

Biotech Daily



Thursday December 20, 2018

Daily news on ASX-listed biotechnology companies

2018 - The Year In Review

The year started exceptionally well with Varian offering \$1.56 billion for Sirtex and while waiting for CDH China to raise the bid to \$1.9 billion, Merck bought Viralytics for \$502 million.

2018 was dotted with under-rated very good news, including Prana back in the clinic with PBT434 for Parkinson's disease, Patrys cleaning up its act to bring PAT-DX1 close to the clinic for brain and breast cancer, Benitec claiming a \$892m Axovant deal and Neuren winning Acadia as a \$630 million backer.

But along the way the sector played the roller-coaster with some bad news, some weird news and some news no one understood.

January saw a rush of medical marijuana announcements. The 15 or so companies on that particular bandwagon are starting to sort themselves out and we are beginning to weed the dope from the grass.

The pioneer, MMJ sans Phytotech, has become "an incubator" investing in other marijuana companies.

Cann Group is growing quite a lot of hooch in its facilities and IDT is turning the dried flowers into 'good manufacturing practice' actual pharmaceutical drugs.

Medlab Clinical, Botanix and Zelda all win points for running clinical trials for cancer pain, acne, eczema, psoriasis, insomnia, autism and opioid reduction. Esense wants to put traces of hooch into beer and honey and Lifespot has a vaporizer. Several others appear to be part of the growing, import-export, bit-of-this-and-that chain, but sadly for patients it is still near impossible – despite all approvals being in place – to actually go to your doctor and be given a script for any form of medical marijuana.

For a moment in January it looked like the former Biota shareholders were going to overthrow the then Aviragen management and stop the merger with Vaxart, but once the US based shareholders won a few extra pennies in the deal, instead of mobilizing the 10,000 Australian investors done-over by the move to the US, they voted for the merger.

There was “trouble at mill” for several companies, with Medibio (formerly Bioprosect) losing chief executive officer Jack Cosentino, followed by the re-emergence of Leo ‘The Gun’ Khouri, formerly a major shareholder and director of Bioprosect, and a spill that ultimately failed but dampened enthusiasm for the company boasting a Kennedy (related to JF and RF, not Graham) and Olympic gold medallist Michael Phelps.

We were shocked to see Archie Fraser depart from Optiscan and then dismayed by a board spill that left the company winged, despite the Carl Zeiss contract continuing.

THC, formerly Hydroponics, also had a board spill with the old guard resuming control, but instead of pursuing equipment sales, joined the pack in growing and selling the much-vaunted medical marijuana.

Medical Developments spent much of the year announcing European – and other – approvals for its Pentrox methoxyflurane inhaled analgesic, just a short 20 years or so after the Victoria Ambulance Service accepted it as the first-line treatment for moderate to severe trauma pain.

In February, Psivida announced a second positive phase III trial of its Durasert for uveitis and in March made plans to delist from the ASX, acquire Icon Bioscience and become Eyepoint on the Nasdaq.

Proteomics launched its Promarkerd for diabetic kidney disease, Sienna claimed its first European sale of its telomerase-based adjunct cancer test, Orthocell claimed its first European sales of Celgro for dental implants, Invitrocue launched its Onco-PDO personalized cancer test, Atcor changed its name to Cardiex to market wearable sensors and Uscom’s Prof Rob Phillips continued expanding the company’s product portfolio, wearing out shoe leather and frequent flyer points only to see the share price fall. LBT sold its first APAS Independence to Melbourne’s St Vincents Hospital.

Innate became Amplia, and in a case of very bad timing, the US Justice Department and FBI began proceedings against former director Chris Collins in relation to share dealing during a trading halt.

In non-ASX news, MTP Connect announced a raft of small but important grants and collaborations, Johnson & Johnson opened innovation offices at Monash University and Queensland University of Technology, and both the Victoria State and Federal Governments continued funding important research and facilities. Biocurate announced its first six grants combining early stage research from traditional rivals The Shop and The Farm – the University of Melbourne and Monash University.

Despite being impressed with Blamey Saunders half-price beautifully designed hearing aids, it is Nuheara which caught the Biotech Daily ear with its Iqbuds Boost for mild to moderate hearing loss. Very cheap and able to do the job of filtering sound without the cost of a proper hearing aid. The most recent announcement of a device that allows a hearing challenged baby boomer to balance the television with the conversation in the room is a clear vote-winner.

