



Biotech Daily

Friday August 5, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: ANTISENSE UP 18%; GENETIC SIGNATURES DOWN 7%**
- * **DR BOREHAM'S CRUCIBLE: 4D MEDICAL**
- * **APTAR BUYS PHARMAXIS ORBITAL INHALER FOR \$7.2m**
- * **SONDERMIND TO ACQUIRE TOTAL BRAIN FOR \$14.4m**
- * **VICTORIA \$3.2m FOR 12 MEDICAL TECHNOLOGY COMPANIES**
- * **INCANNEX COMPLETES APIRX ACQUISITION FOR \$125m IN SCRIP**
- * **ALLEGRA SR-HT-GAHNITE 'SAFE IN RABBITS'**
- * **PHARMAXIS LOSES DIRECTOR WILL DELAAT**
- * **AUDEARA APPOINTS BILL PENG DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.58 percent on Friday August 5, 2022, with the ASX200 up 40.7 points to 7,015.6 points.

Twenty of the Biotech Daily Top 40 stocks were up, six fell, seven traded unchanged and seven were untraded. All three Big Caps were up.

Antisense was the best, on no news, up 1.4 cents or 18.4 percent to nine cents, with 1.3 million shares traded.

Paradigm improved 13.9 percent; Micro-X was up 7.7 percent; Kazia, Orthocell and Starpharma climbed more than six percent; Pharmaxis and Polynovo were up more than five percent; Emvision and Next Science improved more than four percent; Dimerix and Neuren were up more than three percent; Imugene and Volpara rose two percent or more; Atomo, Clinuvel, Cochlear, Oncosil and Telix were up more than one percent; with CSL, Nanosonics, Pro Medicus and Resmed up by less than one percent.

Genetic Signatures led the falls, down 7.5 cents or 6.7 percent to \$1.04, with 130,096 shares traded. Actinogen fell 4.4 percent; Impedimed lost 3.6 percent; Avita and Immutep were down one percent or more; with Opthea down by 0.75 percent.

[DR BOREHAM'S CRUCIBLE: 4D MEDICAL](#)

By TIM BOREHAM

ASX code: 4DX

Share price: 70 cents; **Shares on issue:** 294,491,837; **Market cap:** \$206.1 million

Chief executive officer: Prof Andreas Fouras

Board: Bruce Rathie (chair), Prof Fouras, Lilian Bianchi, Dr Robert Figlin, John Livingston, Julian Sutton, Evonne Collier

Financials (June quarter 2022): customer receipts of \$207,000, cash burn \$8.25 million, cash balance \$51.1 million, quarters of available funding six.

Identifiable major shareholders: Velocimetry Consulting (Prof Fouras) 29.55%, Perennial Value Management 7.1%, Ryder Capital 2.2%.

The Melbourne-based lung imaging innovator soon might be able to boast of 'by appointment to the US military' among its early achievements.

As 4D noted in a recent media release, the US House of Representatives has called on the powerful US Department of Veterans Affairs to evaluate "emerging tech using existing x-ray imaging to derive four-dimensional models of lung function".

That may sound vague, but not so much considering 4D Medical is the only current provider of dedicated 4-D lung imaging in the world.

The problem for Vet Affairs is that 3.5 million military personnel have served in the Middle East since the 2001 al Qaida terrorist attacks and up to 10 percent have returned with serious, but hard-to-diagnose, lung conditions, such as constrictive bronchiolitis (more on this below).

A particular culprit is burn pits: the eco-unfriendly military practice of putting unsorted toxic waste into a hole, adding an accelerant and setting it alight - thus creating plumes of acrid, black smoke.

"We are starting to grasp the true health for many of the (veterans) who now suffer from incurable respiratory diseases which existing technologies failed to detect," says 4D Medical founder and chief Prof Andreas Fouras.

"We owe it to all veterans and their families to get them the help they need and deserve."

Meanwhile - and closer to home - 4D's imaging has been adopted by I-Med, Australia's biggest medical imaging chain.

Happy birthday

The 4D tech was the brainchild of Prof Fouras, a mechanical engineer who hung around Monash University's wind tunnel labs. From this experience he realized that there was a better way to measure air movement through the lungs and the product evolved from that.

Funded with a few coins from the back of the couch, Prof Fouras founded 4DX - as the company was then known - in 2012. 4D listed on August 7, 2020 at 73 cents a share after an oversubscribed initial public offer.

August 7? Many happy returns for Sunday and let's hope we all have enough breath to blow out the candles. Pre-float, 4D had raised \$19 million in equity and \$17 million in convertible notes.

