



Biotech Daily

Monday February 27, 2017

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: BENITEC UP 15%, VIRALYTICS DOWN 8%
- * GUIDELINES BACK NANOSONICS TROPHON DECONTAMINATION
- * ORTHOCELL: '2-YEAR DATA BACKS ORTHO-ATI FOR GLUTEAL TENDINOPATHY'
- * ELLEX H1 REVENUE DOWN 2% TO \$34m, PROFIT DOWN 14% TO \$1m
- * UNIVERSAL BIOSENSORS REVENUE UP 12% TO \$19m, LOSS TO \$1m PROFIT
- * MESOBLAST H1 REVENUE DOWN 92% TO \$1m, LOSS UP 12% TO \$52m
- * MACH7 H1 REVENUE UP 1594% TO \$5m, LOSS UP 205% TO \$4m
- * SUDA H1 REVENUE 26% to \$3.6m, LOSS DOWN 49% TO \$917k
- * OBJ H1 REVENUE UP 3% to \$1.4m, LOSS UP 107% TO \$2.5m
- * ANTEO H1 REVENUE UP 2063% TO \$12m, LOSS DOWN 0.3% TO \$3m
- * GENETIC SIGNATURES REVENUE UP 18% TO \$1m, LOSS DOWN 17% TO \$1.3m
- * BIOXYNE H1 REVENUE DOWN 25% TO \$916k, PROFIT TO \$72k LOSS
- * STARPHARMA H1 REVENUE DOWN 85% TO \$576k, LOSS DOWN 10% TO \$9m
- * CORRECTION: ATCOR
- * CLARIFICATION: CYCLOPHARM
- * AUSTRALIA ACCEPTS IMUGENE HER-VAXX PATENT APPLICATION
- * BOTANIX FILES 5 PERMETREX PATENT APPLICATIONS
- * CVC BELOW 5% OF BIONOMICS
- * ROBINWOOD TAKES 44% OF ALLEGRA
- * ITL REBRANDS AS ITL HEALTH GROUP
- * BIOTECH CAPITAL APPOINTS DR ROCCO IANNELLO BUSINESS DEVELOPMENT

MARKET REPORT

The Australian stock market fell 0.26 percent on Monday February 27, 2017 with the ASX200 down 14.8 points to 5,724.2 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, nine traded unchanged and three were untraded. All three Big Caps rose.

Benitec was the best, up 2.5 cents or 15.15 percent to 19 cents, with 85,376 shares traded. Nanosonics climbed 9.0 percent; Universal Biosensors was up 8.45 percent; Impedimed was up 5.9 percent; Ellex improved 4.1 percent; Polynovo was up 3.6 percent; Uscom rose 2.3 percent; Acrux, Factor Therapeutics, Mesoblast and Resmed were up more than one percent; with Cochlear, CSL and Pro Medicus up by less than one percent.

Viralytics led the falls, down 7.5 cents or 8.1 percent to 85 cents with 285,846 shares traded. Genetic Signatures and Starpharma lost more than six percent; Prima retreated 5.7 percent; Airxpanders, Avita, Clinuvel and Neuren fell more than four percent; Atcor, Compumedics, Oncosil and Orthocell shed more than two percent; with Admedus, Cyclopharm, Medical Developments, Osprey and Sirtex down by less than one percent.

NANOSONICS

Nanosonics says that three sets of guidelines “establish and reinforce ... high level disinfection of semi critical ultrasound probes between every patient use”.

Nanosonics said the World Federation for Ultrasound in Medicine and Biology published its ‘Guidelines for cleaning trans-vaginal ultrasound transducers between patients’; the Australasian Society for Ultrasound in Medicine and the Australasian College for Infection Prevention and Control had published joint ‘Guidelines for reprocessing ultrasound transducers’; and Ireland’s Health Service Executive published its ‘Guidance for decontamination of semi-critical ultrasound probes; semi-invasive and non-invasive ultrasound probes’.

The company said the World Federation’s membership included the American Institute of Ultrasound in Medicine, the Australasian Society for Ultrasound in Medicine, the European Federation for Ultrasound in Medicine and Biology, the Asian Federation for Ultrasound in Medicine and Biology, the Federation of Latin American Ultrasound Societies and the Mediterranean and African Society of Ultrasound.

Nanosonics said that the World Federation guidance defined semi-critical devices as those that pose a higher risk because of contact with non-intact skin or mucous membranes and recommended high level disinfection for such probes.

