



Biotech Daily

Friday November 8, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market slipped 0.4 percent on Friday November 8, 2019, with the ASX200 down 2.5 points to 6,724.1 points. Fourteen of the Biotech Daily Top 40 stocks were up, 19 fell, five traded unchanged and two were untraded.

Impedimed was the best, up one cent or 7.1 percent to 15 cents with 841,775 shares traded. Avita, Genetic Signatures and Patrys climbed more than five percent; Imugene and Prescient improved four percent or more; Immutep was up 3.5 percent; Actinogen, Clinuvel, Next Science, Paradigm and Pharmaxis rose more than two percent; Compumedics was up 1.4 percent; with CSL and Nanosonics up less than one percent.

Oncosil led the falls, down two cents or 11.1 percent to 16 cents, with 7.2 million shares traded. Proteomics lost 9.1 percent; Polynovo shed 5.2 percent; Alterity and Uscom fell four percent or more; Cynata and Kazia were down three percent or more; Ellex, LBT, Optiscan and Osprey shed more than two percent; Medical Developments, Opthea, Orthocell, Resmed, Starpharma and Volpara were down more than one percent; with Cochlear, Mesoblast, Neuren and Pro Medicus down by less than one percent.

DR BOREHAM'S CRUCIBLE: GENETIC SIGNATURES

By TIM BOREHAM

ASX code: GSS

Share price: \$1.025

Shares on issue*: 119,648,477

Market cap: \$122.6 million

Chief executive officer: Dr John Melki

Board:** Dr Nick Samaras (Chairman), Dr Melki, Dr Tony Radford, Michael Aicher (executive director)

Financials: (September quarter): revenue \$1.53 million, loss of \$1.27 million, cash balance \$4.93 million***, estimated December quarter outflows \$3.5 million.

Identifiable Major Holders**:** Christopher Abbott (Asia Union Investments) 31%, Karst Peak Capital 16%, Perennial Value Management, Regal Funds Management.

* Shares on issue include 15,589,040 shares issued on November 4 as tranche one of the \$35 million placement. A further 20,125,246 shares are due to be issued on December 12

** Phillip Isaacs resigned from the board as of the November 22 AGM. A search for a replacement is underway

*** Ahead of \$37 million placement and share purchase plan

**** The Perennial and Regal stakes are not known until the second tranche of the raising is completed.

As the saying goes, if you can make it in New York you can make it anywhere.

But for the home-grown molecular diagnostics house, cracking it in Australia has been the acid test of its greater abilities.

“The Australian diagnostic market is the hardest in the world,” says Genetic Signatures chief Dr John Melki.

“It is highly competitive. Rebates are the lowest in the world and pricing is similar to that in Vietnam.”

What's more, the big three local pathology providers account for 60 to 70 percent of the market - a concentration you do not see elsewhere.

A provider of all-in-one testing for range of bugs, Genetic Signatures is further frustrated by the Medicare reimbursement coding system.

That's because the current rules only allow funding for three tests, but the company might test for 20 diseases in one go.

Despite these trips and traps, Genetic Signatures has gleaned a 10 to 25 percent share of the local market, which in the 2018-'19 year accounted for 97 percent of its revenue.

"We are incredibly proud of what we have done in Australia," Dr Melki says.

"But we are only one or two percent of the world market while the US and Europe account for 75 percent."

To achieve its offshore ambitions, the company has just raised a meaty \$35 million in a share placement that saw Perennial Value Management come on as a cornerstone holder.

The raising was also supported by existing holder Regal Funds Management and an unnamed offshore institution.

Genetic Signatures retail holders have now been invited to fill their boots for up to 30,000 shares (\$29,400 worth) at the 98 cents a share offer price (the same as the placement price).

The story to date

Genetic Signatures was founded in 2001 by prominent fund manager Christopher Abbott and the late Dr Geoffrey Grigg, former head of microbiology at the esteemed Commonwealth Scientific and Industrial Research Organisation.

Dr Melki joined the company in 2003, having researched DNA and microarray technologies.

He was awarded the Sydney University Peter Bancroft Prize in 2001.

Genetic Signatures listed on the ASX in March 2015, raising \$7.5 million at 40 cents apiece.

