Biotech Daily

Friday April 19, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: STARPHARMA UP 4%; IMUGENE DOWN 9%**

*** DR BOREHAM'S CRUCIBLE: 4D MEDICAL**

*** BREAKTHROUGH VICTORIA $25m KICK-STARTS JUMAR INCUBATOR**

*** BRANDON: PATHIOS RAISES $25m FOR SOLID CANCER TREATMENT**

*** GENETIC TECHNOLOGIES ADSs FOR $3m**

*** WESTERN AUSTRALIA $425k FOR MTP CONNECT, BIOTECH TRAINING**

*** INOVIQ: 'SUB-B2M 85% ACCURATE FOR OVARIAN CANCER'**

*** MONASH LINKS IBS GENES TO HEART DISEASE**

*** PARADIGM RESPONDS TO FDA 'TYPE D' MEETING**

*** EMYRIA REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** AUSTRALIAN ETHICAL TAKES 18% OF SOMNOMED**

*** FIL (FIDELITY) TAKES 13% OF SOMNOMED**

*** SALTER BROTHERS DILUTED TO 7.5% OF NUHEARA**

*** MAX JOHNSTON REPLACES NEUROTECH DIRECTOR WINTON WILLESEE**

MARKET REPORT

The Australian stock market fell 0.98 percent on Friday April 19, 2024, with the ASX200 down 74.8 points to 7,567.3 points. Eleven of the Biotech Daily Top 40 stocks were up, 21 fell and eight traded unchanged.

Starpharma was the best, up half a cent or four percent to 13 cents, with 421,846 shares traded; followed by Orthocell up 3.95 percent to 39.5 cents, with 65,944 shares traded. Medical Developments climbed 3.7 percent; Amplia and Genetic Signatures rose more than two percent; 4D Medical, Compumedics, Immutep, Opthea and Resmed were up by more than one percent, with Clarity and Pro Medicus up by less than one percent.

Imugene led the falls, down 0.7 cents or nine percent to 7.1 cents, with 95.8 million shares traded. Next Science shed 7.45 percent; Syntara and Clinuvel lost six percent or more; Avita, Nova Eye and Polynovo were down more than five percent; Alcidion, Percheron, Prescient and Resonance fell four percent or more; Actinogen, Emvision, Micro-X and Neuren lost more than three percent; Curvebeam, Impedimed, Nanosonics and Proteomics shed more than two percent; Cochlear and Mesoblast were down one percent or more; with CSL and Telix down by less than one percent.

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 screening 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, carried out 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 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, 4D won reimbursement for XV LVAS from the Centers of Medicare and Medicaid Services - which is almost as important as FDA approval itself. The per-procedure reimbursement of $US299 ($460) is a benchmark for private insurers and covers 65 million US citizens aged over 65 years, at 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 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-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, with 60 percent of the revenue from Australia and 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 be cash flow positive 12 months after integration. The $US25 million cash (plus earn outs) purchase 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.

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 says that general private US insurance reimbursement accounts for 40 percent of the company’s revenue opportunities and 60 percent of potential profits.

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

When we last covered the stock in August 2022, the US military’s palpable interest in 4D’s tech looked 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.

JUMAR BIO-INCUBATOR, BREAKTHROUGH VICTORIA, CICADA INNOVATIONS

Jumar Bio-incubator says it has received an initial $25 million grant from Breakthrough Victoria to open a Melbourne facility to support “early-stage” biotechnology ventures.
In a media release Jumar said it was based at CSL’s new Melbourne headquarters and operated by Sydney’s Cicada Innovations, an incubator that had supported more than 400 companies with a combined funding raised of more than $2.5 billion.
The incubator said its opening was supported by an initial investment of $25 million from the Victorian Government’s Breakthrough Victoria, with founding partners CSL, the Walter and Eliza Hall Institute and the University of Melbourne to provide “in-kind” contributions of about $45 million over 10 years.
Jumar said it would be “a world-class hub for biotechnology innovation translation, research commercialization, and talent development that will help to progress discoveries towards real-world patient treatments”.
The incubator said its facilities would “facilitate research commercialization and innovation translation by providing scientists and researchers with access to [the] knowledge and skills needed to run successful [bio-medical] and [biotechnology] companies”.
Jumar said 16 ventures had received residency, including Arovella to develop its ALA-101 CD-19, invariant natural killer T-cell therapy platform for blood cancers.
The incubator said the other applicants included Denteric and its vaccine for periodontal gum disease, Symex Labs and its wearable ovulation monitoring device, Tessara Therapeutics and its mini-brains for drug discovery in neurological disorders.
Jumar said its facility was officially opened on April 16, 2024.

