Biotech Daily

Wednesday September 2, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRIMA UP 30%, COMPUMEDICS DOWN 12.5%**

*** HEARTWARE BUYS ISRAEL'S VALTECH FOR $1.2bn**

*** WEHI: 'CHILDHOOD COELIAC SAME AS ADULTS', TREATMENT OPTIONS**

*** MEDIBIO EXPECTS TO RAISE $3m**

*** ITL ACCELERATES $2.45m MYHEALTHTEST ACQUISITION**

*** BLUECHIIP ADDS KIT, READER, BUTTON TO CRYO-TAGS**

*** UNILIFE REVENUE DOWN 10% to $A19m, LOSS UP 57% TO $A129m**

*** PROGEN REVENUE DOWN 40% to $3.4m, LOSS UP 159% TO $4.7m**

*** REGENEUS REVENUE DOWN 2% TO $2m, LOSS DOWN 12% TO $6.6m**

*** AVITA RECELL PATENT VALIDATED IN 11 EUROPEAN COUNTRIES**

*** INNATE APPOINTS RECEPTOS FOUNDER DR ROBERT PEACH DIRECTOR**

MARKET REPORT

The Australian stock market edged up 0.1 percent on Wednesday September 2, 2015 with the ASX200 up 5.1 points to 5,101.5 points. Eight of the Biotech Daily Top 40 stocks were up, 21 fell, nine traded unchanged and two were untraded. All three Big Caps were up.

Prima was the best on no news but following a 24.4 percent jump on the Nasdaq last night, up 1.6 cents or 30.2 percent to 6.9 cents with 39.1 million shares traded. Nanosonics recovered nine percent; Oncosil was up 4.2 percent; Neuren and Starpharma rose more than two percent; Cochlear, CSL, Resmed and Sirtex were up one percent or more; with Clinuvel and Osprey up by less than one percent.

Compumedics led the falls, down 3.5 cents or 12.5 percent to 24.5 cents with 129,037 shares traded. Universal Biosensors lost 9.3 percent; Tissue Therapies fell 7.1 percent; Optiscan was down 6.4 percent; IDT was down 5.6 percent; Biotron and Polynovo fell more than four percent; Actinogen, Avita, Medical Developments, Orthocell and Viralytics were down more than three percent; Benitec, Bionomics, Living Cell, Mesoblast and Pharmaxis shed more than two percent; Admedus, Ellex and Impedimed were down more than one percent; with Acrux down 0.8 percent.

HEARTWARE INTERNATIONAL

Heartware says it has an agreement to acquire the Tel Aviv, Israel-based Valtech Cardio which develops devices for mitral valve and tricuspid valve regurgitation.

Heartware said that the vast majority of patients with mitral valve regurgitation and tricuspid valve regurgitation also had advanced heart failure and the progression of heart failure could accelerate as a result of valvular dysfunction.

Heartware said that under the agreement Valtech shareholders would receive an up-front payment of 4.4 million Heartware shares, with 800,000 shares contingent on Conformité Européenne (CE) mark approval for Cardioband and 700,000 shares on the earlier of first-in-man implants for either Cardioband tricuspid or Cardiovalve.

The company said that transaction included warrants to buy 850,000 shares at an exercise price of $US83.73 a share, exercisable on attainment of $US75 million in net sales of Valtech products and an earn-out payment of $US375 million, in cash or stock, at Heartware's discretion, on attainment of $US450 million of net sales of Valtech products.

Lodge Partners analyst Marc Sinatra said that excluding the warrants, the value of the deal was potentially about $1,218 million and with Heartware's market capitalization of $2,014 million "appeared to be more a merger than an acquisition".

Heartware said that since incorporation in 2005, Valtech had developed a portfolio of technologies for the treatment of mitral and tricuspid valve disease, including the Cardioband trans-femoral system for mitral and tricuspid repair, the Cardinal semi-rigid, adjustable annuloplasty ring system, the Cardiovalve trans-septally delivered, low-profile, transcatheter mitral valve replacement and the V-Chordal surgical and interventional chord replacement system for mitral valve regurgitation repair.

