Biotech Daily

Monday January 23, 2017

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: BIONOMICS UP 6%**
- GENETIC SIGNATURES DOWN 7%

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MARKET REPORT

The Australian stock market fell 0.77 percent on Monday January 23, 2017 with the ASX200 down 43.8 points to 5,611.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and six were untraded.

Bionomics was the best, up two cents or 5.6 percent to 38 cents with 254,403 shares traded. Atcor, Avita and Factor Therapeutics climbed more than four percent; Viralytics was up 3.45 percent; Clinuvel, IDT and Medical Developments rose more than two percent; Acrux, Prana and Pro Medicus were up more than one percent; with Resmed and Starpharma up by less than one percent.

Genetic Signatures led the falls, down three cents or 6.7 percent to 42 cents with 22,644 shares traded. Osprey lost 5.7 percent; Compumedics and Ellex fell more than four percent; Actinogen, Oncosil and Sirtex were down more than three percent; CSL shed 2.7 percent; Mesoblast, Opthea, Pharmaxis and Universal Biosensors were down more than one percent; with Cochlear down 0.5 percent.

BIOTECH DAILY: WELCOME TO 2017 EDITORIAL

In more than 11 years of publishing Biotech Daily we have never editorialized on global politics and never run an opinion piece in the first edition of the year.

But 2017 is different.

What do Brexit and the inauguration of US President Donald Trump mean for Australian biotech companies, universities and research houses?

While there is no crystal ball a few things are obvious.

Killing the US Affordable Care Act (Obamacare) means 20 to 50 million fewer customers. Biotech Daily has never understood why the big pharmaceutical, device and diagnostic companies don't understand "economies of scale" nor that the oxymoron "US healthcare system" has continued increasing layers of middle-people all taking their cut between the technology owner and the customer.

Impedimed's history of reimbursement for a relatively simple diagnostic is a Byzantine journey through bureaucracy. That anyone in Australia would want to emulate the US system beggars belief (see below).

Biotech Daily believes that with politics "what you see is what you get" and the Trump Presidency is going to be marked by chaotic 'twitter-led' policy-making with little or no regard to facts, truth, counsel or advice – a lot like the Australian experience under Prime Minister Tony Abbott and Treasurer Joe Hockey. The only certainty is that market uncertainty will be the order of the day.

What that means for our sector is that if you have a drug, device or diagnostic that people literally can't live without, like CSL's blood products, then the world will be your oyster, but if you are developing something more difficult to understand or prove, funding could become an issue, very quickly.

Biotech Daily believes that any company that can raise capital should be cashed up - either for the next four years, or at least until the timeline for proving your technology is indispensable.

As for the Full English Brexit – as The Guardian's Steve Bell describes it – some companies have relied on the UK as a port of entry to Europe. This is highly likely to change, making it that much more difficult to gain European approvals, although it could make the Republic of Ireland and potentially Scotland quite attractive.

There is also a great concern over the rights of non-British citizens to remain in that country regardless of length of residency. It is likely to cause some brain-drain away from the UK and potentially cause difficulties for London as a financial centre.

One positive is that with the fall of Sterling, Australian companies will be better able to afford UK personnel and facilities.

In Australia, one of former Health Minister Sussan Ley's indiscretions with taxpayer funds was a trip to the US, apparently to gain a better knowledge of their system.

Ms Ley has been replaced by Greg Hunt who has control of National Health and Medical Research Council and Australian Research Council grants as well as that great mythical being, the $20 billion Medical Research Future fund, which is yet to allocate any funds from the $1 billion held by the Hospitals and Charities Fund or all the cuts to the Health Budget redirected to the Fund in the 2014, 2015 and 2016 Federal Budgets.

Mr Hunt has been replaced in Innovation Industry and Science by Senator Arthur Sinodinis and while Biotech Daily welcomes an experienced politician to the portfolio, it is with caution.

