Biotech Daily

Friday September 16, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ONCOSIL UP 9%, BENITEC DOWN 19%**

*** NANOSONICS BREAKS THE $1b BARRIER**

*** BENITEC ddRNAi TT-034 'NO EFFICACY FOR HEPATITIS C'**

*** PARADIGM RHINOSUL PPS EFFECTIVE FOR HAY FEVER IN GUINEA PIGS**

*** MEMPHASYS REQUESTS CAPITAL RAISING TRADING HALT**

*** PHARMAUST'S EPICHEM CERTIFIED TO INTERNATIONAL STANDARDS**

*** KNEEHAB, JAX WIN J&J HEALTH TECHNOLOGY CHALLENGE**

*** WEHI'S EMMA NOLAN WINS $5k PRIZE FOR BREAST CANCER**

*** NANCY LURKER REPLACES PSIVIDA CEO DR PAUL ASHTON**

MARKET REPORT

The Australian stock market was up 1.08 percent on Friday September 16, 2016 with the ASX200 up 56.8 points to 5,296.7 points.

Nineteen of the Biotech Daily Top 40 companies were up, 13 fell, five traded unchanged and three were untraded.

Oncosil was the best, up one cent or 9.1 percent to 12 cents with 241,121 shares traded.

Clinuvel and Factor Therapeutics climbed more than eight percent; Genetic Signatures and Impedimed were up more than six percent; Acrux, Atcor and Pro Medicus rose five percent or more; Cellmid, Compumedics, Nanosonics and Sirtex were up more than three percent; Cochlear was up 2.1 percent; Airxpanders, Avita, CSL, Living Cell, Pharmaxis and Polynovo were up more than one percent; with Medical Developments and Reva up by less than one percent.

Benitec led the falls, down two cents or 19.05 percent to 8.5 cents with 2.6 million shares traded.

Mesoblast lost 5.2 percent; Orthocell fell 4.9 percent; Actinogen and Opthea were down more than three percent; Osprey shed 2.9 percent; Admedus, Anteo, Bionomics, Neuren, Psivida and Starpharma were down more than one percent; with Viralytics and Resmed down by less than one percent.

NANOSONICS

Shortly after this morning's open, Nanosonics share price broke through $3.36 implying a market capitalization of $1 billion.

Biotech Daily congratulates co-inventor Dr Ron Weinberger, chairman Maurie Stang, chief executive officer Michael Kavanagh, chief financial officer McGregor Grant and the team.

Nanosonics climbed as high as $3.45 before closing up 10 cents or 3.0 percent at $3.40 with 1.7 million shares traded.

BENITEC BIOPHARMA

Benitec says its first-in-human phase I/IIa trial of the DNA-directed interference (ddRNAi) TT-034 for hepatitis C failed to show any efficacy.

Benitec said the trial met its primary safety endpoint, TT-034 was well tolerated but "there was no significant decrease in viral load in treated patients", a secondary endpoint.

The trial was expected to begin by the end of 2013, but the first patient was not dosed until May 2014, followed by recruitment delays (BD: Mar 22, Dec 9, 2013; May 29, 2014).

Last year, Benitec hoped to raise $95 million to list on the Nasdaq, eventually settling for $19 million, chief executive officer Dr Peter French resigned in December as the trial was approaching its conclusion and in February, Benitec's share price tumbled on the termination of the trial (BD: Aug 19, Dec 9, 2015; Feb 26, 2016).

Today, Benitec said the trial enrolled nine of the planned 14 patients, who received a single intravenous infusion of TT-034 at escalating doses and were monitored for safety and efficacy over 24 weeks, with liver biopsies collected 21 days after dosing, to assess hepatic TT-034 DNA levels and short hairpin RNA (shRNA) expression.

Benitec chief clinical and development operations officer Georgina Kilfoil said it was "the first time that non-withdrawable RNAi was introduced directly into humans, with the goal of having a new therapeutic modality irreversibly transduce nearly all, if not all, of the patient's hepatocytes".

"Achieving this goal is quite an accomplishment in itself, but to have a clean safety profile is a significant achievement given that these patients have a chronic liver disease and compromised liver function," Ms Kilfoil said.

Benitec said eight males and one female with genotype 1 hepatitis C were enrolled with a range of infection from two to 21 years, including patients who were treatment naïve, as well as those who had failed the then standard-of-care of interferon and ribavirin.