Heartware said that patients with heart failure who received a ventricular assist device commonly underwent a concomitant, therapeutic mitral or tricuspid valve procedure.

The company said that the transaction provided Heartware "with a highly complementary portfolio of technologies to broaden the treatments it offers heart failure patients and enhance patient outcomes".

Heartware chief executive officer Doug Godshall said that his company had been "actively monitoring the mitral space for several years, given the overlap of patient population and referral channel with our [ventricular assist device] business".

"We identified Valtech as having the broadest, most compelling portfolio several years ago, which led to an investment in 2013," Mr Godshall said. "This investment gave us a unique opportunity to observe Valtech's significant progress across their portfolio of valve repair and replacement technologies."

"It is from this vantage point that we have concluded that Valtech's platforms represent the most innovative and comprehensive portfolio of interventional and surgical products for mitral and tricuspid repair and replacement in development today," Mr Godshall said.

Heartware said that the deal was subject to regulatory approvals, as well as Heartware and Valtech shareholder approvals and was expected to close "in late 2015".

The company said that Perella Weinberg Partners was its financial advisor and Canaccord Genuity provided a fairness opinion for the transaction.

Heartware said that in mitral valve regurgitation the mitral valve leaflets failed to close properly, allowing backflow of blood from the left ventricle into the left atrium and if untreated, it could lead to a meaningful deterioration in cardiac function and death.

The company said that about 4.2 million patients had mitral valve disease in the US and a further 1.6 million US patients had tricuspid valve regurgitation.

Last night on the Nasdaq, Heartware fell $US3.79 or 4.43 percent to $81.81 ($A116.38, equivalent to $3.325 before it left the ASX) with 222,919 shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that childhood coeliac disease mirrors the adult condition, so a therapy enabling patients to eat gluten could work in children.

The Institute said that children with coeliac disease were reacting against the same proteins in gluten that caused the disease in adults, overturning the previous theory that coeliac disease differed between children and adults.

WEHI said that the research suggested that new treatments and diagnostic tests in development for adults with coeliac disease would be applicable for children.

The Institute said that the research, entitled 'Consistency in Polyclonal T-cell Responses to Gluten Between Children and Adults with Celiac Disease' was published in the journal Gastroenterology with an abstract available online at: http://www.ncbi.nlm.nih.gov/pubmed/26226573.

WEHI said that the potential new coeliac disease treatment was an immunotherapy that aimed to teach the immune system to tolerate gluten, which would allow patients to reintroduce gluten to their diets.

The Institute said that the Nexvax2 treatment was being developed by US biotechnology company Immusant, was based on research from the Walter and Eliza Hall Institute and was expected to enter phase II trials "soon".

Immusant's chief scientific officer Dr Bob Anderson developed the technology while at the Walter and Eliza Hall Institute (BD: May 9, 2011).

Today, WEHI said that Dr Jason Tye-Din led the study and said that more than 40 children aged between three and 18 years of age were tested to see how their immune system reacted when gluten was reintroduced into their diet.

"We asked the children to eat wheat bread for three days and then studied the immune response that appeared in their bloodstream," Dr Tye-Din said.

"Contrary to the prevailing theory, and to our surprise, we found that children reacted to the same key peptides of gluten that we had previously identified as toxic in adults with coeliac disease," Dr Tye-Din said.

"This is an important finding that has major implications for the relevance of new diagnostic tests and treatments under development for people with coeliac disease," Dr Tye-Din said.

WEHI said that coeliac disease was the most common autoimmune disorder and was caused by an inappropriate immune response to gluten, a protein found in wheat, barley, rye and oats.

The Institute said that coeliac disease affected one 1 in 70 Australians, causing digestive symptoms such as bloating, abdominal pain and diarrhoea, as well as fatigue, anaemia, and even an increased risk of cancer.

WEHI said that the only treatment for coeliac disease is a lifelong gluten-free diet.

Earlier studies indicated that children with coeliac disease might have a different immune reaction to adults with the condition.

