Biotech Daily

Friday February 24, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IDT UP 17%, DIMERIX DOWN 12.5%**

*** DR BOREHAM'S CRUCIBLE: MESOBLAST**

*** AIRXPANDERS COMPLETES $45m PLACEMENT**

*** MAYNE H1 REVENUE UP 132% TO $295m, PROFIT UP 298% TO $71m**

*** CLINUVEL H1 REVENUE UP 395% TO $7m, LOSS TO $2.5m PROFIT**

*** ADMEDUS H1 REVENUE UP 86% to $12m, LOSS DOWN 50% TO $6.4m**

*** IMPEDIMED H1 REVENUE UP 12% TO $3m, LOSS UP 23% TO $14m**

*** ATCOR H1 REVENUE UP 9% TO $1.8m, LOSS DOWN 19% TO $1.9m**

*** PROBIOTEC H1 REVENUE DOWN 4.4% TO $29m, PROFIT UP 81% TO $545k**

*** CRESO'S HEALTH HOUSE APPROVED FOR MARIJUANA IMPORTS**

*** RECCE: 'IMAGES SHOW RECCE 327 KILLS E COLI IN 3 HOURS'**

*** JAPAN, EURO PATENTS FOR ANTISENSE ATL1103**

*** EURO PATENT FOR BPH'S CORTICAL DYNAMICS BRAIN MONITOR**

*** NAOS TAKES 7% OF BIOTECH CAPITAL**

*** LINKS, LOTSA, LAURENCE FREEDMAN REDUCE AGAIN TO 6.45% IN BIONOMICS**

*** PRIVATE PORTFOLIO MANAGERS TAKE 5.5% OF BIONOMICS**

*** AUSBIL DEXIA TAKES 7% OF BIONOMICS**

MARKET REPORT

The Australian stock market fell 0.79 percent on Friday February 24, 2017 with the ASX200 down 45.7 points to 5,739.0 points. Just six of the Biotech Daily Top 40 stocks were up, 22 fell, eight traded unchanged and four were untraded. All three Big Caps fell.

IDT was the best of the few, up 2.5 cents or 17.2 percent to 17 cents, with 433,656 shares traded. Admedus and Prima climbed more than six percent; Neuren was up 5.8 percent; with Factor Therapeutics and Nanosonics up more than one percent.

Dimerix led the falls, down 0.1 cents or 12.5 percent to 0.7 cents with 4.7 million shares traded. Impedimed and Uscom lost more than six percent; Prana retreated 5.6 percent; Airxpanders fell 4.6 percent; Actinogen was down 3.2 percent; Anteo, Atcor, Bionomics, Genetic Signatures, Mesoblast, Osprey and Viralytics shed more than two percent; Clinuvel, CSL, Ellex, Medical Developments, Orthocell, Pro Medicus, Resmed, Sirtex and Universal Biosensors were down more than one percent; with Cochlear, Compumedics and Starpharma down by less than one percent.

DR BOREHAM'S CRUCIBLE: MESOBLAST

By TIM BOREHAM

ASX code: MSB; **Nasdaq code (**American depository receipts**):** MESO

ASX Market cap: $646m (401.6m shares on issue); **Share price:** $1.61

Chief executive officer: Prof Silviu Itescu

Board: Brian Jamieson (chairman), Prof Itescu, William Burns, Donal O'Dwyer, Eric Rose, Michael Spooner, Ben-Zion Weiner

Financials: December quarter revenue of $US218,000 (year to date $US579,000); cash burn $US25.53 million ($US46.36 million year to date) and estimated current quarter outflows of $US26.8 million; cash at December 31, 2016 $US33.9 million ($US60.3 million at September 30, 2016). December balance excludes $US21.7 million from Mallinckrodt Pharma in January 2017, for a share placement.

Major shareholders (as of 2016 annual report): Silviu Itescu 17.9%, Cephalon (Teva Pharmaceuticals) 14.6%, M&G Investment Group 12.3%, Capital Research Global Investors 7.6%, Thorney Holdings 5.1%.

