Biotech Daily

Friday February 9, 2024

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH UP: GENETIC SIGNATURES UP 6%**
- ATOMO DOWN 6.45%

*** DR BOREHAM'S CRUCIBLE: ARTRYA**

*** FEDERAL $229m FOR 110 PROJECTS**

*** RHYTHM HOPES TO RAISE $6.6m IN RIGHTS OFFER**

*** PARADIGM PPS 'SAFE, WELL TOLERATED' FOR MPS-VI**

*** TRIVARX: NORTHERN MICHIGAN UNI TO STUDY STAGER SLEEP TOOL**

*** BVF DILUTED TO 17% OF SYNTARA**

*** CARDIEX CHAIR NIALL CAIRNS, CEO CRAIG COOPER TAKE 23.4%**

*** REGAL FUNDS TAKES 13% OF CARDIEX**

*** BIO-MELBOURNE 2nd mRNA LECTURE SERIES**

MARKET REPORT

The Australian stock market was up 0.07 percent on Friday February 9, 2024, with the ASX200 up 5.6 points to 7,644.8 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell and eight traded unchanged.

Genetic Signatures was the best, up three cents or 6.25 percent to 51 cents, with 53,234 shares traded. Both Alcidion and Resonance climbed six percent; Cochlear, Cynata and Percheron (Antisense) were up more than five percent; Orthocell and Syntara (Pharmaxis) improved four percent or more; Mesoblast and Next Science were up more than three percent; Avita and Curvebeam rose more than two percent; Compumedics, Opthea and SDI were up more than one percent; with Clinuvel, CSL, Cyclopharm and Neuren up by less than one percent.

Atomo led the falls, down 0.2 cents or 6.45 percent to 2.9 cents, with 1.1 million shares traded. Amplia lost 5.1 percent; Dimerix, Impedimed and Micro-X fell more than four percent; Clarity was down 3.6 percent; 4D Medical and Paradigm shed more than two percent; Telix and Universal Biosensors were down more than one percent; with Emvision, Nanosonics, Polynovo, Pro Medicus, Resmed and Volpara down by less than one percent.

DR BOREHAM'S CRUCIBLE: ARTRYA

By TIM BOREHAM

ASX code: AYA

Share price: 27 cents; **Shares on issue:** 78,648,993; **Market cap:** $21.2 million

Chief executive officer: Mathew Regan

Board: Bernard (Bernie) Ridgeway (chair), Kate Hill, Dr Jacque Sokolov (co-founders John Konstantopoulos and John Barrington resigned last year, with Mr Konstantopoulos continuing as the head of commercial and strategy).

Financials (December quarter 2023): revenue nil, net cash outflows $1.15 million, cash of $15.15 million, estimated quarters of funding available 13.18

Major shareholders: John Barrington 9.6%, John Konstantopoulos 8.95%, Richcab Pty Ltd (Dale McKenzie Superfund) 5.1%.

Moseyin' up to the imposing doors of the Food and Drug Administration's Washington HQ and exclaiming 'whaddya think, dudes?" has never been an advisable approach to seeking approval of a drug or device.

Yet time after time, applicants fall short because they haven't done their homework, including eliciting and interpreting the agency's Delphic signals.

Artrya admits it didn't follow the FDA-101 handbook when it sought approval for its algorithmic-based device, Salix coronary anatomy software, to detect the build-up of deadly plaque in coronary arteries. In June last year, the FDA knocked back the device, even though it had been approved in Europe, the UK, New Zealand and - let's not forget - Australia.

Artrya CEO Mathew Regan says the rejection was a case of a "young business trying to push forward" when it wasn't ready. "We probably didn't engage with the FDA in the way we should have," he says.

This time around the company engaged in a Q-submission pre-meeting, whereby management can seek the agency's guidance. It has also engaged regulatory greybeards to navigate the process. "We didn't do that last time – we were winging it."

Last time around, Artrya lodged approval for its Salix device under the 510k predicate route. But the addition of some artificial intelligence (AI) tweaks meant there was also a de novo element and the 510k route led to a dead-end.

The company is now targeting FDA approval by June, with an application expected to be lodged by the end of March. Management is heartened that in December the FDA approved the ancillary Salix Ingest, which enables the secure exchange of data between clinical systems and Salix.

Who needs iron ore?

A bright idea emanating from the West, Artrya was founded by John Barrington and fellow Perth native Ioannis (John) Konstantopoulos in 2018.

The two Johns collaborated 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.

In particular, the company was aided by one of the world's leading researchers of vulnerable plaque, Harry Perkins' Prof Girish Dwivedi.

