Biotech Daily

Friday July 21, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ORTHOCELL UP 17%, LIVING CELL DOWN 4%**

*** DR BOREHAM'S CRUCIBLE: COMPUMEDICS**

*** BOSTON TRIAL BACKS ELLEX REFLEX FOR EYE FLOATERS**

*** INNATE MIS416 ANALYSIS NO HELP, NEW INDICATION OR TECHNOLOGY**

*** CANADA PATENT FOR IMUGENE HER-VAXX CANCER VACCINE**

*** LANSTEAD TAKES 8% OF NEUREN**

*** RACE CEO PETER MOLLOY, CHAIR DR BILL GARNER INCREASE, DILUTED**

*** NASDAQ 2nd GENETIC TECHNOLOGIES NON-COMPLIANCE LETTER**

*** MEDIBIO UNMARKETABLE PARCEL FACILITY**

MARKET REPORT

The Australian stock market fell 0.67 percent on Friday July 21, 2017 with the ASX200 down 38.7 points to 5,722.8 points.

Nine of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and five were untraded. All three Big Caps fell.

Orthocell was the best, up five cents or 17.2 percent to 34 cents, with 98,991 shares traded.

Prima climbed 8.7 percent; Benitec improved 7.7 percent; Impedimed was up 4.3 percent; Genetic Signatures and ITL rose more than two percent; Acrux and Oncosil were up more than one percent; with Sirtex up 0.55 percent.

Yesterday's four percent equal best, Living Cell, led the falls, down 0.5 cents or 3.85 percent to 12.5 cents with 64,129 shares traded.

Dimerix, Factor Therapeutics and Osprey lost more than three percent; Benitec, Mesoblast and Polynovo shed more than two percent; Admedus, Compumedics, Ellex, LBT, Medical Developments, Nanosonics, Pharmaxis, Prana, Pro Medicus, Resmed, Reva and Universal Biosensors were down more than one percent; with Cochlear, CSL and Opthea down by less than one percent.

DR BOREHAM'S CRUCIBLE: COMPUMEDICS

By TIM BOREHAM

ASX Code: CMP

Share price: 45.5 cents; **Market cap:** $80.6 million; **Shares on issue:** 177.2 million

Executive chairman: Dr David Burton

Board: Dr Burton, Dr Alan Anderson, and David Lawson

Financials (December half): revenue $16.2 million (down 7%) earnings before interest taxation depreciation and amortisation (ebitda) $1.2 million (down 50%), net profit $200,000 (down 88%), cash $5.72 million (up 86%)

***** 2016-17 revised guidance: revenue of $33 million (down 12%), ebitda of $2.1 million to $3.6 million (down 24% to 58%).

Major shareholders: Dr Burton (and associated entities) 59.7 percent, Teijin Pharma 4.9 percent, Beijing Bestmed 2.9 percent, Medigas Italia 2.57 percent.

Investors in the sleep and neurological disorders house don't need a hairnet with multiple sensors to work out why they toss and turn at night: the answer lies with the company's erratic share performance.

On June 20, Compumedics shares soared almost 50 percent after the company won a big US contract for its magneto-encephalography (MEG) scanning technology (see below).

But the biotech gods are fickle indeed and on July 7 the stock tumbled as much as 19 percent after a hefty sales and earnings downgrade for 2016-'17.

The revision - prompted by a $5 million sales shortfall in the US - highlights a paradox of Compumedics: it's a global leader in its specialist sectors, but is still a miniscule entity as far as global device and diagnostics plays go.

Perchance to dream

Most of us spend about one-third of our life in slumber and the brain's activity during this time remains a mystery. In his quest to crack the enigma, David Burton founded Compumedics in 1987 and in that year installed Australia's first fully computerized sleep clinic at Melbourne's Epworth Hospital.

Dr Burton (who had a background in electronics for sound recording studios) gained his inspiration after visiting a doctor for a sore throat. Apart from prescribing antibiotics, the physician asked him if it was possible to invent a sleep monitoring device and the idea was thus spawned. The moral of the story: don't put off that visit to the quack.

Awake to global opportunities

Compumedics now has 20,000 systems installed globally and, unusually for a Western Devil, has a strong position in China as the biggest supplier of sleep and neurological equipment - with orders in 2015-'16 for $US8.2 million.

The company owns the US-based Neuroscan and Germany's DWL Elektronishe.

Geographically, Compumedics can lay claim to being truly diversified, with 29 percent of sales from the US, 41 percent from Asia and 15 percent from both Europe and Australia.

