Biotech Daily

Thursday August 27, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ELLEX UP 12%, STARPHARMA DOWN 6%**

*** RACE TO RAISE UP TO $10m FOR 'LOST' BISANTRENE FOR AML**

*** ADMEDUS HSV-2 TRIAL SAFE, PROCEEDS, TAKES 72% OF CORIDON**

*** CLINUVEL, FDA TO DISCUSS SCENESSE FOR EPP PATHWAY**

*** BIOMÉRIEUX PAYS LBT $8m TO PART COMPANY ON PLATE STREAKING**

*** ADHERIUM IPO RAISES $35m FOR SMARTINHALER, ASTRAZENECA TAKES 6%**

*** ELLEX REVENUE UP 15% TO $63m, PROFIT UP 113% TO $1.7m**

*** CRYOSITE REVENUE UP TO $10m, PROFIT DOWN 10% TO $455k, DIVIDEND**

*** RESONANCE REVENUE UP 16% to $2.7m, LOSS TO $463k PROFIT**

*** LBT REVENUE DOWN 41% TO $2.4m, PROFIT UP 66% TO $549k**

*** ANTEO REVENUE DOWN 7% TO $2.4m, LOSS UP 69% TO $4.2m**

*** GENETIC SIGNATURES REVENUE UP 57% TO $2m, LOSS UP 54% TO $2.7m**

*** BRAIN RESOURCE REVENUE UP 6% TO $2.7m, LOSS UP 30% TO $2.6m**

*** OBJ REVENUE UP 59% TO $1.5m, LOSS UP 4% TO $2.3m**

*** CLARIFICATION: CYCLOPHARM H1 $179k PROFIT**

*** MEDIBIO WINS 1st CORPORATE STRESS CONTRACT**

*** CELLMID TO LAUNCH ÉVOLIS HAIR GROWTH CAMPAIGN**

*** HUNTER HALL REDUCES 1% IN SIRTEX TO 7.4%**

*** MMJ REQUESTS 'CANNABIDIOL UPDATE' TRADING HALT**

*** IMUGENE M-D CHARLES WALKER STEPS DOWN, LESLIE CHONG COO**

*** IMMURON APPOINTS PETER ANASTASIOU VICE EXECUTIVE CHAIRMAN**

MARKET REPORT

The Australian stock market climbed 1.17 percent on Thursday August 27, 2015 with the ASX200 up 60.5 points to 5,233.3 points. Nineteen of the Biotech Daily Top 40 stocks were up, 13 fell, four traded unchanged and four were untraded. All three Big Caps rose.

Ellex was the best, up four cents or 11.6 percent to 38.5 cents with 40,636 shares traded. Optiscan climbed 9.3 percent; Actinogen was up 8.8 percent; Osprey rose 7.9 percent; Impedimed was up six percent; Admedus, IDT and Pharmaxis were up five percent or more; Nanosonics, Neuren and Polynovo were up more than four percent Medical Developments was up 3.1 percent; Cellmid, CSL, Prima and Viralytics rose two percent or more; Bionomics, Orthocell, Resmed and Sirtex were up more than one percent; with Cochlear and Mesoblast up by less than one percent.

Starpharma led the falls, down 3.5 cents or 6.1 percent to 54 cents with 106,254 shares traded. Compumedics lost 5.1 percent; Atcor, Genetic Technologies and Oncosil fell more than four percent; Acrux, Anteo and Biotron were down more than three percent; Antisense shed 2.4 percent; with Benitec, Clinuvel and Universal Biosensors down more than one percent.

RACE ONCOLOGY

Race Oncology hopes to raise up to $10 million at 20 cents a share to reinstate and commercialize Bisantrene for cancer.

Race chief executive officer and former Biota chief executive officer Peter Molloy told Biotech Daily that Bisantrene was a phase II/III drug previously trialled in 44 clinical studies and on more than 2,000 patients, which showed it did not have the cardiac toxicities of other anthracycline drugs used as chemotherapy agents for cancer.

Mr Molloy said that Bisantrene had been approved in France for acute myeloid leukaemia (AML) but never launched, because it was effectively “lost” in a string of pharmaceutical company mergers including the Lederle-Immunex merger, then sold to Wyeth and then to Pfizer, with $US100 million spent on it by Lederle and the US National Cancer Institute.

Mr Molloy said that the Dr Bill Garner created Update Pharma to rediscover Bisantrene and reopen the investigational new drug application (IND) with the US Food and Drug Administration through a 505(b)(2) process.

