



Biotech Daily

Thursday December 22, 2016

Daily news on ASX-listed biotechnology companies

2016 - The Year In Review

This was definitely the Year of The IPO and Backdoor Listing, from Recce in January to Zelda last month, not to mention The Rise of Brexit and Trump.

Biotech Daily calculates at least 18 initial public offers, back-door listings and spin-outs for the year, with the biggest the University of Queensland spin-out Protagonist raising \$A117.1 million at \$US12.00 a share to list on the Nasdaq and currently trading at \$US22.

And 2016 has also been the year of Medical Marijuana, with the much derided and feared heathen-devil-weed, now described as the cure-all for brain cancer instead of causing it, as well as efficacy for neurological disorders, acne, psoriasis and just about everything except Alzheimer's ... sorry... what was I saying? Oh yeah, Medical Marijuana.

The problem for some companies will be the business case. We are told by someone we met in a pub who we wouldn't recognize again, that the stuff grows from boulders in North America and allegedly along most Australian waterways, where generations of hippies have been tossing seeds since time immemorial – or at least the 1970s.

Last year, we noted the listings of Phytotech, now MMJ Phytotech and Medlab Clinical and even Cellmid said it had a marijuana midkine brain cancer collaboration, while former Perth MHR Dr Mal Washer announced his unlisted Auscann intended to source the 12,000 year old product from Norfolk Island, although given it is called "weed", perhaps just about anywhere will do. Nimbin has offered to host clinical trials.

This year, the Victoria Government has grown marijuana, distilled medical doses and is currently treating children with epilepsy. The most recent listing, Zelda, has produced some pre-clinical evidence for efficacy. Other companies are developing delivery methods and applications, including medical and cosmetic, but there has to be a concern over the profitability, especially when the recreational home-growing market opens. The person in the pub also said that it grows exceptionally well on kitchen windowsills, allegedly.

The Deputy Prime Minister and Minister for Agriculture, Barnaby Joyce, appears to have backed away from his bold April assertion that Australia would never import a crop that Australian farmers (and the Victoria Government) could grow, with a media officer telling Biotech Daily that any inquiries about importing foreign marijuana should be directed to the Federal Department of Health.

While stem cells are still hot, there has been a greater focus on immunotherapies, boosted by outstanding results for Keytruda and Opdivo, which is good news for Prima and Viralytics, among others.

Did we mention Zika virus? For a moment Zika was the flavor of the second, with Biotron which has not had great success killing HIV or hepatitis C in Thailand, suddenly discovering pre-clinical efficacy for Zika virus, not to mention Starpharma supplying condoms to the Australian Olympic team, with Vivagel touted as a Zika-killer.

But the University of South Australia and Sementis were already developing a vaccine against the mosquito-borne Zika virus, while India's Bharat Biotech said it was working on two vaccines.

Cancer was a big indication this year with millions of mice saved from every version of the disease, from head and neck through to melanoma, colorectal, liver and glioblastomas.

During the year a reader asked: "When was Australia's last successful phase III drug trial or registration?" It is a good question because – apart from CSL - it has been a long time between drinks. Chemgenex's Omapro, Pharmaxis's Bronchitol and Clinuvel's Scenesse come to mind. The late Cytopia's CYT-387 passed through YM Biosciences for \$14 million on the way to Gilead for \$362 million, Psivida's Medidur is a steroid delivery device and Redhill took Giaconda's Heliconda through phase III for Helicobacter pylori infection.

The reason Biotech Daily reports on Israel's Redhill is that it is a paradigm case. Sydney's Giaconda went belly-up and Redhill bought Prof Tom Borody's combination antibiotics, with two of the three technologies in phase III and the third in phase II.

Like last year's Spinifex, Fibrotech and Hatchtech deals showed, we can develop the technology, we just can't get it approved to return blockbuster funds to Australia.

We have had great success with devices and diagnostics, led by Cochlear, Sirtex, Nanosonics, Medical Developments, Compumedics, Ellex, Pro Medicus and Universal Biosensors to name a few, but drugs seem to be much harder.

Yesterday, Clinical Genomics said its 13 year collaboration with the CSIRO had culminated in the US launch of its bowel cancer test, underlining the problem of investing in a sector renowned for its "glacial time frames" to quote CSL's Dr Brian McNamee.

