Biotech Daily

Monday February 29, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: MESOBLAST UP 10%, COMPUMEDICS DOWN 11%**

*** PFIZER: 'QUEENSLAND UNI 2nd NON-US INNOVATION CENTRE'**

*** EURO-COMMITTEE BACKS CSL IDELVION FOR HAEMOPHILIA B**

*** WEHI: 'BIRINAPANT, P38 INHIBITORS COMBINE FOR AML'**

*** BIOTA RESPIRATORY SYNCYTIAL VIRUS BTA585 'WELL-TOLERATED'**

*** ADHERIUM SUPPLIES 5,700 SMARTINHALERS FOR NZ ASTHMA STUDY**

*** ATCOR ROLLS OUT INSURANCE COVER FOR SPHYGMOCOR TESTS**

*** TAIWAN APPROVES ITL SAMPLOK BLOOD SAMPLING KIT**

*** RHINOMED APPOINTS MCARTHUR MEDICAL FOR CANADA**

*** OBJ H1 REVENUE UP 29% to $1.4m, LOSS UP 47% TO $1.2m**

*** CORRECTION: ADMEDUS**

*** PHARMAUST H1 REVENUE UP 47% TO $1.5m, LOSS DOWN 10% TO $1m**

*** REGENEUS H1 REVENUE DOWN 30% TO $881k, LOSS DOWN 46% TO $3m**

*** ADHERIUM H1 REVENUE DOWN 34% TO $1.6m, LOSS UP 481% TO $3.7m**

*** MEDADVISOR H1 REVENUE UP 94% TO $680k, LOSS UP 281% TO $1m**

*** NANOSONICS CHAIRMAN MAURIE STANG SELLS 2.5m SHARES**

*** AUSTRALIAN ETHICAL TAKES 5% OF PHARMAXIS**

*** ELIZABETH GAINES REPLACES IMPEDIMED DIRECTOR JIM HAZEL**

*** SIMON GENNARI REPLACES ALCHEMIA CHAIRMAN KEN POUTAKIDIS**

MARKET REPORT

The Australian stock market edged up 0.02 percent on Monday February 29, 2016 with the ASX200 up 0.9 points to 4,880.9 points. Sixteen of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and three were untraded.

Mesoblast was the best, up 17 cents or 9.7 percent to $1.92 with 1.2 million shares traded. Atcor, Orthocell and Starpharma were up more than six percent; Cellmid, Ellex and Polynovo climbed more than five percent; Clinuvel, Medical Developments and Osprey rose more than four percent; Bionomics and Viralytics were up more than three percent; with Universal Biosensors up 2.6 percent.

Compumedics led the falls, down 4.5 cents or 10.7 percent to 37.5 cents with 20,904 shares traded. Admedus lost 9.8 percent; Anteo fell 8.8 percent; Benitec was down 7.7 percent; Biotron and Neuren fell four percent or more; IDT and Living Cell shed more than three percent; with Opthea and Pro medics down more than two percent.

PFIZER

Pfizer says it has partnered with the University of Queensland as its second Australian 'Centre for Therapeutic Innovation' to advance drug discovery in Australia.

In 2014, Pfizer chose Monash University as its first Australian 'Centre for Therapeutic Innovation', a program it began in 2010 to better integrate the pharmaceutical company with academic discovery (BD: Oct 28, 2014).

Pfizer's Centres for Therapeutic Innovation senior vice-president and chief scientific officer Dr Anthony Coyle told Biotech Daily at that time that Pfizer recognized that "we can make drugs and they do innovation" and there needed to be a better way to work together to overcome cultural differences between the two types of institutions.

Dr Coyle said Pfizer had established Centres for Therapeutic Innovation in the US collaborating with leading universities.

Today, Dr Coyle said that the University of Queensland and Monash University were the only centres outside the US and Pfizer was spending about $1 million a year on the collaboration with Monash.

He said that the Centres were about "a different way of thinking … an enabler and facilitator", they could develop molecules earlier, and although the attrition rate might be higher, the collaboration could develop drug-like compounds earlier.

