Millen told Biotech Daily that if elected "we will examine other technologies that would be compatible and could be brought into the company".

Dr Millen is the former chairman of Clinuvel (previously Epitan) and Elk Orthobiologics (previously Broadvector).

The notice of meeting said that Dr Toder was previously a director of Broadvector and chief executive officer of the Swiss-based Vivendy Therapeutics.

The notice said that Dr de Kauwe was a director of PTO Consolidated involved in oil and gas exploration in the Ukraine and an advisor with Otsana Capital.

Virax last traded at 0.9 cents.

BENITEC BIOPHARMA

Benitec says its share plan at 1.1 cents a share raised \$2.8 million of a hoped for \$3 million taking the total raised to \$10.7 million (BD: Jun 6, 2013).

The company had \$900,000 in oversubscriptions for its placement at the same price raising \$7.9 million.

At the same time the company is completing a 25-for-one consolidation so the post-consolidation shares are equivalent to 27.5 cents each.

Benitec chief executive officer Dr Peter French told Biotech Daily in June that the money raised would "fund the phase I/IIa trial of TT-034 for hepatitis C to its completion, results and beyond".

Benitec said the funds would also be used for a European phase I/IIa trial of Tribetarna for non-small cell lung cancer, as well as the manufacture of clinical material for a potential second hepatitis C trial, business development and working capital.

The company said that Lodge Partners acted as lead manager.

Benitec was down one cent or 2.9 percent to 33 cents.

DAVIES COLLISON CAVE

Melbourne law firm Davies Collison Cave will host a seminar on the three major US intellectual property cases tonight.

Davies Collison Cave said that it would discuss the AMP versus Myriad Genetics, Mayo versus Prometheus and CLS Bank versus Alice Corp cases that have recently helped to clarify the definition of patentable subject matter in the US.

The firm said that its patent attorneys Bill Pickering and Sam Mickan would provide an outline of the revised definitions of patentable subject matter and discuss their impact on patent strategies in the bio-science and software business method fields.

Davies Collison Cave said the seminar was open to interested professionals who should reply to Kate Liscombe by email: kliscombe@davies.com.au.

The seminar is scheduled for 5pm for a 5.30pm start followed by light refreshments from 6.30pm at Level 15, 1 Nicholson Street, Melbourne (enter via Albert Street).