



Biotech Daily

Thursday December 18, 2014

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market rose 0.95 percent on Thursday December 18, 2014 with the S&P ASX 200 up 48.9 points to 5,210.8 points. Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and one was untraded.

Optiscan was the best, up 0.4 cents or 9.5 percent to 4.6 cents with 283,500 shares traded, followed by Compumedics up 9.2 percent to 9.5 cents with 91 shares traded. Starpharma climbed 7.2 percent; Biotron was up five percent; Anteo, Living Cell, Neuren and Prana were up more than four percent; Analytica was up 3.85 percent; Cochlear and Impedimed rose two percent or more; Acrux, Avita, Mesoblast, Nanosonics and Resmed were up more than one percent; with Clinuvel up 0.9 percent.

GI Dynamics led the falls, down three cents or 10.7 percent to 25 cents with 123,729 shares traded. Universal Biosensors lost 7.7 percent; Genetic Technologies was down 6.7 percent; Phosphagenics and Psivida fell four percent or more; Benitec was down 3.45 percent; Alchemia, Bionomics, Oncosil and Prima shed more than two percent; with Antisense, Atcor, Sirtex and Tissue Therapies down more than one percent.

BIOTECH DAILY EDITORIAL: 2014 - THE YEAR IN REVIEW

The sunshine of 2013 turned to stormy weather this year with an overall fall of the Biotech Daily Top-40 Index (**BDI-40**) of 9.6 percent for the year to November 30.

It is cold comfort that the ASX200 fell 0.1 percent for the same period. The three Big Caps of **Cochlear**, **CSL** and **Resmed** (which are not included in the BDI-40) were up a collective 16.8 percent.

But it has been nothing if not a busy year, with a constant stream of significant announcements, some bad, some good and a great deal of small positive progress, overshadowed by a few major disasters.

The failure of **Prana's** PBT2 for Alzheimer's disease and **Alchemia's** Hyact for colorectal cancer, along with **Reva** replacing its Rezolve stent with the Fantom, a European halt to **GI Dynamics** Endobarrier, **Starpharma** making slow progress on its non-condom programs and the train wreck that became **QRX Pharma**, along with across-the-board share price falls, have hurt the sector, not to mention the conviction and gaoling of **Genetic Technologies** founder Dr Mervyn Jacobson and, separately, the **Phosphagenics Three**: former chief executive officer Dr Esra Ogru, Dr Robert Gianello and Dr Woei-Jia Jiang.

It was not all doom gloom. **Sirtex** more than doubled its market capitalization from \$673 million to \$1,526 million, breaking through the \$20 share price, with **OBJ** nearly trebling its value to \$146 million. Both **Circadian** and **Genera** doubled their market capitalizations in the 12 months to November 30. That said, the vastly overvalued **Isona** fell from \$143 million to \$21 million, with **QRX** the worst, losing \$91 million to just \$3 million.

The year started very well for **Acrux** with **Eli Lilly** paying a \$28 million (\$US25 million) dividend for surpassing the \$US100 million Axiron sales milestone. But the news turned sour on reports – since refuted by both the **US FDA** and the **European Medicines Agency** – that testosterone treatments were implicated in cardiac events. Nevertheless, **Acrux** had an acute monetary infarction, not helped by being the short sellers' favorite.

Despite complaints about the FDA from some, the US regulator approved the **Admedus** Cardiocel and **Polynovo's** wound treatment as well as finally signing off on the full approval of the **Chemgenex**-developed **Teva** Synribo, formerly Omapro.

Prana had a very rough year, with its trial of PBT2 showing safety and some efficacy for Huntington's disease, but not in its main game, Alzheimer's disease. The company's market capitalization dived from \$447 million to \$90 million.

Bionomics managed to survive the failure of BNC105 for kidney cancer, announcing the mega **Merck** deal of \$537 million for the BNC375 cognition drug. The return to Bionomics of BNC210 for anxiety from **Ironwood** was not unexpected, given that the American company didn't seem to progress its development. Doesn't **Roche** want the new Valium?