Compumedics claims a six percent share of the sleep diagnostics market, globally worth $US250 million a year. In Australia and China it has number one market position and is third biggest in the competitive US market.

Compumedics also has a sub one percent share of the $US1.3 billion neuro diagnostics clinic market, with similar market positioning in these geographies.

The neuro diagnostics (research) and brain blood flow diagnostics markets are worth $US20 million and $US15 million, respectively, and the company has a 30 to 35 percent share of these.

Like most device plays, Compumedics is moving from a capital equipment model (that is, selling the gizmos) to cloud-based service models that produce ongoing service revenues.

For example, four sites in the US to date have signed up for Nexus360, a cloud-based sleep diagnostics platform.

Currying favour with MEG

In brain imaging, the company's Curry brain analysis software is the leader in the magneto-encephalography market (MEG), which is a small sector but growing at about 10 percent a year.

MEG is considered to be superior to magnetic resonance imaging (MRI) for Alzheimer's disease and similar ailments. MEG maps brain activity using magnetic fields and we are assured it is not skewed for patients with magnetic personalities.

At the heart of the company's Orion Lifespan Curry MEG is a "patented double relaxation oscillator super conducting quantum interference device", or Dros Squid for short, sensor system. Once again, we're assured this surfeit of adjectives has nothing to do with sub-standard calamari.

The potential for using MEG brain imaging is huge, given the prevalence of not just Parkinson's disease but Alzheimer's and other dementia conditions, autism and epilepsy.

On June 20, Compumedics announced a MEG contract with Arizona's Barrow Neurological Institute, the world's biggest neurological disease institution and home to the Muhammad Ali Parkinson Centre.

The circa $5 million deal, which relates to the Orion Lifespan device, is the biggest system contract in the company's history.

The company cites cloud-based sleep diagnosis and, in the neuro-diagnostics sector, long-term epilepsy. Traumatic brain injury applications are also an area of interest.

Another initiative is a cloud-based services platform called Ehealthmedics, which captures or transfers "medical grade sleep parameters from any web-enabled device".

The company reports forward orders of more than $10 million over the next three years for its electronic-health tool, Nexus 360.

Behind the numbers

Compumedics reported $200,000 of net profit and $1.2 million of ebitda for the first (December) half, on revenue of $16.2 million.

Management also guided to a 2016-'17 net profit of $4 million to $6 million and ebitda of $4.5 million to $7.5 million, on sales of $41 million to $43 million.

On July 7, the company said revenues would be about $33 million (compared with $37.5 million in 2015-'16) and ebitda would be $2.1 million to $3.6 million (and that's before $1.6 million of one-off restructuring costs).

Management blamed the timing of US sales and associated restructuring of its core business for the revenue tweak. In the first half, Compumedics also referred to a $2 million shortfall of US sales with this soothing reassurance: "the business has not been lost, just not received in the time frame anticipated".

Burton dubs the revised result as "not entirely as we expected", but insists management is not asleep at the wheel and its growth strategies remain intact.

Dr Boreham's diagnosis:

Compumedics listed in 2000 at 50 cents apiece, but up until late 2014 they did their best Rip Van Winkle impression. A stirring rally saw the stock peak at 93 cents in November last year, before slipping as low as 33 cents in June, then more than doubling to 73 cents, only to sink below the issue price again.

A former Exporter of the Year, Compumedics has much to be proud of in terms of its global presence and reputation. And hats (or hairnets) off to management for not packing it in and pursuing medical pot or graphite exploration instead.

We suspect the stock presents a buying opportunity at these levels, but as usual investors should sleep on it.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Because he doesn't own any Compumedics shares he sleeps soundly at night.

ELLEX MEDICAL LASERS

Ellex says that a 52-patient trial supports the efficacy of its Reflex laser treatment for Weiss ring eye floaters.

Ellex said that the trial was conducted by the Ophthalmic Consultants of Boston, Massachusetts and investigated whether laser vitreolysis, or the removal of eye floaters, with an yttrium aluminum garnet (YAG) laser was safe and effective in the treatment of patients with symptomatic floaters.

The company said that Dr Chirag Shah performed the laser vitreolysis using its Ultra Q Reflex laser, which generated a plasma force needed to vaporize tissue.

The article, entitled 'YAG Laser Vitreolysis vs Sham YAG Vitreolysis for Symptomatic Vitreous Floaters: A Randomized Clinical Trial' was published in the Journal of the American Medical Association (JAMA) Ophthalmology, with the full article available at: http://jamanetwork.com/journals/jamaophthalmology/fullarticle/2643488.

