



Biotech Daily

Wednesday August 31, 2016

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: COMPUMEDICS UP 11%, ATCOR DOWN 12%
- * BENITEC: CASH TO 2018, HEP B DRUG RENAMED BB-101, PIPELINE
- * IMUGENE HER-VAXX STOCKS DELIVERED FOR GASTRIC CANCER TRIAL
- * ITL WINS AUSTIN HEALTH SUPPLY EXTENSION
- * ADALTA, ALFRED HOSPITAL, LA TROBE UNI \$50k FEDERAL GRANT
- * MEDADVISOR TO ACQUIRE HEALTHNOTES FOR \$5.5m
- * BIOMÉRIEUX TAKES LBT REVENUE UP 226% TO \$8m, PROFIT UP 1014% TO \$4m
- * CELLMID REVENUE UP 55% to \$5m, LOSS UP 5% TO \$3.5m
- * ADHERIUM REVENUE DOWN 10% TO 2.6m, LOSS UP 528% TO \$8m
- * MEDLAB REVENUE UP 107% TO \$2.6m, LOSS UP 38% TO \$7m
- * BIOXYNE REVENUE UP 23% TO \$2m, PROFIT UP 11% to \$224k
- * EUROPEAN PATENT FOR REDHILL RHB-104 (MYOCONDA) FOR MS
- * PHOSPHAGENICS TO BEGIN TPM CHICKEN FEED LIFE-CYCLE STUDY
- * GENETIC SIGNATURES REQUESTS CAPITAL RAISING TRADING HALT
- * GLOBAL KINETICS APPOINTS TIMOTHY STILL CEO
- * ALAN FISHER REPLACES BIONOMICS DIRECTOR TREVOR TAPPENDEN
- * ALLAN GRAY REDUCES TO 14% OF ACRUX

MARKET REPORT

The Australian stock market fell 0.83 percent on Wednesday August 31, 2016 with the ASX200 down 45.3 points to 5,433.0 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, 11 were unchanged and one was untraded.

Compumedics was the best, up six cents or 11.2 percent to 59.5 cents with 370,986 shares traded. Acrux and Benitec climbed more than eight percent; Osprey and Reva improved more than four percent; Airxpanders, Bionomics and Orthocell rose more than two percent; with Nanosonics up 1.3 percent.

Atcor led the falls, down 1.5 cents or 12.0 percent to 11 cents with 119,788 shares traded. Ellex and Neuren lost more than six percent; Genetic Technologies fell 5.9 percent, Anteo and Mesoblast shed more than four percent; Uscom lost 3.2 percent; Factor Therapeutics, IDT, Impedimed, Living Cell and Starpharma shed two percent or more; with Admedus, CSL and Oncosil down more than one percent.

BENITEC BIOPHARMA

Benitec says it has funds through to 2018, has renamed BB-HB-331 for hepatitis B infection BB-101 and is expanding its pre-clinical pipeline.

In a quarterly investor teleconference, the company said that recently appointed chief business officer Dr Cliff Holloway was in the process of taking over licencing and partnership discussions and that further studies on BB-101 and a variant, BB-103, for hepatitis B would assist in discussions.

The company said an eight-week follow up showed that a single infusion of BB-101 in mice had reduced the virus by 98.5 percent and an extension trial of 13 weeks was underway with results expected by the end of 2016 (BD: Dec 7, 2015; Mar 8, 2016). Benitec chief clinical and development operations officer Georgina Kilfoil said that the company expected to have a pre-investigational new drug application meeting with the US Food and Drug Administration in early 2017 and in the clinic in 2018.

Benitec chief scientific officer Dr David Suhy said that the last patient in the terminated phase I/II trial of TT-034 for hepatitis C had been dosed and results were also expected by the end of 2016 (BD: Feb 26, 2016).

In a published transcript of the teleconference Dr Suhy said that Benitec had an exploratory program in immuno-oncology, with a chimeric antigen receptor T-cell therapy to modify a patient's immune system to be able to treat their cancer.

Dr Suhy said the chimeric antigen receptor was "a protein that when engineered into the T-cells, reprograms them to recognize a specific antigen on the malignant cells" and early-stage clinical trials had shown "remarkable potential for application of this approach".

Dr Suhy said that a limitation was the need to harvest a patient's T-cells which was cumbersome, time-consuming and expensive, but allogeneic T-cells could be developed by restricting the expression of the T-cell receptor (TCR) protein.