Senator Sinodinis comes with considerable baggage from his days as the Liberal Party treasurer at a time of curious donations and is the third Innovation Minister since Prime Minister Malcolm Turnbull said he would put innovation at the centre of his agenda in appointing Christopher Pyne to the job, 12 months ago.

In three weeks, we shall mark the Chinese Year of the Rooster, and that could be the wake-up call to prepare for the "interesting times" ahead.

The good news is that there is more activity in the sector than ever before, with a record number of companies listed on the ASX, more investment from off-shore investors in both companies and research institutions and strong capital raisings.

To help us understand our way through the array of companies, Biotech Daily is delighted to announce that former Criterion writer for The Australian, Tim Boreham, will contribute regular analyses of the sector, starting with today's assessment of Sirtex (below).

David Langsam, Editor

DR BOREHAM'S CRUCIBLE: SIRTEX MEDICAL

By TIM BOREHAM

Code: SRX; **Market cap:** $871m; **Share price:** $15.09.

Acting chief executive officer: Nigel Lange.

Board: Richard Hill (non-executive chairman), Dr John Eady (deputy chairman), Dr Katherine Woodthorpe, Grant Boyce, Darren Smith (chief financial officer).

Financials for 2015-'16 year: revenue $234.7m (up 32 percent), net profit $53.5m (up 33 percent), dose sales 11,931 (up 16 percent), earnings per share 93.7c (up 31 percent), cash on hand $107m (up 44 percent).

Market darlings trading on high earnings multiples have a nasty habit of reverting to the norm. Sadly that's the case with the liver cancer house, which offers a targeted second line (or survival) therapy for patients with an advanced form of the malady.

There’s no doubting Sirtex’s impressive global market reach. Its SIR-Spheres - microscopic beads that deliver radiation treatment straight to the liver tumor - are sold in 1000 medical centres across 40 countries, with 67,000 patients treated to date.

Early in 2016 Sirtex shares appeared to have shrugged off the previous year’s swoon, which stemmed from the poor (or, more generously, indifferent) results of the long-awaited 550-patient Sirflox trial.

The trial aimed at first-line treatment for metastatic colorectal cancer, but failed to show a difference in “overall progression free survival”.

Sirtex’s inability to expand its repertoire to beyond a salvage treatment is now hurting the company. In a December 9, 2016 trading update, Sirtex reported global dose sales growth was expected to be five to 11 percent for the 2016-’17 year, compared with 15.7 percent growth the previous year.

The company cited “volatile” trading conditions ensuing from a range of factors, including a rival drug approval for salvage metastatic colorectal cancer and restricted reimbursements, especially in Europe.

In constant-currency terms, Sirtex expects earnings before interest, taxation, depreciation and amortisation (Ebitda) to be $65 million -74 million: at best a flat number or a decline of up to 12 percent.

On January 9, 2017, Sirtex reported first half sales growth of 5.6 percent - at the upper end of the guided four to six percent range - and investors exhaled a sigh of relief.

But not for long.

Four days later, Sirtex announced that chief executive officer Gilman Wong - dubbed CEO of the year by CEO Magazine in 2013 and by Biotech Daily in 2012 - had been terminated from the role “with immediate effect”.

Mr Wong had already stepped down pending the outcome of an internal review of his decision to off-load some of his personal holding in Sirtex shares in October.

In short, a financial year annus horribilis. But what’s the prospect for salvage therapy for investors under interim chief executive officer and former chief operating officer Nigel Lange?

To the naysayers, advancing competition has caught up with Sirtex’s stagnating one-trick-pony. Competition from radiotherapy rival BTG is intensifying, while Japanese pharmaceutical house Taiho Oncology has released a new chemotherapy drug called Lonsurf.

In January, the US Food and Drug Administration granted priority review status for Stivarga (regorafenib), a second-line treatment for the most prevalent liver cancer, hepatocellular carcinoma (HCC).

