

Biotech Daily

Monday July 13, 2015

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: PRANA UP 10%; ANALYTICA, ANTISENSE DOWN 9%
- * WEHI: 'MOLECULAR SWITCH CREATES LONG-TERM IMMUNITY'
- * UNIVERSAL BIOSENSORS STRIP FEES UP 137%
- * PHYTOTECH'S MMJ TO DISTRIBUTE AI FAME PRODUCTS
- * MEDLAB IPO RAISES \$6m FOR FOOD ADDITIVES, GUT HEALTH
- * PRIMA TELLS ASX 44% UP, 32% DOWN QUERY: 'SHARE PLAN NOT NEWS'
- * INVION PLEADS SCHULTZ, NEWS TO ASX 63% QUERY
- * OBJ: PROCTOR & GAMBLE SALE TO COTY 'NO KNOWN IMPACT'
- * ACRUX APPOINTS FELICIA COLAGRANDE, CHARLES O'SULLIVAN

MARKET REPORT

The Australian stock market fell 0.34 percent on Monday July 13, 2015 with the ASX200 down 18.8 points to 5,473.2 points.

Eleven of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and three were untraded. All three Big Caps were up.

Prana was the best, up 1.5 cents or 10 percent to 16.5 cents with 10,000 shares traded.

Cellmid climbed 9.1 percent; Tissue Therapies was up 8.8 percent; Genetic Technologies rose 7.7 percent; Cochlear and Optiscan were up six percent or more; Atcor and Bionomics rose more than two percent; Admedus, CSL, Nanosonics, Resmed and Sirtex were up more than one percent; with Mesoblast up 0.5 percent.

Analytica and Antisense led the falls, both down 9.1 percent to one cent and 10 cents, respectively, with 6.2 million shares and 429,004 shares traded, respectively.

Benitec lost 7.7 percent; Compumedics was down 5.1 percent; Biotron, Impedimed and Oncosil fell more than four percent; Actinogen, IDT and Starpharma shed more than two percent; Avita, Clinuvel and Medical Developments were down more than one percent; with Acrux, Osprey and Viralytics down by less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says the Myb protein is responsible for preserving antibody-producing cells that lead to long-term immunity after infection or vaccination. WEHI said that Dr Kim Good-Jacobson, Prof David Tarlinton and colleagues discovered the presence of a protein called Myb, a member of the myeloblastosis family of transcription factors, was essential for antibody-producing plasma cells to migrate into bone marrow, preserving them for many years or even decades.

The article, entitled 'c-Myb is required for plasma cell migration to bone marrow after immunization or infection' was published in the Journal of Experimental Medicine and an abstract is available at: http://jem.rupress.org/content/212/7/1001.abstract.

Dr Good-Jacobson said plasma cells were created when the immune system was exposed to pathogens such as viruses or bacteria.

"When our immune system encounters a new pathogen, it can create plasma cells that secrete antibodies to specifically prevent future infections, generating immunity," Dr Good-Jacobson said.

"Our bone marrow is like a long-term storage facility for plasma cells, allowing them to continue producing antibodies to protect against future infections," Dr Good-Jacobson said. "Until now, it was not known why some plasma cells moved into the bone marrow, while others remained in the blood stream and perished after a few days."

WEHI said that the research team discovered that when the gene that produced the protein Myb was removed, plasma cells were no longer able to move into the bone marrow to provide long-term immunity.

"Myb is a type of protein called a transcription factor, which binds to DNA and, in effect, switches genes on or off," Dr Good-Jacobson said.

"We found that if a plasma cell produced Myb at some stage during an immune response, then those plasma cells had the ability to migrate into the bone marrow," Dr Good-Jacobson said.

"If we can understand how to flip the molecular switch in plasma cells and activate Myb production, we might be able to encourage the immune system to create long-term immunity for a range of infections," Dr Good-Jacobson said.

"Plasma cells are created during an immune response in temporary structures called germinal centres," Dr Good-Jacobson said.

"Germinal centres act as a rapid proto-typing facility, improving the design of antibodies to better recognise invading pathogens in the future," Dr Good-Jacobson said.

"The Myb protein marks the plasma cells that produce high-quality antibodies for preservation," Dr Good-Jacobson said.

Prof Tarlinton said the discovery would mean researchers could now search for the trigger of Mvb production and find out what genes Myb controls.

