Biotech Daily

Thursday June 7, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PATRYS UP 20%, SUNSHINE HEART DOWN 12%**

*** VERVA PHASE II TRIAL: VVP808 REDUCES TYPE 2 DIABETES HbA1c**

*** CIRCADIAN TAKES CAPITAL RAISING TRADING HALT TO SUSPENSION**

*** AVITA APPOINTS VISTEK DISTRIBUTOR FOR RECELL CHINA LAUNCH**

*** US INSERTER PATENT FOR PSIVIDA**

*** ATCOR SUPPLIES NETHERLANDS YOUNG AT HEART**

*** DURBIN SUPER TAKES 5% OF GENERA**

*** ANNMAC INCREASES, DILUTED TO 19% OF AGENIX**

*** SAFETY MEDICAL REQUESTS ACQUISITION TRADING HALT**

MARKET REPORT

The Australian stock market climbed 1.31 percent on Thursday June 7, 2012 with the S&P ASX 200 up 53.3 points to 4,108.6 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and two were untraded. All three Big Caps were up.

Patrys was the best, up 0.5 cents or 20 percent to three cents with 850,000 shares traded.

Anteo and Neuren climbed more than eight percent; Genetic Technologies and Phylogica rose more than seven percent; Living Cell was up 5.7 percent; Starpharma was up 4.3 percent; Viralytics was up 3.45 percent; Alchemia and Cochlear rose more than two percent; Acrux, CSL, Heartware, Mesoblast, Nanosonics, Pharmaxis, Resmed and Universal Biosensors were up one percent or more; with Biota, Clinuvel and Sirtex up by less than one percent.

Sunshine Heart led the falls, down 0.3 cents or 11.5 percent to 2.3 cents with 1.0 million shares traded.

Bioniche and Prima lost more than six percent; Antisense and QRX were down more than five percent; Genera and Tissue Therapies fell more than four percent; Impedimed was down 3.3 percent; Psivida shed 2.6 percent; with Bionomics, Compumedics and Optiscan down more than one percent.

VERVA PHARMACEUTICALS

Verva says its phase II study of insulin sensitizer VVP808 achieved its primary efficacy endpoint, a reduction in the diabetes marker HbA1c compared to placebo after 24 weeks.
Verva said the 76-patient, phase II, proof-of-concept study showed that VVP808 (methazolamide) was safe and well-tolerated and the study identified potential additional clinical benefits beyond HbA1c reduction.
The public-unlisted company said that complete clinical data remained confidential and would be presented at a major diabetes conference in due course.
Verva said that lead clinical product VVP808 was a non-thiazolidinedione, non-PPAR-modulating insulin sensitizer and the active ingredient methazolamide was originally approved in North America more than 50 years ago as a treatment for glaucoma.
Verva said that its unexpected anti-diabetic activity was identified using Verva's proprietary Gene Expression Signature discovery platform.
The company said that in preclinical studies, VVP808 also demonstrated additional benefits such as weight and fat loss and increased glucose-lowering efficacy in combination with metformin.
Verva said the phase II clinical trial was a multi-centre, randomized, double-blinded, placebo-controlled clinical proof-of-concept study evaluating the safety and efficacy of VVP808 in patients with type 2 diabetes.
The company said the trial initially enrolled participants who were not treated with any diabetes medication (naïve) but was expanded to include participants who had been treated with first-line therapy metformin for at least three months and had been stable on their current metformin dose for at least eight weeks prior to study entry.
Verva said that study participants received a single dose level of VVP808 (40mg twice daily) or placebo in identical product presentations for 24 weeks.
The company said that the primary efficacy endpoint was a reduction in HbA1c from baseline in the pooled (naïve + metformin) VVP808 group compared to pooled placebo group after 24 weeks of treatment.
Verva said the primary safety endpoint was the incidence of acidosis and secondary endpoints included the proportion of participants achieving HbA1c targets of less than or equal to 6.5 percent and less than or equal to 7.0 percent after 24 weeks, along with changes in fasting blood glucose, bodyweight, lipids, blood pressure, estimated glomerular filtration rate, microalbumin and hematology, biochemistry and urinalysis.
The company said the study was powered to demonstrate superiority of pooled (naive + metformin) VV808 over pooled placebo for the primary efficacy endpoint.
Verva said that of the 76 participants the mean baseline HbA1c was 7.1 (± 0.7) in the VVP808 group (n=37; 15 naïve and 22 metformin-treated) and 7.4 (± 0.6) in the placebo group (n = 39; 20 naïve and 19 metformin-treated).
The company said that five participants withdrew from each of the VVP808 and placebo treatment groups and the number of adverse events was not different between VVP808 and placebo treated participants and there were no drug-related serious adverse events.
Verva said that its annual general meeting on May 28, 2012 elected Dr Peter Devine and Dr Steve Gourlay as directors and re-elected Prof Michael Cowley.

CIRCADIAN TECHNOLOGIES

Circadian has requested a voluntary suspension to follow the trading halt it requested on June 5, pending “pending an announcement … in respect of a proposed capital raising” (BD: Jun 5, 2012).
Circadian last traded at 52 cents.

AVITA MEDICAL

Avita says it has appointed Vistek (Shida) Medical as a distributor for its products in the People's Republic of China ahead of a commercial launch expected this year.

Avita said the Beijing-based Vistek had branch offices in Shanghai, Guangzhou, Wuhan and Changsha, more than 60 field sales representatives and an extensive network of sales offices and sub-distributors and was "a premier supplier of medical products to the burns and cosmetic markets throughout China".

