



Biotech Daily

Friday June 14, 2019

Daily news on ASX-listed biotechnology companies

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- * **ALTHEA PRESCRIBES 1,000 MEDICAL MARIJUANA PATIENTS**
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- * **AUSBIL BELOW 5% IN BIONOMICS**
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MARKET REPORT

The Australian stock market was up 0.18 percent on Friday June 14, 2019, with the ASX200 up 11.6 points to 6,554.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and four were untraded.

LBT was the best, up one cent or eight percent to 13.5 cents, with 1.4 million shares traded. Nanosonics climbed 6.7 percent; Orthocell improved 4.7 percent; Immutep, Pro Medicus and Telix were up more than three percent; Antisense and Volpara rose more than two percent; Avita was up 1.4 percent; with Clinuvel, Compumedics, Cochlear, CSL and Neuren up by less than one percent.

Optiscan led the falls, down half a cent or 11.1 percent to four cents, with 925,000 shares traded. Proteomics lost seven percent; Benitec, Imugene and Opthea fell more than six percent; Dimerix, Genetic Signatures and Impedimed were down more than three percent; Alterity (Prana), Kazia and Medical Developments shed more than two percent; Mesoblast, Oncosil, Paradigm, Pharmaxis, Polynovo and Prescient were down more than one percent; with Cynata and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: HERAMED

By TIM BOREHAM

ASX code: HMD

Share price: 23 cents

Market cap: \$20.1 million

Shares on issue: 87,528,841

Chief executive officer: David Groberman (co-founder)

Board: Dr Ron Weinberger (chair), Mr Groberman, Tal Slonim, David Hinton, Doron Birger

Financials (March quarter 2019): receipts \$88,000, cash burn \$680,000, cash of \$3.3 million, estimated current quarter cash burn \$1.34 million.

Identifiable major shareholders: Holley Pharma Company 10.81%, David Groberman 9.14%, Ted Slonin 9.14%, The Mayo Clinic 0.85%

As the saying goes, behind every great man there has to be a great woman; and in the case of Israeli biomechanical engineer David Groberman it's his wife Odelia.

During her third pregnancy, Odelia pondered why she had to make frequent hospital visits for a routine ultrasound to monitor the baby's heartbeat.

Surely this could be done in the comfort of one's own home?

"We found ourselves going to the doctor over and over again just to see that everything was okay. It was considered a higher-risk pregnancy," Mr Groberman says.

At the time, Mr Groberman and business partner Tal Slonim were consulting to health giants such as Medtronic, Philips and Bayer, as well smaller Israeli start-ups.

"After doing that for 15 years we decided we wanted to cross the road and bring something unique ourselves to the market, not just provide services to others," he says.

The duo ran with the idea of developing an app-linked device to enable just that and - yada yada yada – Heramed was born (pardon the pun).

Heramed listed on the ASX in December last year, following a well-worn path of other Israeli start-ups drawn by Australian investors' receptive attitude towards riskier shares (such as two-bit explorers and a plethora of marijuana companies).

About Heramed

The philosophy underpinning Heramed and its initial Herabeat device is that pregnancy is the ultimate expression of “wellness”, or what we more commonly call “health”, yet expectant mothers are treated as sick patients.

According to Heramed’s research partner, the Rochester, Minnesota head-quartered Mayo Clinic, on average, 14 “clinical sessions” are required during a pregnancy; and most are for a regular ultrasound.

In contrast, Melbourne’s Royal Women’s Hospital says that healthy pregnancies require three to five visits.

By the time the gravid mum has found a parking spot, argued with her spouse and queued for the consultation, stress levels are raised and that can result in a false reading. Not to mention the danger of coming into contact with germy patients - er other expectant mums.

“All they do is hook you up to professional, big ultrasound monitors and take the baby’s heartbeat and you then have to go back in line and wait for the doctor,” Mr Groberman says.

The Herabeat hardware consists of a round sensor (which goes on the belly) and is linked to a smart phone application.

Based on hundreds of tests to date, the company claims the results are the same as those of an ultrasound clinic machine, give or take one heart beat per minute, of about 110 to 160 beats per minute.

The device reflects the quantum advances in electronics, in terms of miniaturization, battery quality and longevity and sensor development.

“We are leveraging the immense progression of the electronics industry,” Mr Groberman says. “The micro-controller is 10 times more intense than a full laptop computer from four years ago.”

Heramed’s commercialization path

So far, Heramed is approved to sell its \$US299 a pop Herabeats in Mexico, Israel, Australia, Europe and India (locally, they sell for \$450).

In Israel, the product is distributed by big pharma Teva. In Australia, the company plans to launch this month in cahoots with the infant supplies mob Dale Group and marketer Meerkats.

The company also has distribution tie-ups in the UK, Brazil, Mexico and Turkey.

