



Biotech Daily

Thursday February 18, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: COMPUMEDICS UP 25%, ORTHOCELL DOWN 9%**
- * **FDA GRANTS BIOTA FAST TRACK FOR MELBOURNE'S BTA585 FOR RSV**
- * **BIOTRON: BIT225 ACTIVE AGAINST HIV-1 IN DENDRITIC CELLS**
- * **NANOSONICS H1 REVENUE UP 1% TO \$16m, PROFIT TO \$3m LOSS**
- * **MEDICAL DEV H1 REVENUE UP 9% TO \$6m, PROFIT DOWN 68% TO \$236k**
- * **BIONOMICS H1 REVENUE UP 39% to \$10m, LOSS UP 71% TO \$10m**
- * **STARPHARMA H1 REVENUE UP 410% TO \$3.7m, LOSS UP 17.5% TO \$2m**
- * **SOMNOMED H1 REVENUE UP 27% TO \$21m, PROFIT UP 199% TO \$178.5k**
- * **ALLAN GRAY INCREASES, DILUTED TO 14.4% OF IMPEDIMED**
- * **CREDIT SUISSE 'RETURNS' ADHERIUM SHARES TO BELOW 5%**

MARKET REPORT

The Australian stock market climbed 2.25 percent on Thursday February 18, 2016 with the ASX200 up 109.9 points to 4,992.0 points. Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and one was untraded.

Compumedics was the best, up eight cents or 25 percent to 40 cents with 178,752 shares traded, followed by Biotron up 17.5 percent to 6.7 cents with 2.9 million shares traded.

Actinogen climbed 9.1 percent; Tissue Therapies was up 7.9 percent; Genetic Technologies, Neuren and Pro Medicus were up five percent or more; Bionomics and Prana improved more than four percent; Osprey and Universal Biosensors were up more than three percent; Acrux, Anteo, Benitec and Clinuvel rose two percent or more; with Cochlear, Impedimed, Living Cell and Mesoblast up more than one percent.

Orthocell led the falls, down four cents or 8.7 percent to 42 cents with 335,819 shares traded, followed by Medical Developments down 5.4 percent to \$4.00 with 416,880 shares traded.

Both Avita and Optiscan fell 4.8 percent; Pharmaxis lost 3.45 percent; Antisense, Oncosil, Prima and Viralytics shed more than two percent; CSL, IDT, Reva and Starpharma were down more than one percent; with Resmed and Sirtex down by less than one percent.

BIOTA PHARMACEUTICALS

Biota says the US Food and Drug Administration has granted fast track status for BTA585 for respiratory syncytial virus (RSV) infections in infants, young children and adults.

Biota said that the fast track process was designed to expedite the development and review of drugs used in the treatment of serious or life-threatening conditions and which demonstrate potential to address unmet medical needs.

Biota chief executive officer Dr Joseph Patti said that there were “no direct antiviral products approved to treat the millions of RSV infections that occur each year in the US and we are pleased that the FDA has recognized BTA585 and its potential to address this significant unmet medical need”.

Biota said that BTA585 was an oral respiratory syncytial virus fusion inhibitor, which had completed a phase I single ascending dose trial and recently completed dosing in a multiple ascending dose trial with results expected to be reported by April 2016, and a phase II RSV challenge trial expected to begin by July 2016.

Biota began its respiratory syncytial virus program in Melbourne, but in 2009 Astrazeneca halted work on BTA9881 on safety grounds (BD: Aug 10, 2009).

Biota said at that time that BTA9881 was the first of a new class of fusion inhibitors and showed strong oral bioavailability but “the BTA9881 drug profile overall did not meet the desired safety margin required to continue development of this compound”.

The company said BTA9881 had about “100 percent oral bioavailability in humans and a safety profile ... comparable to placebo at the doses examined”, the pharmacokinetic profile indicated a very long plasma half-life in humans.

Biota said all rights to the program reverted to it and it intended to invest \$3 million in 2009-'10 for the development of back-up compounds and to re-licence the program.

A former Biota executive told Biotech Daily that BTA585 was invented in Melbourne.

