Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 21%**
- GENETIC TECHNOLOGIES DOWN 16%

*** REVA DETAILS FANTOM STENT, EUROPEAN REGISTRATION TRIAL**

*** TISSUE THERAPIES FILES EMA 180-DAY REVIEW ANSWERS**

*** PHOSPHAGENICS TO SELL BIOELIXIA COSMETICS DIVISION**

*** ONCOSIL REWORKS EU, US PANCREATIC CANCER TRIAL DESIGN**

*** COMPUMEDICS H1 REVENUE UP 8% TO $16m, PROFIT UP 125% TO $904k**

*** IMPEDIMED H1 REVENUE UP 28% TO $2m, LOSS UP 71% TO $6m**

*** CLINUVEL H1 REVENUE UP 32% TO $1m, LOSS UP 129% TO $7m**

*** CRYOSITE H1 REVENUE UP 10.5% TO $5m, PROFIT UP 8% TO $358k**

*** ALLEGRA H1 REVENUE UP 1% TO $4m, LOSS UP 194% TO $262k**

*** BRAIN H1 REVENUE DOWN 7% TO $1m, LOSS UP 39% TO $1m**

*** PFIZER DROPS CASE AGAINST MAYNE PHARMA'S GENERIC TIKOSYN**

MARKET REPORT

The Australian stock market was up 0.3 percent on Wednesday February 25, 2015 with the S&P ASX 200 up 17.9 points to 5,944.9 points. Nine of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and three were untraded.

Universal Biosensors was the best, up six cents or 20.7 percent to 35 cents with 1.2 million shares traded. Uscom climbed 5.3 percent; Sirtex and Tissue Therapies rose more than four percent; Acrux, Biotron and Neuren were up more than three percent; Starpharma rose 2.9 percent; with Anteo and Cochlear up more than one percent.

Genetic Technologies led the falls, down 1.1 cents or 16.4 percent to 5.6 cents with 11.2 million shares traded. Prana lost 10 percent; Oncosil fell 9.3 percent; Patrys shed 8.3 percent; GI Dynamics was down seven percent; Analytica, Benitec and Mesoblast fell four percent or more; Alchemia, Circadian and Clinuvel were down three percent or more; Ellex, Osprey, Prima and Resmed shed more than two percent; Bionomics, Medical Developments, Pharmaxis, Psivida and Viralytics were down more than one percent; with CSL and Nanosonics down by less than one percent.

REVA MEDICAL

Reva has detailed the size and strength of its Fantom coronary stent and says it will begin a European registration directed trial of more than 110 patients beginning in April 2015.
Reva chief operating officer Robert Schultz told Biotech Daily that the Fantom stent's closed profile of 1.27mm was significantly smaller than the leading supplier of polymer stents currently on the market at 1.44mm and that despite its smaller size was equally strong.
Mr Schultz said that the Fantom could open to 3.0mm and post insertion could be further opened to as much as 4.8mm without causing structural stress.
Mr Schultz said that the company expected acute performance data on the Fantom I clinical trial of up to 10 patients in April 2015, having begun the trial of the bioresorbable drug-eluting stent late last year (BD: Dec 4, 2014).
Mr Schultz said that unlike the leading stent on the market, the Fantom and its predecessor the Rezolve stents were clearly visible to cardiac surgeons during the procedure.
"Nobody else has a truly inherently radio-opaque stent," Mr Schultz said.
Mr Schultz said that the Fantom II European registration trial of at least 110 patients was expected to begin by April 2015.
In a media release, Reva said that the Fantom I trial began enrolling patients in December 2014 at two sites in Brazil and Poland to provide early clinical data on the device.
The company said that in patients implanted to-date, the acute performance of the scaffold had been demonstrated, verifying the company's readiness to initiate a Conformité Européenne (CE) mark trial, Fantom II to begin enrollment by April 2015.
Reva said that the Fantom II trial would enroll a minimum of 110 patients at multiple clinical sites in eight countries and data from the trial was intended to be used in a CE mark application in mid-2016.
The company said that the director of invasive cardiology at the Sao Paulo, Brazil-based Institute Dante Pazzanese of Cardiology and co-principal investigator Dr Alexandre Abizaid presented the bioresorbable scaffold program at the Cardiovascular Research Technologies 2015 conference in Washington, DC on February 23, 2015.
Reva said that the Fantom bioresorbable scaffold used its advanced polymer that allowed for thinner strut thickness and enhanced deliverability, while maintaining its ease-of-use properties including complete visibility under x-ray, expansion of the scaffold with one continuous inflation, no procedural time limitations, and standard storage and handling.
Reva was unchanged at 52 cents.

