

Biotech Daily

Friday October 12, 2018

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian Stock Market defied the US, up 0.2 percent on Friday October 12, 2018 with the ASX200 up 11.9 points to 5,895.7 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 12 fell, three traded unchanged and three were untraded.

Volpara was the best, up 20.5 cents or 19.5 percent to \$1.255 with 820,797 shares traded. Avita climbed 15 percent; Osprey improved 10 percent; Bionomics and Paradigm were up eight percent or more; Immutep rose 7.3 percent; Imugene was up five percent; Dimerix, Medical Developments, Mesoblast, Neuren and Starpharma were up four percent or more; Actinogen, Genetic Signatures, Opthea and Prana rose more than two percent; CSL, Cyclopharm, Factor, Nanosonics, Pharmaxis, Polynovo and Prescient were up more than one percent; with Resmed up 0.6 percent.

Compumedics led the falls, down 3.5 cents or 7.95 percent to 40.5 cents, with 180,104 shares traded. LBT, Reva, Telix and Universal Biosensors fell more than four percent; Ellex was down 3.05 percent; Airxpanders and Pro Medicus shed more than two percent; Clinuvel, Cynata, Impedimed and Optiscan were down one percent or more; with Cochlear down 0.04 percent.

DR BOREHAM'S CRUCIBLE: NOVITA HEALTHCARE

By TIM BOREHAM

ASX code: NHL

Share price: 3.1 cents

Market cap: \$13.9 million

Shares on issue: 449,305,165

Chief executive officer: Glenn Smith

Board: Sue MacLeman (chair), Glenn Smith, Mark Simari, Jefferson Harcourt

Financials (2017-'18 year): revenue \$89,285 (previously nil), loss \$4.19 million (\$1.36 million previously), cash \$1.16 million *

* In July 2018 the company carried out a \$2.8 million placement.

Identifiable major holders: Peter and Diana Diamond 12.13%, Three Zebras (Carlton footballer Chris Judd) 5.79%, Grey Innovation 5.75%, Moonah Capital 4.45%

Move over Thomas the Tank Engine and all aboard the Tali Train: a drug-free algorithmicbased tool to monitor and assist in treating cognitive disorders in children, notably attention deficit disorder and autism spectrum disorder.

Tali Train has already been available in Australia but in September the US Food and Drug Administration approved the tool as a class II medical device. This means it is exempt from the normal 510(k) registration requirements, notably further clinical trials.

In May, the Australian Register of Therapeutics Goods certified Tali Train as a class I device. Perhaps more importantly, the device is registered for what some cynics dub another (gravy) train: the National Disability Insurance Scheme.

Novita estimates about 400,000 Australian children, or 10 percent of the juvenile populace, have attention deficit issues.

"In western countries, 136 million kids have been diagnosed with severe attention deficit disorder, so we figure there is a mighty opportunity for Tali Health," CEO Glenn Smith says.

The company is eyeing a commercial launch in the US in 2019.

Owned by Novita subsidiary Tali Health, Tali Train is applicable for children three to eight.

Novita says the tool can be an adjunct to existing treatments, including psycho stimulants such as methylphenidate (best known as the brand name Ritalin).

Existing treatments (drugs) don't treat the underlying causes and have side effects, with a question mark over long term impacts. They're also not suitable for children under the age of five years.

Avexa hangs up its pick and shovel

Novita evolved from the old Avexa, which tried unsuccessfully to commercialize its HIV drug apricitabine before making a bizarre diversification into coal mining in Alabama.

The company returned home without even a banjo on its knee to show for its efforts.

In early 2016, Avexa acquired the Melbourne based Tali Health for \$4 million, funded by a private placement. Avexa then carried out a 20-to-one share consolidation and changed its name to Novita in December 2016.

Avexa's long serving chairman lain Kirkwood departed in October 2017, while director Bruce Higgins bailed out in May this year.

Sue MacLeman joined the board in September, replacing Mark Simari as chairman (Mr Simari stays on as a director). Ms MacLeman is well known in biotech circles, including as chair of MTP Connect and Anatara Lifesciences, a director of Oventus and partner of Paul MacLeman, who once led Genetic Technologies and IDT Australia.

