



Biotech Daily

Friday November 12, 2021

Daily news on ASX-listed biotechnology companies

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- * **COVID-19 FORCES TOTAL BRAIN M-D LOUIS GAGNON TO RESIGN**

MARKET REPORT

The Australian stock market was up 0.83 percent on Friday November 12, 2021, with the ASX200 up 61.1 points to 7,443.0 points. Twenty of the Biotech Daily Top 40 stocks were up, 11 fell and nine traded unchanged.

Patrys was the best, up 0.5 cents or 13.5 percent to 4.2 cents, with 27.1 million shares traded. Immutep recovered 8.9 percent; Universal Biosensors was up 6.2 percent; Impedimed and Resonance improved five percent or more; Genetic Signatures, Imugene and Mesoblast were up three percent or more; Actinogen, Neuren and Prescient rose two percent or more; LBT, Polynovo, Starpharma and Telix were up one percent or more; with Clinuvel, CSL, Medical Developments, Nanosonics, Opthea and Pro Medicus up by less than one percent.

Uscom led the falls, down one cent or 7.4 percent to 12.5 cents, with 27,890 shares traded. Proteomics lost 5.3 percent; Optiscan and Pharmaxis fell more than four percent; Alterity and Paradigm were down more than three percent; Volpara shed 2.2 percent; Avita, Compumedics, Cyclopharm, Kazia and Resmed were down more than one percent; with Cochlear down by 0.2 percent.

[DR BOREHAM'S CRUCIBLE: ARTRYA](#)

By TIM BOREHAM

ASX code: AYA

Share price*: \$1.35; **Market cap*:** \$105.4 million; **Shares on issue*:** 78,112,590

Chief executive officer: John Barrington

Board:** Bernard (Bernie) Ridgeway (chairman), Mr Barrington, John Konstantopoulos (co-founder and director of product)

Financials (year to June 30, 2021): revenue nil, other income \$210,000 (down 48%), loss of \$4.08 million (previously a \$1.35 million deficit), cash of \$12.98 million***

Identifiable major holders: John Barrington/BHT Family Trust 9.40%, Erika Konstantopoulos/IEMK Family Trust 8.96%, Keeble Nominees (Ridgeway self-managed super fund) 2.56%

* Proforma values ahead of ASX listing scheduled for November 26

** An executive search for a fourth director is in progress

*** Ahead of \$40 million IPO

Heart disease remains the world's number one killer, yet the scourge remains under-appreciated relative to other major ailments such as cancer, Alzheimer's disease (increasingly) and - of course - Covid-19.

With the per-capita incidence of the disease stubbornly high, one could say that advocates of a healthy ticker aren't exactly winning the hearts and minds of Western world citizens.

According to the about-to-be listed Artrya, heart disease kills about 18 million people a year, the equivalent of the adult Australian population. As a subset, coronary arterial disease (CAD) afflicts 120 million people and kills nine million of them.

An algorithm-based artificial intelligence play, Artrya is zeroing-in on detecting vulnerable plaque, which is the build-up of lipids (fats) in the lumen (arterial tube).

Plaque goes on to form harder calcified deposits, which can lead to arterial blockages. But the underrated aspect of plaque is that it's soft and more prone to rupture. The plaque is also difficult and time-consuming to see with the naked eye in traditional images.

While most of us have been more worried about (the) plague than the plaque, the Perth-based Artrya is developing a tool that detects the plaque deposits on x-ray computed tomography (CT) images.

"Early detection is very important and there is a major opportunity to address this major health issue," says Artrya co-founder and chief executive John Barrington.

The heart of the matter

On October 29, Artrya closed its over-subscribed \$40 million initial public offer (IPO), ahead of its scheduled listing on the ASX on November 26.

The company was founded by Mr Barrington and fellow Perth native John Konstantopoulos.

The former has a background in IT, management consulting and fostering start-up entities, while Mr Konstantopoulos has a long tech background including applying IBM's smarts to healthcare uses.

Founded in 2018, Artrya is based on collaborations with the University of Western Australia, the Perth-based Harry Perkins Institute of Medical Research (of which Mr Barrington is a director) and the University of Ottawa Heart Institute.