Cochlear announced it was bringing back a fully implantable cochlear ear implant having conducted initial research in 2005. An 11-patient feasibility trial is underway.

In May the UK National Health Service was not NICE to Clinuvel and remained that way, despite the company's best endeavors. Compumedics announced a \$133 million deal with China Health 100, which fell over, but its China revenue stream continues.

In June, the little-known Melbourne-based Medicines Development for Global Health won US approval for oral moxidectin for River Blindness, the first not-for-profit to win an FDA approval and the first to win a "priority review voucher" worth north of \$100 million. Oh, and it has the potential to save millions of lives.

August began well, with Acadia offering \$630 million for the rights to Neuren's Trofinetide for North America, and the two companies are currently negotiating a deal for the rest of the world.

But August was the month, the Liberal-National Party - at the behest of Murdoch publications and a little man on Sydney radio - dumped the Prime Minister for Innovation Malcolm Turnbull, who promised to put innovation at the centre of his Government, but instead implemented cuts to the R&D Tax Incentive and had five different Innovation Ministers in three years.

At least Malcolm told us the lies we wanted to hear and his wife Lucy was a biotech chair for some years. The current mob wouldn't know their descending colon from an iron ore mine (apologies to Randy Newman).

Not that we think that Federal Labor has much more to offer – there was a terrific Bill Shorten statement on the importance of science and research, but until we see the funding and policies, that has as much value as Malcolm's innovation statement.

It was also the month that Innate's Chris Collins felt the long arm of the law. If only ASIC and the ASX had the investigative powers of the US regulators ...

Dr Greg 'Hercules' Collier has cleaned out the Invion stable, acquiring a light sensitive cancer treatment and packaged the Dr Mitch Glass respiratory assets he inherited into a new company, along with Dr Glass, leaving Invion free to focus on cancer.

Biotron had good news that it downplayed with BIT225 showing "significant benefit" for HIV, while Bionomics anti-anxiolytic BNC210 showed no benefit for post-traumatic stress disorder. Kazia (formerly Novogen) started its long-awaited glioblastoma trial, while Avita and Volpara both won US regulatory approvals, as did Optiscan's Carl Zeiss microscope and Resonance Health's Ferrismart.

Resapp claimed success in its US Smartcough-C-2 trial, despite having missed its stated first primary endpoint, saying that its smartphone algorithm was better than the doctors with stethoscopes. The market disagreed.

As recently as September 30, in a Biotech Daily Top 20 "first" we had four companies worth more than \$1 billion each in the BDI-20. But with a series of negative announcements in October and November, the time came to "rebalance" - as the S&P Indices calls it - the BDI-40.

November gave us many much unwanted "firsts".

At 9.01am on Monday November 12, we started the week with the News Flash that Phosphagenics had lost its hoped-for \$415 million Mylan case.

Seven minutes later we posted the news buried after the market closed the previous Friday that Bionomics would lose long-standing chief executive officer Dr Deborah Rathjen and review its assets.

And if that wasn't a bad enough start to the day at 11.17am a third News Flash went out that Mesoblast's much heralded end-stage heart failure trial had missed its primary endpoint.

We rarely post two news flashes in a week, let alone three in one day.

And, yes, I know. Now that the trial showed the stem cells don't work for the endpoint cited, we all know it was not actually a Mesoblast trial but an independent investigator led study, funded entirely by the US Government, and results that had never been mentioned previously about gastro-intestinal bleeding could be the indication for which the FDA approves the stem cells.

But it didn't stop there. Just when you thought it was safe to go back into the biotech waters on Wednesday November 14, Factor Therapeutics missed its phase II venous leg ulcer endpoint.

Four sets of bad news in three days. Not the record we wanted.

Unlike the Morrison Government, the Australian Biotech sector has seriously talented depth and replacing the demotees and departees of Admedus, Bionomics, Factor and ITL with the promotees of Antisense, Kazia, Patrys and Proteomics was not difficult.

It is also a very clear message that what goes down can go up, with three of the four returning to the Top 40 having had a brief vacation while finding new technologies or further developing existing ones.

And the mice and rats we've cured, can't be believed. There's never been a better time to be rat with cancer. Meanwhile, the Walter and Eliza Hall Institute has taken mouse models a step further developing mice that can be bred with specific human cancers.