BRANDON CAPITAL, PATHIOS THERAPEUTICS

Brandon Capital says the Oxford, UK-based Pathios Therapeutics has raised $25 million to begin human trials of its PTT-4256 for the treatment of solid cancers by 2025.
Brandon Capital said Pathios was developing an orally-dosed immunotherapy called PTT-4265 focused on the inhibition of GPR65, a target that was genetically associated with a range of immunologically-mediated diseases.
The company said other investees were Bristol Myers Squibb and Canaan Partners.
Brandon Capital said the company would use the funds to take PTT-4265 to clinical trials in advanced solid cancers by the end of 2024 and expand its executive leadership team.
Pathios chief executive officer Prof Stuart Hughes said the funding would allow evaluation of “our scientific hypothesis in the clinic, providing the opportunity to illuminate the activity of this novel target in humans for the first time”.
Pathios Therapeutics is a private company.

GENETIC TECHNOLOGIES

Genetic Technologies says it has a “definitive agreement” to raise $US2 million ($A3.14 million) through the sale of 1,000,000 American depositary shares at $US2.00 each.
Genetic Technologies said the American depositary shares (ADSs) were equal to 30 Australian shares, and it would issue 1,000,000 unregistered warrants in a private placement, exercisable at $US2.00 per ADS within five years
The company said the proceeds would be used for Genetype sales and marketing in the US, Europe and South East Asia, and its breast and ovarian cancer risk test.
Genetic Technologies said HC Wainwright & Co was managing the offering which was expected to occur on or around April 22, 2024.
Genetic Technologies fell 3.5 cents or 20 percent to 14 cents.

WESTERN AUSTRALIA GOVERNMENT, MTP CONNECT

The Western Australia Government says it has granted $425,000 to support industry training in the health and medical life sciences sector.

A media release from the Western Australia Minister for Innovation, Science and Medical Research Stephen Dawson said the Government had awarded MTP Connect $125,000 to subsidize its 2024 industry training programs and $300,000 to Perth Biodesign to operate its digital health solution and medical technology course.

In a separate media release, MTP Connect said the funding would support several subsidized courses in medical device quality management systems and good manufacturing practice principles.

The Federally-Funded industry organization said the courses would be held with its partners the Melbourne-based Seerpharma and Melbourne's Centre for Biopharmaceutical Excellence.

MTP Connect said the training would be coordinated through the Western Australia Life Sciences Innovation Hub, a partnership between MTP Connect, the Western Australian Government and Perth's University of Western Australia.

MTP Connect chief executive officer Stuart Dignam said the training was a continuation of its "popular workforce and skills programs rolled out in Western Australia and nationally over the last few years".

"Medical science is rightly considered a priority sector of the Australian economy but achieving our ambitions in biomedical manufacturing are dependent on the skills of the workforce," Mr Dignam said.

"We are delighted to be working with the Western Australian Government to support additional workforce development in advanced manufacturing of medical products which will accelerate the growth of the state's life sciences sector and power the creation of new jobs and economic diversification," Mr Dignam said.

"This is all part of our efforts to continue building an industry-ready workforce with the skills and capacity to keep pace with the demands of a rapidly changing life sciences sector - for now, and the immediate future" Mr Dignam said.

INOVIQ

Inoviq says its Sub-B2M-CA125 blood test identified 85 percent of 334 ovarian cancer assay samples, with 76 percent sensitivity and 94 percent specificity.

Inoviq has previously said that Sub-B2M was an engineered protein that detected the pan-cancer biomarker Neu5Gc (BD: Sep 16, 2022).

In 2022, the company said a study confirmed the presence of Sub-B2M's binding target, Neu5Gc, in tissue sections including breast, prostate, cervical, ovarian, colorectal and skin, which it said supported its program to develop tests to monitor breast, ovarian, and other cancers (BD: Jul 16, 2022).

Today, Inoviq said a study of its test with the existing diagnostic monoclonal antibody CA125 showed less than five percent variability within assays and less than 10 percent variability between assays using less than four units of CA125 per millilitre of serum.

Inoviq chief executive officer Dr Leearne Hinch said "with analytical validation complete, we want to refine our test to see if we can further improve the test performance before moving to clinical validation".

Inoviq chair David Williams said the company was "seeking to demonstrate our Sub-B2M technology can be a superior detection reagent to improve the performance of multiple cancer biomarker tests".

Inoviq fell 11 cents or 17.2 percent to 53 cents.

MONASH UNIVERSITY

Monash University says it has found a link between a genetic predisposition to irritable bowel syndrome and various cardio-vascular diseases.

Monash University said the study analyzed data from 24,735 people with irritable bowel syndrome and 77,149 symptom-free individuals and found four genomic regions, including two previously unidentified regions, associated with increased susceptibility to irritable bowel syndrome and the four were implicated pathways central to gastro-intestinal motility, intestinal mucosal integrity and circadian rhythm regulation.

Monash said researchers found “a remarkable link between irritable bowel syndrome predisposition and various cardiovascular ailments, encompassing hypertension, ischemic heart disease and angina pectoris”.