"In contrast to earlier studies, this is the first time coeliac disease in children has been studied this way and to this level of detail," Dr Tye-Din said. "Our findings are exciting as they support the view that new treatments and tests under development for adults with coeliac disease are likely to apply to children."

Immusant chief executive officer Leslie J Williams said the findings indicated that the immune response to gluten was identical in about 90 percent of people with coeliac disease regardless of age.

"This is very impactful as we use Immusant's targeted immunotherapy discovery platform to advance the development of diagnostic, therapeutic and preventive strategies that focus on restoring tolerance to gluten in both adults and children," Ms Williams said.

MEDIBIO (FORMERLY BIOPROSPECT)

Medibio says it has commitments to raise about $3.1 million through the placement of 7,730,087 shares at 40 cents a share.
Medibio said that it intended to use the proceeds “to fast-track the commercialization of its circadian heart rate (CHR) technology … to assist in the diagnosis of depression, other mental health disorders and the assessment of stress”.
The company said that Foster Stockbroking acted as sole lead manager for the raising.
Medibio fell 4.5 cents or 9.7 percent to 42 cents.

ITL

ITL says it will accelerate the acquisition of the direct-to-consumer pathology test provider Myhealthtest Pty Ltd, a related company.
In April, ITL said that the transaction would be made through a series of call options, pending certain milestones were achieved (BD: Apr 29, 2015).
Today, ITL said that Myhealthtest, which was 67 percent owned by ITL chairman Bill Mobbs, had met certain milestones ahead of schedule and the acquisition had been accelerated.
The company said Myhealthtest customers would order test kits online, do a finger prick blood test at home, submit a sample to Myhealthtest and obtain the results through a secure portal.
ITL said that “a recent survey showed 62 percent of diabetics would prefer the finger prick blood test to the [intravenous] alternative”.
The company said that Myhealthtest had laboratory facilities for test processing of blood samples and developed a HbA1c test for diabetes diagnosis and monitoring.
ITL said that the acquisition was conditional on shareholder approval.
The company said it would buy 450 new Myhealthtest shares for $450,000 and issue $2,000,000 worth of ITL shares at an issue price of 20 cents each for Myhealthtest.
ITL was up 1.5 cents or 7.3 percent to 22 cents.

BLUECHIIP

Bluechiip says it is expanding its product range from its electronic bio-storage tags to a developer kit, a portable handheld reader and button.
Bluechiip said that the new products followed based on customer and original equipment manufacturer feedback and the developer kit for original equipment manufacturer partner development would help partners integrate Bluechiip technology with their own products.
Bluechiip said the developer kit included “a Matchbox reader … delta tags, Stream software and engineering support” and the portable handheld reader would incorporate the electronics of the existing Matchbox reader to open up mobile applications.
Bluechiip said that the button would be “capable of being easily retrofitted into existing bio-bank cryo-vials and samples to aid in identification and temperature tracking.
The company said that the buttons would include a Bluechiip Delta tag in a plastic housing which could be retrofitted into a range of different vials.
Bluechiip said that the portable handheld reader with buttons and the multi-vial reader, would position it to address high volume bio-banking facilities.
The company said that its initial target market of bio-bank cryo-sample storage was forecast to be more than 300 million new cryo-samples a year by 2017.
Bluechiip said trials and testing was expected by the end of 2015.
Bluechiip was up 0.2 cents or 7.1 percent to three cents.

UNILIFE

Unilife says revenue for the year to June 30, 2014, fell 10.4 percent to $US13,158,000 ($A18,745,510) with net loss after tax up 56.9 percent to $US90,849,000 ($A129,427,790).

Unilife said that revenue decreased “due to less revenue recognized related to development activities for various customers primarily due to the timing of when milestones are achieved” for its pre-filled syringe business and the increased loss was due to increased research and development expenses.

The company said that diluted loss per share increased 37.3 percent from 0.59 US cents at June 30, 2014 to 0.81 US cents at June 30, 2015, with net tangible assets per US share increasing 250 percent from a deficit of 6.0 US cents at June 30, 2014 to a deficit of 21 US cents per share at June 30, 2014.

