Biotech Daily

Friday July 27, 2018

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.89 percent on Friday July 27, 2018 with the ASX200 up 55.7 points to 6,300.2 points. Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and one was untraded. All three Big Caps were up.

Prescient was the best, up one cent or 9.1 percent to 12 cents with one million shares traded. Mesoblast climbed seven percent; Immutep and Polynovo improved more than six percent; Universal Biosensors and Uscom were up more than five percent; Ellex and Pharmaxis were up four percent or more; Genetic Signatures, Impedimed, Nanosonics and Starpharma rose more than two percent; Actinogen, Clinuvel, Cochlear, Cynata, Resmed and Reva were up more than one percent; with CSL and Telix up by less than one percent.

Osprey led the falls, down one cent or 5.3 percent to 18 cents with 96,401 shares traded. Dimerix fell 4.1 percent; Airxpanders, Factor Therapeutics and Optiscan were down more than three percent; Prana and Pro Medicus shed more than two percent; Volpara was down 1.3 percent; with Compumedics, Cyclopharm, Neuren and Sirtex down by less than one percent.

DR BOREHAM'S CRUCIBLE: RESONANCE HEALTH

By TIM BOREHAM

ASX code: RHT

Share price: 2.2 cents

Shares on issue: 402,497,568

Market cap: $8.85 million

Chief executive officer: Alison Laws

Board: Dr Martin Blake (chairman), Simon Panton, Dr Travis Baroni, Mitchell Wells

Financials (June quarter): revenue $766,000, (year to June 30 receipts $2.65 million) net cash inflows $49,000, cash balance $1.55 million, estimated current quarter cash outflows $43,000.

Identifiable holders: Southern Investments 17.5%, SG Hiscock & Co 9.2%, Simon Panton 17.7%, University of Western Australia 2.25%, Dr Martin Blake 1.6%.

Given all the marketing hard-sell of iron supplements from the likes of Swisse and Blackmores, it's easy to forget that having too much of the ferrous metal in one's organs and blood stream can be decidedly non-conducive to wellness.

In fact, it can be fatal.

Deficient iron is a lot easier to remedy than too much iron and in the case of the latter, patients can be consigned to a life of difficult "chelation" procedures to remove it.

A provider of non-invasive medical imaging software and analysis, Resonance's focus as a listed company has been on commercializing its flagship device Ferriscan, which measures liver-iron concentration.

The company has now expanded into improved products to do the same thing, as well as measuring fat levels in the liver and the pancreas.

"Because it's such a big product Ferriscan has been our big focus," CEO Alison Laws says.

"But there's a new culture and willingness to accept new revenue streams."

A brief history of Resonance

Ferriscan was devised by the clever bods in the University of Western Australia's physics department, where it was nurtured for four years.

The intellectual property was housed in a company called IVB Technology, which was acquired by the listed GEO2 in 2003 before changing its name.

Resonance initially was chaired by Dr Michael Wooldridge, who had resigned in 2001 as Health Minister in the Federal Government of John Howard.

(Dr Wooldridge's corporate career was curtailed in 2014 when he was banned as a company director for two years over his role in the 2011 collapse of the Prime Retirement aged-care business).

Resonance recently has been managed by a triumvirate of three directors. But in February the company appointed Ms Laws as CEO. Ms Laws joined the company a year earlier as global account manager and held other roles including business development manager.

Building a better mousetrap

The Resonance story is a common one about expanding from an initial product with improved and wider offerings.

To this day Ferriscan is the standard-of-care for thalassemia, a hereditary condition afflicting Mediterraneans and South East Asians.

A debilitating form of anaemia, thalassemia is usually terminal if patients do not receive blood transfusions.

And it is the red blood cell transfusions that lead to the iron overload, so kidney dialysis patients can also have iron overload.

In fact, thalassemia is the third most serious public health problem in South East Asia, behind malaria and HIV. But migration also means the disease is found in Western countries.

While the incidence of thalassemia is hard to pin down, the World Health Organisation estimates that about 330,000 children are born with the ailment each year.