Dr Garner was formerly with Inverseon which merged with CBio to become Invion and repurpose nadolol (BD: Jul 2, 2012).

Dr Garner said that Update had acquired all the rights to Bisantrene including all the previous data generated at the preceding companies.

Mr Molloy said that the IND would assist in having Bisantrene approved for compassionate use in Europe and a bridging study would be required to show that the Update and Race Oncology formulation was equal to the previous formulation.

Mr Molloy said there was no effective treatment for acute myeloid leukaemia but Bisantrene had demonstrated a 48 percent complete response rate.

He said that Race intended to start a named patient program in France which could generate up to $50 million in revenues over five years.

Mr Molloy said a phase II AML bridging study in the US would enable the patient safety database and all historical data to support Bisantrene for a phase III FDA study.

Mr Molloy said the he, Dr Garner and corporate adviser Daniel Moore would make up the board of Race Oncology.

Mr Molloy said that the New Jersey-based Dr John Rothman would be the company’s chief scientific officer.

ADMEDUS

Admedus says an independent safety review has unanimously recommended its 40-patient, herpes simplex 2 vaccine phase II study continue without modification.
Admedus said that 80 percent of the subjects in the herpes simplex 2 (HSV-2) vaccine trial had either begun screening or received their initial dosing regimen.
Admedus chief executive officer Lee Rodne said the safety review was “extremely positive and provides further support for the safety profile of our HSV-2 therapeutic vaccine study”.
“The trial is progressing well, with some participants already receiving their first three doses, and we look forward to the anticipated interim results,” Mr Rodne said.
“The data and progress of the HSV-2 and [human papillomavirus] programs and overall development of the technology is extremely positive,” Mr Rodne said.
Admedus said that it had increased its investment in Admedus Vaccines, formerly Coridon and led by Prof Ian Frazer, from 66.3 percent to 72.2 percent.
The company said that the HSV-2 therapeutic vaccine was based on a platform technology developed by Prof Frazer.
Admedus said that the trial was being run in Brisbane by Q-Pharm at the Queensland Institute of Medical Research (QIMR) Berghofer Medical Research Institute and participants had a 45 day pre-vaccination period to establish a baseline and then each participant would receive three monthly intra-dermal injections, followed by a fourth injection six months after the initial dose.
The company said the primary objective was to explore the safety of the therapeutic vaccine in people with HSV-2 and assess efficacy through evaluating changes in T-cell counts, HSV-2 viral shedding and viral outbreaks with interim data expected “towards the end of 2015”.
Admedus was up 0.4 cents or 5.7 percent to 7.4 cents with 2.5 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it will meet with the US Food and Drug Administration in September 2015 to discuss development of Scenesse or afamelanotide 16mg.
Clinuvel said the meeting would discuss the filing requirements for a new drug application for adults with erythropoietic protoporphyria (EPP).
The company said that its representatives would meet with the FDA’s Division of Dermatology and Dental Products, which would be responsible for the scientific review of Scenesse application, having previously reviewed the investigational new drug application in 2009 and subsequent amendments.
Clinuvel said it would use the meeting to identify the FDA’s thinking on the eligibility of Scenesse for accelerated approval, the requirements for a US post-authorization phase IV trial to monitor EPP patients long term and whether Clinuvel’s annual reporting obligations to the European Medicines Agency would serve the FDA’s requirements.
Clinuvel acting chief scientific officer Dr Dennis Wright said that the European distribution of Scenesse had “evolved into a complex and well considered program with a need to satisfy the EMA”.
“I expect that this program will be subjected to the FDA’s attention as long term follow up of patients is also a US requirement,” DR Wright said. “We will learn whether the current European risk management plan meets the FDA’s criteria,” Dr Wright said.
“The pool of our data, patient reported outcomes and physicians’ declarations of effectiveness all add to the strength of the dossier which we have established over more than a decade.” Dr Wright said.
Clinuvel fell three cents or 1.15 percent to $2.57.