"Now that we know Myb is critical in creating long-term immunity, we can begin dissecting the pathways it uses to mark plasma cells for storage and the genes involved in migrating to the bone marrow," Prof Tarlinton said.

"Some pathogens, such as malaria, typically trigger the creation of short-lived plasma cells," Prof Tarlinton said.

"If we don't create long-lived plasma cells, we don't develop lasting immunity to the disease," Prof Tarlinton said.

"If we can trigger the expression of Myb in plasma cells responding to pathogens, either by infection or by immunisation, we might be able to convince the immune system to store these plasma cells in the bone marrow to offer protection against future infections," Prof Tarlinton said.

UNIVERSAL BIOSENSORS

Universal Biosensors said that Johnson & Johnson quarterly service fees for the 12 months to June 30, 2015 were up 136.7 percent to \$10,390,000.

In its Appendix 4C Quarterly report, Universal Biosensors said the fees generated by sales of the Lifescan Onetouch Verio blood glucose test strips were up 23 percent for the three months to June 30, 2015 compared to the three months to December 30, 2014 and were up 162 percent compared to the three months to June 30, 2014.

The total Onetouch Verio service fees for the 12 months were up \$6,000,000 or 136.7 percent from \$4,390,000 for the year to June 30, 2014 to \$10,390,000 for the 12 months to June 30, 2015 (BD: Jul 14, 2014).

Universal Biosensors chief financial officer Salesh Balak told Biotech Daily the cahs flow statement did not include revenue from Siemens Healthcare Diagnostics for research and development or sale of strips or royalties for the Xprecia Stride Coagulation Analyzer launched earlier this year (BD: May 14, 2015).

Universal Biosensors was unchanged at 35 cents.

PHYTOTECH

Phytotech says that merger partner MMJ Bioscience subsidiary Satipharm AG has an agreement with Ai Fame GmbH to market and distribute its medical cannabis products. Phytotech has previously said the MMJ merger was unconditional and was expected to be settled "in the coming days" (BD: Jul 2, 2015).

The company said that Satipharm had been appointed as the marketing and distribution partner of the Switzerland-based Ai Fame, giving it the exclusive rights across all medical cannabis products manufactured and developed by Ai Fame.

Phytotech said that Ai Fame's portfolio included extracts of tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidoil, cannabidiolic acid and cannabichromene and hemp-flower extract.

The company said that the active pharmaceutical ingredients required high quality control processes throughout the entire extraction procedure, including a full analysis of all substances within the extract.

Phytotech said that Ai Fame was able to extract the organically-derived active pharmaceutical ingredients and intended to begin scaling its production capacity in September 2015.

The company said that the agreement made Satipharm "the only company globally to have the ability to supply the organically derived [active pharmaceutical ingredients] to research groups and pharmaceutical companies in quantities beyond the levels permitted for research purposes and in pharmaceutical quality".

Phytotech said that the currently only synthetic compounds were available and they did not have the same effectiveness as organically produced compounds.

The company said that MMJ had estimated the sale of the active pharmaceutical ingredients could be worth up to \$30 million a year from 2016.

Phytotech said that Satipharm had been working with Ai Fame since 2014 and its, cannabidoil pill Sativol was in production for distribution in Europe was developed in partnership with Ai Fame.

The company said that MMJ had agreed to provide financing to Ai Fame in the form of a loan for up to CHF2 million (\$A2.9 million) for scaling production.

Phytotech was up half a cent or 1.6 percent to 31 cents.

MEDLAB CLINICAL

Medlab says its initial public offer at 20 cents a share has raised \$6.17 million and it will list on the ASX under the code MDC tomorrow, July 14, 2015.

In a media release, the food additives company did not say how much it raised in the offer, which had a minimum raising of \$6 million and a maximum of \$9 million, but a public relations officer for the company told Biotech Daily that the company had raised \$6.17 million (BD: May 12, 2015).

Medlab said that its focus was "on developing bacteria based medicines, guided by the view that poor gut health is the cause of certain chronic health problems".

The company said that the funds raised would go to the development of its food additives business, with six products on the market and 16 in the pipeline, as well as research and development of new bacteria based medicines, of which two were in human trials and development of delivery platforms for those medicines to allow more effective dosing The company said its research and product development was targeting chronic kidney disease, obesity, depression, pain management and anti-ageing and muscular-skeletal health.