Dr Suhy said that the company had "engineered a series of recombinant expression construct that produces short hairpin RNAs against the multiple subunits of the TCR complex resulting in the depletion of its cell surface expression at levels greater than 99 percent and hence robustly inhibit TCR activation".

Dr Suhy said there were similarities to what was being done with gene editing techniques but the multi-target approach of DNA-directed RNA interference had unique advantages. Benitec was up one cent or 8.3 percent to 13 cents.

IMUGENE

Imugene says its HER-Vaxx immune-therapeutic cancer vaccine for gastric cancer has been delivered to a dedicated storage depot in Singapore.

Imugene said the vaccine was manufactured at the Graz-Andritz, Austria-based Pichem Forschungs und Entwicklungs GmbH and individual clinical doses were aseptically filled-and-finished at the Courroux, Switzerland-based Laboratoire Baccinex SA.

Imugene said it had engaged life sciences clinical supply chain company Research Triangle Park, North Carolina-based Marken to manage the transport of its doses from Switzerland to Singapore and then to the individual trial sites throughout Asia.

The company said that the centralised Singapore facility was "a state-of-the-art [good manufacturing practice] compliant depot".

Imugene chief operating officer Leslie Chong said the delivery was "yet another critical milestone met in our preparation for commencing our phase Ib/II clinical trial in patients with gastric cancer".

Imugene fell 0.1 cents or 11.1 percent to 0.8 cents with 5.8 million shares traded.

ITL LIMITED

ITL says it has a one-year contract extension with Melbourne's Austin Health, worth about \$1.5 million a year.

ITL said that Austin Health, comprised the Austin Hospital, Heidelberg Repatriation Hospital and the Royal Talbot Rehabilitation Centre and the contract extended its sole supply to Austin Health to five years.

The company said the contract would transition the Austin's range of surgical drapes and gowns to its Airtech range of "light-weight, environmentally-responsible range" of surgical fabrics and change the Austin's surgical components to its clinically equivalent products manufactured at its Malaysian facility, which was able to provide a full range of surgical components and was fully-equipped for the tooling, manufacture, cleanroom assembly and testing of medical devices and procedure packs.

ITL executive chairman Bill Mobbs said the contract extension was "an excellent achievement ... Airtech is another innovative product to come from the division and its inclusion in this contract is a very positive step".

ITL was up half a cent or 2.5 percent to 20.5 cents.

ADALTA

Adalta says it has received a \$50,000 Federal Government Innovation Connections Grant to support research with Melbourne's Alfred Hospital and La Trobe University.

Adalta said the collaboration would evaluate AD-114 in lung tissue from patients with idiopathic pulmonary fibrosis and look at a broader number of tissue and blood samples. The company said that researchers would aim to validate the potential of AD-114 as a treatment for idiopathic pulmonary fibrosis as well as exploring its potential as a treatment for other lung fibrosis conditions.

Adalta said that in-vitro and in-vivo pre-clinical studies demonstrated positive data in the treatment of idiopathic pulmonary fibrosis and the company had completed an initial analysis of the drug candidate in human lung tissue.

Adalta fell half a cent or 2.2 percent to 22.5 cents.

MEDADVISOR

Medadvisor says it will acquire Health Enterprises 2 Pty Ltd trading as Healthnotes for \$5.5 million with \$3.3 million in cash and the balance in scrip.

Medadvisor said the transaction was subject to due-diligence and shareholder approval and would bring together "the two leaders in medication adherence management".

The company said that it would increase its share of connected community pharmacies to 45 percent, from more than 1,600 to more than 2,400 Australian community pharmacies and would increase the number of Australian patients connected to its platforms from 220,000 to more than 500,000 people.

Medadvisor said that the takeover would increase the number of general practitioners connected to its platforms to more than 4,000 doctors and extended connected channels to more than 1,700 nursing homes.

The company said that the agreement would increase the number and value of prescriptions ordered through its platforms to more than 320,000 prescriptions a month with an annual value of about \$150 million.

Medadvisor said it would finance the acquisition and provide working capital by raising more than \$6 million with Peloton Capital as lead advisor.

Medadvisor was up 0.5 cents or 13.9 percent to 4.1 cents with 11.7 million shares traded.

LBT INNOVATIONS

LBT says the terminated Biomérieux licence increased revenue for the year to June 30, 2016 226.4 percent to \$7,726,000, with net profit after tax up 1014.3 percent to \$3,577,000.