Dr Patti told Biotech Daily yesterday that there were “approximately 9,000 [Australian] shareholders averaging less than 1,000 shares each”, and with about 38.64 million shares on offer, Australian investors own about 23.3 percent of the company.

Last night on the Nasdaq, Biota climbed 27 US cents or 19.57 percent to \$US1.65 (\$A2.30, equivalent to 28.75 cents prior to departing the ASX) with 78,439 shares traded. Biota was trading at \$2.17 a share in August 2009.

BIOTRON

Biotron says that BIT225 is active against HIV-1 in dendritic cells, which are among the first cells to become infected and are responsible for spreading virus through the body.

Biotron said the new data was reported in an article ‘The antiviral compound BIT225 inhibits HIV-1 replication in myeloid dendritic cells’ co-authored by chief executive officer Dr Michelle Miller, published last week in the journal AIDS Research and Therapy and available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4745167/>.

Biotron said that stopping HIV-1 in those cells had the potential to prevent HIV-1 infection becoming established.

The company said the data broadened BIT225's antiviral activity profile within cells of the myeloid lineage and suggested a potential role for BIT225 in reducing HIV-1 production and preventing viral spread in early and chronic infection.

Biotron said that BIT225 activity against HIV-1 in dendritic cells could “assist in limiting virus spread with any on-going viral replication during antiretroviral therapy”.

The company said BIT225 had shown promising efficacy against HCV and HIV, had been tested in more than 200 people, with a phase II HIV trial expected to begin this year.

Biotron was up one cent or 17.5 percent to 6.7 cents with 2.9 million shares traded.

NANOSONICS

Nanosonics says that revenue for the six months to December 31, 2015, was up 0.7 percent to \$16,431,000, with the previous \$1,238,000 net profit after tax, turning to a loss of \$3,245,000.

In a teleconference Nanosonics chief executive officer Michael Kavanagh said that although sales revenue for the Trophon EPR ultrasound probe cleansing system rose 8.6 percent to \$15,577,000, the half year loss was due to increased investment associated with the establishment of the direct North American operations, an increase in marketing investment, increased research and development expenditure, lower production overhead recoveries resulting from lower production volumes and a reduction in other income of \$1,371,000 associated with reduced reimbursement of costs.

Mr Kavanagh said that although there had been no orders from GE Healthcare in the six month period, GE sales were strong and GE would buy more stock "this quarter".

Mr Kavanagh said the company had plans to expand its UK sales force ahead of expected new probe cleaning guidelines in England and Scotland.

He said he expected "positive momentum to continue into the second half" of the year.

Nanosonics said that diluted earnings per share of 0.46 cents for the six months to December 31, 2014, turned to a diluted loss per share of 1.20 cents for the six months to December 31, 2015, with net tangible assets per share up 79.8 percent to 14.76 cents.

The company said it had cash and cash equivalents of \$42,628,000 at December 31, 2015, compared to \$45,724,000 at June 30, 2015.

Nanosonics was unchanged at \$1.97.

MEDICAL DEVELOPMENTS

Medical Developments says revenue for the six months to December 31, 2015, was up 8.9 percent to \$5,991,000 with net profit after tax down 67.7 percent to \$236,000.

Medical Developments said that in the six months to December 31, 2015 it had invested in new premises, new manufacturing processes and facility, patents, legal advice and fees relating to commercial agreements.

The company said that it had received substantial upfront and milestone payments during the half year totalling \$10.9 million, but "for accounting purposes these payments are deferred and amortised into the income statement over the term of the agreements".

Medical Developments said it had one-off costs including a \$300,000 unrealised foreign exchange loss "but we are confident these investments will deliver significant long term sustainable growth for our company".

The company said it would not renew the Pharmac New Zealand respiratory devices supply contract, due to pricing requirements which would reduce the gross margin.

Medical Developments said that the six months to June 30 2016 was "expected to deliver a considerable improvement in sales and profits" but the full effects of Pentrox sales into the UK, EU, South Africa and Singapore and respiratory sales into the US, Canada and the EU would not be seen fully until June 30, 2017.