"We spent 18 months researching where that advantage might best be applied, focusing on medical imaging and then heart diseases," Mr Barrington said.

A pilot product was delivered in December 2019, six months ahead of schedule.

Mr Barrington says the duo was fortunate to meet one of the world's leading researchers of vulnerable plaque, Prof Girish Dwivedi of the Harry Perkins Institute

"It was a partnership made in the cloud," Barrington says – an allusion to the wireless nature of the subscription-based tool.

Here's the problem ...

Plaque is soft so it is vulnerable to rupture. Calcification is the progression of plaque over time which hardens and causes stenosis (arterial narrowing).

The scary thing about fatal heart attacks is that 50 percent of males and 64 percent of women have no warning at all that they are about to keel over.

About two-thirds of victims have no stenosis, which is routinely detected and reported. So contrary to accepted wisdom, it's not a major predictor of death.

But UK-based research suggests a plaque burden of more than just four percent increases the chances of death five-fold.

If plaque build-up is detected earlier, doctors can advise patients on lifestyle changes that usually involve cutting out the cigs and the whopper burgers. Drugs and stenting are also treatment options.

Artrya derives a patient risk score that includes measuring calcification, stenosis and vulnerable plaques.

... and here's the answer

The company is spearheading its efforts with Salix Coronary Anatomy (SCA), which is a software adjunct to coronary computed tomography angiography (CCTA) scans.

The software is working and installed but not yet commercialized, having been included on Australian Register of Therapeutic Goods in November last year as a class 1 medical device.

The idea of the tool is to enable a personalized, three-dimensional heart model and diagnostic report to be presented to the patient immediately.

The report covers not just plaque, but calcification and 'positive remodelling'. The latter isn't a reference to a renovation reality show but rather the clever ability of lumens to grow in diameter to accommodate the plaque build-up.

Under the current process, the images produced by the CT scan are sent to a radiographer for annotation (there are up to 500 separate images).

A radiologist then reviews the images and a typist prepares the report, which then goes back to the radiologist for approval.

"We are able to eliminate these intermediate steps," Mr Barrington says. "The report and 3-D model is presented to a radiologist within 15 minutes of scan completion."

With SCA, scans (400 to 500 x-ray images) are uploaded to the internet 'cloud' and artificial intelligence generates a report within 15 minutes.

"A 3-D image of the patient is presented so the clinician can sit with the patient and show them where the plaque is located and the severity of it," he says.

Mr Barrington says patients are more motivated to address the problem if they see the visual evidence in front of them.

Let's get down to business

This week, Artrya said it had been accepted "as a supplier of artificial intelligence software and platforms" for the UK National Health Service Shared Business Services Framework.

Sales from the deal - which covers 1,250 hospitals - are expected in mid-2022.

Stepping back a bit, Artrya's roll-out strategy is based on a Perth-based pilot and validation program.

Mr Barrington said the company had interstate pilot programs, with 20 programs "in various stages of discussions".

The studies have been bolstered by Perth's Envision Medical Imaging, which provided access to more than 20,000 CT scans.

Australian sales are expected from early 2022.

Of course, other Western markets are bigger and the company has also lodged approval submissions to the US Food and Drug Administration and European and UK device gatekeepers.

The patient benefits aside, the company's pitch to clinics is that it's making the practices more efficient by simplifying the reporting process and smoothing out work flows.

Mr Barrington says SCA is more about eliminating tasks than jobs. With a forecast shortage of 18,000 radiologists in the US alone, the tool will free-up time for them to liaise with their patients.

The tool is intended to reduce the usage of follow-up invasive coronary angiograms, which are uncomfortable, expensive, time-consuming and often unnecessary.

The company hopes to boost its commercial appeal with Salix Coronary Flow, which is a non-invasive assessment of coronary blood flow. This measurement can be included in the overall risk assessment presented to the patient.

"Now that Artrya has developed the core capabilities in plaque detection, it can expand into other diseases but right now we are focused on CAD," Mr Barrington says.

