Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: IDT UP 15%, LIVING CELL DOWN 5.45%**

*** MESOBLAST: 'FUNDS COVER MAJOR PROGRAMS, ON-TRACK'**

*** LIVING CELL PLACEMENT RAISES $2.8m, SHARE PLAN**

*** UNIVERSAL BIO REVENUE UP 76% TO $17m, LOSS DOWN 29% TO $6.6m**

*** ITL H1 REVENUE UP 10% TO $16m, PROFIT DOWN 36% TO $1m**

*** COGSTATE H1 REVENUE UP 109% TO $13m, LOSS TO $2.6m PROFIT**

*** CE MARK FOR BPH, CORTICAL DYNAMICS BAR MONITOR**

*** IMMURON $1.7m NEW YORK EQUITY DRAW-DOWN FACILITY**

*** PRESCIENT DOSES LAST PHASE Ib PTX-200 CANCER PATIENT**

*** JAPAN 'TRANSFER FUNCTION' PATENT FOR ATCOR'S SPHYGMOCOR**

*** VERITAS BELOW 5% OF COCHLEAR**

*** MEDIBIO, VITAL BEGIN FIRST CORPORATE STRESS TEST PILOT TRIAL**

*** RECCE ISSUES 4m PERFORMANCE SHARES, 3m TO DIRECTORS**

MARKET REPORT

The Australian stock market retreated 0.57 percent on Wednesday February 17, 2016 with the ASX200 down 27.9 points to 4,882.1 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and three were untraded.

IDT was the best, up four cents or 14.8 percent to 31 cents with 61,000 shares traded. Avita and Pharmaxis climbed more than nine percent; Biotron, Medical Developments and Oncosil were up more than five percent; Atcor and Orthocell improved more than three percent; Opthea rose 2.8 percent; Mesoblast, Prana, Resmed, Sirtex and Universal Biosensors were up more than one percent; with Starpharma up 0.9 percent.

Living Cell led the falls, down 0.3 cents or 5.45 percent to 5.2 cents with 797,728 shares traded, followed by Cellmid down five percent to 1.9 cents with 187,335 shares traded. Psivida fell 4.3 percent; CSL, Polynovo and Viralytics lost more than three percent; Anteo, Clinuvel, Cochlear and Ellex shed more than two percent; Bionomics, Nanosonics and Pro Medicus were down more than one percent; with Acrux, Impedimed and Reva down by less than one percent.

MESOBLAST

Mesoblast says it has funds to take it through to July 2017 beyond the completion of the first part of its Teva sponsored phase III heart failure stem cell trial.

In its half-yearly report to December 31, 2015, Mesoblast said that its cash burn for the three months to December 31, 2015 was $US19.8 million and it had cash reserves of $US120.8 million.

In a teleconference, Mesoblast chief executive Prof Silviu Itescu said that Teva Pharmaceuticals was running the trial but he expected the company's existing funds to cover the completion of the first trial of 600 patients.

Prof Itescu said the changed design of the trial, agreed between Mesoblast, Teva and the US Food and Drug Administration, reduced the timelines and would require a "confirmatory" 600 patient trial, which Teva would run in parallel with the current trial.

Prof Itescu said that the patients in the trial had a high risk of recurrent heart-failure related major adverse cardiac events and were similar to patients in "breakthrough" trials.

Prof Itescu said that whether the second 600 patient confirmatory trial would be conducted before or after registration was a matter for further discussion with Teva and the FDA.

Prof Itescu said that sales of Temcell, or MSC-100-IV, for graft versus host disease in Japan were expected to begin by April 2016 with royalty revenue by July 2016.

Prof Itescu said that the "top-line" results from its phase II trial of MPC-300-IV for biologic-refractory rheumatoid arthritis showed that a single infusion of the low dose was "safe and resulted in early and sustained clinical responses" (BD: Feb 16, 2016).

