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OCTOBER 2022

HEALTH & BIOTECH

YOUR BEST SHOT

The biotech investments turning health into newfound wealth

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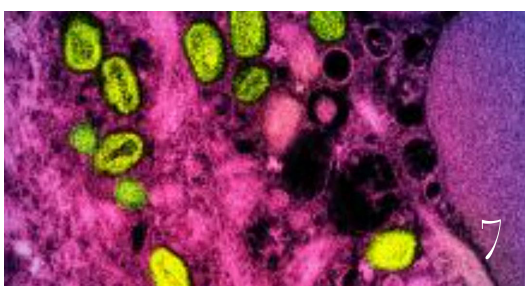

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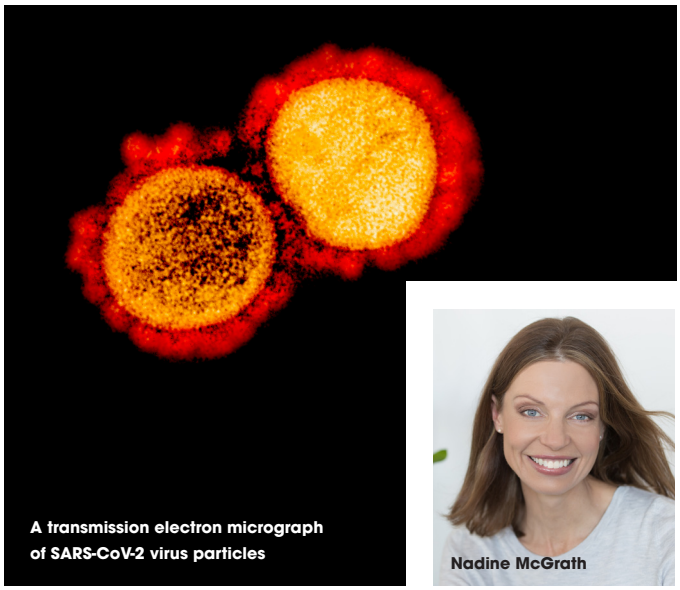
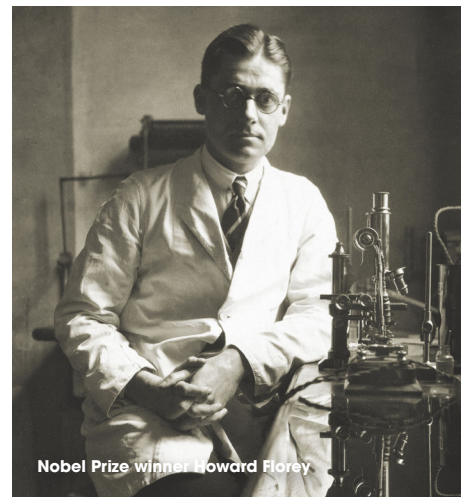


A transmission electron micrograph of SARS-CoV-2 virus particles

Nadine McGrath

HEALTH / BIOTECH



Nobel Prize winner Howard Florey

Health & Biotech

What's not to love about an industry as brilliant as the minds and the passion of the people who drive it?

NADINE MCGRATH

Healthcare and medical research is one of Australia's strongest research areas and of enormous global importance as the world's population – in particular the ageing population – continues to grow.

Australian researchers have a proud track record in medical science discoveries resulting in multiple Nobel Prizes in areas of Physiology or Medicine.

Our impressive list of medical discoveries and developments include the bionic ear, penicillin, spray on skin and the cervical cancer vaccine.

In 2020, when the world was brought to a standstill by the Covid-19 pandemic, the worldwide race to find a preventative vaccine and effective treatment began. All eyes were on the biotechnology sector with Pfizer, AstraZeneca, and Moderna becoming household names.

In the face of a health crisis like Covid-19 and the ongoing fight against chronic disease, the Australian government's commitment to support and grow a vibrant biotechnology sector through R&D tax incentives, clinical trials, and a skilled workforce remains crucial.

Underpinning that future growth is Australia's biotechnology representative body AusBiotech, with its decade-long blueprint to support the industry.

AusBiotech reports a 40% growth in company numbers in the past two years. That makes the sector one of the fastest rising in Australia, providing contributions of social good alongside potential benefits of a business including growth.

However, the sector is not without challenges. Biotechnology is based on science – a field where discoveries can take years to reach clinical trials and commercialisation.

> "AusBiotech reports a 40% growth in company numbers in the past two years"

The landscape is littered with ideas that didn't work, and where luck plays a huge role.

"Most Nobel Prize winners look on themselves as being extremely fortunate," Australian Howard Florey, who was involved in the development of penicillin, noted. "We happened to have hit an antibiotic which worked in man."

And while the list of ASX health stocks includes huge names like CSL, ResMed and Cochlear, it's worth remembering every big company started small, with the seed of an idea that has grown through support, thought leadership and solid scientific work.

There's a growing number of small and midcap biotechs on their way up through the ranks, and Stockhead's here to support and share their journey for many years to come.

EDITORIAL

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NEXT ISSUE

Investor Guide: Energy 2023
Date: October 2022

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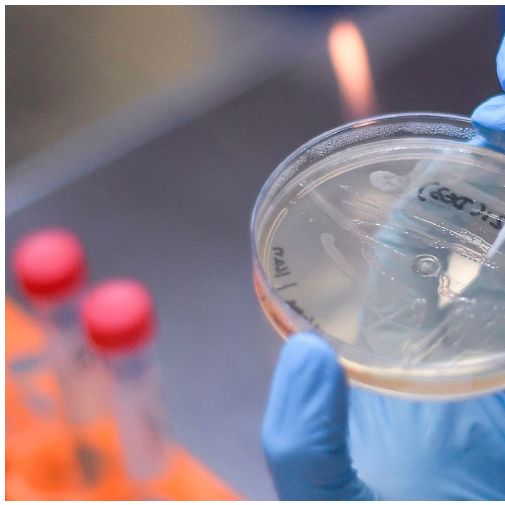
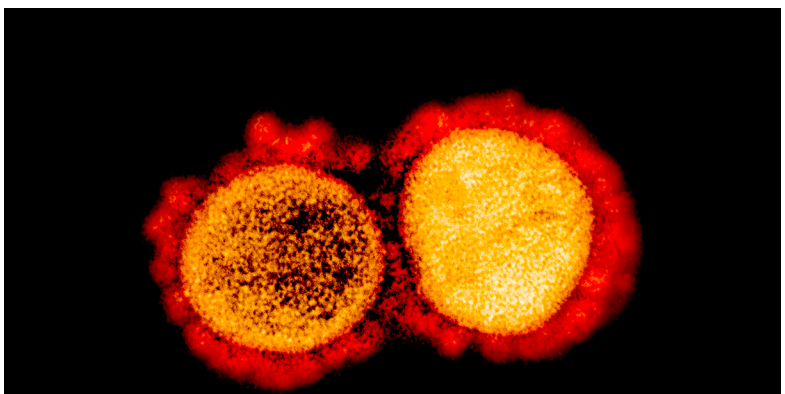
EDUCATION OVERVIEW

Dissecting the biotech boom


Scott Power




National Institute of Allergy and Infectious Diseases (NIH/NIAID), shows a transmission electron micrograph of SARS-CoV-2 virus particles

These 5 life sciences themes are the key to reshaping our health – and our economy

SCOTT POWER

Coming from a medical family, I've always had an interest in healthcare and life sciences; so naturally when starting as an analyst with Morgans more than 25 years ago, I gravitated towards the sector.

I've seen exceptional technology and health care businesses over that time. Not all have been commercial successes. However, from heart assist devices and rapid diagnostics; to therapeutics and treatments saving lives and improving well-being, Australia has developed an enviable global reputation as a biotechnology leader.

Also known as life sciences, biotechnology concerns the study of living organisms including microorganisms, plants, animals, and human beings.

I view the sector as being split into four different buckets:

- Pharmaceuticals (including drug discovery)
- Medical devices
- Health services (including pathology and radiology)
- Health technology (machine learning and software innovation)

While resources have historically contributed to Australia's high level of economic growth, life science has now become a major player in our economy.

The Australian life sciences ecosystem is worth more than $8 billion in annual revenue with annual growth projected at 3% from 2021-2026.

Globally the sector is projected to be worth around US$3.44 trillion by 2030, and the Federal Government is ensuring Australia is at the party.

Australia's medical and biotechnology sector has benefited from a multimillion-dollar windfall of government funding along with substantial tax breaks for companies investing in R&D.

The R&D tax incentive program is probably the most efficient and effective program to encourage non-dilutive funding into the sector. It's a program that should be maintained and enhanced.

Health and life science is considered one of Australia's strongest research sectors to be fostered by federal, state, and territorial governments.

High profile examples of Australian biotechnology developments include the Cochlear implant now being sold by Cochlear globally and Resmed's (RMD) CPAP device helping many people with sleep apnoea.

Other home-grown technologies occupying a spot on the world stage include a disinfection system for ultrasound probes by Nanosonics (NAN) and Polynovo's (PNV) synthetic absorbable polymers.

Healthcare has outperformed the ASX 200 index in 8 of the last 10 years. The CAGR over the last 10 years for healthcare is 18.1% compared to the ASX 200 at 12.9%.

As of June 30, 2022, there were 156 companies with a market capitalisation of $206 billion on the ASX, according to Bioshares. The top 10 represent 94% of market cap, including world-renowned blood products giant CSL (CSL), hearing solutions company Cochlear (COH) and diagnostics provider Sonic Healthcare (SHL).

But every large company started as a small one, which is one of the exciting aspects of Australia's health and biotechnology sector.

> "Globally the sector is projected to be worth around US$3.44 trillion by 2030"

Australia also has a burgeoning medicinal cannabis sector with 16 stocks listed with a market capitalisation of $840 million. Medical cannabis is one of the world's fast-growing industries as scientists discover ways to use the plant's medicinal compounds.

Spend on legal cannabis is


Biotech research


Workers on the production line building new Cochlear Implants

QUICK FACTS

- Australia's life science ecosystem worth more than $8 billion in annual revenue.
- Annual growth projected at 3% from 2021-2026.
- 5 key themes underpin Australia's burgeoning health and biotech space.
- Australia has a growing medicinal cannabis sector with 16 stocks listed.

forecast to be worth more than US$60 billion by 2024, as regulations worldwide catch up with the demand. Australia is considered one of the most progressive.

In 2020 a significant change in Australia's medicinal cannabis market occurred when TGA regulations changed to allow medicinal cannabis products to be sold as an over-the-counter medicine under the TGA's S3 schedule.

Medicinal cannabis is currently only available under the SAS-B scheme, where patients must obtain a prescription from a registered doctor (S4 medicinal cannabis product).

Investors eyeing Australia's health and biotech space should consider 5 key themes which underpin this burgeoning sector.

1. M&A activity

Costs to develop pharmaceutical drugs and medical devices are high, so it's no surprise the health and biotechnology sector is ripe for merger and acquisitions.

Larger pharmaceutical and medical devices companies often take over smaller ones, which they may see as either a competitor or offering a value add. When it comes to M&A activity in Australia, there's always a deal on the table.

2. Hospitals without walls

Remote monitoring of various health conditions and consultations through telemedicine is becoming a modern phenomenon.

The shift to hospitals without walls has been fast-forwarded by the Covid-19 pandemic. Health companies are increasingly developing devices enabling monitoring and diagnostics beyond the confines of hospitals and medical facilities.

3. Personalised medicine

Personalised medicine uses a patient's genetics, history and other factors for prevention, diagnosis, monitoring and treatment of disease. Therapies, for example, can be matched to specific patient types to achieve optimal outcomes. Personalised medicine has become an increasing focus of biotechnology globally.

4. Value of medical data

Simply, medical data has currency. Unlocking insights from health data sets is providing significant value to patients, healthcare providers, insurance payers, pharmaceutical companies, and medical device companies.

Benefits are widespread including operational savings in hospitals and health care networks, greater disease understanding and earlier detection, better treatment outcomes, more efficient clinical trials leading to reduced time to market.

5. Improving clinical trial efficiency

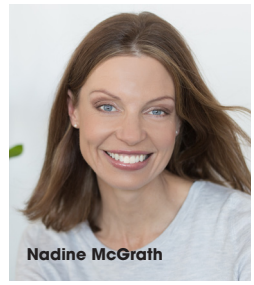
Clinical trials are expensive to recruit, run and interpret. Contract research organisations (CROs) worldwide help with recruitment of patients into trials.

There are always issues around recruitment – it might take longer or they don't always get the right patients. Big pharma seeks innovation and efficiency in clinical trials.

AusBiotech plots a path for prosperity

AusBiotech chief Lorraine Chiroiu on the groundbreaking new blueprint for chasing biotech growth over the next decade

NADINE MCGRATH


Nadine McGrath


Biotech research


AusBiotech CEO Lorraine Chiroiu

It has been a milestone year for life sciences in Australia, with the industry's representative body AusBiotech launching the Biotechnology Blueprint: A Decadal Strategy for the Australian Biotechnology Industry.

