Biotech Daily

Friday May 13, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ACTINOGEN UP 25%; AVITA DOWN 9%**

*** DR BOREHAM'S CRUCIBLE: MICRO-X**

*** AUSBIOTECH RELEASES 10-YEAR INDUSTRY STRATEGY**

*** DOHERTY STARTS SARS-COV-2 VACCINES DOSING**

*** AMPLIA: VICTORIA OKAYS AMP945 PANCREATIC CANCER TRIAL**

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*** ZELIRA LOSES FORMER CHAIR HARRY KARELIS**

MARKET REPORT

The Australian stock market climbed 1.93 percent on Friday May 13, 2022, with the ASX200 up 134.1 points to 7,075.1 points. Twenty-one of the Biotech Daily Top 40 stocks were up, eight fell, nine traded unchanged and two were untraded.

Actinogen was the best, on chief executive officer Dr Steve Gourlay buying 2,000,000 shares on-market, up 1.6 cents or 25.4 percent to 7.9 cents, with 3.6 million shares traded; followed by Polynovo up 14.0 percent on chair David Williams buying a further 218,468 shares, taking his purchases in the past week to 2,419,468 shares.

Clinuvel climbed 13.5 percent; Prescient was up 10.3 percent; Imugene improved 9.4 percent; Orthocell was up 8.8 percent; Genetic Signatures and Telix were up more than seven percent; Impedimed, Micro-X and Universal Biosensors climbed more than six percent; Mesoblast, Paradigm and Patrys were up more than four percent; CSL, Nanosonics and Opthea were up more than three percent; Cochlear, Neuren, Next Science and Resmed rose more than two percent; Antisense and Medical Developments were up more than one percent; with Pro Medicus up by less than one percent.

Avita led the falls, down 15 cents or 8.7 percent to $1.58, with 390,947 shares traded. Cyclopharm and Proteomics fell more than four percent; Alcidion and Pharmaxis were down more than three percent; Starpharma shed 2.5 percent; with Emvision and Volpara down by less than one percent.

DR BOREHAM'S CRUCIBLE: MICRO-X

By TIM BOREHAM

ASX code: MX1

Share price: 16.5 cents; **Shares on issue:** 461,454,266; **Market cap:** $76.1 million

Chief executive officer: Peter Rowland

Board: David Knox (chair), Mr Rowland, Yasmin King, Dr Alexander Gosling, Jim McDowell, Patrick O'Brien

Financials (March quarter 2022): receipts $2.06 million, revenue $1.5 million, net cash outflows $3.56m, cash of $16.1 million, quarters of available funding: four.

Identifiable major holders: Perennial Value Management 14.6%, Tiga Trading-Thorney Investments 5.7%, Acorn Capital 5.3%, Australian Super 5.2% (Regal Funds Management held 5.6% but ceased to be a substantial holder on March 23, 2022.)

The Adelaide based innovator in lightweight and portable x-ray technology can't be accused of not doing its bit for the war effort in the Ukraine which - frankly - is looking like an old-fashioned battle between good and evil.

Micro-X is supplying its so-called Rover bedside imaging units to the US-based charity Revived Soldiers Ukraine. Developed at the request of the Australian Defence Force, these "ruggedized" battery-operated units are designed to be used in the field.

At 95 kilograms, the Rovers are much lighter than standard mobile x-ray units which weight between 350kg and 600kg.

At last count, 11 units had been shipped to the front line. Intriguingly, Revived Soldiers Ukraine is a well-established, registered US charity, having been set up in 2015 to provide medical and humanitarian assistance. Suffice to say they really have their work cut out, now …

About Micro-X
Based on its patented cold cathode know-how, Micro-X is also pursuing airport security, stroke detection and explosives detection applications.

Micro-X's mobile medical x-ray device, the Carestream DRX Revolution Nano, is already approved in more than 30 countries, with 250 units sold to date. Then there's the aforementioned Rover, for use in military applications such as mobile army hospitals.