The co-founder of boutique investment house Maple Brown Abbott, Christopher Abbott has a 31.7 percent stake.

He is also not on the board and lets management get on with the job, much to the envy of certain other biotechs with pesky major shareholders.

Bug off!

In short, Genetic Signatures tests for rapid screening of pathogens so that the appropriate antibiotic or treatment can be swiftly dispensed.

The tests replace old lab methods such as the 'stool on a slide' under a microscope and can be done in hours rather than days.

Dr Melki says the 3-base test can be used with urine samples or swabs for STIs, throat swab for respiratory disease or stools for gut problems and the test reads out the presence of target pathogens.

This is especially appealing to hospitals as they grapple to control antibiotic-resistant bugs.

The company's Easyscreen tests are based on the company's 3-base technology, which allows for faster and more accurate diagnosis of a number of ailments.

The existing tests cover 'flu and gastro enteric strains, flavivirus and alphavirus, antibiotic resistant bugs and sexually transmitted infections (STIs).

The most advanced product Easyscreen Enteric tests for 20 tummy bugs including norovirus, the bane of many a cruise ship.

How the tests work

Glad you asked.

The tests take the genetic information of the targeted organism and change the genetic sequence to make it easier to detect.

As the name implies, 3-base converts the original four-base microbial genome to three, which reduces the variables from more than one million to a mere 60,000 or so.

All readers really need to know is that it reduces pathology turnaround times from five days to less than five hours.

"We can do what no-one else can," Dr Melki says. "For example, we can look for 20 causes of gastro and do 200 tests at a time."

Seal of approval

The company's kits are approved in Australia and Europe and are sold in 30 countries, with more than 500,000 patients treated to date.

The current tests are for a range of gastroenteric and respiratory bugs (notably the 'flu) and antibiotic resistant superbugs.

The company expects to lodge applications for STIs and other genital pathogens and flavivirus and alphavirus in Australia and Europe, with a view to selling in 2020.

A submission to the US Food and Drug Administration for enteric protozoan testing is also imminent, also with a view to launching the tests there in 2020.

Found in the gut of human and other mammals, enteric protozoa are diarrhoea-inducing parasitic infections including giardia and cryptosporidium.

Like enteric bacteria and viruses, they can be found in water following direct or indirect contamination by faeces.

Sydneysiders may recall the water contamination crisis in 1998 when they were forced to boil their drinking water.

“Essentially they can be hard to detect with traditional methods and can cause chronic illness,” Dr Melki says.

Genetic Signatures is targeting a 10 to 15 percent share of the 5.5 million enteric protozoan tests done in the US annually.

In the US, the company is already allowed to sell analytical spectrum re-agents, in effect ingredients to be incorporated in tests that are self-developed by the labs.

In Europe, the company has assembled a small sales force for a concerted push into that market, targeting path labs with mid to high throughput.

Dr Melki says Europe is moving to a higher standard of testing, which raises the bar in terms of registration requirements.

Given Genetic Signatures products are grandfathered from the new requirements, this should work in the company's favor.

Finances and performance

Dr Melki says he is “absolutely delighted” by the \$35 million raised, with the prospect of another \$2 million to come.

Of this amount, \$10 million will be used to expand the company's sales force from 13 staff to 36, with \$6 million earmarked for clinical trials.

A further \$5 million will be spent on new customer installations.

Genetic Signatures recorded record third (September) quarter revenue of \$1.53 million, 54 percent better than a year previously.

The company also made a \$1.27 million loss.

In the year to June 2019, Genetic Signatures generated revenue of \$4.9 million, 75 percent higher and with a \$3.5 million deficit.

Genetic Signatures revenues derive from a mix of capital equipment and consumables, a.k.a the 'printer and cartridge' model.

Customers can use their own diagnostics or buy their own hardware and in some cases it's worthwhile for Genetic Signatures to fund this capital equipment.

Dr Boreham's (non-molecular) diagnosis:

Genetic Signatures revenue has grown steadily from a standing start in 2014. But as this business is almost entirely derived locally, the European push should boost turnover, meaningfully.

The company doesn't exactly have the field to itself, in that it competes with other molecular diagnostics outfits as well as the traditional lab assays.

