



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: 4D Medical

By **TIM BOREHAM**

ASX code: 4DX

Share price: 61 cents; **Shares on issue:** 391,374,870; **Market cap:** \$238.7 million

Chief executive officer: Prof Andreas Fouras

Board: Lilian Bianchi (chair), Prof Fouras, Dr Robert Figlin, John Livingston (executive director), Julian Sutton and Dr Geraldine McGinty (Bruce Rathie and Evonne Collier resigned in November 2023)

Financials (December half 2023): revenue \$793,000 (up 63%), research and development concession/government grants \$7.1 million (up 18%), loss \$14.8 million (\$16.3 million deficit previously), cash of \$47.9 million (down 31%).

Identifiable major shareholders: Andreas and Helen Fouras 16.8%, Ryder Innovation Fund 1.2%, Alex and Christine Petrou 0.63%, Damen Diamantoulos 0.79%

The world's only provider of "four-dimensional" lung imaging software, 4D Medical has \$US280 billion reasons to thank the US Congress - and President Joe Biden - for signing off on a clumsily-worded piece of legislation.

The title: 'The Sergeant First Class Heath Robinson Honouring Our Promise to Address Comprehensive Toxics (PACT) Act.'

Passed by Congress last month, PACT addresses a range of respiratory illnesses and cancers borne by veterans exposed to burn pits and other toxic nasties while on service.

Sgt Robinson was an Ohio army medic who died in 2020 from lung cancer, attributed to toxic exposure as a result of his military service in Iraq in 2006 and 2007.

As the name suggests, burn pits are bulldozed holes created on deployment, in which all sorts of items and substances are combusted indiscriminately. The result is plumes of acrid, black smoke.

The tangible monetary support for healing these “invisible wounds of war” is a boon for 4D Medical, which has developed the non-invasive screening tech to identify the resulting respiratory illnesses and loss of lung function.

It's no small matter: 5.5 million US veterans deployed to Middle East conflicts have developed hard-to-diagnose diseases - such as constrictive bronchiolitis - that current methods cannot detect. Of course, not every lung problem is burns-pit related but there's a reverse onus for the medics to show the pits weren't the cause of the ailment.

About the tech

4D's patented XV Technology platform enables doctors to understand 'regional' airflow in the lungs, thus identifying illnesses with greater efficacy as patients breathe.

4D's tools supplement - but do not replace - the images produced by conventional x-rays, computed tomography (CT), magnetic resonance imaging (MRI) and the relatively crude spirometry (breathing into a handheld device to measure the amount of air expelled).

The technology underpins XV Lung Ventilation Analysis Software (XV LVAS), which quantifies lung ventilation. A variant, CT LVAS is - you guessed it - an adjunct to computed tomography (CT).

XV LVAS interfaces with current imaging techniques by uploading the images to produce a “rich high-resolution picture of the lungs”. The fourth dimension (4D) is time. The technology 'sees' what the lung is doing.

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

In August 2022, 4D announced the results of a study for the burns pit disease constrictive bronchiolitis, at the Vanderbilt University Medical Center in Nashville, Tennessee. Preliminary results confirmed 4D's tech could detect the disease - which affects the lung's smallest airways of 1.0mm or less - when CT and pulmonary tests could not.

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

In late November last year, the FDA also ticked off CT-LVAS, thus greatly expanding 4D's potential market reach.

Wind tunnels not windbags

The 4D tech was the brainchild of Prof Andreas Fouras, a mechanical engineer who hung around Monash University's wind tunnel laboratories while everyone else was at the famed student hangout, The Nott (Nottingham Hotel).

By listening to wind movements rather than windbags at the pub, Prof Fouras realized that there was a better way to measure air movement through the lungs than current imaging.

He founded 4D in 2012, having ploughed all of his own money into the venture. The company listed on August 7, 2020 at 73 cents a share after an oversubscribed initial public offer.

Prof Fouras since has relocated his family to Los Angeles to focus on the US market.

It's all happening

Last year ended with a flurry of announcements for 4D Medical.

In November, the company won reimbursement for XV LVAS from the Centers of Medicare and Medicaid Services (CMS) - which is almost as important as FDA approval itself.

The per-procedure reimbursement of \$US299 (\$460) provides a benchmark for private insurers. The reimbursement covers 65 million US citizens aged over 65 years, across 4,000 Medicare certified hospitals.

A week later, imaging house Precision IR said it would offer outpatient screenings across its clinics in Detroit and Memphis, from January 1, 2024. This will result in subscription revenue flowing to 4D Medical.

The company then signed a memorandum of understanding with Philips, which provides imaging equipment to almost half of US veterans' lung screening clinics.

Upgraded to a contract in January this year, the distribution deal provides "an accelerated and expanded pathway for commercialisation of veterans' lung screening products".

In December, the company announced the acquisition of Imbio, a private US outfit specialising in artificial intelligence-based lung and heart analysis.