Micro-X was founded in 2011, based on technology acquired from Xinray, a University of North Carolina spin-off company. Xinray planned to develop the tech itself, but these plans were sidelined, apparently because Xinray's people had more of an academic bent - understandably.

Off its own bat, Micro-X took up the quest of making its own carbon nanotubes and mass producing them to consistent quality. This is not as easy as it sounds and took some clever people to implement.

Micro-X listed on December 21, 2015, raising $20 million at 50 cents apiece.

Mr Rowland is the former chief executive of Adelaide optical equipment maker Ellex (Medical Lasers) and among other jobs was BAE (British Aerospace) Systems business development head.

Micro-X carries out most of its development in the Adelaide suburb of Tonsley, but it recently opened a Seattle facility to oversee its sizeable US operations.

Warning! X-ray-ted content

X-rays still sound science fiction-y but the underlying technology is little changed since Germany physicist Wilhelm Rongen's accidental brainwave in 1895: a heated filament cathode that generates electrons in a vacuum tube.

These electrons are then accelerated by high voltage on to a tungsten anode target to produce x-rays on impact.

In short, the process is inefficient because a lot of waste heat is produced and the electrons don't all move in the right direction. Micro-X's cold cathode technique is based on an array of four-nanometre wide carbon tubes, under an electrified fine mesh structure.

While standard computed tomography (CT) scanners use only one x-ray source to rotate around an object, these electronically-controlled x-ray tubes enable x-ray beams to be fired from different angles and with no moving parts.

The upshot is the tubes can be made substantially smaller and 95 percent lighter - one kilogram compared with 20 kilograms.

Deals deals deals

Micro-X attributes its early sales momentum to its tie up with its worldwide distributor, Carestream Health Inc (formerly Kodak Medical Imaging). Carestream and Micro-X struck a five-year exclusive agreement in 2016, but in November 2020 the deal was modified to allow Micro-X to sell directly or via other agents.

On March 28, 2022 the company announced a non-exclusive, multi-year US distribution deal with the San Diego based MXR Imaging Inc, the country's biggest independent provider of radiology equipment

On April 4, Micro-X followed up with a collaboration and supply deal with the listed French x-ray equipment manufacturer DMS Imaging SA.

The idea is that DMS will embed Micro-X's x-ray tech in an "innovative" product. As a guide to what it might mean financially for Micro-X, DMS has annual revenue of $54 million and sells in 140 countries.

In July 2021, the company unveiled a version of the Rover, using third-party imaging software tailored for small animal examinations.

Australians spend $2.6 billion a year on veterinary services, so globally the market is a multi-billion-dollar opportunity.

Screening at an airport near you

Also based on its cold-cathode technology, Micro-X is developing self-directed screening portals called Checkpoint, which integrates with passport scanning, photometric identification, body scans and luggage CT scans.

The big selling point is fewer staff and better detection.

"The concept is to shrink the x-ray component so it can be part of a self-service checkpoint," Mr Rowland says.

Micro-X already has two contracts with the US Transportation Safety Administration (TSA), which operates 2,200 x-ray lanes across 440 US airports. The TSA is an arm of the US Department of Homeland Security, which has stumped up $US4 million in funding.

Micro-X also has two contracts with Britain's Transport Department, under its Future Aviation Security Solutions program. These deals pertain to funding the development of lightweight x-ray imaging for detecting explosives hidden in consumer devices.

The company cites a total addressable market of $US24 billion for airports alone: $US8 billion in the US and $US16 billion for the rest of the world. Micro-X aims to launch Checkpoint in 2026.

"This is going to change the future of checkpoints at every American airport, and from there, the world," Mr Rowland says.

Bomb disposal

Micro-X is developing an imaging camera, called Argus, for remote one-sided-viewing of suspected improvised explosive devices (IEDs).

Weighing a mere 15 kilograms, Argus consists of a self-contained camera carried by a robot. In 10 seconds, the device can determine whether a suspicious object such as a backpack contains a bomb or something less innocuous.