TISSUE THERAPIES

Tissue Therapies says its comprehensive response to the 180-day review questions for its Vitrogro wound therapy has been accepted by the European Medicines Agency.
Tissue Therapies said that the response was lodged by its notified body the British Standards Institute (BSI) and the response would be considered by the EMA review committee during the last week of March 2015.
The company said that the EMA review committee opinion was expected to be conveyed to the BSI during early April 2015.
The EMA has delayed the application several times for more questions as well as for the Christmas New Year holidays (BD: Feb 26, Sep 30, Nov 4, 2014; Jan 21, 2015).
Tissue Therapies was up one cent or 4.3 percent to 24.5 cents.

PHOSPHAGENICS

Phosphagenics says it hopes to sell its Bioelixia cosmetics division “to allow resources to be focused on the company’s core areas of strength”.

In 2009, Phosphagenics said that the New York-based Métier Tribeca would launch cosmetic products using its TPM tocopheryl phosphate mixture (BD: Jul 20, 2009).

Last year, Phylogica, which had a licence with Le Métier Tribeca to formulate and market glycinemide into a cosmetic product for sunburn, said the New York-based company had filed for bankruptcy (BD: May 16, 2014).

Under former chief executive officer Dr Esra Ogru, Phosphagenics licenced AOD9604 as a “fat-buster” drug from the then Calzada, formerly Metabolic and now Polynovo, but the UK-based Boots the Chemists dropped the Bodyshaper product four months after agreeing to market it (BD: May 21, Sep 26, 2012).

In 2007, a phase II Metabolic trial of 536 patients demonstrated that AOD9604 did not reduce obesity (BD: Feb 21, 2007).

The drug, which was the topic of Dr Ogru’s doctoral thesis, has been at the centre of the Essendon Football Club doping scandal (BD: Apr 26, 2013).

Dr Ogru is currently in gaol for her part in the $6 million fraud of Phosphagenics, along with AOD9604 co-inventor Dr Woei-Jia Jang and her doctoral supervisor Dr Robert Gianello (BD: Nov 7, 2014).

Today, Phosphagenics said it had received “a number of expressions of interest in purchasing its range of skincare products sold under the Bioelixia brand”.

The company said that “the Bioelixia brand and product range .... has been growing over the last few years and has the capacity to provide potential purchasers with an opportunity to acquire a brand with an established distribution network and product differentiation based on the TPM technology”.

Phosphagenics is yet to report its results for the year to December 31, 2014, but inits report for the six months to June 30, 2014 said revenue had fallen percent but did not specify revenues from the Bioelixia division other than to say it was “expected to show increased revenue in the second half of 2014”.

Recently appointed chief executive officer Dr Ross Murdoch said that the company had “demonstrated that the addition of TPM has real potential across a large number of areas, it is essential for a relatively small company like Phosphagenics to recognize where it can maximize value for shareholders, and apply its precious resources in those areas”.

“This decision reflects our commitment to focus on the areas where we believe we can add most value and find experts to maximize shareholder value for the others,” Dr Murdoch said.

Phosphagenics chairman Lawrence Gozlan said the brand “has a growing following and growing distribution network”.

“We are now focused on seeking to ensure that the ultimate sales arrangement recognizes the unique value of the brand and provides the opportunity for shareholder upside,” Mr Gozlan said.

Phosphagenics said that if commercially attractive terms were reached with a purchaser, the sale was likely to be limited to its own brand of Bioelixia products.

The company said that its ongoing strategy for consumer skincare was to retain the rights to licence TPM to global or regional companies for use in cosmetics products.

Phosphagenics said that the arrangement with GNC had been terminated and the arrangement with Korean Drug Company was likely to be changed, as it did not intend to retain the resources necessary to manufacture cosmetics products for third parties and licencing arrangements with Le Metiér de Beauté were unchanged.