The company said that the guidance identified its Trophon ultra-sound probe disinfection system, describing it as “very efficient, rapid (approximately 7 min), environmentally friendly and quality-ensured and disinfects the transducer handle”.

Nanosonics said that the Australian new guidelines emphasized applying high level disinfection to all surface probes used in semi-critical procedures.

The company said the Irish guidelines said that “the use of an automated validated process for decontaminating ... will provide enhanced risk reduction of infection”.

Nanosonics chief executive officer Michael Kavanagh said the three new guidelines showed “the growing international recognition of the risks associated with the potential for cross contamination with ultrasound transducers and the importance of implementing strict controls to mitigate these risks”.

“Our Trophon technology is ideally positioned to meet the requirements outlined in these new guidelines,” Mr Kavanagh said.

Nanosonics climbed 23 cents or 9.0 percent to \$2.78 with 1.5 million shares traded.

ORTHOCELL

Orthocell says that two-year data on its autologous tenocyte injection (Ortho-ATI) for in degenerate hip, or gluteal, tendons shows reduced pain and increased function. Orthocell said that the study was of 12 women with a mean duration of symptoms of 33 months who had failed to respond to existing conservative treatments including physiotherapy and corticosteroid injections.

The article, entitled 'Autologous Tenocyte Injection for the Treatment of Chronic Recalcitrant Gluteal Tendinopathy' was co-authored by Orthocell chief scientific officer Prof Ming-Hao Zheng was published in the Orthopaedic Journal of Sports Medicine with an abstract at: <http://journals.sagepub.com/doi/full/10.1177/2325967116688866>.

The abstract concluded that Ortho-ATI for gluteal tendinopathy was "safe, with improved and sustained clinical outcomes to 24 months".

The company said that Ortho-ATI "significantly improved the clinical outcome of patients with long term gluteal tendon degeneration including reduced pain and increased functionality at three months and maintained out to two years following a single ultrasound guided injection of Ortho-ATI".

Orthocell said that the paper supported Ortho-ATI as a durable long term product for degenerate, treatment resistant tendons.

The company said that gluteal tendinopathy was a common and difficult injury to treat, affecting mostly women between the ages of 35 and 65 years.

Orthocell said that high levels of dysfunction had been found in people with gluteal tendinopathy who failed conservative treatment including loss of full time employment, higher pain levels and poorer quality of life.

Orthocell quoted the chief investigator Dr Greg Janes saying the research "highlights the exciting potential of Ortho-ATI as a minimally invasive and targeted cellular therapy for degenerate tendon conditions".

Orthocell managing-director Paul Anderson said the data supported "the on-going validation of Ortho-ATI as a minimally invasive cell therapy to treat tendons that have failed to respond to conservative treatments and adds to the growing body of published data that supports Ortho-ATI as a treatment option for degenerate tendons".

Orthocell fell one cent or 2.25 percent to 43.5 cents.

ELLEX MEDICAL LASERS

Ellex says revenue for the six months to December 31, 2016, fell 1.6 percent to \$34,259,000 with net profit after tax down 14.0 percent to \$1,004,000.

Ellex said that revenue fell 3.5 percent to \$30,386,000 in its laser and ultrasound sector, the Itrack division was up 32.4 percent to \$3,637,000, with the 2RT segment down 58.5 percent to \$236,000.

Ellex chief executive officer Tom Spurling said the company's production facility had been unable to meet demand late in the six month period, following the launch of the Tango Reflex multi-modality laser in November, resulting in "a significant customer order backlog as at December 31, 2016".

The company said that net tangible assets per share was up 63.2 percent to 31 cents and diluted earnings per share fell 19.4 percent to 0.87 cents at December 31, 2016 compared to 1.08 cents for the previous period.

Ellex said that cash and cash equivalents of \$14,146,000 at December 31, 2016 compared to \$4,215,000 at December 31, 2015.

Ellex was up five cents or 4.1 percent to \$1.28.

UNIVERSAL BIOSENSORS

Universal Biosensors says revenue for the 12 months to December 31, 2016 rose 12.3 percent to \$18,830,817, turning the previous \$6,576,416 loss to a \$1,250,276 net profit after tax.

Universal Biosensors executive chairman Andrew Denver said it had been “a solid year with a focus on two lead products we developed, LifeScan’s Onetouch Verio blood glucose test strips and Siemens’ Xprecia Stride Coagulation Analyzer and lowering the cost base of the business”.