With a background in healthcare and recruitment, Glenn Smith was anointed CEO in October last year.

The Tali Train technology evolved from work by Monash University neuro-scientists and was developed in league with Torus Games and the commercialization business (and Novita substantial shareholder) Grey Innovation.

Novita's biggest shareholder, Peter Diamond, is the former principal of listed Perth stockbroker Euroz. He came on board more recently because he simply liked the story.

Tali Train explained

Tali Train is an "adaptive fun-based interface" delivered under a software-as-a-service model. In effect, it's a touch-screen game that adapts to the child's performance and sharpens the challenges to increase attention skills.

The program involves 20-minute sessions five days a week, over five weeks. After that short period, clinicians will have a result.

Tali Train's efficacy is supported by completed trials carried out at Monash University's neuro-sciences division. Carried out over a long period, these trials showed Tali Train's ability to focus kids on avoiding distractions while also honing academic skills (notably numeracy).

Mr Smith says the trial results have been supplemented by ongoing 'real life' data from the 150 clinicians on Tali Health's books.

"Some of them effectively are in trials with us," he says. "We do the same with pilot schools who are assisting us with performance data."

Tali Health is engaging directly with parents, whom the company hopes will become "Tali champions" and spread the word.

The company is also working on Tali Direct, a variation that can assess all children for potential problems. This variant is currently being trialed in some Victorian state and Catholic schools.

Recruitment sideline 'fired'

Having acquired Tali Health, Avexa decided to accommodate both ends of the age spectrum by acquiring the Newly on-line recruitment site for \$920,000 upfront, with an earn out of four times Newly's 2018-'19 pre-tax profit.

Claiming one of the biggest carer databases in Australia, Newly is a platform for care or support professionals seeking work, or aged care or support providers seeking staff.

It then dawned on Novita's management that there were no synergies between a kids' digital health assessment tool and a jobs wrangler.

In July this year, a mere year after the purchase, Novita entered a heads of agreement to divest Newly to online market place Healthcarelink (HCL).

The deal involved Novita receiving HCL scrip equating to 10 percent of HCL, but with Novita contributing \$400,000 to a HCL capital raising.

Financials and performance

In July, Novita raised \$2.7 million in a placement to sophisticated investors and institutions, issuing 89.8 million shares at 3.1 cents apiece. The company also garnered \$3.5 million at three cents in July 2017 through a placement and rights raising.

The company's inclusion on the National Disability Insurance Scheme (NDIS) approved list is crucial: of the 140,000 current scheme participants, about 38,000 (29 percent) have autism listed as their primary disability, while the portion is similar for those with an intellectual disability. Of the autism cohort, 40 percent is in Tali's target market.

Under the scheme, the company is charging \$399 plus GST for each Tali Health package. The NDIS rules do not oblige providers to seek permission to set or increase their rates, but if their price looks like gouging they risk being chucked off the scheme.

Clinicians (usually paediatricians or psychologists) pay \$299 but they're encouraged to charge patients \$399 to cover admin costs. Otherwise the clinicians benefit from more chargeable hours if the tests are done in situ.

The company expects Tali revenues to support cash flows "beyond the next 12 months".

Under the Novita moniker, the company's shares have traded in a range of 2.6 cents (December 2016) and 4.8 cents (January this year). The current share price ascribes a lowly \$14 million market capitalization.

Dr Boreham's diagnosis:

Relative to most other life science plays, there's not much complexity attached to the Tali technology. But in a commercialization sense, simplicity can be a wonderful thing.

Novita reports strong interest from overseas, with Tali Health setting up clinics in Singapore and an initial early learning centre in Hong Kong.

Competition wise, the coast is clear. A company called Akili recently raised \$150 million to develop an assessment test for teenagers. Mr Smith says it's much harder to tackle the three to eight-year-old market because they are more difficult to recruit for trials.

"Other sophisticated university-based companies will seek venture funding to get in this early intervention space," Mr Smith says. "We really have to hit this hard and get the key revenue indicators up and going."