Phosphagenics was unchanged at 7.2 cents.

ONCOSIL MEDICAL

Oncosil says a review of a planned pivotal trial for its localized radiation treatment for pancreatic cancer has led to a “comprehensively reworked” trial design.

Last year, Oncosil said it had ethics approval for Australian hospital sites in a pivotal 150-patient clinical trial for pancreatic cancer, was finalizing arrangements for the first group of hospitals to begin recruiting patients, was preparing an investigational device exemption submission to the US FDA and the then chief executive officer Dr Neil Frazer told Biotech Daily he hoped to treat the first patient before the end of 2014 (BD: Mar 17, Jul 15, 2014).

Today, Oncosil said that “under the leadership of new chief executive officer Daniel Kenny [it had] conducted a detailed strategic clinical and regulatory review of the Oncosil device program, and as a result has determined to aggressively pursue a global registration program in pancreatic cancer”.

The company said it aimed to secure both Conformité Européenne (CE) mark and US Food and Drug Administration investigational device exemption approval for Oncosil in pancreatic cancer by the end of 2015.

Oncosil said that an investigational device exemption submission would be a significant formal step for pre-market approval and would require a pivotal study.

“Based on the findings of the recently completed clinical and regulatory review the design of the currently proposed pivotal study will be comprehensively reworked,” Oncosil said.

The company said it would provide updates on the new design of the pivotal study before the end of June, 2015 following receipt of scientific advice from regulatory authorities.

Oncosil said that active patient recruitment was expected to begin by October, 2015.

Oncosil chief executive officer Daniel Kenny said that “following our strategic review the company is now better positioned to secure both the CE mark and US FDA [investigational device exemption] this year”.

The company said that Oncosil was an implantable device that emitted radiation directly into a pancreatic tumor, delivering radiation therapy locally for up to three months.

Oncosil said that i the US, more than 40,000 patients were diagnosed with pancreatic cancer each year and treatment was a major unmet medical need, with median survival after diagnosis of five months.

Oncosil said that surgery was only feasible in 20 percent of patients, and chemo-therapeutic treatments worked in around 15 percent of patients.

The company said that radiation therapy had systemic side effects in an already sick patient population and localized radiation therapy might offer a potential treatment option without systemic side effects.

Oncosil fell 0.9 cents or 9.3 percent to 8.8 cents with 3.7 million shares traded.

COMPUMEDICS

Compumedics says revenue for the six months to December 31, 2014, was up 8.0 percent to $15,634,000 with net profit after tax up 124.9 percent to $904,000.

Compumedics said that sales increased six percent with a 13 percent rise in Asia, including China, and a 10 percent increase by its Germany-based DWL trans-cranial Doppler business, a six percent rise in US sales and a four percent increase in Australia.

The company said that net tangible assets per share was up 39.4 percent to 4.6 cents and diluted earnings per share was up 150 percent to 0.5 cents at December 31, 2014 compared to 0.2 cents for the previous corresponding period.

Compumedics said that cash and cash equivalents at December 31, 2014 was $1,646,000 compared to $1,054,000 at June 30, 2014.

Compumedics was unchanged at 14 cents

IMPEDIMED

Impedimed says that revenue for the six months to December 31, 2014, was up 28.3 percent to $2,110,000 with net loss after tax up 70.7 percent to $6,122,000.
Impedimed said the sales of good, namely its L-Dex U400 lymphoedema test increased 31.2 percent to $1,971,000 with services up 3.7 percent to $113,000.
The company said that diluted loss per share was up 50.0 percent to three cents for the six months to December 31, 2014.
Impedimed said that net tangible assets per share was up 333.3 percent to 13 cents at December 31, 2014 compared to three cents at December 31, 2013.
The company said it had cash and cash equivalents of $38,241,000 at December 31, 2014, compared to $10,812,000 at June 30, 2014.
Impedimed was unchanged at 88 cents.

