

Biotech Daily

Friday June 9, 2017

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market edged up 0.02 percent on Friday June 9, 2017 with the ASX200 up 1.2 points to 5,677.8 points. Ten of the Biotech Daily Top 40 stocks were up, 20 fell, seven traded unchanged and three were untraded.

Neuren was the best, up 0.3 cents or 5.1 percent to 6.2 cents with 937,774 shares traded. Living Cell climbed 4.55 percent; Factor Therapeutics and Opthea improved more than three percent; Medical Developments, Polynovo and Uscom rose more than two percent; Admedus, Impedimed and Osprey were up more than one percent; with Cochlear and Resmed up by less than one percent.

Compumedics led the falls, down three cents or 8.3 percent to 33 cents with 223,107 shares traded. Prima lost 6.1 percent; Atcor shed 5.4 percent; Actinogen, Cellmid, Clinuvel and Pharmaxis were down more than three percent; Airxpanders, Avita, Nanosonics, Orthocell, Starpharma and Viralytics shed more than two percent; Bionomics Ellex, Mesoblast, Pro Medicus and Psivida were down more than one percent; with CSL, ITL and Sirtex down by less than one percent.

DR BOREHAM'S CRUCIBLE: ELLEX MEDICAL LASERS

By TIM BOREHAM

ASX Code: ELX

Market cap: \$125 million

Share price: \$1.03

Shares on issue: 121.1 million

Chief executive officer: Tom Spurling

Board: Victor Previn (chairman), Alex Sundich, Giuseppe Canala, Rhamon Coupe, Dr Meera Verma

Financials (December half): revenue \$34.26m (down 1.5%), ebitda \$3.2 (down 9%), net profit \$912,000 (down 39%), earnings per share 0.87c (down 19%), cash on hand \$14.1m (up 94%)

Major shareholders: Australian Ethical 7.4%, National Nominees 10.5%, Sedico Pty Ltd (Previn) 8.2%, Pine Street (Sundich) 5.5%.

Here's an eye-opener: a biotech with a 32 year history - 16 as a listed ASX stock - with an enduring earnings track record and global sales in more than 100 countries.

Ellex also wins some kind of novelty award for having its global headquarters in Adelaide, although we note that others including Mayne Pharma and Bionomics are based in the city more known for kinky murders, pie floaters and (for those with a longer memory) the proposed multi-function polis.

It was thus with justifiable pride that chief executive officer Tom Spurling and his management team recently paraded analysts around Ellex's new HQ and manufacturing centre at Mawson Lakes in the city's north. The building and land was only acquired in March last year, with the Therapeutic Goods Administration approving the facility in February this year.

The 4000 square metre digs - which augment a leased central business district premises and more than doubles Ellex's capacity - will be the base for Ellex's design, manufacturing and marketing of its ophthalmic laser and ultrasound devices.

Ellex's lasers and other devices help eye surgeons treat glaucoma, diabetes-related retinal disease, secondary cataracts, vitreous opacities and age-related macular degeneration (AMD) - pretty much the A to Z chart of optical woes.

Bearing devices with funky names such as the Tango Reflex and Itrack (glaucoma), 2RT (early AMD), Ellex boasts a circa 15 percent global share of the core ophthalmic device market.

Ultra Q Reflex is a minimally invasive treatment for cataract-related floaters (not to be confused with the pie floaters).

Ellex 2RT facilitates retinal rejuvenation therapy, a pioneering laser treatment that may slow the progression of AMD.

"Based on results to date, 2RT is demonstrating that it has the potential to be the world's first interventionist treatment for early to intermediate AMD," Ellex says.

The Tango Reflex is an alternative laser treatment for glaucoma, obviating the need for a regimen of daily drops.

Of Ellex's \$72 million in annual sales last year, 36 percent was derived from the US and 25 percent from Europe. Japan at 15 percent is also an important market and China is a growing one.

Local sales account for about 9 percent.

In the US, Ellex has a direct sales subsidiary, based in Minneapolis. Elsewhere, Ellex deploys both direct sales and third party arrangements across 50 distributors.