Biotron managed to make one-day jumps of 314 percent and 90 percent on very good news in very small numbers for its BIT225 for HIV and hepatitis C and has now enrolled all the patients in a serious 60-patient trial. For the year, Biotron is up 40 percent.

In May, **Japan** approved **Starpharma's** Vivagel coated condom, but later withdrew, apparently due to a review of medical device categories and despite approvals and sales of the **Ansell** Vivagel condom in Australia and New Zealand.

And who could forget the disaster that was **Biota Pharmaceuticals**? Biotech Daily has already commented on Biota's failing, but it is worth noting that having gone to America to merge with **Nabi** for its \$US54 million in cash and settling for \$US27 million, the company moved office away from the regulatory decision-makers, and apparently had poorer communications with the **Biomedical Advanced Research and Development Authority** (BARDA) than Biotech Daily in Melbourne (BD: Jun 3, 2014).

On two occasions, Biota said it had no idea why its long-acting acting neuraminidase inhibitor laninamivir octanoate program had been halted and terminated by **BARDA**, with Biotech Daily receiving that information overnight in email exchanges with the Authority.

Government

The **Federal Government's** approach to biotechnology is mystifying, at best. In May, the Abbott Government-appointed **Audit Commission** recommended the closure of a raft of programs including **Innovation Investment Funds**, and **Cooperative Research Centres**. It was depressing rather than merely ironic that the Audit Commission made its announcement on the same day that **Shire** bought **Fibrotech** for about \$600 million. Fibrotech was underpinned with \$3 million from Federal sources and returned \$24 million to the Treasury. The following day the **Hearing CRC** published data showing that the use of hearing aids might delay the onset of dementia, but it was clearly too late for the Audit Commission.

The **Federal Government** thought-bubble hailed as the **\$20 billion Medical Research Future Fund** sounded brilliant at first blush, until it became clear that it was a stalking horse to kill **Medicare** bulk-billing and thereby destroy one of the world's best national health services. And has any work started on the **MRFF**? The answer appears to be "No" despite the \$1 billion already available.

The **Federal Budget** penny-pinching in reducing the much-needed 45 percent **R&D Tax Incentive** to 43.5 percent and the closure of IIF loans, the CRCs and the lacklustre **Commercialisation Australia** – with no replacements - was indicative of the lack of thought that has contributed to the Federal Government's budgetary problems.

The one positive for the Federal Government was the announcement that the **Australian Therapeutic Goods Administration** would be subject to cross-border regulatory acceptance, potentially making Australian approval easier for companies that have satisfied European or US regulators.

While tax changes for employee share plans were broadly welcomed, Biotech Daily would like to see those plans used for employees, rather than directors, and director plans clearly labelled as such.

Benitec finally treated its first patient at the end of May and in June, **Living Cell** resumed its trial of NTCell encapsulated pig-brain cells for Parkinson's disease. **Psivida** continued winning EU country approvals for Iluvien, capping its year with US FDA approval and a \$US25 million milestone payment from licensee **Alimera Sciences**.

Despite the set-backs of this year **Pfizer** chose **Monash University** for its first non-US innovation centre and Australia was listed as Number Four in global biotechnology industries.

Simavita listed on the ASX and began US sales, the FDA approved **Dorsavi's** Vimove diagnostic and **Polynovo** won Conformité Européenne (CE) mark approval for its Novopore wound treatment.

Orthocell took awhile but raised \$8 million and listed on the ASX in August, **Dimerix** was hoping for a \$9 million IPO but it was shelved, as was the **Ascend** \$11 million IPO, with **Proteomics** still in the midst of its \$6 million IPO.

The US based **Retropin** offered up to \$95 million for the then \$71 million **Clinuvel**, which rejected the offer, won European approval and was last worth \$188 million.

Calzada finally became **Polynovo** and has sought to divest its subsidiary **Metabolic** and its troublesome drug AOD9604. Open for offers. Quick sale. Won't last.