A multi-faceted excitement machine in the emerging global stem-cell therapies sector? Or a multi-pronged disappointer with a penchant for burning cash and with little prospect of serious near-term revenues?

Investors can take their pick with Mesoblast, the world's biggest listed player in the art of applying mesenchymal precursor cell (MPC) and mesenchymal stem cell (MSC) therapies to a range of serious and largely untreatable maladies.

Across its portfolio of 796 patents, Mesoblast is targeting cardiovascular disease, inflammatory disorders, such as rheumatoid arthritis, orthopaedic disease and oncological and haematologic conditions.

To the naysayers, Mesoblast's clinical results have not delivered the goods and are dispersed across too many indications. To the true believers, the light on the hill burns brightly if only one or two of its therapies crack their multi-billion dollar markets.

Without getting bogged down in the science, MPCs and MSCs are able to develop into other cells by flowing through the lymphatic and circulatory systems, as well as connective tissues such as bones and cartilage.

As such, they potentially have more useful applications than a Swiss Army Knife and the science is just as cutting edge.

Notably, Mesoblast has regulatory approval for one product – although critics would say just one product – and that was bought from Osiris in 2013 for about $100 million in a mix of cash and scrip.

In 2015, Japan licencee JCR Pharma won full approval from the country's gatekeepers to use the previously Osiris-owned and developed mesenchymal stem cells (MSCs) to treat acute graft versus host diseases (GvHD), an immunological condition following the receipt of foreign transplanted tissue.

The product, Temcell is to deliver unquantified royalty and milestone payments to Mesoblast.

Mesoblast also has three programs in phase-three stage, for advanced (class three) heart failure, chronic lower back pain and acute GvHD.

The heart failure program (MPC-150-IM) involves recruiting 600 patients in the US, with 300 enrolled already. An interim analysis, due in the current quarter will "guide" the company's discussions with the US Food and Drug Administration on an approval pathway.

Similarly, a 360-patient lower back pain trial (MPC-06-ID) is "recruiting well'' with enrolment completed this year. This follows a 100-patient phase-two trial over 24 months which showed a meaningful reduction in pain among the treated cohort.

The acute GvHD trial (MCS-100-IV) is targeted at paediatric patients with a severe immunological reaction to bone marrow transplants. This trial involves recruiting at least 60 patients across 40 centres, with a primary endpoint of an "overall response" at day 28.

A secondary endpoint is survival at day 100 for those with the 28-day response.

In the latest news, Mesoblast last week reported a "durable response" among rheumatoid arthritis patients after nine months having been treated with a single intravenous MPC dose.

The 48 patients in the phase II trial were resistant to the standard treatment, of anti-tumor necrosis factor (TNF) biologics. TNFs are the over-produced proteins causing the inflammation.

In what Prof Itescu dubs "highly encouraging" results, the company noted a "durable improvement in clinical symptoms, physical function and disease relative to the placebo [group]".

Prospects:

With apologies to Bill Lawry, it's all happening at the MSB. The trouble is the white-coat brigade is so busy it's hard to make sense of the busy clinical schedule, although maybe Dr Criterion is just a bit dense.

Mesoblast's current year timetable includes an interim analysis of the phase III heart failure results by April 2017 and a further read out on the phase II program by the end of 2017.

Also expect nine-month data on the MPC-300-IV program by July 2017, as well as a GvHD update by the end of the year.

Management also promises “potential corporate partnerships” - hopefully the variety yielding up-front dollars and lucrative milestone payments.

The deal with Mallinckrodt includes an exclusive right to negotiate a development partnership for moderate to severe chronic lower back pain and acute GvHD (globally, but excluding Japan and China).

Mesoblast can also tap up to $120 million of equity over the next few years, via an equity facility with the small Melbourne investment house Kentgrove Capital. Ultimately, the funding is sourced from a cabal of high-net worth families.