Drowned out by the noise of the claqueurs in the Sirtex cheer squad, Lodge Partners analyst Marc Sinatra saw the Sirtex problems coming some time ago, warning about the "very significant risks" in the clinical trials and over-enthusiastic projections about the potential size of the market, especially in China.

"Lodge tried very hard some time ago to inform investors that we saw very significant risk in the Sir-Spheres clinical trials, that the market for the product was a lot smaller than most were projecting and that competition would increase substantially in several forms in the near/medium term," Mr Sinatra said.

"It looks very much like the speculative risks we saw back then, have become very reality since," Mr Sinatra said.

The more consensual view is that dosage growth of five to 11 percent still amounts to advancing sales and the stock looks keen value if it can regain its growth trajectory.

The optimists also note that Mr Lange has a sales background and this discipline should help Sirtex retain market share in the US, its most important geography.

According to Bell Potter, there's still potential if an eight-month extension of the Sirflox trial can generate a survival benefit. Bear in mind that the original trial showed the treatment slowed the spread of cancer in the liver by 7.9 months.

Meanwhile Sirtex retains the faith of major holder Hunter Hall Investments, despite January's surprise departure of Hunter Hill founder and chief investment officer Peter Hall. After buying stock on December 9, the fund disclosed its stake at 6.69 percent compared with 4.97 percent previously.

Several funds trade in Sirtex, with Goldman Sachs, AMP and Perpetual all trading around the five percent substantial mark.

Sirtex shares are trading close to their January 3 low of $14, compared with the previous February's 12 month peak of just over $38 per share.

Sirtex shares trade on an earnings multiple of 18 times, which is modest for the health care sector.

Thankfully, Lodge's Marc Sinatra doesn't see Sirtex as an "Acrux in the making", a reference to the roll-on testosterone house which has had its own libido issues in the face of intensifying competition.

"But (Sirtex) will need everything to go their way if they are to return to anywhere near their former glory," Mr Sinatra said.

Dr Boreham concurs. Sirtex needs a period of rest and recuperation and investors should tip-toe past the recovery ward to healthier exposures.

**** Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Nor is he a licenced financial adviser.***

REGENEUS

Regeneus says it has received $US5.5 million ($A7.3 million) from AGC Asahi Glass as an upfront payment for the rights to manufacture Progenza (BD: Jan 22, 2017).
Regeneus said in December that it had a collaboration and licence agreement with the Tokyo, Japan-based AGC and expected to receive a further $US11m in specific development and approval milestone payments and would be entitled to a share of upfront licence fees, milestone payments and royalties from sub-licencing the development and commercialisation of Progenza for osteoarthritis and all other clinical indications in Japan.
The company said that AGC would be responsible for funding the manufacture of Progenza for the proposed phase II trial for osteoarthritis in Japan.
Regeneus was up one cent or 6.25 percent to 17 cents.

CYNATA THERAPEUTICS

Cynata says it has raised $6.0 million in a placement to existing and new sophisticated and institutional investors at 65 cents a share.
Cynata said that the "heavily over-subscribed" placement with the previous $3.97 million Fujifilm investment would fund the acceleration and expansion of the development of its Cymerus mesenchymal stem cell technology, "specifically to build on the existing data supporting the potential utility of [the stem cells] in developing cellular therapies to treat respiratory disease, cardiovascular disease and a number of other serious conditions" (BD: Jan 22, 2017).
Cynata fell 11.5 cents or 14.7 percent to 66.5 cents with 1.4 million shares traded.