Pharmaust was bedevilled by issues with its PPL-1 cancer treatment, with the first terminally ill human patient dying and delaying the trial, while the oral version for dogs had to be reformulated. Both trials were back on track by the end of the year.

In the Departures Lounge, **Acuvax** decided to go **Activistic** funds collecting, **Safety Medical** has swapped a Brazilian gold mine for 3-dimensional printing, **Healthlinx** is doing something in social media and **IM Medical** is expected to become a data centre.

In the Almost Medical Department, **Narhex** has progressed from HIV to coal, gold and diamond mining and is now investigating respiratory 'apps' or mobile telephone applications. They might want a quiet word with **Isona** about that.

Solagran and **Sterling Products** both threatened to resume trading, but so far have not, while Solagran's sometime step-sister company **Biopropect** has rebadged itself **Medibio**, significantly changed its share registry, appointed a new board and hopes to develop a circadian heart variability test for mental illness.

Bone Medical ended its long association with founder **Proxima** and Dr Roger New, having failed to progress any of the oral treatments for bone disease. The biotech shell is reviewing its options.

Actinogen has given up on its former pursuits including its original actinomycetes for a raft of diseases and acquired a serious technology from the **University of Edinburgh** for Alzheimer's disease.

The second half of the year saw Michael Dale appointed **GI Dynamics** chief executive officer just in time to deal with a Euro ban on the Endobarrier, and had the problem solved in two months. Welcome aboard, Michael.

Antisense claimed ATL1103 success for acromegaly, but received scant attention from the market, while **Impedimed** won its full-fee US CPT reimbursement code and doubled in market capitalization. Including a capital raising, Impedimed at \$166 million is nearly four-fold its January 1 market capitalization of \$47 million.

With a great deal of hard work and patience **Team Genera** led by Lou Panaccio put the company back on its feet, advancing its human papillomavirus and respiratory tests, with diagnostics for sexually transmitted infections in the pipeline

Legal Matters

A significant intellectual property matter ended at the **Federal Court** with the **Myriad Genetic Technologies** case relating to the BRCA gene patents upheld, primarily meaning that once removed from a human body, a gene or a mutation was patentable. Specifically, that isolating DNA and RNA was deemed a manner of manufacture.

That was Friday. On Monday, the man who founded **Genetic Technologies** and licenced the non-coding DNA, Dr Mervyn Jacobson, pleaded not guilty to 35 charges of conspiracy and market manipulation. At the end of an eight week trial the jury didn't believe him and he was gaoled for two years and eight months with a minimum of 12 months.

In any case, **Genetic Technologies** has ended what it calls its 'heritage' business of genetic testing to rename itself **Phenogen** and focus on Brevagen

The change of name is serendipitous with **Genetic Signatures** hoping to raise \$15 million in its current initial public offer for its molecular diagnostics

Among the plethora of positive news was: **OBJ** working with **Proctor and Gamble**, first on cosmetics and now on cartilage treatment; **Bergen Asset Management** helping **Prima** acquire **Immutep** for \$32 million; the then \$9.5 million **Circadian** placing \$17.4 million; CE mark for **Analytica's** intra-vaginal Pericoach pelvic floor diagnostic; **Antara** raising \$7 million to list and develop bromelain for pig diarrhoea; **Hatchtech** demonstrating success for its phase II Xeglyze trial killing 100 percent of head lice eggs; **Novogen** ramping up claims for in-vitro and in-vivo efficacy of TRXE-009 for brain cancers; European, US and Australian approval for **Rhinomed's** Mute anti-snoring nasal plugs; Innate beginning its multiple sclerosis trials; **Carl Zeiss** paying a \$258,000 microscope milestone to revive **Optiscan**; FDA approval for **Osprey's** Avert Plus; and EU approval and **Siemens** launch of the **Universal Biosensors** coagulation test and

The unlisted **Sienna Diagnostics** told Bio21 that in 10 years it had grown from developing DNA telomeres for cancer diagnostics to signing partnering deals.