The company said that TT-034 was "very well tolerated with no related serious adverse events observed … and there were three adverse events including diarrhoea, light-headedness and bradycardia … related to study drug and all were mild in nature".

Benitec said there were no T-cell capsid response seen in any of the subjects, as has been previously reported at similar high dose levels in other systemic trials with adeno-associated virus and patients would be followed annually for four and a half years.

Benitec chief scientific officer Dr David Suhy said the company was "obviously disappointed that we did not see a reduction in viral burden".

"It is likely that TT-034 produced insufficient levels of the anti-[hepatitis C] shRNA," Dr Suhy said. "Several years ago, we published a paper in which we made genetic changes into the TT-034 construct to down-regulate expression levels of shRNA in order to avoid toxicity at exceptionally high doses in animal models," Dr Suhy said.

"It is possible that the reduction in shRNA levels was further exacerbated when TT-034 was administered to human subjects … [but] we have already used these learnings from this clinical study to make design modifications to other programs," Dr Suhy said.

Benitec fell two cents or 19.05 percent to 8.5 cents with 2.6 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says that its Rhinosul pentosan polysulfate sodium in buffered solution nasal spray is an effective treatment for allergic rhinitis and hay fever in guinea pigs.
Paradigm chief executive officer Paul Rennie said that the industry standard validated animal model used in the pre-clinical trials conducted by Sweden's Lund University Prof Jonas Erjefalt's team was a good analogy to humans as guinea pigs had similar immune responses.
Paradigm said the trials showed that the pentosan polysulfate sodium nasal spray was as effective as the industry leading treatment, an intra-nasal corticosteroid, budesonide.
The company said that Prof Erjefalt presented the data today at the Australian Society of Clinical Immunology and Allergy's meeting the Queensland Gold Coast.
Prof Erjefalt said that pentosan polysulfate sodium (PPS) blocked the TH2 cytokines, such as interleukin-4 (IL-4), IL-5 and IL-13 which were known to be responsible for the late stage of the disease causing nasal congestion.
"Our data showed that the anti-inflammatory properties of PPS were as effective as well-known intra-nasal corticosteroid-based treatments," Prof Erjefalt said.
"Corticosteroids are known to have undesirable side effects so treatment with this drug represents a potential breakthrough for those people wanting a steroid-free treatment for hay fever," Prof Erjefalt said.
Paradigm chief scientific officer Dr Ravi Krishnan said that independent and peer-reviewed experimental data demonstrated that pentosan polysulfate sodium was an effective mast cell stabiliser, reducing histamine release.
"Anti-histamines are important in the early phase of the allergic response and combined with the anti-inflammatory activity would suggest that Rhinosul has the hallmark of a first-in-class drug for the treatment of hay fever symptoms," Dr Krishnan said.
Paradigm said that based on the guinea pig efficacy data and the safety profile in the phase I clinical trial, it was preparing for a phase II, randomized, double-blind, placebo-controlled, crossover trial of Rhinosul for allergic rhinitis in Sweden in December 2016.
The University of Sydney's Prof Janet Rimmer said that recent surveys on the use of nasal sprays for the treatment of hay fever showed patient dissatisfaction and poor compliance.
"Current nasal corticosteroids have anti-inflammatory activity but do not have the other effects shown by Rhinosul," Prof Rimmer said.
"An effective, non-steroid-based therapy such as PPS with anti-inflammatory properties as well as the prevention of histamine release would represent a major global advance in the treatment of what is a distressing and debilitating condition," Prof Rimmer said.
Paradigm chief executive officer Paul Rennie said that repurposing pentosan polysulfate sodium for hay fever was "a breakthrough in the treatment of hay fever" and the non-steroid drug had "the potential to attenuate the symptoms of both the early and late phases of the disease".
"The global market for hay fever therapeutics is $US11 billion," Mr Rennie said.
"With a potential first-in-class drug for this massive market, the treatment of hay fever represents a major commercial opportunity," Mr Rennie said.
Paradigm was up 4.5 cents or 8.1 percent to 60 cents.

MEMPHASYS (FORMERLY NUSEP)

Memphasys has requested a trading halt "pending the completion of a capital raising".
Trading will resume on September 20, 2016 or on an earlier announcement.
Memphasys last traded at 0.8 cents.