Dr Boreham’s Diagnosis:

When Mesoblast shares hit $10.04 a share on October 24, 2011, investors were dazzled by the blue sky potential of the emerging science. Few on the institutional side questioned the lofty valuation, with the exception of Macquarie Equities then health analyst Dr Craig Collie.

Then the merde hit the oscillating cooling device.

Apart from slower than expected clinical and commercial progress, the market was underwhelmed by the $US68 million November 2015 Nasdaq raising (and listing), struck at a steep discount to the then value of the ASX-listed shares.

In June last year, the shares fell 28 percent in a day (to $1.52) after partner Teva Pharmaceuticals walked away from backing an expensive chronic heart failure trial.

The problem here is that the deal was struck with Cephalon in 2011, but Cephalon was then subsumed by the Israel-based Teva which has more of a focus on generic drugs.

Fair enough, but management had continued to stress Teva’s involvement as a sure thing – right up to the day it wasn’t. Despite terminating its partnership, Teva remains a 14 percent shareholder.

Mesoblast shares then drifted to as low as $1.01, before being turfed out of the ASX200 index.

Since its October 2016 nadir the stock has gained favour with a drip feed of promising results and internal efforts to reduce the cash burn.

Dr Boreham has more reservations than the Hilton on this one (the hotel, not Paris). On balance though, the stock looks to have hit its nadir and a smidgen of decent news from the upcoming trials will spur a rerating.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Nor does Dr Pepper and he runs a multi-billion dollar soft drink conglomerate, so don’t be too critical.

AIRXPANDERS

Airxpanders says it has issued 22,376,544 Chess depository instruments (CDIs) in the $20.6 million tranche, completing its $45 million placement at 92 cents per CDI.
Airxpanders fell four cents or 4.6 percent to 83 cents.

MAYNE PHARMA GROUP

Mayne Pharma says its revenue for the six months to December 31, 2016 rose 131.7 percent to $294,831,000 taking net profit after tax up 298.3 percent to $71,323,000.
Mayne said that diluted earnings per share was up 110.5 percent to 5.03 cents for the six months to December 31, 2016, with net tangible assets per share up 27.5 percent to 5.1 cents.
The company said it had cash and cash equivalents of $80,820,000 at December 31, 2016 compared to $49,735,000 at December 31, 2015.
Mayne fell 2.5 cents or 1.7 percent to $1.475 with 14.6 million shares traded.

CLINUVEL

Clinuvel says revenue for the six months to December 31, 2016, was up 395.2 percent to $6,990,666 with the previous loss turned to net profit after tax of $2,522,519.
Clinuvel said that commercial sales of Scenesse began in June 2016 and it had its first full six months of sales under its marketing authorisation.
The company said that revenue for the six months to December 31, 2016 was $4,180,724, with sales to centres in the Netherlands, Germany, Austria and Italy.
Clinuvel said that the subsidised supply of Scenesse implants under the special access reimbursement schemes of Italy and Switzerland generated $2,669,292 in revenue for the six months, compared to $1,317,195 for the six months to December 31, 2015.
The company said that the previous diluted loss per share of 7.3 cents for the six months to December 31, 2015 turned around to 5.3 cents diluted earnings per share for the six months to December 31, 2016, while net tangible assets per share climbed 115.0 percent to 43 cents at December 31, 2016 compared to 20 cents at December 31, 2015.
The company said it had cash and cash equivalents of $19,550,345 at December 31, 2016, compared to $7,498,767 at December 31, 2015.
Clinuvel fell 12 cents or 1.7 percent to $6.78.

ADMEDUS

Admedus says that revenue for the six months to December 31, 2016, was up 86.4 percent to $12,241,195 with net loss after tax down 50.3 percent to $6,397,387.
Admedus said that all businesses and geographical sectors improved with Cardiocel sales up 51 percent to $3.5 million compared to the previous corresponding period, with the infusion business up 103 percent to $8.7 million and expenses were reduced by 32 percent to $11.9 million.
The company said that basic loss per share fell 61.4 percent to 2.68 cents for the six months to December 31, 2016, with net tangible assets per share up 62.2 percent to 9.05 cents.
Admedus said it held cash and cash equivalents of $14,343,543 at December 31, 2016, compared to $19,152,186 at December 31, 2015.
Admedus was up two cents or 6.7 percent to 32 cents.