AusBiotech CEO Lorraine Chiroiu says the substantial blueprint is considered the most significant and comprehensive strategy ever developed for the Australian biotech industry by its members.

"Industry leaders worked on the blueprint and more than 300 organisations actively helped shape it," said Chiroiu.

The blueprint offers a framework for further developing the local life sciences industry over the next decade.

It has three overarching goals, including a more mature and vibrant ecosystem, an increased local and global standing, and becoming a more positive contributor to Australian prosperity.

Among the eight recommendations are calls for governmental support, reorienting commercialisation towards academia and industry partnerships, specific programs to help SMEs grow, and bolstering capital flow to the sector by $1 billion annually.

"We've ended up with a high-level document of what the industry wants to achieve over the next decade and it also goes right down to targeted tactics and what we need to see happen," she said.

According to AusBiotech figures, the sector is one of Australia's fastest growing and has grown 43% since 2019.

The number of companies undertaking biotech research and development has surged by 40% since 2019.

Employment in Australia's biotech companies has also expanded, increasing 21% compared to 2019, from approximately 87,397 people to more than 105,000 in 2022.

"The Covid-19 pandemic has catapulted the sector into the global spotlight and given it a really strong boost," said Chiroiu.

However, the industry is unique to others, particularly the length of time needed to get a product to market, she stresses.

"It's rare in the business world to have such a long-time pre-revenue and that makes it similar to the mining industry," she said.

"But the mining industry is extracting rather than inventing so biotech stands as a contributor of social good from a health perspective along with business benefits.

"Eighty percent of our companies are sitting pre-revenue and are still early in their journey."

"The pandemic has catapulted the sector into the global spotlight and given it a really strong boost"

QUICK FACTS

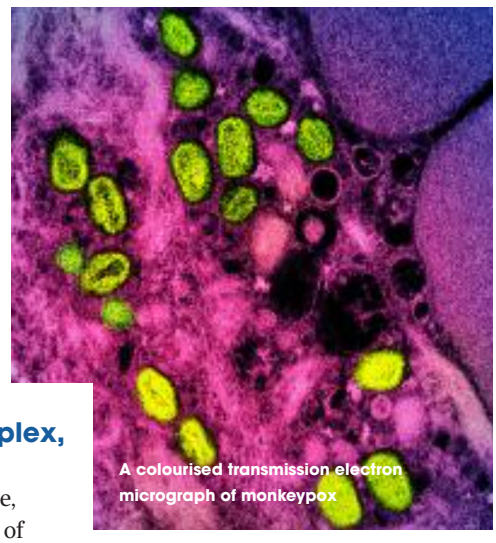
- AusBiotech's blueprint is considered the most significant and comprehensive strategy ever developed for the Australian biotech sector.
- Australia's biotechnology industry has grown 43% since 2019 while employment has increased 21%.
- Biotech sector contributes to social good but has its challenges with companies often spending a long-time pre-revenue.

MARKET INSIGHTS

6 biotech sector traps to avoid

As with other tech stocks, the ASX-listed biotechs have had a bumpy ride. But investors who follow some simple rules stand to steer clear of road hazards over the longer term.

Tim Boreham



A colourised transmission electron micrograph of monkeypox

TIM BOREHAM

After surfing a wave of Covid-era sentiment in 2020 and the first half of 2021, the global biotech sector subsequently suffered one of its worst sell-offs in history - and ASX-listed life sciences stocks have not been immune.

Prominent biotech CEO Chris Behrenbruch, the chief executive of Telix Pharmaceuticals, sums up the conditions this way:

"It's been pretty damned brutal. You would think the whole planet has forgotten about the fact that biotechs saved millions of people (during the pandemic)."

The good news is that investors tentatively have returned and much-needed capital is flowing. Capital raisings include eye disease specialist Opthea's novel and record-breaking $300 million effort.

With bargains and value traps abounding in equal measure, here are the six golden rules of what not to do when investing in the sector:

1: Hang on for regulatory approval

According to Medicine.net, there's a one in 5000 chance of a preclinical drug being approved – and it takes an average of 12 years.

The blue sky potential tends to be valued more highly than the hard slog of bringing a drug to market. Share valuations might be higher after milestones such as clinical results, or collaborative alliances with deep-pocketed partners.

2: It's all about drugs

Wrong. Roughly half of the ASX life sciences sector is perfecting better imaging to detect diseases or novel devices to make life easier for patients or clinicians.

Nanosonics struck global success with its novel device to sterilise surgical probes, while Telix Pharmaceuticals won US approval for its isotope to diagnose prostate cancer.

Devices and diagnostics usually offer a shorter route to market than drugs with a higher chance of success, typically with lower blockbuster potential.

3: Bet on a big pharma takeover

Most ASX biotechs fancy themselves as a takeover target for the pharma giants, who are loaded with cash and running short of new blockbuster drugs.

It won't happen – 99 per cent of the time at least. More likely is a development deal involving an upfront cash injection and milestones. Takeovers are the exception rather than the rule.

4: Only invest in complex, cutting-edge tech

Yep – the ones with the dense, acronym-laden explanations of theoretical mechanisms of action. Usually the boffin, rather than a commercial guy, is firmly in charge.

As with other avenues in life, the 'keep it simple' approach typically is the winner. For instance, Rhinomed has gained global sales traction with a simple nasal device to make collecting samples for rapid antigen tests easier.

5: Play the Covid game

The pandemic worked wonders in terms of highlighting the life-saving work of biotechs and also directly helped to develop the telehealth and digital medicine sectors.

Pathology labs such as Australian Clinical Labs and Sonic Healthcare also directly benefited and sanitiser companies cleaned up for a while.

Otherwise, the market for rapid antigen tests is hotly contested and a Covid 'cure' has proved elusive.

6: Bet it all on black

As with other speculative sectors, a portfolio approach is more prudent than betting it all on an individual stock.

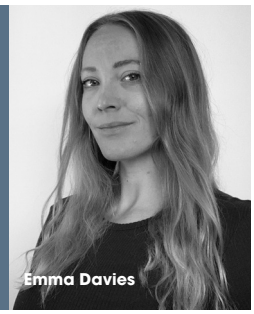
While there are plenty of examples of shares delivering manifold gains, there are also many instances of companies going from hero to zero overnight after unfavourable trial results.

In a basket of, say, a dozen stocks, two or three winners can more than compensate for the inevitable plodders.

■ *This column does not constitute investment advice*

How to catch the biotech bounce back

A re-capitalisation cycle is imminent, says Bell Potter healthcare analyst John Hester, and health and biotech stocks with cash in the bank will sit ahead of the pack


Emma Davies

EMMA DAVIES

The biotechnology sector has been hit hard this year. A market correction saw stock valuations decimated despite making progress in the clinic or commercialisation – but things are looking up.

Bell Potter healthcare analyst John Hester says regardless of whether it's the start of a recovery, or just a bounce off the bottom, now is the time to focus on companies who've got cash in the bank.

Normally, in the absence of adverse macroeconomic conditions, biotechnology companies can raise money if they've got good management and some strong early-stage clinical data from phase one or phase two trial.

"I absolutely see the biotech market returning from the last quarter of this year, as the dust settles on interest rate rises, and we get back to normal business conditions," Hester said.

"In fact, we're already seeing strong signs of that, the **Paradigm Biopharmaceuticals (PAR)** ~$60 million raise from a few weeks ago is one example, and **Mesoblast (MSB)** recorded a $45 million raising recently as well.

"Both these companies have outstanding drug candidates in areas of high unmet need, and both are in relatively late-stage trials, so that market is absolutely beginning to re-open."

Hester says companies that raised money in 2020-2021 are sitting pretty, pointing to **Avita Medical (AVH)** and **Polynovo (PNV)** as examples.

"Avita is still burning cash at quite a rate, but it's held up really well because it's got plenty of cash in the bank, and also a bit of revenue," he said.

"Polynovo doesn't have a lot of cash in the bank but, similarly, it does have strong revenue growth.

"In contrast, a stock like **Aroa Biosurgery (ARX)** which has ~$50 million in the bank, is not yet cashflow positive, but has held up really well.

"Cash is at a premium and you just want to avoid a situation where the market perceives that you need to raise money in this environment."

Cash is king, Hester reiterates, because while good results go a long way in maintaining a company's market capitalisation, in the absence of that, what is needed most is a strong balance sheet.

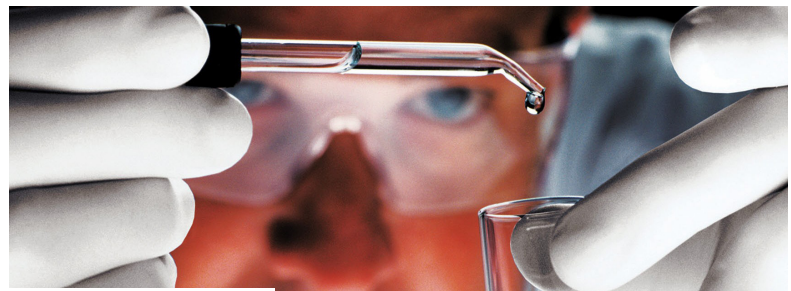
> "I absolutely see the biotech market returning from the last quarter of this year, as the dust settles on interest rate rises"

MARKET INSIGHTS

Invested in health

Demand will never cease for a market class that offers long-haul investors much more than just financial returns

DAMON BIRRELL




Damon Birrell

Just a few years ago, it's fair to say biotech and medical research weren't exactly the hot topic of dinner table conversations. Cue the pandemic and it became almost impossible to traverse a conversation without a mention of Delta or Omicron, mRNA vaccines, Pfizer or Moderna. The spotlight was firmly on the sector and the world was watching.

Globally, Australia has long been recognised for its biotech strength, and this was again demonstrated at the start of the pandemic. Australia was the first country to isolate and sequence the virus, sharing this important genetic information with countries and pharmaceutical companies and underpinning the design and development of the vaccines that followed.

Commercially, home grown success stories like CSL and Cochlear are well known, but more often success comes in the form of early acquisition or licensing of Australia's innovations by Big Pharma before these opportunities reach the public market, leading to them being developed and commercialised offshore. There are several reasons for this, but one key factor is the depth of capital required to take a drug through development to market. The US alone represents around 50 per cent of the total global pharmaceutical market by expenditure, fuelling a burgeoning biotech sector well positioned to respond to public demand for access to the very best and latest medicines.

In parallel, Australia's biotech sector has experienced rapid growth over the past decade, and will continue to do so, due to several factors unique to the sector. The first is that biotech is ultimately recession-proof and has continued to deliver stable returns over the long-term. Like any investment class, biotech is subject to the same forces that drive overall market sentiment, like the recent drop we have seen across all sectors driven by the pandemic, war between Ukraine and Russia, and inflation concerns. However, while biotech experiences the same market fluctuations, it is rare for the sector to 'bust' due to the unwavering demand for medicines and healthcare services, irrespective of the macroeconomic environment.

The second, is that on all measures, Australia ranks in the top four to five countries globally in terms of our medical research and biotechnology capabilities, resulting in a similar level of medical discoveries. With strong, long-term commitment to the sector from successive governments, this level of innovation and output will only increase in the coming years as the impact of the newly minted $20 billion Medical Research Future Fund starts to generate research outcomes.

Thirdly, investors are increasingly focusing on sectors where their investment dollars have a positive impact on society, and biotech is a sector well positioned to meet the environmental, social and governance considerations of the modern institutional and retail investor. One of the really appealing aspects of biotechnology as an investment class is that when a portfolio company outperforms, success is correlated with the fact that their therapy, device, diagnostic or service is positively impacting the lives of patients.

In terms of timelines to market, the inherent complexities in developing medical technologies can mean biotech takes longer to generate investment returns compared to other assets. While in many cases this is true, I would compare this to an investment class very familiar to Australian investors – the mining sector – where the timeline from initial allocation or exploration licence to when the resource is harvested and revenues commence can average around 10+ years, if successful.

This compares favourably with biotechnology, where a drug can take between 7-15 years to reach approval, and if successful, also delivers positive healthcare outcomes.

> "Investors are increasingly focusing on sectors where their investment dollars have a positive impact on society"

FEATURED COMPANIES

As Australia's biotechnology body AusBiotech releases its ten-year plan to boost the sector, investors stand to make big returns from one of the nation's fastest growing industries. Meet the companies at the forefront of our pursuit of health and wealth.

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DR TIM OLDHAM
CEO & MANAGING DIRECTOR

ADALTA

(ASX:1AD)

- **Company Name:** AdAlta
- **Company ASX code:** 1AD
- **Key areas:** Biotechnology, antibodies, i-body technology, fibrotic diseases, immuno-oncology
- **Key Personnel:** Dr Tim Oldham, CEO & Managing Director | Dr Claudia Gregorio-King, Vice President, Clinical Product Development | Dr Patrick James, Director Product and Platform Development.
- **Locations:** Victoria, Australia
- **Market Cap as of 15/09/22:** $16.02M
- **52 Week share price as of 15 September:** $0.042 - $0.099
- **Company Website:** adalta.com.au

COMPANY PROFILE

We have heard plenty about antibodies these past few years – but one Australian biotech company is going a step beyond in the fight against today's most challenging and pervasive medical problems.