The other persistent issue has been the quality of Australian biotechnology directors. Compared to directors in other ASX sectors, they seem to be no worse and possibly better, but there are clearly some companies that lack a well-planned, proactive strategy to create shareholder value, coasting from bump to bump like dodgem cars at Luna Park.

While Biotech Daily knows everything that moves about the sector, that is only the external notifications. We have very little idea of what goes on behind the closed doors of the board rooms, although we can guess with some, and draw a correlation between some directors and the performance of some companies.

There is a group of directors known as “the usual suspects” who re-appear in new companies, sometimes overlapping and appear to be appointed – like those in other ASX sectors – because they are someone’s “mate” rather than having any particular skills.

Money

For the year to November 30, the BDI-40 climbed 13.3 percent, the ASX200 was up 5.3 percent, the Big Caps fell 0.6 percent and the Nasdaq Biotechnology Index (NBI) was down 18.1 percent.

But on July 1, the Biotech Daily Top-40 Index (BDI-40), which does not include the three Big Caps of Cochlear, CSL and Resmed, marked 10 years with a long term unadjusted increase in collective market capitalization of 163 percent over the decade compared to the ASX200 effectively flat-lining – up just three percent in 10 years.

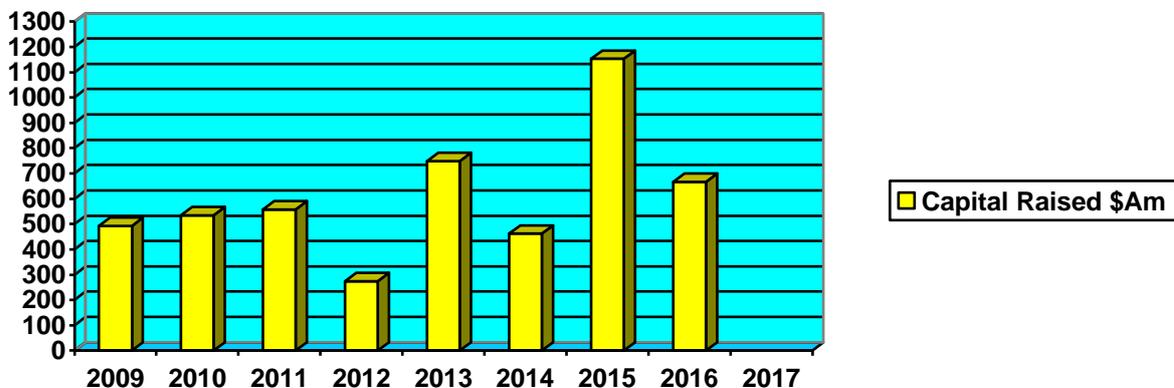
The NBI climbed 262 percent in the same period and the three Big Caps were up a massive 308 percent – mostly due to the Magic Pudding we call the privatized Commonwealth Serum Laboratories.

Resapp was the ASX star performer, climbing from next to nothing when it back-doored into Narhex to nearly \$300 million on an algorithm-based mobile telephone application to diagnose respiratory illness, posting good Australian data and preparing to convince us with a US study currently underway. Well done Dr Tony Keating and Brian Leedman.

Total capital raisings have continued to exceed expectations with more than \$667 million raised, not including CSL’s \$727 million, Protagonist’s \$117 million, Mesoblast’s \$120 million facility and Mayne Pharma’s giant economy sized \$888 million.

Including these raisings takes the total to \$2,517 million for the year, compared to the eight year average of \$611 million and last year’s \$1,136 million.

Capital Raising Chart 2009 -2016



The Good News

The year started with Living Cell posting that its NTCell pig brain implants stopped Parkinson's disease and the Cancer co-operative research centre (CRC) announced an up to \$731 million deal with Merck Sharp and Dohme for blood disorders.

In March, Living Cell started its 18-patient phase IIb trial of NTCell for Parkinson's disease and in April, Dr Christian Behrenbruch bid farewell to his ASX Longtail musings – to the great relief of some companies and tears from his dedicated readers - and raised \$15 million for the ailing Tissue Therapies, now rebadged as Factor Therapeutics and cleared by the US FDA for its phase II venous leg ulcer trial.