Other causes of iron overload relevant to Ferriscan are transfusions for sickle cell anaemia (75,000-100,000 cases in the US annually) and myelodysplastic syndrome (a bone marrow deficiency resulting in lack of red blood cells).

Then there is hereditary haemochromatosis – with patients inheriting a primary iron overload – and affecting about one in 250 people of Northern European descent.

While a biopsy covers only a minute liver sample, a Ferriscan measure covers five to 20 percent of the organ and is thus more accurate.

Of course, such a non-invasive procedure is also much, much, less painful.

Based on artificial intelligence, Ferrismart is a bells-and-whistles version of Ferriscan that measures liver iron from a magnetic resonance imaging (MRI) readout. It's designed for acute care situations and for developing countries.

Ferrismart is much quicker than Ferriscan, producing a result in seconds rather than around 40 minutes.

Ferrismart performs the tests in real time, with an added feature of a QR ("quick response", if you really want to know) code to prevent counterfeit results.

But the real benefit is that using artificial intelligence reduces labor costs, which makes the tests more affordable in countries such as The Philippines and Vietnam where health subsidies are not exactly generous.

Another Resonance product, Hepafat scans for liver and pancreatic fat loads, which means Resonance is playing in obesity-related diseases such as non-alcoholic steatohepatitis (NASH) and diabetes.

On a related theme, the Resonance DR Grader tests for diabetic retinopathy. Tests in Singapore show the device can test for the disease with 92 percent efficiency by using images of the eye.

Finally, Cardiac T2 measures heart iron loading and is usually used with Ferriscan to capture heart and liver measures in the one sitting. Cardiac T2 is approved here and in the US and Europe.

Finances and performance

As of March, Resonance had sold 45,000 Ferriscans in 45 countries. Ferriscan has had US Food & Drug Administration approval since 2005 and also has European CE mark and local Therapeutic Goods Administration approval. To date 10,000 Ferriscan procedures have been done in the US.

In mid-July, Ferrismart also won local TGA approval, as well as CE mark certification. The company plans to submit an FDA dossier by the end of July.

Also in July, Resonance announced a distribution tie up with Blackford Analysis, a global medical image analysis platform.

Currently, 80 percent of Ferriscan's revenues derive from the US and the UK. However through major pharmaceutical companies there is some funding for private use in developing countries.

Ferriscan is reimbursed by the UK, German and Canadian governments and also has won the crucial private health insurance codes in the US.

Management reported $2.4 million of revenue for the financial year to April 30, 2018, an improved run rate of turnover of $2.5 million for the whole 2016-'17 year.

The June quarter results - a 23 percent revenue uptick to $766,000 and a small cash surplus of $49,000 - were also encouraging.

Management expects a net profit of $100,000 to $200,000 for the 2017-'18 year, compared with a $304,000 loss in 2016-'17 and a $384,000 deficit in 2015-'16.

Revenue should also be boosted by a recently announced deal to provide $US677, 000 of tools to three pharmaceutical companies for clinical research.

Over the last 12 months, Resonance shares have traded between 1.9 cents (late September 2017) and 3.0 cents (mid-June 2017).

Ms Laws says the take-up of Hepafat has been slower than expected, probably because there is no effective current drug for NASH despite many developers working on it.

Dr Boreham's diagnosis:

Given Ferriscan has been approved - and around - for a while sales are still modest (bearing in mind the developing world skew of its patient base).

"Resonance has done well with what it has, but as an ASX listed company we understand we have a smaller market cap than potentially investors would like to see," Ms Laws says.

We couldn't have put it better!

Ms Laws says her number one priority is to ensure the platform is stable and revenue generating and then expand the company from there.

To achieve this, Resonance intends to pursue in-house development and partnerships, as well as distributor services for products "that are an excellent fit with the Resonance core business and distribution network".

The company is talking to scanner manufacturers and "various other parties in Australia to do with licencing or something corporate".

The company should gain more resonance with investors if the current profitability proves to be more than a purple patch.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never been mistaken for an Iron Man and perhaps that's all for the better.