Finances and performance

Artrya is no shrinking violet when it comes to attracting funds, having raised money on three previous occasions. A so-called 'angel' round in May 2019 brought in \$1 million.

"The aim was to introduce a blue-chip shareholder base, not just the old 'family, friends and fools'," Mr Barrington says.

In May 2020, the company raised a further \$2.8 million, having sought only \$2 million.

Bell Potter then led a private placement in May this year. While only \$10 million was sought, the round attracted \$30 million of applications and the company took \$15 million.

In 2020, the company pocketed a \$1 million grant from the Federal Government's Biomed Tech Horizons Program

Pre-IPO, the company had \$12.8 million in the bank. The raising - at \$1.35 per share - boosts the cash kitty to \$62.8 million.

Of the \$40 million of IPO proceeds, \$13.3 million will be earmarked for clinical research and development and regulatory activities over the next two years. A further \$9.5 million will be devoted to product development.

The company expects first revenue by next year.

Post-IPO, Mr Barrington will account for just shy of 10 percent of the register, with Mr Konstantopoulos speaking for another nine percent. As per standard protocol, these holdings are escrowed for two years.

Pre-IPO investors include the ubiquitous Thorney Investments, SG Hiscock, Watermark Funds Management and Washington H Soul Pattinson.

Dr Boreham's diagnosis:

Artrya's potential is reflected in the fact that 11 million CT angiography scans are done in US and Europe each year, with 19.5 million forecast to take place by 2025.

Given artificial intelligence is a broad and emerging discipline, Mr Barrington says focus is important: "It's as much about what you're not going to do as what you are going to do."

In the short term, Artrya is about the boring-but-important stuff such as regulatory approvals and - more importantly - insurance reimbursement.

Mr Barrington is coy about the likely cost of the subscription-based product, but cites streaming giant Netflix as an exemplar.

Why? The subscription-based Netflix culled its rivals by coming in at an "effective price point".

Speaking of competition - and Netflix - Artrya won't have to engage in a Squid Games style fight to the death with rivals.

While Mr Barrington knows of two entities going down a similar path in China, he believes the company has first mover advantage in the Western world. Of course, other rivals will emerge.

According to the mandatory risk factors outlined in the prospectus "there is uncertainty in relation to the quantum and timing of Artrya's revenue, given the status of its research and early rollout of its Salix product".

True, but your columnist believes there's no reason Artrya can't emulate the success of the ASX-listed, \$300 million market cap Volpara Health Technologies which has commercialized an algorithm to detect breast cancers in difficult situations.

In that case, Artrya's \$100 million market valuation looks to be justified.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He deserves to have a plaque erected in his honor for brushing his teeth daily to protect against plaque, but suspects that's not quite the heart of the matter.

PLANET INNOVATION

Melbourne's Planet Innovation says it has acquired BIT Analytical Instruments GmbH, adding \$25 million to revenue, but did not disclose the price.

Planet Innovation said that the Irvine, California-based BIT had a 29,000 square feet (2,694 square metres) plant which would more than double its manufacturing capacity. The company said that its revenue for the year to June 30, 2021 was up by 69 percent on the previous year and the acquisition of BIT from the Bad Soden, Germany-based Messer Group would add a further \$25 million to its annual revenue.

Planet Innovation said it had the capacity for product design, engineering and manufacturing services to develop and commercialize products for the diagnostics, life sciences and healthcare industries and BIT Group focussed on the research, design, development and manufacture of haematology systems.

The company said the acquisition would increase its US manufacturing capabilities and support its US customer base.

Planet Innovation said the acquisition would provide BIT Group's US client base with all 80 staff joining the company, taking its worldwide team to 500 employees.

Planet Innovation chief executive officer Sam Lanyon said the company would have "two state-of-the-art facilities close to our development teams and clients, with plans for further expansion in the near future".

"Unlike typical contract manufacturers, [Planet Innovation] believes that manufacturers have invaluable insight into how products perform, which enables them to drive innovation and help them conceive new product opportunities," Mr Lanyon said.

The company said medical technology contract design and manufacturing was expected to double by 2025 to \$US100.9 billion with the US comprising 55 percent of the industry. Planet Innovation is a public unlisted company.

