



Biotech Daily

Friday April 12, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: VIRALYTICS UP 5%, PATRYS DOWN 10%**
- * **SIRTEX COMPLETES 1st LINE SIRFLOX RECRUITMENT**
- * **FDA APPROVES MAYNE'S 200mg DELAYED-RELEASE DORYX**
- * **SUNSHINE HEART RAISES \$12m**
- * **ALCHEMIA PLAN 3-FOLD OVER-SUBSCRIBED, RAISES \$2.75m**
- * **NOVOGEN PLACEMENT RAISES \$2.5m**
- * **REGENEUS, CRYOSITE DEVELOP STORAGE PROCEDURE**
- * **ISONEA LAUNCHES ASTHAMSENSE CLOUD SMART-PHONE APPLICATION**
- * **PRANA CHAIR GEOFF KEMPLER, BAYWICK DILUTED BELOW 5%**
- * **VATICAN GONG FOR MESOBLAST'S PROF SILVIU ITESCU**

MARKET REPORT

The Australian stock market climbed 0.13 percent on Friday April 12, 2013 with the S&P ASX 200 up 6.4 points to 5,013.5 points. Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and six were untraded.

Viralytics was the best, up 1.5 cents or five percent to 31.5 cents with 30,000 shares traded.

Bionomics, Cellmid, Living Cell, Pharmaxis and Psivida climbed more than two percent; Alchemia, Impedimed, Nanosonics and Starpharma were up more than one percent; with Heartware up 0.85 percent.

Patryst led the falls, down 0.3 cents or 10 percent to 2.7 cents, with 1.5 million shares traded.

Antisense lost 9.1 percent; Benitec and Ellex fell more than seven percent; GI Dynamics was down 6.1 percent; Avita, Genetic Technologies and Prana fell more than four percent; Clinuvel, Prima and Tissue Therapies were down more than three percent; Neuren shed 2.9 percent; Acrux, Anteo, Cochlear, Mesoblast and Universal Biosensors were down more than one percent; with CSL, QRX and Sirtex down by less than one percent.

SIRTEX MEDICAL

Sirtex says it has completed patient recruitment for its flagship 'Sirflox' randomized controlled trial of SIR-Spheres in patients with metastatic colorectal cancer.

Sirtex chief executive officer Gilman Wong said the company was "committed to delivering the level one clinical evidence from large randomized controlled trials confirming the effectiveness of SIR-Spheres microspheres".

"We believe that if the results from the Sirflox study are positive, SIR-Spheres microspheres will be elevated to a first-line therapy for patients with colorectal liver metastases, providing important clinical benefits to patients and leading to a step-change in Sirtex's business," Mr Wong said.

"The completion of patient recruitment ... has required the participation of more than 100 leading hospitals globally and considerable resources over six years," Mr Wong said.

Sirtex said that the study was the largest randomized, controlled trial undertaken in the field of interventional oncology and was expected to deliver primary results in late 2014.

The company said that the study would evaluate whether first-line treatment of standard-of-care chemotherapy plus SIR-Spheres microspheres was more effective than chemotherapy alone, in patients with inoperable liver metastases from primary colorectal cancer or bowel cancer.

In the Sirtex posting to www.clinicaltrials.gov the company said that the trial would compare Oxaliplatin, Leucovorin and 5- Fluorouracil (Folfox) against Oxaliplatin, Leucovorin and 5- Fluorouracil with the administration of Sirtex Yttrium-active microspheres.

The Clinical Trials notice said the company expected to enroll 518 patients and a spokesman for the company said it had enrolled about that number.

The company has discussed the Sirflox first line treatment at a number of investor and specialist meetings (BD: Mar 2, Jul 25, 2012).

Sirtex fell five cents or 0.5 percent to \$10.30.

MAYNE PHARMA GROUP

Mayne says the US Food and Drug Administration has approved a 200mg strength of Doryx (doxycycline hyclate) delayed-release tablet.

Mayne said that US marketing and distribution partner Warner Chilcott was expected to commence launch of the tetracycline-class oral antibiotic by July 2013.

Mayne was unchanged at 46 cents with 1.6 million shares traded.

SUNSHINE HEART

Sunshine Heart says it has raised up to \$US13,125,000 (\$A12,431,355) through the issue of 2,500,000 US shares at \$US5.25 a share.

Yesterday, Sunshine Heart filed a 'shelf registration' document to the ASX and US Securities and Exchange Commission, allowing it to raise up to \$US75 million and saying the funds were for its pivotal trial of the C-Pulse aorta cuff for heart failure as well as general purposes and its share price on the Nasdaq at the close of April 9, 2013 was \$US6.07 (\$A5.77).

Each US common share is equivalent to 200 Australian Chess depositary interests.

The company said that Canaccord Genuity was the manager for the offering and said the underwriter had a 30-day option to buy up to 375,000 US shares to cover over-allotments. Sunshine Heart fell 0.2 cents or 7.1 percent to 2.6 cents.

ALCHEMIA

Alchemia says its share plan raised \$2.75 million and with last month's \$10.2 million placement the phase III trial of HA-irinotecan in metastatic colorectal cancer is fully-funded. Alchemia said the share purchase plan at 30 cents a share was "heavily oversubscribed" raising more than the initially hoped-for \$2 million (BD: March 11, 2013).

The company said it scaled-back demand for shares and would allot 9,166,364 shares at 30 cents a share.

Alchemia said that more than \$9.5 million in application funds were received and applicants would receive 30.684 percent of the amounts for which they applied.

