Biotech Daily

Tuesday February 23, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NEUREN UP 9.5%, GENETIC TECHNOL DOWN 13%**

*** OBJ CLAIMS KNEEGUARD PAIN, MOBILITY TRIAL SUCCESS**

*** UNILIFE SIGNS $104m AMGEN COLLABORATION**

*** PARADIGM STARTS ZILOSUL FOR BONE BRUISING SAFETY TRIAL**

*** NUSEP, NEWCASTLE, PROF JOHN AITKEN WORK ON HUMAN, HORSE IVF**

*** RESMED BUYS BRIGHTREE SOFTWARE FOR $1.1b**

*** USCOM H1 REVENUE UP 54% to $1.5m, LOSS UP 114% TO $837k**

*** SIRTEX SIRFLOX RESULTS REPUBLISHED IN ONCOLOGY JOURNAL**

*** DAVID SIETSMA TAKES 5% OF ANTEO**

*** MATTHEW CALLAHAN, SRV TAKE 6.4% OF DIMERIX**

MARKET REPORT

The Australian stock market fell 0.43 percent on Tuesday February 23, 2016 with the ASX200 down 21.6 points to 4,979.6 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 21 fell, three traded unchanged and two were untraded. All three Big Caps fell.

Neuren was the best, up one cent or 9.5 percent to 11.5 cents with 659,778 shares traded. Antisense and Atcor climbed more than six percent; Prana was up 3.75 percent; Admedus and Tissue Therapies rose more than two percent; Opthea, Osprey, Pro Medicus, Sirtex and Starpharma were up more than one percent; with Clinuvel, Medical Developments and Nanosonics up by less than one percent.

Genetic Technologies led the falls, down 0.3 cents or 13.0 percent to two cents with 1.6 million shares traded. Psivida lost 9.3 percent; Oncosil and Polynovo shed more than eight percent; Living Cell fell 7.55 percent; Bionomics and Cellmid were down five percent or more; Acrux and Biotron fell more than four percent; Actinogen, Benitec and IDT were down more than three percent; Compumedics, Mesoblast, Prima, Resmed and Viralytics shed more than two percent; with Anteo, Avita, Cochlear, CSL, Orthocell, Pharmaxis and Reva down by more than one percent.

OBJ

OBJ says a 114-patient University of Queensland trial shows its Bodyguard Kneeguard improved physical performance and reduced pain compared to a drug product.

OBJ said that the trial, which began last year, compared the efficacy of Kneeguard with "one of the world's largest selling topical non-steroidal anti-inflammatory drug products" in males aged between 40 and 55 years with pre-existing knee pain (BD: May 20, 2015).

The company said that the Kneeguard Lubricen formulation used "naturally-occurring macro-molecules including glucosamine, hyaluronic acid and chondroitin sulphate, in preference to utilising non-steroidal drugs".

OBJ said that Lubricen was formulated with the assistance of the London School of Pharmacy's Prof Adrian Davis and has already received TGA approval.

The company said the study found that Kneeguard significantly improved performance in the aggregated function score, over a two week period and was equivalent to the non-steroidal anti-inflammatory drug (NSAID) for the sport and function components of the knee injury and osteoarthritis outcome score questionnaire.

OBJ said that Kneeguard achieved a statistically greater reduction in worst pain score of 32 percent compared to the NSAID's 17 percent after two weeks use.

The company said that trial participants reported higher skin irritation levels with Bodyguard, but it had addressed the issue with a new hydrogen gel technology, expected to eliminate the issue and enhance the efficacy of Kneeguard.

OBJ said that a follow-up consumer study conducted by Ipsos Australia examined "purchase intent, overall liking, value and uniqueness" of Kneeguard and participants indicated a preference for Kneeguard over the NSAID and Kneeguard outperformed the drug on purchase intent, intent to recommend the product, value and uniqueness.

OBJ said that three of 10 users considered Kneeguard to be the best product they have tried and more than one in four claimed they would definitely buy the starter kit.

