



# Biotech Daily

Monday April 16, 2018

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: FACTOR UP 7%; ELLEX DOWN 9%**
- \* **SIRTEX SORAMIC TRIAL: 'SIR-SPHERES NO SURVIVAL BENEFIT'**
- \* **TELEX FRENCH TRANSLATIONAL NUCLEAR MEDICINE PARTNERSHIPS**
- \* **RESAPP TELLS ASX: 'RESULT UNKNOWN AT TRADING HALT'**
- \* **PROTEOMICS OPTIONS DILUTE DR LIPSCOMBE, DR PARKER, MR DUNLOP**
- \* **PHARMAUST 'GLOBAL PHARMA AGREEMENT' TRADING HALT**
- \* **AUSBIOTECH: 12<sup>th</sup> MEDICAL TECHNOLOGIES CONFERENCE IN ADELAIDE**

## MARKET REPORT

The Australian stock market was up 0.21 percent on Monday April 16, 2018 with the ASX200 up 12.2 points to 5,841.3 points.

Nine of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and three were untraded. All three Big Caps were up.

Factor Therapeutics was the best, up 0.3 cents or 7.3 percent to 4.4 cents with 147,134 shares traded.

Bionomics climbed 5.9 percent; LBT, Oncosil and Pro Medicus were up more than three percent; Compumedics and Genetic Signatures rose two percent or more; Telix was up 1.6 percent; with Cochlear, CSL, Nanosonics and Resmed up by less than one percent.

Ellex led the falls, down 7.5 cents or 9.1 percent to 75 cents with 770,821 shares traded.

Cyclopharm lost 6.4 percent; Airxpanders and Optiscan fell more than five percent; Immutep was down 4.2 percent; Avita and Osprey were down more than three percent; Acrux, Opthea, Psivida and Starpharma shed more than two percent; Impedimed, Mesoblast, Neuren, Pharmaxis, Polynovo and Reva were down more than one percent; with Clinuvel, Sirtex and Volpara down less than one percent.

## SIRTEX MEDICAL

Sirtex says its 424-patient Soramic trial study shows that adding SIR-Spheres to sorafenib shows no overall survival benefit for liver cancer.

In 2016, Sirtex said that Germany's University of Magdeburg had completed recruitment of 420 patients in the trial of sorafenib with SIR-spheres Y-90 resin microspheres for inoperable primary liver cancer (BD: Mar 8, 2016).

Then Sirtex chief executive officer Gilman Wong said the 'Sorafenib and Micro-therapy Guided by Primovist-Enhanced MRI in Patients with Inoperable Liver Cancer' (Soramic) trial was "the largest SIR-Spheres Y-90 resin microspheres combination study ever undertaken in [hepatocellular carcinoma]".

The company said at that time that the primary endpoint was overall survival with secondary endpoints of quality of life and safety.

Today, Sirtex quoted the study authors conclusion that "the addition of [selective internal radiation therapy] SIRT to sorafenib did not result in a significant improvement in overall survival compared to sorafenib alone".

"Subgroup analyses led to hypothesis generating results for patient groups with potential clinical benefit," Sirtex quoted the study authors saying.

Sirtex said that the results were presented on April 14, 2018 at the European Association for the Study of the Liver meeting in Paris, France.

Sirtex chief executive officer Andrew McLean said that "while we are disappointed the study did not meet the primary endpoint of an [overall survival] advantage versus sorafenib alone, we continue to focus on executing our multi-tiered growth strategies for SIR-Spheres microspheres, while prudently managing operating expenditures".

"It is important to note the outcomes from this study in no way effects Sirtex's financial position as the capitalized costs of this study were written-off in June 2017 and the results have no bearing on the proposed acquisition of Sirtex by Varian Medical Systems, which is due to be implemented on May 25, 2018," Mr McLean said.

Sirtex said that the study would be presented as an oral abstract entitled 'The impact of combining Selective Internal Radiation Therapy (SIRT) with Sorafenib on overall survival in patients with advanced hepatocellular carcinoma: The Soramic trial palliative cohort.'

The Munich-based Ludwig-Maximilians University principal investigator Prof Jens Ricke said that "although we were disappointed to find no overall survival benefit of adding SIRT to sorafenib across the entire study population, we did observe a survival benefit in younger patients, those with non-alcoholic aetiology of the cirrhosis, and those with no cirrhosis at all".

Sirtex said that in the intent-to-treat palliative treatment cohort, 216 patients were randomised to SIR-Spheres microspheres with sorafenib and 208 to sorafenib alone.

The company said that the median overall survival was 12.1 months in the SIR-Spheres microspheres with sorafenib arm, and 11.5 months in the sorafenib-alone arm ( $p = 0.93$ ).

Sirtex said that in the per protocol group, median overall survival was 14.1 months for the SIR-Spheres and sorafenib combination and 11.1 months for sorafenib alone ( $p = 0.25$ ).

The company said that subgroup analyses of the 356 patients who completed the trial or the per protocol population "suggested a survival benefit for patients receiving SIR-Spheres microspheres and sorafenib" for patients aged 65 years or under ( $p = 0.05$ ); those without cirrhosis ( $p = 0.02$ ); and those with a non-alcoholic aetiology ( $p = 0.01$ ).