In the US, the company last month submitted an application to the Food and Drug Administration (FDA) for section 510k device approval.

“We expect the FDA to come back before the end of this year with a view to a launch next year,” Mr Groberman says.

But measuring heartbeats is one thing; interpreting them is another. “The real impact comes when you have a service where the data is uploaded to the cloud and can be reviewed by a professional (a midwife or a nurse),” he says.

Hence Heramed is also rolling out Heracare, a \$US69 a month subscription-based pregnancy management service, by which mums have 24-hour telephone access to clinical professionals.

Heramed intends to partner with third parties that have relevant call centres in place, such as tele-medicine providers or health management organizations (combining insurers and hospitals). Over time, this ‘care manager platform’ is also expected to be extended to monitor the mum’s blood pressure, weight and temperature.

Step three is an artificial intelligence (AI) product called Orion AI, being developed with the Mayo Clinic. By crunching millions of data records over time, Orion AI will be ‘trained’ to detect factors that indicate potential pregnancy complications before they become a problem.

This one is still in the lab, but is expected to come to market in 2021 with an indicative price of \$US4.90 a month for home users, or \$US1.90 per session for professionals.

Of course, some expectant mothers might not fancy being advised by a robot. The truth is, the human experts are said to be wrong up to 40 percent of the time.

Heramed is fortunate enough to have the esteemed Mayo Clinic as a shareholder and “research and development collaborator”. The Minnesota-based institution has a long interest in fostering at-home prenatal monitoring, if only to reduce the burden of face-to-face hospital health costs.

Mayo’s head of cardiovascular medicine Prof Paul Friedman is on Heramed’s advisory board. Also, a global expert in artificial intelligence for medical applications, Prof Friedman reckons Orion AI will “potentially enable the healthcare community ... to develop preventative and personalized healthcare models”.

No market is the same

Mr Groberman says Heramed’s sales approach will differ from geography to geography. In Brazil, for instance, the company has dealt directly with health giant Hapvida, which has 100 hospitals and 1000 clinics.

In a pilot program, the company is working with the hospitals to ensure the patient data goes seamlessly to their electronic medical records, ready for midwives or physicians to review.

If there’s a problem, the patient - and by that stage she is one - can be taken to hospital.

In Mexico, the company has an entirely different alliance with IBL Group, which has 50 Apple electronics shops.

“They decided to establish a store-within-a-store for digital health and chose our device to be the first one to be featured,” Mr Groberman said.

“The consumer aspect of being featured in an Apple store is unbelievable.”

Finances and performance

In the March quarter, Heramed reported receipts of \$88,000 and cash outflows of \$680,000, with cash on hand of \$3.33 million and no debt.

The December ASX-listing was accompanied by an oversubscribed \$6 million raising, at 20 cents a share.

The raising was supported by Perth paediatrician Dr Paul Porter, who is an advisor to Resapp (see below).

Heramed chairman Dr Ron Weinberger was a mover and shaker behind the highly successful probe disinfection play, Nanosonics.

Messrs Groberman and Slonim each account for just over nine percent of the register. The biggest holder is China’s Holley Pharma, on 10.8 percent.

Mr Groberman is coy on revenue projections, but volunteers the company expects to sell “at least several thousand devices this year and much more than that next year”.

In their short-listed life, Heramed shares have wavered between 15 cents (early January this year) and 33 cents (mid-March).

For the worried well?

One worry for us is the device might feed on the parents’ natural anxiety about what can go wrong in pregnancy.

The truth is the overwhelming majority of pregnancies and childbirths in Western countries are normal: according to Emory University School of Medicine’s genetics department, 96 percent to 97 percent are born healthy (that is, without any birth defects).

According to the UK pregnancy support organization Tommy’s, one in four pregnancies miscarry, but 85 percent of these are within one to 12 weeks. Late term miscarriages are very rare.

Mr Groberman agrees there will always be a cohort of “extremely anxious people” but implies the benefits of early detection of problems outweigh the risks.

Besides, he says, at-home monitoring fosters bonding with the unborn child. “Listening daily and sharing with husband and kids is an amazing experience,” he says. “On the medical aspect, any obstetrician will say two to three times a week is good enough.”

Dr Boreham’s diagnosis:

Heramed must be doing something right in the eyes of investors, because the remuneration report attracted a ‘no’ vote of nil, yada and zip at the company’s May 29 AGM in Melbourne.

The company evokes comparisons with the Resapp and the former Isona, which found the app-based respiratory diagnosis game to be not such a wheeze.

There’s another direct link with Resapp in that the Porter family’s investment advisor, Chris Ntoumenopoulos of Twenty 1 Corporate, is a Resapp director.

