



Biotech Daily

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Daily news on ASX-listed biotechnology companies

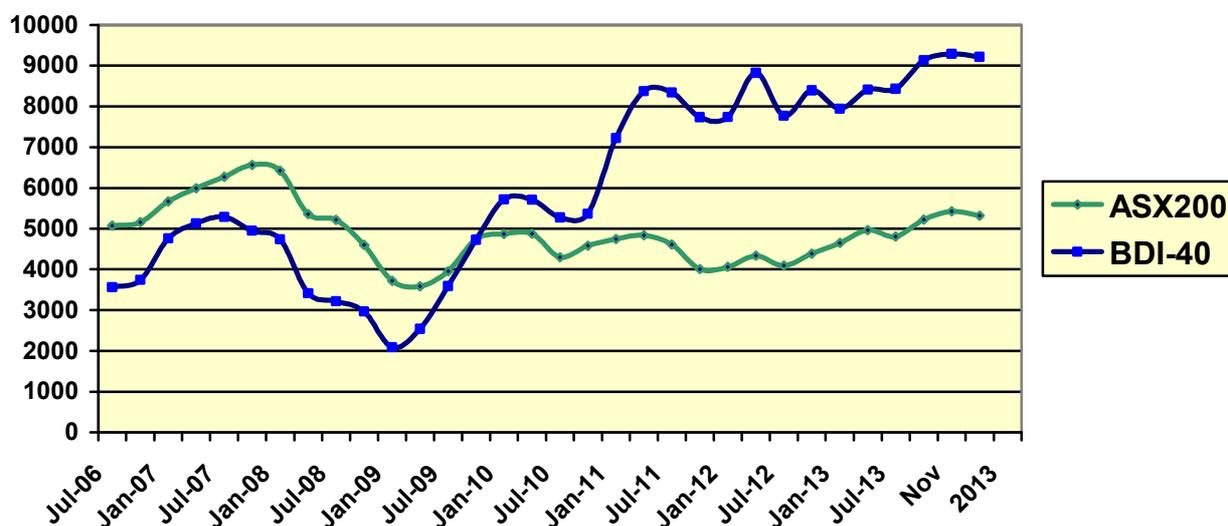
The Year In Review

The past 12 months have shone on biotech more than most years with an array of capital raisings, regulatory approvals, clinical trial progress, backdoor listings, the odd front-door listing and a steady flow of funds into the sector.

Some of the money is coming from self-funded retirees and former high-risk-low-reward mining enthusiasts, but most is from serious investment houses including **Australian Ethical**, **Allan Gray** and **M&G Funds**. Other players are effectively day-trading, but hiding from their co-investors through nominee companies fronted by share-lenders like **UBS AG** and **NAB Nominees**. While the anonymous speculation activity is a snub to the spirit of the **Corporations Act**, it is not in breach of the letter of the Act. Unfortunately we only have the **Australian Securities and Investments Commission** to police the Corporations Act, so don't expect any dawn raids anytime soon.

It has been annoying to the victims of the share-lenders and short sellers, chiefly **Acrux** and **Mesoblast**. Come out in the open and speculate in your own names, you cowards!

Regardless, the biotech sector has had a very good year, with the **Biotech Daily Top 40 Index (BDI-40)** climbing 15.1 percent for the year to November 30, 2013, in-line with the **ASX200** up 18.1 percent. Since inception on June 30, 2006 to November 30, 2013, the adjusted BDI-40 was up 158.6 percent compared to the ASX200 up 4.8 percent.



It has been an exciting year, and for some more interesting than they would have liked, with the **Federal Election** and change of Government dominating the latter half, and so far, touch wood, with no cuts to innovation and biotechnology.

In fact, **Prime Minister Tony Abbott** even made a passing reference to sunrise industries including bio-medical research in his statements on discontinuing funding to sunset industries like the Australian sub-division of the US-based **General Motors Holden**.

It is worth noting that the **Greens Member for Melbourne Adam Bandt** won an historic victory in his re-election and is fully aware of his role as the Federal Member for Biotech with about 25 percent of all Australian biotechnology companies in his electorate, along with their voting personnel. At the beginning of 2013, Mr Bandt and the **Liberal Member for Higgins Kelly O'Dwyer** made strong commitments to preserve funding for National Health and Medical Research Council and Australian Research Council grants and thus far they appear to have been successful. They both deserve credit for their work.