Antibodies are natural proteins that react when a foreign agent, such as a virus, enters the body. They bind to these invasive species, eliminate them, and strengthen the body's response to future infections.

AdAlta is a clinical stage drug development company that uses its i-body technology to create new medicines to treat diseases unserved by traditional antibody technologies. This includes fibrotic diseases and cancers.

The novel technology, currently being used in clinical trials of AdAlta's lead drug AD-214, is described as "producing next generation human protein therapeutics".

"The i-body is a human protein scaffold, engineered to mimic the structure and binding properties of very small, 'single domain' antibodies, originally found in sharks," says Dr Tim Oldham, AdAlta CEO and managing director.

"AdAlta's engineering enables the i-bodies to engage and bind in unique ways with the particular target that is causing the disease.

"The result is a range of unique drug candidates capable of interacting with high selectivity, specificity and affinity with previously difficult to access targets such as G-protein coupled receptors (GPCRs), implicated in many serious diseases."

Phase I clinical studies of Adalta's lead asset, AD-214, for intravenous use in fibrotic diseases were successfully completed last year. The company is now developing a more patient-convenient and cost-effective inhaled version, specifically for Idiopathic Pulmonary Fibrosis (IPF).

"IPF is degenerative and fatal. It affects about five million people globally, and claims more lives annually than prostate cancer and almost as many as breast cancer," Dr Oldham says. "It is an important market because IPF is life threatening: most patients survive less than four years from diagnosis, despite two currently available therapies generating about $3 billion per year in sales."

In addition to IPF, AdAlta has also generated data in the areas of eye and kidney fibrosis, creating multiple potential partnership opportunities ahead of Phase II trials. It is soon to report new pre-clinical data across the three areas.

"It is clear that there is substantial interest in our first in class approach to fibrosis across all indications – lung, eye and kidney. Demonstrating efficacy across a range of fibrotic diseases positions AdAlta well to progress separate partnering discussions for each indication of AD-214 from mid FY2023."

In cancer, AdAlta hopes to bring new hope to patients through collaborative partnerships in the field of cellular immunotherapy. One is with Carina Biotech, developing precision engineered, i-body enabled CAR-T cell therapies (immune cells engineered to be able to seek out and destroy cancer cells).

"Our collaboration with Carina has the potential to make breakthrough therapies available to a wider range of patients with solid cancers," Dr Oldham says.

"Together, we have demonstrated that we can successfully create i-CAR-T cells for the first of up to five targets and we anticipate commencing work on additional targets in the coming year."

Another collaboration is with GE Healthcare, to develop i-bodies as diagnostic imaging agents against Granzyme B, a biomarker of response to immuno-oncology drugs.

These recent collaboration successes enabled AdAlta to recently launch a business development campaign to identify additional partners who could benefit from, and potentially fund the application of i-bodies for additional uses in cellular immunotherapy programs.

AdAlta
next generation protein therapeutics

KEY INVESTMENT HIGHLIGHTS

JUNE 14, 2022: European patent for lead program, AD-214 "CXCR4 binding molecules" granted, adding to existing protection in Australia, China, India, Singapore and US.

JULY 4, 2022: Imminent report on significant new pre-clinical data for multiple fibrosis diseases for lead drug, AD-214. Outcomes inform next steps for manufacturing and partnering discussions.

JULY 25, 2022: Immuno-oncology collaboration with Carina Biotech continues to build the first of five CAR-T cell targets, with a business development campaign launched to identify additional partners.

RICK LEGLEITER
CEO

ADHERIUM

(ASX:ADR)

- **Company Name:** Adherium
- **Company ASX code:** ADR
- **Key areas:** Respiratory e-health, remote patient monitoring, and data management solutions
- **Key Personnel:** Rick Legleiter, CEO | Lou Panaccio, Independent Non-Executive Chair
- **Locations:** Australia and New Zealand
- **Market Cap as of 15/09/22:** $17.82M
- **52 Week share price as of 15 September:** $0.006 - $0.020
- **Company Website:** adherium.com

COMPANY PROFILE

Adherium is a respiratory eHealth company that has set a new standard for preventative treatment with its integrated remote patient monitoring data solutions, enabling doctor reimbursement in the US while costing zero to little for the patients.

The company's Hailie solution is the world's most clinically supported asthma medication adherence solution, and has sold more than 180,000 sensors globally.

The cloud-based platform captures medication use data from FDA-cleared Bluetooth sensors that wrap around a patient's inhaler, providing real-time feedback to the patients via the Hailie app, and to their physicians via the Hailie portal or with an SDK and API through third party platforms.

By monitoring inhaled medication adherence and technique, the technology provides insights to reduce the severity and frequency of exacerbations and associated hospital admissions, improving patients quality of life.

An independent study shows that the Hailie solution increases adherence to preventative medication by 180% in children, and 59% in adults and reducing severe exacerbations in adults by 61%.

The technology has also been referenced in more than 100 independent peer-reviewed publications. These publications include validation studies and clinical trials in which the Hailie sensor was used as the gold standard method for adherence measurement.

COPD (chronic obstructive pulmonary disease) and asthma represent a huge global market, with 25 million asthmatics and 26 million COPD patients in the US alone - creating an ongoing cost burden to the health system.

There is a big opportunity for Adherium's preventative Hailie platform in the US, particularly since remote patient monitoring (RPM) is now reimbursed through the private US payors system.

In September 2021 , Adherium received a US FDA 510(k) clearance to market application connecting AstraZeneca's Symbicort aerosol inhaler users with the next generation Hailie sensor for monitoring asthma and COPD medication use. Then the Company added the 510(k) for GlaxoSmithKline's Ellipta inhalers in July 2022.

The FDA specifically gave the clearance enabling physiological measures to be included and coupled with existing adherence sensor capability, allowing Hailie to deliver the best value proposition of any smart inhaler digital solution in the world.

Adherium now has 510(k) clearances for use with, 91% of the US top 20 branded inhalers for adherence usage.

The company sees a clear path to scalable revenue as it targets its first RPM sales in FY23.

To do this, Adherium is focused on establishing new commercial partnerships and engaging with well-respected US hospital systems, with the aim of proving and then expanding to cash flow positive.

Adherium is managed by a highly experienced leadership team.

CEO Rick Legleiter has more than 20 years of experience in global healthcare and medical technology across the US, Australia, Europe, and Asia.

He has held the CEO position at Universal Biosensors in Australia (ASX: UBI), and was also senior vice president, Corporate Accounts at Siemens Healthcare in the US and Germany.

The Board of Adherium is independently chaired by Lou Panaccio, who possesses extensive experience in the life sciences sector at the executive and board level.

He is currently a director at Sonic Healthcare, Avita Therapeutics, VGI Health Technology, NeuralDX and Haemokinesis.

KEY INVESTMENT HIGHLIGHTS

JUNE 2, 2022: Announced the contract for the supply of the Hailie solution to Avillion LLP in partnership with AstraZeneca, sponsor of a US-based clinical study in mild asthma.

JULY 20, 2022: Signed a distribution agreement for US patient monitoring with Perigon Health 360 to sell the Hailie platform.

JULY 25, 2022: Received US FDA 510(k) clearance to market application connecting GlaxoSmithKline's Ellipta inhaler users with its next generation sensors.

KATE QUIRKE
CEO & MANAGING DIRECTOR

ALCIDION GROUP

(ASX:ALC)

- **Company Name:** Alcidion Group
- **Company ASX code:** ALC
- **Key areas:** Smart technology for healthcare organisations to create a clinically relevant environment with digitally enabled care
- **Key Personnel:** Kate Quirke, CEO & Managing Director
- **Locations:** Australia, New Zealand, United Kingdom
- **Market Cap as of 15/09/22:** $183.87M
- **52 Week share price as of 15 September:** $0.100 - $0.388
- **Company Website:** alcidion.com

COMPANY PROFILE

The global healthcare landscape is rapidly evolving and Alcidion's foresight has seen it establish itself as a leading force already delivering high-tech solutions others are only just starting to develop.

Alcidion has long been supplying software solutions that address the critical needs of healthcare such as greater demand for services and scarce resources.

The company's focus is on providing tools to clinicians to enable a proactive, rather than reactive, approach to patient care. Using FHIR-based interoperability, user-centred design and real-time management of data flows, its flagship product Miya Precision streamlines clinical and logistics processes to facilitate timely and effective care.

The ever-increasing volume of patients flowing through hospitals and on hospital waiting lists continues to increase complexity and strengthens the value and benefits for interoperability of data and systems.

The popularity of the company's smart, intuitive technology solutions is evident in the FY22 financials, which show a 96% year-over-year increase in new total contract value (TCV) sales, marking a new record of $57.7M.

Some of these new contracts are with customers where Alcidion is deploying the first modules of the Miya Precision platform into important and well recognised digital health leaders, such as the recent contract with Alfred Health.

Alcidion has also signed several upgrade agreements with existing long-term customers like Northern Territory Health and Western Health, underscoring their satisfaction with – and long-term commitment to – the company.

In the United Kingdom, at least one of Alcidion's products is in 39 National Health Service (NHS) Trusts, or about 27% of all acute NHS sites.

In December 2021, the company completed the transformational acquisition of Silverlink PCS Software, one of the largest and few remaining specialist Patient Administration System (PAS) providers servicing the UK NHS market.

This was accompanied by a strongly supported $55M capital raising to complete the strategically important acquisition, which provided Alcidion with core PAS capability allowing the company to offer a cloud-native, modern and modular Electronic Patient Records (EPR) solution to rival global incumbents.

Importantly, the integration of Silverlink into Alcidion's product suite strategically positions the company – both in terms of market perception and capability – to further expand its UK market penetration to 38 trusts (~26% market presence) while also expanding the addressable market.

In May 2022, the company announced it had been chosen to become part of a global consortium, led by Leidos Australia, to build a new $299M Health Knowledge Management (HKM) system for the Australian Defence Force (ADF).

The HKM system is a critical project for the ADF that will improve the care delivered to current and past military personnel. Importantly, the project has demonstrated that Alcidion's solutions are increasingly scalable and able to play a central role in enabling integration across diverse healthcare settings.

Alcidion is backed by management with decades of experience and who are veterans in the healthcare information technology space.

Group managing director Kate Quirke has over 25 years' experience and has held leading management roles at some of the largest healthcare software firms, including international healthcare software supplier iSOFT.

Chief medical officer Malcolm Pradhan has over 20 years of experience in medical informatics, making him one of the world's leading minds in Clinical Decision Support. Prior to co-founding Alcidion in 2000, Malcolm was the associate dean of IT and director of Medical Informatics at the University of Adelaide.

ALCIDION

KEY INVESTMENT HIGHLIGHTS

DECEMBER 16, 2021: Alcidion completes acquisition of Silverlink PCS Software, one of the largest and few remaining specialist Patient Administration System providers servicing the UK NHS market.

MAY 3, 2022: Alcidion partners with consortium to build new $299M Health Knowledge Management system for Australian Defence Force.

AUGUST 30, 2022: Alcidion delivers record new FY22 sales with a total contract value (TCV) of $57.7M, which is a 96% increase over FY21.

DR DAVID STAMLER
CEO

ALTERITY THERAPEUTICS

(ASX:ATH)

- **Company Name:** Alterity Therapeutics
- **Company ASX code:** ATH, NASDAQ: ATHE
- **Key areas:** Developing first-in-class therapies to treat neurodegenerative diseases, with a special focus on parkinsonian disorders
- **Key Personnel:** Dr David Stamler, CEO | Kathryn Andrews, CFO | Geoffrey Kempler, Chairman and Founder
- **Locations:** Melbourne and San Francisco, United States
- **Market Cap as of 15/09/22:** $36.10M
- **52 Week share price as of 15 September:** $0.013 - $0.033
- **Company Website:** alteritytherapeutics.com

COMPANY PROFILE

Alterity Therapeutics is a clinical stage biotechnology company dedicated to creating an alternate future for people living with neurodegenerative diseases.

The company is focused on Parkinson's disease and related disorders where there is a high unmet medical need.

While available therapies address the symptoms of these disorders, Alterity is targeting the underlying pathology of the disease. The company's lead drug candidate, ATH434, is designed to inhibit the aggregation of alpha-synuclein, a protein implicated in neurodegeneration, preserve nerve cells, and improve function by restoring normal iron balance in the brain.

Through this mechanism it has excellent potential to treat Parkinson's disease as well as less common Parkinsonian disorders such as Multiple System Atrophy (MSA).

MSA is a rare, degenerative neurological disease characterized by failure of the involuntary (autonomic) nervous system and impaired movement that affects up to five out of every 100,000 people globally. It is a rapidly progressive disease and causes profound disability.

Alterity's lead program could be the first approved treatment for MSA that is neuroprotective, meaning it preserves nerve cells, maintains function and slows the progression of disease.

