



Biotech Daily

Friday October 14, 2022

Daily news on ASX-listed biotechnology companies

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- * **DR MICHELLE BOYLE, DR SAM FORSTER WIN \$1.25m CSL FELLOWSHIPS**
- * **CANADA APPROVES TELIX ILLUCCIX FOR PROSTATE CANCER IMAGING**
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- * **INVION 22m CEO THIAN CHEW OPTIONS AGM**
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- * **RECCE: 1.1m DIRECTOR ALISTAIR MCKEOUGH OPTIONS AGM**
- * **ARTRYA 440k M-D JOHN BARRINGTON RIGHTS AGM**
- * **GENETIC SIGNATURES 250k M-D DR JOHN MELKI OPTIONS AGM**
- * **HEXIMA 224k DIRECTOR OPTIONS, RE-ELECTION AGM**
- * **BIOTRON 2nd STRIKE BOARD SPILL AGM**

MARKET REPORT

The Australian stock market was up 1.75 percent on Friday October 14, 2022, with the ASX200 up 116.2 points to 6,758.8 points. Twenty of the Biotech Daily Top 40 companies were up, 11 fell, six traded unchanged and three were untraded. All three Big Caps rose.

Next Science was the best, up 7.5 cents or 10.7 percent to 77.5 cents, with 11,810 shares traded. Medical Developments climbed 7.7 percent; Actinogen, Cochlear and Nanosonics improved five percent or more; Clinuvel and Opthea were up more than four percent; Alcidion, Atomo, Micro-X, Paradigm, Prescient and Pro Medicus were up three percent or more; Pharmaxis and Starpharma rose more than two percent; CSL, Impedimed, Nova Eye, Resmed and Telix were up more than one percent; with Emvision, Polynovo and Proteomics up by less than one percent.

Universal Biosensors led the falls, down 3.5 cents or 12.1 percent to 25.5 cents, with 27,034 shares traded. Dimerix lost 6.25 percent; Cynata fell 4.2 percent; Orthocell was down 3.7 percent; Antisense shed 2.2 percent; Cyclopharm, Resonance and Volpara were down more than one percent; with Avita, Genetic Signatures and Neuren down by less than one percent.

DR BOREHAM'S CRUCIBLE: IMRICOR MEDICAL SYSTEMS

By TIM BOREHAM

ASX code: IMR

Share price: 29.5 cents;

Market cap: \$44.6 million

Shares on issue: 151,347,625 Chess depository interests, or CDIs

Founder, chair and chief executive officer: Steve Wedan

Board: Mr Wedan (chair), Mark Tibbles (deputy chair), Anita Messal, Peter McGregor

Financials (June half 2022): customer revenue \$US538,000 (\$A857,400) (up 47%), net loss \$9.77 million (previously a \$9.96 million deficit), cash balance \$US9.1 million (down 41%). The company subsequently raised \$2.92 million in a placement in mid-September

Identifiable major shareholders: Blackrock Investment 7.8%, Warren G Herreid 7.1%, Saville Capital 6.3%, Siemens Medical Solutions 5.5%, Regal Funds 4.7% Mark Tibbles 3.2%, Steve Wedan 3.03%.

The brightest innovations in medical science usually stem from a mix of serendipity, perspicacity and being in the right place at the right time.

In the case of American electrical engineer and Imricor founder Steve Wedan, a series of casual conversations convinced him of the need for heart procedure catheters that could be guided by magnetic resonance imaging (MRI), rather than traditional x-ray fluoroscopy.

Mr Wedan was working for GE Medical designing MRI scanners and ultrasounds and knew of unsuccessful attempts by major companies to design MRI-compatible catheters. He started a consultancy which led him to Maryland's Johns Hopkins Hospital, where doctors asked him for help with difficult projects, including MRI-friendly probes.

"I did some due diligence to find out whether this was a tech in search of a medical application, or a real medical need that needed a technological solution," he says. "I was convinced it was the latter."

At the heart of the problem is the poor success rates with cardiac ablation. The heart is invisible to x-rays, without potentially toxic dyes, and by the 1990s doctors could see the limitations of x-ray guided ablations, notably the cumulative radiation exposure.

The MRI-guided procedure is called interventional cardiac magnetic resonance (ICMR) imaging.

"We are not creating a new therapy, we are simply making the devices that are MRI compatible," Mr Wedan says.

