



Biotech Daily

Thursday December 17, 2015

Daily news on ASX-listed biotechnology companies

2015 - The Year In Review

A number of readers seem surprised that despite the doom and gloom on the front page of some newspapers, 2015 was excellent for the biotechnology sector.

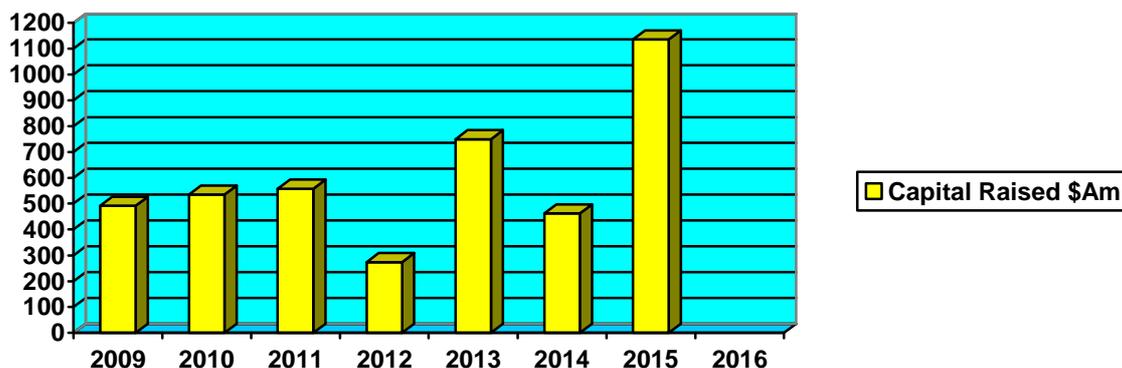
Last year the Biotech Daily Top-40 Index (BDI-40) fell 9.6 percent for the 12-months to November 30, 2014, but this year, the BDI-40 was up 22.0 percent, compared to the ASX200 down 2.7 percent and the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) up 21.8 percent for the year.

What is most amazing is that the capital raisings this year have been literally through the roof (of our chart), with more than \$1.136 billion raised to date, compared to a previous high of \$754 million and a seven-year average of \$439 million a year.

Even discounting the excellent \$200 million raising by Brandon Capital's Medical Research and Commercialization Fund, the total raised is the highest on record, with a large number of initial public offers and back-door listings, starting with Phytotech, Safety Medical becoming 3D Medical, Genetic Signatures, Proteomics, Actinogen, IQ3, Airxpanders (\$36.5 million), Narhex becoming Resapp, Medlab, Paradigm, Adherium (\$35 million), Medadvisor and Progen becoming TBG.

The single largest raising of the year by an existing company was Mesoblast's \$96 million, followed by Mayne Pharma's \$72 million, Unilife's \$57 million, Dr Jackie Fairley's Starpharma raise of \$32 million and Viralytics most recent \$28 million.

Capital Raising Chart 2009 -2015



The Good News

It's been a very good year, with a far greater number of significant announcements than ever before, and far more good news than bad news. It has also been a year of specific trends, with stem cells, immunotherapies and medical marijuana the leaders in the field.

Phytotech, now MMJ Phytotech, was the first out of the blocks to list in January at a 60 percent premium, followed by Medlab announcing a New South Wales Government-approved medical cannabis trial and even Cellmid has a marijuana midkine brain cancer collaboration.

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 a "weed", perhaps just about anywhere will do. Nimbin has offered to host trials.

The Victoria and New South Wales Governments are involved in three combined trials and the Victoria Government has set a 2017 deadline for legalization of trials of a plant used and studied for millennia, across scores of cultures, but so far without a single definitive large, randomized, controlled trial published in a peer-reviewed journal. Perhaps, as Dr Hook and the Medicine Show said: "they got stoned and they missed it".

The immunotherapy field is a bit more complex with established players including Prima, Viralytics, Immuron and Innate Immunotherapeutics. Viralytics has presented the most compelling data so far, but all are involved in clinical trials.