Asked whether the absence of "p" values from the data on 24 patients was being held back for publication or conferences, Prof Itescu referred to two imminent rheumatoid arthritis meetings.

Prof Itescu said that the American College of Rheumatology 20 percent improvement (ACR20) efficacy endpoint was "a low bar".

"It's the approvable bar, but it's a low bar," Prof Itescu said.

Yesterday, Mesoblast said that 47 percent of all mesenchymal precursor cell-treated patients and by 60 percent of MPC-treated patients who had failed one or two biologics reached the ACR20 level, compared to 25 percent and 17 percent, respectively, of matched placebo-treated controls.

The company said that 27 percent of the low dose MPC-treated patients achieved ACR50 or ACR70 at week 12 of the trial, with no placebo-treated patients reaching that level.

A Cochrane Library meta-analysis of six trials showed that 275 patients (45.8%) of 600 rheumatoid arthritis patients, on six different biologics, reached ACR50.

An abstract of the Cochrane analysis of the six different biologics is available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007848.pub2/abstract.

Prof Itescu told Biotech Daily after the teleconference that a competitor stem cell company had a four percent ACR20 efficacy result compared to Mesoblast's 47 percent.

Mesoblast said that revenue was up 1.6 percent to $US11,527,000, research and development spending fell 23.2 percent to $US23,604,000, management and administration expenses were down 22.3 percent to $US11,251,000, with manufacturing commercialization costs up 25.1 percent to $US14,321,000.

The company said that its net loss after tax fell 18.3 percent to $US35,485,000.

Mesoblast said the diluted loss per share fell 24.6 percent to 10.31 US cents

The company said that cash and cash equivalents were up from $US110,701,000 at June 30, 2015 to $US120,783,000 at December 31, 2015, following the November $US58.8 million capital raise (BD: Nov 16, 17, 19, 20, 2015).

Mesoblast climbed as much as 20 cents or 14.8 percent to $1.55 before closing up 1.5 cents or 1.1 percent at $1.365 with 1.2 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says it has raised $2,764,621 through a placement at 5.063 cents a share and hopes to raise more funds through a share purchase plan.
Living Cell said the proceeds would be used for working capital to carry out the phase IIb clinical trial of lead product NTCell in Parkinson's disease and to apply for provisional consent to treat paying patients in new Zealand in 2017.
The company said the record date for the share plan was February 16, the plan would open on February 24 and close on March 11, 2016.
Living Cell said that shareholders would each be entitled to parcels of shares in $1,000 increments up to $15,000.
Living Cell fell 0.3 cents or 5.45 percent to 5.2 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says its revenue for the 12 months to December 31, 2015 rose 76.0 percent to $16,774,978, reducing its net loss after tax 29.4 percent to $6,576,416.
Universal Biosensors said that Johnson & Johnson Verio Onetouch quarterly service fees were up 99 percent to $12.8 million, with the balance of revenue strip sales to Siemens and a milestone payment.
Universal Biosensors chief executive officer Paul Wright said that revenue generated by the quarterly service fees "drops straight through to the bottom line, so this growing revenue stream underpins our improving profitability and cash flow".
"With the momentum already established and regulatory changes in Europe driving the industry to higher accuracy standards, we should see this revenue stream continue to grow in 2015-'16," Mr Wright said.
Universal Biosensors said that research and development expenses increased by 15 percent to $19.8 million.
The company said that net tangible asset per share fell 27.3 percent to eight cents at December 31, 2015 and diluted loss per share fell 20 percent to four cents compared with a five cents loss in the previous corresponding period.
Universal Biosensors said it had cash and equivalents of $14,350,307 at December 31, 2015 compared to $16,329,829 at December 31, 2014.
Universal Biosensors was up half a cent or 1.3 percent to 39.5 cents.