Alterity has received Orphan Drug designation for ATH434 in MSA in the US and EU which provides market exclusivity for several years after approval.

The company is currently enrolling MSA patients in its global Phase 2 clinical trial evaluating the effect of ATH434 on MRI endpoints and protein biomarkers, such as aggregating alpha-synuclein. A prior Phase 1 study has found the molecule to be safe and well-tolerated.

The first Phase 2 patient was enrolled in New Zealand and study was recently launched in the United Kingdom. Alterity plans to expand the trial to other regions including Australia, the US, and other European countries by the end of the year.

Alterity also has a broad R&D pipeline that includes a natural history study in MSA designed to de-risk the Phase 2 trial, preclinical studies to optimize dosing of ATH434 for Parkinson's disease, and a strong drug discovery and research arm.

The company holds a strong intellectual property portfolio, with over 800 validated compounds from its chemical library. Alterity was recently granted new US patents covering 230 novel compounds as next generation therapies targeting major neurodegenerative diseases. Alterity is led by a team with deep R&D experience that includes three drug approvals by the US FDA.

Alterity was incorporated in Melbourne, Australia in 1997 as Prana Biotechnology. The company listed on the Australian Securities Exchange in 2000 and Nasdaq in 2002, changing its name in 2019.

Alterity has a strong leadership team with Dr David Stamler appointed CEO in January 2021. He previously served as the company's chief medical officer and senior vice president, clinical development since 2017.

Stamler has vast experience in the development of pharmaceuticals, beginning his career at Abbott Laboratories.

He held senior positions at Teva Pharmaceutical Industries after it acquired Auspex Pharmaceuticals for $US 3.5 billion, where he served as CMO. He also held senior positions at XenoPort, Prestwick Pharmaceuticals, and Fujisawa Pharmaceutical Co and its subsidiaries.

Founder Geoffrey Kempler has served as chairman of the Board of Directors since November 1997. He was CEO from November 1997 until August 2004 and assumed the position again from June 2005 until January 2021.

Kempler has extensive experience in investment and business development and has been responsible for the implementation of the Company's strategic plan.

Alterity THERAPEUTICS

KEY INVESTMENT HIGHLIGHTS

JUNE 23, 2022: The Italian Medicines Agency granted regulatory authorization for Alterity to conduct its Phase 2 trial.

JULY 6, 2022: The first patient dosed in Alterity's Phase 2 clinical trial of ATH434 in MSA.

AUGUST 25, 2022: Alterity announces the UK launch of its Phase 2 clinical trial of ATH434 in Multiple System Atrophy (MSA), a rare Parkinsonian disorder.

DR JOHN LAMBERT
CEO & MANAGING DIRECTOR

AMPLIA THERAPEUTICS

(ASX:ATX)

- **Company Name:** Amplia Therapeutics
- **Company ASX code:** ATX
- **Key areas:** Therapeutics for cancer and chronic fibrosis
- **Key Personnel:** Dr John Lambert, CEO & Managing Director | Dr Rhiannon Jones, COO | Dr Warwick Tong, Chairman of the Board
- **Locations:** Australia
- **Market Cap as of 15/09/22:** $19.40M
- **52 Week share price as of 15 September:** $0.090 - $0.250
- **Company Website:** ampliatx.com

COMPANY PROFILE

This drug development company is focused on developing new treatments for cancer and fibrotic diseases. In cancer, Amplia's novel approach targets the tumour microenvironment (TME), which are fibrotic shields that protect many solid tumours from chemotherapy.

Amplia has developed focal adhesion kinase (FAK) inhibitor AMP945 which aims to remove that shield by blocking fibrosis around solid cancers, making them more vulnerable and responsive to currently used chemotherapies.

The inhibitor was discovered in Australia, as part of the former Cancer Therapeutics Cooperative Research Centre, involving scientists from Monash Institute of Pharmaceutical Sciences, Peter MacCallum Cancer Centre, St Vincent's Institute of Medical Research, the Walter and Eliza Hall Institute of Medical Research and the CSIRO.

AMP945 is in clinical development for both pancreatic cancer and Idiopathic Pulmonary Fibrosis (IPF).

A clinical trial of the drug is currently underway – called ACCENT - in first-line patients with advanced pancreatic cancer, with AMP945 added to gemcitabine/nab-paclitaxel (standard of care for this disease). Patient recruitment commenced in August 2022 and the trial is based on cutting edge collaborative work between Amplia and the Garvan Institute of Medical Research.

The trial will be conducted in two stages, with the first stage (Phase 1) aiming to select an optimal dose of AMP945 by assessing safety and preliminary efficacy in cancer patients.

The second stage (Phase 2) is designed to perform an assessment of the selected optimal dose of AMP945 in a larger group of pancreatic cancer patients. The aim will be to determine whether AMP945 helps shrink tumours more effectively when it is added to normal chemotherapy.

Dose escalation and initial efficacy assessments from the trial are expected in Q4 CY22, with dose selection and early efficacy readouts as well as interim analysis of the drug's efficacy and safety expected to be released in CY23.

The Company's FAK inhibitors have also been shown to block fibrosis, which is the formation of excessive fibrous connective tissues or scarring that can result from chronic inflammation, chronic injury or disease.

This excessive fibrous tissue can impair the normal functioning of various organs in the body, such as the lungs, liver, heart and kidneys, resulting in major health issues.

Recently, Amplia announced new data showing the efficacy of AMP945 in a preclinical model of IPF – where in the industry-standard bleomycin challenge mouse model of IPF, AMP945 had comparable activity to OFEV®, the current market leader.

To put that in context, in 2020, net sales of OFEV® and the other current drug to treat IPF, Esbriet®, were AU$3.7 billion and AU$1.6 billion respectively.

The company is confident this information should provide significant encouragement to clinical investigators and patients in the planned clinical trials of AMP945 in this devastating disease and will also strengthen ongoing discussions with potential commercial and strategic partners.

Notably, Orphan Drug Designations for both pancreatic cancer and IPF have already been granted by the US FDA and the FDA supported Amplia's overall development plan for AMP945 in a pre-IND meeting.

In addition to AMP945, Amplia's second pipeline drug, AMP886, also inhibits two key disease drug targets (VEGFR3 and FLT3) and is currently being evaluated in animal models of different cancers and fibrotic diseases.

Amplia's commercialisation strategy is to secure key regulatory approvals in oncology – which it says are feasible for small to medium sized biotechs – and to partner with big pharma for its work in pulmonary fibrosis.

KEY INVESTMENT HIGHLIGHTS

MAY 12, 2022: Amplia receives second HREC approval for Phase 2 clinical trial of its FAK inhibitor AMP945 in first-line patients with advanced pancreatic cancer.
JUNE 2, 2022: New data shows efficacy of the company's investigational focal adhesion kinase (FAK) inhibitor AMP945, in a preclinical model of idiopathic pulmonary fibrosis (IPF).
AUGUST 2, 2022: First patient dosed in the Phase 1b/2a ACCENT clinical trial of FAK inhibitor AMP945.

WAYNE PATERSON
CEO & MANAGING DIRECTOR

ANTERIS TECHNOLOGIES

(ASX:AVR)

- **Company Name:** Anteris Technologies
- **Company ASX code:** AVR
- **Key areas:** Aortic valve replacement
- **Key Personnel:** Wayne Paterson, CEO & Managing Director | John Seaberg, Chairman
- **Locations:** Australia and United States
- **Market Cap as of 15/09/22:** $347.50M
- **52 Week share price as of 15 September:** $7.810 - $30.890
- **Company Website:** anteristech.com

COMPANY PROFILE

Anteris is an Australian structural Heart company focused on creating the world's most durable heart valve through better science and better design.

The company's ADAPT® Tissue technology is a true innovation that addresses the critical issue of durability, allowing replacement heart valves to last longer and work better.

Invented in Australia by cardiothoracic surgeon Professor Leon Neethling, the company's ADAPT® Tissue Treatment is the first and only next-generation technology that removes all potential triggers of inflammation and calcification – the leading causes of heart valve failure, thereby extending the durability of tissue used for making replacement heart valves and other cardiac solutions.

A significant body of peer-reviewed, published evidence over two decades provides strong evidence in support of ADAPT® technology, strongly distinguishing Anteris from its peers.

Calcium deposits are the major cause of aortic stenosis (AS) - a highly prevalent disease that stiffens and narrows the heart valve opening. Without treatment, severe AS can lead to heart failure and death.

Anteris' second major innovation, the DurAVR™ THV System (Transcatheter Heart Valve) has been designed in partnership with an Advisory Board of the world's most influential and experienced interventional cardiology pioneers.

DurAVR™ THV is the first and only 3-D shaped, single-piece aortic valve in the world for minimally invasive TAVR, specifically designed to mimic native aortic valve form and function.

Patients deemed unsuitable for a gruelling open-heart surgery could now have their heart valves replaced in a non-invasive TAVR procedure lasting about 30 minutes with new generation transcatheter aortic valve technology like DurAVR™ THV.

The combination of durability provided by ADAPT™ Tissue and the unique design of DurAVR™ optimises blood flow and has the potential to restore normal pre-disease blood flow and deliver a functional cure to aortic stenosis patients.

The DurAVR™ THV valve addresses the needs of tomorrow's younger and more active aortic stenosis patients, by delivering the durability needed to last the remainder of a patient's lifetime.

The DurAVR™ THV First-in-human study demonstrated remarkable flow characteristics and patient outcomes. "DurAVR™ has been rationally engineered to provide ease of implantation of the valve for the doctor, immediate haemodynamic benefit for the patient post-implantation, and the potential to provide a long-term durable effect which is of utmost importance when treating younger, low-risk patients", commented Dr. Vinnie Bapat, MD, Lead Investigator and Cardiothoracic Surgeon at the Minneapolis Heart Institute.

Anteris' third innovation is the ComASUR™ TF Delivery System. It is aimed at providing physicians the ability to deliver precision alignment of new heart valves to the patient's native valve. There is growing evidence that malalignment impacts device performance and leads to negative clinical outcomes.

The market opportunity for Anteris is huge, with the aortic valve replacement market predicted to grow by 12% CAGR to US$14 billion by 2028.

Anteris is managed by a team of experts. CEO Wayne Peterson has held numerous, senior positions in multinational companies and has lived in seven countries during the past 25 years.

His experience includes managing multibillion-dollar businesses throughout the world, including mergers, integrations, acquisitions and restructures.

Chairman John Seaberg meanwhile, was the founder, chairman and CEO of NeoChord Inc, a venture capital-backed company commercialising technology developed at the Mayo Clinic for the repair of the mitral valve via minimally invasive techniques.

ANTERIS

KEY INVESTMENT HIGHLIGHTS

- Successfully completed first-in-human DurAVR™ THV System study at the Tbilisi Heart and Vascular Clinic in Georgia. Six-month follow-up demonstrating excellent results with an 86% improvement in haemodynamics.
- Expansion of Medical Advisory Board with the appointments of Australian interventional cardiologists Dr Karl Poon and Associate Professor Dion Stub.
- $US20 million ($A27.6 million) placement of 1,840,000 new shares to Perceptive Life Sciences Master Fund at $A15 per share.

DR LIZ DALLIMORE
CEO & MANAGING DIRECTOR

ARGENICA THERAPEUTICS

(ASX:AGN)

- **Company Name:** Argenica Therapeutics
- **Company ASX code:** AGN
- **Key areas:** Novel neuroprotective therapeutics to reduce brain damage after stroke
- **Key Personnel:** Dr Liz Dallimore, CEO & Managing Director | Professor Bruno Meloni, Chief Scientific Officer | Geoff Pocock, Non-Executive Chairman
- **Locations:** Western Australia
- **Market Cap as of 15/09/22:** $56.49M
- **52 Week share price as of 15 September:** $0.340 - $1.020

Company Website: argenica.com.au

COMPANY PROFILE

Argenica Therapeutics is a clinical biotechnology company developing novel neuroprotective therapeutics to reduce brain damage after stroke and other brain injuries. Its lead asset, ARG-007, is a cationic, arginine-rich peptide which has shown potential to reduce brain tissue death in pre-clinical models of stroke.

Argenica was incorporated in 2019 and listed on the ASX in June 2021 after raising $7M in the IPO round to fund its Phase 1 clinical trial.

Globally, approximately 15 million people suffer a stroke every year, but only about 10% will recover completely. About 85% of strokes are ischemic (blood clots), and 15% are haemorrhagic (bleeding).

Ischemic strokes starve the brain of oxygen (hypoxia), leading to brain cell death at a rate of more than 100 million cells per hour without treatment. This can cause long term disability, lasting brain damage and death for victims. There are currently no marketed drugs available to protect brain cells from hypoxic cell death.

Treatment for ischemic stroke involves the removal of blood clots either mechanically or by using thrombolytic drugs to dissolve the clots, with the critical time window for treatment being up to 4.5 hours. Only 35% of patients make it to the hospital within that window.