LBT said that it received \$7.52 million for the termination of the France-based Biomérieux licence for its automated plate streaking system (BD: Aug 27, 2015).

The company said diluted earnings per share increased 1,000.0 percent from 0.28 cents at June 30, 2015 to 3.08 cents at June 30, 2016, with net tangible asset backing per share up 72.7 percent from 2.2 cents at June 30, 2015 to 3.8 cents at June 30, 2016.

LBT said it had cash and equivalents of \$4,682,000 at June 30, 2016 compared to \$1,818,000 at June 30, 2015.

LBT was up half a cent or 2.8 percent to 18.5 cents

CELLMID

Cellmid says revenue for the year to June 30, 2016, was up 55.4 percent to \$4,611,108 with net loss after tax up 4.8 percent to \$3,498,916.

Cellmid said that revenue from the sale of goods, primarily its Advangen hair loss products.

Cellmid said that diluted loss per share fell 11.6 percent to 0.38 cents at June 30, 2016, net tangible assets per share was up 12.5 percent to 0.27 cents and it had \$2,686,329 in cash and cash equivalents at June 30, 2016, compared to \$1,582,899 at June 30, 2015. Cellmid was unchanged at 3.1 cents with 1.85 million shares traded.

ADHERIUM

Adherium says that revenue for the 15 months to June 30, 2016 fell 9.7 percent to \$2,626,000, with net loss after tax up 528.3 percent to \$7,885,000, compared to the 12 months to March 31, 2015.

Adherium said it changed its reporting period following its \$35 million ASX listing to commercialize its Smartinhaler medication monitoring products (BD: Aug 27, 2016).

The company said that in 15 months period it sold 56,000 Smartinhaler devices generating operating revenue of \$2,626,000.

Adherium said diluted loss per share was up 247.4 percent from 1.9 cents at March 31, 2015 to 6.6 cents at June 30, 2016, with net tangible asset backing per share up 1,292.3 percent from 1.3 cents at March 31, 2015 to 18.1 cents at June 30, 2016, with cash and equivalents of \$27,211,000 at June 30, 2016 compared to \$3,468,000 at March 31, 2015. Adherium was untraded at 48 cents.

MEDLAB CLINICAL

Medlab says that revenue for the year to June 30, 2016 was up 106.9 percent to \$2,620,118, with net loss after tax down 1.7 percent to \$3,493,083.

Medlab said that revenue was primarily from sales of its probiotic and food additive products.

The company said diluted loss per share fell 31.7 percent from 3.12 cents at June 30, 2015 to 2.13 cents at June 30, 2016, with net tangible asset backing per share up 500 percent from 0.2 cents at June 30, 2015 to 1.2 cents at June 30, 2016, and cash and equivalents of \$801,368 at June 30, 2016 compared to \$115,815 at June 30, 2015.

Medlab was unchanged at 37.5 cents.

BIOXYNE

Bioxyne says revenue for the 12 months to June 30, 2016 was up 22.5 percent to \$2,025,335 with a net profit after tax up 11.3 percent to \$223,846.

Bioxyne said the revenue was primarily from the sale of probiotics Lactobacillus fermentum VRI-003 or PCC with sales up 29.0 percent to \$1,924,454.

Bioxyne said net tangible assets per share was unchanged at one cent, with diluted earnings per share constant at 0.1 cents, with \$1,353,604 in cash and cash equivalents at June 30, 2016, compared to \$958,469 at June 30, 2015.

Bioxyne was untraded at 2.2 cents.

REDHILL BIOPHARMA

Redhill says Europe will grant a patent entitled 'Combination of antibiotics for treating an autoimmune disease' covering RHB-104 for multiple sclerosis until 2032.

RHB-104 was originally developed as Myoconda at Sydney's Giaconda and the asset was sold with Heliconda (RHB-105) and Picoconda (RHB-106) to Redhill (BD: Aug 17, 2010). Earlier this month Redhill said the last of 18 patients had completed the final follow-up in its phase IIa trial of RHB-104 for relapsing-remitting multiple sclerosis (BD: Aug 2, 2016).

The company said at that time that the open label phase IIa 'Cease-MS' study was designed to evaluate safety and potential efficacy of fixed oral dose RHB-104 as an adjunct to interferon beta-1a, patients received RHB-104 for 24 weeks and were evaluated for a further 24-weeks while being treated with interferon beta-1a alone.

Redhill said that final results were expected by the end of 2016 but 24-week results showed "positive safety and efficacy signals".

