Biotech Daily

Friday April 9, 2021

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market slipped 0.05 percent on Friday April 9, 2021, with the ASX200 down 3.6 points to 6,995.2 points. Twenty of the Biotech Daily Top 40 stocks were up, 14 fell, five traded unchanged and one was untraded. All three Big Caps fell.

Universal Biosensors was the best, up 18.5 cents or 38.95 percent to 66 cents, with 6.7 million shares traded. Impedimed climbed 16.7 percent; Imugene improved 12.5 percent; Proteomics rose 8.3 percent; Uscom was up 6.45 percent; Oncosil improved five percent; Paradigm was up 3.9 percent; Avita, Orthocell and Resonance rose more than two percent; Clinuvel, Cyclopharm, Dimerix, Genetic Signatures, Next Science, Pharmaxis and Telix were up more than one percent; with Medical Developments, Neuren and Opthea up by less than one percent.

Optiscan led the falls, down 2.5 cents or 9.1 percent to 25 cents, with 718,329 shares traded. Immutep lost 8.1 percent; LBT and Osprey were down five percent or more; Prescient and Starpharma fell more than four percent; Kazia was down 3.2 percent; Antisense shed 2.1 percent; CSL, Cynata, Mesoblast, Nova Eye and Pro Medicus were down one percent or more; with Cochlear, Nanosonics, Resmed and Volpara down by less than one percent.

DR BOREHAM'S CRUCIBLE: 4D MEDICAL

By TIM BOREHAM

ASX code: 4DX

Share price: $1.68; **Market cap:** $494.7 million

Shares on issue: 294,439,795 - with 1,736,255 shares in ASX escrow until August 7, 2021 and 85,536,074 until August 7, 2022

Chief executive officer: Dr Andreas Fouras

Board: Bruce Rathie (chair), Dr Fouras, Lilian Bianchi, Dr Robert Figlin, Lusia Guthrie, John Livingston, Julian Sutton, Heath Lee

Financials (December half 2021): revenue of $150,728 (down 86%), loss of $13.1 million (previously $5.37 million deficit), cash of more than $80 million (post raising)

Identifiable major shareholders: Velocimetry Consulting (Dr Fouras) 22%, Perennial Value Management 5.3%.

What's the difference between a wind tunnel and a set of lungs?

For mechanical engineer Andreas Fouras, the answer is not much. His dabbling in the wind tunnel laboratories at Melbourne's Monash University made him realize there must be a better way to measure air movement through lungs than current imaging methods.

And while you can punch a hole into a wind tunnel to take measurements, it's not so easy to do the same with our bodily bellows.

"I was able to take a couple of ideas and cross pollinate them to develop the technology," Dr Fouras says.

The upshot of Dr Fouras' 'Eureka moment' is the $550 million market cap 4D Medical, which is in the throes of developing the world's first dedicated lung function scanner.

4D already has approved imaging software in the market, which draws on data from traditional x-rays and provides a more granular analysis of where the air is moving (or not moving) in the lungs. This algorithm-based tool allows for an earlier diagnosis of diseases including asthma, chronic obstructive pulmonary disease (COPD) and lung cancer.

"Doctors say 'where have you been, we could have used this 25 years ago'," Dr Fouras says.

4D currently sells its software, XV LVAS, which interfaces with current imaging techniques by uploading the images to produce a "rich high-resolution picture of the lungs".

LVAS stand for lung ventilation analysis software.

In a consortium called the Australian Lung Health Initiative (ALHI), 4D is developing the so-called XVD scanner (the hardware) which offers several advantages over x-rays, computed tomography (CT) and magnetic resonance imaging (MRI).

In March, the Federal Government's Medical Research Future Fund (MRFF) program granted ALHI $28.9 million over five years, to fund the XVD development. 4D promptly raised the requisite matched funding via a $40 million placement and then followed up with a heavily oversubscribed share purchase plan to raise $6 million.

4D's multi-dimensional approach

4D's formal remit is to "supplement or replace existing respiratory diagnostic modalities". Dr Fouras ploughed all his money into the company, which he founded in 2012 as 4DX. He later relocated his family to Los Angeles to focus on the US market.

4D listed on August 7, 2020 at 73 cents a share after an oversubscribed initial public offer. Pre-float, 4D had raised $19 million in equity and $17 million in convertible notes.

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

Dr Fouras says 4D combines the best features of computed tomography (CT), x-rays, magnetic resonance imaging (MRI) and the relatively crude spirometry.

Spirometry - which involves breathing into a handheld device to measure the amount of air expelled - has been around since 1846, which makes them almost as old as lungs. In the US, a spirometry procedure costs around $US70.

X-rays were invented in 1895 and the science is little changed. The two-dimensional technique is still cost-effective and good for imaging most bodily parts, but on a bad day can spew out unacceptable radiation.