The same month, the Government of Victoria legalized medical marijuana and demonstrated how easy it is to grow, synthesize and deliver the product, initially for paediatric epilepsy patients, but expected to be broadened to a range of other indications.

Allegra Orthopaedics (formerly Advanced Surgical Design & Manufacture) began a renaissance with its Sr-HT-gahnite bone substitute. About the same time Bluechiip changed its strategic direction to win more customers.

Mayne Pharma raised \$888 million to buy a suite of 42 drugs from Teva.

Oncosil began its board renewal, losing Martin Rogers and appointing Cochlear's Dr Chris Roberts, who is expected to replace chairman and Brachysil inventor Dr Roger Aston, ahead of the start of its very long-awaited Brachysil pancreatic cancer trial.

Nanosonics broke through the \$1 billion market cap mark, LBT won FDA approval for its automated plate assessment system, Medadvisor signed Pfizer for its patient medication adherence program and Impedimed unveiled its impressive Sozo body fluid detection device, with approvals expected in 2017.

In November, Sienna won FDA, EU and TGA approvals for its telomerase-based adjunct diagnostic for bladder cancer, the Royal Melbourne Institute of Technology won a \$US500,000 Johnson & Johnson Quick Fire Challenge for a nebulizer - one of three awarded from 470 applicants, and Genetic Technologies licenced a new colorectal cancer test from the University of Melbourne and raised \$8.1 million. Well done Eutillio Buccilli.

Less Good News

The latest, saddest, baddest news is The Fall of Sirtex, despite strong support from long term investor Hunter Hall, which also supported GI Dynamics through very thick and not so thin times.

Last Friday's 6.09pm announcement that chief executive officer Gilman Wong was stepping aside for an investigation of his share dealing was a classic case of cack-handed investor relations mismanagement.

In the presumed hope of burying the news, it forced Biotech Daily to send out a late news flash, and realizing that would then not be included in the searchable headlines in the open-access library, we needed to report it in Monday's edition, as well. And we are still writing about it on Thursday.

If the decision really was made at, say, 5.30pm on Friday, and we were advising anyone, we would have held the announcement until 8.30am on Monday, so as not to look like we were hiding it. Appearances can be very important.

The fall from \$40 to \$14 means that Sirtex critics including Lodge Partners Marc Sinatra and Morgans Derek Jellinek look less like naysayers and more like oracles.

Benitec finally confirmed zero efficacy for TT-034 for hepatitis C, having been totally jumped by Gilead's \$90,000 a course, 12-week oral Harvoni, provided by the Federal Government at \$90 a course. Or \$15 if you have a Health Care Card. Benitec immediately said its hepatitis B drug was attracting a lot of big pharma attention, then announced a 2018 phase II trial of Nantventures antisense head and neck cancer drug. The appointment of Cliff Holloway to the Benitec team attracted some attention as he had recently been appointed chief executive officer of Sienna diagnostics which has announced quite a lot of progress since his departure.

In March, Antisense said that Strongbridge had handed back COR-004 or ATL1103 for endocrinology applications, including acromegaly, citing its "cash position". It was the second drug handed back after Teva's 2010 ALT1102 for multiple sclerosis.

GI Dynamics said its halted pivotal Endobarrier trial for obesity and type 2 diabetes failed to meet its primary endpoints. Much was made of the reduced numbers, but with 325 patients one might have thought there would be significance, if the device worked.

In April, Neuren tumbled on the failure of Trofinetide, or NNZ-2566, for traumatic brain injury, and is awaiting results from trials in Rett and Fragile X syndromes.

June heralded Rhinomed's second ASIC non-disclosure penalty as well as non-significance for its nasal plugs for sleep apnoea.

Mesoblast confounded the market with a June 1 trading halt for an "asset development" which had the rumor mill running, from a new acquisition to chief executive Prof Silviu Itescu retiring, and the mill kept spinning as the halt became a suspension, ending the suspense on June 14 with Teva handing back the cardiac program, which of course was an opportunity for Mesoblast to regain "full worldwide rights and full strategic flexibility to our mesenchymal precursor cell technology platform for the cardio-vascular field", as well as arranging an up-to \$120 million equity facility with Melbourne's Kentgrove Capital.