RESONANCE HEALTH

Resonance says it has allowed free access of its Ferrismart liver iron concentration test to the Thalassaemia International Federation for patients from December 2021.

Resonance said the Federation was an umbrella organization for 240 member associations, in 62 countries.

The company said its agreement with the Federation would deploy 500 Ferrismart vouchers provided by Resonance at no cost across targeted low-and-middle income countries in Asia, West Pacific, and Europe.

Resonance said it would provide EUR10,000 (\$A15,704) in instalments over 12 months to support a Federation executive to manage distribution, management and administration of the Ferrismart magnetic resonance imaging liver iron concentration test access initiative.

Resonance said it would engage with National Thalassaemia Associations and physicians to facilitate use of Ferrismart.

The company said the agreement had an initial term of 12 months and any unused vouchers would expire, unless extended by the company.

Resonance said that with the Thalassaemia International Federation it would assess the success of Ferrismart's establishment and uptake in the new markets.

Resonance managing-director Mitchell Wells the company was "delighted to partner with [the Federation] on the deployment of Ferrismart into new markets where our device is needed".

"Our immediate objective is to ensure that patients and clinicians across the world learn of Ferrismart and have an opportunity to use it and benefit from it," Mr Wells said.

Resonance was up half a cent or five percent to 10.5 cents.

AUSCANN GROUP

Auscann says it has begun designing a clinical trial to evaluate its marijuana-derived cannabinoid formulations for treating spinal cord injury symptoms.

In September, Auscann said it appointed Melbourne's Cannvalate Pty Ltd to review its animal data and research to develop drugs for human traumatic injury and neurological disorders (BD: Sep 21, 2021).

Today, the company said that following the Cannvalate review it had withdrawn from and investigator-led trial and would "redirect its resources to a research and development program which is better designed to support product registrations in targeted medical conditions".

Auscann said it would conduct a program to generate clinical data on the benefits of cannabinoid-based formulations for people suffering from symptoms associated with spinal cord injury, which could be used to support a US Food and Drug Administration approved development program.

The company said the global market for treatments associated with spinal cord injury was estimated at more than \$US6 billion.

Auscann said its medical advisors had seen "encouraging benefits" in patients with spinal cord injury after the use of its Neuvis tetrahydrocannabinol and cannabidiol capsules.

The company said that it expected to apply for ethics approval for a trial "in early 2022".

Auscann was up half a cent or 5.3 percent to 10 cents.

OPTISCAN IMAGING

Optiscan says it completed recruitment for its breast cancer margin assessment trial, imaging 42 breast cancer lumpectomy samples and 38-patient cavity shaves.

Optiscan said the samples were taken from Royal Melbourne Hospital, Frances Perry House at the Royal Women's Hospital and the Epworth Hospital.

In 2018, the company said it would conduct a trial of its confocal microscope to assess the surgical margin in patients having breast cancer conservation surgery (BD: Oct 15, 2018).

Today, Optiscan said the analysis of the images was "underway including comparisons with post-operative histopathology examination"

The company said the trial's aim was to assess whether its technology would detect cancerous tumor cells at the margin of the excised sample while during surgery, allowing the removal of further cancerous tissue, reducing the requirement for repeat surgery.

Optiscan fell one cent or 4.55 percent to 21 cents.

INVION

Invion has requested a trading halt "pending an announcement ... in relation to a capital raising".

Trading will resume on November 16, 2021, or on an earlier announcement.

Invion last traded at 2.7 cents

BARD1 LIFESCIENCES

Bard1 says the US Patent and Trademark Office has granted its patent relating to its auto-antibody test for the diagnosis of lung cancer.

Bard1 said the patent, titled 'Lung Cancer Diagnosis' would protect its intellectual property until February 5, 2035.

Bard1 was up 41 cents or 41.41 percent to \$1.40 with 3.1 million shares traded.

ANTEOTECH

Anteo says its annual general meeting voted 43.8 percent the prior issue of placement fee options and the special resolution to adoption the constitution was rejected.

Anteo said the resolution for the ratification of 9,230,769 fee options to PAC Partners Securities was carried but with 482,414,407 votes (43.84%) against and 618,102,396 votes in favor (56.16%).