Medlab said that its most advanced program in human trials was for depression and obesity.

PRIMA BIOMED

Prima has told the ASX that its 32.9 percent fall from 8.5 cents on July 7 to 5.7 cents on July 8, 2015 followed its five cents a share plan announced late on July 7.

The ASX said that the company's share price rose 44.1 percent from 5.9 cents on July 6 to 8.5 cents on increased volumes on July 7, following an announcement that claimed the European Medicines Agency had "confirmed in writing its endorsement of the development program of IMP321 in metastatic breast cancer" (BD: Jul 7, 2015). The ASX did not ask the company about the content of that announcement, although Biotech Daily is aware that there has been significant discussion of the claim that a regulator would "endorse" a program.

The ASX questioned the timing of the Prima share plan announcement and asked whether Prima considered the information in share plan announcement "to be information that a reasonable person would expect to have a material effect on the price or value of its securities?"

The ASX said that if the answer was "yes" the company should address why the share plan announcement was not released at the same time as the EMA announcement. Prima told the ASX it had previously announced its intention to offer a share plan on May 14, 2015 and as it was seeking to raise up to \$10 million, "the share price reaction, if attributed solely to the [share plan] announcement, seems disproportionate given the prior notice of Prima's intention to offer a [share plan] and the size of the raising" (BD: May 14, 2015).

Prima said it "first became aware of the information after board approval was received" in response to an email sent by chief executive officer Marc Voigt to the board at 3.36pm on July 7, 2015, which recommended announcing the plan that day so the pricing could be determined based on the previous 5-day volume-weighted average price, subject to consultation with external advisors.

The company said that the decision to release the share plan announcement on July 7, 2015 was not made until after the market close, after Prima had consulted with external advisors and calculated the share plan price.

Prima was unchanged at 5.6 cents with 4.8 million shares traded.

INVION

Invion has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 63.2 percent from 1.9 cents on July 6 to 3.1 cents today, July 13, 2015 and noted a significant increase in the trading volume. Invion said that it published a milestones update on July 3 and was the subject of "newspaper publications on July 5, 2015 which included 'share price tips'. Invion closed unchanged at 2.5 cents with 25.3 million shares traded.

OBJ

OBJ says that it is not aware of any potential material impact the sale of Proctor and Gamble assets to Coty Inc will have on its agreements.

OBJ said that Proctor and Gamble made the announcement on Friday July 10, 2015 regarding the sale "of certain brands from its beauty and grooming assets".

OBJ said it had not been advised of any material impact to the product development program with Proctor and Gamble as a consequence of the sale of the brands.

The company said that Proctor and Gamble would keep its largest hair, skin and personal-care brands, which included the SK-II skin care products that the two companies were codeveloping (BD: Dec 16, 2014; Jul 8, 2015).

OBJ said that it had been working with Coty's skincare group since 2013 on the development of a new skin care and beauty platform, based on the Dermaportation technology project which had progressed to an advanced stage with initial testing of the completed device underway in the US (BD: Dec 3, 2014).

OBJ fell 0.1 cents or 1.8 percent to 5.4 cents.

ACRUX

Acrux says it has appointed Felicia Colagrande as product development and technical affairs director and Charles O'Sullivan to portfolio director.

Acrux said the appointments would support its growth strategy, focused on developing and commercializing products for the pharmaceutical market.

The company said that Ms Colagrande had 25 years experience in the pharmaceutical and biotechnology industry, joining Acrux in 2001.

Acrux said that Ms Colagrande previously held positions at Faulding Pharmaceuticals, the Austin Hospital's Department of Clinical Pharmacology and Therapeutics, Silliker-Microtech Laboratories, was a lecturer with the Faculty of Pharmacy and Pharmaceutical Sciences at Monash University and held a Bachelor of Science from La Trobe University. Acrux said that Mr O'Sullivan had 20 years in senior executive and clinical roles with pharmaceutical businesses and had held senior roles in scientific affairs, health economics and government relations.

The company said that Mr O'Sullivan was a qualified pharmacist, with experience in hospitals including pharmacy management, including bio-ethics, drug and therapeutics committee membership and held a Bachelor of Pharmacy from Monash University and a Graduate Diploma of Epidemiology and Biostatistics from Melbourne University. Acrux fell half a cent or 0.6 percent to 85.5 cents.