About Imbio

According to 4D, Imbio is a "recognised leader in lung and heart [artificial intelligence]-driven tech with a focus on providing structural analysis that delivers visual qualitative and quantitative assessments of lung and heart anatomy".

The Imbio purchase added 20 staff, taking 4D's total complement to 160.

"Imbio enables a full-service capacity for lungs: everything you need in medical imaging," Prof Fouras says.

For example, Imbio enables 4D to screen chronic obstructive pulmonary disease (COPD) patients for suitability for valve treatment to improve lung ventilation.

The purchase expands 4D's reach to more than 300 sites, while 4D also plans to sell Imbio products in Australia.

"We are already cross selling to each other's sites," Prof Fouras says.

The deal involved the payment of \$US25 million of cash and contingent earn-outs of up to \$US20 million. These are based on revenue targets and FDA approval of any one of three Imbio products in development.

Scanners for wiggly kids

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

The scanners were launched at Sydney's Prince of Wales Hospital in March 2021, by then Federal Health Minister Greg Hunt.

4D Medical operates on a software-as-a-service model, so facilities don't need the circa \$650,000 scanners to be able to use its imaging.

However, the scanners are useful for high-throughput clinics because they are faster and produce less radiation and don't require contrast agents.

The units are also better for patients with bad lung disease, who can't hold their breath long enough to enable diagnosis.

The scanners should appeal to children's hospitals because the scan only takes four seconds - handy for wiggly subjects - and involves 100 times less radiation.

4D intends to seek a partner for its scanner rollout, with the 'usual suspects' including GE Health, Canon, Siemens and current partner Philips.

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.

The Federal Government's Medical Research Future Fund (MRFF) has extended \$28.9 million of funding over five years, which includes hardware (scanner) development costs and US FDA expenses.

The Australian rollout

In October last year, 4D announced a contract with Australian imaging chain Integrated Diagnostics to use its products. Pilot programs are being carried out at two Integrated Diagnostics sites in the Victorian town of Ballarat.

Integrated Diagnostics has 71 sites on the Eastern seaboard and in Western Australia, while it recently bought 20 clinics in New Zealand.

In 2022, 4D signed a nationwide contract with I-Med Radiology Network, Australia's largest medical imaging chain with more than 250 clinics.

4D products are being used at about 50 I-Med sites, generating revenue.

The automated I-Med platform involves x-ray images being run through 4D's software to enhance their clinical value.

Finances and performance

4D Medical generated \$793,000 of revenue in the December half year, up 63 percent derived from software licences and subscriptions, hardware leases and support.

About 60 percent of the revenue was from Australia, the rest from the US.

The company also pocketed \$2.83 million of Federal Research and Development Tax Incentives and \$4.29 million of government grants.

"There is strong growth in terms of transforming the business and letting go of some development costs which we no longer need," Prof Fouras says.

Imbio chipped in \$183,000 of revenue and a \$28,064 profit, bearing in mind 4D only competed the deal in mid-December.

Assuming ownership for the full half year, 4D achieved revenue of \$3 million and a 14.4 percent decline in adjusted expenses.

Imbio is expected to deliver revenue of \$US6.3 million in the current year and is also expected to be cash flow positive 12 months after integration.

The Imbio purchase of \$US25 million cash (plus earn outs) was funded by a \$35 million placement at 79 cents, a 17 percent discount on the prevailing price with a one-for-two free attached option.

Shortly after listing, 4D shares peaked at \$2.60 and in March 2023 bottomed at 32 cents. The shares traded at around 50 cents in mid-November and had doubled by the end of the month – only to retreat to 56 cents by early March this year.

Other opportunities

4D Medical is girding for the 2025 rollout of a Federally-funded Australian lung cancer screening program.

“The tricky thing is that for every patient you identify with lung cancer, you probably identify 10 patients with something else non-cancerous in their hearts and lungs,” Prof Fouras says. “We can make early screens on those incidental findings much more streamlined, cost effective and reliable.”

In Europe, 4D is “slowly and cost efficiently” moving towards approvals and the company is doing ground work in Japan and China.

“But for the time being we need to spend 90 percent of our effort in the US and Australia and be successful there,” Prof Fouras says.

Dr Boreham’s diagnosis:

With close to 400 million procedures worth more than \$US30 billion taking place globally every year, 4D’s opportunities are - well - breath taking.

Prof Fouras estimates that general private US insurance reimbursement accounts for a chunky 40 percent of the company’s global revenue opportunities and 60 percent of potential profits.

The 4D Imbio products are now available at 300 sites - 80 percent of them in the US. But Prof Fouras says management’s emphasis is on increasing revenue per site, rather than the number of sites.

But as we posited when we last covered the stock in August 2022, the US military’s palpable interest in 4D’s tech looks like shaping the company’s fortunes in the short term.

“Veterans Affairs is a very exciting opportunity in the here and now because reimbursement is not required,” Prof Fouras says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never been exposed to a burns pit but dad’s backyard incinerator came close.