Dr Melki says the nearest rival is the South Korean molecular diagnostics testing house Seegene, which is active in the Europe but not the US. Listed on the South Korean exchange, Seegene is valued at around \$700 million.

Genetic Signatures revenues are influenced by the severity or otherwise of the influenza season, which was a good one this year as it started early.

(Not good for the sufferers of course).

The beauty of a Northern Hemisphere business is that the 'flu seasons don't align with Australia's which smoothes out revenues over the year.

With a cabal of deep-pocketed backers and a strong record of customer retention, there's no reason why Genetic Signatures shouldn't prevail in the battle of the bugs on the global stage.

Let's not forget the Australian market accounts for a little more than one percent of the world's \$US7.6 billion molecular diagnostics market.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He would also be "absolutely delighted" to diagnose \$35 million if anyone is offering.

STANDARD & POORS, AVITA MEDICAL

Standard & Poor's Dow Jones Indices says it has promoted Avita to the S&P ASX200, effective from November 14, 2019, replacing Aveo Group.

Standard & Poor's said Aveo Group had been acquired by the Toronto, Canada-based Brookfield Asset Management.

Standard & Poor's previously told Biotech Daly that the inclusions reflect market capitalization, meaning that Avita was one of the 200 largest companies listed on the ASX (BD: Mar 10, 2019).

Avita was up 3.5 cents or 5.3 percent to 69 cents with 25.9 million shares traded.

SIENNA CANCER DIAGNOSTICS, VIVAZOME THERAPEUTICS

Sienna says the Melbourne-based Vivazome Therapeutics will assess its Exo-net exosome capture technology for the treatment of critical limb ischaemia.

Sienna said its Exo-net technology was able to capture exosomes, small particles released by cells that aided inter-cell communication.

The company said Vivazome was working on exosome-based therapies for debilitating and life-threatening diseases, including peripheral artery disease-related arterial obstruction, or critical limb ischaemia, and was developing a large-scale manufacturing process for exosome production and purification.

Sienna said this would be Exo-net's first potential therapeutic application.

Sienna was up 2.6 cents or 74.3 percent to 6.1 cents.

TOTAL BRAIN

Total Brain says it has raised \$14 million in a placement at 4.6 cents a share to investors, including Platinum Asset Management and Regal Funds Management.

Total Brain said the issue price was a premium to the closing price of 4.5 cents and a 13.9 percent discount to the 30-day volume weighted average price.

The company said the funds would go towards its mental health testing sales and marketing initiatives, product development and deployment and support other working capital requirements.

Total Brain said the capital raising was led by Bell Potter.

Total Brain was up 1.2 cents or 26.7 percent to 5.7 cents with 6.6 million shares traded.

BIOTRON

Biotron says it will raise \$5.1 million through Gleneagle Securities underwriting its 103,098,597 listed options, exercisable at five cents by December 12, 2019.

Biotron said the agreement with Sydney's Gleneagle had an underwriting fee of five percent and that deal could be terminated if there was a seven percent fall in the ASX200 or if the five-day volume weighted average price of shares was less than four cents.

Biotron was up 0.1 cents or 1.4 percent to 7.1 cents with 3.8 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says it has received \$1,629,821 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Prescient said the incentive was for the year to June 30, 2019.

Prescient was up 0.2 cents or 4.55 percent to 4.6 cents with 2.8 million shares traded.

INVICTUS BIOPHARMA, AZURE HEALTH TECHNOLOGY

The suspended Azure says it will acquire Invictus for up to 35 million of its shares and assume up to \$1.2 million in debt for its food additive and supplements assets.

Azure said it would also issue options exercisable at 47.9 cents each and assume up to \$1.2 million of Invictus' liability to creditors and lenders.

The company said it hoped to raise between \$7 and \$10 million through a capital raising at 20 cents a share, as well as lend Invictus up to \$550,000 through a convertible note issue and provide up to \$300,000 to fund ongoing and necessary expenditure.

Azure said Avita chairman and Sonic director Lou Panaccio, would be appointed its non-executive chairman.

Mr Panaccio was previously the chairman of the delisted Genera Biosystems and is currently a director of Rhythm Biosciences.