In a flutter

Cardiac ablation addresses the common problem of heart arrhythmia, or irregular heartbeat. This can be manifested in atrial fibrillation or atrial flutter, or Wolff-Parkinson-White syndrome and other tachycardias (rapid heartbeat).

Atrial fibrillation and atrial flutter account for 39 percent and 23 percent of all ablation procedures, respectively.

Cardiac ablation uses heat or cold energy to create tiny scars in the heart to block irregular electric signals and restore normal heartbeat.

A catheter is popped up a vein and delivers the electric impulses to destroy the abnormal tissue.

The process is carried out by electro-physiologists (specially trained cardiologists).

“There’s a really big need in interventional cardiology, electrophysiology and ablation for better visualization to specialize treatment for each patient,” Mr Wedan says.

“This will give the doctors a procedural endpoint so they can verify the therapy [and ensure] the patient will go home with a first-time success rate.”

Getting started

Mr Wedan founded Imricor in 2006, with an initial focus on ablation of ventricular tachycardia (or VT, more on that below).

The company is based in Burnsville, Minnesota, where it has its manufacturing and carries out research and development.

Imricor listed on the ASX on August 30, 2019, having raised \$13 million at 83 cents apiece.

In 2011, the first human ICMR procedure was carried out at Germany’s Leipzig Heart Centre.

In 2012, Imricor licenced its technology to Dutch tech giant Koninklijke Philips, and in 2018, the company inked its first contract with the Dresden Heart Centre.

Mr Wedan is Imricor’s founder, chair, president and CEO, which means the buck stops very much with him.

Imricor, by the way, is listed on the ASX because the company latched on to a US roadshow pitching the bourse as an alternative to venture capital.

“The ASX was a perfect niche for a stage of the company we were at,” Mr Wedan says.

Ablation proliferation

Imricor's mainstay product is its Vision-MR Ablation Catheter, which is designed to look, feel and function like a traditional ablation catheter.

The European Union approved the device for atrial flutter in 2020, while also green-lighting the Vision-MR Dispersive Electrode. This gizmo minimizes eddy currents induced on the device's conductive pads during MRI scanning.

Then there's Imricor's Advantage-MR EP (electro-physiology) recorder/stimulation system, which is the hardware that enables the catheters to be deployed. This device was approved earlier in Europe, in 2016.

Imricor's devices are used at 15 European sites, including Germany's Helios Hospital Berlin-Buch, Berlin's German Heart Centre, the Henry Dunant Hospital Centre in Greece and Rome's Policlinico Casilino. There's also a pipeline of further German, Dutch and Swiss centres.

In the US, the company has filed an application to the Food and Drug Administration for a trial, also for type one atrial flutter.

VT = Very Tricky

Imricor is targeting an expanded indication for ventricular tachycardia (VT) in Europe and has applied to carry out a 64-patient trial to support a marketing application.

The company hopes to kick off the trial by the end of 2022, with assent targeted in 2023 and a launch in early 2024.

One problem with our physiology is that the left side of the heart is hard to access, so God gets D-minus for architecture on that front. Imricor is working on a steerable sheath and trans-septal needle to access the left side of the heart.

"VT is a growing indication," Mr Wedan says. "Doctors report a wave of VT patients starting to come because patients with planted defibrillators are alive when a couple of decades ago they would [have died earlier]."

"It's a very difficult procedure and one for which MRI will offer substantial and immediate benefits."

Finances and performance

Imricor clocked up a record \$US136,000 (\$A217,000) of consumables revenue in the three months to June 30, 2022, almost double year-on-year and 46 percent up on the March 2022 quarter.

Over the June half-year, the company recorded \$US229,000 of consumables revenue and \$US250,000 of equipment revenue.

The total June quarter revenue of \$US250,000 reflects limited European sales after the product was relaunched post-pandemic.

“We have seen the last major effects of the pandemic drop away,” Mr Wedan says. “We expect very robust sales in the third [September] quarter and more in the fourth quarter.”

In September 2021, the company raised \$16.5 million in a placement, followed by a \$1 million share purchase plan. In September this year, the company followed up with a \$2.92 million placement to existing investors, at 38 cents apiece.

Meanwhile, management is on the job with the scalpel, excising \$US10 million of costs from the current-year budget. Costed at \$US1.5 million, the vaunted European VT trial is Imricor’s main expense.

Even if the US application is approved, any trial there is likely to be delayed until European revenues flow in earnest.

Imricor shares peaked at \$2.78 on October 30, 2020, but it’s been a downhill trajectory since then, bottoming at 14 cents on June 24 this year.