Democracy Asleep

We are always amazed at how many companies can issue their directors and management options and so-called performance shares without raising the ire of shareholders who are paying to be diluted.

But the most amazing failure of shareholder activism has to be the acquisition of Sirtex by CDH. While 99.7 percent of votes at the meeting backed the \$1.9 billion deal, a staggering 92.6 percent of shareholders didn't bother to vote for their \$33.60 a share.

Valuations

A number of CEOs and directors have complained to Biotech Daily of what they consider to be poor valuations or a lack of understanding of the work of the company.

The Four Rules of Australian Biotech Valuations are quite simple:

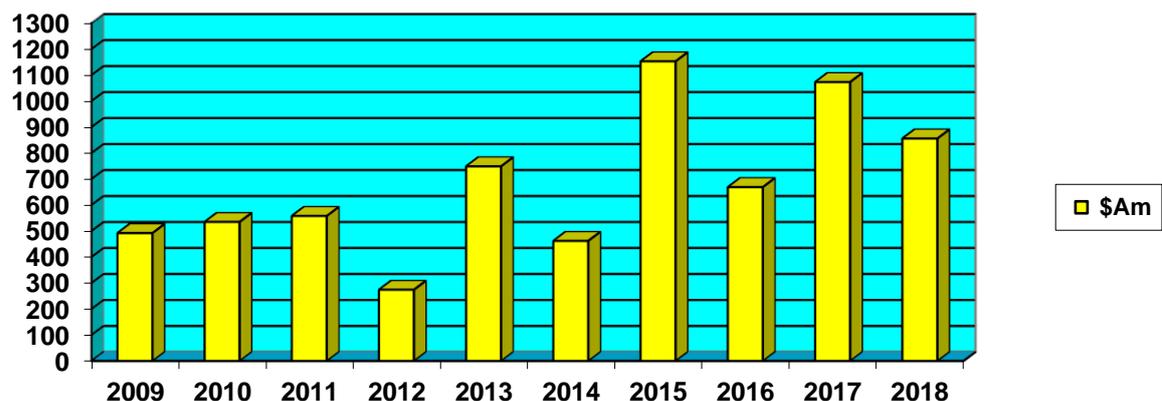
- i) When a company announces good news, the share price goes down;
- ii) When a company announces bad news, the share price goes down;
- iii) When a company announces no news, the share price goes down;
- iv) From time to time, for no apparent reason whatsoever, the share price goes up.

... and this proves that the market is always right.

Nevertheless, despite all the shocks, for the year to November 30, 2018 the benchmark ASX200 has only marginally outperformed the Biotech Daily Top 40, with the ASX200 down 5.1 percent and the BDI-40 down 5.9 percent.

In October, Telix made an announcement each day for four days in a row, with three and six percent rises. The day it didn't make an announcement, the share price went up 12.8 percent.

Capital Raising Chart 2009 -2018



While the total funds raised by the ASX listed biotechs for human health was down 23.3 percent from last year at \$855.7 million so far, it was the third highest on record and well above the 10-year average of \$677.1 million.

Kamikaze of the Year

Unfortunately, there have been several contenders for the ignoble prize, again.

The marijuana companies have not been backward in coming forward, with Esense's internal brawling making it sound more like Nonsense, not to mention THC (formerly Hydroponics) having similar but faster results. Can someone tell MGC it doesn't have to have a trading halt every time a board member passes wind?

Optiscan was clearly in the mix, having been rebuilt by Archie Fraser only to be brought undone by senior staff resignations and the board spill, and is now trying desperately to maintain the Zeiss contract. Talk about self-inflicted wounds ... and they were far from microscopic.

But for all 'round "we have no idea what you are doing and don't think you do either" the award has to go to Admedus and former chairman and current chief executive officer Wayne Paterson for taking a Top 20 company and putting it in a suspension for four months for a recapitalization, having taken the Prof Ian Frazer blue-sky virus vaccine business and spun it into a private company, majority-owned by Hong Kong and having made himself chairman for "at least five years".

Most of the December \$18.9 million capital raising appears to be at rates of 12.5 percent and possibly even 25 percent. The company has had three chief financial officers and four company secretaries in 12 months and that almost equals the Bruce Mathieson Karmelsonix/Isonea/Respiri four chief executive officers in 12 months.

