Biotech Daily

Thursday August 29, 2013

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: VIRALTYICS UP 17.5%, PRANA DOWN 14%**

*** HEARING CRC REMOTE COCHLEAR IMPLANT MAPPING MODULE**

*** LIVING CELL DIRECTION CHANGE, PHASE IIb TRIAL QUESTIONS**

*** IDT PLACEMENT, RIGHTS ISSUE TO RAISE $6m**

*** MESOBLAST REVENUE DOWN 9% TO $35m, LOSS DOWN 13% TO $62m**

*** REIMBURSEMENT DELAYS PHARMAXIS FRENCH BRONCHITOL LAUNCH**

*** CRYOSITE REVENUE UP 9% to $9m, PROFIT UP 22% TO $1m, DIVIDEND**

*** IDT REVENUE UP 7% to $11m, LOSS up 191% TO $5m**

*** PRIMA FILES US SEC 'SHELF REGISTRATION' TO RAISE UP TO $67m**

*** CAMBRIDGE'S DR GREG WINTER IN BIO-MELBOURNE BLOCKBUSTER**

*** BONE PAYS ASX FEES, RETURNS TO LISTING**

MARKET REPORT

The Australian stock market edged up 0.1 percent on Thursday August 29, 2013 with the S&P ASX 200 up 5.2 points to 5,092.4 points. Eleven of the Biotech Daily Top 40 were up, 21 fell, two traded unchanged and six were untraded. All three Big Caps fell.

Viralytics was best, up 5.5 cents or 17.5 percent to 37 cents with 686,918 shares traded. Living Cell climbed 6.1 percent; Bionomics and Cellmid rose more than three percent; Alchemia and Psivida were up more than two percent; Anteo, Clinuvel, GI Dynamics and Neuren were up more than one percent; with Osprey up 0.8 percent.

Prana led the falls, down 8.5 cents or 14.05 percent to 52 cents with 3.7 million shares traded.

Atcor lost eight percent; Ellex and Pharmaxis fell more than seven percent; Antisense was down 6.7 percent; Allied Health and Tissue Therapies were down more than five percent; Avita, Genetic Technologies, Impedimed and QRX fell more than three percent; Mesoblast and Patrys shed more than two percent; with Benitec, Cochlear, CSL, Medical Developments, Phosphagenics, Prima, Resmed, Starpharma and Universal Biosensors down more than one percent.

THE HEARING COOPERATIVE RESEARCH CENTRE

The Hearing Cooperative Research Centre says that Greens Senator Rachel Siewart has launched its training module for remote programming of cochlear implants.

The Hearing CRC said the module had been created to improve access to specialized cochlear implant fitting procedures for patients, families and professionals living in regional, rural and remote settings.

A Hearing CRC media release said the module was “a paradigm shift in how hearing health services can be delivered to regional, rural and remote Australia”.

The Hearing CRC said the training module would be available to hearing health professionals via the Hearing Education and Research Network (Hearnet) online training portal https://www.hearnetlearning.org.au.

The Hearing CRC said it had four major research programs, biomedical, genetic and physiological; intelligent sound processing; integrated bioengineering; and clinical tools, services and techniques.

The CRC said the programs were focused on innovative research and development across the healthcare spectrum and benefit from the capabilities and infrastructure provided by the Members involved.

The CRC said that its four research program areas were supported by a commercialisation program for clinical trials and product development that tested the efficacy of novel approaches and products as the first step in the commercialization process.

The Hearing CRC said that it had five ‘core members’ including Australian Hearing Services, Cochlear, Macquarie University, Siemens Hearing Instruments and the University of Melbourne, along with 21 ‘support members’ including a range of hospitals, institutes and companies.

LIVING CELL TECHNOLOGIES

Living Cell will not use its planned 20-patient Argentinean phase IIb trial of Diabecell for type 1 diabetes for registration purposes.

Earlier this week Living Cell said that following “a preliminary internal review” it was consulting with a third party auditor, regarding the Argentinean trial (BD: Aug 27, 2013).

Today, the company said that a review of research and development work performed by its 50/50 joint venture with Japan’s Otsuka Pharmaceutical Factory, Diatranz Otsuka, “indicates that there is a genuine opportunity to develop an improved formulation of Diabecell which has the potential to be registered globally by 2018”.

Living Cell said that Diatranz Otsuka would “no longer use for registration purposes the Dia-12 phase IIb study of the current Diabecell formulation in Argentina”.