Anyone who is able to lobby our elected representatives should not hesitate to do so.

The major events of 2013 included a very poor start for **Pharmaxis** with an overwhelming refusal from the **US Food and Drug Administration** Pulmonary-Allergy Drugs Advisory Committee, followed in March by the departure of founding chief executive officer Dr Alan Robertson, replaced by chief operating officer Gary Phillips. In April the company's bronchiectasis trial failed to meet its endpoints. Despite sales of Bronchitol in Europe and Australia, the company has continued a downward price slide all year. That said, Australian Ethical has been buying Pharmaxis and at 10.5 cents it appears to be below cash-backing.

QRX Pharma faced a similarly hard time at the FDA, with chief executive officer Dr John Holaday and his team maintaining a politely determined resilience to get the dual opioid Moxduo approved by the US regulator. Psivida also received another FDA knock-back for Iluvien for diabetic macular oedema. Perhaps we need an Australian Chapter of the FDA Veteran's Association.

In February, the FDA detailed its '**Breakthrough Therapy**' pathway, dramatically reducing the pre-approval regulatory burden to potentially a single trial and expediting approvals for treatments for "a serious or life-threatening disease or condition" followed by post-approval trials. To date no Australian companies has received the designation.

To be fair, in 2013, the FDA approved **Mayne Pharma's** 200mg delayed action Doryx, **Impedimed's** L-Dex U400, **Osprey's** Avert system, **Ellex's** 2RT and SLT laser treatments and **Medical Developments** spacers – or one generic drug and a raft of devices and diagnostics. Some might suggest the FDA change its name to the Federal Device and Diagnostic Administration. **Isona's** asthma monitor Airsona was approved by the **Australian Therapeutic Goods Administration** with approvals for **Sirtex** SIR-Spheres in the UK, Pharmaxis Bronchitol in Scotland and **Psivida's** Iluvien in Spain. **Immuron's** Travelan was approved in Canada, **Cyclopharm's** Technegas got the nod in Japan, **Atcor** won approval for its Sphygmocor in both Mexico and South Korea and South Korea also approved **Nanosonics** Trophon.

The biggest biotech capital raising of the year was **Mesoblast's** \$170 million for a spine trial in March, a month when **CSL** raised \$497 million and the Federal Government provided \$100 million in Innovation Investment Funds. Later in the year, **GBS Ventures** said its IIF offer of \$30 million was not sufficient to spread its risk and knocked back the offer.

Despite **Starpharma's** 2012 non-significant phase III results for Vivagel 'cure' of bacterial vaginosis, in April the company released non-significant phase II results for prevention of bacterial vaginosis and said it would take the drug to a phase III prevention trial. Some analysts said that insignificance was insignificant. The good news is that work continues on dendrimer-modified anti-cancer drugs that look both innovative and promising.

'**The McKeon Review** - Strategic Review of Health and Medical Research – Better Health through Research Report' was released by the then **Minister for Health Tanya Plibersek** and was welcomed by the research community. Like other major reports to Government little has been heard since, but the best advice is the new Government is not opposed.

Biota cut staff by 30 percent, closed several early-stage programs and moved from the office in Maryland close to the FDA - cited at the time as one of the key reasons for migrating from the ASX to the Nasdaq – to Atlanta, Georgia.

Cochlear recovered from the previous year's Nucleus 5 implant recall, albeit at a lower share price, attributed to tougher competition, and unveiled its Nucleus 6 processor and product range.

The financial year ended with the High Court resolving the artificial price questions in the matter of the Commonwealth Director of Public Prosecutions versus JM and the new financial year opened with Phosphagenics suspending chief executive officer Dr Esra Ogru (see below).

Several companies added a number of pieces to their respective jigsaw puzzles that on their own could go unnoticed, but over the course of the year meant significant change. **Bionomics** extended its pipeline to include BNC375 for Alzheimer's amongst other candidates, while **Prana** raised capital, appointed **Alchemia's** Dr Pete Smith as a consultant and produced trial data. Ellex and Nanosonics sold product, Alchemia partner Dr Reddy's continued selling fondaparinux and the company approached the end of its phase III hyaluronic acid-irinotecan trial, with **Biotron** publishing news from its HIV and hepatitis C trials.