ARG-007 is to be used by first responders to quickly protect the brain tissue from hypoxia prior to hospitalisation, minimising brain cell damage and extending the critical time window for later thrombolytic intervention. Published in vitro studies have shown ARG-007 could be combined with thrombolytic drugs in the hospital, as the combination does not degrade the efficacy of ARG-007.

Argenica is gearing up for a Phase 1 clinical trial of ARG-007. An ethics application has been submitted to Bellberry's Human Research Ethics Committee seeking approval to commence the trial. The Phase 1 trial will be in healthy human subjects (not stroke patients) to test the safety, tolerability, and pharmacokinetics of the drug. In preparation for the Phase 1 trial, Argenica successfully completed pre-clinical studies on the safety of ARG-007.

In January, Argenica appointed Dr Meghan Thomas, previously vice president of clinical programs and operations of Zelira Therapeutics (ZLD), as head of its clinical development to drive the Company's clinical program. Argenica expects Phase 1 tobe complete in about six months to complete.

Besides stroke, pre-clinical studies on ARG-007 have also shown efficacy in other indications such as traumatic brain injury and perinatal hypoxic-ischaemic encephalopathy (brain injury due to a lack of oxygen in an infant during pregnancy or labour).

Argenica is managed by a highly experienced leadership team. CEO and managing director Dr Liz Dallimore has over 20 years' experience in R&D and commercialisation in the UK and Australia. She was previously KPMG Australia's national lead in Research Engagement & Commercialisation. She holds a PhD in Neuroscience, an MBD and GAICD.

Chief scientific officer, Professor Bruno Meloni, has over 25 years' experience as a research scientist, the last 20 of which were in the field of stroke.

ARG-007 is a product of Professor Meloni's research over the last ten years, being the head of Stroke Laboratory Research at University of Western Australia and the Perron Institute.

The Board of Argenica is independently chaired by Geoff Pocock, who has over 20 years' experience in the commercialisation and funding of early-stage research projects from universities, as well as taking companies to successful ASX listings.

ARGENICA THERAPEUTICS

KEY INVESTMENT HIGHLIGHTS

- Argenica's lead asset, ARG-007, has shown safety and efficacy in preclinical studies of stroke and other brain injuries in 25 published papers
- Argenica is progressing clinical development of ARG-007 in stroke, with preclinical data to be generated in other indications including hypoxic ischaemic encephalopathy, traumatic brain injury and cardiac arrest.
- ARG-007 is now entering clinical trials, with the ethics application submitted to seek approval to commence the Phase 1 trial of ARG-007 in healthy human volunteers.

DR PAUL GAVIN
CEO

AVECHO BIOTECHNOLOGY

(ASX:AVE)

- **Company Name:** Avecho Biotechnology
- **Company ASX code:** AVE
- **Key areas:** Pharmaceutical cannabinoid products
- **Key Personnel:** Dr Paul Gavin, CEO | Dr Roksan Libinaki, COO | Dr Greg Collier, Chairman of the Board
- **Locations:** Australia
- **Market Cap as of 15/09/22:** $20.21M
- **52 Week share price as of 15 September:** $0.011 - $0.023
- **Company Website:** avecho.com.au

COMPANY PROFILE

Avecho Biotechnology is a Melbourne-based biotechnology company backed by a highly experienced team, which has spent more than two decades developing and commercialising pharmaceutical products together.

The company's proprietary Tocopheryl Phosphate Mixture (TPM®) drug delivery system is now being leveraged to develop differentiated and highly competitive cannabinoid products for a variety of markets.

TPM® is derived from Vitamin E and is proven to enhance the solubility and oral, dermal and transdermal absorption of drugs and nutrients – including, most notably, the absorption of the active ingredients in medicinal cannabis, such as cannabidiol (CBD).

The company is currently proceeding toward a pivotal Phase III clinical trial for its CBD soft-gel product for an insomnia related indication, which will be conducted in Australia.

The Phase III protocol is rigorous, having been designed with subsequent FDA and EMEA submissions front of mind. This trial design will increase the likelihood of licensing the product in overseas markets – a significant market opportunity.

Avecho's oral CBD capsule has also completed a Phase I clinical trial, a key milestone that has informed the design of the imminent Phase III clinical trial, and is a pivotal part of the company's data package to support the registration of its soft-gel product with the Therapeutic Goods Administration (TGA) as an over-the-counter (S3) medicine.

Avecho has also cultivated a successful research collaboration with the Lambert Initiative, Australia's leading research group for the discovery, development, and optimisation of safe cannabinoid therapeutics.

Recently, they co-published and attracted international exposure for Phase II data demonstrating the effectiveness of topical cannabinoids for treating osteoarthritis – a common, painful, and irreversible condition that significantly impairs hand strength and function.

During four weeks of dosing, the study demonstrated statistically significant daily improvements in hand pain, hand functionality, grip strength, finger stiffness and anxiety. Plans for larger placebo-controlled studies are now underway.

Targeted business development and revenue generation opportunities are also a focus for the company, alongside its clinical program.

Avecho has secured a licensing and partnership agreement with Perland Pharma in the US licensing its CBD capsule for use in arthritis indications. This partnership will place the CBD capsule before the US Food and Drug Administration (FDA) and provide a potential pathway for another indication too.

Avecho has also secured a lucrative deal in the US to develop and commercialise a unique cannabis distillate for use in consumer cannabis products – like edibles. Initial findings have demonstrated that the inclusion of TPM® in edible gummies containing cannabis may increase the onset, duration or magnitude of effect.

Avecho is now commencing strategic outreach in North American markets to educate key recreational cannabis companies about how TPM® can enhance their products. Recreational cannabis represents a large and lucrative additional market for Avecho, with sales of cannabis-related products totalling US$17.5B in 2020.

Avecho

KEY INVESTMENT HIGHLIGHTS

- Avecho is a highly credentialed biotechnology company, extending its expertise in drug development for human and animal health products to the emerging cannabinoid space.
- Avecho's R&D program is differentiated by its proprietary Tocopheryl Phosphate Mixture (TPM®) drug delivery system, which significantly increases the absorption of cannabinoids such as cannabidiol (CBD), allowing for the development of cannabinoid products with increased effectiveness, commercial differentiation, and true patent protection.
- TPM® is primed for disrupting the global cannabis market and targeted licensing/revenue deals, as it supports enhanced bioavailability of the molecule across multiple applications and product types.

JENNIFER CHOW
CEO

CHIMERIC THERAPEUTICS

(ASX:CHM)

- **Company Name:** Chimeric Therapeutics
- **Company ASX code:** CHM
- **Key areas:** Biotechnology, cell therapies, CAR-T cell therapy, NK cell therapy
- **Key Personnel:** Jennifer Chow, CEO | Paul Hopper, Chairman | Dr Jason Litten, Chief Medical Officer | Eliot Bourk, Chief Business Officer
- **Locations:** Australia, United States
- **Market Cap as of 15/09/22:** $42.52M
- **52 Week share price as of 15 September:** $0.085 - $0.342
- **Company Website:** chimerictherapeutics.com

COMPANY PROFILE

Chimeric Therapeutics is a clinical stage cell therapy company focused on bringing the promise of cell therapy to life for patients with cancer. Chimeric believes that cellular therapies have the promise to cure cancer, not just slow its progress.

Traditional oncology therapeutics including chemotherapies and immunotherapies focus on targeting either the host or the tumour with a goal to delay cancer progression. Cellular therapies target both the host and the tumour with the goal to cure cancer not just delay its progression.

This goal to cure cancer has recently been realised as patients treated over a decade ago with CAR-T cell therapies remain cancer free.

The current cell therapy market is valued at US$10 billion and is estimated to reach US$60 billion by 2030. Notable exits have included the Celgene acquisition of Juno for US$9B and the Gilead acquisition of Kite for US$12B.

Chimeric has a diversified portfolio that includes seven next-generation autologous and allogeneic therapies that utilise Natural Killer and T cells. Chimeric assets are being developed across 10+ disease areas in oncology with three current clinical programs and plans to open additional clinical programs in 2023.

Chimeric Antigen Receptor (CAR) T Cell therapies are custom therapies manufactured for each patient. CAR-T cell therapy begins with a patient's T cells which are enhanced in a lab to find and destroy that patient's unique cancer.

CHM 1101 is a first in class CLTX CAR-T cell therapy currently in a phase 1 clinical trial for patients with glioblastoma. Chimeric recently reported promising early phase 1 data with CHM 1101 showing ~70% of patients treated in dose cohort 1 and 2 achieved disease stability with no notable adverse events.

CHM 2101 is a first in class CDH17 CAR-T cell therapy currently headed for a phase 1 clinical trial in 2023 in gastrointestinal cancers. The preclinical data for CHM 2101 was published as the cover article in the prestigious Nature Cancer publication and demonstrated complete eradication of tumour cells with no relapse.

Natural Killer (NK) cell therapy utilises healthy donor cells rather than a patient's own cells. NK cells form part of our immune system and have an innate ability to detect and destroy cells that look abnormal. NK cells can also be genetically modified to enhance their cancer killing ability.

CHM 0201 is a CORE (Clinically validated, Off the shelf, Robust, Enhanced) Natural Killer cell platform. An initial phase 1 clinical study has demonstrated early promise in both solid tumours and blood cancers with one patient having a complete response to CHM 0201 therapy (achieving complete eradication of the cancer) and remaining cancer free more than 15 months after therapy.

Based on the initial positive signals with CHM 0201, a new clinical trial has recently been initiated and is the first-ever trial to explore NK cells (CHM 0201) in combination with Vactosertib and IL2.

Additionally Chimeric is leveraging CHM 0201 to develop four new assets, an enhanced NK platform (CHM 0301) and three novel CAR NK (CHM 1301, 2301 and 3301) assets.

Chimeric has an industry leading team with more than 50 combined years of experience developing and commercialising cell therapies. The team has extensive CAR-T cell therapy experience having worked on four of the six currently approved CAR-T cell therapies.

CHIMERIC THERAPEUTICS

KEY INVESTMENT HIGHLIGHTS

- **Early Positive Signals in Multiple Clinical Trials:** Positive phase 1 data in Glioblastoma with CHM 1101 and in blood cancers with the CORE NK platform.
- **Innovative & Diversified Portfolio:** Seven novel individualised T cell and off the shelf NK cell therapies in development.
- **Extensive Clinical Development Plan with a Broad Focus:** Development across 10+ types of cancer with three current clinical trials and planned expansion in 2023
- **Industry Leading Experience:** Internal team of experts in cell therapy development and commercialization.

WILLIAM LAY
CEO & MANAGING DIRECTOR

CRESO PHARMA

(ASX:CPH)

- **Company Name:** Creso Pharma
- **Company ASX code:** CPH
- **Key areas:** Innovative plant based (including cannabis and hemp) products for humans and animals
- **Key Personnel:** William Lay, CEO & Managing Director | James Ellingford, Chairman | Bruce Linton, Non-Executive Board member
- **Locations:** Australia, Canada, Switzerland, United States
- **Market Cap as of 15/09/22:** $64.28M
- **52 Week share price as of 15 September:** $0.035 - $0.160
- **Company Website:** cresopharma.com

COMPANY PROFILE

Creso Pharma developed as a global innovator in medicinal cannabis, and has built a reputation for itself as one of the most trusted providers of cannabis and hemp derived products.

The company has significant operations in Canada and Switzerland and is making rapid inroads into the potentially lucrative US market.

In Canada, Creso is currently a multi-million-dollar revenue-generating cannabis producer through its wholly-owned subsidiary Mernova, which operates a 2,230m2 state-of-the-art facility, cultivating and selling cannabis to provincial markets under the Ritual brand, including dried flower, pre-rolled joints and handheld vapes.

The company has made great leaps and rapidly grown its revenue, and the number of markets it services – and with crop yield at the facility increasing dramatically, Mernova expects to see that translate into lower cost per gram and higher sales margins.

Creso made significant inroads into the North American market by recently acquiring US-based Sierra Sage Herbs, maker of the best-selling Green Goo natural products brands.

Sierra Sage has over 90,000 points of distribution across the US including Whole Foods, Walmart, Amazon, Target.com, CVS, and Walgreen's. Creso and Sierra Sage are working together to bring Creso's broader portfolio of non-THC products to the US.

As part of its US strategy, Creso has also acquired the assets of ImpACTIVE, a company that develops a range of CBD-based products to reduce muscle and joint inflammations.

Recently, Creso also launched itself into the emerging US$100 billion global medical market for psychedelics after acquiring Canadian psychedelics specialist, Halucenex Life Sciences.

Halucenex operates a 560m2 medical facility, with six treatment rooms and a secure laboratory dedicated to performing psychedelic-assisted psychotherapy and clinical research.

Halucenex is also one of only four public Canadian companies to receive a Dealer's License from Health Canada and is about to commence a Phase 2 trial on psilocybin-based treatment for post-traumatic stress disorder (PTSD).

The clinical trial has the potential to unlock a new and potentially large market for Halucenex and Creso, as independent studies have shown that natural psilocybin is less compatible in clinical settings due to its inconsistency of potency.