"At the moment there is no choice but to get closer to the device than you would really like to be," Mr Rowland says.

He cites a total addressable market of $US1.8 billion; the key markets being police counter terrorism units, the military and border forces looking for contraband.

The company reports that nine US agencies have requested trials, including the FBI. Mr Rowland notes there are 468 police bomb squads in the US alone.

“It’s a marketer’s dream,” he says. “No matter how we price it, it’s a rare bomb squad commander who will decide it’s too expensive and put the lads in harm’s way.”

Argus was planned to be launched at the International Association of Bomb Technicians conference in July - always an explosive affair - but the big reveal is now expected towards the end of the year.

Stroke of fortune

Micro-X’s stroke prevention work involves developing a lightweight computed tomography (CT) scanner for in-ambulance stroke diagnosis. As emergency medicos know, there’s a so-called Golden Hour after a stroke in which patients need to be treated; otherwise, they’re likely to end up with a permanent disability.

Three-quarters of strokes are clots rather than bleeding and they can be effectively treated if help - and drugs - are administered swiftly.

Micro-X’s challenge was to replicate the imaging performance of the current standard-of-care, an eight-slice helical, or spiral, CT scan. Called a ring scanner, the stroke imaging device would be small and light enough to be standard kit in ambulances. The device has 29 miniature x-ray tubes flashing on and off, creating the illusion of a rotating x-ray beam.

Each mini x-ray tube will use Micro-X’s cold cathode tech, but the diameter of the tube will be reduced from 150mm to 40mm - about the size of a golf ball … or large hail stone.

In late March, the company declared that it had reached the second milestone in its program to developer a point-of-care stroke imager. This one is with the Australian Medical Research Future Fund and the Australian Stroke Alliance (ASA).

The milestone involved the ASA’s clinical review team accepting Micro-X’s submission that its CT design elements can “produce images to best practice clinical standards for stroke detection”.

Micro-X also receives a $900,000 milestone payment.

The company cites a total addressable market of $US5 billion across 48,000 ambulances in North America and 60,000 in Europe.

Each unit is expected to cost around $100,000, which sounds like good value given the average long-term cost of treating a stroke patient is around $150,000

The company hopes to start patient trials within two years.

Finances and performance

Micro-X's March quarter was one of its best quarters to date, with revenue of $3.56 million and receipts of $2.06 million. The revenue included $1.8 million of mobile Rover sales - $800,000 from the Ukrainian charity - and a further $1.7 million from grant and consulting fees (pertaining to the brain CT and baggage scanner projects).

The company has about $16 million in cash, enough for four quarters. The company last went to the well in mid-2020, raising $15 million in a placement and rights issue.

Broker Morgans forecasts revenue of $12.2 million for the current year to June 2022, rising to $32 million in 2022-'23 and $63 million in 2023-'24. The broker also expects the company to post its maiden full year profit of around $5 million in the 2023-'24 stanza.

Since listing, Micro-X shares have traded between 56 cents (December 24, 2015) and 10 cents (March 24, 2020).

Dr Boreham's diagnosis:

Mr Rowland says Micro-X has been going from "strength to strength" as it develops new products and forges alliances. Indeed, the company looks to be making good progress with its strategy of commercializing the easiest products before rivals come along and commoditization occurs.

Disappointingly, Micro-X shares have lost about one-third value over the last 12 months.

When we last 'assayed' Micro-X in December 2020, the stock traded at 38 cents. As Kamahl (sort of) said: "Why are some investors so unkind?"

But as we all know, the market's appetite for riskier plays has diminished and there's not management can do about the valuation.

Your columnist believes Micro-X is in a better position than your average device play, given the multiple products that tackle real problems.

Broker Morgans believes the Argus is likely to be a key revenue and profit driver, given attractive margins and lower regulatory hurdles. Over the four businesses there's an addressable market of $US30 billion.