As a guide to the addressable market, Mr Smith estimates there are 500 relevant clinicians in Australia. If they apply Tali Train to one child every fortnight, that implies a \$5 million a year opportunity.

Because the company started selling in earnest in July, the revenue uptick should become apparent in the September quarter results that are imminent.

Management warns that Tali Health's commercialization strategy depends on factors including "assumptions relating to development and marketing expenditure, market demand, sales volume and pricing, working capital requirements and regulatory compliance".

Okay! This may be stating the obvious, but it's worth remembering nonetheless.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His attention can wander off the tracks when Friday beer-o-clock looms.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says it has genetically-engineered a mouse that mimics the complexity of human cancers, enabling accurate testing of cancer drugs. The Institute said that with the mouse model, researchers would be able to discover the

safest and most effective ways to use myeloid cell leukaemia-1 (MCL-1) inhibitors. WEHI doctoral student Margs Brennan told Biotech Daily that "the mouse was the primary model, which we crossed to an established lymphoma mouse model (eµ-MYC) and then we could generate cell lines from the tumors from these mice, that have human MCL-1". "Now we can cross these mice to other known cancer models and generate other different cancer cell lines, and mouse models, that have the human MCL-1 too," Ms Brennan said. The research article, titled, 'Humanized Mcl-1 mice enable accurate pre-clinical evaluation of MCL-1 inhibitors destined for clinical use', was published in Blood, with an abstract available at: <u>https://www.biorxiv.org/content/early/2018/05/31/335430</u>.

WEHI said that the work was led by Ms Brennan, Dr Gemma Kelly and Prof Marco Herold and the mouse model was "the best available for preclinical testing of MCL-1 inhibitors and will help to identify the right patients for these drugs".

The Institute said that MCL-1 inhibitors targeted a protein essential for the sustained growth of many blood cancers and solid tumors including breast cancers and melanoma. Dr Kelly said that MCL-1's role in promoting cancer cell survival made it "an attractive therapeutic target".

"MCL-1 allows cancer cells to evade the process of programmed cell death, or apoptosis, that normally removes damaged or unwanted cells from the body," Dr Kelly said.

"Because so many cancer cells depend on MCL-1 for survival, it is like cancer's Achilles' heel," Dr Kelly said. "If we can attack this weak point with a drug, we may be able to successfully trigger apoptosis and destroy cancer cells for good."

WEHI said the Paris-based Laboratories Servier had developed "a highly potent inhibitor of MCL-1", S63845, and while the drug was known to trigger cancer cell death in the laboratory, until now there was no accurate tool to predict how it would work in patients. Ms Brennan said the laboratory model would allow researchers to find the best ways to match MCL-1 inhibitors with the right patients and by using the mouse model "we can get a handle on key questions such as which types of cancers are sensitive to MCL-1 inhibitors, which patients will benefit, which combination treatments will be most effective and the best dosing regimens to use".

"Working with laboratory models that closely mimic human cancer allows us to gain as much knowledge about MCL-1 inhibitors as we can before the drugs even reach the clinic," Ms Brennan said. "This lays the groundwork for future clinical trials, hopefully improving treatment options for patients."

WEHI said that to demonstrate its potential, the researchers used the mice to test whether MCL-1 inhibitors could effectively treat a pre-clinical model of lymphoma.

"We found that treatment with the MCL-1 inhibitor S63845 led to remission in six out of 10 cases of lymphoma," Prof Herold said. "This was achieved without significant side effects, suggesting that S63845 will be safe and effective in the clinic."

Prof Herold said MCL-1 inhibitors could be "particularly powerful" when combined with standard treatments like chemotherapy, because "MCL-1 allows cancer cells to resist treatments like chemotherapy that would otherwise trigger cell death".

"In our preclinical model, we found that combining an MCL-1 inhibitor with chemotherapy led to remission in almost all cases of lymphoma," Prof Herold said.

WEHI said that the team was using the mice to test whether MCL-1 inhibitors were effective for other types of blood cancers and would share the mice with other members of the scientific community studying MCL-1 inhibitors.