Dr Coyle said that the University of Queensland was chosen because "there is great science and so many opportunities here".

"There are many credible opportunities here in Australia. I think the University of Queensland and Uniquest understand more about drug development," Dr Coyle said.

"Our partnership is based on Pfizer's biologics with the University of Queensland's expertize in small molecules," Dr Coyle said.

Dr Coyle said the partnership would focus on the three core areas of inflammation and immunology, rare diseases and antibodies for neurology.

In a media release the University of Queensland's deputy vice-chancellor Prof Robyn Ward said the alliance would enable collaboration between the University's researchers and Pfizer with the aim of speeding drug discovery and development.

"The agreement combines UQ's research excellence with Pfizer's extensive drug discovery and development experience, technology and resources," Prof Ward said.

"It offers new opportunities to develop effective treatments for challenging medical conditions that affect people around the world," Prof Ward said.

CSL

CSL says the European Committee for Medicinal Products for Human Use has recommend for marketing authorisation of Idelvion for our haemophilia B.
CSL said that the Committee recommendation would be reviewed by the European Commission and it expected approval in the next few months.
The company said that Idelvion, formerly known as CSL654, was a coagulation factor IX recombinant, albumin-fusion protein for patients with haemophilia B providing “prolonged dosing intervals of up to 14 days”.
CSL said that Idelvion was designated as an orphan medicinal product in 2010 by the European Commission.
CSL research and development director and chief scientific officer Dr Andrew Cuthbertson said the Committee’s “positive opinion for Idelvion moves us one step closer to bringing this long-acting treatment option to haemophilia B patients in Europe”.
“Once approved, Idelvion will provide haemophilia B patients in the European Union with a treatment option with prolonged dosing intervals up to 14 days,” Dr Andrew Cuthbertson said. “These intervals have been achieved while maintaining high levels of factor activity and very low annualized bleeding rates, delivering on our promise to develop and bring to market innovative specialty biotherapies that help patients live full lives.”
CSL said that haemophilia B was a congenital bleeding disorder characterized by deficient or defective factor IX, affects more than 10,000 people in Europe.
The company said that Idelvion was approved in Canada and regulatory agencies in the US, Australia, Switzerland and Japan were reviewing Idelvion licence applications.
CSL was up 33 cents or 0.32 percent to $102.72 with 1.3 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

Walter and Eliza Hall Institute says the combination of birinapant and p38 inhibitors shows promise for acute myeloid leukaemia in laboratory samples and mouse models.
The Institute said that both drugs had been studied alone in clinical trials for treating cancer, but its staff the found that the combination of p38 inhibitors and birinapant had a much stronger anti-cancer effect than either agent alone.
WEHI said that Dr Najoua Lalaoui, Prof John Silke and colleagues made the discovery when searching for ways to enhance birinapant’s anti-cancer effects.
The research article, entitled ‘Targeting p38 or MK2 Enhances the Anti-Leukemic Activity of Smac-Mimetics’ was published in the journal Cancer Cell and an abstract is at: http://www.cell.com/cancer-cell/abstract/S1535-6108(16)00035-0.
Dr Lalaoui said the current treatment, high-dose chemotherapy, had toxic side effects and the combination of birinapant and a p38 inhibitor could be more effective with less toxicity.
“We tested forms of [acute myeloid leukaemia] that are highly resistant to chemotherapy and found that birinapant and p38 inhibitors could even kill these cancer cells, which is great news,” Dr Lalaoui said.
Prof Silke said the discovery was underpinned by two decades of research into proteins called inhibitors of apopstosis (IAPs), which were targeted by birinapant.
“Our research into how IAPs work made an important contribution to the initial development of birinapant as a specific IAP inhibitor,” Prof Silke said.
WEHI said that Birinapant was being developed by the Malvern, Pennsylvania-based Tetralogic Pharmaceuticals Corp.
The Institute said that acute myeloid leukaemia caused about 850 deaths in Australia each year, more than any other type of blood cancer, with many patients responding poorly to treatment, and fewer than one-third surviving for five years after diagnosis.