At a market capitalization of \$400 to \$500 million those funds are going to be somewhat dilutive, if required. Then again, after falling from more than \$2 billion, what's another 25 percent dilution between friends? It only needs one of the many programs to work, we keep telling ourselves.

In March, the Sydney-based CVC called for the removal of Bionomics chairman Graeme Kaufman and director Trevor Tappenden, following a controversy over a capital raising with eyebrow-raising attaching warrants or options, and by August they were gone, with new directors appointed.

Acrux lost further ground on an Axiron patent ruling, currently under appeal, and with a pipeline of generics in development, its recovery could be glacial.

The CM Capital and GBS Venture Partners-backed Sunshine Heart had its final seizure on September 30, dropping the innovative non-blood contact, aorta cuff pump for moderate heart failure. Sunshine Heart raised \$14 million to list on the ASX in 2004 and raised funds virtually every year since, to a total of more than \$120 million, prior to delisting from the ASX for the “better biotech valuations” of the Nasdaq, raising a further \$62 million. No one from the company was available to say what would happen to the technology and intellectual property.

Strange But True

Probably the weirdest announcement of the year was Prima’s \$400 million deal with the curious New York-based Sydys Corp, which had \$US856 in the bank at that time. Then again, it was in the longest Federal election campaign ever and Prima’s chair Lucy Turnbull may have been distracted by a close relative.

Equally curious is the amount of good work that can be done and the market won’t value. Uscom signed a five year \$65 million China deal in June, and climbed all the way from 24 cents to 35 cents and has eased back to 24 cents, which is better than January’s 14 cents, but doesn’t reflect the work done by executive chairman Prof Rob Phillips.

The same is true for Resonance Health, Universal Biosensors, ITL and Cellmid, all of which have put out good announcements and seen the share price stuck at historic lows. IDT has made significant announcements and gone backwards.

Government

In January, the Victoria Government appointed the Launchvic innovation board chaired by Australia Post chief executive officer Ahmed Fahour, with former Circadian chair Dominique Fisher the only person remotely connected to our sector. In February, Victoria appointed a 15-member Innovation Expert Panel with just two people known to the sector, Small Technology Cluster’s Dr Buzz Palmer and TBG director Emily Lee.

Last year Biotech Daily warmly welcomed the new Prime Minister Malcolm Turnbull, going so far as to describe him as St Malcolm of Wentworth. He immediately put innovation and Christopher Pyne at the centre of his agenda. We did say at the time that the focus on the future could not be more welcome, but the funds needed to increase.

Despite the very positive rhetoric, the funds appear to have been cut rather than expanded. There have been continuous announcements with big numbers, that on closer inspection are the total including matched funding and often over six or 10 years.

Now known as The Point Piper Fizza, it appears that Mr Turnbull's "innovative, nimble and agile" really means "the pea and thimble trick". Innovation Minister Greg Hunt (formerly Chris Pyne, previously Ian 'Fake Rolex' Macfarlane) has made announcements about all sorts of Federal initiatives, most of which are old money rebadged as new - and almost nothing said or done about the Tony Abbott/Joe Hockey thought-bubble we still call the \$20 billion Medical Research Future Fund.

It is now three years since the Great Concept was first mooted and the \$1 billion Hospitals and Charities Fund is still sitting there, but at least we have several high-powered committees and a thousand submissions to show for it. Nimble and agile. Like a \$US400 million deal with a company with \$US856 in the bank.

"Yeah, right." Australian – the only language in which a double positive is a negative.

In March, the Federal Government-dictated National Health and Medical Research Council awarded two grants worth \$3.3 million to study the effects of wind farms on human health. The Council's chief executive officer Prof Anne Kelso said that further research was needed despite a recent NHMRC report saying there were no impacts. In 2014, Joe Hockey and Tony Abbott derided politically-mandated wastes of grant monies. This one was a doozey.

Showing true bi-partisan co-operation following the Federal election, the Australian Labor Party reneged on a clear 2016 election promise and joined the Liberal National Coalition Government on reneging on its clear 2014 election promise and voted to cut the universally-loved 45 percent R&D Tax Incentive to 43.5 percent.

Biotech Daily said at the time the penny-pinching saved insignificant taxpayer funds while damaging innovation. Worse, the Ferris-Finkel-Fraser R&D Review proposed a \$2 million cap on refunds. Biotech Daily has the utmost respect for chief scientist Dr Alan Finkel, but that was not his best call.

