



Biotech Daily

Wednesday October 28, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: SIRTEX UP 10%; LIVING CELL DOWN 26%**
- * **UK APPROVES MEDICAL DEVELOPMENTS PENTHROX, \$1m MILESTONE**
- * **3D MEDICAL RAISES \$4m FOR MACH7 MERGER, \$6m TO GO**
- * **IMUGENE RECEIVES \$756k FEDERAL R&D TAX REFUND**
- * **ORTHOCELL: 'ORTHO-ATI IMPROVES TENNIS ELBOW'**
- * **US PATENT FOR MESOBLAST CARDIO-VASCULAR STEM CELLS**
- * **PRESCIENT REQUESTS CAPITAL RAISING TRADING HALT**
- * **CHALLENGER, ENTITIES TAKE 6% OF SIRTEX**
- * **TIM ROBERTSON, FARJOY TAKE 9% OF MEDLAB**
- * **GOLDMAN SACHS ABOVE 5% OF NANOSONICS, YET AGAIN**
- * **PHARMAUST BACKS 20:1 CONSOLIDATION, LOSES PROF DAVID MORRIS**
- * **ANDREA GOLDIE REPLACES POLYNOVO CFO CO SEC CHRIS MEWS**

MARKET REPORT

The Australian stock market shed 0.21 percent on Wednesday October 28, 2015, with the ASX200 down 11.0 points to 5,335.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, nine traded unchanged and one was untraded. All three Big Caps rose.

Sirtex was the best, up \$3.34 or 9.65 percent to \$37.94 with 548,293 shares traded. Genetic Technologies climbed 5.9 percent; Clinuvel, Cochlear, Oncosil, Orthocell and Pharmaxis rose more than two percent; Actinogen, Atcor, Medical Developments, Mesoblast, Resmed and Universal Biosensors were up more than one percent; with CSL and Pro Medicus up by less than one percent.

Yesterday's 76.9 percent best, Living Cell, led the falls, retreating 1.8 cents or 26.1 percent to 5.1 cents with 17.75 million shares traded. Cellmid, Neuren and Osprey lost more than six percent; Uscom fell 5.4 percent; Prana lost 4.2 percent; Antisense and Biotron were down more than three percent; Acrux, Anteo, Reva and Starpharma shed more than two percent; Admedus, Bionomics, Impedimed, Nanosonics and Prima were down more than one percent; with Ellex down 0.95 percent.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has final approval to sell its inhaled methoxyflurane analgesic Pentrox for trauma and associated pain in the UK.

Medical Developments said that the approval from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) allowed Craigavon, Northern Ireland-based distributor Galen to sell Pentrox effective immediately, with a launch planned for an intensive care conference in London in December 2015 and first sales expected in January 2016.

The company said that the approval meant that Galen would pay it a further milestone payment of GBP450,000 (\$A966,554).

Medical Developments chief executive officer John Sharman said the final approval was "a defining moment for the company".

"Our partner Galen ... has already submitted its forecast orders for the UK and Irish markets which we are beginning to manufacture in preparation for delivery in January," Mr Sharman said.

Mr Sharman said he expected "significant sales" in the six months to June 30, 2016 and beyond and told Biotech Daily that Galen would distribute Pentrox in both the UK including Northern Ireland and, pending final approval, the Republic of Ireland.

"The MHRA approval overnight is also the trigger for final approval in France and Ireland," Mr Sharman said. "We already have approval in Belgium."

Mr Sharman said that the Cambridge UK-based distributor Mundipharma had submitted forecast orders for France and Belgium with sales expected by July 2016 and Mundipharma was responsible for other European approvals including Germany, Italy and Spain which were expected by July 2017 (BD: Sep 28, 2015).

Medical Developments said that French approval would trigger a \$US3 million (\$A4.2 million) milestone payment from Mundipharma.

Medical Developments was up five cents or 1.55 percent to \$3.27.

3D MEDICAL

3D Medical says it has raised \$3,984,080 through the issue of 53,121,066 shares at 7.5 cents a share as part of a \$10 million raising to merge with Mach7 Technologies.

This week, 3D said it would merge with the Singapore-based Mach7 Technologies Pte Ltd for its medical imaging management systems (BD: Oct 26, 2015).

3D said that Wilson HTM acted as lead manager of the oversubscribed placement to professional and sophisticated investors.

The company said the balance would be raised through a share purchase plan and the exercise of existing options.