“There are similarities but there are differences,” Mr Ntoumenopoulos says of Heramed and Resapp. Both are [internet] cloud plays but Resapp has the advantage of no hardware and therefore no cost of goods sold (COGS). Heramed has a higher COGS, but pregnant woman make for a more fertile target.

Excuse the pun yet again.

“They are both very good stories and very commercial from a consumer and a medical point of view which is very important and why we invested in it,” Mr Ntoumenopoulos says.

With 45 million infants born every year - including 310,000 in Australia - Heramed is addressing a vast and fecund market. But, of course, it’s a quantum leap between being preggers and buying the product.

Another issue is that mums tend to donate maternity paraphernalia to the next expectant mum when the need has passed. Conceivably - and excuse the pun yet yet again - these hand-me-downs will include Heramed.

But the company is onto this potential problem: each device has a serial number enabling the application connection, which means that after a short period of grace the new mum can be prompted to pay a licence fee.

No, Luther Vandross and Janet Jackson - the best things in life aren’t free.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. The father of two accepts that pregnancy is a wonderful expression of wellness, but as for childbirth itself ...

THE BURNET INSTITUTE

Melbourne's Burnet Institute says its scientists played "a key role" in a study that identified the human antibodies that prevent the malaria parasite from entering blood cells.

Burnet director and chief executive officer Prof Brendan Crabb said the research that he co-authored was "a highly significant step forward in the field of malaria and a potential key to creating a highly effective malaria vaccine".

The research article, led by the University of Oxford's Jenner Institute and Department of Biochemistry, is titled 'Human Antibodies that Slow Erythrocyte Invasion Potentiate Malaria-Neutralizing Antibodies' was published in the journal Cell and is available at: [https://www.cell.com/cell/pdf/S0092-8674\(19\)30553-7.pdf](https://www.cell.com/cell/pdf/S0092-8674(19)30553-7.pdf).

The Burnet Institute said that the study focused on the RH5 protein produced by the malaria parasite, which must bind to a human protein on red blood cells called basigin to infect them.

The Institute said the researchers were able to demonstrate which human antibodies effectively blocked RH5 from binding with basigin, thus preventing the parasite from spreading through the blood.

The Burnet said that the study was done as part of a clinical trial in Oxford of the first vaccine that targetted the RH5 malaria protein.

The Institute said that, until now, it was not clearly understood which specific antibodies could be generated by vaccination of a human volunteer and would effectively prevent RH5 from binding to red blood cells.

Co-author Dr Daniel Alanine said that "when someone is vaccinated, they make many different types of antibodies against the same RH5 target".

"This study is key to understanding which specific antibodies are actually effective against malaria, and which are not," Dr Alanine said.

The Burnet said the study identified a new antibody, which worked by slowing down the speed in which RH5 bound to red blood cells.

The Institute said the parasite could still invade, but the antibody slowed the invasion, giving the antibodies that blocked RH5 more time to act, making them more effective.

University of Oxford professor of molecular parasitology Prof Matthew Higgins said the finding showed that antibodies that did not prevent the parasite from getting into red blood cells "might still be useful, by making the protective antibodies more potent".

"There has long been speculation that experimental vaccines against malaria don't work well because the parasite invasion process they are designed to block is simply too fast ... for the antibodies generated by the vaccine to do their job and stop the parasite in its tracks," Prof Crabb said.

"We now know that this idea is indeed quite likely and not only that, but we have a tool to slow invasion so that protective antibodies can work effectively," Prof Crabb said.

"Enhancing RH5 antibodies like this provides a surprising and potentially powerful avenue for greatly improving a number of vaccine and therapeutic approaches," Prof Crabb said.

The Burnet Institute said that despite the increasing use of bed nets, insecticides and drugs in malaria-endemic regions, malaria still kills about 430,000 people a year, and scientists have been unsuccessful at developing a vaccine that works against the malaria parasite in the blood.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has been upgraded from the Standard & Poors ASX 300 Index to the ASX 200 Index, effective from June 23, 2019.

Clinuvel climbed 31 cents or 0.9 percent to \$34.10 with 214,078 shares traded.

[ANATARA LIFESCIENCES](#)

Anatara says the Florham Park, New Jersey-based Zoetis Inc has terminated its exclusive worldwide licence to the Detach diarrhoea treatment for livestock and horses.

Last year, Anatara said the deal with Zoetis comprised an upfront payment of \$US2.5 million (\$A3.4 million) with aggregate milestone payments of up to \$US6.3 million and royalties of three to four percent (BD: May 15, Jul 18, 2018).

Today, Anatara chief executive officer Steve Lydeamore told Biotech Daily that the company had not received any of the milestone payments nor royalties on sales.

Mr Lydeamore said that prior to the Zoetis licence agreement, Anatara had engaged with more than 10 animal health companies and would review the opportunities for Detach.