Stem cells are the flavor of the year, again, with Mesoblast dominant, but a raft of smaller companies claiming stem cell status, from Cynata to Regeneus, Admedus and most recently Cytomatrix and International Stem Cells. We recall that Stem Cell Sciences hit \$1.09 in April 2007 falling to 15 cents by March 2009 before disappearing.

Orthocell has announced positive trial news for its collagen scaffolds, tenocytes and chondrocytes for cartilage repair, including presentations and publications.

Medibio listed for its heart rate diagnostic for depression and Avexa has acquired Monash University spin-out Tali Health for its development disabilities diagnostic.

At the other end of the scale and far less sexy in terms of cutting-edge biological science are a number of diagnostic and device companies that deserve to be rewarded for doing the hard slog of building relationships and sales.

Sirtex is in a \$40-a-share and \$2 billion market capitalization league of its own, but smaller companies working hard include Ellex which posted a record \$63 million revenue for the year to June 30, 2015, along with Compumedics, Cyclopharm, IDT, Impedimed, ITL, Medical Developments, Nanosonics and Universal Biosensors. Pro Medicus tripled its market capitalization to \$342 million in the 12 months to November 30, 2015.

Cochlear posted a record \$926 million revenue, CSL had a record \$1.9 billion profit, with Sirtex posting record revenue of \$178 million.

Atcor achieved a CPT code for its Sphygmocor and Impedimed was granted serious reimbursement for its lymphoedema test. Medical Developments won EU approval for Pentrox in May and country approvals began with the UK and the Republic of Ireland.

Pharmaxis announced a \$40 million deal with Boehringer Ingelheim for PXS4728A for non-alcoholic steato-hepatitis, or fatty liver disease, later upgrading the deal to more than \$750 million and Antisense signed an up-to \$131 million deal with Cortendo, now Strongbridge, for ATL1103 for endocrine indications including acromegaly.

Both Cogstate and Dorsavi have announced a large number of contracts, but the revenue is taking time to show up in the quarterly accounts. The coming year will tell, which is also true for Uscom which acquired Hungary's Thor respiratory diagnostics adding to its BP+ central blood pressure system and the original ultrasonic cardiac output monitor.

Living Cell claimed four patient efficacy for its NTCell for Parkinson's disease, went even further saying it stopped Parkinson's progression, but has been validated by New Zealand allowing an 18-patient phase II trial of the pig brain cells.

3D Medical joined the ASX with what sounded like an imaging program before announcing it had printed a titanium jaw bone custom-designed for a particular patient and is completing a merger with Mach7 for medical imaging systems.

In June, the sector awoke to a new commentator on the block, Dr Christian Behrenbruch and his ASX Long Tail. Biotech Daily does not comment on commentary, but it is fair to say that Dr Behrenbruch has gingered-up the sector, some of his writing is amusing, some is excruciatingly accurate and some is opinion with which readers may disagree – and to his credit Dr Behrenbruch allows space for disagreement. He has been appointed a director of Tissue Therapies.

It highlights the absence of a serious publicly available biotechnology companies analyst, since Marc Sinatra decided he'd prefer real wages at Lodge Partners to the odd pub dinner from Biotech Daily.

To close the financial year Novartis agreed to pay Spinifex \$916 million for its University of Queensland-developed EMA401 for pain.

Resapp backdoored into Narhex, announced the first patient tested with its cough analysis for respiratory disease and in November posted what appears to be definitive sensitivity and specificity results, and a lot quicker than Isonex, which has changed its name, again, this time to Respiro but its 4.3 cents is a long way from the 88 cents high in 2013, which might have something to do with the Karmelsonix device not recording breath sounds.

In September, Starpharma signed a potential \$180 million plus deal with AstraZeneca for its dendrimer delivery of cancer drugs; Hatchtech sold its Xeglyze lice and eggs treatment to Dr Reddy's for \$279 million; and Ellex reduced glaucoma surgery from 45 minutes to a five minute procedure.

Less Good News

But it wasn't all chocolates and roses. Even GI Dynamics new chief executive officer Michael Dale couldn't turn his Titanic, as what appeared to be reporting issues and a few US liver infections led to a complete halt of the company's program.