UNIVERSITY OF MELBOURNE

The University of Melbourne says it has a partnership with Beijing No 1 Biochemical Pharmaceutical Co to provide opportunities for researchers and students.

The University said the agreement would fund university researchers to deliver biotechnology research and enable students "to travel abroad to strengthen their learnings in biotech studies".

University of Melbourne research deputy vice-chancellor Prof James McCluskey said the agreement would fund "significant research and learnings".

"The [memorandum of understanding] is important in that it provides a real boost to our researchers, in part through funding, and more importantly through access to [No 1 Biochemical Pharmaceutical's] significant connections and capabilities as a global biotech business," Prof McCluskey said.

University of Melbourne enterprize vice-principal Dr Doron Ben-Meir said that the agreement would deliver "great opportunities" for the University and the company.

"The [agreement] enables our researchers to leverage commercialization and market access capabilities that will ensure research is supported during conceptual stages, and is then able to be delivered to market in a way that may have been difficult to achieve in the past," Dr Ben-Meir said.

"As the [agreement] progresses, the intention is to also enable [sic] University of Melbourne biotechnology students to gather experience in locations such as China, to further grow their capabilities," Dr Ben-Meir said.

Beijing No 1 Biochemical chairman Bowen Zhang said the company had a 60-year history in industry and owned "first class research labs, [a good manufacturing practice] certified production line and a sales net of 8000 hospitals".

"We have built up cooperative relationships with Chinese Academy of Science, Chinese Academy of Medical Sciences and Peking University," Mr Zhang said.

"The University of Melbourne is the leading university in Australia and the world, and we see the [agreement] as delivering widespread benefits for both our company and the University, through collaborative research and internships," Mr Zhang said.

MESOBLAST

Mesoblast says it has received \$US40 million (\$A57 million) from Tasly comprising a \$US20 million upfront fee and \$US20 million for Mesoblast shares.

Mesoblast said it had issued Tasly 14,464,259 shares and Tasly had exclusive rights and would fund all development, manufacturing and commercialization activities in China for MPC-150-IM for the treatment and prevention of chronic heart failure and MPC-25-IC for the prevention and treatment of acute myocardial infarction.

The company said it would receive \$US25 million on achievement of product regulatory approvals in China, double-digit royalties on net product sales, and six additional escalating milestone payments on the product candidates reaching sales thresholds. Mesoblast said the companies would establish a joint steering committee to oversee, review and co-ordinate the development, manufacturing and commercialization activities for the cardiovascular product candidates in China, and through the committee, the companies would expedite development and commercialization of the cardiovascular product candidates, leveraging each other's trial results in China, and the US and other major jurisdictions to support regulatory submissions for MPC-150-IM and MPC-25-IC. In August, Mesoblast said that China had approved the Tasly's investment to commercialize cell therapies (BD: Jul 18, Aug 29, 2018).

Mesoblast was up 9.5 cents or 4.8 percent to \$2.08 with 2.0 million shares traded.

CYCLOPHARM

Cyclopharm says a meeting with the US Food and Drug Administration has opened the 505 (b) 2 process as an alternative pathway to approve Technegas for lung imaging. Cyclopharm said that the proposed pathway was likely to allow for a faster market entry and reduced risk profile and a new drug application by July 2019.

The company said the meeting followed submission of its first 40-patient interim study and in addition to positive results from its current phase III trial, the 505 (b) 2 pathway would allow the use of existing clinical data on Technegas' efficacy, safety and performance compared to Technegas' competing products and technologies.

Cyclopharm said it would continue to recruit patients for the phase III CYC009 study, file an amendment to the current special protocol assessment that was expected to accelerate the rate of patient recruitment, submit a 505 (b) 2 new drug application to the FDA by July 2019 and target US Technegas sales for "late 2019".

Cyclopharm managing-director James McBrayer said that "being allowed to submit a new drug application protocol for Technegas via a 505 (b) 2 pathway significantly de-risks the FDA approval process, gives confidence to our timeline target to start sales of Technegas in the US in 2019 and is likely to reduce the anticipated overall costs [of] \$US7.5 million of gaining approval substantially".