BIOTA PHARMACEUTICALS

Biota says its 66-patient, phase I, multiple ascending dose trial of BTA585 for respiratory syncytial virus showed it was generally well tolerated at all dose levels.
BTA585 was invented in Biota's then Melbourne facility.
Biota said that the safety and pharmacokinetic study of the oral drug found no serious adverse events and no drug-related clinically-significant adverse changes in electro-cardiogram or clinical laboratory values.
Biota chief executive officer Dr Joseph Patti said that antiviral levels of BTA585 were rapidly achieved and maintained in the plasma and nasal wash fluid.
Dr Patti said that the favorable safety and pharmacokinetic data, along with the recent US Food and Drug Administration fast track designation "we are looking forward to starting a phase IIa [respiratory syncytial virus] challenge efficacy study next quarter [by July 2016] and anticipate top-line results in the second half of 2016" (BD: Feb 18, 2016).
Biota said that the trial evaluated the safety and pharmacokinetics of three cohorts of healthy volunteers at 100mg, 400mg and 600 mg of BTA585, dosed orally twice a day for seven consecutive days.
The company said that adverse events in more than two BTA585-treated subjects were headache and chromaturia, with plasma maximum concentration achieved at about one hour following dosing, exposure was dose-proportional, there was no accumulation of BTA585 over the duration of dosing and the half-life was about five to six hours.
On the Nasdaq on Friday Biota rose nine US cents or 5.92 percent to $US1.61 ($A2.26 equivalent to 28.25 cents before departing the ASX) with 42,107 shares traded.

ADHERIUM

Adherium says it will supply the Medical Research Institute of New Zealand 5,700 Smartinhaler device systems "for a major international clinical study".
Adherium said that the Smartinhaler devices, associated communications, software and support services would be used in the 'Randomised Controlled Trial of the efficacy and safety of an Inhaled Corticosteroid [versus] Long Acting Beta Agonist reliever therapy regimen in Asthma'.
The company said that the Medical Research Institute of New Zealand was the sponsor and would initiate and co-ordinate the study in New Zealand, Australia, the UK and Italy.
Adherium said that the institute would monitor each randomized subject's compliance and inhaler use and the Smartinhaler platform would be used to capture the data.
The company said that it was providing Smartinhaler devices, software and data management to 31 clinical projects and programs globally involving the deployment of more than 89,000 devices over the life of those projects.
Adherium chief executive officer Garth Sutherland said that clinical projects were important because "in addition to the revenue they provide, [they] validate our ever-improving technology".
"These represent important validation and sales and position the company strongly for its dual objectives to satisfy increasing demand from clinical trials and to lock in new large commercial agreements," Mr Sutherland said.
Adherium said it would provide Smartinhaler device, internet cloud services and access to medication use data via the Smartinhaler Live system, which allowed for the monitoring of large numbers of Smartinhaler devices used in multiple countries concurrently.
Adherium sad the supply agreement would run throughout the study, expected to conclude by the end of 2018.
Adherium was up four cents or 7.55 percent to 57 cents.

ATCOR MEDICAL

Atcor says that one national and three regional health plans covering 18 million insured lives have begun reimbursement of the Sphygmocor test.

Atcor chief executive officer Duncan Ross said he was “pleased that these private health plans have initiated reimbursement so soon after the US CPT-1 code was introduced”.

Last year, the American Medical Association recommended a current procedural terminology (CPT) category 1 code for arterial pressure waveforms covering the Sphygmocor test, which became effective on January 1, 2016 (BD: Mar 10, 2015).

“This enables millions of patients to benefit from non-invasive central arterial pressure waveform analysis, and supports our commercial launch to doctors following the availability of the Category 1 CPT code,” Mr Ross said.

Mr Ross said the company was working with a private reimbursement consultant to educate private payers and discussions continued with a number of private plans and it had confirmed reimbursement to doctors in several US Government Medicare regions and under a number of state Medicaid plans.

Atcor said it was targeting initially four major metropolitan areas through its sales force supported by a telemarketing campaign and was hiring additional sales staff in regions with a high concentration of reimbursed lives.

Atcor was up one cent or 6.7 percent to 16 cents.