The company said that the key strengths of Kneeguard were its ease of use, wearability, comfort, aesthetic and its ability to reduce knee pain over time.

OBJ said that the trial provided "valuable data that a prospective partner will be able to use as claims support for any potential products launched in the future, further distinguishing Bodyguard from existing drug based products in the market".

The company said that the US Food and Drug Administration-compliant trial was conducted by the University of Queensland's Prof Bill Vicenzino with Prof Tony Wright.

Professor Wright said that the Bodyguard trial results were "very positive in demonstrating an improvement in function that is at least equivalent to the results achieved with a gold standard topical non-steroidal and a reduction in pain that was greater than the comparator treatment".

OBJ managing-director Jeff Edwards said the results "confirm the potential that our Bodyguard technology products can provide a safe, effective and easy to use method of restoring and maintaining a physically activity lifestyle, even for those already suffering from joint pain".

"While the use of such a wearable technology product represents a large shift in consumer behaviour, the feedback from the trial participants highlights the appeal of this new approach to joint health maintenance can bring," Mr Edwards said.

OBJ said that joint pain was traditionally managed with topical and oral NSAIDs, but increasing longevity and more active lifestyles were rendering this approach unsustainable both from a regulatory, safety and consumer need standpoint.

The company said that its approach of treating the underlying causes of joint pain using natural drug-free ingredients provided a new means of managing joint degeneration.

OBJ was up 0.2 cents or three percent to 6.8 cents with 3.3 million shares traded.

UNILIFE CORP

Unilife says it has a strategic collaboration with Amgen for its wearable injectable drug delivery systems worth up to $US75 million ($A103,760,000).
Unilife said that Amgen paid a separate $US15 million in connection with the exclusivity letter of December 31, 2015 and would pay a non-refundable $US20 million licence fee (BD: Jan 25, 2016).
The company said that Amgen had purchased a $US30 million "senior secured convertible note" and could buy an additional $US25 million in convertible notes over the next two years with $US15 million in January 2017 and $US10 million in January 2018.
Should Amgen convert all the $US55 million in notes it would hold about 22 percent of Unilife at last night's Nasdaq closing market capitalization of $US194.9 million.
The company said that in addition to the payments, it expected to generate future revenue from the strategic collaboration with Amgen.
Unilife said that the collaboration, included licencing, investment, development and supply agreement components of its prefilled, customizable wearable injectors and it had granted Amgen exclusive rights to its wearable injectors within select drug classes for use with certain Amgen assets, while preserving rights previously granted to other Unilife customers.
Unilife said it had granted Amgen non-exclusive rights to all proprietary Unilife delivery systems within the therapeutic areas of oncology, inflammation, bone health, nephrology, cardiovascular and neuroscience.
The company said that the collaboration included terms for the development, production and supply of Unilife delivery systems, with development programs to begin in 2016.
Unilife was unchanged at 23.5 cents with 7.1 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it is sponsoring an open-label, trial of Zilosul for bone marrow oedema lesions, or bone bruising, at Melbourne's Box Hill Sportsmed Biologic medical clinic.
Paradigm said that the 40-patient clinical trial was investigating whether Zilosul, a formulation of pentosan polysulphate sodium, could resolve bone bruising from sporting or accidental injuries to the knee such as a ruptured anterior cruciate ligament.
The company said that the Box Hill Sportsmed Biologic principal investigator Dr Ruben Branson was actively recruiting patients at the clinic.
Paradigm said that unresolved bone marrow oedema was a potent risk factor for osteoarthritis following injury and the use of Zilosul shortly after the injury might resolve the bone bruise and potentially improve the long-term health of the knee cartilage.
The company said that the Sportsmed Biologic clinic was one of two centres involved in the trial to determine the safety and tolerability of Zilosul.
Paradigm said that Zilosul would be administered twice weekly for three weeks in patients with a lesion identified by magnetic resonance imaging (MRI) in association with bone pain and reduced joint function following an anterior cruciate ligament injury (ACL).
The company said that Dr Branson had experience in sports medicine with the Collingwood Football Club and the Melbourne Storm rugby team.
"People, especially athletes who have anterior cruciate ligament injuries, are more likely to develop osteoarthritis compared to people who haven't had an ACL injury" Dr Branson said.
Paradigm chief executive officer Paul Rennie said the company had achieved "a significant commercial milestone within six months of its ASX listing".
Paradigm was untraded at 28 cents.