ATCOR MEDICAL

Atcor says its Sphygmocor XCEL measured the primary end-point in a trial which showed the Novartis drug was more effective than standard hypertension treatment.
Atcor said that the Novartis Pharmaceuticals Parameter study of 454 multi-ethnic elderly patients with systolic hypertension was published in the journal Hypertension and showed that the Novartis new drug compound of sacubitril and valsartan was more effective than the currently used olmesartan in reducing and central aortic systolic pressure and central aortic pulse pressure within the trial period ($p=0.01$).
The company said that the study aim was to determine the effectiveness of the Novartis drug in reducing central aortic systolic pressure in elderly patients, which was the primary end point and measured using Sphygmocor XCEL.
Atcor chief executive officer Duncan Ross said the company had worked "closely with Novartis on a number of its trials over the years".
"It is pleasing to see positive results that will lead to better outcomes for at-risk patients, further demonstrating the clinical benefit of utilising Sphygmocor in patient management including drug selection and dosing," Mr Ross said.
Atcor was up 0.3 cents or 4.6 percent to 6.8 cents.

COGSTATE

Cogstate says it earned record revenue for the six months to December 31, 2016, up 43 percent to $18.5 million, with cash of $11.2 million.
Cogstate fell two cents or 1.5 percent to $1.32.

REPRODUCTIVE HEALTH SCIENCE

The South Australian Government Financing Authority says it has sold its 8,808,367 shares in Reproductive Health.

The Authority said in May 2015 that it became substantial with 8,808,367 shares for "no consideration" and with no voting power and today said it sold those shares for $660,627 or 7.5 cents a share.

Reproductive Health said that on January 20, 2017, Taylor Collison exercised a call option on behalf of clients to place all of the shares held by the South Australian Government Financing Authority at the agreed exercise price of 7.5 cents a share, "consistent with the pricing of the rights issue being undertaken … during September 2016, at the time the call option deed was executed between Taylor Collison and [the Authority]".

The company said that the Authority's 8,808,367 shares comprised 11.12 percent of its issued capital and it "would like to acknowledge and thank the Commonwealth Government and the South Australian Government, through Playford Capital and [the Authority], for their support … to the current commercial phase".

Reproductive Health was untraded at 9.5 cents.

FEDERAL GOVERNMENT SEMINARS

The Federal Government says it will sponsor one-day seminars for biotechnology companies wanting to enter the Chinese market.

The Department of Industry, Innovation and Science entrepreneurs' program director Dr Ashley Bates told Biotech Daily that the February and March seminars were organized by Ausindustry, Austrade and the Medical Technologies and Pharmaceuticals Industry Growth Centre (MTP Connect) with one day seminars to be held in Sydney, Brisbane, Melbourne and Adelaide and would be provided at no cost.

A media release from the Department of Industry, Innovation and Science said that senior executives looking at the China market to participate in the 'China Market Ready Medtech and Pharma Seminar'.

The Department said that China was "the world's second largest and fastest growing [medical technologies and pharmaceuticals] market" and the seminars would provide senior executives with knowledge to develop a successful business strategy in China.

The media release said that the seminars would include sessions on developing a market entry strategy, successful partnering approaches, regulatory pathways, distribution and marketing, market risks, common mistakes, and key success factors for Australian healthcare products, technologies and services in China, with contributions from former Cochlear China general-manager Brendan Mason and China Bluesky director Rob Scott, and would include two hours of tailored consultation time for companies to confidentially seek advice on market development and key China market challenges, along with presentations, case study discussions and workshop forums.

The seminars will be held in Sydney on February 28, Brisbane on March 2, Melbourne on March 7 and Adelaide on March 9, 2017. For more information and to register go to: https://www.business.gov.au/events/china-market-ready-medtech-exporter-workshops.

AIRXPANDERS

Airxpanders has requested a trading halt "pending an announcement … in relation to a proposed capital raising".

Trading will resume on January 25, 2017 or on an earlier announcement.

Airxpanders last traded at $1.075.

DIMERIX

Dimerix has requested a trading halt pending “an announcement of a capital raising”.
Trading will resume on January 25, 2017 or on an earlier announcement.
Dimerix last traded at 0.8 cents.

RECCE

Recce says that director Dominic Barnes has resigned as a director with immediate effect.
Recce said that Mr Barnes joined was appointed a director in May 2016.
Recce fell 2.5 cents or 11.9 percent to 18.5 cents with 1.3 million shares traded.