CLINUVEL

Clinuvel says that revenue for the six months to December 31, 2014, was up 32.3 percent to $1,068,865 with net loss after tax up 128.8 percent to $7,347,382.
Clinuvel said most of the revenue came from the supply of its Scenesse (afamelanotide 16mg) implants under the reimbursement schemes of Italy and Switzerland, up 40.1 percent to $865,080 for the six months to 31 December 2014, with interest income up 6.9 percent to $203,785.
The company said that basic loss per share was up 106.0 percent to 17.3 cents for the six months to December 31, 2014.
Clinuvel said that net tangible assets per share was up 7.1 percent to 30 cents at December 31, 2014 compared to 28 cents at December 31, 2013.
The company said it had cash and cash equivalents of $11,979,340 at December 31, 2014, compared to $14,625,583 at June 30, 2014.
Clinuvel fell 12 cents or 3.4 percent to $3.40.

CRYOSITE

Cryosite says revenue for the six months to December 31, 2014, was up 10.5 percent to $5,088,000 with net profit after tax up 8.4 percent to $358,000.
Cryosite said that it provided cord blood storage, bio-repository management and distribution of biological materials and pharmaceutical products used in clinical trials, and “revenue was enhanced by the successful introduction of mesenchymal stem cell cord tissue storage”.
Cryosite said it would pay a half cent per share unfranked dividend with a record date of March 17, 2015 to be paid on March 31, 2015.
The company said that net tangible assets per share fell 44.9 percent to 7.0 cents with diluted earnings per share up 8.6 percent to 0.76 cents at December 31, 2014 compared to 0.70 cents for the previous corresponding period.
Cryosite said that cash and cash equivalents at December 31, 2014 was $4,205,596 compared to $6,252,193 at June 30, 2014.
Cryosite was up one cent or 2.5 percent to 41 cents.

ALLEGRA ORTHOPAEDICS (FORMERLY ADVANCED SURGICAL DESIGN)

Allegra says that revenue for the six months to December 31, 2014, was up 0.9 percent to $4,297,844 with net loss after tax up 193.5 percent to $261,601.
The company said that diluted loss per share increased 155.0 percent to 0.51 cents for the six months to December 31, 2014.
Allegra said that net tangible assets per share fell 21.7 percent to 7.10 cents at December 31, 2014 compared to 9.07 cents at December 31, 2013.
The company said it had cash and cash equivalents of $1,237,775 at December 31, 2014, compared to $26,017 at June 30, 2014.
Allegra was untraded at eight cents.

BRAIN RESOURCE

Brain says revenue for the six months to December 31, 2014 was down 6.8 percent to $1,331,000 with a net loss after tax up 38.6 percent to $1,126,067.
Brain said its net asset backing per share fell 3.3 percent to 17.8 cents and diluted loss per share increased 12.5 percent from 0.8 cents to 0.9 cents.
The company said it had cash and cash equivalents of $7,149,613 at December 31, 2014 compared to $1,992,613 at June 30, 2014.
Brain was untraded at 28.5 cents.

MAYNE PHARMA GROUP

Mayne Pharma says it has reached an agreement with Pfizer Inc to end litigation over its generic version of Tikosyn.
A spokesperson for Mayne told Biotech Daily that the agreement was at no cost to the company and that it would instead save funds otherwise expended on US litigation.
Mayne said that Tikosyn, or dofetilide capsules in 0.125mg, 0.25mg and 0.5mg formulations, was an anti-arrhythmic agent to prevent irregular heartbeats such as atrial fibrillation and atrial flutter.
The company said that Pfizer had withdrawn its legal action, enabling it to enter the US market with a generic version of Tikosyn following approval by the US Food and Drug Administration.
Mayne said that its abbreviated new drug application for generic Tikosyn was currently under a priority review with the FDA.
Mayne chief executive officer Scott Richards said the “expeditious resolution of the patent litigation with Pfizer on what we expect is a first-to-file [abbreviated new drug application] for Tikosyn is a significant event for our US generics business”.
“This agreement allows Mayne Pharma to bring a generic version of Tikosyn to the US market prior to the October 2018 expiration of Pfizer’s patent, without incurring the uncertainty, cost and risk inherent with patent litigation,” Mr Richards said.
“Furthermore, we expect to be awarded a 180-day exclusivity period upon approval which we anticipate as early as 2016,” Mr Richards said.
Mayne said it had an agreement with the active pharmaceutical ingredient supplier Johnson Matthey Inc to share equally the potential profits from the sale of the product.
Mayne was up five cents or six percent to 88 cents with 5.9 million shares traded.