The company dead-batted an ASX query as to why its share price zoomed from 29 cents on August 10, to 49 cents on August 12.

Sizing up the revenue potential

In Europe, there are currently about 1,000 ICMR laboratories carrying out an average of 70 atrial flutter procedures a year, each. The company estimates that snaring only five percent of this market would generate revenue of \$US12 million, at an average \$US3,500 per procedure.

Adding the indications of VT and atrial fibrillation would greatly expand the market size.

The expected US market is about 1,100 sites, but probably double European revenue because of superior reimbursement.

Imricor’s revenue would derive from the ‘razor/razor blade’ model, by which clinics buy the recorder/stimulator device, with single-use catheters and electrodes purchased for each new patient.

Mr Wedan describes the cost as similar to that of a standard ablation catheter.

“The value proposition is that if we can get the procedure right in one go instead of two or three, the overall price per patient goes down.”

Mr Wedan says medical device adoption is always gradual, but when clinicians are convinced they usually don’t waver.

“Just as it’s hard to change to [a new device], it’s hard to change from.”

Getting cosy

Imricor has more alliances than a NATO war room, including a global development agreement with global MRI hardware vendors Siemens and a distribution agreement with Philips.

The company has development or distribution agreements with Nordic Neurolab AS, which makes MRI-compatible in-room monitors, as well as a strategic investment in Mirtle Medical LLC, which makes MRI-compatible 12-lead electro-cardiogram (ECG) systems.

In 2021, the company entered a compact with the Sydney based Regional Health Care Group to facilitate local Therapeutic Goods Administration. And – hey bro - the catheter is already approved in New Zealand.

Of course, the Aussie market is small, but Mr Wedan says “it’s good to be a relevant local story for investors.”

Some readers might be wondering why the big heart device companies have not cracked the MRI-compatible nut.

“There wasn’t a great understanding of the electro-magnetic fields in MRI with the engineers who make pacemakers,” Mr Wedan says.

Dr Boreham’s diagnosis:

Imricor is playing in a global catheter ablation market worth \$US5.5 billion and growing at a compound rate of just over eight percent a year.

“Only Imricor makes MRI-compatible devices so we capture 100 percent of the market,” Mr Wedan says.

The growth drivers include a higher incidence of heart disease, a shift to minimally invasive treatments and the cost effectiveness of the procedure.

On a more negative company-specific note, Imricor is reliant on third-party equipment while obsolescence is an ever-present threat. It also has a heavy cash-burn. Nonetheless, Mr Wedan says Imricor’s “heavy lifting” is paying off.

“We are really changing the world of interventional cardiology and fulfilling a dream we have had for 16 years,” he says.

“For many of us [at the company] it will be the most significant thing we do in our career. We have the chance to do what no-one has been able to do and add real tangible value to healthcare and patients around the world.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But at least he knows the difference between ablations and ablutions, so scrubs up well in that regard

CSL

CSL says Dr Michelle Boyle and Dr Samuel Forster have won the CSL Centenary Fellowship worth \$1.25 million each over five years.

CSL said that both scientists were “investigating fundamental mysteries for the human immune system and applying their discoveries to the fight against microbes that cause chronic disease and suffering around the world”.

The company said that Dr Boyle and her team at the Queensland Institute of Medical research (Berghofer) discovered how the immune response to malaria could be disrupted by the malaria parasite, reducing the effectiveness of vaccination in children.

CSL said that malaria infected more than 240 million people each year, with children particularly susceptible.

The company said the fellowship would assist Dr Boyle’s work at Melbourne’s Burnet Institute to bypass the parasite’s suppression of T-cells, investigate the function of T-cells in infection and vaccination, and develop ways to boost protection against malaria.

CSL said that Dr Forster’s team at Melbourne’s team at the Hudson Institute of Medical Research would use the fellowship “to investigate the causes of inflammatory bowel disease (IBD) and to attempt to design treatments”.

The company said that inflammatory bowel disease was “a chronic, painful, and disruptive inflammation of the lining of the gut” affecting about 130,000 Australians.

“Its cause is a mystery, and it is incurable,” CSL said. “Treatment can involve expensive immune suppression and surgery to remove parts of the gut.”

The company said the research team would apply genomics, computational biology, stem cells, and micro-biomics, to answer questions about the immunology of the gut.

CSL said Dr Forster had identified bacteria that appeared to block the programmed death of cells lining the gut and he hoped to design safe and effective IBD treatments.