We're not greedy: we'll take 10 percent of that which means that Micro-X should be a $US300 million a year business with a multi-billion-dollar market capitalization.

Meanwhile, investors have the opportunity to grill management at the company's open day at its Tonsley digs on June 2.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. As his contribution to the war effort, he will forego Beluga caviar in favor of borscht, which he is reliably informed* has Ukrainian and not Russian origins. (***** by Wikipedia)

AUSBIOTECH

Ausbiotech says it has released a 10-year strategy for the Australian biotechnology industry, in consultation with more than 350 members of the industry.

Ausbiotech said the strategy, titled 'Biotechnology Blueprint: A Decadal Strategy for the Australian Biotechnology Industry', set out eight core areas of focus and had been written to align with the Federal Government's strategy for the industry.

In March, the Federal Minister for Health Greg Hunt released the 'Biotechnology in Australia - strategic plan for health and medicine' (BD: Mar 29, 2022).

This week, Ausbiotech said the eight-point plan began with support for commercialization form academia and industry, through programs, initiatives, partnerships and by supporting the development of collaborative structures.

Ausbiotech said it would deliver programs aimed at transitioning small companies to medium-sized companies, and medium-sized companies to large companies, by helping to address capability and skills gaps, and ensuring the industry had access to a diverse capital base and incentives to ensure companies continued to operate in Australia.

The organization said it would seek to increase the competitiveness of the Australian biotechnology sector relative to its overseas peers, using a mix of government and industry-led initiatives while ensuring the sector remained open to foreign investment.

Ausbiotech said the sector would work with the domestic service industry to build "sovereign capabilities" and enable local sourcing and partnering, including in manufacturing, scale-up and the development of core drugs and devices.

The industry organization said it would increase the knowledge, awareness and understanding of the contribution made by the biotechnology sector, including through reporting on delivery progress of the blueprint.

Ausbiotech said it would "build, diversify and address gaps in access to capital across the variety of industry organizations to significantly increase the flow of capital to the biotechnology sector by $1 billion annually".

The industry organization said it would work to address gaps in access to appropriate skills and talent through initiatives that it said would attract, build and retain skilled workers essential for the industry.

Ausbiotech said it would "delivery consistent momentum of the blueprint recommendations, using aligned metrics and evidence-based decision-making to guide changes and update, with shares accountabilities".

Ausbiotech chief executive officer Lorraine Chiroiu said Australia had "a wealth of innovative medicines, vaccines, and medical technologies being developed".

"To support them reaching Australian patients and improve and extend the quality of human life, we need to focus on creating the right environment for companies to innovate and grow, build dedicated research infrastructure, and enlist the Australian healthcare system as an active partner," Ms Chiroiu said.

Ausbiotech director Dr James Campbell said that "tackling industry's stubborn issues to develop a solutions-focused blueprint has been a challenging and exacting process, and I offer my congratulations to the executive of Ausbiotech for producing this visionary and extensive strategy for the coming decade".

"Lorraine and her team have done a great job of recognizing and addressing the core value drivers, and have developed a strategy that should motivate and enthuse all of Ausbiotech's stakeholders," Dr Campbell said.

"This process underscores the need for, and value of, Ausbiotech as the peak body for biotechnology in the country," Dr Campbell said.

Ausbiotech said the strategy was at https://www.ausbiotech.org/documents/item/703.