ITL

ITL says that the Taiwan Food and Drug Administration, Ministry of Health and Welfare has approved its Samplok blood sampling kit for sale in Taiwan.

ITL said that the approval followed the recently grant of the Samplok kit patent in the US and would help build the momentum to reach new markets.

The company said that the Samplok kit was used to transfer platelet samples when performing bacterial detection testing across the blood banking market and included safety features for laboratory personnel.

ITL said that it had a range of bacterial detection ancillaries as part of its wider portfolio of biological sampling and transfer kits.

The company said that it had begun supplying its first Taiwan blood centre and was being evaluated by additional blood centres.

ITL executive chairman Bill Mobbs said that “a very positive gain from the Taiwan approval is that together with the recently granted patent in the US it gives us confidence that [Amplok] can grow sales in new markets around the globe”.

ITL was untraded at 21 cents.

RHINOMED

Rhinomed says the Toronto based McArthur Medical with distribute its Mute sleep and snoring technology and Turbine sports technology in Canada.

Rhinomed said that the agreement was exclusive and subject to minimum annual performance hurdles being achieved.

Rhinomed was unchanged at 2.4 cents.

OBJ

OBJ says that revenue for the six months to December 31, 2015, was up 28.5 percent to $1,395,545 with net loss after tax up 46.5 percent to $1,185,313.

OBJ said that the six months to December 31, 2015 “was a very successful year highlighted by the support from Procter & Gamble for the planned inclusion of OBJ's technologies into various … products”.

“This follows the execution of the multi-product development agreement in 2014 and the very successful launches of the SK-II magnetic eye wand earlier last financial year,” OBJ said.

“Development of the Wave 11 product for P&G's SK-II, the delivery to COTY of the commercial evaluation products that contain the OBJ dermaportation technology and progress with Bodyguard have all been significant accomplishments during the period,” OBJ said.

OBJ said that diluted loss per share was up 40 percent from 0.05 cents in the previous year to 0.07 cents for the six months to December 31, 2015, with net tangible assets per share up 66.7 percent to 0.5 cents.

The company said it had cash and cash equivalents of $8,191,606 at December 31, 2015, compared to $3,519,337 at December 31, 2014.

OBJ was unchanged at 6.2 cents.

ADMEDUS

On Friday, Biotech Daily incorrectly reported that Admedus had posted revenue for the six months to December 31, 2015, up 37.0 percent to $6,568,000 with net loss after tax up 20.4 percent to $20,868,000.

The revenue figure was correct but the loss after tax was up 19.3 percent to $13,598,520.

Biotech Daily apologizes for the error by the Half-Yearly Report Sub-Editor, whose brain had turned to mush under all the different numbers.

Admedus fell five cents or 9.8 percent to 46 cents.

PHARMAUST

Pharmaust says revenue for the six months to December 31, 2015 was up 46.9 percent to $1,457,000 with a net loss after tax down 10.25 percent to $963,000.

Pharmaust director Sam Wright said that the majority of its income came from its Epichem division, which provided synthetic and medicinal chemistry services.

The company said that Epichem was awarded a two year extension to its contract with the Geneva, Switzerland-based Drugs for Neglected Diseases Initiative.

Pharamust said that the contract was due to finish on December 31, 2015, but Epichem would continue to provide synthetic and medicinal chemistry support to the Initiative’s drug discovery projects until December 31, 2017, generating a further $2.3 million in revenue during that period.

Pharmaust said its net tangible assets per share climbed 279.5 percent to 3.04 cents at December 31, 2015 from 0.105 cents at December 31, 2014 with diluted loss per share up 14.3 percent from 0.07 cents to 0.08 cents.

The company said it had cash and cash equivalents of $1,317,056 at December 31, 2015 compared to $3,411,767 at June 30, 2015

Pharmaust was up 0.5 cents or 4.55 percent to 11.5 cents.