Late last month, Ellex said it would buy back the royalties for its Itrack glaucoma device for \$US2.15 million (\$A2.9 million).

The payment, which includes \$US650,000 already made, removes the need to pay royalties to Itrack's original vendor, ISCI Holdings, over the next five years.

In doing this, Ellex obviously believes the royalties are worth more than the \$US2.5 million over the period. Itrack is a single-use micro catheter for minimally invasive glaucoma surgery (MIGS) and currently has the honour of being the only MIGS device approved in China.

'Looking' at the financials:

Over the last four years to 2015-'16, Ellex increased revenue consistently, by a cumulative 74 percent to \$73 million while earnings before interest taxation depreciation and amortisation (Ebitda) was up 1,480 percent to \$7.9 million.

But 2016-'17 first half revenue was affected by production bottlenecks, with unfilled demand for the Tango Reflex.

Ebitda was affected by the investment in the Itrack and 2RT products.

While first-half revenues are skewed to the core laser and ultrasound division - \$30.3 million of the total \$34 million - glaucoma (Itrack) is cited as a fast growing business and 2RT (AMD) as an emerging one. Itrack sales jumped 37 percent to \$3.6 million.

In a recent prezzo, management guided to the core division's revenue being higher than the first half, with "accelerating" growth for Itrack revenues that grew 37 percent to \$3.6 million in the first half. Ellex 2RT sales are expected to be flat, depending on clinical trial results due in mid-2018.

And here's the one we're all waiting for: second half Ebitda is expected to be higher than the first half number, which means "modest growth" over the full-year number.

Dr Boreham's diagnosis:

Ellex shares have taken a breather after whizzing up to \$1.62 in late November. Even so, the shares trade on a dizzying earnings multiple and a generous dollop of upside has been factored-in.

There's no shortage of patients: the company estimates the global glaucoma market at \$US4.6 billion (82 million patients), retinal disease \$US1.9 billion (107 million patients), early AMD \$US5.1 billion (122 million patients) and cataracts \$US3.3 billion (25.3 million patients).

As any experienced bio-watcher knows, the real metric is: 'How much of such a ginormous market a minnow from Adelaide can snare?'

Ellex competes against bigger and more monied providers.

But on its track record to date, the company has shown enviable vision in developing differentiated offerings.

It's a moot point whether Ellex shares present value, but we would rather be buying them at \$1 than \$1.60.

Investors who bought into a \$10 million placement last December at \$1.47 a share may be feeling less charitable.

Still there's always the local feel-good angle: after the last Holden Commodore rolls off the production line at nearby Elizabeth on October 20, Adelaidians will have more than Eddie Betts' boundary line heroics to be proud of.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Happily he has experienced neither optical floaters nor pie floaters.

IMMURON

Immuron says it hopes to raise \$US6.1 million (\$A8.1 million) through the issue of 610,000 American depository shares at \$US10 each along with 610,000 attaching warrants. Immuron said that each American depository share (ADS) would be equivalent to 40 Australian shares valued at 33.2 cents each.

The company said that the US warrants would be exercisable at \$US10.00 each within five years.

Last week, Immuron put the Nasdaq listing on hold for phase II trial results and said it had a \$1.5 million related-party loan from Grandbridge (BD: Jun 1, 2017).

Immuron said last week that the Nasdaq listing pricing was "not acceptable for shareholders" which brokers said was due to the pending interim analysis inflection point, in early July, for the 134-patient, phase II trial of IMM-124 for non-alcoholic steato-hepatitis (NASH) or fatty liver disease (BD: Apr 6, 2017).

Last month, Immuron said it hoped to raise \$US8,750,007 (\$A11,918,262), through the issue of 416,667 American depository shares (ADSs) at \$US21.00 (\$A28.38) each, to list on the Nasdaq, with each ADS equal to 40 Australian shares, or 71 Australian cents per Australian share, when it was trading at 53.5 cents (BD: May 9, 2017).