Living Cell implanted its first pig NTCell in a person with Parkinson's disease, while **Prima** suspended its phase II/III CVac cancer trial to review endpoints. **Osprey** enrolled its first cardiac dye reduction and removal patient before changing the indication to primarily dye reduction

October was a great month for capital raisings with **Neuren** placing \$21.5 million, **Osprey** \$14 million, **Hatchtech** \$13 million, **Admedus (then Allied Health)** \$10.4 million and **Suda** \$5.6 million.

The data is not final for the year but 2013 has been by far the best year for fund raising in four years and probably ever. Details will be in the January 2, 2014 BDI-40 special edition.

Clinuvel continued to chase its elusive registration, frustrated by missing a US phase III trial endpoint and delays at the European regulator. It seems that there is no question that Scenesse works to repigment skin, but the EMA review is taking a very long time.

Sirtex founder Dr Bruce Gray finally reduced to below substantial in his company selling \$87 million in shares in one transaction. **Novogen** began its revival last year and **Progen** came back from the dead with the appointment of chief executive officer Heng Tang and the start of a Melbourne clinical trial. If Progen's Taiwanese investors can leave the board alone for awhile it might even recover.

The annual general meeting season was bizarre with 'proxy advisors' a bit like vote whisperers opposing a range of resolutions, but Stephen Mayne explained their case in the November 22 edition.

Calzada's meeting lost chairman David Franklyn, Prima lost Martin Rogers, **Circadian** lost Don Clarke and in turn chief executive officer Robert Klupacs, **Avita** lost both chairman Dalton Gooding and chief executive officer Dr Bill Dolphin and Progen lost chairman Stuart James.

Replacing Mr Franklyn was Biotech Daily's favorite serial chairman Dr Roger Aston who seemed to be everywhere and anywhere, which is not a bad feat for a man who formally retired from Mayne Pharma to spend more time with his ... other director and chairmanships. Dr Aston resigned from **IDT** having become the chairman of **Oncosil** (then Neurodiscovery) as well as **Pharmaust**, **Acuvax** and **Immuron** and is a mere director of **Regeneus**. Have I forgotten any?

Almost in the same league is Dr Stewart Washer as chairman of Isona and **Cynata**, formerly of Calzada, Hatchtech, Immuron, **Phylogica** and **Resonance**, as well as unlisted companies Firefly Health and Minomic.

Antisense deserves a mention for both surviving and undertaking a share consolidation which appears to have deterred the day-traders.

Throughout the year, the **Walter and Eliza Hall Institute** led the major research institutions in keeping a spotlight on commercializable basic research.

Ausbiotech faced a difficult year with chief executive officer Dr Anna Lavelle absent with illness for many months. Biotech Daily is glad to welcome Dr Lavelle back and wish her a full recovery and a return to the driving force we all know in 2014.

Nevertheless, we have to note that there were many people concerned with the splitting of the Ausbiotech investment and main conferences between two cities and a consequent drop in attendees at both events. We heard the explanations, but they didn't wash.

A rough guide to the performance of the one hundred or so listed biotechs is the vast number of companies that have doubled their market capitalization over the past 12 months compared to those who have managed to halve their value, with 30 up by more than 100 percent and just four down by more than 50 percent.

The 30 includes rises attributed to backdoor listings and/or recapitalizations at Cynata (Eco Quest), **Imugene**, Oncosil, Pharmaust and **Virax**, with spectacular organic growth at Admedus (Allied Health) up 944.4 percent; Neuren (313.3%), IDT (240.0%), Bionomics (197.3%), **Cellmid** (187.5%), Prana (180.5%), Benitec (180%), Psivida (171.0%), **Anteo** (161.7%), Atcor (145.5%), Osprey (126.3%) and Living Cell (116.7%).

Outside the BDI-40, the best improved were Isona up 1000.0 percent from \$13 million to \$143 million and Mayne Pharma up 189.1 percent. Poker machine operator Bruce Mathieson is a substantial shareholder in both companies.

Less spectacular but still significant were **Analytica**, Cyclopharm, **Invision**, Novogen, Resonance and Suda, along with initial public offerings from **Regeneus** (\$10.5 million), **Simavita** (\$14 million) and just yesterday **Innate Immunotherapeutics** (\$10 million).