Azure said that Invictus executive chairman Dr Glenn Tong would be the company's managing-director and chief executive officer.

The company said that Dr Tong was previously the chief executive officer of Gordagen Pharmaceuticals, Molecular Plant Breeding and Aggenomics.

Azure said Richard Estalella would be Invictus Nutraceuticals Inc chief executive officer.

According to Commsec and ASX, Azure has only released financial and other mandatory announcements since May 2019, with its latest Appendix 4C quarterly report saying it had cash and cash equivalents of \$5,000 at September 30, 2019.

The company has listed as its directors Steve Jiayi Yu, Wei Jiang, and Weidong Chen.

Azure was in a suspension with Commsec saying its price was 0.0 cents.

CARDIEX

Cardiex says that from October 1, 2019, Beijing Auden Technologies will be its Atcor medical device division distributor in China.

Cardiex said that Auden would further commercialization efforts for Atcor's non-invasive central blood pressure monitoring technology in public and private hospitals as well as sports medicine institutions in China, Hong Kong and Macau.

The company said that Auden would further its cardiology distribution business with a commercial strategy around Atcor's Sphygmocor XCel system as its primary product.

Cardiex corporate development head Zi Han Lin said the distribution deal was "a material step forward" as the company focussed on China for its products and services.

Cardiex was unchanged at 2.9 cents.

BOD AUSTRALIA

Bod Australia says it will participate in Project Twenty21, a 20,000-patient collaborative study run by the London-based drugs advisory committee Drug Science.

Bod said the UK-based study would collate data "to convince policy makers that medicinal cannabis should be made more readily available and affordable" and would investigate the effects of marijuana on patients with chronic pain, epilepsy, multiple sclerosis, post-traumatic stress, Tourette's syndrome, anxiety disorders and substance abuse-related harm, with enrolment expected to be completed by December 31, 2021.

The company said it was one of five participating companies and aimed to treat 1,000 patients with its Medicabilis cannabidiol oil, and would be paid per prescription sold.

In June, Bod said it wanted to recruit 300 people to pay for a 12-month medical marijuana post-traumatic stress disorder "observational study" (BD: Jun 12, 2019).

Bod fell 1.5 cents or 4.55 percent to 31.5 cents.

GI DYNAMICS

Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 1,227,178,430 shares (71.37%) to 1,305,918,587 shares (72.62%).

The Guernsey-based Crystal Amber said it received 78,740,157 shares for \$1,457,139 or 1.85 cents a share through the conversion of warrants on October 20, 2019.

In August, GI Dynamics said it had \$US10 million (\$A14,773,150) in convertible notes and warrants with Crystal Amber to fund trial enrolments and European approval and in October exercised \$US2 million (\$A2,962,200) in Chess depositary interests (CDIs) to Crystal Amber (BD: Aug 22, Oct 4, 2019).

GI Dynamics was untraded at 3.5 cents.

SUDA PHARMACEUTICALS

Suda says it will cease its US-based business development role, headed by Andrew Curtis, effective in 30 days.

Suda said the role's function would be assumed by its incoming chief executive officer with international business development serviced from Australia.

The company said "other cost savings" included its chief financial officer Joseph Ohayon moving from full-time to part-time, three days a week.

Suda fell 0.05 cents or 16.7 percent to 0.25 cents with 5.15 million shares traded.

ESENSE LAB

Esense says it has appointed Michael Edwards as a non-executive director replacing Galit Assaf, effective immediately.

Esense said Mr Edwards had more than 20 years of management experience and had worked in Barclays Australia's corporate finance department for three years, as well as working for eight years as an exploration and mine geologist with Gold Mines of Australia, Eagle Mining and International Mineral Resources.

The company said Mr Edwards had been both a geologist and corporate advisor in Australia and Africa since 2010, and had been involved in several reverse take overs in a range of commodities and industries.

Esense said Mr Edwards held a Bachelor of Business from the Perth-based Curtin University and a Bachelor of Science from the University of Western Australia, as well as a Graduate Diploma in oenology from the University of Adelaide.

Esense fell 0.1 cents or 8.3 percent to 1.1 cents with 1.6 million shares traded.