In 2009, China issued "an unrestricted import licence" for Recell (BD: Aug 17, 2009)

Avita said that its Recell spray-on skin technology had strong sales potential in China, with target markets including plastic and reconstructive surgeons, dermatologists, burns surgeons and cosmetic specialists at high end military hospitals and large private hospitals in major metropolitan centres.

The company said that estimates of China's cosmetic and plastic surgery markets were about $1.5 billion and increasing exponentially, with more than 10,000 cosmetic surgery clinics in China's major hospitals.

Avita said that subsequent to securing regulatory approval for Recell from the Chinese State Food and Drug Administration (SFDA) it had been working with Vistek and specialist hospitals in burns and plastic reconstructive surgery as well as cosmetic clinics focusing on the key provinces of Beijing, Shanghai and Guangzhou.

The company said that with Vistek in April, it sponsored workshops conducted by inventor and Prof Fiona Wood at the Chengdu Vitiligo Institutes of Medicine in Chengdu and Chongqing.

Avita said that Prof Wood was the keynote speaker, opening the first International Symposium on Burn Rehabilitation and Wound Healing in Chongqing from April 29 to May 1, 2012 and Recell was "prominently featured in special sessions highlighting the latest technological advances and developments in burns treatment".

The company said it hosted Recell workshops in Beijing, Guangzhou and Shanghai with scientific and clinical presentations and panel discussions lead by prominent surgeons from prestigious Chinese hospitals.

Avita said that it was in the process of obtaining a "critical" official pricing code, necessary for the commencement of commercial sales, which required "small-scale clinical evaluation studies based on a limited number of procedures at major hospitals within key provinces".

The company said that more than 100 Recell procedures had been performed for indications spanning burns, scar revision, dyspigmentation, aesthetic procedures and vitiligo.

Avita said that data obtained in these evaluation studies would be used to obtain endorsement by senior hospital administrators and support the submission of pricing applications in the respective provinces.

Avita chief executive officer Dr William Dolphin said that China was "a massive and highly attractive market for the company's products".

"Recell addresses the growing demand for cosmetic surgery, scar revision and the treatment of burns and chronic wounds," Dr Dolphin said.

"The product is being targeted to China's burgeoning middle class, a rapidly growing segment of the country's 1.3 billion people," Dr Dolphin said.

"With SFDA approval in place, the Company is focused on obtaining pricing approval and introducing Recell to China's key surgeons and clinicians," Dr Dolphin said.

Dr Dolphin said the company expected to have its commercial launch in China by the end of 2012.

Avita was unchanged at 19.5 cents.

PSIVIDA

Psivida says it has been issued a US patent entitled ‘Ocular Trocar Assembly’ for a new inserter to facilitate administration of micro-drug delivery devices.

Psivida chief executive officer Dr Paul Ashton said the company had designed the inserter for drug delivery devices, such as the Medidur implant for back of eye diseases, through a far smaller needle than was previously possible.

Dr Ashton said the new inserter would “require significantly less force to administer”.

“We anticipate using this new inserter in the planned phase III trials of our posterior uveitis insert,” Dr Ashton said.

“Another advantage is that the new inserter allows for use of larger reservoir delivery devices,” Dr Ashton said.

“Thus our Durasert technology can now be used with a larger number of drugs,” Dr Ashton said.

Psivida said it held more than 100 granted patents in the US, Europe, Japan, China and Australia.

Psivida fell five cents or 2.6 percent to $1.85.

ATCOR MEDICAL

Atcor says it will supply technology to Young at Heart BV for its Heart testing platform.

Atcor said its Sphygmocor system non-invasively measured central aortic blood pressures and arterial stiffness and the Netherlands-based Young at Heart was “a leader in health informatics and integrated consumer self-testing systems”.

Young at Heart does not have an established internet presence.

The company said that sales were expected to begin in 2013 and the agreement was forecast to generate minimum new annual sales of $US1 million to Atcor.

Atcor said that Young at Heart offered tests of relative arterial age, blood pressure, and body mass index outside a medical facility through Young at Heart self-testing kiosks and a web-based platform that included a sophisticated marketing backend.

Atcor was up one cent or 12.5 percent to nine cents.

GENERA BIOSYSTEMS

Durbin Superannuation has become a substantial shareholder in Genera with the acquisition of 3,618,899 shares or 5.16 percent.

The initial substantial shareholder notice signed by director Graham Durbin said the Hunter’s Hill, Sydney-based investment superannuation fund acquired the shares for $800,000 or an average price of 22.1 cents.

Genera fell one cent or 4.8 percent to 20 cents.

AGENIX

Annmac Investments as trustee for the Anne McNamara Investment Trust increased its share-holding in Agenix but has been diluted through placements.

In the change of substantial shareholder notice, Annmac said it increased and was diluted from 147,251,831 shares (20.49%) to 150,251,831 shares (19.14%).

Annmac said the shares were held by director Christopher McNamara and Diana McNamara.

Agenix was unchanged at half a cent with 1.8 million shares traded.

SAFETY MEDICAL PRODUCTS

Safety Medical has requested a trading halt “pending the release of an announcement, in relation to a proposed acquisition”.

Trading will resume on June 12, 2012 or on an earlier announcement.

Last year, Safety Medical said research for a review of its Securetouch syringe showed a continuing demand for safer syringes, but it would go copper and gold mining instead (BD: Dec 2, 2011).

The company said at that time that it had reviewed its patent families and decided to allow all patents to lapse other than two core patent families and that it had an option to acquire two tenements in the Three Rivers area of north western Australia with copper and gold the most likely commodities of interest.

Safety Medical fell 0.2 cents or 25 percent to 0.6 cents.