The pain was deepest felt at Pharmaxis tumbling 90.6 percent from \$361 million at November 30, 2012 to a mere \$34 million at November 30, 2013 and a very long way from \$682 million at April 30, 2011, followed by Prima down 57.8 percent, with **Advanced Surgical**, **Tyrian** and **Bioxyme** all down 50 percent from low bases.

The CEO of The Year Award has been very hard to pick with a bounty of excellent runners-up. Previous winners like Dr Richard Treagus and Dr Paul MacLeman came very close for their renewals of Neuren and IDT, respectively, as did Gilman Wong for keeping the Sirtex ship on a steady course.

Benitec's Dr Peter French has totally revived his company, Dr Deborah Rathjen has announced a series of important pipeline milestones, tripling her company's market capitalization to \$330 million and the Admedus trio of Lee Rodne, Dr Julian Chick and Bob Atwill took Biomd's Cardiocel all the way to European approval and a market capitalization rise of 944.4 percent from \$18 million to \$188 million.

Other companies greatly strengthened have been Nanosonics (Dr Ron Weiberger), Osprey (Mike McCormick) Anteo (Dr Geoff Cummings), **Patrys** (Dr Marie Roskrow), Biotron (Dr Michelle Miller) and Living Cell (Dr Andrea Grant).

Lodge Partners (and former Biotech Daily) companies' analyst Marc Sinatra says that we must measure companies in terms of real progress and share price performance, but then we dismissed that and decided that for spending \$25 million in cash (up to \$50 million) to wipe out all opposition, having raised \$170 million, as well as a consistent run of positive clinical trial news - despite the equally consistent negative reviews from Macquarie Bank's Dr Craig Collie - we have to agree with the Vatican and the Biotech Daily CEO of The Year Award Goes to Mesoblast's **St Silviu Of The Saved Embryos, Prof Silviu Itescu**.

The Biotech Kamikaze Award goes to Bioniche for a complete failure to leverage its Australian and Canadian listing and commercialize its phase III Urocidin bladder cancer treatment and then attempt to resist disgruntled shareholders, while selling-off assets to preserve the board and management and ultimately capitulate and appoint said disgruntled shareholders to the board. What a waste of everyone's time and money that was! Graeme McRae take a bow.

And the year cannot be allowed to pass without a reprise of the Turkish Tragedy that was Phosphagenics' chief executive officer Dr Esra Ogru.

The biotechnology community is still puzzled by the misappropriation of more than \$5 million by someone as likeable and personable as Dr Ogru, who, with two young children and a sparkling career ahead of her, appears to have admitted her role in the debacle.

While Biotech Daily was always skeptical of the fat-busting qualities of AOD9604 and concerned that Phosphagenics was being distracted with its cosmetics business, not to mention the quiet shelving of transdermal insulin, as Monty Python said so well: no one expected the Spanish Inquisition.

The facts of the event are emerging that the invoicing irregularities truly don't match the result at the company's Clayton laboratory and office, but the reason for the theft is what puzzles the scores of people who thought they knew Dr Ogru better than they did.

On more of a sad note than a bad note, Australia finally lost **Heartware**, which returned home to America and delisted from the ASX in September. The loss of the then \$1,365 million (now \$1,682 million) company put a hole in the BDI-40, but forced a review of how the index is calculated. Even we were surprised by the chart (above) which is a more fair comparison with the ASX200, as detailed in the November 1 edition.

The loss of **Sunshine Heart** was also a dent, with the New-Zealand-founded, GBS Venture Partners-backed company reaching US pivotal trials and departing the ASX with a market capitalization of \$57 million in April and today is worth \$159.9 million on the Nasdaq. Well done to both Heartware's Doug Godshall and Sunshine Heart's Dave Rosa.

Despite excellent work by Julie Phillips building **Biodiem's** infectious disease vaccines and therapies pipeline, the company never resolved its tight ownership, lack of liquidity and consequent share price issues. Biodiem was not alone with the problem, merely the first to recognize it and delist. Biodiem continues work as an unlisted company.

Biotech Daily's last formal edition for 2013 will be published tomorrow and we return on January 20, 2014. All important news filed to the ASX in the summer holiday period will be reported in the January 19 catch-up edition. The subscription price will have a slight increase to a base rate of \$890 in the New Year.

We wish all our readers a Merry Christmas, Happy Hogmanay, a Sunny Summer Solstice and a booming biotech New Year in 2014.

David Langsam
Editor