3D Medical was up 0.2 cents or 2.6 percent to eight cents with 5.6 million shares traded.

IMUGENE

Imugene says it has received \$755,854 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Imugene chief operating officer Leslie Chong said the tax incentive was "valuable non-dilutive capital for Imugene".

"Australia is a great source of medical innovations and this funding helps our company and others to convert those innovations to commercial tangible outcomes," Ms Chong said.

Imugene was unchanged at 0.9 cents.

ORTHOCELL

Orthocell says its autologous tenocyte implantation Ortho-ATI treatment “significantly improved the clinical outcome of patients with long term tennis elbow degeneration”.

Orthocell said the study of 25 workers’ compensation patients with lateral humeral epicondylitis, or tennis elbow, showed that Ortho-ATI “reduced pain and increased functionality enabling patients to return to work”.

The company said that the retrospective study was a collaboration between the University of Western Australia and orthopaedic surgeons Dr Alex O’Beirne from Perth and Dr Jeff Hughes from Sydney.

Orthocell said that the data showed that 22 patients were able to return to work and more than half of these returned at full capacity following treatment.

The company said that assessments carried out by the treating surgeons three to six months following ATI treatment showed there was a reduction in pain by almost 90 percent at rest and 54 percent with use of the affected limb.

Orthocell said that most of the patients returned to work in one to three months with a gradual increase in productivity to pre-injury levels at 5.33 months.

“These are very positive outcomes in a group of patients that did not respond to other treatments, with injuries that inhibited their ability to remain in the workplace,” Dr O’Beirne said.

Dr Hughes said the study group included “difficult to treat patients who are impeded in their ability to work and to carry out their essential duties”.

“Ortho-ATI has been instrumental in helping my patients to recover from long term tennis elbow injuries which have proved resistant to other modes of therapy,” Dr Hughes said.

Orthocell said that patients described persistence of symptoms for an average of 22 months prior to treatment with Ortho-ATI and they had failed in varying degrees to respond to alternative treatments including steroid injections, autologous blood and platelet rich plasma injections, physiotherapy, bracing, acupuncture and anti-inflammatory drugs.

The company said that the patients had received at least one and as many as eight prior treatments, with an average of 2.52 treatments.

Orthocell chief executive officer Paul Anderson said the data demonstrated that Ortho-ATI could help people with a difficult to treat tendon injury.

“This type of injury can hinder a person’s ability to work and lead to individual hardship, as well as significant socio-economic costs from the loss of individual productivity and health care costs,” Mr Anderson said.

Orthocell said that tennis elbow was a common work-related injury affecting up to three percent of adults and 16 percent of patients with tennis elbow required work restrictions and frequently needed prolonged absences from work, with an average 29 days missed per patient.

The company said that office work, health care and manual work had been identified the top three affected occupations.

Orthocell said that although tennis elbow was generally a self-limiting condition, it resulted in significant disability, health care utilisation, lost productivity and cost.

The company quoted a study that showed that in the 18 percent of tennis elbow patients who continued to require clinical care six months after diagnosis, the median duration of care was 844 days.

Orthocell said that the US, Europe and Japan markets for tennis elbow treatment was estimated to be worth more than \$US700 million in 2015.

Orthocell was up 1.5 cents or 2.5 percent to 61 cents with 135,862 shares traded.

MESOBLAST

Mesoblast says that the US Patent and Trademark Office has granted a patent entitled 'Perivascular Mesenchymal Precursor Cell Induced Blood Vessel Formation'.

Mesoblast said that the patent covered the use of its adult mesenchymal precursor cells for the formation and repair of blood vessels in ischemic tissues until January 8, 2025 and further patent term extension could occur along with regulatory exclusivity extensions.

The company said that the granted claims covered the use of the its allogeneic or off-the-shelf mesenchymal precursor cells obtained from any source, for use in conditions including ischemic heart disease, stroke and peripheral arterial disease.

The patent abstract, cited on the USPTO website said that "mesenchymal precursors cells have been isolated from perivascular niches from a range of tissues utilizing a perivascular marker".

"A new mesenchymal precursor cell phenotype is described characterized by the presence of the perivascular marker 3G5, and preferably also alpha smooth muscle actin together with early developmental markers such as STRO-1 and CD146/MUC18," the abstract said. "The perivascular mesenchymal precursor cell is shown to induce neovascularization and improvement in cardiac function."