4D contends that existing methods do not assess 'regional' performance in various parts of the lung, so are a substandard assessment. In essence, 4D's tools supplements - but does not replace - the images produced by conventional x-rays, computed tomography (CT), magnetic resonance imaging (MRI) and the relatively crude spirometry.

X-ray and spirometry have been around since the late 1800s and are tried and trusted - but also have their limitations. For instance, CT scans work better with bones and dense structures rather than our air-filled bellows.

Here's to 'boring' lungs

4D's imaging can detect conditions including emphysema, chronic obstructive pulmonary disease (COPD), asthma, pulmonary and cystic fibrosis and occupation diseases such as silicosis.

4D's algorithms assess the nature of air movements through the lungs, which can indicate the type of disease based on where exactly the airflow is deficient.

Prof Fouras describes healthy lungs as "boring", in that air flows in and out uniformly.

"As soon as you have an illness it upsets the pattern," he says.

The four-dimensional data shows exactly where the air is flowing in the lungs and - worryingly - where it's not. For instance, pulmonary fibrosis will result in a lot of flow near the heart, but only a little at the edges.

And those poor veterans? Those with toxic exposures have lungs that "look like a patchwork quilt of small little problems everywhere".

LVAS has entered the building

4D's imaging software is called XV LVAS (as in lung ventilation analysis). The company has also developed physical scanners, in a consortium called the Australian Lung Health Initiative (ALHI).

In May 2020, the US Food and Drug Administration granted the XV LVAS clearance for imaging any lung indication, while Australia's Therapeutics Goods Administration followed suit in September last year.

A key point is that 4D is a software-based company and clients don't need the circa \$650,000 scanners to be able to use its imaging. "We are an absolute, straight-up-and-down software-as-a-service company," Prof Fouras says.

He likens 4D to Microsoft, which sells laptops and such but will always be known as a software company. Having said that, the scanners are useful for high-throughput clinics because they are faster and produce less radiation. The resulting abbreviated procedure also means they're more useful for wiggly kids and older people.

The scanners are yet to be approved but in March this year the first unit was launched at Sydney's Prince of Wales Hospital, by then Federal Health Minister (and now feather duster) Greg Hunt.

Founded by 4D Medical, the ALHI includes the University of Adelaide, the South Australian Health and Medical Research Institute, the University of New South Wales and the Royal Melbourne Hospital.

Getting in bed with I-Med

Coming back to the software, in June 2022, 4D signed a nationwide contract with I-Med Radiology Network, Australia's largest medical imaging chain with more than 250 clinics.

The two companies will also form a Lung Centre of Excellence, "to enable world class research and development activities to advance diagnostic imaging". The three-year deal formalizes an existing commercial arrangement.

The I-MED platform is predicated on an automated platform, by which the low-value x-ray images will be run through 4D's software without any human intervention. Prof Fouras says seven I-Med sites to date - those with higher standard x-ray equipment - have turned on the LVAS software.

"We're broadening that rollout," Prof Fouras says. "As we progress it will also be compatible with CT and the vast majority have CT equipment."

In the clinic

Prof Fouras describes clinical studies as the "fundamental pillar" of its commercialization strategy. The company lists eight active advanced studies, with results expected soon.

In May 2022, attendees at the American Thoracic Society's international conference in Los Angeles were treated to the findings of a completed chronic obstructive pulmonary disease (COPD) imaging study, overseen by investigators from John Hopkins and the University of Miami.

The study enrolled 15 COPD sufferers and showed that XV LVAS was up to the task.

Melbourne's Alfred Hospital is taking the "interesting" approach of analyzing about 40 lung transplant patients who have undertaken no fewer than 17 diagnostic procedures.

"Our test is being put head-to-head with all 17 of those, so it is the most comprehensive study by far," Prof Fouras says.

A US military trial focuses on veterans who have come back with constrictive bronchiolitis.

X-rays and computed tomography (CT) scans can't detect this ailment, because it affects the smallest airways of two millimetres or less.

Instead, suspected sufferers need to undergo a biopsy, which is not only painful but could involve a three-day hospital stay and the high risk of complications.

Management is confident the results will show good results on both specificity (false positives) and sensitivity (false negatives).

It is estimated that up to 10 percent of the 3.5 million US veterans might have constrictive bronchiolitis, while they are also three times more likely to have a tobacco smoking-related illness.

"Constrictive bronchiolitis is the most problematic toxic exposure [for veterans], but COPD also common and we have that covered too."