The company said that 295,465,624 votes (26.73%) opposed the adoption of the constitution, which was a special resolution requiring a 75 percent majority.

Anteo said there was 24.71 percent opposition to elect Jack Hamilton as a director, 19.75 percent opposed the remuneration report, 18.88 percent opposed the employee equity incentive plan, 14.04 percent were against the ratification of the prior issue of placement shares, 13.85 percent opposed the ratification of share plan shares and 9.27 percent were against the increase in aggregate remuneration payable to non-executive directors.

Anteo said the resolutions to re-elect Glenda McLoughlin and Katherine Woodthorpe as directors passed easily.

According to its most recent filing, Anteo had 1,971,916,706 shares on issue, meaning the votes against the prior issue of fee options amounted to 24.46 percent of the company, sufficient to requisition extraordinary general meetings.

Anteo was unchanged at 20.5 cents with three million shares traded.

CRONOS AUSTRALIA

Cronos says its CDA merger annual general meeting will vote to issue 5,000,000 performance rights to five directors and 18 million options to four directors.

Cronos said it would issue one million performance rights each to chair Shane Francis Turner, chief executive officer Rodney Cocks, company secretary Thomas Howitt, and CDA's Guy Headley, Dr Benjamin Ngahuaia Jansen and Jessimine Kiritea Jansen.

The company said the rights would vest in three equal tranches, the first tranche would vest on the date of completion of the CDA merger, the second six months from completion and the third at 12 months from completion, expected on December 16, 2021.

In September, Cronos said it would acquire the Gold Coast, Queensland marijuana company CDA Health Pty Ltd for up to \$61 million in cash and scrip (BD: Sep 14, 2021).

Today, Cronos said it would issue 4,500,000 options each to Mr Cocks, Mr Howitt, Mr Headley, Dr Jansen and Ms Jansen, expiring four years from the date of completion.

Cronos said the options would vest, pending revenue performance, in three equal tranches with the first on June 30, 2022, exercisable at a 33.3 percent premium to the price at the date of completion, the second on June 30, 2023, at a 66.7 percent premium to the price at completion and the final tranche on June 30, 2024, at a 100 percent premium to the price at completion.

Cronos said the gross revenue of Cronos Australia for each financial year must exceed the combined revenues for the previous by 25 percent for each tranche to vest.

Cronos said shareholders would vote on the remuneration report, the election of Shane Turner, Mr Headley, Dr Jansen, Dr Marcia Walker and Kurt Schmidt as directors, the approval of the acquisition of CDA, the approval of the issue of shares to the CDA shareholders under the merger agreement, the approval of the issue of shares under the loan conversion deed, the approval of the issue of securities under the equity incentive plan, amendments to constitution, the approval of potential termination benefits, the approval of the additional 10 percent placement capacity.

The virtual meeting will be held on December 15, 2021, at 3.30pm (AEDT).

Cronos was up half a cent or 2.6 percent to 19.5 cents.

PATRYS

Sydney's Macquarie Group says it has become a substantial shareholder in Patrys with 98,104,192 shares or 5.15 percent.

Macquarie Group said it bought, sold and transferred shares in several hundred trades between July 9 and November 8, 2021, at prices ranging from 3.5 cents and five cents a share.

Patrys was up half a cent or 13.5 percent to 4.2 cents with 27.1 million shares traded.

TOTAL BRAIN

Total Brain says managing-director Louis Gagnon has resigned citing health reasons effective today, but would continue as an advisor for 12 months.

"After contracting Covid earlier in the year, I have been dealing with the fallout of long-haul Covid symptoms," Mr Gagnon said.

"As we, at Total Brain, know well, sustained levels of acute stress led to health deterioration," Mr Gagnon said.

"Unfortunately, I am no exception, as the high stress levels of navigating a business through the challenges of a pandemic have exacerbated my health issues," Mr Gagnon said.

"It appears wise to give my body and mind a respite, at this point in time," Mr Gagnon said.

Total Brain fell one cent or 7.4 percent to 12.5 cents with 1.4 million shares traded.