Biotech Daily

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Daily news on ASX-listed biotechnology companies

The Year In Review

For many, 2012 has been an annus horribilis and they are glad to see the back of it, but it hasn't been all bad news.

At the last market capitalization update on December 3, the Biotech Daily Top 40 Index (BDI-40) which does not include the three Big Caps of Cochlear, CSL and Resmed was up 5.5 percent for the year to November 30, 2012, compared to the ASX200 up 9.4 percent for the 12 months. Collectively, the Big Caps were up 54.8 percent for the year.

The best performing biotechs were Sirtex, up 185 percent to $652 million and still climbing, and Alchemia up 133 percent to $149 million. Other companies that should feel reasonably comfortable with their efforts are Heartware up 17.0 percent to $1,025 million, Avita (87.5%), Neuren (66.7%), Sunshine Heart (43.9%), and from smaller bases, Ellex (54.5%), Patrys (90%), Prana (79.2%) and Uscom (120%).

Currently outside the BDI-40, Medical Developments has pleased long-suffering investors by climbing 331.8 percent to $101 million. Mayne Pharma has doubled to $147 million, primarily from capital raisings for the acquisition of Metrics and GSK's Kapanol.

Down in the doghouse from the penthouse were Impedimed down 76.2 percent to $20 million; QRX down 43.6 percent to $110 million, as well as Bionomics and Genetic Technologies both down 35.8 percent for the year to November 30, but for very different reasons (see below), followed by Bioniche (55.7%), Phylogica (54.2%), Antisense (39.3%), Compumedics (35.7%) and GI Dynamics (26.2%).

(The full-year BDI-40 update will be published early this year on Friday December 28).

Probably the single major success of 2012 was Heartware's US Food and Drug Administration approval (BD: Nov 21, 2012).

The company has grown 10-fold since listing in Australia and its success raises the interesting question of whether US companies listing on the ASX are a net benefit or disbenefit when all factors are taken into account. Apart from Heartware itself, the brokers, banks, managers and public relations companies all benefited; and Heartware maintained a token office in Australia for some time.

Many Australian investors did well as the share price climbed, but as it did, the shares migrated to the US, so the greatest benefit has not remained in Australia. Indeed, while the loss-making occurred in Australia, possibly earning grants and tax relief from Australian taxpayers, the potential profits will primarily return to the US. Biotech Daily would like to see a comprehensive cost-benefit analysis.

The other billion-dollar plus biotech, Mesoblast, (down 10.2% in 12 months) has had a rocky ride, apparently at the hands of both US-based short-sellers and an unusual series of notes from Macquarie Equities analyst Dr Craig Collie who has repeatedly asserted incorrect endpoints for the phase II congestive heart failure trial as well as correctly challenging Mesoblast to publish data and confirm Teva's commitment to the major cardiac trial.

Prior to the Macquarie criticism, Biotech Daily also challenged Mesoblast executive director Prof Silviu to publish serious trial data.

In response to an ASX price fall query and 'market speculation' Mesoblast said it was working with Teva on its trial and at a major conference last week Teva's head of research and development and chief scientific officer Dr Michael Hayden confirmed the company's commitment to the trial (BD: Dec 12, 2012). Dr Collie claimed to find wiggle room that it was really only a phase II trial. Dr Hayden unequivocally said it was a phase III trial.

The next day Mesoblast republished a University of Texas MD Anderson Cancer Center phase I/II trial showing that expanding cord blood using Mesoblast's mesenchymal stromal cells was safe and effective. The data was published in the New England Journal of Medicine, described by some as the single most prestigious journal in clinical research. Biotech Daily believes this debate is now closed and from here, only trial results matter.

Sirtex has overtaken Pharmaxis, Starpharma and Acrux to emerge as the third largest company in the BDI-40. The Biotech Daily quiet achiever chief executive officer of 2012 award goes to Sirtex's media-shy, but hard working and diligent Gilman Wong and - before he corrects me again – his team.

Mr Wong has continued pushing sales of SIR-Spheres for primary and secondary liver cancer and at the same time developed a series of trials to move the microspheres from last line to first line therapy. His presentations have been polished and professional. With great humility, and an underlying grace, he notes Sirtex is a small nuclear power. Well done, on an excellent year, Gilman.

Pharmaxis finally won Australian reimbursement and began Bronchitol sales in Europe, Alchemia's fondaparinux has paid its dues and is returning funds to the company and the US Food and Drug Administration approved Leo Pharma's Picato or ingenol mebutate gel, formerly known as Peplin's PEP005, for actinic keratosis. Prima has begun a phase III trial for ovarian cancer.

Many expected Roche to acquire Bionomics' non-addictive, side-effects-free, anti-anxiety drug BNC210, but in a licence worth up to $US345 million, CEO Dr Deborah Rathjen calmly signed the first major deal of 2012 with Massachusetts-based Ironwood.

The year also saw the US-based Osprey listing for its Melbourne-designed catheter treatments; Novogen has come back to the future with founder Dr Graham Kelly as CEO; Prana's news flow moved from journal papers on PBT2 to clinical trials; Benitec bought back its Tacere hepatitis C assets; Biotron claimed some hepatitis C success for BIT225; and Biodiem has all its ducks lined up, except for share liquidity. CBio's XToll failure led to a rebirth as Invion for inflammatory diseases including XToll renamed INV103 for lupus and INV102 for mild asthma and smoking cessation.