The company said that negative net tangible assets per Australian depositary interest (CDI) increased 200 percent from a deficit of one cent at June 30, 2014 to a deficit of three cents per CDI at June 30, 2015.

Unilife said it had $12,303,000 in cash and cash equivalents at June 30, 2015, compared to $US8,368,000 at June 30, 2014.

Unilife was up half a cent or 1.7 percent to 29.5 cents.

PROGEN PHARMACEUTICALS

Progen says revenue for the year to June 30, 2015 fell 40.2 percent to $3,443,201 increasing net loss after tax by 159.2 percent to $4,684,104.

Progen said that most of the revenue was derived from manufacturing by its subsidiary Pharmasynth, which was previously primarily due to contracts from Taiwan licencee Medigen and two regular large customers, but had fallen significantly.

The company said there had been increased research and development expenditure including the phase I trial of PG545.

Progen said that diluted loss per share increased 157.6 percent to 8.5 cents at June 30, 2015 and net tangible assets per share fell 56.6 percent from 14.5 cents to 6.3 cents.

Progen said it had $2,813,301 in cash at June 30, 2015, compared to $2,981,215 at June 30, 2014.

Progen was untraded at 15.5 cents.

REGENEUS

Regeneus says that revenue for the year to June 30, 2015, was up 18 percent to $2,094,643 with net loss after tax down 12.2 percent to $6,607,000.

Regeneus said sales declined in the six months to June 30, 2015 compared to the previous six months “predominantly due to the decline in Hiqcell treatments driven by uncertainty in the local regulatory environment”.

The company said that net tangible asset backing per share fell 12.0 percent from 4.49 cents at June 30, 2014 to 3.95 cents at June 30, 2015, with diluted loss per share down 40 percent to 3.0 cents.

Regeneus said that it had cash and cash equivalents of $3,012,812 at June 30, 2015 compared to $2,507,497 at June 30, 2014.

Regeneus was up 1.5 cents or 13.6 percent to 12.5 cents.

AVITA MEDICAL

Avita says that its European patent number EP2343079 entitled ‘Cell Suspension Preparation has been validated in 11 European countries.
The European Patent Office said the inventors were the Perth, Western Australia-based Prof Fiona Wood and Marie Stoner and it had an Australian priority date of February 7, 2001 and aUS priority date of April 4, 2001.
Avita said that the patent had been validated in Austria, Belgium, France, Germany, Great Britain, Italy, the Netherlands, Portugal, Spain, Sweden and Turkey and covered the broad use of the Recell cell suspension preparation device and related to a simple, rapid and cost-effective technique for grafting cells.
The company said that the patent covered a device for preparing a suspension of cells using a tissue sample obtained from a donor site.
Avita chief executive officer Adam Kelliher said the patent was “an important addition to our intellectual property estate, which further strengthens Avita’s position as a leader in skin repair technology”.
Avita fell 0.3 cents or 3.85 percent to 7.5 cents.

INNATE IMMUNOTHERAPEUTICS

Innate says it has appointed Dr Robert Peach as a non-executive director.
Innate said that Dr Peach was the co-founder and chief scientific officer of the San Diego, California-based Receptos which was acquired by Celgene last week for $US7.2 billion.
The company said that Receptos was developing a drug for patients with relapsing multiple sclerosis, inflammatory bowel disease and other autoimmune diseases.
Innate said that Dr Peach had experience in research and drug development and had held senior executive and scientific positions in Apoptos Inc, Biogen Idec, Idec Pharmaceuticals Corp and Bristol-Myers Squibb Pharmaceutical Research Institute.
The company said that Dr Peach had multidisciplinary research expertise in biochemistry and cell biology within the disease areas of immunology, inflammation, and oncology.
Innate said that Dr Peach held a Bachelor of Science and a Master of Science from the Christchurch, New Zealand-based University of Canterbury and a Doctorate of Philosophy in biochemistry from the University of Otago, New Zealand.
Innate fell half a cent or three percent to 16 cents.