Living Cell chief executive officer Dr Andrea Grant told Biotech Daily that the trial had not been closed, but said she could not elaborate on the media release nor say how many patients had been treated.

Dr Grant said the priority for Living Cell and Diatranz Otsuka were consulting with regulatory and ethics committees “in order to ensure we uphold our safety and ethical commitments to patients already enrolled in the study”.

The company said that a revised regulatory development pathway for the improved formulation of DiabecelI encapsulated porcine islets of Langerhans was in preparation.

Last year, Living Cell said that an interim analysis of its Argentinean phase I/IIa trial of Diabecell for unstable type 1 diabetes showed significant efficacy and that a 20-patient phase IIb trial had begun (BD: Nov 22, 2013).

Living Cell was up 0.3 cents or 6.1 percent to 5.2 cents.

IDT AUSTRALIA

IDT says it will raise $5,983,508 through a fully underwritten placement and one-for-five rights issue at 27 cents a share.
IDT said that the capital raising was underwritten by Wilson HTM Corporate Finance with a placement of 11,481,482 shares to institutional and sophisticated investors to raise $3.1 million, subject to shareholder approval expected in “early October”.
The company said that shareholders at the record date of September 9, 2013 could apply for shares in the rights issue to raise $2,883,508.
IDT said that director David Williams would sub-underwrite the rights issue to $50,000 and funds would be used to improve efficiency, sales and marketing efforts, funding the clinical site management business and conversion of assets into generic drug registrations.
IDT said the rights offer would open on September 11 and close on September 25, 2103.
IDT was unchanged at 36 cents.

MESOBLAST

Mesoblast says its net loss after tax for the 12 months to June 30, 2013 was reduced 13.3 percent to $61,663,000 on revenue down 9.3 percent to $34,710,000.
Earlier this year, Mesoblast raised $170 million and today said that it had $315.3 million at June 30, 2013, compared with $205.6 million at June 30, 2012 (BD: Mar 6, 14, 2103).
Mesoblast said that interest income was constant at $10.5 million, with commercialization income down 34.0 percent to $18,260,000 reflecting “an extension of the period over which the upfront payment of $US130.0 million [from Cepahlon/Teva] is being amortized”.
The company received a $5,924,000 Federal Government R&D Tax Incentive during the financial year.
Mesoblast said that research and development expenditure increased 16.7 percent to $43,108,000 for the year to June 30, 2013.
Mesoblast said its working capital enabled it “to execute additional phase III trials, to broaden its clinical development programs in diseases of inflammation and immunity, to access complementary technologies for product diversification and to ramp up its commercial manufacturing operations”.
In a presentation accompanying the company’s results Mesoblast said its strategic product focus was guided by specific mechanisms of action of its mesenchymal precursor cells.
Mesoblast said its mesenchymal precursor cells responded to signals from inflammation and /or tissue damage by releasing a range of factors which induced: polarization of pro-inflammatory monocytes to a non-inflammatory phenotype; inhibited activated T-cells and induced regulatory T-cells; stimulated blood vessel growth and maturation and reversed endothelial dysfunction; and increased survival and improved function of cardiac muscle cells, cells of central nervous system, bone-forming cells and cartilage-producing cells.
The presentation included a pipeline diagram showing 12 products in development led by the phase III bone marrow transplantation trial with congestive heart failure, spinal fusion and inter-vertebral disc repair all at the end of phase II and ready for phase III trials.
Indications at phase II included type 2 diabetes, acute myocardial infarction, wet age-related macular degeneration, rheumatoid arthritis and diabetic complications.
Mesoblast said that net tangible asset per share was up 80.2 percent from 40.07 cents at June 30, 2012 to 72.19 cents at June 30, 2013.
The company said diluted loss per share was 21.06 cents compared with 25.15 cents in the previous corresponding period.
Mesoblast fell two cents or 2.7 percent to $5.47.

PHARMAXIS

Pharmaxis says French sales of Bronchitol for cystic fibrosis have been delayed by the lack of agreement with French authorities on reimbursement.

Pharmaxis said it would scale back resources and investments for the launch.

Pharmaxis chief executive officer Gary Phillips said that “negotiations with the French Healthcare Products Pricing Committee have been protracted and, given the current economic climate and prevailing healthcare policy in France, I do not believe we are yet close to agreement on an acceptable price for Bronchitol”.

“France has an adult cystic fibrosis population of approximately 3,000 patients and it is very disappointing not to be able to secure timely reimbursement,” Mr Phillips said.