The trial article reported that the YAG laser group reported greater symptomatic improvement (54%) than controls (9%) ($p < 0.001$).

The article said that the 10-point visual disturbance score improved by 3.2 in the YAG group compared to 0.1 for controls ($p < 0.001$).

The article said that 19 patients (53%) in the YAG laser group reported significantly or completely improved symptoms compared to none in the sham group ($p < 0.001$).

The article reported that "no differences in adverse events between groups were identified".

The article concluded that YAG laser vitreolysis "subjectively improved Weiss ring-related symptoms and objectively improved Weiss ring appearance".

"Greater confidence in these outcomes may result from larger confirmatory studies of longer duration," the article concluded.

Ellex chief executive officer Tom Spurling said that the work by Dr Shah "has demonstrated that laser floater removal, performed with our proprietary Reflex technology, is both clinically effective and safe in the treatment of floaters".

"With the release of this data, we expect a broader cross-section of ophthalmologists to adopt Reflex technology in the treatment of patients suffering from symptomatic floaters which, hitherto, have not been considered candidates for treatment due to the significant risk profile associated with conventional surgical treatments," Mr Spurling said.

"Given that one in seven people are estimated to be affected by floaters, this offers a considerable opportunity for our business," Mr Spurling said.

Ellex said that since becoming commercially available in 2014 the Ultra Q Reflex had become one of its fastest growing product lines and was expected to be a key growth driver over the coming financial year.

The company said the system was designed specifically for laser eye floater removal and was the first laser optimized for floater removal.

Ellex said that the global installed base potential for the Reflex technology lasers for secondary cataracts was 28,000 units worth about $US600 million to be accessed over several years.

"We have a unique opportunity to replace the global installed bases of conventional secondary cataract lasers with our Ultra Q Reflex or Tango Reflex product lines, and thereby enable doctors to expand their scope of patient care from those that have secondary cataracts to patients suffering from secondary cataracts and/or symptomatic floaters," Mr Spurling said.

Ellex fell 1.5 cents or1.5 percent to 96 cents.

INNATE IMMUNOTHERAPEUTICS

Innate says it will halt work on MIS416 for secondary progressive multiple sclerosis but will consider other indications and the acquisition of other technologies.

In June, Innate reported that its 93-patient randomized, double-blind, placebo-controlled, phase IIb trial of MIS416 for secondary progressive multiple sclerosis (SPMS) failed to meet its primary efficacy endpoints (BD: Jun 27, 2017).

The company said at that time that the trial of weekly injections of MIS416 “did not show clinically meaningful or statistically significant differences in measures of neuromuscular function or patient reported outcomes”.

Today, Innate chief executive officer Simon Wilkinson said that “all previous reports of MIS416 making a meaningful difference in the lives of many patients must either be dismissed as a very robust placebo effect or the trial failure is attributable to some other reason”.

“It is my view that there may be other reasons,” Mr Wilkinson said.

“Patients with SPMS have a complex mix of symptoms and their disease can't be monitored by a simple blood test or [magnetic resonance imaging] scan,” Mr Wilkinson said.

“We used the best assessment tools available as recommended by expert practitioners in [multiple sclerosis] but we suspect they weren't sensitive enough to pick up the small but potentially significant changes that can lead to a substantial impact on patients' activities of daily living and quality of life,” Mr Wilkinson said.

Innate chairman Michael Quinn said that “whatever the possible explanations, we have not delivered a result that would support our continued trialling of MIS416 in patients with SPMS”.

“We now need to look to the future of Innate,” Mr Quinn said.

“In doing so we are mindful of the interests of our shareholders and other committed stakeholders including patients still receiving MIS416 on compassionate use grounds in Australia and New Zealand,” Mr Quinn said.

“Over the next two to three months the company will actively review other possible applications for MIS416 as well as the potential value of Innate as a vehicle for a new technology,” Mr Quinn said.

Innate said it had completed an analysis of efficacy assessments for the per protocol population, of patients who completed at least 75 percent of the study and otherwise adhered to all significant aspects of the trial protocol, which included 43 patients in the MIS416 treatment group and 27 subjects in the placebo group.

The company said that the per protocol population analysis “showed no clinically meaningful or statistically significant differences in measures of neuromuscular function or patient-reported outcomes”.

Innate said it sponsored an analysis of the trial results at the patient level to see if there was a group of clinical responders which might not have been evident from the top line population-based analysis, but the first report from this subsequent analysis did not indicate that such a responder group exists.