ITL

ITL says revenue for the six months to December 31, 2015, was up 9.6 percent to $15,803,000 with the net profit after tax down 35.9 percent to $1,044,000.
ITL said it would not pay an interim dividend with a fully franked final dividend of 0.25 cents for the year to June 30, 2015 paid on September 3, 2015.
The company said that net tangible asset backing per share fell from 11.8 cents at December 31, 2014 to 9.8 cents at December 31, 2015, while diluted earnings per share was down 36.8 percent from 1.9 cents to 1.2 cents.
ITL said that cash and cash equivalents was $1,458,000 at December 31, 2015 compared to $1,103,000 at June 30, 2015.
ITL was up one cent or five percent to 21 cents.

COGSTATE

Cogstate says revenue for the six months to December 31, 2015, was up 109.1 percent to $13,020,778 turning the previous $2,656,492 loss to a net profit after tax of $2,556,288.
Cogstate 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 transcranial 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 28.6 percent to 9.0 cents and diluted earnings per share was 2.3 cents at December 31, 2015 compared to a loss of 2.7 cents for the previous corresponding period.
Cogstate said that cash and cash equivalents at December 31, 2015 was $5,089,974 compared to $5,497,197 at June 30, 2015.
Cogstate was up three cents or 5.9 percent to 54 cents.

BPH ENERGY

BPH Energy says that investee company Cortical Dynamics has been granted the Conformité Européenne (CE) mark for its brain anaesthesia response (BAR) monitor.
BPH said it held 3.89 percent of Cortical Dynamics and had the option to increase its holding to more than 10 percent through the conversion of a secured loan.
BPH was up 0.1 cents or 20 percent to 0.6 cents.

IMMURON

Immuron says it has a $1,700,000 draw-down equity facility with an unnamed New York-based investment fund.
Immuron said that the funds would allow the immediate start of a clinical trial of IMM-529 for Clostridium difficile, accelerate sales and marketing initiatives for Travelan in the US, and provide working capital.
The company said that funds would be available in three tranches with a mix of equity financing and convertible securities.
Immuron said that the first tranche would be a $100,000 private placement with a $678,000 repayable convertible note; the second tranche at Immuron's election, 45 days after the first tranche would be on the same terms; and the third tranche by mutual consent would be for a further $339,000 repayable convertible note.
The company said that the convertible notes were repayable monthly over an 18 month period with each repayment to be settled at Immuron's discretion monthly the issue of new shares at a 10 percent discount to a 5-day volume weighted average price over the 20 trading days immediately prior to a repayment due date or by cash repayment plus a 2.5 percent premium to the repayment amount, at Immuron's discretion.
Immuron said it would also issue the investment fund 1,000,000 options exercisable at a 130 percent premium to the current share price with a three year expiry date and 2,000,000 untradeable escrowed collateral shares accessible to the investment fund in the unlikely event of Immuron falling into default.
The company said that at the cessation of the agreement period, the fund would either return the 2,000,000 shares to Immuron or purchase them.
Immuron was unchanged at 41 cents.

PRESCIENT THERAPEUTICS

Prescient says the seventeenth and final patient has been dosed in the escalation stage of its phase Ib breast cancer trial at the New York Montefiore Cancer Centre.

Last year, Prescient said it had “encouraging early clinical data” from its phase Ib/II clinical study of PTX-200 for breast, lung and oesophageal cancer, with 14 patients treated with PTX-200 in combination with weekly paclitaxel chemotherapy and the study showed “evidence of anti-tumor activity” (BD: Aug 26, 2015).

In 2015, the company said that dose escalation of PTX-200 had proceeded to the third and final dose level of 35mg/m2 and the researchers would initiate an expansion cohort in 12 patients at the expected 35mg/m2 recommended phase II dose of PTX-200 to better characterize the safety profile of the combination.

Today, Prescient said that the trial was targeting women with metastatic and locally advanced HER2 negative breast cancer and the last patient had received treatment on the third dose level and had no dose limiting toxicity.

The company said that the recommended phase II dose would be 35mg/m2 PTX-200, with chemotherapy.