Producing synthetic psilocybin in-house will therefore allow Halucenex to replace third-party supply agreements, potentially allowing the company to expand into a supplier role to other distributors and practitioners.

In Switzerland, Creso is producing hemp-based products for both humans and animals with "Swiss Made" labels at third-party GMP certified facilities.

The company now has a network of over 3,000 points of sale in the European continent, selling a range of supplements under the 'cannaQIX' brand, and animal products under the 'anibidoil' brand.

Creso's experienced pharmaceutical leadership team meanwhile have an unparalleled track record of success commercialising a wide range of CBD products.

Legendary Canadian cannabis entrepreneur Bruce Linton, the co-founder of NYSE-listed weed stock Canopy Growth, recently joined Creso to become a Board member, alongside CEO William Lay – a former investment banker and an experienced cannabis executive who previously led >C$5 billion of M&A deals as Associate Director at Canopy Growth.

Chairman James Ellingford is a former President of an international publicly listed billion-dollar business with its headquarters in Geneva and New York.

It's an exciting time for Creso shareholders as the company targets a NASDAQ listing sometime in 2022.

CRESO
PHARMA

KEY INVESTMENT HIGHLIGHTS

JANUARY 17, 2022: Creso appoints NYSE-listed Canopy Growth Corp founder and former chief executive officer Bruce Linton as board member, and William Lay as CEO and Managing Director.
FEBRUARY 3, 2022: Announces most significant acquisition to date and entry into US CBD market with acquisition of Sierra Sage Herbs LLC.
AUGUST 31, 2022: Half year report shows both significant revenue growth and substantial reduction in operating costs.

DR NINA WEBSTER
CEO & MANAGING DIRECTOR

DIMERIX

(ASX:DXB)

- **Company Name:** Dimerix
- **Company ASX code:** DXB
- **Key areas:** Pharmaceutical product development across inflammatory diseases, including kidney and respiratory diseases
- **Key Personnel:** Dr Nina Webster, CEO & Managing Director | Dr Ash Soman, Chief Medical Officer
- **Locations:** Melbourne, Australia
- **Market Cap as of 15/09/22:** $44.92M
- **52 Week share price as of 15 September:** $0.120 - $0.350
- **Company Website:** dimerix.com

COMPANY PROFILE

Dimerix is a clinical-stage biopharmaceutical company with a portfolio of drug candidates for inflammatory diseases, including kidney and respiratory diseases. Dimerix' lead clinical asset, DMX-200, is in Phase 3 trials as a treatment for FSGS, a rare kidney disease, as well as in clinical studies in patients with infection related pneumonia or diabetic kidney disease.

In addition, DMX-700 is under development for Chronic Obstructive Pulmonary Disease (COPD). Both DMX-200 and DMX-700 drug candidates were identified using Dimerix' proprietary Receptor-HIT assay, which can be leveraged to identify new opportunities, thereby strengthening the Company's development pipeline and diversifying development risk.

DMX-200 is currently in a Phase 3 trial for the treatment of FSGS kidney disease and was granted Orphan Drug Designation for FSGS in the US, Europe and UK, in recognition that it addresses a very niche, underserved market with no approved treatment.

The promising Phase 2 data underpins the decision to progress into the Phase 3 clinical study, which is actively recruiting patients and spans ~70 clinical sites across sites globally, including the US under an open IND.

The Phase 3 study is a randomised, double-blind, placebo-controlled study of DMX-200 in patients with FSGS who are receiving a stable dose of an angiotensin receptor blocker (ARB). The primary endpoints for potential Accelerated Approval are the change in proteinuria and in eGFR from Baseline to Week 35 following treatment with DMX-200 compared with placebo.

As a result of regulatory and policy changes, kidney treatments have caught the interest of many stakeholders, which is reflected in the number of licensing transactions that have been completed globally in this space since 2020. Dimerix is one of the only two companies with a potential drug candidate in Phase 3 clinical stage for FSGS and more notably, DMX-200 likely complements other drug candidates under development. Interim data is anticipated from the study mid-2023.

Dimerix has granted patents for DMX-200 until at least 2032 and has filed two new global patent applications that could extend this protection to 2042 if granted. As a new chemical entity, the compound is also eligible for orphan exclusivity of 10 years in Europe and 7 years in the US, during which time the patents may not be challenged.

The company has also entered into a key agreement with The Australian Centre for Accelerating Diabetes Innovations (ACADI), which aims to progress DMX-200 into a new clinical trial in patients with diabetic kidney disease.

The Company's second drug candidate DMX-700 is being developed as a treatment for COPD, a progressive and life-threatening lung disease. COPD is the third-leading cause of death in the world, causing 3.23 million deaths globally in 2019.

COPD affects 1 in 8 Americans aged 45 and older, and 1 in 20 Australia aged 45 years and older, but millions more may have the disease without even knowing it. Although treatments exist to improve the symptoms of COPD, there is currently no way to slow progression of the condition or cure it.

In June 2022, Dimerix announced that DMX-700 demonstrated statistically significant 80% reduction in lung injury in mice versus control, which supports progression of DMX-700 into a clinical trial, planned for first half 2023.

Leading Dimerix is an experienced team having previously delivered drug programs right through to market approval. CEO and managing director Dr Nina Webster has more than 30 years' experience in the pharmaceutical industry.

Dimerix

KEY INVESTMENT HIGHLIGHTS

MAY 31, 2022: Dimerix initiates recruitment of first patients in Phase 3 clinical study of lead drug DMX-200 in rare kidney disease, FSGS.

JUNE 7, 2022: Dimerix enters agreement with The Australian Centre for Accelerating Diabetes Innovations (ACADI) to progress DMX-200 into new clinical trial for diabetic kidney disease.

JULY 4, 2022: Dimerix announces DMX-700 promising data in chronic obstructive pulmonary disease (COPD).

JOHN MCCUTCHEON
PRESIDENT & CEO

EBR SYSTEMS

(ASX:EBR)

- **Company Name:** EBR Systems
- **Company ASX code:** EBR
- **Key areas:** Leadless pacemakers, heart failure
- **Key Personnel:** Allan Will, Chairman | John McCutcheon, President & CEO | Frank Hettmann, CFO
- **Locations:** Sunnyvale, California
- **Market Cap as of 15/09/22:** $129.55M
- **52 Week share price as of 15 September:** $0.330 - $1.095
- **Company Website:** ebrsystemsinc.com

COMPANY PROFILE

As many as half of patients with traditional pacemakers undergoing cardiac resynchronisation therapy (CRT) either don't benefit from treatment, or develop issues related to the wires leading to the heart.

It's an issue that remains poorly addressed, and Australian-listed medtech EBR Systems is determined to drive better patient outcomes.

To that end, EBR Systems invented the WiSE® CRT System, which uses a proprietary wireless technology to deliver pacing stimulation directly to the inside of the left ventricle of the heart.

Designed to address the persistent limitations of current CRT systems, WiSE® provides a more customised, patient-specific solution.

Traditional artificial cardiac pacemakers generate electrical pulses delivered by electrodes to the chambers of the heart, causing the targeted chambers to contract and pump blood.

They are commonly used by patients suffering from heart problems, such as those suffering from heart failure, in which the heart is unable to pump enough blood to meet the body's demands.

Heart failure afflicts more than 25 million people across the world, however there are limitations to CRT, which requires the insertion of wires into the left and right ventricles of the heart.

"WiSE® is the world's first and only inside-the-heart leadless cardiac pacing device for heart failure," says Allan Will, chairman of EBR.

"Traditional CRT devices use wires to deliver energy to the heart; however, many patients are unable to receive effective CRT because their anatomy or disease prevents the use of these wires.

"WiSE® provides an alternative solution by providing leadless CRT to patients who would otherwise suffer poor prognosis."

It's working, too. A prospective, multi-center, non-randomised study of 35 patients who previously failed conventional CRT demonstrated hugely promising results.

Patients were treated with the WiSE® CRT System at six leading clinical centers in Europe and evaluated 30 days and six months after treatment; 97 per cent achieved cardiac resynchronisation within a month and 85 per cent reported ongoing clinical benefits after six months.

The company is now focused on the SOLVE-CRT trial, which it needs to successfully pass in order to submit the device to the FDA.

Enrolment has been completed for the trial, which will evaluate the safety and efficacy of WiSE® in heart failure patients who are classified as acute lead failures, chronic lead failures, high-risk upgrades, or leadless upgrades.

"The completion of interim enrolment for the pivotal SOLVE trial is a significant milestone and value catalyst," says president and CEO John McCutcheon.

"We remain confident that we will achieve the six-month primary endpoints, resulting in a successful pivotal trial and the basis for FDA approval. Our confidence is underpinned by outcomes from previous clinical trials of WiSE®, which have exceeded the performance endpoints set for the SOLVE trial."

Excitingly for the company, there is little in the way of competition in the field, giving EBR unprecedented access to an initial global addressable market of $3.6 billion in 2024.

"WiSE® is the only device that can potentially support the upgrade of patients currently implanted with a leadless right ventricle pacemaker, which solves a significant unmet need by providing a solution to patients with no other upgrade options," says McCutcheon.

"We have come a long way since our IPO late last year, further de-risking the business and strengthening EBR's investment proposition, and we are well-funded with $115 million in cash as of 2Q 2022."

ebr SYSTEMS

KEY INVESTMENT HIGHLIGHTS

JULY 1, 2022: EBR completes interim enrolment in pivotal SOLVE-CRT IDE clinical trial.

JULY 1, 2022: EBR secures 5-year US$50M growth capital facility with a leading venture debt provider Runway Growth Capital.

AUGUST 29, 2022: Clinical Study Demonstrating Feasibility of WiSE® in Left Bundle Branch Area Pacing published in Heart Rhythm Journal.

RON DUFFICY
GLOBAL CEO

ELIXINOL WELLNESS

(ASX:EXL)

- **Company Name:** Elixinol Wellness
- **Company ASX code:** EXL
- **Key areas:** Hemp derived nutraceutical and natural food products
- **Key Personnel:** Ron Dufficy, Global CEO | Helen Wiseman, Independent Non-Exec Chair
- **Locations:** NSW and Colorado, United States
- **Market Cap as of 15/09/22:** $11.06M
- **52 Week share price as of 15 September:** $0.019 - $0.110
- **Company Website:** elixinolwellness.com

COMPANY PROFILE

Elixinol Wellness is a global leader in the hemp industry - innovating, marketing and selling hemp-derived and other plant-based nutraceuticals, cosmetics and food products, capitalising on hemp's "new" status among consumers as something of a miracle crop, with many potential uses.

While being useful in the production of things from fuel to fabrics, furniture to medicine, and paper to bioplastics, the plant itself is capable of removing more CO2 from the air than trees and is pest, weed and drought resistant.

Elixinol's focus on hemp means that the company is well positioned in the global consumer wellness space towards natural and plant-based food and nutraceuticals, while its simplified business model targets established markets in the US and Australia – two markets representing Elixinol's stronger competitive positions, whilst maintaining a watching brief in the EU and UK depending on regulatory progress.

The continued rise in dietary changes around the country has seen many Australians turning to a more plant-based diet, with vegans, vegetarians and "flexitarians" driving a decreased demand for meat and building a market for other sources of nutrition.

Elixinol's Hemp Foods Australia (HFA) business is a leading hemp food wholesaler, retailer, manufacturer and exporter of bulk and branded raw materials and finished products in the southern hemisphere, helping to bridge that market gap.

HFA has, to date, launched a wide range of products that include hemp seeds, hemp protein shakes, hemp oil and the highly regarded Sativa Skincare range.

Located near Byron Bay, HFA has been steadily increasing its importance and place within the group, accounting for 44% of total revenues at near break-even levels.

In the US, Elixinol sells high quality hemp derived CBD nutraceutical and skincare products. Elixinol's comprehensive range includes CBD oils and capsules, liposomes, gummies, topicals and a pet range.

From its base in Colorado, Elixinol USA distributes these hemp-derived CBD and other natural wellness products to 40 countries globally including North and South America, throughout Europe, Asia, and the Pacific region.

Research by Brightfield Group points to a market increase of CBD based products in the US to reach $12 billion by 2026, driven by accelerated growth of ingestibles, as well as larger mainstream distribution channels, like groceries.

The regulatory environment in the US is developing positively with new Congressional bills receiving bi-partisan support, and California legalising CBD as a dietary supplement, and prices also appear to be stabilising indicating that the oversupply pressure is easing.

In the United Kingdom, South Africa, Japan, Brazil, Mexico and Malaysia, Elixinol branded products are available to consumers via exclusive distribution and/or Trademark and Know-How Licensing Agreements.

Elixinol recently undertook a company wide strategic review which has identified opportunities to reduce operating costs by approximately $3.2M on an annualised basis, further strengthening the company's fundamentals as it drives entry into new product categories.

Elixinol is currently headed by Global CEO, Ron Dufficy, who was previously the company's CFO. His extensive senior leadership and strategy experience includes senior international finance roles leading large international teams, including CFO of Aristocrat America.