"Suitable administration of preparations of the mesenchymal precursor cells are useful for treatment of cardiovascular diseases, cerebrovascular diseases and peripheral vascular diseases," the Mesoblast patents abstract said.

Mesoblast said it had been previously granted patents in Europe and Japan derived from the same patent family, which provided exclusive commercial rights in those two markets to at least March 29, 2024.

The company said that the patent extended and broadened its intellectual property position in the US with respect to the treatment of cardiac and vascular diseases beyond previously granted patents which covered allogeneic culture-expanded mesenchymal stem cell product candidates for cardiovascular diseases.

Mesoblast said it had more than 661 patents or patent applications across more than 72 patent families which provided competitive advantages for the commercial development of cellular therapy products based on mesenchymal lineage cells.

Mesoblast was up five cents or 1.5 percent to \$3.42 with 646,260 shares traded.

PRESCIENT THERAPEUTICS

Prescient has requested a trading halt "pending the release of an announcement to the market in relation to a capital raising".

Trading will resume on October 30, 2015 or on an earlier announcement.

Prescient last traded at 5.8 cents.

SIRTEX MEDICAL

Challenger Limited and its entities say they have increased their substantial holding in Sirtex from 2,864,215 shares (5.01%) to 3,461,198 shares (6.06%).

The Sydney-based Challenger named BNP Paribas Nominees, Citicorp Nominees, JP Morgan Nominees, National Nominees, HSBC Custody Nominees and UBS Nominees as the registered holders of the shares, with five pages of named holders of the securities.

The company said that between September 9 and October 23, 2015 it primarily bought, but also sold shares, with the single largest purchase on October 22 of 43,292 shares for \$1,422,575 or \$32.86 a share.

Sirtex climbed \$3.34 or 9.65 percent to \$37.94 with 548,293 shares traded.

MEDLAB CLINICAL

The Sydney-based Farjoy Pty Ltd says it has increased its substantial shareholder in Medlab from 10,000,000 shares (6.22%) to 15,000,000 shares (9.33%).

The substantial shareholder notice, signed by managing-director Timothy Frank Robertson, of Weston Woodley Robertson, said that 5,000,000 shares were acquired on October 26, 2015 for \$880,945 or 17.6 cents a share.

Medlab was up one cent or 5.7 percent to 18.5 cents.

NANOSONICS

The Delaware-based Goldman Sachs Group says that, yet again, it has become substantial in Nanosonics with 14,704,724 shares or 5.19 percent.

Goldman Sachs said that between June 24 and October 23, 2015 it acquired between one single share and 1,344,230 shares for no cost, with the single largest purchase 194,961 shares for \$258,323 or \$1.325 a share, which the company has previously reported.

Throughout October, Goldman Sachs has repeatedly increased above or reduced below the five percent substantial threshold in Nanosonics, primarily borrowing or returning shares "to the counterparty under a repurchase agreement" for no applicable consideration (BD: Oct 2, 5, 15, 16, 20, 23, 27, 2015).

Previously, under a counterparty agreement, Goldman Sachs returned, lent and borrowed shares held by subsidiaries, Rothesay Life, JP Morgan Chase, RBC Dexia Australian, HSBC Custody Nominees Australia and the Bank of New York Mellon (BD: Apr 13, 2015). Nanosonics fell two cents or 1.4 percent to \$1.38.

PHARMAUST

Pharmaust says its annual general meeting has passed all resolutions including the 20-to-one consolidation and director Prof David Morris has resigned.

Pharmaust said that Prof Morris planned "to concentrate on his work at St George Hospital and research work with his foundation".

Pharmaust executive chairman Dr Roger Aston said Prof Morris had been a director since August 2013 and had been "a valuable contributor to the company and the research and development of its three oncology technology platforms".

Pharmaust fell 0.1 cents or 16.7 percent to 0.5 cents.

POLYNOVO

Polynovo' says that Chris Mews has resigned as chief financial officer and company secretary and Andrea Goldie has been appointed to those roles, effective immediately. Polynovo said it thanked Mr Mews for his long service and described him as a "rock of support" in the company's recent history.

The company said that Ms Goldie held an Bachelor of Economics from the Szechenyi Istvan University, Hungary and a Masters of Business Administration from the Budapest University of Technology.

Polynovo said that Ms Goldie previously worked at Glaxosmithkline and Monash College. Polynovo was unchanged at 14 cents.