The company said it had not received the detailed results from the analysis but there was nothing to suggest that the final outcome would be any different.

“This apparent lack of efficacy at either the overall study population level or the individual patient level is extremely disappointing and inconsistent with previous clinical experience and the reporting of MIS416 treatment benefits by many compassionate use patients over the past eight years,” Innate said.

Innate fell half a cent or 9.3 percent to 4.9 cents with seven million shares traded.

IMUGENE

Imugene says the Canadian Patent Office has granted a patent relating to its HER-Vaxx cancer vaccine.
Imugene said that the patent entitled 'HER-2/neu multi-peptide vaccine' would provide intellectual property coverage until 2027).
The company said that HER-Vaxx was "a next generation HER2 cancer therapy using B cell peptides, which harness the body's ability to develop antibodies against the disease".
Imugene said it was currently enrolling gastric cancer patients in a trial at hospitals in Hong Kong, Thailand and Taiwan.
Last year, Imugene said that the up-to 18-patient phase Ib trial was an open-label, multicentre, dose-escalation study, designed to assess the safety, tolerability and immunogenicity, which would show how well the vaccine was directing production of HER2 antibodies in patients (BD: Nov 7, 2017).
Imugene was up 0.1 cents or 6.7 percent to 1.6 cents with 11.1 million shares traded.

NEUREN PHARMACEUTICALS

Lanstead Capital says it has become a substantial shareholder in Neuren with 169,354,839 shares of 8.37 percent.
The London-based Lanstead said the shares were indirectly held by Lanstead Partners, Cogent Capital, Greg Kofford and Mark Holden.
In June, Neuren said it had raised $11.5 million at 6.2 cents a share to prepare for a phase III trial of trofinetide for Rett syndrome, with Lanstead Capital investing $10 million (BD: Jun 29, 2017).
Neuren said it would receive $3 million in July 2017, with $1.5 million from Lanstead and $1.5 million from Rettsyndrome.org and Neuren's directors and management, with the remaining $8.5 million from Lanstead to be invested in a "sharing agreement" varying with Neuren's share price.
The company said that the 18 monthly settlements would be measured against a benchmark price of 8.86 cents a share and the amount received would vary with the share price movement above and below that benchmark.
Neuren said that Lanstead would be issued 161.3 million shares for the $10 million commitment with a further 8.1 million shares in consideration for the sharing agreement.
Neuren was unchanged at 6.1 cents with 2.3 million shares traded.

RACE ONCOLOGY

Race chairman Dr William Garner has increased his substantial holding but has been diluted from 15,000,000 shares (28.47%) to 15,100,000 shares (23.56%).
Dr Garner said the shares were acquired on March 27 and May 11, 2017 for $22,402 or an average price of 22.4 cents each.
Race chief executive officer Peter Molloy said he had increased his substantial holding and was diluted from 4,000,000 shares (7.59%) to 4,020,000 shares (6.27%).
Mr Molloy said that on March 30, 2017 he bought 20,000 shares for $4,220 or 21.1 cents a share.
Earlier this week, Race said it raised $2.5 million in a "heavily over-subscribed" placement at 20 cents a share (BD: Jul 17, 2017).
Race fell half a cent or 1.8 percent to 27 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has received a second non-compliance letter from the Nasdaq requiring it to ensure its share price is above $US1.00 within 180 days.

In 2014, Genetic Technologies received a Nasdaq $US1.00 bid compliance letter and rectified the issue five months later (BD: Sep 3, 2014; Feb 4, 2015).

Today, Genetic Technologies said that the Nasdaq had informed it, that its share price had been below the $US1.00 minimum for 30 consecutive business days and it had 180 days to January 15, 2018 to regain compliance, with the minimum bid price at or above $US1.00 for 10 consecutive business days.

Genetic Technologies said that the deficiency notice did not immediately affect its Nasdaq listing and the letter only applied to the Nasdaq and not the shares trading on the Australian Securities Exchange.

Genetic Technologies climbed 0.1 cents or 14.3 percent to 0.8 cents.

MEDIBIO

Medibio says it will offer a share sale facility for holders of unmarketable parcels of shares, below $500 in value, at the record date of July 17, 2017.

Medibio said that an unmarketable parcel was any holding of 1,428 ordinary shares or fewer, based on the closing price of 35 cents a share.

The company said that the sale price would be determined once all the shares were sold and the proceeds would be free of brokerage or handling costs.

Medibio was up one cent or 2.9 percent to 36 cents.