The company is also keenly interested in silicosis; the disease suffered by artisans such as stonemasons who have not masked up.

Finances and performance

The hardware (the scanners) were kindly funded by the Federal Government's Medical Research Future Fund (MRFF), to the tune of \$28.9 million over five years.

But with 4D required to match the funds, the company last year raised \$40 million in a placement and \$6 million in a share purchase plan.

The funding will cover the work required to support a marketing application to the US Food and Drug Administration, but 4D pays for the cost of commercializing the scanners and any other regulatory submissions.

In the June 2022 quarter, the company reported cash of just over \$51 million, with \$15 million of MRFF funding yet to be received.

4D's June quarter customer receipts of \$207,000 are modest, but should get a wiggle-on given the "material" I-Med deal,

Shortly after listing, 4D shares peaked at \$2.60 and in late June this year slumped to a low of 36 cents.

Nutting out the pricing

Prof Fouras says 4D's underlying philosophy is to 'democratize' the availability of the scanning. But to get into influential public sites, more clinical data is required and reimbursement is fiddly.

In Australia, the scan is likely to cost around \$150 a pop, on top of the core - Medicare subsidized - x-ray imaging of a similar quantum.

"Our intent it to be very accessible and inexpensive," Prof Fouras says.

"The basic paradigm in healthcare is that if you are 10 percent better you can charge 25 percent more and we want to be twice as good at half the price," he says. "Not only is it ethically the correct thing to do, but the pathway to the best profitability in the long term."

Commercially, Prof Fouras says I-Med was the "by the far the most effective place for us to put our efforts in Australia".

In the US, Veteran Affairs has agreed on \$US171 (\$250) per scan. Multiply that by 3.5 million vets and that's an addressable market of - tap, tap - \$US600 million.

He says feedback to date suggests that few patients consider the out-of-pocket cost to be excessive.

Dr Boreham's diagnosis:

Prof Fouras says 4D's research and development budget of \$10 million is overshadowed by the likes of Siemens, which spends EUR4 billion (\$5.8 billion) a year in its laboratories.

"We are an ant on a cork in the ocean and Siemens is the cruise liner coming on fast."

Still on the maritime analogy, 4D looks to be enough nautical miles ahead so as not to be crushed by a larger 'vessel'. The company's boffins are already developing technology to measure blood flow through the lungs, with an announcement expected "in coming weeks".

Locally, the I-MED deal makes for a promising start, but the US military interest could determine the company's fortunes in the land of the free - albeit wheezing.

Bear in mind that the US military spends more on healthcare than the entire Australian government - even if it is to clean up the mess it made in the first place.

4D cites an overall global market of 377 million lung procedures annually, worth \$US31 billion. Of this, the US accounts for 73 million procedures worth almost \$US14 billion, so the potential is truly breath-taking.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His boring lungs have never been dubbed the life of the party and he hopes it stays that way.

PHARMAXIS

Pharmaxis says the Crystal Lake, Illinois-based Aptar Pharma will pay \$US5 million (\$A7,180,000) to acquire its Orbital inhaler.

In 2021, Pharmaxis said that Aptar would pay \$US250,000 for a 12-month option for Orbital and a further \$US2.5 million on exercising the option (BD: Aug 17, 2021).

Today, Pharmaxis said in addition to the \$US2.5 million to exercise the option, Aptar would pay a further \$US2.5 million to buy the technology outright, and Pharmaxis would retain the rights to Orbital devices used to deliver inhaled mannitol.

The company said that the Orbital technology allowed powder payloads of up to 400mg or more to be inhaled by patients in divided doses without the need to reload.

Pharmaxis said that the platform was developed as a life cycle extending product for its mannitol Bronchitol cystic fibrosis drug but met a need to deliver high doses of other drugs, such as antibiotics, to the lungs

Pharmaxis chief executive officer Gary Phillips said "I am delighted that Aptar Pharma, who are one of the world's foremost drug delivery device companies, have seen the potential in the Orbital technology".

"We look forward to them building on the technical evaluations carried out during the option period and delivering new product solutions that can benefit drug developers and patients," Mr Phillips said.

"Today's announcement is a further example of the capability of the Pharmaxis team and is part of our strategy to generate non-dilutive cash from the mannitol respiratory business," Mr Phillips said.

Pharmaxis was up 0.4 cents or 5.5 percent to 7.7 cents.

TOTAL BRAIN

Total Brain says the Denver, Colorado-based telehealth company Sondermind will buy it for \$US10 million (\$A14.4 million), pending shareholder approval.