Anatara fell as much as 19 cents or 54.3 percent to 16 cents, before closing down 15 cents or 42.9 percent to 20 cents with 1.5 million shares traded.

[ADALTA](#)

Adalta says its entitlement offer at 15 cents a share had applications for \$730,335 in shares but raised the hoped-for \$2 million.

Last month, Adalta said it raised \$5 million in an “oversubscribed” placement and expected to raise \$2 million in the one-for-8.8 rights issue (BD: May 23, 2019).

Today, the company said it had placed the shortfall and would issue 6,682,075 one-for-two options, exercisable at 25 cents a share by June 30, 2021.

Adalta was unchanged at 14.5 cents.

[OPTISCAN IMAGING](#)

Optiscan says it has raised \$1.7 million in a placement at four cents a share.

Optiscan said directors would participate in the placement through an interest free loan for a total of \$200,000 of shares, subject to shareholder approval.

The company said the funds would be used for regulatory approvals, marketing and working capital, and Patersons Securities was the lead manager to the placement.

Optiscan fell half a cent or 11.1 percent to four cents.

[VOLPARA HEALTH TECHNOLOGIES](#)

Volpara says it has acquired the Seattle-based Mammography Reporting Systems Inc.

Last week, Volpara said it would purchase MRS Systems Inc for \$US14.59 million (\$A21.15 million) (BD: Jun 3, 2019).

Today, the company said the acquisition would increase the number of US breast clinics to which it had access from 400 clinics to more than 2,000 clinics.

Volpara said this would “enable many more women to benefit from Volpara’s clinical and enterprise management software while ultimately generating the massive amounts of data that optimize [artificial intelligence]”.

Volpara was up 4.5 cents or 2.8 percent to \$1.65 with 1.3 million shares traded.

[BARD1 LIFE SCIENCES](#)

Bard1 has requested a trading halt “pending an announcement to the market regarding a potential equity raising”.

Trading will resume on June 18, 2019 or on an earlier announcement.

Bard1 last traded at 2.5 cents.

GI DYNAMICS

GI Dynamics says a 10-patient study of its Endobarrier for obesity and type 2 diabetes shows that it reduces the number of apnoea hypopnea index events.

GI Dynamics said adult patients with moderate obstructive sleep apnoea, type 2 diabetes or pre-diabetes, obesity and treated with continuous positive airway pressure (CPAP), were implanted with Endobarrier for up to 12 months and the Endobarrier reduced apnoea hypopnea index events from a baseline average of 18.8 to 10.6 at explant, below the 15 events per hour threshold requiring CPAP according to the UK guidelines.

The company said the study, titled 'EndoBarrier in Type 2 Diabetes/Pre-Diabetes with Obstructive Sleep Apnoea (OSA) Study – Maintenance of Improvement after EndoBarrier Removal' was presented at the American Diabetes Association meeting in San Francisco.

GI Dynamics said the study was initiated and funded by the Association of British Clinical Diabetologists based at City Hospital of Sandwell and West Birmingham Hospitals.

GI Dynamics was untraded at 1.8 cents.

ALTHEA GROUP HOLDINGS

Althea says it has prescribed its 1,000th medical marijuana patient through 185 healthcare professionals, five months ahead of schedule.

In April, Althea said it had prescribed 511 patients through 128 healthcare professionals since May 2018 (BD: Apr 4, 2019).

The company said it expected to reach 200 Australian healthcare professionals in June.

Althea was up 2.5 cents or 3.4 percent to 76.5 cents.

VOLPARA HEALTH TECHNOLOGIES

Harbour Asset Management says it has increased its holding in Volpara from 9,025,027 shares (5.032%) to 13,786,895 shares (6.465%).

The Wellington, New Zealand-based Harbour said that between February 28 and June 13, 2019, it bought 4,908,192 shares for \$6,976,119 or \$1.42 a share and sold 146,324 shares for \$246,494 or \$1.685 a share.

BIONOMICS

The Sydney-based Ausbil Investment Management says it has ceased its substantial holding in Bionomics, reducing by 5,314,963 shares.

Last October, Ausbil said it held 30,768,312 shares (6.372%) and Biotech Daily calculates Ausbil continues to hold 25,453,349 shares or 4.7 percent (BD: Oct 8, 2018).

Today, Ausbil said it bought and sold shares between November 9, 2018 and June 12, 2019, with a single largest sale of 2,521,546 shares for \$162,640 or 6.5 cents a share.

Bionomics was unchanged at 6.3 cents with 5.8 million shares traded.

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

TPI says it will change its name from TPI Enterprises to Palla Pharma and its ASX code from TPE to PAL, effective from June 19, 2019.

TPI fell 1.5 cents or 1.35 percent to \$1.10.

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