CT scans are three dimensional, but also emit radiation and are expensive at around $US525 a pop. The current gold standard, CT scans work better with bones and dense structures, rather than the squishy lungs that contain 80 percent air.

Hammering out the hardware strategy

Founded by 4D Medical, the Australian Lung Health Initiative also includes the University of Adelaide, the South Australian Health and Medical Research Institute, The University of New South Wales and the Royal Melbourne Hospital. A key provision is that 4D has the exclusive rights to manufacture the scanners and market them globally - and in effect reap the commercial proceeds.

The aforementioned MRFF funding will cover the cost of most of the research and development, as well as a proposed marketing application to the US Food and Drug Administration.

4D foots the bill for commercializing the scanners and any other regulatory submissions.

The XVD scanners have several claimed advantages over the current methods. For a start, no contrast imaging agents are needed and the radiation is 100th the level of a CT scan. They're also much quicker - 10 seconds compared with a several minutes - which is especially useful for testing children.

"Anything that requires kids to sit still for a long time is hard," Dr Fouras says. "They can sit and lie and the process is tolerant of them wriggling around a bit during the scan."

The units are also better for patients with bad lung disease. Ironically, these patients often can't be imaged under current methods because they can't hold their breath long enough.

Development is at prototype stage, with the first dinky-di unit expected to be delivered to an Australian hospital by early 2022. 4D then plans clinical trials across seven sites, over the next five years. As per normal practice, the equipment will be provided to lead clinicians in the hope they speak fondly of the product to their learned peers.

The scanners are expected to be marketed more broadly by 2023.

The size of the prize

4D cites a 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 it is no surprise the company is targeting the land of the free and wheezing?

The Australian market, by the way, is worth $US285 million across more than five million procedures.

In the US, the top-tier hospitals account for about two percent of all hospitals, but service about seven percent of the population. This translates to demand for 120 to 130 scanners, a market size of $US300 million-plus.

Dr Fouras expects only one-third of the elite hospitals will adopt the scanners at first, but most eventually will because they don't want to be without a core technology. For lower-tier hospitals doing decent volumes, the economics are enhanced because the device will enable three times as many scans to be done in a day.

Dr Fouras says the 4D technology is also relevant for cancer and heart disease imaging "but the lungs are low-hanging fruit because not much works well in that space".

Sizing up the ASX 'competition'

4D Medical has things in common with the $330 million market cap Volpara Health Technologies, the breast imaging play that's snared about 10 percent of the US market.

Fellow lung imaging house Cyclopharm is developing a better imaging agent called Technegas. The company is kicking goals but remains an old-school nuclear medicine play. Then there's the runaway imager Pro Medicus, now valued at $4.5 billion.

Pro Medicus founder, Melbourne doctor Sam Hupert, is on the 4D's advisory board and has invested in the company.

"Every month I'm on the phone to Sam. He has been very generous and very supportive of the company," Dr Fouras says.

Finances and performance

It goes without saying that 4D is well cashed-up post the raising and the generous government grant. But we'll say it anyway. The placement raised $40 million through the issue of 25.8 million shares at $1.55 each - a 10 percent discount to the 5-day volume-weighted average price, but a meaty 23 percent discount to the average 30-day price.

A share purchase plan aimed to raise $3 million but was upped to $6 million after the company received $30 million in applications. (As a rule, retail investors avoid share plans in droves and have a habit of leaving money on the table).

The placement saw existing holder Perennial Value Management up the ante, while an unnamed US fundie joined the register.

The economics of the 4D business are interesting, to say the least.

Dr Fouras cites a $650,000 "recommended retail price" for the first-generation XVDs and $900,000 for the deluxe second-gen version. The company will charge 'market price' - about $150 - for the XV LVAS scans and glean further service revenue, estimated at 12 percent of the hardware revenue.

Over the life of the device, the scanning revenue is expected to be three to five times the initial hardware revenue. So … get out your calculator …

The company cites an indicative return of $30.3 million on the first 10 scanners sold, over a three-year period.

This is predicated on $23.8 million of scanning revenue and $US6.5 million in upfront revenue on scanner sales and $5 million of income from manufacturing the machines.

The scanning revenue assumes 52,800 scans a year - or just over 14 per machine for every day of the year (weekends and public holidays included).

Overly ambitious? Perhaps so, but bear in mind you can have a patient in and out in about 10 minutes (including pleasantries about the weather).

4D shares closed at a 110 percent premium on the first day and have never looked back, having traded between $1.41 (August 27, 2020) and $2.72 (October 15, 2020).

Speaking of Covid …

As the virus raged, Covid-19 was a curse for the company because its key customers - respiratory doctors - were struggling to stay alive themselves. Now, with around 110 million Americans already vaccinated, the lung docs are making appointments again and clinical trials are resuming recruitments.