Today, Immuron said it had granted the underwriters a 45-day option to purchase up to an additional 91,500 ADSs and/or warrants to purchase 91,500 ADSs to cover overallotments, if any.

The company said that the funds would be used for its ongoing clinical programs, repayment of debts, manufacturing costs and marketing initiatives and for working capital and other general corporate purposes.

Immuron said the ADSs and warrants were scheduled to begin trading on the Nasdaq over the counter market on June 9, 2017, under the symbols IMRN and IMRNW, respectively.

The company said that the offer was expected to close on June 14, 2017, subject to closing conditions.

Immuron said that Joseph Gunnar & Co and Rodman & Renshaw were joint book-running managers, with Sichenzia Ross Ference Kesner US legal counsel to Immuron and Loeb & Loeb US counsel to the underwriters.

Immuron fell five cents or 10 percent to 45 cents.

BOTANIX PHARMACEUTICALS

Last night's edition described the Botanix compound BTX1701 as a synthetic cannabidiol, like another compound in the company's pipleine.

The reporter was misinformed.

Today, chief executive officer Matt Callahan told Biotech Daily it was "a new use of a wellstudied excipient utilized in many if not most [prescription dermatology] products which is monographed and safe, but not previously recognized as an excellent oil and sebum solubilization agent".

Mr Callahan said that "more will be said about it in a later update" for intellectual property reasons.

Yesterday the company claimed that BTX1701 was safe and had "prospective activity in removing excess skin oiliness and reducing bacterial infection", but did not cite the number of subjects in the trial of the over-the-counter facial cleanser.

Despite repeated requests for the number of subjects in the trial, Mr Callahan would only say that it was fewer than 20 patients.

Botanix fell 0.1 cents or 2.4 percent to 4.1 cents with 10.4 million shares traded.

GI DYNAMICS

GI Dynamics says there was a clerical error in the annual general meeting voting results on director Dr Oern Stuge's grant of options.

GI Dynamics said that Dr Stuge was granted 30,000 options in resolution five but lost the vote on resolution 11 of the grant of 8,000 options.

In May, the company reported that up to 80 percent of votes at its annual general meeting voted down proposals to give directors options over shares "in the money" and said that Dr Stuge had his 8,000 "annual" options approved but all other director options were overturned (BD: May 23, 2017).

Dr Stuge's 30,000 "initial" options over US shares, exercisable at 76 US cents was equivalent to 1,500,000 options exercisable at 2.025 Australian cents over CDIs. GI Dynamics fell half a cent or 8.9 percent to 5.1 cents.

AIRXPANDERS

Airxpanders says its Aeroform breast tissue expander system is available in more than 100 US medical institutions and health systems.

Airxpanders said that the Aeroform was a needle-free alternative for women who choose reconstructive surgery following a mastectomy and was activated by a handheld wireless controller administering small amounts of carbon dioxide up to three times a day, to gradually stretch the tissue to prepare for a breast implant.

Airxpanders said that Aeroform was granted clearance by the US Food and Drug Administration on December 21, 2016.

Airxpanders fell two cents or 2.9 percent to 68 cents.

BENITEC BIOPHARMA

Benitec says it has received an additional \$636,056 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program. Benitec said the rebate was in addition to \$5,590,235 received in March and related to the costs of research and development for the year to June 30, 2016 and the funds would be used for its therapeutic programs in gene silencing (BD: March 24, 2017). Benitec was unchanged at 14.5 cents.

SIRTEX MEDICAL

Allan Gray says it has become a substantial shareholder in Sirtex with 3,034,868 shares or 5.26 percent.

Biotech Daily believes it is the first time that Allan Gray (previously Orbis Investment Mangement) has been substantial in Sirtex, at least since April 2009.

Allan Gray said it bought and sold shares between February 10 and June 7, 2017 with the single largest purchase 400,069 shares for \$5,542,668 or \$13.85 a share.

Sirtex fell four cents or 0.3 percent to \$11.81 with 341,828 shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics has requested a trading halt "pending the release of an announcement of the results from the Promarkerd clinical validation study".