CSL chief scientific officer Dr Andrew Nash said that both scientists were conducting research into serious chronic diseases to improve treatments and find new therapies.

“Great science leads to great medicines and vaccines,” Dr Nash said. “It is this long-term purpose that the CSL Centenary Fellowships aim to support, by providing funding stability for leading mid-career Australian researchers and enabling the delivery of innovations that address rare and serious diseases and protect public health.”

CSL was up \$4.00 or 1.45 percent to \$280.43 with 571,451 shares traded.

TELEX PHARMACEUTICALS

Telex says Health Canada has approved its Illuccix prostate cancer imaging kit for staging and re-staging intermediate and high-risk prostate cancer.

Last year, Telex said the US Food and Drug Administration approved Illuccix, which was “the first commercially available FDA-approved product to enable wide accessibility to 68Ga-based PSMA-PET imaging for physicians and eligible patients in the US” and the Australian Therapeutic Goods Administration had approved Illuccix for diagnostic imaging of men with prostate cancer (BD: Nov 2, Dec 20, 2021).

Today, Telex said Illuccix was the first prostate-specific membrane antigen positron emission tomography imaging agent to be granted regulatory approval in Canada.

Telex Americas chief executive officer Kevin Richardson said that prostate-specific membrane antigen positron emission tomography imaging was “one of the most important developments in prostate cancer detection in recent years and we are very pleased that we can now bring this important diagnostic imaging agent to physicians and their patients across Canada.”

Telex was up six cents or 1.1 percent to \$5.41 with 1.1 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it has received a further \$909,040 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

In April, Antisense said it had received \$570,999 for Australia research and development expenditure for the year to June 30, 2021 (BD: Apr 14, 2022).

Today, the company said the \$909,040 related to overseas research and development, bringing the total incentive received for the year to June 30, 2021 to \$1,480,039.

Antisense fell 0.2 cents or 2.2 percent to nine cents.

INOVIQ

Inoviq says it has received \$865,625 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Inoviq said the tax incentive related to research and development expenditure for the year to June 30, 2021.

Inoviq was up one cent or 1.7 percent to 61 cents.

EBR SYSTEMS

EBR has requested a suspension from trading "pending an announcement ... in relation to a potential manufacturing change to its product".

The company said it did not expect the pending announcement "to affect the results or completion date of its Solve study" which was on-track for July, 2023.

EBR last traded at 55.5 cents.

ANTEOTECH

Anteo says its annual general meeting will vote to issue 56,211,200 options to chief executive officer David Radford and directors.

Anteo said that shareholders would vote to issue chief executive officer David Radford 30,000,000 options under "his chief executive officer service agreement" exercisable at the higher of 11.25 cents or 143 percent of the five-day volume-weighted average price to his appointment, within three years, subject to share price hurdles.

The company said it would vote to issue Mr Radford an additional 2,211,200 options as part of its "senior staff incentives", exercisable at 0.01 cents an option, vesting on performance hurdles and expiring on July 31, 2025.

Anteo said it proposed to issue 7,000,000 options to chair Ewen Crouch, 5,000,000 options each to Glenda McLoughlin and Dr Katherine Woodthorpe and 3,500,000 options each to Dr Geoff Cumming and Christopher Parker, all exercisable at 16.03 cents, within three years.

The company said it would vote to elect Dr Cumming, Mr Parker and Mr Crouch as directors, approve the remuneration report and the 10 percent placement facility.

The meeting will be held at Rooftop South, Rydges South Bank, Level 12, 9 Glenelg Street, South Brisbane, on November 17, 2022 at 11am (AEST).

Anteo was unchanged at five cents with 1.2 million shares traded.

INVION

The Invion annual general meeting will vote to issue chief executive officer Thian Chew 22,013,745 options exercisable by at 1.7 cents, November 17, 2026.

Invion said that Mr Chew would receive the options in addition to his \$90,000 chair fees, his \$309,000 annual salary and his annual short-term incentives of up to 50 percent of his salary, inclusive of superannuation, and that if Mr Chew exercised all of his options, his substantial holding in Invion would increase from 8.53 percent to 11.36 percent.

The company said investors would vote to re-elect director Alan Yamashita, renew the employee incentive plan, the 10 percent placement facility and the remuneration report. The virtual meeting will be held on November 17, 2022 at 12pm (AEDT) with registration at: https://us02web.zoom.us/webinar/register/WN_MLCJhZTuQW-Y0sPKiyKOew.