NUSEP

Nusep says it will commercialize sperm separation for humans and animals with the University of Newcastle and has a consultancy agreement with Prof John Aitken.

Nusep said that the agreement was with the University's Faculty of Health and Medicine, and followed a heads of agreement on in-vitro fertilization (IVF) last year (BD: Mar 30, 2015).

The company said that Prof Aitken, who was the Faculty's pro vice-chancellor, would continue to chair its scientific advisory team.

Nusep said that with the University it had developed a process and associated laboratory instruments for separating the most viable sperm from a sperm sample.

The company said that it held the patents and had developed proprietary membrane technology for separating components of biological fluids, as well as the laboratory instruments and industrial processes for using the technology.

Nusep said the University of Newcastle had "know-how and expertise in human and animal fertility" and had patented the specific application, which Nusep had licenced.

Nusep chairman Alison Coutts said the agreements with the University and Prof Aitken "will enable us to accelerate the development of the Spermsep program".

"We already had established an extremely beneficial working relationship with Professor Aitken and his research team and now, with the full agreements executed, we are in the position to finally develop the Spermsep technology to its full potential," Ms Coutts said.

Prof Aitken said the Spermsep technology "selects the most viable sperm and that it has vast potential to be applied in global markets, not just for human IVF but also in animals".

Nusep said that the terms of the agreement were confidential.

The company said that with the University it had conducted in-vitro human in-vitro fertilization clinical trials, which would be continued and extended with the next generation separation device currently in development.

Nusep said the parties would continue to undertake research on equine reproduction.

Nusep was up 0.1 cents or 14.3 percent to 0.8 cents.

RESMED

Resmed says it will acquire the privately held Lawrenceville, Georgia-based acute care software provider Brightree for $US800 million ($A1,106.0 million) in cash

Resmed said that the acquisition added to its "global leadership in connected healthcare" products and Brightree's internet-based software helped customers improve clinical and business performance in the post-acute care industries of home and durable medical equipment, home health and hospice care, all of which had a high prevalence of sleep-disordered breathing, chronic obstructive pulmonary disease, neuromuscular disease, and other chronic diseases.

Resmed chief executive officer Mick Farrrell said that the acquisition "furthers Resmed's position as the leading tech-driven medical device company and gives our customers new tools to help them increase operational efficiency and improve cash-flow while delivering best-in-class patient care".

The company said that Brightree was majority-owned by Battery Ventures and had net sales of about $US113 million and earnings before interest, depreciation and amortization of about $US43 million in 2015, with an estimated $US300 million from an expected future tax benefit, which was expected to positively impact Resmed's cash flows over 15 years.

Resmed said that Brightree would continue to operate as a separate entity under its own name.

Resmed fell 19 cents or 2.3 percent to $8.05 with 3.2 million shares traded.

USCOM

Uscom says that revenue for the six months to December 31, 2015, was up 54.4 percent to $1,477,165 with net loss after tax up 113.9 percent to $837,128.
Uscom said that during the six months to December 31, 2015, sales of its ultra-sonic cardiac output monitor Uscom 1A continued to grow worldwide and it had fully-funded the cash acquisition of the Budapest, Hungary-based Thor Laboratories and the associated one off costs (BD: Jul 20, Sep 1, 2015) .
The company said it was preparing the Uscom BP+ central blood pressure diagnostic for market and rebranding and remarketing of the Thor Spirosonic range of digital ultrasonic spirometers for worldwide markets.
Uscom said that diluted loss per share increased 80 percent to 0.9 cents for the six months to December 31, 2015, with net tangible assets per share down 13.6 percent from 2.2 cents at December 31, 2014 to 1.9 cents at December 31, 2015.
The company said it had cash and cash equivalents of $1,068,825 at December 31, 2015, compared to $526,317 at June 30, 2015.
Uscom was untraded at 14 cents.