"We will redeploy any savings we make from adopting this alternative approval pathway to building the distribution, sales and marketing capabilities needed to initiate US sales in 2019," Mr McBrayer said.

Cyclopharm said that the US accounted for about half of the total addressable market for Technegas and the market for nuclear medicine ventilation imaging in the US was about \$US90 million a year for about 600,000 individual procedures.

Cyclopharm said Technegas could achieve a 50 percent US market share over three years, with an 80 percent share or 480,000 procedures a year in seven years. Cyclopharm was up two cents or 1.9 percent to \$1.07.

ALCIDION GROUP

Alcidion says that with its MKM Health and Patientrack acquisitions, customer receipts for the three months to September 30, 2018 rose 228.8 percent to \$5,061,000.

For the previous corresponding period, Alcidion posted customer receipts of \$1,539,000. Alcidion said that it completed the MKM Health and Patientrack acquisition on July 3, 2018 and published pro-forma unaudited results for the year to June 30, 2018 including MKM Health and Patientrack, as though they were owned by Alcidion for the whole year. The company said that its own revenue was \$4.2 million for the year and with \$8.5 million in MKM revenue the total was \$12.7 million.

Alcidion said that staff costs were expected to stabilize at \$2.9 million per quarter and its cash balance at September 30, 2018 was \$2.8 million which was \$273,000 below the previous quarter due to investments of \$326,000 in equipment and an initial payment of cash consideration for the MKM acquisition.

Alcidion executive chairman Ray Blight said it was "a very positive result for Alcidion which clearly demonstrates the impact of the MKM Health and Patientrack acquisition in delivering a strong uplift in quarterly revenue and improved cash flow".

"It was particularly pleasing to achieve positive operational cash flow, despite incurring significant one-off costs relating to the acquisition," Mr Blight said.

Alcidion said it had written contracts with a total value of \$9.1 million in the three months to September 30, 2018.

Alcidion was up 0.3 cents or 7.5 percent to 4.3 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says Breastscreen Central as a provider for Breastscreen New Zealand is the first public screening sector to buy its Volpara Enterprise software.

According to the New Zealand Ministry of Health the Breastcreen network provides free mammography to eligible women.

Volpara said the Enterprise analytics software helped deliver high-quality, breast cancer screening to women living in the Wellington region of New Zealand.

The company said that Breastscreen Central was the first organization to buy the Enterprise software "to use as a key component of its quality assurance protocols, monitoring breast compression, positioning and other factors to improve the consistency of mammographic imaging and patient experience".

Breastscreen Central lead technologist Hayley Shatford said that "having access to a tool that analyzes our mammograms is helping us to maintain and to continually seek to improve our image quality and the overall experience of our clients".

Volpara said the software delivered key indicators for more than 100 performance and quality metrics, including patient positioning and compression, which were the causes of most clinical image deficiencies and associated with delayed detection of breast cancer. Volpara was up 20.5 cents or 19.5 percent to \$1.255.

IMPEDIMED

Impedimed says it has agreed to sell Xitron Technologies Inc to Vitrek LLC for \$US500,000 (\$A702,007).

Impedimed said the sale included the net assets of the test and measurement business, subject to any working capital adjustment.

The company said it had "a perpetual world-wide licence for all technology and know-how related to the medical segment of the business and agreed to provide certain transition services to Vitrek LLC as part of the transaction".

Impedimed said the sale was not subject to any conditions and was completed today. Impedimed chief executive officer Richard Carreon said the company was "very pleased to have completed this transaction so that we can fully focus the organization on the opportunities we have with our Sozo digital health platform".

"I would like to thank the Xitron employees for their dedication and hard work to support the business over the last few years," Mr Carreon said.

Impedimed fell half a cent or 1.15 percent to 43 cents.

SIENNA CANCER DIAGNOSTICS

Sienna will vote to grant chairman Dr Geoffrey Cumming 600,000 options with 400,000 options each to directors Carl Stubbings, Dr David Earp and Helen Fisher.