All three companies that left Australia for the better-informed US market had significant setbacks. The first was Biota, but both Sunshine Heart and Heartware have been hit with bad news. Sunshine Heart reported not unexpected deaths and long-serving chief executive officer Dave Rosa departed the company.

Despite strong revenue Heartware tumbled on the news that it would acquire or merge with Israel's Valtech, and then fell a further 20 percent on halting its Conformité Européenne (CE) mark miniaturized pump trial. "James, James, Morrison, Morrison ..."

Osprey lost 72 percent when its Avert system failed to reduce contrast-induced nephropathy, its original raison d'être.

Wound care companies, Tissue Therapies and Avita, were sent back to the regulatory drawing board, but Avita and Polynovo secured BARDA burns trial contracts, worth \$77 million and \$38 million, respectively.

Alchemia has sold its assets and today announced a return of funds to shareholders. Fondaparinux has gone to partner Dr Reddy's, the VAST platform has been acquired for \$100,000 from the VAST inventors and Hyact was last seen with Panther Biotechnology.

Benitec wanted to raise \$95 million but took a 22.5 percent discount for \$19 million, while Mesoblast was discounted 35 percent but raised \$96 million. Starpharma lost six percent to raise \$32 million, Viralytics' \$28 million cost 5.2 percent, while Bionomics raised \$16 million at a 15 percent discount. Biotech Daily stands by its mantra that "bad money is better than no money", but it is also true that a premium is better than a discount.

Biotron suffered a major set-back with its Thailand phase II hepatitis C trial, expressing concern about the rigor of the trial more than the data.

Strange But True

Sirtex tumbled on apparently non-significant results to \$14.80, before recovering to \$40 a share. CSL hit \$100 a share, for the second time. The last time, it split three-ways, meaning those \$15 shares I didn't buy in 2003 are worth \$300 each. Not to mention the \$2.30 shares that smart punters bought in the public offer or were given to CSL staff.

And who could forget the 1s and 0s expended by Pharmaust's dog-by-dog PPL-1 trial announcements, or the even more prolific Novogen papers on the potential for its cancer cures in petri dishes and mice, until July, when Iain Ross announced the departure of founder and chief executive officer Dr Graham Kelly.

Polynovo, formerly Calzada, nee Metabolic, had a quick sale for the anchor on its operations, AOD9604, taking a quick \$1.5 million from the alleged drug's champion David Kenley and colleagues.

Prof Barry Marshall's Ondek bought 19.9 percent of Bioxyne and it looked like a marriage made in bio-heaven. But we have heard nothing since, except that Bioxyne has amazed with Mariposa licencing Hunter Immunology's HI-164OV to China.

In October the High Court of Australia found the Myriad and Genetic Technologies BRCA genes were not patentable, which concerned some but does not appear difficult to resolve. One can't patent an object found in nature, one can patent something one does to the object, or creates from the object.

There were philosophical issues issued to torment us as well, not least of which was the expectation of consistency from stock market data provider Iress. Biotech Daily had a number of therapeutic exchanges with company directors, executives, Iress staff and personnel at the Chi-X trading platform.

Apart from an inability to correctly update company market caps from Friday night to Monday, possibly due to computer penalty rates for working weekends, Iress would quote the last price of the day whether on the ASX or Chi-X, but then only report the ASX closing price. This year-long battle has culminated in Iress saying it will fix both issues. We live in hope.

Over at the institutional shorting and day-trading industries, there is little hope. Biotech Daily has been exasperated by the Goldman Sachs Rothery Life playing with Nanosonics, as well as UBS AG and several other companies but the daily in and out is entirely legal, which is why we want the law changed. There is an argument that short-selling balances the market, but when it is the prime motive, one needs to wonder. Perhaps the concept of "lending" shares needs review, in so far as one can't lend a prescription drug or a pilot's licence.