SIRTEX MEDICAL

A Journal of Clinical Oncology article says the addition of Sirtex SIR-Spheres to first-line chemotherapy for metastatic colorectal cancer delays progression the liver.
Sirtex said that the article reported on the 530-patient Sirflox trial, which last year found that SIR-Spheres with chemotherapy “does not result in a statistically significant improvement in the overall progression-free survival” but it did show “a statistically significant improvement in progression-free survival in the liver” (BD: May 17, 2015).
Last year, Sirtex said the trial compared its SIR-Spheres with the current standard of-care, oxaliplatin, leucovorin and 5- fluorouracil (Folfox) - to standard-of-care alone for non-resectable metastatic colorectal cancer, with a primary endpoint was progression-free survival and secondary endpoints including overall survival, tumor response rate, quality of life and surgical resection rate.
The Journal of Clinical Oncology article, co-written by investigator Prof Peter Gibbs, is entitled ‘SIRFLOX: Randomized Phase III Trial Comparing First-Line mFOLFOX6 (Plus or Minus Bevacizumab) Versus mFOLFOX6 (Plus or Minus Bevacizumab) Plus Selective Internal Radiation Therapy in Patients With Metastatic Colorectal Cancer’ and was published in the Journal of Clinical Oncology, with an abstract at: http://jco.ascopubs.org/content/early/2016/02/17/JCO.2015.66.1181.abstract.
The article concluded that “the addition of SIRT to Folfox-based first-line chemotherapy in patients with liver-dominant or liver-only metastatic colorectal cancer did not improve [progression-free survival] at any site but significantly delayed disease progression in the liver [and] the safety profile was as expected and was consistent with previous studies”.
Sirtex said the Journal published the study as “a ‘rapid communication’, which they define as a commitment to freely disseminate ground-breaking and practice-changing information”.
Sirtex chief medical officer Dr David Cade said the “addition of SIR-Spheres microspheres delivered a 7.9 month improvement in the duration of tumor control in the liver, together with a 31 percent reduction in risk of the tumors in the liver progressing”.
“Given that liver metastases are the dominant site of disease in patients with metastatic colorectal cancer and the dominant cause of death, these are important results,” Dr Cade said.
Sirtex was up 67 cents or 1.9 percent $36.18 with 351,313 shares traded.

ANTEO DIAGNOSTICS

The Sydney-based David Sietsma says he has become a substantial shareholder in Anteo with the acquisition of 53,300,300 shares (5.23%).

Mr Sietsma said he acquired 31,700,000 shares, held with Elizabeth Sietsma, Sietsma Holdings and Masali Pty Ltd, during the past four months for $2,319,000 or 7.3 cents a share.

In 2014, Sietsma Holding became substantial in Phylogica and in 2015 said the group held 8.95 percent of that company (BD: May 20, 2014; Aug 17, 2015).

Anteo fell 0.1 cents or 1.45 percent to 6.8 cents with 3.9 million shares traded.

DIMERIX (FORMERLY SUN BIOMEDICAL)

SRV Custodians says it has increased its substantial shareholder in Dimerix (formerly Sun) from 81,574,778 shares (6.16%) to 89,732,256 shares (6.42%).

Last year, the Perth, Western Australia -based SRV substantial notice, signed by director Matthew Callahan, said that SRV was the trustee for the SRV Tech Trust and acquired the shares in consideration for 7,390,267 Dimerix shares (BD: Jul 6, 2015).

Sun acquired Dimerix in 2015 (BD: May 13; Jul 3, 2015).

Today, SRV company secretary Sofie De Wolf said in the substantial shareholder notice that SRV acquired 8,157,478 shares through the conversion of performance shares at no cost.

Dimerix was unchanged at 0.6 cents.