REGENEUS

Regeneus says that revenue for the six months to December 31, 2015, fell 30.4 percent to $881,360 with net loss after tax down 46.2 percent to $3,095,367.
Regeneus said that diluted loss per share was down 48.3 percent from 2.9 cents in the previous year to 1.5 cents for the six months to December 31, 2015, with net tangible assets per share down 41.9 percent from 4.3 cents to 2.5 cents.
The company said it had cash and cash equivalents of $3,406,849 at December 31, 2015, compared to $3,012,812 at June 30, 2015.
Regeneus was up 1.4 cents or 19.7 percent to 8.5 cents.

ADHERIUM

Adherium says that revenue for the six months to December 31, 2015, fell 34.0 percent to $1,602,000 with net loss after tax up 480.7 percent to $3,757,000.
Adherium said that revenue was from sales of its Smartinhaler device systems to monitor asthma puffer and other medications use.
Adherium said that diluted loss per share was up 270 percent from 1.0 cent in the previous year to 3.7 cents for the six months to December 31, 2015, with net tangible assets per share up 839.1 percent from 2.3 cents to 21.6 cents.
The company said it had cash and cash equivalents of $30,780,000 at December 31, 2015, compared to $984,000 at December 31, 2014.

MEDADVISOR

Medadvisor says that revenue for the six months to December 31, 2015, was up 94.4 percent to $679,741 with net loss after tax up 281.0 percent to $1,107,112.
Medadvisor said that revenue was from sales of its internet-based system ensuring that customers' prescriptions were filled correctly.
Medadvisor said that diluted loss per share was up 8.3 percent from 0.24 cents in the previous year to 0.26 cents for the six months to December 31, 2015, with net tangible assets per share up from negative 0.0372 cents to 0.6121 cents.
The company said it had cash and cash equivalents of $4,680,479 at December 31, 2015, compared to $571,366 at June 30, 2015.
Medadvisor was untraded at 3.5 cents.

NANOSONICS

Nanosonics says that non-executive chairman Maurie Stang sold 2,500,000 shares on market for $4,750,000 or $1.90 a share.
In an Appendix 3Y change of director's interest notice, Mr Stang said that he held 22,483,333 shares directly and 116,368 indirectly a total of 7.97 percent of the company.
Nanosonics said that following the sale, Mr Stang continued as one of its largest shareholders".
Nanosonics fell 1.5 cents or 0.8 percent to $1.86.

PHARMAXIS

Australian Ethical Australian Share Fund says it has become a substantial shareholder in Pharmaxis, acquiring 15,956,240 shares or 5.03 percent.
Australian Ethical said that on June 29, 2015 it sold 5,000,000 shares for $1,150,000 or 23 cents a share, and acquired shares between July 1, 2015 and February 25, 2016 in 39 separate trades, of which the largest was the purchase of 500,000 shares for $110,000 or 22 cents a share and the most recent was the purchase of 91,963 shares for $24,830 or 27 cents a share.
Pharmaxis fell half a cent or two percent to 25 cents.

IMPEDIMED

Impedimed says Elizabeth Gaines with replace Jim Hazel as a non-executive director and chair of the audit and risk committee, effective from March 1, 2016.
Impedimed said that Ms Gaines was most recently the chief executive officer, and previously the chief financial officer and chief operating officer of the Helloworld travel distribution business.
The company said that Ms Gaines was a non-executive director of Fortescue Metals Group, Nextdc and has been appointed as a director to Nine Entertainment Co.
Impedimed was up half a cent or 0.6 percent to 87 cents with 4.5 million shares traded.

ALCHEMIA

Alchemia says it has appointed Simon Gennari as its non-executive chairman replacing Ken Poutakidis.
Alchemia said that Mr Gennari had more than 20 years of experience in investment management, corporate finance and equity research in Europe and Australia.
The company said he was currently a principal of Dinimus Capital, an investment management and corporate advisory firm and served on its investment committee.
Alchemia said that Mr Gennari previously held senior investment positions within a UK family office and a global hedge fund, with experience in mergers and acquisitions, capital markets, transaction structuring, strategy and valuation for listed and private enterprises including venture capital across debt and equity.
Alchemia was up 0.1 cents or 14.3 percent to 0.8 cents with 78.8 million shares traded.