Prescient was up 0.4 cents or 4.5 percent to 9.3 cents.

ATCOR MEDICAL

Atcor says that Japan has granted a patent for measuring central aortic pressure waveforms using a standard brachial cuff with a transfer function.

Atcor said that the patent, entitled ‘Brachial Cuff’, provided protection until November 2032.

The company said that a transfer function was “the only proven methodology to non-invasively derive all central pressure waveform features … [which] were directly related to cardiovascular function and ensured equivalence to invasive measurement of central aortic pressures”.

Atcor said that its Sphygmocor diagnostic “pioneered this application of a transfer function and its intellectual property continues to protect the company from competitors replicating its precision”.

The company said that an application for the same patent was well advanced in US.

Atcor was up half a cent or three percent to 17 cents.

COCHLEAR

In two notices to the ASX yesterday, Veritas Asset Management says it had ceased its substantial holding in Cochlear, selling 1,074,184 shares.

In 2014, the London-based Veritas Asset Management said it had become substantial in Cochlear with the acquisition of 3,768,439 shares or 6.60 percent (BD: Nov 5, 2014).

Yesterday the company said it had bought and sold shares between November 17, 2014 and February 11, 2016 reducing its holding to 2,944,452 shares (5.15%) and later said it had sold a further 230,197 shares for $23,718,995 or $103.04 per share.

Veritas said the registered holders of the shares were State Street UK, Bank of New York Mellon, JP Morgan, National Bank of Australia, Northern Trust UK, Citibank Ireland, HSBC Ireland and BNP Paribas UK.

Cochlear fell $2.67 or 2.5 percent to $$104.00 with 384,188 shares traded.

MEDIBIO

Medibio says the first commercial pilot study of its heart rate stress test with corporate partner Vital Conversations has begun.

Medibio said that 27 employees of a Vital Conversations unnamed corporate client would undertaking their initial stress assessment overnight with further participants taking the initial stress assessment this week (BD: Sep 25, 2015).

The company said that Vital would provide the participants a variety of stress management support and activities over the next five weeks and at completion, the employees would retest using its corporate stress product.

Medibio said that along with measuring the impact of stress, the pilot study aimed to measure usability, employee acceptance and satisfaction, the delivery of the corporate stress product in the workplace and the ability to scale.

The company said that the pilot trial would allow collection of traditional subjective measures for stress and mental health assessment for comparison purposes.

Medibio said that the unnamed corporate client was a professional services company with more than 5,000 employees in Australia.

The company said that Vital had received “strong interest” for similar programs from a number of other potential corporate clients.

Medibio said that it expected a second commercial pilot trial of its corporate stress product to start in the next three weeks, which would include 30 to 50 participants in a “staff wellness program”.

The company said it expected revenue for the commercial pilot trial is in line with previous guidance of $40 to $60 per staff member per test.

Medibio was up one cent or five percent to 21 cents.

RECCE

Recce says that it will issue 4,152,423 shares, of which 2,907,717 will be issued to directors, on the conversion of the class A performance shares.

Recce said that the shares were conditional on achieving the milestone of the 20-day volume weighted average price exceeding 30 cents a share.

In January, Recce raised $5 million in an initial public offer at 20 cents a share (BD: Jan 27, 2016).

The company said that the shares would be escrowed until January 15, 2018.

In a series of Appendix 3Y director’s interest notices, Dongke Zhang acquired 56,250 shares, chief executive officer Dr Graham Melrose acquired 1,472,043 held jointly with his wife Olga Melrose, Ian David Brown acquired 56,250 shares, James Hamilton Bray Graham as trustee for the J Graham Family Trust acquired a direct and indirect interest in 745,962 shares and Michele Dilizia acquired 577,212 shares.

In a separate announcement, James Graham said that he and the J Graham Family Trust held 3,729,811 Recce shares or 5.13 percent.

Recce was unchanged at 33.5 cents.