IMPEDIMED

Impedimed says that revenue for the six months to December 31, 2016 was up 11.6 percent to $3,053,000 with net loss after tax up 23.0 percent to $13,793,000.
Impedimed said the revenue was primarily from sales of its L-Dex U400 lymphoedema test, as well as its body composition diagnostic technology.
The company said that diluted loss per share was constant at 4.0 cents for the six months to December 31, 2016, while net tangible assets per share climbed 137.5 percent to 19 cents, compared to 8.0 cents at December 31, 2015.
The company said it had cash and cash equivalents of $73,236,000 at December 31, 2016, compared to $25,152,000 at December 31, 2015.
Impedimed fell 5.5 cents or 6.7 percent to 76.5 cents with 1.6 million shares traded.

ATCOR MEDICAL

Atcor says its revenue for the six months to December 31, 2016 was up 8.7 percent to $1,838,977 reducing net loss after tax by 18.7 percent to $1,868,095.
Atcor said that its net tangible asset backing per share fell 52.0 percent from 2.5 cents at December 31, 2015 to 1.2 cents at December 31, 2016.
The company said that diluted loss per share was 0.89 cents compared to the previous corresponding period's 1.17 cents.
Atcor said it held cash and cash equivalents of $1,747,247 at December 31, 2016 compared to $3,784,442 at December 31, 2015.
Atcor fell 0.1 cents or 2.6 percent to 3.8 cents.

PROBIOTEC

Probiotec says its revenue for the six months to December 31, 2016 fell 4.4 percent to $28,617,000, but net profit after tax was up 81.3 percent to $545,000.
Probiotec said it would pay a fully franked 0.5 cents a share dividend for holders at the record date of March 22, 2107.
The company said that the decrease in sales "was primarily due to the rationalization of several low margin products within the contract manufacturing segment together with supply disruptions within our Europe segment".
Probiotec said that excluding the impacts, sales revenue was consistent with the prior corresponding period.
The company said that its net tangible assets per share was up 5.1 percent to 46.0 cents at December 31, 2016, with diluted earnings per share for continuing activities was up 80.7 percent to 1.03 cents.
Probiotec said it held cash and cash equivalents of $141,203 at December 31, 2016 compared to $123,514 at December 31, 2015.
Probiotec was up two cents or 4.1 percent to 51 cents.

CRESO PHARMA

Creso says the Federal Government has granted an import and export licence to its facilitator in Australia, Health House International Pty Ltd (BD: Feb 2, 2017).
Creso was up four cents or 14.8 percent to 31 cents with 3.0 million shares traded.

RECCE

Recce says its Recce 327 synthetic antibiotic can kill Escherichia coli gram-negative bacteria in three hours, in-vitro.
Recce released electron microscope images showing healthy, smooth and intact E coli cells, followed at 20 minutes demonstrating significant cell membrane weakening and disruption and at three hours there was cell lysis and the bacteria were dead.
The company said that the electron microscope images were generated by Dr Peta Clode and Lyn Kirilak of the Centre for Microscopy, Characterisation and Analysis, at the University of Western Australia.
Recce said the images and data along with in-vitro and in-vivo data would be used to support its investigational new drug application (IND) submission to the US Food and Drug Administration for a phase I trial in sepsis, or blood poisoning from bacteria.
Recce was up 1.5 cents or 6.25 percent to 25.5 cents.