A tweaking of the proposed tax measures in the National Innovation and Science Agenda could make long-term investment more attractive than day-trading. Which brings us to:

Government

Well, what a difference a new Prime Minister and 85 days can make. St Malcolm of Wentworth dismissed his predecessor Tony Abbott on September 14, announced his Ministry on September 21, putting innovation and Chris Pyne at the centre of his agenda and just last week announced \$1.1 billion for innovation spending over four years

As Biotech Daily said in September and last week, the new focus on the future could not be more welcome, but the funds need to increase. On Monday, Mr Pyne said he had talks with Israel's Prime Minister Benjamin Netanyahu and would like to see Australia emulate Israel's innovation.

In that case with three times the population, the innovation budget should be three-fold Israel's, which has a \$US350 million a year research and development budget as well as \$US520 for life science, venture capital and nanotechnology funds. According to the OECD, Israel spends about 4.5 percent of its GDP on research and development, compared to Australia's 2.25 percent. Israel is first on the list, Australia is fourteenth.

If any readers have influence over the Government, three more important steps would be to: set aside 25 percent of funds from the proposed \$20 billion Medical Research Future Fund for commercialization; drop the Senate proposals for the miserly 1.5 percent cut to the R&D Tax Incentive; and broaden the welcome tax exemptions in the National Innovation and Science Agenda to include eligible publicly-listed innovation companies so that retail investors can also take the risk and support start-ups.

In June, the Federal Government said it was looking for a new chief scientist to replace the departing Prof Ian Chubb, who did not say very much about innovation or biotechnology to the best of our memory.

In October, following the ascent of the bright shiny new Prime Minister Malcolm Turnbull, Australia was rewarded with the even brighter, albeit slightly older, but definitely shiniest Dr Alan Finkel. The very outgoing Monash Chancellor has a track record of innovation and creating start-ups, investment in biotechnology and an understanding of academia as well as finance. What more could we want? Funding.

Legal Matters

Thankfully not much on the fraud and market manipulation front this year apart from former Acuvax chief executive officer Dr William Ardrey enjoying Her Majesty's Pleasure in Perth for a fraud not related to Acuvax.

Genetic Technologies founder Dr Mervyn Jacobson and Phosphagenics Three co-conspirator – and co-inventor of the AOD9604 wonder drug – Dr Woei Jia-Jiang have both served their time, while Dr Esra Ogru and Dr Robert Gianello have another year to go.

Not quite the legal department, Optiscan chairman Angus Holt was questioned by the ASX over director's interest statements and shortly after was no longer Optiscan chairman.

The **2015 CEO of the Year Award** was even harder to pick than last year. If Spinifex chief executive officer Dr Tom McCarthy was running a publicly-listed company he would be the front runner.

Previous winners Richard Carreon, Prof Silviu Itescu, Gilman Wong, Dr Paul MacLeman and Dr Richard Treagus have put in massive efforts for their companies this year, along with serious candidates like Dr Jackie Fairley, Dr Megan Baldwin who has turned Circadian into Opthea, Medical Developments John Sharman who has worn out more shoe-leather than most, Viralytics' Dr Malcolm McColl, Pharmaxis' Gary Phillips, Hatchtech's Hugh Alsop and Actinogen's Dr Bill Ketelbey.

But the 2015 Biotech Daily CEO of the Year Award goes to Bionomics Dr Deborah Rathjen for more than a decade of running a start-up company in the public spotlight culminating in two major deals with Merck Inc, \$172 million in 2013 and \$US506 million plus royalties for BNC375 last year, and raising \$US21 million from Merck and four other investors. Well done, Dr Rathjen.

Thankfully, **the Biotech Daily Kamikaze Award** has been withheld in 2015.

Biotech Daily's last formal edition for 2015 will be published tomorrow and we return on January 27, 2016.

All important news filed to the ASX in the summer holiday period will be reported in the catch-up edition.

The subscription price remains unchanged as a thank you to all subscribers to mark our 10 years as the sector's journal-of-record.

We wish all our readers a Merry Christmas, Happy Hogmanay, a Sunny Summer Solstice and a very big biotech New Year in 2016. I think we've all earned it.

David Langsam
Editor