Sienna said the options would be exercisable at a 25 percent premium to the 30-day volume-weighted average price to the date of the annual general meeting.

The company said that the options were intended "to foster an ownership culture within the company and to motivate directors and staff to achieve strategic objectives" and the options proposed to be issued would replace options that had expired.

The company said investors would vote on the remuneration report, to elect Ms Fisher, ratify the prior 27,039,349 shares issue and approve the 10 percent placement capacity. The meeting will be held at K & L Gates, Level 25, 525 Collins Street, Melbourne on November 15, 2018 at 10am (AEDT).

Sienna was up 0.6 cents or 7.5 percent to 8.6 cents.

THE HYDROPONICS COMPANY

Hydroponics will vote to issue executives 6,000,000 options, directors 380,000 shares and change its name to THC Global Group

Hydroponics said it proposed to issue chief executive officer Ken Charteris 4,000,000 performance options, vesting pending performance conditions and exercisable at 75 cents and \$1.20 by Jul 11, 2021; Jason Colquhoun 2,000,000 options exercisable at 40 cents by December 31, 2020; chairman Steven Xu 190,000 shares; and directors Lou Cattelan and Gary Radcliff 95,000 shares each.

The company said that shareholders would vote to adopt the employee option plan, ratify the prior issue of 14,898,414 shares and 4,500,000 options, approve the 10 percent placement capacity.

Hydroponics did not refer to a vote on the remuneration report.

The meeting will be held at the Function Centre, Level 4, 60 Carrington Street, Sydney on November 15, 2018 at 3pm (AEDT).

Hydroponics was up two cents or 3.9 percent to 53 cents.

ZELDA THERAPEUTICS

Zelda says that chief executive officer Dr Richard Hopkins will have a pay rise of 20 percent to \$300,000, with the cost of exercising his 25,000,000 options dropped. In May, when Zelda was trading at 11.5 cents a share, the company said that Dr Hopkins would receive a base salary of \$250,000 including superannuation and he would be issued with 25 million options, subject to shareholder approval, at three months, 15 months and 27 months, exercisable at prices 15 cents, 25 cents, 35 cents, 45 cents and 50 cents each within three years of issue (BD: May 22, 2018).

Today, with the share price at 6.5 cents, the company said that 5,000,000 options would vest on the date of issue, with 10,000,000 vesting on October 16, 2019 and 10,000,000 vesting on October 16, 2020, exercisable at 10 cents, 15 cents, 20 cents, 28 cents and 30 cents each within three years of issue.

Zelda was up 0.1 cents or 1.5 percent to 6.6 cents.

STEMCELL UNITED

The Singapore based Jianfang Wang says he has reduced below substantial in Stemcell, transferring off-market, 20,000,000 shares for \$100 or 0.0005 cents a share. In February, Mr Wang said he held 41,775,000 shares or 8.3 percent and Biotech Daily calculates that his continuing 21,775,000 holding was 4.2 percent of the company. In July, Stemcell said it had a \$US10 million (\$A13.5 million) five-year deal to supply Daemonorops draco blume resin to China's Zhejiang Forest Rainbow Medical (BD: Jul 13, 2018).

In its prospectus of June 29, 2015, Stemcell (then On Q Group) said it would extract Resina from Daemonorops draco blume or Dragon's Blood for traditional Chinese medicines, saying that "whether or not [traditional Chinese medicine] is believed, studies have shown that Chinese herbal medicine can be successful in treating a range of disorders" (BD: May 18, 2017).

In June, Stemcell said China had granted an industrial hemp licence to its partner Yunnan Hua Fang Industrial Hemp Co allowing it to grow, process and sell hemp product, with Stemcell saying it could use cannabis seeds for research into traditional Chinese medicine cosmetic products (BD: Jun 7, 2018).

Stemcell was up 0.1 cents or 4.55 percent to 2.3 cents.

CARDIEX

Cardiex has requested a trading halt "pending an announcement regarding a material transaction".

Trading will resume on October 16, 2018 or on an earlier announcement. Cardiex last traded at 3.1 cents.