Then there's the spectre of millions of recovered Covid-19 patients requiring ongoing testing for any permanent fibrotic lung damage.

"Published data from Sars [severe acute respiratory syndrome, also a coronavirus] shows about one in three patients need ongoing health assessments," Dr Fouras says. "The early data [from Covid-19] suggests the incidence is similar."

"With tens of millions of positive cases, that is a new market created, overnight. To put it simply, if you want to test millions of people for a public health crisis, you want the test to be safe, cheap and sensitive."

Guess who fits the bill?

Dr Boreham's diagnosis:

While 4D would have a viable business even if just the blue-chip US hospitals adopted its wares, Dr Fouras is daring to dream about a much bigger business.

"The current market is being suppressed by the lack of really good solutions," he says. "I don't want to sound crazy because time will tell … but I feel there's an opportunity for us to be 70 to 80 percent of that market. "Maybe we'll have to partner with the big players to deliver that."

An intriguing scenario is a formal tie-up with Pro Medicus, which is not so much a rival but a potential partner to get 4D's imaging to market.

"At the moment we grab images off the equipment and take them to the cloud," Dr Fouras explains. "Pro Medicus' software sits in that space; it could send us images and manage the 'plumbing' to connect us to the hospital."

Focused firmly on the US and its wheezing denizens, 4D still carries out its research and development grunt-work at its St Kilda Road HQ in Melbourne.

"The Australian government has funded our research and Australian investors have funded our business, so it's the right thing to do."

The company respects its Australian roots, but the clear message for investors is that, based on the US potential, 4D could be the next home-grown billion-dollar biotech hero.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never been in a wind tunnel but knows plenty of wind bags.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has co-developed a Tn antigen finger-prick test to detect most cancers, with Lubris Biopharma LLC to assist commercialization.

Universal Biosensors said that the Tn antigen test was developed by researchers at Melbourne's Deakin University and Swinburne University and the New South Wales-based University of Wollongong using Lubricin technology supplied by the Weston, Massachusetts Lubris for its point-of-care test strip diagnostic.

Universal Biosensors chief executive officer John Sharman told Biotech Daily: "The Tn antigen is the body's first response to a healthy cell becoming a cancer cell".

"It does not appear in healthy cells," Mr Sharman said.

In a media release, the company said that the Tn antigen was an O-glycan which was rarely detected in human healthy tissues and was "almost exclusively expressed in many, but not all cancers".

Universal Biosensors said the Tn antigen had been found in cancers including pancreas, colorectal, breast, stomach, lung, prostate, ovary, bladder, cervical and thyroid.

The company said the Tn antigen had been studied in 1,012 patient samples and there were "rarely" false positives, indicating the antigen could be used a biomarker for early cancer screening, determining cancer aggressiveness and tracking cancer progression.

Universal Biosensors said that under the "exclusive perpetual licence", Lubris would supply its artificial human protein Lubricin, or PRG4, for use in the company's finger-prick Tn antigen test and strip-based device point-of-care diagnostic products.

The company said Lubricin was an anti-fouling coating which, when applied to the company's electro-chemical bio-sensor platform technology, enhanced specificity and improved sensitivity and the limit of detection by up to one million times, from micro-molar to pico-molar concentrations.

Universal Biosensors said that with Lubricin, its bio-sensor platform could "accurately detect a signal at 200 picomolar".

Mr Sharman said that the supply agreement for Lubricin would advance its bio-sensor platform and progressed the company's aim of developing biosensors for human healthy, veterinary sciences, wine and the environment.

Universal Biosensors said the supply agreement covered the intellectual property, commercialization, development and manufacturing rights of the Tn antigen in various sample matrices including blood, saliva, urine, beverages, effluent streams and chemical waste using Lubricin.

The company said it would own all resulting intellectual property and products developed under the agreement.

Universal Biosensors said the supply agreement did not contain any minimum purchase requirements or upfront fees but could become non-exclusive if the company was not successful in commercializing a product using Lubricin.

The company said it would pay Lubris a "non-material annual maintenance fee".

Mr Sharman said that "Deakin, Swinburne and [the University of Wollongong] have been working on the Tn antigen biosensor for five years".

"The research and feasibility work has been successfully completed which means [the company's] time to market is significantly reduced," Mr Sharman said. "The next step to develop a commercial product is to ensure the Tn biosensor can be reproduced on our manufacturing line and measured reliably using patients' whole blood."

"Based on our initial feasibility we estimate this could take three years and cost between $5 million and $7 million," Mr Sharman said.

Universal Biosensors climbed 18.5 cents or 38.95 percent to 66 cents with 6.7 million shares traded.

KAZIA THERAPEUTICS

Kazia says the commercial launch of paxalisib for glioblastoma is on schedule with pharmaco-kinetic data supporting a single daily 60mg dose of the drug.