Invion was unchanged at 1.1 cents.

KAZIA THERAPEUTICS

Kazia says shareholders at its annual general meeting will vote on the issue of 3,500,000 options to managing-director Dr James Garner.

Kazia said the options would be exercisable at about 26 cents, or a 43 percent premium on what the company expects will be the five-day volume-weighted average price on date of issue, vesting in six-monthly tranches, by November 17, 2026.

The company said shareholders would vote on the remuneration report, the election of director Steven Coffey, to ratify 17,160,230 at-the-market shares, approve the placement capacity, adoption a new constitution and approve the proportional takeover provisions. The meeting will be held at Level 46, Tower One, 100 Barangaroo Avenue, Sydney and virtually at <https://meetnow.global/MLNFM5D> on November 16, 2022, at 10am (AEST).

Kazia was unchanged at 17.5 cents.

RECCE PHARMACEUTICALS

Recce says its annual general meeting will vote to issue 1,125,000 options to director Alistair McKeough exercisable at \$1.56 each within five years from the date of issue.

Recce said the meeting would vote to increase the non-executive director remuneration pool by \$70,000 to \$250,000, approve the remuneration report, the 10 percent placement facility and re-elect directors Dr John Prendergast, Dr Alan Dunton and Mr McKeough.

The meeting will be held at the offices of Automic, Level 5, 126 Philip Street, Sydney on November 14, 2022 at 2pm (AEDT) and virtually at:

https://us02web.zoom.us/webinar/register/WN_nM9xzjjCSXWTzcUPOwdeHQ.

Recce fell one cent or 1.5 percent to 66 cents.

ARTRYA

Artrya says its annual general meeting will vote on the issue of 439,815 performance rights to managing-director John Barrington.

Artrya said Mr Barrington's performance rights would vest in two tranches pending market capitalizations of \$200 million by June 30, 2024 and \$350 million by June 30, 2025.

The company said shareholders would vote to adopt the remuneration report and elect Jacque Sokolov as a director.

The meeting will be held at Hay Street, West Perth, Western Australia on November 14, 2022, at 11am (AWST).

Artrya was up one cent or 1.5 percent to 67 cents.

GENETIC SIGNATURES

Genetic Signatures says its annual general meeting will vote to issue managing-director Dr John Melki 250,000 options exercisable at 93 cents, within 15 years of vesting. Genetic Signatures said shareholders would vote to approve the remuneration report, elect directors Dr Anthony Radford and Caroline Waldron and the equity incentive plan. The meeting will be held at Clifton Venues, Level 13, 60 Margaret St, Sydney, on November 16, 2022, at 10am (AEST). Genetic Signatures fell 0.5 cents or 0.6 percent to 81 cents.

HEXIMA

Hexima says its annual general meeting will vote to issue director Steven Skala 224,000 options and re-elect directors Michael Aldridge and Scott Robertson. In July, Hexima said it was winding-up after lead candidate HXP124 failed its nail fungus trial and the share price fell 85 percent to four cents (BD: Jun 24, Jul 11, 2022). Today, the company said shareholders would vote to issue Mr Skala 224,000 options under the long-term incentive plan, exercisable at 37 cents each within 10 years. Hexima said the meeting would vote on the re-election of former chief executive officer Mr Aldridge and Mr Robertson as directors, approve the 10 percent placement facility and accept the remuneration report. The meeting will be held virtually on November 16, 2022 at 10am (AEDT) at: www.meetings.linkgroup.com/HXL22. Hexima was up 0.2 cents or 9.5 percent to 2.3 cents.

BIOTRON

The Biotron annual general meeting will vote on the remuneration report, a potential second-strike board spill and the re-election of directors. Last year, Biotron's meeting voted a remuneration report 'first strike' with 20,275,720 votes (32.97%) against and 42,141,141 votes (67.03%) in favor (BD: Nov 23, 2021). Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting and if passed by more than 50 percent of votes the directors must stand for re-election. If the spill vote fails, the trigger is reset to no opposition. At that time, the company had 701,932,713 shares on issue, meaning that the votes against the remuneration report amounted to 2.95 percent of the company, not sufficient to requisition extraordinary general meetings. Today, Biotron said that shareholders would vote to re-elect directors Prof Stephen Locarnini and Robert Thomas. The meeting will be held at Level 3, 60 Carrington Street, Sydney on November 16, 2022 at 11am (AEDT). Biotron fell 0.2 cents or four percent to 4.8 cents.