

Biotech Daily

Monday September 11, 2017

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: ACTINOGEN UP 9%, MESOBLAST DOWN 4%
- * IMAGION PREPARING FOR HUMAN CANCER IMAGING TRIALS; FUNDING
- * FEDERAL, BIOSCIENCE MANAGERS BTF \$13m FOR 3 PROJECTS
- * PARADIGM: 'CASE STUDY BACKS PPS FOR OA BONE BRUISING'
- * TDM TAKES 15% OF SOMNOMED
- * MICRO-X APPOINTS JIM MCDOWELL DIRECTOR

MARKET REPORT

The Australian stock market was up 0.71 percent on Monday September 11, 2017 with the ASX200 up 40.5 points to 5,713.1 points.

Twelve of the Biotech Daily Top 40 stocks were up, seven fell, 15 traded unchanged and six were untraded. All three Big Caps were up

Actinogen was the best, up 0.5 cents or 8.9 percent to 6.1 cents with 321,548 shares traded.

Living Cell, Neuren and Polynovo climbed more than three percent; Acrux, Airxpanders, Nanosonics and Opthea rose more than two percent; Cochlear, ITL, Osprey, Pro Medicus and Resmed were up more than one percent; with CSL and Starpharma up by less than one percent.

Mesoblast led the falls, down six cents or four percent to \$1.44 with 1.1 million shares traded.

Avita, Bionomics, Clinuvel, Ellex and Factor Therapeutics lost more than one percent; with Sirtex down by 0.3 percent.

IMAGION BIOSYSTEMS

Imagion chief executive officer Robert Proulx is in Australia to prepare potential investors for funding in the next three to six months.

In June, the Albuquerque, New Mexico-based Imagion raised \$12 million at 20 cents and listed on the ASX to complete development of its Magsense nanotechnology magnetic imaging technology for the early detection of cancer (BD: Jun 7, 2017).

With a six month cash burn of about \$4 million, the company has more than a year of funds, which Mr Proulx said should last to the first-in-human trial at Melbourne's Peter MacCallum Cancer Centre and the Houston, Texas-based MD Anderson Cancer Centre. Mr Proulx said that with the Los Alamos nuclear research facility and the Kirtland US Air Force base nearby, Albuquerque was a strong technical development centre despite its small size of about one million people.

Mr Proulx said the company had trialled its Magsense in mice and rats using small doses of iron oxide attached to HER2+ antibodies that bound with breast cancer tumors. He said that when activated the bound iron oxide showed up, while the unbound iron oxide was eliminated through the liver.

Mr Proulx said that the low doses of less than five milligram per kilogram was lower than iron supplements and could be directly injected in the suspected tumor area or lymph nodes or infused systemically.

He said that safety was not an issue with the antibodies, already approved by regulators. Mr Proulx said that the company would trial the system on pigs in the next three to six months while completing scale-up and confirming supply of the nanoparticle iron oxide. He said that when the area being examined was magnetically pulsed, the particles bound to tumor cells took longer to relax than unbound particles and could be imaged. Mr Proulx said that the detail of imaging meant that earlier detection of smaller cancers would be possible and could reduce the need to remove lymph nodes following breast

Mr Proulx said the company would complete scale-up for the first-in-human trial, but an early trial, in about 12 months, would investigate samples from breast cancer patients. "Lymph node involvement is the starting point," Mr Proulx said. "But we intend to pursue lung cancer, prostate cancer and ovarian cancer."

He said the ability to detect smaller cancerous tissue earlier could lead to earlier accurate diagnoses of cancers, with a consequent improvement in treatment outcomes.

Mr Proulx said the company was looking for longer term investors. Imagion was untraded at 14.5 cents.

FEDERAL GOVERNMENT

cancer treatment.

The Federal Government says Bioscience Managers will invest \$13.3 million from the Biomedical Translation Fund in three projects.

A media release from Innovation and Science Australia said that \$5 million would be invested in Sydney's Rex Bionics' hands-free robotic device to help people with reduced mobility, with \$3.3 million for Sydney's Saluda Medical for neuro-modulation technologies for chronic back pain and \$5 million for Melbourne's Charm Informatics for data aggregation and commercialization services for makers of medical devices.