Last year, Kazia said an interim analysis of its ongoing phase II, 29-patient study of paxalisib, or GDC-0084, showed a median progression-free survival of 8.4 months and an overall survival of 17.5 months, outperforming standard-of-care temozolomide which has a median progression-free survival of 5.3 months and median overall compared to 12.7 months for temozolomide (BD: Nov 18, 2020).

Today, the company said the phase II trial's analysis of food effect showed "no significant difference between taking paxalisib with food versus on an empty stomach, allowing for a less restrictive administration schedule".

Kazia said the trial remained ongoing and expected final data within the six months to December 31, 2021.

Kazia chief executive officer Dr James Garner said that the pharmacokinetics results were "extremely useful and encouraging data, as we begin to compile regulatory documentation for paxalisib and give shape to its potential commercial approval".

"These results give us great confidence that we are administering the drug at the right dose, at the right frequency and under the correct conditions," Dr Garner said.

"Moreover, the data helps to confirm the approach that we have taken in the GBM Agile pivotal study," Dr Garner said.

In January, Kazia said it had begun recruitment of between 50 and 200 glioblastoma patients for the phase II/III, multi-drug glioblastoma adaptive, innovative learning environment (GBM Agile) trial (BD: Dec 11, 2019; Jan 17, 2021).

Kazia fell six cents or 3.2 percent to $1.82.

NEXT SCIENCE

Next Science says it will release 72,847,807 shares from ASX escrow on April 18, 2021.

According to Next Science's most recent Appendix 2A new share issue, following the release from escrow, the company will have 194,201,409 shares available for trade on the ASX, with no further shares in ASX escrow.

Next Science was up 1.5 cents or 1.1 percent to $1.375.

IMPEDIMED

The Sydney-based Australian Ethical Investment says it has become a substantial shareholder in Impedimed with 86,592,358 shares or 5.81 percent of the company.

Australian Ethical said that on April 7, 2021 it bought 26,666,667 shares for $1,000,000 or 3.75 cents a share.

Earlier this week, Impedimed says it raised $17.9 million of a possible $18.2 million through the exercise of options at 3.75 cents each, issued as part of its $18.2 million rights offer in April 2020 (BD: Apr 3, 28, 2020; Apr 7, 2021).

Impedimed was up two cents or 16.7 percent to 14 cents with 6.7 million shares traded.

KAZIA THERAPEUTICS

Platinum Investment Management says it has reduced its substantial shareholding in Kazia from 8,532,217 shares (6.76%) to 7,084,856 shares (5.60%).

The Sydney-based Platinum said it disposed of shares between February 11 and April 7, 2021 with the single largest sale 305,344 shares for $498,138 or $1.63 a share.

ANTEOTECH

Anteo says it will pay $500,000 and in-kind contributions over four years to join the Future Battery Industries Co-operative Research Centre (CRC) super anode project.
Anteo said it was one of nine collaborators in the project, which had about $130 million in cash and in-kind contributions and aimed to develop the materials, processes and cell-level technology to advance Australia's battery industry.
The company said it was the "exclusive contributor of silicon composite materials for refinement" for the project.
Anteo said it was entitled to a share of any intellectual property developed as part of the project, based on a percentage of its contribution to the work.
Anteo was up one cent or 4.2 percent to 25 cents with 13.1 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has completed validation and data-based analysis and is finalizing distribution for the US launch of its Covid-19 risk test.
Genetic Technologies said that distribution partner, Infinity Biologix LLC, was completing the "technical interface with their telehealth partner for the commercial availability of the Covid-19 risk test across the US".
The company said the technical interface was mandatory for the submission to US Centres for Medicare and Medicaid Services, which was required prior to the commercial release of the test.
Genetic Technologies did not specify when the launch was expected.
Genetic Technologies fell 0.05 cents or five percent to 0.95 cents with 3.3 million shares traded.

MGC PHARMACEUTICALS

MGC says Nadine Barry will replace joint company secretary Narelle Warren and it plans to issue 70,000,000 performance rights to directors and management.
MGC said Ms Warren had resigned effective from April 7, 2021, and Ms Barry would be joint company secretary with Rachel Kerr.
The company said Ms Barry had three years' experience as a corporate secretary for Chieftain Securities.
MGC said it planned to issue 57,000,000 performance rights to directors and 13,000,000 to key management staff, subject to shareholder approval.
The company said the performance rights would have a share price hurdle and a tenure of service of between 12 and 24 months from April 1, 2021.
MGC said the performance rights would either be Class A or Class B; Class A would vest when the company's 10-day volume weighted average price was equal to or exceeded 8.75 cents; and Class B would vest when MGC's 10-day volume weighted average price was equal to or exceeded 10.5 cents.
MGC fell 0.2 cents or 2.9 percent to 6.8 cents with 5.5 million shares traded.