POLYNOVO

Polynovo says Saudi Arabia has approved its Novosorb biodegradable temporizing matrix (BTM) wound treatment with Al Mofadaly appointed as the exclusive distributor.
Polynovo said that the Riyadh, Saudi Arabia-based Al Mofadaly Trading Est had “an extensive range of critical care products promoted by a well-trained surgical sales team” and Novosorb BTM was “a strong fit in their product portfolio”.
The company said that entry into Saudi Arabia would allow sales across the Middle East through Al Mofadaly and its partners and sub-distributors.
Polynovo chief executive officer Paul Brennan said that the Saudi Arabia approval of Novosorb BTM would “offer patients in the region a significant improvement in their clinical outcomes and enable us to serve our global key opinion leaders”.
Polynovo was up three cents or 6.25 percent to 51 cents with 5.6 million shares traded.

ELLEX MEDICAL LASERS

Ellex says that sales for the year to June 30, 2018 rose 10.47 percent to $79.1 million compared to the previous corresponding period.
Ellex said that earnings before interest, tax, depreciation and amortization was a $1.5 million loss, compared to a $1.5 million profit the previous corresponding period, due to increased expenditure on sales and marketing infrastructure.
The company said its sales in the US, its largest market, were up 47 percent to $6,392,000.
Ellex was up three cents or 3.95 percent to 79 cents.

GENETIC SIGNATURES

Genetic Signatures says that revenue for the year to June 30, 2018 rose 39 percent to $2.8 million compared to the previous corresponding period.
In its Appendix 4C quarterly report Genetic Signatures said that receipts from customers for the year to June 30, 2018 increased 38.1 percent to $3,199,000 compared to the previous corresponding period.
The company said it had cash and cash equivalents of $8,970,000 at June 30, 2018.
Genetic Signatures was up one cent or 2.5 percent to 41 cents.

VISIONEERING TECHNOLOGIES

Visioneering says that revenue for the six months to June 30, 2018 rose 264.9 percent to $US1,162,314 ($A1,573,703) compared to the previous corresponding period.
In its Appendix 4C quarterly report, Visioneering said that receipts from customers for the six months to June 30, 2018 increased from a low base by 421.98 percent to $US1,211,000 (about $A1,639,540) compared to the previous corresponding period.
The company said it had cash and cash equivalents of $US7,099,000, with an estimated outflow of $US4,452,000 for the three months to September 30, 2018 and receipts from customers for the three months to June 30, 2018 of $US578,000.
Visioneering fell four cents or 15.4 percent to 22 cents.

PHYLOGICA

Phylogica says its cell penetrating peptides have shown “substantially stronger” anti-cancer cell expansion in mice, when compared to industry standard peptides.
Phylogica said it treated mice with its peptides joined to an antigen derived from the herpes simplex virus 1 (HSV-1) to trigger the expansion of cytotoxic T-cells and found that its cell penetrating peptides produced the greatest expansion of T-cells.
The company said it ran a complementary experiment to confirm that the stimulated responding T-cells were effective in recognizing and killing target cells.
Phylogica was up 0.3 cents or 10 percent to 3.3 cents with 1.9 million shares traded.

MEDLAB CLINICAL

Medlab says that the Leamington, Ontario based Aphria has completed its largest export shipment of cannabis oil for its cancer pain trials (BD: May 15, 2018).
Biotech Daily understands that the shipment was several litres of the cannabis oil.
Medlab said that the shipment was part of the agreement between the two companies to supply the marijuana extract to test the management of intractable pain in oncology patients, which the company said was “the first trial of its kind globally”.
The company said that Aphria had provided a high-cannabidiol (CBD) cannabis oil and a high-tetrahydrocannabinol (THC) cannabis oil, both of which were designed specifically for its use.
Medlab said the products would be combined with its Nanocelle delivery system to produce its Nanabis oral spray.
The company said that the product formulation, manufacturing and final product validation had met the standard set by the Australian Therapeutic Goods Administration and permits had been approved by Health Canada.
Medlab chief executive officer Dr Sean Hall told Biotech Daily that the company had “more than enough raw product for all of our trials and for compassionate use patients, as approved by Australian regulatory authorities”.
Medlab previously said it expected to use 3,500 units of Nanabis in the cancer pain trial, with each unit designed to be about a one month supply (BD: Oct 24, 2017).
Aphria chief executive officer Vic Neufeld said that Medlab “was our very first international partner and as Aphria expands its operations around the globe we will continue [to] support the advancement of medical cannabis research through these valuable partnerships”.
Medlab was unchanged at 48 cents.