Artrya delivered a pilot product in December 2019, six months ahead of schedule and listed on November 26, 2021, having raised $40 million in an initial public offer (IPO) at $1.35 a share.

The company's CEO up to March 2023, Mr Barrington has a background in information technology (IT), management consulting and fostering start-up entities. Mr Konstantopoulos has a long technology background including applying IBM's smarts to healthcare uses.

Mr Konstantopoulos resigned from the board in February 2023 but remains a major shareholder. Mr Barrington quit as CEO and director the following month.

Mr Barrington's replacement, Mr Regan has worked for several ASX-listed companies, private equity firms and cooperatives across several industries.

Plaque: the invisible killer

Coronary artery disease affects 129 million people annually and causes 17.1 million deaths.

In the US, one person dies from a heart attack every 33 seconds.

Putting a dollar figure on it, $US378 billion ($A580 million) is spent on heart disease a year in the US and $12 billion here.

Early detection is vital.

To enable this, Artrya is zeroing-in on detecting vulnerable plaque, which is the build-up of lipids (fats) in the lumen (arterial tube).

An algorithm-based artificial intelligence tool, Salix detects the plaque deposits on x-ray coronary computed tomography angiograph (CCTA) images

Despite vulnerable plaque being the cause of most heart attacks, plaque currently is not routinely reported in cardiac imaging and diagnostics as it's difficult to detect with the naked eye in traditional images.

Plaque is soft and prone to rupture, but it also can calcify and harden over time, causing 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.

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

How Salix works

As the 510k predicate application implies, Salix is not ‘new-new’. A US mob called Cleerly Health has an algorithm plaque-detecting device for patients, physicians and health insurers, but Artyra argues Salix is more automated and generally more useful.

Salix is a real-time device that clinicians can use to determine the need to stent a patient.

Currently, the images produced by the computed tomography (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.

Salix aims to eliminate these intermediate steps, by producing a three-dimensional model for the radiologist within 15 minutes of scan completion.

The company says clinicians continue to control the process and are responsible for the final report.

Doing deals (but not boiling the ocean)

Ahead of the expected US launch of Salix, in November 2023 the company signed a “strategic partnership agreement” with Northeast Georgia Health Ventures, part of the Northeast Georgia Health System.

The venture’s five hospitals carry out 10,000 heart scans a year. The tie-up will help the company with the ‘last mile’ integration: hooking up the hospital’s systems with Artrya’s post FDA approval.

The agreement includes a collaboration to develop a novel, point-of-care, non-invasive blood flow assessment test (see below).

“We will be looking for three of four more of those strategic partners in America and will look to do more [pilot programs] early 2024 in Australia,” Mr Regan says.

“We are looking for not the biggest ones and not the smallest ones: that’s the sweet spot for us. We are not trying to boil the ocean immediately.”

A pertinent question is why the company is not selling in the geographies in which Salix is approved.

The short answer is the economics don't yet stack-up.

In the UK, Artrya already has a deal to supply 1,250 hospitals under the auspices of the National Health System.

First sales were expected in mid-2022, but the trouble is there's a race to the bottom on pricing.

"As we renegotiate those contracts to a better price point, then it will make more sense," Mr Regan says.

As for Australia, the company has signed pilot study agreements with a top-tier imaging chain as well as a second-tier one.

Mr Regan says it would be a "source of pride" to introduce Salix to Australian clinicians.

"We are expecting first revenues this financial year and they will likely derive from the Australian market."

Artrya also has a version of Salix for use by research organisations, which does not have to be approved. Research clients, such as pharma companies, are a source of peer review and advocacy and such use generates more data to train the artificial intelligence models.

Blood-flow assessment

Artrya hopes to boost its commercial appeal with Salix Coronary Flow, a non-invasive assessment of coronary blood flow.

The 10-minute test simulates blood flow strength and identifies the best place to locate a stent (or multiple stents). The blood-flow measurement can be included in the overall risk assessment presented to the patient.

For instance, areas showing up in pink show an almost 100 per cent narrowing.

"When a patient sees that, they are more likely to follow a treatment plan," Mr Konstantopoulos says. "And when they see the next scan, they can know whether it has improved or not."

(Plaque is reversible by way of cholesterol-lowering drugs and lifestyle changes).

Conversely, about 40 percent of patients don't need a stent and the analysis is equally helpful.

"If the heart is getting blood, why send the patient for a risky procedure?"

Finances and performance

As of the end of December 2023, Artyra had a comfortable $15.15 million in the bank - enough to reach anticipated FDA approval - but wouldn't mind some more spendoolies.

Wouldn't we all?

"Clearly we would like more money because that makes the path to revenue smoother and quicker," Mr Regan says. "But all going well we have enough to get [to commercialization]. We have the levers to reduce spend but would rather not."