Sirtex said that adverse events of grade three or more were reported in 115 of 159 (72.3%) patients in the SIR-Spheres microspheres with sorafenib arm compared to 135 of 197 (68.5%) patients in the sorafenib-alone arm.

Sirtex fell three cents or 0.1 percent to \$27.73 with 183,812 shares traded.

## TELIX PHARMACEUTICALS

Telix says it has a research partnership with France's Institute of Health and Medical Research and the Nantes Accelerator for Research in Radiochemistry and Oncology. Telix said the agreements with the Paris-based (Institut national de la santé et de la recherche médicale (French National Institute of Health and Medical Research or Inserm) and the Nantes-based cyclotron operator the Accelerator for Research in Radiochemistry and Oncology at Nantes Atlantic (Arronax) would "explore the feasibility of using several of its clinical targeting agents with astatine".

The company said that astatine was an alpha particle emitter, a very high-energy radionuclide capable of significantly altering the tumor microenvironment when attached to a molecular targeting agent specific for cancer cells.

Telix said that the agreement would fund sufficient staff and facility time to conduct a number of studies over a two-year period, including preparation for pilot clinical studies in the nuclear medicine department of University Hospital of Nantes.

The company said that the agreement accessed "a portfolio of intellectual property that has been developed within the Nantes cluster that may lead to new products and indications for [its] therapeutic pipeline".

Telix Europe president Odile Jaume said that the Nantes nuclear research cluster had "a particular strength and capability in astatine, including production facilities and processes that are capable of making materials for human research".

"This collaboration has the potential to expand the clinical utility of Telix's technology and build a set of next generation products that may deliver even greater clinical utility to cancer patients," Ms Jaume said.

Inserm University of Nantes team leader Prof Michel Chérel said the partnership was "a great example of translational research aiming at truly personalized medicine".

Arronax director Prof Ferid Haddad said his facility was established with the development of alpha-nuclide therapy in mind.

"To this end, this highly innovative partnership with Telix is an important step forward and we believe that it will result in the development of new cancer treatment strategies," Prof Haddad said.

Telix was up one cent or 1.6 percent to 63 cents.

## RESAPP HEALTH

Resapp says it was not aware of the results of the evaluation of its sleep apnoea screening test when it called a trading halt for the clinical studies.

Resapp responded today to an ASX aware query of April 11, 2018 regarding its trading activity on April 9 and 10, 2018 which said the company's share price rose 50 percent from a closing price of 12 cents on April 3 to an intra-day high of 18 cents on April 9, prior to the company requesting the trading halt (BD: Apr 10, 2018).

The company said the ASX query referred to its April 10 announcement that it had "excellent preliminary results" for its proof-of-concept studies in obstructive sleep apnoea.

Resapp said in its response to the ASX aware query that it first became aware of the study's results at 11.31pm (AEST) on April 9, 2018.

The company said in its response to an ASX price query on April 10, 2018, that it was "aware of information relating to its clinical studies that [had] not been announced to the market that, if known by some in the market, could explain the recent trading in its securities", as well as its presentation at the Techknow Invest Conference that had "historically generated keen interest in the company".

Resapp was up one cent or 6.25 percent to 17 cents with 4.5 million shares traded.

## PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics chief executive officer Dr Richard Lipscombe says he has increased but was diluted from 16,253,781 shares (27.55%) to 19,011,204 shares (23.73%).

Dr Lipscombe said that with Bjouxz Pty Ltd and the Loz Superannuation Fund, he exercised 2,757,423 options to shares on April 6, 2018 for \$551,485, or 20 cents a share.

Proteomics director John Dunlop says he has increased but was diluted from 5,429,188 shares (9.20%) to 5,804,188 shares (7.25%).

Mr Dunlop said that with Randolph Resources, he exercised 375,000 options to shares on April 6, 2018 for \$75,000, or 20 cents a share.

Proteomics founder Dr William Parker says he has reduced his substantial holding and been diluted from 5,277,594 shares (8.95%) to 5,027,594 shares (6.28%).

The substantial shareholder notice said that the shares were held by Xylo Pty Ltd for the Parker Family account, with 250,000 shares sold on-market on January 23, 2018 for \$85,000, or 34 cents a share.

In March, Proteomics said it had commitments to raise \$3.4 million through the exercise of options at 20 cents each by March 31, 2018 (BD: Mar 14, 2018).

Proteomics fell half a cent or 2.3 percent to 21.5 cents.

## PHARMAUST

Pharmaust says it has requested a trading halt “pending an announcement of a material agreement with a global pharmaceutical company”.

Pharmaust said it would resume trading on April 18, 2018, or on an earlier announcement.

Pharmaust last traded at 5.1 cents.

## AUSBIOTECH

Ausbiotech says it will run its twelfth Ausmedtech medical technologies conference at the Adelaide Convention Centre on May 1 and 2, 2018.

Ausbiotech said that the conference would “feature a suite of topics relevant to the global medical technology industry ... [and] bring together the Australian and international medical devices and diagnostics sector to discuss major issues in global medical technology and help prepare the industry sector for its changing landscape”.

The industry organization said the conference would have trade exhibitions, networking events and a networking and partnering platform for delegates to schedule 30-minute meetings with other attendees.

For more information go to: <http://ausmedtech.com.au> or contact the event manager Vincent Portier [vportier@ausbiotech.org](mailto:vportier@ausbiotech.org).