“The quarterly service fees [have] a 100 percent margin which bolsters the company’s growing revenue stream, improving overall profitability and cash flow,” Mr Denver said. “With increasing corporate activity in the US and Europe, we expect to see the revenue stream continue to grow in [2017] for the Xprecia StrideM Coagulation Analyzer,” Mr Denver said.

Universal Biosensors said that research and development expenses fell 19.7 percent to \$15,867,462 or 84.3 percent of total revenue.

The company said that net tangible asset per share was constant at eight cents at December 31, 2016 and last year’s 4.0 cent diluted loss per share turned around to a 1.0 cents diluted earnings per share.

Universal Biosensors said it had cash and equivalents of \$20,402,322 at December 31, 2016 compared to \$14,350,307 at December 31, 2015.

Universal Biosensors was up three cents or 8.45 percent to 38.5 cents.

MESOBLAST

Mesoblast says that revenue for the six months to December 31, 2016 fell 91.8 percent to \$US945,000 (\$A1,229,160), with net loss after tax up 12.3 percent to \$US39,849,000 (\$A51,832,950).

Mesoblast said that research and development spending increased 23.1 percent to \$US29,047,000, management and administration expenses fell 8.1 percent to \$US10,338,000, with manufacturing commercialization costs down 50.5 percent to \$US7,085,000.

The company said that its net tangible liability per ordinary security increased 134.7 percent to 5.00 cents.

Mesoblast said the diluted loss per share was up 1.8 percent to 10.50 US cents

The company said that cash and cash equivalents at December 31, 2016 was \$US33,902,000, compared to \$US120,783,000 at December 31, 2015.

Mesoblast climbed two cents or 1.2 percent to \$1.66.

MACH7 TECHNOLOGIES

Mach7 says that revenue for the six months to December 31, 2016, was up 1594 percent to \$4,786,000 with net loss after tax up 205 percent to \$3,945,000.

Mach7 said that revenue came primarily from software licence fees and, professional service fees and annual maintenance fees.

The company said that diluted loss per share increased 33.3 percent to 0.4 cents for the six months to December 31, 2016, with net tangible assets per share up 25 percent to 0.5 cents.

Mach7 said it had cash and cash equivalents of \$5,511,315 at December 31, 2016, compared to \$2,580,444 at December 31, 2015.

Mach7 was up three cents or 9.7 percent to 34 cents.

SUDA

Suda says that revenue for the six months to December 31, 2016, was up 25.5 percent to \$3,557,000 with net loss after tax down 49.3 percent to \$917,000.

Suda said it received \$390,828 from its first licence agreement with China's Eddingpharm for its Zolpimist project and subsidiary Westcoast Surgical and Medical Supplies increased revenue by 12 percent for its supply of pharmaceuticals, consumables and vaccines.

The company said that diluted loss per share fell 50 percent to 0.08 cents for the six months to December 31, 2016, with net tangible assets per share down 52.2 percent to 0.11 cents.

The company said it had cash and cash equivalents of \$1,219,834 at December 31, 2016, compared to \$3,395,612 at December 31, 2015.

Suda fell 0.4 cents or 17.4 percent to 1.9 cents with 1.2 million shares traded.

OBJ

OBJ says that revenue for the six months to December 31, 2015, was up 3.2 percent to \$1,439,943 with net loss after tax up 106.9 percent to \$2,452,847.

OBJ said that the revenue was primarily licencing fees from Procter & Gamble.

The company said that diluted loss per share was up 100 percent from 0.07 cents in the previous year to 0.14 cents for the six months to December 31, 2016, with net tangible assets per share down 20.0 percent to 0.4 cents.

The company said it had cash and cash equivalents of \$5,560,028 at December 31, 2016, compared to \$8,191,606 at December 31, 2015.

OBJ fell 0.4 cents or 6.25 percent to six cents with 1.5 million shares traded.

ANTEO DIAGNOSTICS

Anteo says that revenue for the six months to December 31, 2016, was up 2,063 percent to EUR8,567,000 (\$A11,769,770) with net loss after tax down 0.3 percent to EUR2,024,000 (\$A2,780,670).

Last year, Anteo posted revenue for the six months to December 31, 2015 of \$1,144,411 with net loss after tax of \$3,080,089, but acquired the Belgium-based Diasource Immunoassays SA last year (BD: Jan 25, 2016).