Crucially, in the US, a reimbursement code was approved in November 2022, for plaque assessment systems such as Artrya's. Clinics receive $US800 to $US1,000 per procedure, which leads them being far more amenable to subscribe to Salix. In turn, Artyra enjoys "software-as-a-service type margins".

Over the last year, Artyra shares have fluttered between 17 cents (December 12) and 56 cents (February 6 last year). The stock peaked at $1.52 post listing.

Dr Boreham's diagnosis:

Since listing in late 2021, Artrya shares have lost more than 80 percent of their value while the company inarguably has progressed. But like a rip at a wild ocean beach, market sentiment is a powerful force that can't be fought.

Of course, FDA approval would change all that and management is maximising its chances of success.

"We want to be the perfect client for the FDA, which means engaging with them enough but not over engaging with them so we are not mucking them around," Mr Regan says.

Despite the importance of FDA assent, the US accounts for only one-third of Artrya's addressable markets. According to the company,11 million coronary computed tomography angiograph (CCTA) scans are done in the US and Europe each year, with 19.5 million forecast to take place by 2025.

Saving lives aside, Artrya will be pushing the economic benefit of Salix in terms of freeing up the workload of frazzled radiologists.

Meanwhile, shareholder hearts are pumping by the experience of the ASX-listed algorithm-based breast imager Volpara Health Technologies, which fell into a similar share-price funk but is now being acquired by artificial intelligence-based cancer imaging house Lunit for $295 million.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is reasonably literate but is plaqued by errant spell check algorithms

FEDERAL GOVERNMENT

The Federal Government says its Medical Research Future Fund will provide $229,460,000 in clinical trial and research funding for 110 research projects.

A media release from the Federal Minister for Health and Aged Care Mark Butler said the funding was for research projects, including cardiovascular disease, cancer, primary and preventive health care, respiratory diseases, maternal health, dementia, mental health and First Nations citizens' health.

The Government said the funding would support trials to test the effectiveness and safety of new treatments, including collaboration with international researchers.

The Federal Government said the single largest investment was $50 million to establish the Biomedtech Incubator "to fast track the commercialization of up-to 15 early-stage Australian research projects for dementia and cognitive decline".

The government said that the program would be delivered by a partnership between Brandon Biocatalyst and Australia's National Digital (AND) Health.

The media release said that among the 110 research projects to receive funding, almost $5 million each had been awarded to the University of Melbourne, Queensland University, the University of Newcastle and Deakin University.

Mr Butler said he was "pleased to announce that nearly $230 million in funding will help Australia's researchers to discover new ways to tackle many of the health and medical issues that impact people every day".

"Emerging researchers will be helped to develop their skills and grow their careers in Australia, while promising new treatments will get to market earlier and fulfil their promise of new hope for Australian patients," Mr Butler said.

The full list of awarded projects is at: https://bit.ly/3wdNgP9.

RHYTHM BIOSCIENCES

Rhythm says it hopes to raise up-to $6.6 million in a three-for-10 rights offer at 10.0 cents a share, with one attaching option for every two shares purchased.

According to Commsec data, Rhythm closed at 17.5 cents on February 6, 2024, making the offer price a 42.9 percent discount to the last closing price.

Rhythm did not state the discount level.

The company said it was in discussions with executive chair Otto Buttula to underwrite the offer by more than $1.0 million "conditional on his continuing directorship and the results of the [extraordinary general meeting], scheduled for February 12, 2024".

In January, Rhythm said that an extraordinary general meeting would vote to remove chair Otto Buttula as a director, following receipt of a section 249D shareholder requisition (BD: Dec 15, 2023; Jan 21, 2024).

Today, the company said that the other directors would participate in the entitlement offer with their commitment less than $100,000,

Rhythm said that the funds would be used to transition its Colostat test to new regulation standards, resubmitting Colostat for regulatory approvals in Europe and Australia, supporting distribution partnerships with sales and marketing, developing products for other cancers and general working capital.

The company said that the attaching options were exercisable at 20.0 cents each by March 31, 2026.

Rhythm said the offer had a record date of February 22, would open on February 27 and close on March 14, 2024.