Alchemia chairman Dr Mel Bridges said the "outstanding response from shareholders primarily ensures the company has sufficient capital to fund its pivotal phase III trial of HA-irinotecan in metastatic colorectal cancer, which has finished recruitment, having enrolled 415 patients".

"Top line data from this trial is expected to be reported in early 2014," Dr Bridges said.

Dr Bridges said that the oversubscription indicated investors acknowledged the near term potential of this lead therapeutic and platform technology and was endorsement of Alchemia's longer term commercial prospects.

Alchemia was up half a cent or 1.5 percent to 34.5 cents.

NOVOGEN

Novogen has raised \$2.5 million through a placement at 16.6 cents a 20 percent discount to the closing price of 20.5 cents on April 10, 2013.

Novogen said the funds were for the development of cancer drug candidate CS-6 and working capital.

Novogen fell 2.5 cents or 12.2 percent to 18 cents.

CRYOSITE, REGENEUS

Regeneus says it has developed a procedure with Cryosite for storing a patient's regenerative stem cells from adipose, or fat, tissue.

Regeneus said that when patients had the company's Hiqcell procedure taking the patients stem cells from extracted fat tissue to be re-injected into joints for osteoarthritis treatment, surplus cells could be stored as a patient's own bio-bank for future injections.

Regeneus executive Steve Barbera said the partnership would "offer patients the option to store some of their own cells to be used for future treatment".

Mr Barbera said cryo-preservation would be available to patients of Sydney Sportsmed Specialists' Dr Diana Robinson and her colleagues, with further deployment expected across other medical facilities and Hiqcell licenced practitioners.

Regeneus said it worked with sports physicians and orthopedic surgeons to conduct the Hiqcell treatment, which harvested fat tissue, separated and concentrated the regenerative cells, re-injecting them in osteoarthritic knees, hips and ankles.

The company said that the cryo-preservation would be available only when a patient had a Hiqcell procedure in an accredited medical facility.

Regeneus said that the stored cells could be held for an indefinite period of time until required for a future injection.

Regeneus said it had developed assays to ensure the viability of the cells after freezing and before future re-injection.

Regeneus is a public unlisted company.

Cryosite was untraded at 37 cents.

ISONEA

Isona says it has launched its Asthmasense Cloud smart-phone asthma management application to help medical experts track patient asthma data.

Isona said that the product enabled transfer and storage of asthma tracking data from the Asthmasense smart-phone application to a 'cloud-based' site where it would be accessible to physicians and other caregivers.

Isona chief executive officer Mike Thomas said the launch of Asthmasense Cloud was a key milestone as it prepared to launch the Airsona device in Australia later this year.

The company said that the Airsona would enable wheeze rate monitoring through a smart-phone for the first time, using its acoustic respiratory monitoring technologies.

"We are committed to continually upgrading our existing technologies to ensure we remain at the forefront of digital mobile health," Mr Thomas said.

Isona said the telephone application featured: safe storage of a user's asthma profile and event history in a password-protected, cloud-based data warehouse; protected access and easy data recovery if a telephone was replaced, lost, stolen or damaged; allowed viewing and editing of data by computer; a tracking system to identify potential risk patterns and trends in symptoms, medication use and testing results; interactive medication and testing reminders and medication usage records; one-touch dialing of contact numbers, including auto-selected emergency number based on Global Positioning System location; and the ability to maintain multiple patient profiles with a single application for families with more than one asthmatic.

Mr Thomas said that growing asthma trends were a serious challenge and there was "strong demand for better consumer-oriented asthma management tools".

Isona said that there were about 300 million asthma sufferers globally, with 25 million adults and children affected in the US and nearly 2.5 million in Australia.

Isona was unchanged at eight cents.

MESOBLAST

Mesoblast says chief executive Professor Silviu Itescu has received the first Key Innovation Award from the Pontifical Council for Culture and the Stem for Life Foundation.

Mesoblast said the award was announced during the Second International Vatican Adult Stem Cell Conference currently being held in Vatican City and was presented by the Pontifical Council for Culture's head of Science and Faith Department Tomasz Trafny and Stem for Life Foundation president Dr Robin Smith.

Dr Smith said the award was being given "with admiration of Prof Itescu's leadership and ingenuity in translational science and clinical medicine within the field of adult stem cell therapy".

"In every emerging industry, there are always individuals who stand out as pioneers," Dr Smith said. "Prof Itescu has distinguished himself as an innovator in the field of regenerative medicine, one that has brought hope and healing to a world struggling to manage chronic disease and serious medical conditions."

Prof Itescu said the award was "important recognition of the contributions made by the dedicated team at Mesoblast".

Mesoblast said that the Second International Vatican Adult Stem Cell Conference, entitled 'Regenerative Medicine: a Fundamental Shift in Science and Culture' was being held in the Vatican, from April 11 to 13, 2013 as part of a five-year collaboration between the Vatican's Pontifical Council for Culture and its Foundation, the Science, Theology and the Ontological Quest, the Stem for Life Foundation and Neostem.

Mesoblast fell 11 cents or 1.8 percent to \$5.89.

PRANA BIOTECHNOLOGY

Baywick Pty Ltd says its 17,811,000 shareholding in Prana has been diluted from 5.23 percent to below five percent, following a placement.

In its change of substantial shareholder notice signed by Baywick director and Prana executive chairman Geoffrey Kempler, Baywick said no shares had been sold.

In March, Prana said it would raise \$7,000,500 through the issue of 35.9 million shares at 19.5 cents a share in a placement and underwritten share plan (BD: Mar 28, 2013).

Prana fell one cent or 4.8 percent to 20 cents.