LBT INNOVATIONS

LBT says a new agreement with the Lyon, France-based Biomérieux changes the exclusive licence to its Microstreak culture plate-streaking technology to non-exclusive.
LBT said the agreement terminated the 2007 exclusive licence and Biomérieux would retain the sole rights to service and support the installed base of its Previ Isola systems, including supply of the patented disposable applicators used in the streaking process and would discontinue sales of new systems by July 30, 2016.
The company said both parties would "be free to pursue their development in laboratory automation independently", Biomérieux would focus on its alliance with Italy's Copan and LBT would receive a final payment of $US5.5 million ($A7.7 million) and non-exclusive technology rights to Microstreak improvements developed by Biomérieux.
LBT was up two cents or 28.6 percent to nine cents with 1.2 million shares traded

ADHERIUM

Adherium opened on the ASX under the code ADR, yesterday, at 55 cents, 10 percent above the $35 million initial public offer price of 50 cents, closing at 60 cents a share.
The Auckland New Zealand-based Adherium said it was a digital health company "developing technologies that address suboptimal medication use and remote patient management in chronic disease".
The company has a range of 'Smartinhaler' devices that attach to prescription inhalers and delivery devices to record patient use and compliance, automatically transmitting the data to a smart telephone application, home monitoring hub, or personal computer, and then to the company's internet cloud-based servers, where it could be accessed by the patient's health care professional and care giver.
Adherium recently announced a long-term supply and development agreement with Astrazeneca.
The company said that initial public offer was led by Bell Potter Securities and the funds would allow it to supply commercial quantities of Smartinhalers to its customers as well as expand international sales and marketing.
Adherium said it intended to sell the Smartinhaler platform directly to pharmaceutical companies, who would then provide the device and supporting applications to end users via their own distribution channels.
The company said it also supplied its Smartinhaler platform to disease management organisations and organisations conducting clinical trials.
Adherium chief executive officer Garth Sutherland said the company's objective was "to develop and deliver technologies that improve the quality of life of people with chronic disease, especially people with asthma and [chronic obstructive pulmonary disease]".
"Improving medication adherence means better outcomes for patients, for pharmaceutical customers and for governments and payers and ultimately great outcomes for our shareholders as we grow," Mr Sutherland said.
Adherium said that clinical outcomes data had shown that the Smartinhaler platform could improve adherence by up to 59 percent in adults and 180 percent in children with asthma, with severe episodes reduced by 60 percent in adults with asthma.
The company said that devices in the Smartinhaler range had Conformité Européenne (CE) mark approval, US Food and Drug Administration 510(k) clearance, as well as Australian Therapeutic Goods Administration and New Zealand's Medsafe approvals.
Separately, the England and Wales-based Astrazeneca PLC said it had become substantial in Adherium with 8,079,720 shares (5.77%).
Adherium was up seven cents or 11.7 percent to 67 cents with 2.7 million shares traded.

ELLEX MEDICAL LASERS

Ellex says revenue for the 12 months to June 30, 2015 was up 15.3 percent to $62,679,000 taking the net profit after tax up 113.2 percent to $1,680,000.

Ellex chief executive officer Tom Spurling said that “the improved operating performance has been driven by strong global sales of our treatment laser portfolio, including early-adopter sales of the proprietary 2RT laser, indicated for early age-related macular degeneration and clinically significant macular oedema”.

“Additionally, sales of the Integre Pro retinal laser and the full-year sales impact of the Itrack glaucoma surgical device, acquired on January 1, 2014, combined with the lower Australian dollar relative to the US dollar, also contributed to revenue improvement,” Mr Spurling said.

Ellex said that net tangible asset backing per share was up 13.5 percent to 17.6 cents.

The company said that diluted earnings per share was up 113.7 percent to 1.56 cents compared to the previous year’s 0.73 cents.

Ellex said it had $4,593,000 in cash and equivalents at June 30, 2015 compared to $1,768,000 for the previous corresponding period.

Ellex was was up four cents or 11.6 percent to 38.5 cents.

CRYOSITE

Cryosite says revenue for the 12 months to June 30, 2015 was up 4.5 percent to $9,844,000 with net profit after tax down 10.0 percent to $455,000.

Cryosite said that the reduction in profit “was a result of decisions made by the board to continue focusing on its long term strategy by restructuring its senior management team, investing in sales, marketing and other initiatives to improve competitiveness in its existing operations and to develop additional revenue streams in new markets to position the company for continuing growth performance in the following years”.

The company said that an unfranked 0.5 cent dividend per share for shareholders on the record date of September 10 would be paid on October 1, 2015.

The company said that diluted earnings per share fell 10.3 percent to 0.96 cents at June 30, 2015, compared to the previous year’s 1.07 cents and net tangible asset backing per share was down 46.4 percent from 12.5 cents to 6.7 cents.