Anteo said that diluted loss per share fell 38.5 percent from 0.26 Euro cents in the previous year to 0.16 Euro cents for the six months to December 31, 2016, with net tangible assets per share up from 0.01 Euro cents to 2.4 Euro cents.

The company said it had cash and cash equivalents of EUR2,331,406 (\$A3,202,358) at December 31, 2015, compared to \$A3,601,873 at December 31, 2015.

Anteo was unchanged at 3.8 cents.

GENETIC SIGNATURES

Genetic Signatures says that revenue for the six months to December 31, 2016 was up 17.7 percent to \$1,003,175 with net loss after tax down 16.9 percent to \$1,339,595.

Genetic Signatures said that diagnostic kit sales were up 8.8 percent to \$968,814.

The company said that net tangible assets per security was UP 116.3 percent to 16.89 cents with diluted loss per share down 31.2 percent to 1.52 cents.

Genetic Signatures said it had cash and cash equivalents of \$16,008,374 at December 31, 2016 compared to \$4,315,181 at December 31, 2015.

Genetic Signatures fell 2.5 cents or 6.3 percent to 37 cents.

BIOXYNE

Bioxyne says that revenue for the six months to December 31, 2016, fell 25.1 percent to \$916,156 with the previous profit turned to a net loss after tax of \$72,186.

Bioxyne said that the fall in revenue for its probiotics was due to the timing of orders from a US customer.

The company said that that diluted earnings per share fell from 0.2 cents to a diluted loss per share of 0.04 cents for the six months to December 31, 2016, with net tangible assets per share constant at 0.1 cents.

Bioxyne said it had cash and cash equivalents of \$1,185,536 at December 31, 2016, compared to \$1,183,586 at December 31, 2015.

Bioxyne was unchanged at 2.1 cents.

STARPHARMA

Starpharma says that revenue for the six months to December 31, 2016 fell 84.6 percent to \$576,000, with net loss after tax down 10.1 percent to \$9,017,000.

Last year, Starpharma said that it had received a \$2.9 million upfront fee from AstraZeneca (BD: Sep 7, 2015).

Today, the company said that research and development expenditure fell 41.2 percent to \$6,868,000 with administration and finance costs up 30.6 percent to \$2,726,000.

Starpharma said that diluted loss per share fell 21.0 percent to 2.45 cents for the six months to December 31, 2016 and it had cash and cash equivalents of \$36,280,000 at December 31, 2016 compared to \$54,688,000 at December 31, 2015.

Starpharma fell five cents or 6.9 percent to 67.5 cents with 1.3 million shares traded.

ATCOR MEDICAL

Friday's night's edition reported Atcor's first half financials, but incorrectly reported the company's closing price as 3.8 cents, which should have been 6.8 cents.

Biotech Daily apologizes unreservedly for the error made by a Friday sub-editor overwhelmed by far too many numbers.

The Friday sub-editor has been seconded to Alan Kohler's ABC-TV News business segment to look at pretty graphs until she has recovered from the reporting season.

Atcor fell 0.2 cents or 2.9 percent to 6.6 cents with 1.6 million shares traded.

CYCLOPHARM

Last week, Biotech Daily reported Cyclopharm saying that revenue for the 12 months to December 31, 2016 was up 14.3 percent to \$14,385,507 with net profit after tax down 83.4 percent to \$795,936 (BD: Feb 22, 2017).

Today, Cyclopharm revised the data saying that there had been a \$95,432 "reduction in income tax expense" relating to a deferred tax asset which took its correct net profit after tax to \$891,368.

No sub-editors were hurt making this clarification.

Cyclopharm fell one cent or 1.2 percent to 84 cents.

IMUGENE

Imugene says the Australian Patent Office has accepted a patent application protecting its HER-Vaxx cancer immunotherapy, in development for gastric cancer.

Imugene said that if granted, the patent, 'A vaccine composition and uses thereof' would provide coverage until 2036 for its vaccine formulations designed to enhance the immune response through its HER-Vaxx, HER2 positive cancer immunotherapy that stimulated a polyclonal antibody response in patients with HER-2 positive cancers.

Imugene said that the enhanced HER-Vaxx formulation incorporated the existing, clinically and commercially validated vaccine carrier protein CRM197 together with an adjuvant.

Imugene chief executive officer Leslie said the patent protection to 2036 was "significantly longer than the vast majority of competing clinical stage products and technologies".

Imugene said that gastric or stomach cancer was the second most common cause of cancer-related death in the world and the fourth most commonly diagnosed cancer, with more than one million new cases diagnosed each year.