The University said that irritable bowel syndrome heritability, or the weight of genes in determining one’s risk of disease, might be higher than previously thought.

Monash said irritable bowel syndrome (IBS) was “one of the most prevalent gastro-intestinal disorders globally, affecting up to 10 percent of the population, with a disproportionate impact on women”.

Monash said the research, titled ‘Rome III criteria capture higher irritable bowel syndrome SNP-heritability and highlight a novel genetic link with cardiovascular traits’ was published in Cellular and Molecular Gastroenterology and Hepatology, with the full article available at: https://www.cmghjournal.org/article/S2352-345X(24)00093-6/fulltext.

Lead researcher, Monash University’s Dr Leticia Tavares said "although we're yet to conclusively pinpoint specific genes and mechanisms, these findings provide novel insights into IBS pathophysiology, highlighting potential therapeutic targets”.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has responded to its US Food and Drug Administration type D meeting to progress its phase III trial of pentosan polysulphate sodium for osteoarthritis.

According to the FDA, type D meetings were “focussed on a narrow set of issues, addressing no more than two issues that did not require input from more than three disciplines or divisions”.

In 2022, Paradigm said it had dosed the first of 930 patients in its randomized, double-blind, placebo-controlled phase III trial of zilosul, or injectable pentosan polysulphate sodium (PPS) for knee osteo-arthritis (BD: Jan 16, 2022).

Today, the company said the items addressed included a “minimal effective dose justification, additional non-clinical studies completed to good laboratory practice standards to address previously noted adrenal findings, draft clinical trial protocol, and revised safety monitoring and mitigation plan”.

Paradigm said its response included data from five non-clinical studies, its phase II trial, and the available data from the 600 patients dosed in stage one of the phase III trial.

The company said the data justified a dosing regimen of 2.0mg/kg twice weekly for six weeks, and it had submitted a draft of the trial protocol for FDA review and comment.

Paradigm said that, subject to FDA clearance, it would continue enrolling its phase III trial, with clinical trial sites planned to commence preparation activities by June 30, 2024 to “move the phase III program forward as quickly and efficiently as possible”.

Paradigm chief executive officer Paul Rennie said “this is important progress for Paradigm as we deliver a significant amount of new data to the FDA for review to progress to the next stage of the phase III [osteoarthritis] program”.

Paradigm fell 0.4 cents or 4.2 percent to 9.1 cents with 2.5 million shares traded.

EMYRIA

Emyria has requested a trading halt “pending the release of an announcement by the company regarding a capital raising”.
Trading will resume on April 23, 2024, or on an earlier announcement.
Emyria last traded at 1.3 cents.

SOMNOMED

Australian Ethical says it has increased its holding in Somnomed from 13,835,756 shares (12.74%) to 24,530,768 shares (18.03%).
Australian Ethical said on December 20, 2023 it bought 500,000 shares for $211,599 or 42.3 cents a share, and on April 10, 2024 it bought 10,195,012 shares at 21.0 cents each.
Last week, Somnomed said its institutional one-for-1.01 rights offer at 21.0 cents a share raised $7.5 million, with a $16.8 million retail offer to follow (BD: Apr 10, 2024).
Somnomed was up 1.5 cents or 7.3 percent to 22 cents.

SOMNOMED

The Hong Kong-based FIL Limited (Fidelity) says it has increased its substantial holding in Somnomed from 8,349,794 shares (8.43%) to 17,800,389 shares (13.08%).
FIL said that between December 19, 2023 and April 10, 2024 it bought shares in nine transactions at prices ranging from 21.0 cents to 42.25 cents (see above).

NUHEARA

Salter Brothers Emerging Companies Ltd says its 20,000,000 share-holding in Nuheara has been diluted from 8.97 percent to 7.45 percent in a capital raise.
The Melbourne-based Salter Brothers said that between October 19, 2023 and April 15, 2024 its share-holding was diluted due to the issue of shares by Nuheara.
Earlier this month, the company said it had “firm commitments” to raise $1.85 million in a placement at six cents a share to support a review “to evaluate and determine its future strategic options” (BD: Apr 9, 2024).
Nuheara was in a suspension and last traded at 8.1 cents.

NEUROTECH INTERNATIONAL

Neurotech says Max Johnston has been appointed as a non-executive director, replacing retiring Winton Willesee, effective from today.
Neurotech said Mr Johnston had been chief executive officer of Johnson & Johnson Pacific for 11 years, and a director of Polynovo, Medical Developments, Tissue Repair, Enero Group, chair of Probiotec and Auscann and interim chief executive officer of Polynovo and was currently a director of Inoviq.
The company said it would issue Mr Johnston 1,000,000 options exercisable at 16.0 cents each within two years, as an incentive, pending shareholding approval.
Neurotech thanked Mr Willesee for his “valuable contributions” to the company.
Neurotech was up 0.1 cents or 1.05 percent to 9.6 cents with 3.5 million shares traded.