Last year, the Federal Government launched the \$500 million matched funding Biomedical Translation Fund with Brandon Capital Partners, Oneventures Management and Bioscience Managers (BD: Dec 13, 2016).

Innovation and Science Australia chair Bill Ferris said the investment by Bioscience Managers was "a very positive signal for the Australian life sciences sectors".

PARADIGM

Paradigm says a single patient case study shows its pentosan polysulfate sodium for bone marrow oedema lesions in osteoarthritis is "a paradigm shift in treating ... pain".

Paradigm said the case study of a 70-year-old female patient with bone marrow oedema lesions and advanced osteoarthritis treated with pentosan polysulfate sodium (PPS) intramuscularly twice weekly, for three weeks.

Paradigm chief executive officer Paul Rennie told Biotech Daily that the woman was one of more than 30 patients to receive pentosan polysulfate sodium for bone marrow oedema, or bone bruising, under an Australian Therapeutic Goods Administration special access scheme.

The company said the case study was entitled: 'Improved clinical outcome measures of knee pain and function with concurrent resolution of subchondral Bone Marrow Edema Lesion and joint effusion in an osteoarthritic patient following Pentosan Polysulphate Sodium treatment: A case report', and had been accepted for publication in the openaccess Springer Biomed Central Musculoskeletal Disorders.

Paradigm said the study showed that treatment with PPS eliminated the patient's subchondral bone marrow oedema lesions, had eliminated the patient's pain level and significantly improved joint movement.

The company said that the patient's pain response was reduced from a score of eight of 10 to zero of 10.

Paradigm said that before PPS treatment, the patient was being treated with a nonsteroidal anti-inflammatory drug and was on a public hospital waiting list for a total knee replacement.

The company said that following PPS treatment, the patient discontinued the use of the drug and the surgical procedure was no longer required.

Paradigm said that 30 people with bone marrow oedema lesions and osteoarthritis had been treated with PPS with similar clinical outcomes and the company expected to start a 100-patient, randomized, double-blind, placebo-controlled phase IIb trial of PPS for bone marrow oedema lesions and osteoarthritis "later this year".

The company said that all patients experienced similar clinical outcomes of reduced bone marrow oedema lesion volume, significant reduction in pain and knee effusions.

Mr Rennie said that "targeting the entire degenerative joint, including the cartilage breakdown and the bone marrow oedema lesions in the underlying bone of the joint, represents a paradigm shift in treating painful [osteoarthritis]".

Mr Rennie said that the company hoped PPS could significantly reduce osteoarthritis pain and stop or slow the structural destruction of the joint and "hope PPS may offer an alternative to the use of opioids by treating osteoarthritis".

The company said that osteoarthritis was a condition with a significant unmet medical need and a market size of \$US5 billion a year, while the total economic burden in the US alone was estimated at \$US128 billion.

Paradigm climbed 11 cents or 38.6 percent to 39.5 cents with 3.4 million shares traded.

SOMNOMED

The New York-based TDM Asset Management says it has increased its holding in Somnomed from 8,129,563 shares (14.05%) to 8.850,032 shares (15.29%).

TDM said it bought 720,469 shares at "market prices" but again failed to disclose the price paid as required under the Corporations Act 2001 (BD: Jul 5, 2017). Somnomed was untraded at \$3.65.

MICRO-X

Micro-X says it has appointed Jim McDowell as a non-executive director, effective from September 11, 2017.

Micro-X said that Mr McDowell had more than 30 years of experience in international defence and aerospace sectors and had lived and worked in the UK, the US, South Korea, Singapore, Hong Kong and Australia.

The company said that Mr McDowell joined British Aerospace in 1996 prior to the merger with Marconi to become BAE Systems in 1999 and his last appointment with the company was as chief executive officer of the \$5 billion a year Saudi Arabia business.

Micro-X said that previously Mr McDowell was chief executive officer of BAE Systems Australia for 10 years.

The company said that prior to British Aerospace Mr McDowell was with Bombardier Shorts in legal, commercial and marketing positions.

Micro-X said that Mr McDowell was currently the chairman of the Australian Nuclear Science and Technology Organisation, director of Austal and Codan, and the chancellor of the University of South Australia.

Micro-X was untraded at 37.5 cents.