PHARMAUST

Pharmaust says its wholly-owned synthetic and medicinal chemistry subsidiary Epichem Pty Ltd has been certified under international standards.

Pharmaust said that the certification as ISO 9001:2015 covered Epichem's quality management system for “the synthesis and distribution of fine chemicals, reference standards, technical services and provision of contract research and consulting”.

The company said that the certification meant Epichem had joined “a select group of companies who have demonstrated a commitment to quality at the highest level”.

Epichem managing-director Dr Wayne Best said the company was “delighted to have been recognised by certification to ISO 9001:2015”.

“It is a reflection of our commitment to quality, continuous improvement and customer focus,” Dr Best said. “Many of Epichem's clients operate in the highly regulated pharmaceutical sector and our certification will be seen as a significant development in our relationship with them.”

Pharmaust was unchanged at 8.2 cents.

JOHNSON & JOHNSON

Johnson & Johnson says the Sydney-based Kneehab has won its $8,000 Heath and Technology Challenge Hatchathon contest for its knee rehabilitation technology.

Johnson & Johnson said that the contest challenged participants “to create innovative solutions for a range of significant healthcare problems including obesity, medication compliance, patient empowerment, the burden on the hospital system, and rural and regional access to healthcare”.

The company said that Kneehab’s mobile telephone application to improve rehabilitation for knee reconstructions helped increase recovery times and reduce healthcare costs.

Johnson & Johnson said that the camera and motion senses of a smart phone were used to map the contours of the knee joint area, allowing for precision monitoring of how the patient was using their knee.

The company said it was hoped the technology would improve patient compliance and reduce the burden on the hospital system for the more than 54,000 Australians who have knee reconstructive surgery each year.

Johnson & Johnson said that the runner-up was Brisbane’s Jax for its electronic monitoring device to help carers of the elderly to monitor medication compliance.

The company said that Kneehab was awarded $8,000 and Jax won $2,000 and both companies had the opportunity to work with the Johnson & Johnson Australia family of companies to commercialize their work.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that doctoral student Emma Nolan has won the inaugural $5,000 Prof Joseph Sambrook PhD Student or Postdoctoral Fellow Award.

WEHI said that the award was supported by the National Breast Cancer Foundation and Ms Nolan won the award for her discovery that an existing medication could prevent breast cancer in women who carry the BRCA1 risk gene and the travel grant would enable her to attend an international cancer conference to present her research.

WEHI’s Prof Jane Visvader said that “Emma’s research has pinpointed the cells that cause breast cancer in certain women with high genetic risk, and importantly has underpinned new clinical trials aimed at preventing breast cancer in these women”.

PSIVIDA

Psivida says it has appointed Nancy Lurker as president, chief executive officer and a director, replacing Dr Paul Ashton.

In 2005, Psivida acquired the US-based Control Delivery System and its then chief executive officer Dr Ashton joined Psivida as an executive director (BD: Nov 15, 2005).

Psivida said at that time that Dr Ashton was the inventor of the only two US Food and Drug Administration-approved devices for sustained release of drugs to the back of the eye.

In 2007, Psivida promoted Dr Ashton from director of strategy to its chief executive officer (BD: Jan 24, 2007).

Today, Psivida said that Dr Ashton had “resigned to pursue other interests”.

The company said that Ms Lurker had “leadership and extensive experience in maximizing the potential of new therapies and successfully implementing innovative US and global drug launches”.

Psivida said that from 2008 to 2015, Ms Lurker was the Parsippany, New Jersey-based PDI Inc’s chief executive officer and rebuilt the company’s contract sales business, launching numerous pharmaceutical products for multiple companies across diverse therapeutic areas, including ophthalmology, in advance of the company’s sale to Publicis Healthcare Communications Group.

The company said that previously Ms Lurker was Novartis Pharmaceuticals Corp’s senior vice-president and chief marketing officer, overseeing a product portfolio covering cardiovascular, bone, pain, urology, respiratory, dermatology, biologics, neurology and metabolic therapeutic areas and before that was with Bristol-Myers Squibb for 14 years.

Psivida said that Ms Lurker held a Bachelor of Science from Seattle Pacific University and a Masters of Business Administration from the University of Evansville, Indiana.

Psivida fell five cents or one percent to $4.75.