Rhythm fell five cents or 28.6 percent to 12.5 cents with 1.3 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says a 13-child, phase II trial shows its injectable pentosan polysulfate sodium (PPS) is safe and well-tolerated for muco-poly-saccharidosis (MPS) type-VI.
Paradigm said muco-poly-saccharidosis type VI (six), or Maroteaux-Lamy syndrome, was a rare, inherited lysosomal storage disease that occurred “due to errors with one of the enzymes that break down and recycle glycosaminoglycans”.
The company said that in most cases symptoms were not apparent at birth but emerged gradually as a result of defective lysosomal storage and resulting cell damage over time and that “the heart, bones, joints, respiratory system and central nervous system … may eventually be affected”.
Paradigm said the randomized, placebo-controlled, phase II trial dosed patients weekly for 24-weeks and that the trial met its primary endpoint of safety, with only “mild to moderate” adverse effects.
The company said secondary endpoints included pain assessment, function assessment, impression of change and childhood health disability assessment and urinary glycosaminoglycan measurements.
Paradigm said results from the phase II trial indicated “overall average … pain calculated over seven days at baseline and after 25 weeks showed improvement in both PPS and placebo groups” with improvement greater in the PPS group than placebo.
The company said a functional assessment test showed patients receiving PPS showed “greater improvement than placebo … from baseline to week-25 on at least one hand”.
Paradigm said that the childhood assessment questionnaire disability index score showed a change in disability score for the treated group of minus 0.350 compared to minus 0.125 for the placebo group and that “a minimally clinically important difference for improvement is minus 0.188”.
The company said urinary glycol-samino-glycan levels changed slightly from baseline in both placebo and PPS groups at 25 weeks but that “the values generally fell within the normal range for healthy controls”.
Paradigm said it had completed clinical studies for “MPS-I and MPS-VI with strong data sets and meaningful endpoints identified to progress the clinical development of IPPS as an adjunctive therapy with a commercial partner”.
The company said the phase II trial results would be presented at the 20th World Symposium for lysosomal disease research in San Diego from February 4 to 9, 2024.
Paradigm chief executive officer Paul Rennie said “to demonstrate improvements in pain and function measures is a positive outcome for the company”.
Paradigm fell one cent or 2.8 percent to 34.5 cents.

TRIVARX (FORMERLY MEDIBIO)

Trivarx says it will provide its Stager sleep analysis tool to the Marquette-based Northern Michigan University in exchange for its sleep research program data.
Trivarx said the University would use its sleep research software Stager as part of its ongoing sleep study program “to monitor brain activity during sleep and heart rate variability”.
Trivarx said the agreement had “the potential to unlock breakthroughs relating to the role of brain activity during sleep and the level and type of mental illness, potentially including predictors of the onset of mental disorders”.
The company said the agreement would be the first time its product was used in an external research program.
Trivarx was up 0.1 cents or 4.2 percent to 2.5 cents with 19 shares traded.

SYNTARA (FORMERLY PHARMAXIS)

San Francisco's BVF Partners says its 201,488,850 share-holding in Syntara has been diluted from 24.24 percent to 16.92 percent due to a capital raising.
Last week, Syntara said it had raised $303,000 of a hoped-for $2 million in a share purchase plan at 2.2 cents a share, taking the total raised with its December placement to $10.3 million (BD: Dec 19, 2023, Feb 2, 2024).
Syntara was up 0.1 cents or 4.8 percent to 2.2 cents with four million shares traded.

CARDIEX

Cardiex Chair Niall Cairns and chief executive officer Craig Cooper say they have increased their holding from 27,234,394 shares (20.95%) to 68,689,830 shares (23.35%).
Through the Sydney-based C2 Ventures, Mr Cairns and Mr Cooper said they acquired 20,955,436 shares at 7.95 cents a share in an entitlement offer, 9,875,000 shares at 8.0 cents a share in a placement and 10,625,000 shares through a convertible note facility at 8.0 cents a share.
Earlier this week, Cardiex said its one-for-2.87 entitlement offer at 8.0 cents a share raised $4 million, taking the total raised with the placement to $8 million, with $1 million underwritten by Mr Cairns and Mr Cooper through C2 Ventures (BD: Feb 7, 2024).
Cardiex was in a suspension and last traded at 13.5 cents.

CARDIEX

Regal Funds Management says it has become a substantial shareholder in Cardiex with 25,047,077 shares, or 12.59 percent.
The Sydney-based Regal Funds said it acquired the shares on February 6, 2024 for $2,003,766 or 8.0 cents a share, through an entitlement offer (see above).

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says the second mRNA lecture in its four-part series will be held on February 20, 2024 is open for registration.
Last year, the Bio-Melbourne Network said that it would hold the first of four lectures in an mRNA series on November 10, 2023, with the remaining lectures to be held on February 20, March 14 and May 28, 2024 (BD: Nov 9, 2023).
Today, the Network said the lecture titled 'mRNA Clinical Trials: Enhancing Research-Clinician Collaboration to Accelerate Patient Outcomes' would discuss mRNA clinical trial opportunities for researchers and clinicians with four keynote speakers.
For more details and registration, go to: https://bit.ly/42wZSga.