Cryosite said that cash and cash equivalents at June 30, 2015 was $4,167,302 compared to the previous year’s $6,252,193.

Cryosite was untraded at 29 cents.

RESONANCE HEALTH

Resonance says revenue for the year to June 30, 2015, was up 15.9 percent to $2,676,760 turning last year’s loss of $72,415 to a net profit after tax of $463,234.

Resonance said that sales and Ferriscan radiology services increased and the company received an $86,934 Export Market Development Grant, along with a $75,000 Western Australia Innovator of the Year award.

The company said that basic earnings per share was 0.12 cents at June 30, 2015, compared to a 0.02 cents loss per share at June 30, 2014 and net tangible assets per share improved 52.2 percent from 0.46 cents at June 30, 2014 to 0.70 cents at June 30, 2015.

Resonance said it had $2,797,203 in cash at June 30, 2015, compared to $2,097,607 at June 30, 2014.

Resonance was up 0.1 cents or 2.9 percent to 3.6 cents with 1.3 million shares traded.

LBT INNOVATIONS

LBT says that revenue for the year to June 30, 2015 fell 40.7 percent to $2,367,000, with net profit after tax up 65.9 percent to $549,000.
LBT said that it received $1.00 million in milestone payments for its Automated Plate Assessment System program with Hettich AG Switzerland along with $846,000 in royalties from the France-based Biomérieux for its automated plate streaking system.
The company said diluted earnings per share fell 3.4 percent from 0.29 cents at June 30, 2014 to 0.28 cents at June 30, 2015, with net tangible asset backing per share down 15.4 percent from 2.6 cents at June 30, 2014 to 2.2 cents at June 30, 2015.
LBT said it had cash and equivalents of $1,818,000 at June 30, 2014 compared to $1,791,020 at June 30, 2014.

ANTEO DIAGNOSTICS

Anteo says that revenue for the year to June 30, 2015, fell 7.3 percent to $2,443,870 with net loss after tax up 69.3 percent to $4,220,342.
Anteo said that Mix&Go sales increased 50 percent to $465,000, offset by a lower Federal Government R&D Tax Incentive and a lower Commercialisation Australia grant.
Anteo said that its net tangible asset backing per share fell 27.1 percent to 0.62 cents, with diluted loss per share up 66.7 percent to 0.5 cents.
Anteo said that it had cash and cash equivalents of $5,206,567 at June 30, 2015 compared to $7,070,722 at June 30, 2014.
Anteo fell 0.3 cents or 3.2 percent to 9.2 cents.

GENETIC SIGNATURES

Genetic Signatures says that revenue for the year to June 30, 2015, was up 57.0 percent to $2,053,371 with net loss after tax up 53.8 percent to $2,659,120.
Genetic Signatures said that sales revenue of its Easyscreen enteric and respiratory virus detection kits climbed 52.5 percent to $1,043,269, with most of the balance of revenue a Federal Government R&D Tax Incentive.
The company said that net tangible asset backing per share rose 80.0 percent to 10.8 cents, with diluted loss per share down 57.0 percent to 5.2 cents and cash and cash equivalents of $5,461,686 at June 30, 2015 compared to $1,852,707 at June 30, 2014.
Genetic Signatures was up two cents or five percent to 42 cents.

BRAIN RESOURCE

Brain Resource says revenue for the 12 months to June 30, 2015 was up 6.3 percent to $2,714,000, with a net loss after tax up 29.9 percent to $2,595,000.
Brain Resource said that net assets per share fell 1.2 percent to 16.7 cents at June 30, 2015 compared to 16.9 cents in the previous period.
The company said that its assets were primarily intellectual property which were “excluded from the net tangible asset calculation, with the effect that the greater the value our intellectual property becomes, the lower the NTA value”.
Brain Resource said that diluted loss per share was up 2.0 percent to 2.02 cents compared with 1.98 cents in the previous corresponding period and cash and equivalents of 4,335,284 at June 30, 2015 compared to $1,992,613 at June 30, 2014.
Brain Resource was untraded at 17 cents.

OBJ

OBJ says that revenue for the year to June 30, 2015 was up 59.3 percent to $1,515,000, with net loss after tax up 4.3 percent to $2,299,000.
The company said that its net tangible asset backing per share fell 15.4 percent from 0.26 cents at June 30, 2014 to 0.22 cents at June 30, 2015, with diluted loss per share down 6.25 percent to 0.15 cents.
OBJ said that it had cash and cash equivalents of $3,519,337 at June 30, 2015 compared to $4,025,038 at June 30, 2014.
OBJ was up 0.1 cents or 1.6 percent to 6.2 cents.