Helen Wiseman is the incumbent Independent Chair and non-executive director, bringing extensive international experience in food, pharmaceutical, natural healthcare, professional services, energy and natural resources and manufacturing industries.

As a former partner of KPMG and previously named as one of the 2014 Australian Financial Review and Westpac 100 Women of Influence, she brings diversity and seasoned governance skills to the board.

ElixinolWellness

KEY INVESTMENT HIGHLIGHTS

DECEMBER 21, 2021: Signed a 3-year exclusive Trademark and Know-How Licensing Agreement with BRITISH CANNABIS™, to manufacture, market and sell Elixinol CBD products across the UK.
MARCH 28, 2022: A strategic review identifies opportunities expected to reduce annual operating costs by approx. $3.2M.
JULY 29, 2022: Strategic review completed and Ron Dufficy confirmed as Global CEO; Hemp Foods Australia secures national distribution deal with Coles.

DR MICHAEL WINLO
MANAGING DIRECTOR

EMYRIA

(ASX:EMD)

- **Company Name:** Emyria
- **Company ASX code:** EMD
- **Key areas:** Ultra-Pure Cannabinoid-based medical treatments, MDMA-inspired drug discovery, Real-World Data (RWD), specialist clinics
- **Key Personnel:** Dr Stewart Washer, Executive Chairman | Dr Michael Winlo, Managing Director | Dr Karen Smith, Executive Director
- **Locations:** Perth, Australia
- **Market Cap as of 15/09/22:** $68.75M
- **52 Week share price as of 15 September:** $0.170 - $0.505
- **Company Website:** emyria.com

COMPANY PROFILE

Emyria is an award-winning, clinical-stage biotech focused on accelerating the development of new treatments for unmet clinical needs. The company's three-pronged strategy involves collecting and analysing real-world data, using this data to improve formulations of and find new indications for select medications, and collaborating with leading institutions to develop life-changing treatments.

Emyria, one of three health and biotech companies to receive a significant multi-million dollar cash injection from Andrew Forrest's private investment vehicle Tattarang, is kicking goals toward its endgame of creating a more efficient drug development system.

The company gathers ethically sourced evidence from patients across five independent Australian clinical sites, and that real-world data on over 6,000 patients is providing deep treatment and drug development insights.

In just eight months, the company has developed a proprietary Ultra-Pure CBD capsule, EMD-RX5, and demonstrated its safety, tolerability and performance compared to the global leading registered CBD medication, Epidyolex.

Emyria is preparing to begin phase three clinical trials of EMD-RX5 in FY23, after the drug received Human Research Ethics Committee approval, in parallel with the development of a second Ultra-Pure CBD capsule, EMD-RX7.

The company is targeting global registration opportunities for these candidates as over-the-counter (OTC) and prescription-only medicines.

These EMD-RX cannabinoids will be among the first to achieve Australian OTC registration, a market worth +$200M a year. The company would then seek regulatory approval in other major markets including the US, which opens up a +US$1B a year opportunity.

Emyria has also made strides in its MDMA analogue program and has initiated pre-clinical studies. In 2021, the company partnered with elite Western Australian university to initiate the New Drug Development Program that aims to establish a large drug candidate library.

The library now comprises over 120 novel MDMA-like compounds, with three drug discovery priority areas identified. These priority areas include drug-assisted psychotherapy for major mental health disorders and novel, small molecule treatments for neurological disorders such as Parkinson's disease.

2022 has been a defining year for Emyria, with the company named as one of ACS' Digital Disruptors after its Openly digital solution took out the title of ICT Service Transformation for the Digital Consumer. Openly is a mobile phone app that can track vital signs via a user's smartphone camera.

Emyria also bolstered its board and international reach by tapping global bio-pharmaceutical expert Dr Karen Smith to join its board. Dr Smith is a biotech/pharmaceutical executive, director and clinical/scientific advisor in the US, Europe, Canada, and Asia.

Her breadth of experience covers over 100 clinical trials and 20+ major regulatory approvals in multiple jurisdictions including FDA (USA), EMA (Europe), TGA (Australia), ANVISA (Brazil), and PMDA (Japan), leading to product launches across diverse therapeutic areas such as oncology, rare disease, cardiology, dermatology, neuroscience, and anti-infectives.

At the helm is Stanford University educated Dr Michael Winlo, who prior to joining Emyria served as CEO of Linear Clinical Research. Before that he lived in Silicon Valley where he worked for Palantir, helping major healthcare institutions in the US and UK solve complex data integration and analysis challenges.

Emyria is also backed by a board with drug registration and deep biotech experience which has built an extensive portfolio of real-world data and drug candidates that have outperformed in safety and efficacy tests.

emyria

KEY INVESTMENT HIGHLIGHTS

JULY 18, 2022: Emyria and the University of Western Australia make drug discovery. and development progress by expanding their proprietary MDMA analogue library.
AUGUST 16, 2022: Human Research Ethics Committee approval granted, allowing Emyria to begin pivotal phase three trial of its Ultra-Pure CBD candidate, EMD-RX5.
AUGUST 18, 2022: Emyria and the University of Western Australia receive positive screening results from the third batch of MDMA analogues sent to Eurofins.

GLENN CROSS
CHAIRMAN

EZZ LIFE SCIENCE HOLDINGS

(ASX:EZZ)

- **Company Name:** EZZ Life Science Holdings
- **Company ASX code:** EZZ
- **Key areas:** Health supplements, health foods, personal care products
- **Key Personnel:** Glenn Cross, Chairman | Mark Qin, CEO and Director | Anthony Guarna – CFO
- **Locations:** Australia, New Zealand, Asia
- **Market Cap as of 15/09/22:** $13.25M
- **52 Week share price as of 15 September:** $0.270 - $0.595
- **Company Website:** ezzdna.com

COMPANY PROFILE

EZZ is a genomic life science company with a mission to improve life quality and health in an increasingly global ageing population. The company is focusing its genomic research and product development to isolate and unpack four key areas including:

Genetic longevity, human papillomavirus, helicobacter pylori (a bacteria that grows in the digestive tract which causes stomach ulcers and increases risk of stomach cancers) and weight management.

EZZ has entered local and international university partnerships to drive the momentum of research into human papillomavirus and genetic longevity.

Along with health supplements, health food and probiotics, EZZ, which listed on the ASX in March 2021, has expanded into personal care products leading with a hair care collection.

Ingredients used in the collection contain well-researched components proven to be beneficial to targeting hair problems, including caffeine, amino acids, peptides, and eucalyptus stem cell extract.

EZZ also holds the distribution rights for EAORON skin care products in Australia and New Zealand. Both EZZ and EAORON products are stocked in leading retailers and pharmacies Australia-wide including Chemist Warehouse and Priceline.

Growth has also come from China, where EZZ has established a successful business on e-commerce platforms Tmall Global and TikTok, known as Douyin, and short video platform Kuaishou.

During China's mid-year e-commerce festival, known as "618" in June, EZZ's Bone Growth Capsule was ranked the number one product in its category of children's nutritional supplements on Tmall Global for sales, reviews and repurchase.

EZZ products are also stocked in supermarkets and beauty stores in China, including Sasa in Hong Kong.

EZZ is looking to explore and launch into other potential markets to replicate its China success, including Singapore, Malaysia, Vietnam and the US.

On the financial side, EZZ is one of the rare biotechnology and life sciences companies on the Aussie bourse turning a profit, closing FY22 with a robust cash balance of more than $10M.

The company has earmarked establishing a Good Manufacturing Practice (GMP) certified manufacturing facility in Australia or New Zealand to improve production capabilities and efficiencies.

EZZ is also evaluating potential M&A opportunities to grow and scale the business.

The company has committed to using Australian and certified organic ingredients. As a life sciences company focused on improving people's health, EZZ believes part of that mission is to also look after the environment which can have a detrimental effect on people's overall wellbeing.

The company is working to ensure it not only uses natural and organic ingredients as much as possible, but also recyclable and environmentally friendly packaging.

At the helm, EZZ has a strong leadership team, including former CEO and COO of AusBiotech, Glenn Cross, as its chairman and non-executive director.

Cross has more than 40 years' experience in the life science sector domestically and internationally, including ~20 years' in senior executive roles.

With its collaborations with world-class research institutions and commitment to strategic integration, Cross believes EZZ is well placed to further expand its business and pursue growth opportunities in the genomics area.

CEO and director, Mark Qin, is an award-winning research analyst and business entrepreneur and author.

EZZ

KEY INVESTMENT HIGHLIGHTS

- EZZ has established a successful and profitable genomic life science company targeting high-quality consumer health products for key healthcare markets benefitting from the world's ageing populations.
- Experienced management team with proven track records to drive growth initiatives such as; new product development, expanded distribution channels, new target markets, and M&A opportunities.
- Robust balance sheet, supported by positive operating cash flow, allows EZZ to implement and accelerate strategic growth plans.

ROBERT PROULX
PRESIDENT & CEO

IMAGION BIOSYSTEMS

(ASX:IBX)

- **Company Name:** Imagion Biosystems
- **Company ASX code:** IBX
- **Key areas:** Early cancer detection - molecular imaging technology using bio-safe magnetic nanoparticles to non-invasively find tumors
- **Key Personnel:** Robert Proulx, President & CEO
- **Locations:** Australia and United States
- **Market Cap as of 15/09/22:** $39.24M
- **52 Week share price as of 15 September:** $0.026 - $0.105
- **Company Website:** imagionbiosystems.com

COMPANY PROFILE

Imagion Biosystems is developing new medical imaging techniques using its ground-breaking MagSense® magnetic nanoparticle technology, with an aim to provide a non-invasive, more accurate means of identifying the presence of various types of cancer.

The molecular imaging technology helps patients avoid radiation exposure used in alternative imaging methods, as well as reduce the need for invasive and risky biopsy procedures.

It's a combination of biotechnology and nanotechnology, using magnetic nanoparticles coated with a targeting molecule to detect cancer tumours.

Patients are given a low dose injection of the nanoparticle imaging agent, and the targeting molecule affixed to the nanoparticles finds and binds to tumor cells.

Once attached, the magnetic property of the particles acts as a magnetic beacon and is detectable by magnetic imaging technologies.

The tiny nanoparticles don't stay in the body either, they're cleared through the liver with the iron "repurposed" to produce ferritin which is used in hemoglobin production.

And the tech has been designated as a 'breakthrough device' by the US Food and Drug Administration (FDA) – which is only granted to novel medical devices that have the potential to provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

The MagSense® HER2 Breast Cancer imaging agent is already being evaluated in a clinical study investigating the potential for it to be used for nodal staging of HER2-positive breast cancer (where the patient tests positive for a protein called human epidermal growth factor receptor 2) by detecting if tumor cells have metastasized to the lymph nodes.

In 2022 alone, there are estimated to be around 287,000 new breast cancer cases in the US alone, with approximately 20% or around 57,000 being HER2 with metastatic spread to the lymph nodes.

Currently, nodal staging requires a patient's lymph nodes to be surgically biopsied for histopathological examination, a process that hasn't changed much in the last 50 years, whereas the MagSense® imaging agent can reduce the need for biopsies.

In fact, Imagion says its tech is expected to eliminate a whopping 48% of unnecessary biopsies for patients that do not have metastatic spread to the lymph nodes, reducing the incidence of lymphedema and associated morbidity.

Looking at cancer more broadly, making imaging more specific and less invasive is a huge market opportunity for Imagion because the global cancer diagnostic market is estimated to be worth around US$100 billion – yep, billion, with a "B" – annually.

The disease is still the leading cause of mortality, but the company is confident its tech will have improved sensitivity than current diagnostic techniques, making it better for routine use in early detection, and early detection means better survival outcomes.

As an added bonus, the tech is cheaper than PET or CT scanning machines and doesn't require the installation expense of a shielded room.

Imagion is also undertaking R&D to build a pipeline of imaging products for other types of cancer such as prostate, ovarian, and brain cancers, in partnership and collaboration with world-class global universities and hospitals.

But cancer diagnostics isn't the only commercial opportunity for the company, as Imagion is confident that the possibilities abound for its magnetic nanoparticles, from an MRI contrast agent, to therapy, to drug delivery, and even a printer-ink revenue model.

IMAGION BIOSYSTEMS

KEY INVESTMENT HIGHLIGHTS

AUGUST 17, 2021: Establishes Joint Development Agreement with Global Cancer Technology to develop nanocrystals for treating breast cancer.

MARCH 17, 2022: Reports interim results from MagSense™ HER2 Breast Cancer First-in-human Study indicating imaging agent is safe and well tolerated by patients.

APRIL 14, 2022: Enters Sponsored Research Agreement with researchers at Massachusetts General Hospital focusing on nanoparticle use with MRI.