Redhill said that RHB-104 was an oral antibiotic combination therapy, "with potent intracellular, anti-mycobacterial and anti-inflammatory properties".

The company said that a phase III study of RHB-104 for Crohn's disease was on-going. Redhill said that patents covering the antibiotic combination therapy, including the RHB-104 formulation and uses, had been granted in more than 25 countries, including the US, Australia, Canada, Japan and multiple European countries.

Overnight on the Nasdaq, Redhill climbed 11 US cents or 0.74 percent to \$US15.00 (\$A19.94) with 13,892 shares traded.

PHOSPHAGENICS

Phosphagenics says it will begin a feed efficiency study of its tocopheryl phosphate mixture (TPM) in chicken feed with results expected by the end of 2016.

Phosphagenics said that the poultry study in broiler chickens would be "conducted at a large research facility ... [and would] be the first to monitor TPM's utility across an animal's full life-cycle" and would assess a range of TPM doses in birds kept within a controlled research environment.

The company said that the study would support and expand on the statistically significant performance data obtained from newly weaned pigs, while providing information on TPM's benefits within the broader livestock feed additive market.

Phosphagenics chief executive officer Dr Ross Murdoch said the animal health and nutrition market was "a large and very attractive opportunity for Phosphagenics and this poultry study is a key part of our strategy within this market place".

"The speed of this study means that we should be in a position to assess the utility of TPM to improve feed efficiency across multiple species by the end of the year," he said.

Phosphagenics fell 0.2 cents or 9.5 percent to 1.9 cents with 4.65 million shares traded.

GENETIC SIGNATURES

Genetic Signatures has requested a trading halt pending “an equity raising by way of a book-build … [and] placement of ordinary shares to institutional investors”.

Trading will resume on September 2, 2016 or on an earlier announcement.

Genetic Signatures last traded at 51 cents.

GLOBAL KINETICS CORP

Global Kinetics says it has appointed the San Francisco, California-based Timothy Still as its chief executive officer.

Global Kinetics director and of Brandon Capital managing director Dr Chris Nave said that Mr Still had “a wealth of experience in healthcare and medical diagnostics … had led a number of medical technology companies and has been responsible for building these companies into commercially viable entities”.

Global Kinetics said that Mr Still had more than 26 years in healthcare and medical diagnostics with experience in designing and implementing commercial and business development strategies.

The company said that co-founder and chief scientific officer Prof Mal Horne had led the company during the search for a new chief executive officer.

Global Kinetics said there was “escalating demand” for its Parkinson’s Kinetigraph which was used to improve the management of Parkinson’s disease in 200 movement disorder clinics across the US, Europe and the Asia Pacific (BD: Jun 23, 2016).

Global Kinetics is a private company

BIONOMICS

Bionomics says that Alan Fisher will replace director Trevor Tappenden, following the departure of chairman Graeme Kaufman as requested by the Sydney-based CVC.

Earlier this month Bionomics said that CVC had withdrawn its notice of intention to call a general meeting (BD: Aug 15, 2016).

In March, CVC called for the removal of Mr Kaufman and Mr Tappenden and Bionomics announced “a consultation process to consider the views of shareholders as to the governance arrangements and future direction of the company” (BD: Mar 16, 2016).

In June, Bionomics appointed David Wilson and Peter Turner as directors and in August said that chairman Graeme Kaufman would retire at the end of this month saying that Mr Tappenden remained a director (BD: Jun 16, Aug 8, 2016).

Today, Bionomics said Mr Tappenden had “decided, having served on the board for 10 years, not to stand for re-election and will retire at the company’s annual general meeting in November”.

Bionomics said that Mr Fisher had spent 24 years at accounting firm Coopers & Lybrand including as lead advisory partner of corporate finance heading the Melbourne corporate finance division.

The company said that Mr Fisher was currently the non-executive chairman of Centrepoint Alliance, a director of IDT Australia, chairman of Australian Renewable Fuels and DMC Corporate managing-director.

Bionomics was up half a cent or 2.1 percent to 24 cents.

ACRUX

Allan Gray Australia has reduced its substantial holding in Acrux from 25,728,874 (15.45%) to 24,010,724 shares (14.42%).

Allan Gray said that between August 24 and 26, 2016 it sold 1,718,150 shares for \$731,163 or an average price of 42.55 cents a share.

Acrux was up three cents or 8.7 percent to 37.5 cents with 475,852 shares traded.