Trading will resume on June 14, 2017 or on an earlier announcement.

Proteomics last traded up four cents or 25 percent to 20 cents with 37,300 shares traded.

CRESO PHARMA

Creso says that 1,395,000 shares will be released from escrow on June 21, 2017. According to the company's most recent Appendix 3B new issue statement Creso would have 63,303,848 shares available for trading after the release with a further 25,047,501 shares held in escrow.

Creso fell 2.5 cents or 5.3 percent to 44.5 cents.

REVA MEDICAL

Reva has disclosed that Australian director Anne Keating has retired as a director with chief executive officer Dr Regina Groves appointed to the board.

Reva did not publish a stand-alone announcement but told the market through an Appendix 3X initial director's notice and Appendix 3Z final director's notice of the changes. Following an inquiry regarding the absence of a standalone announcement as required under ASX Listing Rules, Reva later posted an announcement of the changes.

Ms Keating's resignation followed the grant of options at the recent annual general meeting and said she was departing the company with 580,881 Chess depository instruments (CDIs) as well as options over 543,000 CDIs.

Dr Groves told Biotech Daily that Rob Thomas remained as an Australian director of the company.

Reva was untraded at 88 cents.

ADMEDUS

Admedus says it has appointed David St Denis as its chief operating officer, replacing Dr Julian Chick, who resigned in May, 2017.

Admedus said that Mr St Denis would take up the role in July after relocating his family from Europe to Minneapolis where he would be based.

The company said that Mr St Denis with 20 years in the life sciences and pharmaceutical sectors.

Admedus said that Mr St Denis was most recently with Merck in Germany as head of commercial operations for Europe and Canada.

Admedus chief executive officer Wayne Paterson said that Mr St Denis had "formidable sales and marketing capability and will provide a powerful boost to our current momentum".

The company said that Mr St Denis had experience in operations management, strategy development, marketing and sales, new product introduction and launch, market access and pricing.

Admedus said that Mr St Denis held a Bachelor of Science from the University of Connecticut, a Masters of Arts from Boston University and a Masters of Business Administration BA from Babson College.

Mr Paterson thanked Dr Chick for his service.

"Julian has been a great advocate for Admedus over the past five years," Mr Paterson said.

"On behalf of the board, we offer our appreciation and we wish him every success," Mr Paterson said.

Admedus said that Dr Chick would work with the company through the transition with Mr St Denis to ensure a smooth changeover in the role.

Admedus was up half a cent or 1.8 percent to 28 cents.

ADHERIUM

Adherium says it has appointed Arik Anderson as its chief executive officer replacing founder Garth Sutherland and starting on \$US400,000 (\$A531,146) a year.

Adherium said that Mr Anderson would focus on business opportunities while Mr Sutherland would remain an executive director working on new areas of development. The company said that along with his base salary Mr Anderson would be entitled to

"associated benefits customary to a role of this nature in accordance with US employment practices and obligations" including motor vehicle, health and life insurance,

superannuation, initial housing relocation allowance as well as a short term incentive of up to \$200,000 a year subject to key performance indicators and a long term incentive of upto 1,500,000 shares at 50 cents a share subject to conditions.

Adherium said that Mr Anderson had more than 25 years' experience in the medical technology and medical device manufacturing industries, most recently as Terumo Cardiovascular Systems head of perfusion and surgical devices.

The company said that previously Mr Anderson was Somanetics head of research and development and operations.

Adherium said that Mr Anderson would be based in San Mateo California and held a Bachelor of Science from the University of Wisconsin, Madison.

Adherium was unchanged at 14.5 cents.

BIOTRON

Biotron says it has appointed the Shanghai-based Lynx Financial as its corporate adviser for commercialization in China.

Biotron said that Lynx would assist it in identifying and negotiating with suitable partners to licence its anti-viral programs in China.

The company said that Lynx had offices in Shanghai, San Diego and Tel Aviv.

Biotron was up 0.2 cents or 9.5 percent to 2.3 cents with 1.1 million shares traded.