Neuren demonstrated safety and some efficacy in its Rett syndrome trial, which should have pushed the share price up several-fold, but the 54 percent increase will have to suffice, until the company publishes the next results from the four trials underway

In less good news, the European regulators and **Tissue Therapies** continued their chess game over the approval of the Vitrogro wound treatment, **Phosphagenics** showed that its acne treatment was no better than the standard of care, the **European Medicines Agency** effectively told **Avita** that its small area Recell wound treatment might be better suited for large area wounds, which was what the company was originally doing with its Cellspray XP system when it was founded by burns surgeon Prof Fiona Wood.

In October, **Alchemia** chief scientific officer Prof Tracey Brown won the Victoria State **Telstra** businesswoman of the year award, normally a herald of great things to come, but in this case, the harbinger of the unexpected failure of the hyaluronic acid-irinotecan to show any significant difference to the standard-of-care in its pivotal phase III metastatic colorectal cancer trial. The share price fell from 60 cents to eight cents.

On the same day, the **European Committee for Medicinal Products for Human Use** finally voted for authorization for **Clinuvel's** Scenesse for erythropoietic protoporphyria, just eight short years after treating the first patient and a brief two years and nine months after filing the application. Congratulations chief executive officer Dr Philippe Wolgen.

Which brings us to the **2014 CEO of the Year Award**. Again a very hard choice between Benitec's Dr Peter French for keeping his company's hepatitis C trial on track and raising \$31.5 million at exactly the right moment; Biotron's Dr Michelle Miller for keeping her HIV and hepatitis C trials on track with excellent results in small numbers; and Bionomics Dr Deborah Rathjen for the foresight in producing a pipeline of drug candidates, not to mention the mega deal with Merck (above).

The tenacity and perseverance award belongs to Dr Philippe Wolgen, but the **CEO of the Year Award** goes to Impedimed's **Richard Carreon** for winning a seriously good US reimbursement code. Oh and raising \$32.5 million off the back of the announcement. Biotech Daily would also like to congratulate former Impedimed CEO Greg Brown for much of the original ground work.

Thankfully, the **Biotech Daily Kamikaze Award** has been withheld in 2015. Despite the large number of failures and set-backs none were obviously predictably, even with hindsight. **QRX** was certainly the runner-up.

Biotech Daily's last formal edition for 2014 will be published tomorrow and we return on January 19, 2015. All important news filed to the ASX in the summer holiday period will be reported in the January 18 catch-up edition. The subscription price will have a slight increase to a base rate of \$940 in the New Year.

We wish all our readers a Happy Chanukah, Merry Christmas, Happy Hogmanay, a Sunny Summer Solstice and a better biotech New Year in 2015.

David Langsam
Editor

NANOSONICS

Nanosonics says it will move to the former Cochlear headquarters in Lane Cove Sydney by the end of next year.

Nanosonics said the site would more than double its existing space with the opportunity for further expansion, with all operations on a single site.

Nanosonics chief executive officer Michael Kavanagh said that the move had been “on our agenda for some time”.

“The move gives extended flexibility in manufacturing capacity and capability as well as affording the opportunity for greater operational expansion and efficiencies,” Mr Kavanagh said. “Despite the increase in the size of the facility, the total ongoing occupancy cost will not increase materially.”

“As the building was an established medical technology facility, capital investment is expected to be less than \$2.0 million to tailor the facilities to our specific operational requirements,” Mr Kavanagh said.

Nanosonics was up two cents or 1.9 percent to \$1.09.

GENETIC TECHNOLOGIES

Genetic Technologies says that a panel of 77 single-nucleotide polymorphisms improves the predictive accuracy of four commonly used breast cancer risk assessment models.

Genetic Technologies said that the panel of 77 single-nucleotide polymorphisms was used in its Brevagenplus predictive risk test for sporadic, or non-hereditary, breast cancer.