Imugene was up 0.1 cents or 7.1 percent to 1.5 cents with 3.2 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it has filed five patent applications for its Permetrex-enabled products including uses for its synthetic cannabidiol for skin diseases outside acne and skin care.

Botanix said that Permetrex was the delivery technology used for its lead acne treatment BTX-1503 in clinical development and the patent applications were filed in the US and Australia.

The company did not specify the titles of any of the applications.

Botanix executive director Matt Callahan said the company had identified "a number of new uses for synthetic cannabidiol which are supported by scientific literature and which could be enabled by the Permetrex delivery system".

"With a proof of concept formulation in hand, we have taken steps to protect these new products while we continue development and commercialisation planning," Mr Callahan said.

Botanix said some of the patent applications aimed at protecting new formulations of approved active ingredients, which could be "developed quickly and commercialized without the need to submit the new products for regulatory agency approval".

The company said it planned limited early stage development work on some of these products in the coming months.

Botanix was up 0.2 cents or 4.2 percent to five cents.

BIONOMICS

CVC has reduced its substantial holding in Bionomics to below the five percent level.

The Sydney-based CVC said that on February 15, 2017 it bought 275,000 shares on-market for \$100,834 or 36.7 cents a share and on February 22, sold 2,400,000 shares on-market for \$958,032 or 39.9 cents a share.

Last year, CVC became substantial in Bionomics with 24,901,120 shares or 5.18 percent, saying it bought 10,000,000 at 33.1 cents a share and then called for the removal of chairman Graeme Kaufman and director Trevor Tappenden, which occurred later that year (BD: Feb 4, Mar 16, Aug 9, 31, 2016).

Biotech Daily calculates that CVC retains 22,776,120 shares in Bionomics or 4.7 percent of the company.

Bionomics was unchanged at 40 cents.

ALLEGRA ORTHOPAEDICS

Robinwood Investments Pty Ltd says it has increased its substantial holding in Allegra from 22,557,364 shares (35.38%) to 31,996,321 shares (43.75%)

The Bowral, New South Wales-based Robinwood said it bought 9,438,957 shares for \$755,117 or eight cents share on December 13, 2016.

Last year, Allegra said it had a conditional placement agreement to raise \$755,117 from related party Robinwood Investments Pty Ltd (BD: Oct 18, 2016).

Allegra said at that time that Robinwood held 33.50 percent of its shares and if the placement was approved, Robinwood would increase to 42.15 percent and with associates would have 43.76 percent.

Allegra said Robinwood was controlled by its director and majority shareholder Dr Nicholas Hartnell whose father Anthony Hartnell was a director of Allegra.

The company said that Robinwood provided a loan of \$1 million on commercial terms in June 2016, which was then drawn down to \$700,000 and was due for repayment on December 30, 2016 (BD: Jun 30, 2016).

Allegra was unchanged at 23.5 cents.

ITL HEALTH GROUP

ITL Limited says it has “re-branded” itself as the ITL Health Group.

ITL said it was an innovative medical technology company, supplier and strategic partner providing products to healthcare markets.

The company said the name change was part of its “unified global rebranding plan and is supported by the launch of an integrated corporate website, ITLHealthGroup.com ...[to support] the company’s brand promise, Innovating to Make Life Easier.

ITL said the new brand and website encompassed its four divisions of bio-medical, healthcare, clinical and Myhealthtest, supplying human and animal health.

ITL executive chairman Bill Mobbs said the change “aims to provide a comprehensive company overview for shareholders, customers and strategic partners”.

“The intention of the rebrand was to achieve our vision of becoming a world leader in providing products and solutions to healthcare markets and empowering individual health management,” Mr Mobbs said.

ITL was up one cent or 2.2 percent to 47 cents.

BIOTECH CAPITAL

Biotech Capital says it has appointed Dr Rocco Iannello as group business development director to lead its services marketing.

Biotech Capital said that Dr Iannello had more than 25 years’ experience in bio-medical research, business development, technology commercialization and industry and government engagement, between 2002 and 2015 Dr Iannello held executive business development positions at Monash Commercial and Monash Institute of Pharmaceutical Sciences and had held directorships with industry organizations and start-up companies. The company said that Dr Iannello held a Doctorate of Philosophy from the University of Sydney and a Masters of Business Administration from Monash University.

Biotech Capital fell half a cent or 4.2 percent to 11.5 cents.