Ausbiotech

Biotech Daily was concerned at reports that long-serving Ausbiotech chief executive officer Dr Anna Lavelle had been unwell and was not surprised when she was replaced at the top of the peak industry organization by chief operating officer Glenn Cross.

We were delighted to see Dr Lavelle at the October conference and in good form, now adding a couple of boards to her ceevee, including Medicines Australia.

The conference initially looked a little lacklustre, but turned out to be the event of the year, with stand-out addresses from CSL's Paul Perreault: "Innovate, focus on the patient or leave" and from Johnson & Johnson's Dr Jeanne Bolger: "We have no limit on our investments for the right technology".

Victoria's Innovation Minister Phillip Dalidakis was a little miffed at being bumped from opening the conference by his boss, Premier Daniel Andrews, but it was a good sign that the State Government "gets" biotech.

Biotech's favorite bureaucrat, Dr Amanda Caples was promoted to the position of Victoria's "lead scientist". Congratulations, Dr Caples.

And Finally

The **Biotech Daily CEO of the Year Award for 2016** has been a more difficult decision than previous years, with more than a dozen strong candidates.

The Nanosonics team of Michael Kavanagh, chief financial officer McGregor Grant and Dr Ron Weinberger broke the \$1 billion market capitalization barrier, Reva's Dr Reggie Groves, Genetic Technologies' Eutillio Buccilli, Pharmaxis' Gary Phillips and Phosphagenics Dr Ross Murdoch have turned their respective companies around, Dorsavi's Dr Andrew Ronchi and Resapp's Dr Tony Keating have impressed with deals and data, as have Opthea's Dr Megan Baldwin, Ellex's Tom Spurling, Compumedics Dr David Burton and Uscom's Prof Rob Phillips.

The three runners up were Pro Medicus' Dr Sam Huppert for all round good work, LBT's Lusia Guthrie for finally winning FDA approval for the company's second technology and Viralytics' Dr Malcolm McColl for excellent trial results in a complex strategy that at times has confounded your editor.

But the 2016 CEO of the Year award has to go to **Medical Developments' John Sharman** for continuing to wear out more shoe leather than anyone else and winning a raft of approvals and distribution deals across Europe for the company's Pentrox methoxyflurane analgesic. Take a bow, John, you've earned it.

Not many CEOs have behaved reprehensibly this year, although several boards have shown they are way overdue for "renewal", the polite word for a spill of the deadwood.

We considered withholding the **Biotech Daily Kamikaze Award** for a second year, but Unilife's Alan Shortall, who was vindicated by an internal inquiry as not costing the company anything material, has been the subject of much discussion. No one truly understands how Unilife kept posting significant revenues and licencing deals while posting ever-increasing losses. It's like the Magic Pudding gone wrong.

Runner-up, former Simavita chief executive officer Philippa Lewis, was for a short period of time one of Australia's best remunerated CEOs, taking a total of \$784,667 in the year to June 30, 2016 and more than \$1 million in the year to June 30, 2014, and despite a great deal of travel and many quite expensive investor meetings, was unable to progress the incontinence technology from an excellent idea at the time to commercial success. The combination of executive chairman Michael Spooner and chief operating officer Peta Jurd appears to be turning the Simavita ship.

That said, former Phosphagenics chief executive officer Dr Esra Ogru was due to be released from gaol on November 7, with claimed sightings in Mt Waverly, while Genetic Technologies founder Dr Mervyn Jacobson was released the previous year, and Acuvax's Dr William Ardrey is out on bail pending a retrial for fraud.

* * * * *

Biotech Daily's last formal edition for 2016 will be published tomorrow and we return on January 23, 2017.

Special thanks to Biotech Daily's team of advisers, Prof George Fink, Dr Stuart Garrow, Marc Sinatra and Michael Ibbott.

All important news filed to the ASX in the summer holiday period will be reported in the catch-up edition, with any bad news filed on Christmas Eve or New Year's Eve to be highlighted as such.

We wish all our readers a Happy Chanukah, Merry Christmas, Happy Hogmanay, a Sunny Summer and Snowy Winter Solstice and a bigger better biotech New Year in 2017.

David Langsam
Editor