In breaking news, today, Perth-based GBU Capital has orchestrated Acuvax's acquisition of Biolife Science, returning Dr Roger Aston and Paul Hopper to the company formerly known as Avantogen or Australian Cancer Technology.

The bad news, and there has been too much of it, includes lengthy European delays for Tissue Therapies Vitrogro wound treatment and long delays in US rebates for Impedimed's lymphoedema test.

The QRX crash from $265 million to $110 million has been described as the biggest shock to investors, with expectations that the FDA would easily approve Moxduo as it equaled its components parts (BD: Jun 27, 2102).

But one of Biotech Daily's first questions to CEO Dr John Holaday was: "How does Moxduo compare to equi-analgesic doses of morphine or oxycodone?" Four years later the FDA has asked the same question.

That said, the combination drug appears to be no worse than existing opioids for pain and Biotech Daily believes the strong board and management will simply not stop until the FDA approves the drug, which is already partnered by Actavis (now Watson Pharmaceuticals) in the US and Paladin Labs in Canada.

Equally mystifying was Biota's departure to America via Nabi, ostensibly for $US54 million in cash, finally settling for $US27 million and leaving 10,000 Australian investors with a lot of forms to fill in to sell shares if the price ever recovers from what must be one of the worst executed events of the year. The loss in value the company suffered in the move was multiples of the cost it would have incurred by maintaining its ASX listing. There is the hope that the US Government contracts will lead to revenue, but much-hyped replenishment of US Government influenza pandemic stocks failed to materialize.

Acrux lost chief executive officer Dr Richard Treagus and following uncertainty over a patent case and a revision of income expectations the share price has fallen from a high of $4.77 to a low of $2.59. But when Allan Gray (formerly Orbis) buys in, it's a strong signal the share price is going up, regardless of certain speculative research notes.

In the really bad news department, Hunter became Bioxyne, listed on the ASX in April, failed to meet its endpoints for chronic obstructive pulmonary disease exacerbations in June, had a failed board spill in October and a successful one in November and is now under new-ish management.

Tyrian was unable to commercialize its Diagnostiq technologies and effectively shut up shop, but Agenix has acquired the platform for human use and appears ready to breathe new life into the test system, but not the company.

Several companies mortally wounded in the 2009 global financial crisis or failing through their own means took three years to leave the biotech lists to become mining companies including Fermiscan, Fluorotechnics, Select Vaccines, Safety Medical and OMI.

And how can we mention mining and biotech in the same sentence without immediately thinking of Avexa chairman Iain Kirkwood who will steer the company to a 25.5 percent holding in a disused coal mine in Alabama, with Avexa 17 percent shareholder and Singapore entrepreneur Jonathan Lim holding a further 25.5 percent, ostensibly to fund a new phase III trial of apricitabine for HIV.

Thank you to all our readers – especially the southern state Americans – for your most humorous responses to that announcement.

Less enjoyable was the disaster-in-waiting at Genetic Technologies. After all the hard work by former chief executive officer Dr Paul MacLeman to make the company look respectable after the last board spill by founder and major shareholder Dr Mervyn Jacobson, with sales underway in the US, Dr Jacobson busy earning licencing revenue and a renewed board with the talent of chairman Dr Mel Bridges and director Greg Brown, lightning struck for the second time. It will be interesting to see how new chairman Dr Mal Brandon and chief executive officer Alison Mew fare in rebuilding faith in the company.

The last of the unpleasant news for the year (we hope) is the failure of Starpharma's Vivagel to work for treatment of bacterial vaginosis. Biotech Daily was concerned that the company was describing the endpoint of 'cure' at two to three weeks without follow-up testing when the patients had not been on the drug for some time. The response seemed more like a brief cessation of symptoms than a cure and in any case it only 'cured' 46 percent of patients in the phase II trial.

It was surprising to hear chief executive officer Dr Jackie Fairley blaming lower socio-economic women with potentially less education for causing the non-significance in the phase III trial, possibly by not complying with the trial protocol. Another possibility is that those women were more likely to do what they were ordered by the doctor and stopped inserting cosmetics and other treatments known to cause and/or exacerbate bacterial vaginosis. One expert on the subject told Biotech Daily that there was anecdotal evidence that the HEC control gel had a high rate of 'placebo effect'.

The trial, along with the failure to market Vivagel for HIV in Africa or for rape victims in the highlands of Papua New Guinea, is beginning to make it look like a drug in search of an indication. On the other hand Biotech Daily remains impressed with the core dendrimer nanotechnology about to be trialed with docetaxel for cancer, as well as several other deals Dr Fairley has forged with pharmaceutical, agriculture and veterinary partners across a range of uses. Again, it is worth noting where Allan Gray puts its money.

Allied Health, Benitec, Cellmid, Genera, Living Cell and Viralytics all have promising technologies and all have ended the year well by simply surviving in difficult times. Living Cell CEO Dr Andrea Grant and Biodiem's Julie Phillips deserve accolades for transforming their respective companies over the past year.

Finally, the loss of GBS Venture Partners Dr Andrew Baker at the age of 51 years deeply affected many in the industry. Andrew was a great guy, an erudite scientist and thoughtful investor. His death from cancer reminds us why we are here.

Biotech Daily's last formal edition for 2012 will be published tomorrow and we return on January 22, 2013. All important news filed to the ASX in the summer holiday period will be reported in the January 21 catch-up edition. The subscription price will have a slight increase to a base rate of $850 in the New Year.

We wish all our readers a very relaxing Summer holiday break, Merry Christmas, a sunny Summer Solstice and a better biotech New Year in 2013.

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