CYCLOPHARM

Last night's edition said that Cyclopharm had a net loss after tax for the six months to June 30, 2015 of $132,307.
Cyclopharm managing director James McBrayer told Biotech Daily that the company had posted a net profit after tax of $178,842.
Mr McBrayer said the $311,149 in "exchange differences on translating foreign controlled entities" was an accounting measure for restating the retained earnings Cyclopharm's foreign subsidiaries and the then implied comprehensive loss for the six months for the company of $132,307 did not reflect the company's profit and loss position.
Following the clarification of accounting standards, the sub-editor reported that his "brain hurts" and no further disciplinary action has been taken.
Cyclopharm was unchanged at 50 cents.

MEDIBIO

Medibio says it has its first commercial agreement with an unnamed Australian corporation, with more than 10,000 employees, to provide its corporate stress test.
Medibio said that its stress test was "the first objective test to measure the level of stress and its impact on health and wellbeing" and was based on algorithms to measure the type, degree and significance of deviation of the subject's circadian heart rate from normal.
The company said the algorithms classified individuals into three categories from 'normal to mild', where no immediate action was needed, to 'moderate', where the impact of stress was approaching unhealthy levels and 'serious' where stress had an unhealthy impact and lifestyle changes were recommended.
Medibio said its stress test had mobile telephone application-based intervention or treatment modules tailored specifically for the employees' stress level.
The company said that the agreement would bring revenue in the current year.
Medibio said that the agreement had two phases starting with measurement of employee stress symptoms through their circadian heart rate followed by development of an online mental health training program and it would receive revenue of $100 per participant from each phase.
Medibio was up 1.5 cents or 3.3 percent to 46.5 cents.

CELLMID

Cellmid says it will launch a national advertising and media campaign on August 30 2015 to promote sales of its Évolis hair growth products in Australia.
Cellmid was up 0.1 cents or 2.9 percent to 3.5 cents with 6.4 million shares traded

SIRTEX MEDICAL

Hunter Hall Investment Management has reduced its substantial holding in Sirtex from 4,786,548 shares (8.38%) to 4,214,004 shares (7.37%).
In March, following the failure of the Sirflox trial to meet its primary endpoint, the Sirtex share price fell as much as 55 percent and Hunter Hall bought 1,251,375 shares for $21,829,457 or $17.44 a share, the first time Hunter Hall had bought Sirtex shares since May 2013 when it reached an internal maximum (BD: Mar 17, 19, 2015)
Hunter Hall has been a long term shareholder in Sirtex and in 2009 increased to 16,684,884 shares (29.92%) when the company was at $2.35 a share and has sold shares at prices ranging up to $34 a share (BD: Mar 5, 2009).
Today, Hunter Hall said that it bought and sold Sirtex shares between July 22 and August 24, 2015 with the single largest sale 119,120 shares for $3,952,224 or $33.18 a share.
Sirtex was up 60 cents or 1.8 percent to $34.35 with 318,081 shares traded.

MMJ PHYTOTECH

MMJ Phytotech has requested a trading halt “pending an update on the release of the company’s [cannabidiol] pill”.
Trading will resume on August 31, 2015 or on an earlier announcement.
MMJ last traded at 29 cents.

IMUGENE

Imugene says managing-director Charles Walker will become a non-executive director and Leslie Chong will be appointed chief operating officer, from mid-September.
Imugene said that most recently Ms Chong was a Genentech senior clinical program leader in San Francisco and would relocate to Sydney within the month.
Imugene executive chairman Paul Hopper said that Ms Chong had “deep immuno-oncology experience, industry networks and [was] from one of the world’s most successful and prestigious drug developers”.
Mr Hopper said that Mr Walker had “provided outstanding leadership over the past 12 months and has been instrumental in laying the groundwork for our phase Ib/II trial in addition to securing the manufacture of our vaccine material for that trial”.
Imugene was up 0.1 cents or 12.5 percent to 0.9 cents with 2.8 million shares traded

IMMURON

Immuron says that non-executive director and major shareholder Peter Anastasiou will assume the title of vice-executive chairman with immediate effect.
Immuron was up three cents or 7.3 percent to 44 cents.