DOHERTY INSTITUTE

The Doherty Institute says it has dosed the first six participants in a trial of two Melbourne-made vaccines for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).
The Doherty said the two vaccine candidates were developed with the Monash Institute of Pharmaceutical Sciences and were distinct from existing vaccines.
The Institute said the vaccines would focus the immune response on the tip of the Sars-CoV-2 spike protein, called the receptor binding domain, which enabled the virus to enter and infect cells and elicited more than 90 percent of neutralizing antibodies following infection.
In January, the Institute said the Federal Government had provided $1.5 million for two safety trials of Sars-Cov-2 vaccines (BD: Jan 17, 2022).
In March, The Doherty said it would begin a 114-person, phase I trial of two Australian-made 'proof-of-principle' vaccines for Sars-Cov-2, one of which it said was a protein vaccine, and the other an mRNA vaccine (BD: Mar 25, 2022).
The Institute said that the vaccines would present the Beta variant to the immune system, which was of the greatest concern when these vaccines were designed, but that it might improve immunity to Omicron, with the variants sharing two of the same key receptor binding domain (RBD) mutations.
Today, the Doherty said it would assess the safety and efficacy of a single dose of these vaccines as a fourth dose of a Covid-19 vaccine, with all participants already having received their third dose of an existing vaccine at least three months prior.
The Institute said the participants assessed at the Royal Melbourne Hospital would receive the RBD protein vaccine, the RBD mRNA vaccine or a placebo.
The Doherty said the randomized, double-blind, placebo-controlled study was the first time a side-by-side comparison would be undertaken of a protein and an mRNA based vaccine, with each vaccine being dosed at three levels.
Doherty Institute head of vaccine and immunization and principal investigator Prof Terry Nolan said the participants would be required to keep a diary of any symptoms they experienced over the following month.
The Doherty said it was uncertain how long the trial would take, but the analysis would begin after all 114 participants had been vaccinated and provided a blood sample.
The Institute said the trial was open to healthy individuals aged 18 to 64 years in Victoria, who had received their third dose of a Covid-19 vaccine at least three months ago.
For details on participating, go to: https://bit.ly/39Zepu3, call 8344 9325, or email: virgo-studies@unimelb.edu.au.

AMPLIA THERAPEUTICS

Amplia says it has received ethics approval in Victoria for its phase II trial of AMP945 in first-line patients with advanced pancreatic cancer.
In April, Amplia said it had ethics approval in New South Wales to begin a 38-patient, open-label, single-arm phase II trial of its AMP945 in patients with advanced pancreatic cancer, but was awaiting the outcome of a second application to conduct the trial in Victoria (BD: Apr 6, 2022)
Today, the company said it had received approval for the Victoria trial, which would allow it "to accelerate recruitment into the trial".
Amplia managing-director Dr John Lambert said the second ethics approval would "allow us to recruit patients more rapidly and begin to generate early efficacy and safety results in people with pancreatic cancer".
Amplia was unchanged at 12 cents.

EBR SYSTEMS

EBR says its annual general meeting voted more than 15 percent opposition to the resolution on the 10 percent placement facility.
EBR said the resolution was opposed by 26,862,561 votes (15.30%) with 148,642,108 votes (84.69%) in favor.
The company said the re-elections of directors Trevor Moody and Allan Will passed overwhelmingly with 99.99 percent of the vote.
According to EBR's most recent filing, the company had 264,168,574 shares on issue, meaning that the 26,862,561 votes opposing the placement facility amounted to 10.2 percent of the company, normally sufficient to requisition extraordinary general meetings.
EBR told Biotech Daily that it as a Delaware-based company it was exempt from that provision of the Corporations Act 2001.
EBR was unchanged at 55 cents.

GENETIC SIGNATURES

Genetic Signatures says it has appointed Caroline Waldron as a non-executive director, effective from May 13, 2022.
Genetic Signatures said that Ms Waldron was currently a director at Resimac Group and AMA Group, and had experience in law, human resources, marketing and risk.
Ms Waldron's Linkedin page said she held a Bachelor of Laws from the University of London.
Genetic Signatures was up nine cents or 7.4 percent to $1.30.

ZELIRA THERAPEUTICS

Zelira says deputy chair Harry Karelis has resigned effective from May 12, 2022.
According to Commsec data, following Mr Karelis' resignation, the Zelira board will comprise chair Osagie Imasogie, managing-director Dr Oludare Odumosu, company secretary Tim Slate, and Lisa Grey.
Zelira fell two cents or 1.6 percent to $1.26.