

Biotech Daily

Wednesday March 18, 2015

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH DOWN: SIRTEX UP 20%, PHOSPHAGENICS DOWN 23%
- * BIOTECH DAILY EDITORIAL: SIRTEX NOT ALL DOOM AND GLOOM
- * ADMEDUS PLACES \$12m, RIGHTS ISSUE FOR \$16m MORE
- * NANOSONICS SHARE PLAN RAISES \$3m
- * NOVOGEN 'ANISINA (ATM-3507) KILLS CANCER CYTOSKELETON IN MICE'
- * SIMAVITA CONTINUES INCONTINENCE MONITOR ROLL-OUT
- * SOLAGRAN US PATENT FOR 'PROCESSING VEGETABLE RAW MATERIALS'

MARKET REPORT

The Australian stock market was barely changed on Wednesday March 18, 2015 with the S&P ASX 200 up 0.2 points to 5,842.3 points.

Ten of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and five were untraded. All three Big Caps were up.

Sirtex was the best, recovering from yesterday's 55 percent plummet, up \$3.42 or 19.5 percent to \$20.95 with 3.4 million shares traded.

Viralytics climbed 7.95 percent; Oncosil was up 6.9 percent; Bionomics, Medical Developments and Resmed rose more than two percent; Avita, Cochlear, Nanosonics, and Tissue Therapies were up more than one percent; with Acrux, CSL and Impedimed up by less than one percent.

Phosphagenics led the falls, down one cent or 23.3 percent to 3.3 cents, believed to be its lowest share price since listing, with 5.3 million shares traded, followed by Admedus down 19.4 percent to 7.9 cents with 26.0 million shares traded and Atcor down 10.3 percent to 17.5 cents with 2.3 million shares traded.

Living Cell and Optiscan lost more than eight percent; Genetic Technologies fell 7.7 percent; Anteo and Benitec fell more than four percent; Biotron, GI Dynamics, Pharmaxis and Prima were down more than three percent; Clinuvel and Starpharma shed more than two percent; Alchemia and Antisense were down more than one percent; with Mesoblast down 0.3 percent.

BIOTECH DAILY EDITORIAL: SIRTEX MEDICAL

Biotech Daily very rarely comments on the results of pivotal clinical trials, especially in the difficult area of oncology, but the concerns around the Sirtex results merit discussion.

While yesterday's result of a non-significant difference between SIR-Spheres with the current standard-of-care, oxaliplatin, leucovorin and 5- fluorouracil (Folfox) compared to standard-of-care alone for non-resectable metastatic colorectal cancer, has hurt the Sirtex share price, will impact severely on the March Biotech Daily Top 40 Index (BDI-40) and damage the sector's reputation to investors, it is not all doom and gloom.

Taken with Alchemia's failure to find a significant difference by adding hyaluronic acid to irinotecan in the folinic acid, fluorouracil and irinotecan (Folfiri) regime, also for metastatic colorectal cancer, one could deduce that it is difficult to improve on the triple drug chemotherapy approach for this cancer (BD: Oct 27, 2014).

Should the coming Sirtex studies, including Foxfire, Foxfire Global or Sarah trials, show significance in favor of SIR-Spheres, Sirtex may yet have a chance at more than salvage treatment, but the first results are not due until the end of this year.

Even if SIR-Spheres can be shown only to be equal to chemotherapy for some patients with some cancers, then a single infusion of the localized radiation may be preferable to long and painful courses of chemotherapy, giving doctors and patients some greater choice of treatment.

While some have raised concerns that yesterday's results could impact on the current use of SIR-Spheres for salvage patients, it will take some months to see if there is a drop in use, while the most recent half-yearly report shows an increase in revenue for the six months to December 31, 2014 of 37.3 percent to \$80,452,000, with dose sales up 26.3 percent to 4,950 units for the six months (BD: Feb 18, 2015).

Three years ago, Biotech Daily believed that Sirtex at \$5 a share was significantly undervalued and it was worth at least \$10. Some analysts later said that at \$15 it was overvalued. Curiously, the recent buying seems to be matched by the recent selling and Sirtex is trading at about \$20, in line with average market multiples of its earnings.

Sirtex is a well-run company earning revenues greater than the combined market capitalizations of a dozen ASX-listed biotechnology companies and has plans to expand its indications and increase existing sales.

A failed pivotal trial may be bad news for the company, some investors (but not those who bought at \$2.50 and \$5.00) and the sector, but it is far from the end of the world.

The reason we have large, randomized, controlled, pivotal trials is to determine whether treatments work. It will be interesting to see by how much Sirtex missed its endpoint when the company releases its data.

David Langsam Editor

ADMEDUS

Admedus says it has raised \$12 million in "a heavily oversubscribed placement" at seven cents a share and hopes to raise a further \$16 million in a one-for-seven rights issue. Admedus said the non-renounceable offer would not be underwritten and any shortfall would be placed by the directors at their discretion.

The company said that the record date for the rights issue is March 26, the offer opens on March 30 and closes on April 14, 2015.

Admedus chief executive officer Lee Rodne said that capital raising "places the company in a strong financial position and allows us to continue to build our sales teams and ongoing sales activities across the group as well as make significant progress in our regenerative tissue product development and immunotherapy programs".