NUHEARA

Nuheara says it has renewed its contract with the Federal Government’s Hearing Services Program to June 30, 2019, with an optional extension to June 30, 2020.
Earlier this year, Nuheara said it had been registered as an approved supplier to the Federal Government’s Hearing Services Program (BD: Mar 16, 2018).
The company said that the 2017-’18 Federal Budget had allocated $539 million towards the Program which was responsible for about 70 percent of the Australian hearing services market.
Nuheara said that all suppliers’ contracts expired on June 30, 2018.
Nuheara was up 0.2 cents or 2.3 percent to nine cents with 2.8 million shares traded.

ADHERIUM

Adherium says the US Food and Drug Administration has granted it 510(k) clearance for over-the-counter sales of its Hailie, formerly Smartinhaler, asthma inhaler sensor.
In addition to the 510(k) clearance, Adherium said it was launching an online portal for healthcare professionals and clinicians that used Bluetooth wireless technology to provide patient data collection from the Hailie sensor.
Adherium was unchanged at 10.5 cents.

CELLMID

Cellmid has requested a trading halt pending an announcement regarding “a proposed capital raising”.
Trading will resume on July 31, 2018 or on an earlier announcement.
Cellmid last traded at 46 cents.

IMPEDIMED

Mitsubishi UFJ Financial Group and Morgan Stanley say they have become substantial in Impedimed with 18,968,277 shares or 5.00 percent of the company.
The Tokyo, Japan-based Mitsubishi UFJ Financial and the New York and Sydney-based Morgan Stanley filed similar substantial shareholder announcements with more than 600 trades across 13 pages detailing shares bought, shares borrowed and collateral received between March 26 to July 24, 2018, with the single largest purchase of 340,624 shares for $164,351 or 48.25 cents a share on May 23, 2018.
Impedimed was up one cent or 2.35 percent to 43.5 cents with 1.5 million shares traded.

AVITA MEDICAL

Deutsche Bank and related corporate bodies say they have reduced its substantial holding in Avita from 70,838,849 shares (6.74%) to 72,856,256 shares (5.70%).
The Frankfurt, Hong Kong and Sydney-based Deutsche Bank AG said its Sydney branch bought and sold shares between January 11 and July 25, 2018, with the single largest purchase 2,741,871 shares on June 13 for $137,094, or five cents a share and the single largest sale of 4,000,000 shares on July 24 for $320,000, or eight cents a share.
Avita was unchanged at eight cents with 3.1 million shares traded.

NOVITA HEALTHCARE (FORMERLY AVEXA)

Peter and Diana Diamond say they have increased their holding in Novita from 30,000,000 shares (8.35%) to 50,000,000 shares (11.13%).
In May, Peter Diamond, Crazy Diamond and Dak Drafting Services said they sold their holding to the Peter and Diana Diamond Superannuation Fund.
Today, the Perth, Western Australia Peter and Diana Diamond said that they bought 20,000,000 shares for $620,000 or 3.1 cents a share in last week’s placement which raised $2.7 million (BD: Jul 20, 2017).
Novita was unchanged at 3.4 cents.

BOTANIX

Botanix says it has appointed Dr Stephane Levy as chief medical officer and Jillian Chapas-Reed as senior director of clinical operations.

Botanix said that previously Dr Levy was Aqua Pharmaceuticals head of research and development and Novartis US medical unit head of immunology and dermatology for and Sanofi's North America head of medical affairs.

The company said Ms Chapas-Reed had worked for Churchill Pharmaceuticals, where she led a phase II/III study that was approved by US Food and Drug Administration in May 2018.

Botanix was unchanged at 10 cents with 1.8 million shares traded.