Admedus is a train wreck, only paralleled by the Morrison Federal Government.

Worse, the promising anti-virus vaccines have now gone to Mr Paterson and his Hong Kong friends. Where are the PLA and Triads when you need them?

Chairman of the Year

This award gives credit to those admirals of the fleet who give strategic directions to the captains of their ships. If the objective is unclear, the mission will fail.

While tribute must always be paid to "Chairman Mel", Dr Mel Bridges of Too Many Companies to List, and we acknowledge last year's inaugural winner, David Williams, this year's award was pretty much decided in February.

Paul Hopper signed the \$502 million Merck acquisition of Viralytics and both Imugene and Prescient (of which he is a mere director) are Top 40 companies working on cancer trials. Well done, Paul

CEO of the Year

This is always the hardest decision.

We are blessed with some very hard-working chief executive officers and deciding who wins is difficult.

The Pharmaxis twins Gary Phillips and David McGarvie have scores on the board, despite the lack of valuation. Uscom executive chairman Prof Rob Phillips, Antisense managing director Mark Diamond and Rhinomed's Michael Johnson are three tireless Eveready batteries constantly on the road keeping their companies ticking over and Cellmid's Maria Halasz has worked exceptionally hard to keep Cellmid keeping on.

Starpharma's Dr Jackie Fairley, Opthea's Dr Megan Baldwin, Immutep's Marc Voigt, Genetic Signatures Dr John Melki, Volpara's Dr Ralph Highnam and Proteomics' Dr Richard Lipscombe have all impressed in 2018.

But only one has built their company into a billion dollar biotech from just \$114 million four years ago.

This year's winner is unequivocally Dr Sam Hupert for taking Pro Medicus into the billion dollar club, firstly with a technology he co-developed, acquiring the synergistic Visage Imaging and then landing the contracts to use the technologies.

Regulation

A few tips for making your media release make sense:

1. Give all finance figures in Australian dollars. Constant currency, head winds, tail winds and cross winds just sound like data mining, whether you are CSL or Start-Up From Nowhere. The Anteo debacle of reporting in Euro for 12 months meant that no one believes any of their figures.

2. AGM results: People who don't vote don't count. It's very simple. Give the total number of ALL votes on ALL resolutions and say what the resolutions were and the percentage required to pass. And then provide the total number of shares on issue.

If the opposition is less than 25 percent in the room on the day you will win the remuneration report and any special resolutions, but if it is more than five percent of the total on issue you could face expensive and time-consuming extraordinary general meetings.

3. Make sure your company's substantial shareholders understand the Corporations Act. Hiding behind "nominee" companies makes most people think they are crooks; and failing to state how much they paid for shares is a breach of the Corporations Act. Filing illegible or unreadable forms is also failing to comply with the Act.

Biotech Daily was very pleased to learn during the course of this year that we have been directly responsible for a number of changes to ASX regulations and/or guidelines.

Previously, Listing Rule 3.1 allowed companies themselves to decide what was "material" making a mockery of the Rule. This has been changed to "the reasonable person test" and we believe that is ... reasonable.

Other changes include the disallowance of hiding multiple news items in announcements or providing vague headlines such as "Investor Letter" or "Quarterly Report" when the real headline should be "Drug Fails, Board Quits, Sails to Venezuela".

Biotech Daily continues to encourage both the ASX and ASIC to enforce their existing regulations, as well as develop additional ones, such as disclosing the real identity of people hiding behind nominee companies.

Summer holiday publishing schedule

Biotech Daily will shut down for the long, hot, Australian Summer tomorrow, December 21 and be back on deck refreshed and recharged on Monday January 21, 2019.

Australia is on holidays, so DO NOT put out any announcements - that no-one will read anyway - for the next month. Go to the beach.

That said, we shall monitor all announcements and publish a Summer Holiday Catch-Up edition, highlighting any companies posting bad news after the market closes on Christmas Eve (Monday) and New Year's Eve.

Biotech Daily would like to thank its team of advisers: Prof George Fink, Dr Stuart Garrow, Marc Sinatra and Michael Ibbott for invaluable wisdom, insights and cautions throughout the year.

We wish everyone an excellent Southern Hemisphere Summer break, a Merry Christmas, a Happy Hogmanay/New Year and see you all in 2019.

David Langsam
Editor