ANTISENSE THERAPEUTICS

Antisense says it has been granted European and Japanese patents relating to ATL1103 targeting the growth hormone receptor for acromegaly.
Antisense said that both patents were entitled ‘Modulation of Growth Hormone Receptor Expression and insulin like growth factor expression, with that both patents providing protection to February 2024 and could be extended to 2029.
The company said the European claims covered ATL1103 “and many other active oligonucleotides 20 nucleo-bases in length that target [growth hormone receptor]”.
Antisense said it planned to register the patent in Germany, France, Italy, UK, Spain, Netherlands, Switzerland, Sweden, Finland and Denmark.
The company said that the Japanese Patent covered ATL1103 “and many other potent oligonucleotides to [growth hormone receptor] for use in the reduction of serum insulin growth factor-1 (sIGF-1).
Antisense said it had all its patents that covered ATL1103 registered or allowed in the US, Canada, Europe, Japan, and Australia.
The company said it was expanding and extending the life of its intellectual property protection by filing applications on the use of ATL1103 in combination with the marketed acromegaly treatments Somavert and the somatostatin analogues, including applications under examination in the US, Europe, Japan, Canada and Australia, which would provide protection to 2033 and 2034 and potentially extendible up to a further five years.
Antisense said that a New Zealand patent was the first granted relating to patent family applications covering the use of ATL1103 in combination with Somavert for potential enhanced efficacy in patients who do not have their sIGF-1 normalized with mono-therapies, and was registered to 2033.
The company said it expected new patent applications on ATL1103 as data was generated in other disease indications such as cancer.
Antisense was up 0.2 cents or 5.7 percent to 3.7 cents with one million shares traded.

BPH ENERGY

BPH says the European Patent Office has granted 3.9 percent subsidiary Cortical Dynamics a patent relating to its brain anaesthesia monitor.
BPH said the patent was entitled ‘Brain function monitoring and display system’ but did not state the duration of coverage.
BPH was up 0.05 cents or 8.3 percent to 0.65 cents.

BIOTECH CAPITAL

Naos Asset Management has increased its substantial shareholding in Biotech Capital from 5,561,812 shares (5.12%) to 8,754,085 shares (7.19%).
The Martin Place, Sydney-based, Naos said it was acting as investment manager for "various trustee companies" and the registered holder was Australian Executor Trustees, but failed to cite the cost of the 3,192,273 shares acquired on-market, as required under the Corporations Act 2001.
Biotech Capital was up one cent or 9.1 percent to 12 cents.

BIONOMICS

Laurence Freedman and associated companies have reduced their shareholding in Bionomics again, from 37,537,873 shares (7.80%) to 31,037,837 shares (6.45%).
Last year, the Laurence Freedman group reduced their holding from 40,187,873 shares (9.75%) to 37,537,873 shares (7.80%)(BD: Apr 11, 2016).
Today, the substantial shareholder notice, signed by the Sydney-based Mr Freedman, said the shares were held through Link Superannuation Fund, Link 405 Pty Ltd, Link Enterprises (International) Pty Ltd and Lotsa Nominees Pty Ltd.
The notice said that between September 21, 2016 and February 22, 2017 the group sold shares with the single largest sale 3,000,000 shares for $1,103,895 or 36.8 cents a share.
Bionomics fell one cent or 2.4 percent to 40 cents.

BIONOMICS

The Sydney-based Private Portfolio Managers says it has become a substantial shareholder in Bionomics again with 26,403,534 shares (5.48%).
Private Portfolio Managers previously became substantial in Bionomics in 2015 but was diluted below 5.0 percent in a series of issues of shares in employee share schemes (BD: Oct 29, 2015).
Private Portfolio Managers said that it bought and sold shares between October 4, 2016 and February 15, 2017, with the single largest purchase 3,000,000 shares on February 15 for $1,113,663 or 37.1 cents a share.

BIONOMICS

Ausbil Dexia says it has increased its substantial shareholding in Bionomics from 27,449,999 shares (5.71%) to 33,737,603 shares (7.007%).
The substantial shareholder notice said that Ausbil Dexia bought shares between September 26, 2016 and February 22, 2017 with the single largest acquisition on February 22 of 3,372,418 shares for $1,348,967 or 40 cents a share.
Ausbil Dexia said it was an investment manager for a number of institutional investors which were generally superannuation funds.