“Our pricing has already proved acceptable to some of the world’s most rigorous reimbursement authorities in the UK and Australia and I remain optimistic that we will eventually reach agreement in France,” Mr Phillips said.

“In order to protect our short term cash position, personnel and contractors working on Bronchitol in France will be reduced from six to one by the end of September and other French marketing investments will be significantly scaled back,” Mr Phillips said.

“Marketing resources will be focused on increasing growth of Bronchitol sales in the launched markets of Germany, UK, Denmark and Australia whilst gaining access to new European markets,” Mr Phillips said.

Pharmaxis fell one cent or 7.1 percent to 13 cents with 1.5 million shares traded.

CRYOSITE

Cryosite says that revenue for the 12 months to June 30, 2013 was up 9.3 percent to $8,764,000 with net profit after tax up 22.3 percent to $1,250,000.

Cryosite said the increased revenue was due to organic growth in both its biological services and warehousing and distribution divisions.

Cryosite said it would pay an unfranked dividend of one cent a share compared to the previous year’s half a cent a share.

The company said that net tangible asset backing per share was up 16.6 percent to 22.5 cents and diluted earnings per share was up 22.1 percent to 2.65 cents for the year to June 30, 2013 compared to 2.17 cents for the previous corresponding period.

Cryosite said it had in cash and cash equivalents of $5,777,097 at June 30, 2013, compared to $4,524,750 at the end of the previous financial year.

Cryosite was untraded at 50 cents.

IDT AUSTRALIA

IDT says that revenue for the year to June 30, 2013, was up seven percent to $10,660,000 with net loss after tax up 191 percent to $5,354,000.

IDT said the increased revenue was “a result of a stronger performance from [its] cl;incial trials operation, CMax”.

The company said that net tangible assets per share fell 24.1 percent to 44 cents, with diluted loss per share up 181.4 percent to 12.1 cents.

IDT said that it had cash and cash equivalents of $578,000 at June 30, 2013 compared to $13,000 at June 30, 2012.

PRIMA BIOMED

Prima says it has filed a shelf registration with the US Securities and Exchange Commission to issue up to $US60 million ($A66.85 million) in shares over three years.
Prima said the shares would trade in the US as American depository shares.
The company said that shelf registrations were common practice in the US as they allowed a company "to complete the usually extensive SEC review process prior to the issuing of any securities and then have up to three years within which to use the prospectus" and the registration statement had been filed with the SEC, but was not yet effective.
The company said its American depository shares traded on the Nasdaq Global Market under the code PRMD and each American depository share was equivalent to 30 Australian shares.
Prima fell 0.1 cents or 1.1 percent to 8.7 cents with 6.1 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says that Cambridge Antibody Technology founder Dr Gregory Winter will discuss discovering or creating the next blockbuster therapeutic.
Bio-Melbourne Network chief executive officer Michelle Gallaher said that Dr Winter was "best known for his pioneering work in the development of therapeutic antibodies that have revolutionized the pharmaceutical industry in recent years".
"His technology has been used in the development of the well-known therapeutic antibodies used in oncology and rheumatoid arthritis, namely Herceptin and Humira," Ms Gallaher said.
Ms Gallher said that Dr Winter founded Cambridge Antibody Technology in 1989 which was acquired by Astrazeneca and Domantis in 2000, which was bought by Glaxosmithkline.
Dr Winter founded Bicycle Therapeutics in 2009 and continues as a director and was appointed Master of Trinity College Cambridge in 2012.
Dr Winter was awarded a Commander of the British Empire award in 1997 and a Knight Bachelor in 2004 and is also known as 'Sir Gregory Winter'.
The Bio-Melbourne Network said that Dr Winter would speak about "discovering or creating the next blockbuster therapeutic or platform technology [and … share his insights on whether the next class of therapeutics are likely to be blockbusters or more personalized therapies and how to successfully commercialize these".
The Network said that the September 5, 2013 Bio-Briefing would be held at RMIT Storey Hall, 336 Swanston Street, Melbourne.
Registration is from 3:45pm for a 4pm presentation until 5:15pm.
For more information go to: http://www.biomelbourne.org/events/view/294.

BONE MEDICAL

Bone says it has paid its ASX listing fees and will be reinstated tomorrow.
Last week Bone said that La Jolla Cove's delayed payments led to it being suspended from trading for failing to pay its ASX listing fees (BD: Aug 23, 2013) .
Bone was unchanged at 0.1 cents with 1.5 million shares traded.