The company said that the research, entitled ‘Value of Adding Single-Nucleotide Polymorphism Panel Markers to Phenotypic Algorithms of Breast Cancer Risk’ was presented at the San Antonio Breast Cancer Symposium on December 13, 2014 and was conducted by Prof John Hopper and co-authored by Dr Gillian Dite from the University of Melbourne’s Centre for Molecular Epidemiology.

The company said the study investigated the impact of adding the panel to breast cancer prediction models Boadica and BRCApro, BCRAT or Gail score and IBIS.

Genetic Technologies said that the researchers studied a population-based sample of 750 cases and 405 controls from the Australian Breast Cancer Family Registry and used the same methodology as a previous study of seven single-nucleotide polymorphisms (SNP).

Genetic Technologies chief executive officer Alison Mew said the results “demonstrate that incorporating genetic information derived from the SNP panel [used] in Brevagenplus, improves the discriminatory accuracy of these four breast cancer risk tools”.

The company said that publication of the data was expected by April 2015, removing a significant barrier to test acceptance in the US market.

Genetic Technologies fell 0.1 cents or 6.7 percent to 1.4 cents with 7.3 million shares traded.

IDT AUSTRALIA

IDT says it has completed the acquisition of 23 US generic drugs for conditions including Parkinson’s disease, depression, infection, hypertension and pain (BD: Nov 3, 2014).

IDT said that it expected to begin manufacture by early 2015 and the company was in discussions with potential commercialization partners for US distribution.

IDT chief executive officer Dr Paul MacLeman said the acquisition “signals the birth of Australia’s newest pharmaceutical company [and] IDT is set to become a manufacturer and supplier of its own range of US specialty generic drugs”.

IDT was unchanged at 16 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has extended the closing date for its up to \$6 million initial public offer at 20 cents a share to January 27, 2015 (BD: Nov 14, 2014).

Proteomics said that it was "in material negotiations with a major Chinese drug and diagnostic development company in relation to a significant agreement to commercialize and market [its] next generation diagnostic test for the early diagnosis of diabetic kidney disease".

The company said that the agreement related to the provision of funding and licencing partners for the diagnostic in China and would be the first commercial agreement for the diagnostic

Proteomics said the agreement was potentially a step-change in the company's growth and development plans.

The company said that offer extension beyond the proposed closing date of December 12, 2014, would give it sufficient time to conclude negotiations with the Chinese party, and allow potential investors time to consider their investments.

NUSEP

Nusep says it has received \$821,879 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Nusep said that the funds would be used to develop its Spermsep business including running clinical trials and for working capital.

Nusep was untraded at five cents.

IMPEDIMED

The Singapore-based FIL Limited, formerly Fidelity Investments, says it has become a substantial shareholder in Impedimed with 14,748,056 shares (5.04%).

FIL said it acquired the shares between August 19 and December 11, 2014, with 13,519,599 shares acquired at 60 cents on December 11, 2014, as shortfall shares in the \$32.5 million underwritten rights issue (BD: Nov 13, 2014).

Impedimed was up 1.5 cents or two percent to 76.5 cents.

IMMURON

Immuron says it has received a letter of resignation from interim chief executive officer Amos Meltzer.

Immuron said that Mr Meltzer had agreed to be available to assist beyond his three-month notice period, if required, to facilitate a smooth transition to a new chief executive officer.

Immuron chairman Dr Roger Aston said the company was "thankful for both Amos' commitment and achievements including steering the company's turnaround and progressing its development and commercialization programs over the last few years".

"Since his commencement at Immuron in early 2010, Mr Meltzer has filled several positions ... including his appointment to interim CEO in February 2013," Dr Aston said.

Immuron said that Mr Meltzer's resignation followed the establishment of the platform for implementation of the clinical trial for non-alcoholic steatohepatitis, with the required contractors and processes in place and patient recruitment imminent.

The company said it would search for a new chief executive officer to oversee the trial and focus on the extended marketing of Travelan for travellers diarrhoea.