Admedus said the funds would be used to expand the Cardiocel sales teams in Europe and North America, for post-market studies and further product development to expand Cardiocel in cardiovascular surgical applications, such as heart valve repairs, expand the Adapt regenerative tissue product portfolio and fund the human papillomavirus therapeutic vaccine phase lb study and supporting research activities for the vaccine programs. Admedus fell 1.9 cents or 19.4 percent to 7.9 cents, with 26.0 million shares traded.

NANOSONICS

Nanosonics says its share plan at \$1.65 a share has raised \$3.0 million on receipt of applications exceeding the maximum allowed.

Earlier this month, Nanosonics raised \$25 million in a placement at the same share price (BD: Mar 5, 2015).

Nanosonics was up two cents or 1.2 percent to \$1.72 with 862,315 shares traded.

NOVOGEN

Novogen says that one of its oncology pipeline drug candidates Anisina, or ATM-3507, can destroy cancer cell cytoskeleton, in a mouse model.

Novogen said the in-vivo anti-cancer effect was "a major milestone" having previously said that anti-tropomyosin drugs in combination with anti-mitotic drugs boosted the cancer-killing ability 20-fold against neuroblastoma cancer cells in-vitro (BD: Nov 21, 2014). Today, the company said commonly used anti-mitotic drugs in chemotherapy targeted the cytoskeleton by destabilizing one of its two key components, the microtubules and included taxanes such as paclitaxel and docetaxel) and the vinca alkaloids including vincristine and vinblastine.

Novogen said that Anisina was developed specifically to destroy the other key component, the microfilaments, and to work in combination with the anti-mitotic drugs to deliver comprehensive destruction of the cancer cell's architecture.

The company said that Anisina targeted the tropomyosin Tpm3.1 protein which provided structural integrity to the microfilaments of a cell.

Novogen said the proof-of-concept study was done as part of the Children's Oncology Drug Alliance, involving the Kids' Cancer Project charity the University of New South Wales and the Columbus, Ohio-based Nationwide Children's Hospital, using cancer cells derived from children who had neuroblastoma (BD: May 5, 2014).

Novogen anti-tropomyosin program director Dr Justine Stehn said the company would take Anisina to clinical trials for adults and children in 2016.

Novogen was up 3.5 cents or 20.6 percent to 20.5 cents with 21.2 million shares traded.

SIMAVITA

Simavita says it has two new Smart Incontinence Monitor (Sim) supply agreements and is further rolling out the product, valued at about \$800,000 a year.

Simavita said the Melbourne-based McKenzie Aged Care Group had agreed to deploy its technology across all of its 20 sites by the end of 2015, the Brisbane-based Queensland Rehabilitation Services agreed to roll out Sim across all five of its sites and the Melbourne-based Arcare group had installed Sim in 19 of its 24 sites, with all sites expected to be installed by June 2015.

Simavita chief executive officer Philippa Lewis said that the importance of the three contracts went "beyond a commercial arrangement".

"Each one is recognized as a leading aged care provider who is focused on the efficiencies and potential revenue uplift gained from implementing cutting edge technologies like Sim," Ms Lewis said.

Simavita said that a 14-facility group in Ontario Canada had established a pilot of the Sim technology in a 231-bed facility, and if adopted the minimum aggregate value of Sim installed at all of its sites, could be in the order of \$450,000 a year.

The company said that its first customers in Denmark were ordering the technology and distribution partner Abena was in consultation with additional municipalities. Simavita was up one cent or 2.3 percent to 44 cents.

SOLAGRAN

Solagran says it has a US patent protecting its core production technology for the manufacture of its pine needle extract known as Bioeffectives.

Solagran said that the patent, entitled 'Method for Processing Vegetable Raw Materials' had corresponding patents granted in Australia, Russia, Canada, Indonesia and Latvia, and applications had been filed in other jurisdictions.

Solagran chairman Dr Vagif Soultanov said "the granting of our core technology patent in the US is a very important milestone for Solagran".

"It establishes our proprietary position in the manufacture from different plant species of high-purity polyprenols and other products across major jurisdictions, and gives us a firm foundation for future commercial success," Dr Soultanov said.

Solagran describes itself as a "healthcare and wellness company" based in South Melbourne and was developing a treatment for liver cancer, Alzheimer's disease and a raft of other indications based on its Siberian pine needle extract Ropren and 'Bioeffectives' (BD: Feb 25, 2009; Feb 5, 2010).

Despite claiming large contracts and building a manufacturing plant, Solagran was twice suspended by the ASX for failing to lodge accounts (BD: Mar 1, 2011; Mar 9, 2012). In February 2012, Solagran said it would form a joint venture with Russia's Art Life to develop and manufacture food additive products using its conifer needle extract 'Bioeffectives' and quoted Art Life founder Prof Alexander Avstrievskih "forecasting revenues in the order of \$US100 million [\$A93.6 million] for 2012".

Despite Solagran personnel joining Bioprospect (now Medibio), an agreement between the two companies on Bioeffectives was terminated with Bioprospect alleging it could source the pine needle extract cheaper elsewhere and the two companies were involved in litigation (BD: Jun 28, Aug 5, Sep 20, Oct 27, 2010).

Solagran remained suspended at 3.9 cents.

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