Total Brain said that Sondermind would pay Total Brain \$US10 million less any debt it provided Total Brain until the completion of the transaction, the value of employee leave entitlements assumed by Sondermind, and an agreed \$US133,000.

The company said an additional payment of \$US3 million may be payable if the company implements a previously executed clinical services agreement with one of its key customers by 22 August 2022.

Total Brain said it expected the sale to be completed in "late September 2022".

Total Brain has a market capitalization of about \$8 million.

Total Brain fell 1.2 cents or 20.7 percent to 4.6 cents.

VICTORIA GOVERNMENT

Victoria says 12 businesses including Compumedics, Global Kinetics Polynovo and 4D Medical will share \$3.2 million through the Medtech Manufacturing Capability Program.

The Victoria Government said the businesses would receive grants of up to \$500,000 to undertake new projects, scale up production and upgrade equipment.

The State Government said that the co-funded projects were worth more than \$7 million collectively.

The Government said that the grants were delivered through the Australian Medtech Manufacturing Centre, an initiative to help medical technology manufacturers expand production and connect with local suppliers.

A full list of recipients is at: <https://bit.ly/3P1wnuw>.

INCANNEX

Incannex says it has completed its acquisition of the Apirix, marijuana and psychedelics company, issuing \$125 million of its shares to Apirix's stakeholders.

In March, Incannex said it intended to acquire Scottsboro, Alabama-based Apirix for \$US93.3 million (\$A124.6 million) in scrip (BD: Mar 24, 2022).

Today, the company said that Apirix stakeholders had entered a 12-month voluntary escrow deed restricting the disposal of any of the shares.

Incannex said that Apirix founders Dr George Anastassov and Lekhram Changoer had joined Incannex as non-executive director and chief technology officer respectively.

The company said 22 additional clinical and pre-clinical research and development projects comprising 19 granted patents and 23 pending patents had been transferred to Incannex as a result of the acquisition.

Incannex managing-director Joel Latham said "the acquisition of Apirix follows a long relationship with Dr Anastassov and Mr Changoer that first began in 2018 when Incannex transitioned its business towards the development of pharmaceutical cannabinoids".

"After extensive due diligence and corporate strategy assessments of the Apirix assets, we are excited and readied to commence development activities over our newly acquired portfolio of drug candidates," Mr Latham said.

Incannex was up 5.5 cents or 24.4 percent to 28 cents with 17.7 million shares traded.

ALLEGRA ORTHOPAEDICS

Allegra says its Sr-Ht-Gahnite is non-cytotoxic, non-sensitizing, non-irritating, and non-pyrogenic in rabbits.

Allegra previously said Sr-HT-gahnite was composed of strontium, hardystonite (a calcium-zinc-silicate) and gahnite, a zinc-aluminium-oxide (BD: Jun 8, 2016).

Today, the company said its small animal safety study, at the Northwood, Ohio-based North American Science Associates, involved implanting its Sr-Ht-Gahnite cervical spinal fusion cage in rabbits for up to 13-weeks.

Allegra said that a large animal study, based at the South Australian Health and Medical Research Institute in Adelaide was complete, with analysis underway, and that it hoped to obtain a 90-day US Food and Drug Administration 510(k) clearance in early 2023.

Allegra was unchanged at 17 cents.

PHARMAXIS

Pharmaxis says that director Will Delaat has resigned "due to ill health".

Pharmaxis said joined as a director in June 2008, and that his resignation "marks the end of his significant contribution to the evolution of the Pharmaxis business".

Pharmaxis chair Malcolm McComas said that Mr Delaat had been "an outstanding non-executive director bringing his 40 years of global pharmaceutical experience to the Pharmaxis board".

"He has made a significant contribution to the company over his 14-year tenure including involvement in the approval of Pharmaxis' two respiratory products now available in world markets and clinical work to advance the company's latest drug discoveries," Mr McComas said.

"Will departs the Board with the very best wishes of all at Pharmaxis," Mr McComas said.

"His wisdom, dedication, quiet counsel and friendship will be greatly missed," Mr McComas said.

AUDEARA

Audeara says it has appointed Bill Peng as an executive director, effective from today. Audeara said Mr Peng had most recently “founded an [unnamed] Australian company specializing in electronic medical products.”

The company said Mr Peng held a Bachelor of Business from Brisbane’s Griffith University and a Master of Business from the University of Queensland.

Audeara was untraded at 12 cents.