Immuron was untraded at 21 cents.

NUSEP HOLDINGS

Nusep says it has an enforceable undertaking with the Australian Securities and Investments Commission relating to potential contraventions of the Corporations Act 2001. Nusep said that ASIC had investigated suspected contraventions of the Corporations Act between 2009 and 2012 and the company had signed the undertaking binding it to a standard of governance and compliance with conditions set out in the undertaking. The company said that ASIC had concerns that it might have breached its continuous disclosure obligations in relation to acquiring shares in itself by issuing and holding shares in a suspense account.

Nusep said ASIC had concerns over record keeping, the issuing of bonuses to former executives and a range of other suspected breaches of the Corporations Act.

The company said that the conduct took place prior to 2012 and the appointment of the current board and there had been a significant change to the composition of the board, following the resignation of the executive chairman [John Manusu] and managing director [Prakash Patel] in November 2013 and the appointment of new directors.

Nusep said that ASIC had acknowledged the co-operation and assistance of the company in relation to the undertaking and that Nusep had already taken to address a number of ASIC's concerns including the change of directors and company secretary.

The company said that it would appoint an independent compliance expert to review and report to ASIC on its corporate governance procedures within 30 days and the review period would extend for three years from the date of the undertaking.

Separately, former chairman and substantial shareholder, John Manusu, has told Biotech Daily that he had complained to the company about a number of resolutions to be considered at tomorrow's annual general meeting (BD: Nov 20, 2014).

A letter from Mr Manusu's legal representatives to Nusep raises issues relating to the repayment of loans and convertible notes.

PRESCIENT (FORMERLY VIRAX HOLDINGS)

Prescient, which was formerly Virax, has begun trading on the ASX under the code PTX, following a suspension for its 20-to-one consolidation.

Prescient was unchanged at 14 cents.

ACTINOGEN MEDICAL

Actinogen says non-executive director Dr Brendan de Kauwe has retired, effective immediately.

Dr de Kauwe is a corporate adviser with the Perth, Western Australia-based Otsana Capital and was appointed to the board in September 2013, and promoted to chairman in April this year (BD: Feb 13, Apr 23, 2014).

Actinogen was developing actinomycetes for antibiotics and anti-fungals, then turned to bio-fuels and ran out of cash (BD: Nov 9, 2011; Oct 29, 2012; Aug 2, 2013).

Last year, the company signed a \$100,000 loan agreement with Otsana Capital and replaced the board, later raising \$1.5 million (BD: Sep 24, Dec 13, 2013).

Today, Actinogen said that chief executive officer Dr Bill Ketelbey had been appointed managing director.

Actinogen fell 0.2 cents or five percent to 3.8 cents.

CLARITY PHARMACEUTICALS

Clarity says it has appointed University of Sydney and professor of medical radiation sciences Prof Dale Bailey to its scientific advisory group.

Clarity said that Prof Dale was a director of clinical trials imaging and analysis organization Pharmscint and was principal physicist in the Department of Nuclear Medicine at Sydney's Royal North Shore Hospital.

The company said that Prof Baily led neuro-endocrine tumor unit of Sydney's Northern Translational Cancer Research Centre.

Clarity executive chairman Dr Alan Taylor said that it was "timely to have an esteemed nuclear medicine physicist join our rapidly growing company as we prepare to move into early stage clinical trials with our radiopharmaceutical pipeline".

"Prof Bailey brings strong clinical experience and a potential collaboration with the nearby Royal North Shore Hospital with a path to progress our radiopharmaceutical pipeline into the clinic," Dr Taylor said.

Clarity said the advisory group included the New York-based Brookhaven National Laboratory's Dr Suzanne Smith and the University of Melbourne's Dr Paul Donnelly.

The company said that it is commercializing medical diagnostic and imaging technology developed by the Australian Nuclear Science and Technology Organisation and the University of Melbourne (BD May 2, 2014).

Clarity is a private company.