Medical Developments declared a two cent per share dividend for the half year to December 31, 2015 for record holders at March 4, 2015 to be paid on April 8, 2016.

The company said that diluted earnings per share fell 67.7 percent to 0.41 cents at December 31, 2015 compared to 1.27 cents for the previous period, with tangible asset per share up 200 percent to 0.3 cents.

Medical Developments said that cash and cash equivalents at December 31, 2015 was \$9,552,000 compared to \$954,000 at June 30, 2015.

Medical Developments fell 23 cents or 5.4 percent to \$4.00 with 416,880 shares traded.

BIONOMICS

Bionomics says that revenue for the six months to December 31, 2015, was up 39.4 percent to \$10,209,076 with net loss after tax up 70.7 percent to \$9,690,834.

Bionomics said that revenue of \$4,076,756 consisted of drug discovery and development, contract services, licence fees, collaboration income, royalties, sales income, rental income and interest income received as a result of ordinary activities, while \$6,132,320 of other income came from government grants and assistance including the Research and Development Tax Incentive and other forms of income.

The company said that diluted loss per share increased 57.1 percent to 2.2 cents for the six months to December 31, 2015 and net tangible asset backing per share was up 34.4 percent from 6.1 cents at December 31, 2014 to 8.2 cents at December 31, 2015.

Bionomics said it had cash and cash equivalents of \$51,407,979 at December 31, 2015, compared to \$26,558,006 at June 30, 2015.

Bionomics was up 1.5 cents or 4.8 percent to 33 cents.

STARPHARMA

Starpharma says that revenue for the six months to December 31, 2015 was up 410.2 percent to \$3,740,000 mostly from an Astrazeneca up-front fee.

Starpharma said that net loss after tax was up 17.5 percent to \$2,089,000, with research and development expenditure up 64.6 percent to \$11,685,000 and administration and finance costs reduced by \$85,000 or 3.9 percent to \$2,089,000.

The company said the revenue came from royalty, licencing and research of which \$2.9 million was an upfront payment for the Astrazeneca licence (BD: Sep 7, 2015).

Starpharma said that diluted loss per share increased 9.5 percent to 3.10 cents for the six months to December 31, 2015 compared to the previous corresponding period and it had cash and cash equivalents of \$54,688,000 at December 31, 2015.

Starpharma fell one cent or 1.7 percent to 57.5 cents.

SOMNOMED

Somnomed says revenue for the six months to December 31, 2015, was up 26.7 percent to \$21,375,411 with net profit after tax up 198.5 percent to \$178,529.

Somnomed said that unit sales of its anti-snoring devices climbed 28.8 percent in North America, 2.2 percent in Europe and 11.2 percent in the Asia-Pacific region.

The company said that diluted earnings per share was up 191.7 percent to 35 cents at December 31, 2015 compared to 0.7 cents for the previous period with net tangible asset backing per share up 4.1 percent to 23.76 cents.

Somnomed said that cash and cash equivalents at December 31, 2015 was \$7,423,561 compared to \$8,305,556 at December 31, 2014.

Somnomed was up seven cents or 2.75 percent to \$2.62.

IMPEDIMED

Allan Gray Australia has further increased its substantial holding in Impedimed but has been diluted from 45,389,539 shares (15.48%) to 48,791,564 shares (14.44%).

Allan Gray said that it bought and sold shares between July, 21, 2015 and February 9, 2016, including acquiring shares in last week's placement of \$75 million at 95 cents a share (BD: Feb 15, 2016).

Impedimed was up 1.5 cents or 1.7 percent to 88.5 cents.

ADHERIUM

Credit Suisse Australia on behalf of Credit Suisse Group AG says it has ceased its substantial shareholding in Adherium by “returning” 2,792,674 borrowed shares.

On Tuesday, Credit Suisse said it had become a substantial shareholder in Adherium with 7,173,182 shares (5.01%), of which 4,669,425 shares were acquired under a securities lending agreement (BD: Feb 16, 2016).

Today the company said it had returned 2,792,674 shares “under [a] master prime brokerage agreement”, implying that it retains 4,380,508 shares or 4.05 percent of the company.

Adherium was unchanged at 50 cents.