STEVEN LYDEAMORE
CEO

IMMURON

(ASX:IMC)

- **Company Name:** Immuron
- **Company ASX code:** IMC, NASDAQ: IMRN
- **Key areas:** Orally delivered polyclonal antibodies produced from hyperimmune antibody-rich bovine colostrum, for prevention and treatment of gut-mediated diseases
- **Key Personnel:** Steven Lydeamore, CEO | Jerry Kanellos, COO
- **Locations:** Australia, United States, Canada
- **Market Cap as of 15/09/22:** $18.90M
- **52 Week share price as of 15 September:** $0.076 - $0.170
- **Company Website:** immuron.com.au

COMPANY PROFILE

It is rare to find a biopharmaceutical company generating revenue from both product sales and developing new drugs in the clinic, but dual-listed, Australian-North American company Immuron is one such example.

Immuron has developed two commercial oral immunotherapeutic products for the treatment of gut-mediated diseases, and it has four clinical programs entering Phase II trials.

The company's advanced stage reflects a substantial market opportunity, according to CEO Steven Lydeamore, who joined the company in June this year.

"Our products are a subset of the multi-billion dollar global digestive health market," he says.

"There are opportunities to grow sales of our two commercialised products, Travelan® and Protectyn®, and opportunities to further develop our intellectual property portfolio.

"We have a patented and validated technology platform from which three products, IMM-124E, CampETEC and IMM-529, are entering trials in traveller's diarrhoea, campylobacter and enterotoxigenic Escherichia coli (E.coli) and Clostridioides difficile infections, respectively, and there are opportunities for expanded use of Travelan®.

"Travelan® is presently in clinical trials for traveller's diarrhoea and Immuron is conducting additional research into infectious diseases with various divisions of the U.S. Department of Defense."

Resurgence of Travelan® drove Immuron global sales increase of 425% in FY22 approaching $1 million. Prior to the pandemic, sales peaked at $2.9 million for three quarters of FY20.

Travelan® is an orally administered passive immunotherapy in tablet form that prophylactically reduces the risk of traveller's diarrhoea, a digestive tract disorder commonly caused by pathogenic bacteria. Travelan® is experiencing renewed growth in North America, with sales up 494% in FY22, as travel begins to rapidly increase following two years of heavy restrictions.

The active ingredient in Travelan® is hyperimmune bovine colostrum powder, a rich source of antibodies that bind to E. coli in the gastrointestinal tract, preventing them from attaching to the intestinal wall and thereby neutralising their ability to cause traveller's diarrhoea.

The global market for traveller's diarrhoea is growing by 7% each year, and, assuming a penetration rate of just 15%, Travelan® stands to be worth $83 million in North America and around $50 million in Europe.

Meanwhile, Protectyn® is an immune supplement scientifically formulated to be rich in anti-LPS antibodies to target pathogenic bacteria and the harmful LPS toxins they produce in the gut, reducing their ability to disrupt the healthy function of the gut, liver and immune system.

The two drugs are produced through Immuron's proprietary technology platform, which combines the natural health benefits of bovine colostrum with a novel class of specifically targeted oral polyclonal antibodies that offer delivery within the gastrointestinal tract.

Travelan®'s potential has recently been rubber-stamped by the US Department of Defense, which provided a $6.4 million grant to Immuron and the US Naval Medical Research Center (NMRC) to examine a dosing regimen more suited for use by the US military; clinical trials are underway.

The Uniformed Services University is anticipated to commence a randomised clinical trial with Travelan® this financial year to evaluate the effectiveness for prophylaxis during deployment or travel to a high-risk region for traveller's diarrhoea.

In addition, market evaluation is being undertaken before initiating further trials of IMM-529 for treatment of Clostridioides difficile infections, and Immuron partner NMRC is on clinical hold for two proposed trials of a new therapeutic, CampETEC in campylobacter and enterotoxigenic E.coli.

KEY INVESTMENT HIGHLIGHTS

JANUARY 12, 2022: US Department of Defense awards $6.2M to IMC to clinically evaluate a military strength dosing regimen of traveller's diarrhoea drug Travelan®.

JULY 7, 2022: Immuron receives European Patent Notification on drug composition to treat Clostridioides difficile associated disease.

JULY 11, 2022: Immuron reports North American Travelan® sales have skyrocketed by 494%, and global sales up 431%.

JOEL LATHAM
MANAGING DIRECTOR

INCANNEX HEALTHCARE

(ASX:IHL)

- **Company Name:** Incannex Healthcare
- **Company ASX code:** IHL, NASDAQ: IXHL
- **Key areas:** Novel combination cannabinoid pharmaceuticals and psychedelic therapies.
- **Key Personnel:** Joel Latham, Managing Director | Dr Mark Bleackley, Chief Scientific Officer | Rosemarie Walsh, VP, Clinical Operations
- **Locations:** Sydney, Melbourne, Perth, New York
- **Market Cap as of 15/09/22:** $472.31M
- **52 Week share price as of 15 September:** $0.185 - $0.755
- **Company Website:** incannex.com.au

COMPANY PROFILE

In the burgeoning area of medicinal cannabis and psychedelic therapy on the ASX, Incannex Healthcare stands out, with a mission to create first-in-class pharmaceutical drugs and therapies for patients with unmet medical needs.

Incannex listed on the ASX in 2016 and in February moved to a dual listing on the Nasdaq, to be accessible to a wider audience of investors with sophisticated understanding of medicinal cannabinoids, psychedelic therapies and pharmaceutical development.

Incannex is developing targeted and scientifically validated fixed-dose combinations of synthetic cannabinoid and psychedelic agents, applying proprietary insights to create long term benefit for patients and shareholders.

The company is focused on developing patented pharmacotherapies (drugs) to the point of FDA registration for prescription by a doctor.

Incannex's competitive advantage over other medicinal cannabis companies is that its cannabinoid drug candidates are combined with existing off-patent pharmaceuticals to synergistically enhance therapeutic outcomes.

Incannex is undertaking clinical projects for its cannabinoid combination drug candidates designed to treat obstructive sleep apnoea, lung inflammation, rheumatoid arthritis, inflammatory bowel disease, concussion and traumatic brain injury

In partnership with the Clinical Psychedelic Research Lab at Monash University, Incannex is undertaking a Phase II trial investigating psilocybin assisted psychotherapy to treat generalised anxiety disorder (GAD). The trial is considered one of the top 5 most advanced trials in the psychedelic space globally.

Furthermore, Incannex's portfolio of clinical indications expanded rapidly since its landmark acquisition of APIRx Pharmaceuticals in August, supercharging its technical and drug development capability and patent portfolio.

APIRx researches and develops prescription pharmaceutical cannabinoid medicines with 22 active pre-clinical and clinical projects at various stages of development, underpinned by 19 granted patents and 23 pending patents.

APIRx has cannabinoid treatment candidates for pain management, dementia, Parkinson's disease, restless leg syndrome, gastrointestinal diseases, periodontitis, addiction disorders, skin, and ophthalmic conditions.

It also has multiple patents for cannabinoid-based drug candidates designed for treatment of addiction to different drug classes including opioid, cannabis and nicotine.

The APRIx acquisition marks possibly the most significant in the medicinal cannabis sector since the takeover of GW Pharmaceuticals (developer of CBD-based Epidiolex) by Jazz Pharmaceuticals for US$7.2B announced in May 2021.

APIRx was established as a corporate entity in the Netherlands to amalgamate the intellectual property assets of medicinal cannabinoid pioneers, and the company's co-founders Dr George Anastassov and Lekhram Changoer.

The pair have developed the world's largest privately-held patent portfolio of pharmaceutical cannabinoid inventions, ideas and products.

In a strong vote of confidence in its drug candidates and development strategy, former Pfizer executive and now Novo Nordisk A/S vice president, US regulatory affairs expert Robert B. Clark has joined the Incannex board of directors.

Clark is an international pharmaceutical regulatory heavyweight with more than 38 years of US and global regulatory experience, overseeing FDA approval of 12 new pharmaceutical drugs over the past 10 years. Experience will benefit Incannex as it focuses on US and European programs.

Incannex

KEY INVESTMENT HIGHLIGHTS

JULY 21, 2022: Incannex earns approval to start a milestone clinical trial into its multi-use, anti-inflammatory drug IHL-675A to treat various inflammatory disorders.

AUGUST 5, 2022: Incannex completes the acquisition of APIRx Pharmaceuticals to become the world's largest holder of patents related to medicinal cannabis product candidates.

AUGUST 17, 2022: Incannex appoints former Pfizer executive and now Novo Nordisk A/S Vice President, US regulatory affairs Robert B. Clark as a Non-Executive Director.

DR LEEARNE HINCH
CEO

INOVIQ

(ASX:IIQ)

- **Company Name:** INOVIQ
- **Company ASX code:** IIQ
- **Key areas:** Exosome capture tools and precision diagnostics for cancer and other diseases
- **Key Personnel:** Dr Leearne Hinch, CEO | Dr Gregory Rice, Chief Scientific Office | Dr Rocco Iannello, Business Development and Licensing Director
- **Locations:** Australia and United States
- **Market Cap as of 15/09/22:** $62.11M
- **52 Week share price as of 15 September:** $0.385 - $1.500
- **Company Website:** inoviq.com

COMPANY PROFILE

INOVIQ is developing and commercialising next generation exosome capture tools and precision diagnostics for the screening, diagnosis, prognosis and monitoring of cancer and other diseases.

The global cancer diagnostics market is worth $US250 billion, and INOVIQ is targeting markets worth over $US15 billion for some of the most common and deadliest cancers.

INOVIQ is using its patented biomarker isolation and detection technologies and a multiomics approach to develop earlier and more accurate diagnostics to improve outcomes for patients with cancer and other diseases.

The company's diagnostics pipeline includes blood tests in development for earlier detection and monitoring of ovarian, breast and other cancers.

INOVIQ already has two products in-market - its EXO-NET® research tool for pan-exosome capture and its hTERT test for bladder cancer detection.

EXO-NET pan-exosome capture is a 'research use only' product for the isolation of exosomes from blood and other body fluids with speed, purity, and yield advantages. EXO-NET meets an unmet need for fast, precise and scalable isolation of exosomes for research and commercial applications.

Exosomes are extracellular vesicles released by cells that carry biomolecules such as DNA, RNAs, proteins and lipids that can have important applications in the research, diagnosis and treatment of cancer, inflammatory, metabolic, and neurodegenerative diseases.

INOVIQ recently hit a key milestone on the path to global expansion, accelerating the commercial roll-out of its EXO-NET research products in North America by engaging Percorso Life Sciences for sales and logistics services. The global exosome research market is expected to reach $US661m by 2026, with the US accounting for 41.5% of the market.

In April 2022, INOVIQ announced its first EXO-NET collaboration with the University of Queensland to develop a world-first exosome-based ovarian cancer screening test. This blood test could fill an important unmet need for an accurate and reliable screening test for ovarian cancer to improve women's health outcomes and save lives.

The company's proprietary SubB2M technology detects the pan-cancer biomarker Neu5Gc found at elevated levels in multiple human cancers.

SubB2M immunoassays are being developed to "supercharge" existing FDA-approved blood tests for monitoring ovarian and breast cancers, and a SubB2M-SPR test is also being evaluated to detect Neu5Gc as a pan-cancer indicator in a general health panel.

In May 2022, INOVIQ executed an agreement with MP Biomedicals, a global supplier of life science and diagnostic products, for the contract manufacture of the SubB2M protein.

In April 2022, contract diagnostics firm ResearchDx was engaged to further develop and validate the SubB2M-based tests, with the SubB2M/CA15.3 and SubB2M/CA125 immunoassays for breast and ovarian cancer monitoring expected to commence clinical studies by the end of 2022.

INOVIQ's team has a strong track record in healthcare, diagnostic development, and commercialisation and is building a strong footprint in the exosome and diagnostics markets.

CEO Dr Leearne Hinch is an experienced biotechnology executive with expertise in corporate development, capital raising, product development, commercialisation and licensing.

CSO Dr Greg Rice is an internationally recognised academic and commercial scientist with over 30 years of experience in oncology, perinatology, exosome-based research, clinical translational research, IVD development and commercialisation.

INOVIQ

KEY INVESTMENT HIGHLIGHTS

APRIL 1, 2022: INOVIQ and the University of Queensland expand collaboration to develop world-first exosome-based ovarian cancer screening test.

APRIL 5, 2022: INOVIQ signs agreement with US-based contract diagnostics organisation ResearchDx to develop and validate SubB2M test for the monitoring of breast and ovarian cancers.

JULY 21, 2022: INOVIQ accelerates commercial roll-out of its EXO-NET research products in North America with engagement of US-based contract sales team.

DR DAVID FOSTER
MANAGING DIRECTOR

ISLAND PHARMACEUTICALS

(ASX:ILA)

- **Company Name:** Island Pharmaceuticals
- **Company ASX code:** ILA
- **Key areas:** Antiviral therapeutics
- **Key Personnel:** Dr Paul MacLeman, Executive Chairman | Dr David Foster, Managing Director | Teresa Byrne, Vice President, Clinical Product Development
- **Locations:** Victoria, Australia
- **Market Cap as of 15/09/22:** $12.59M
- **52 Week share price as of 15 September:** $0.115 - $0.365
- **Company Website:** islandpharmaceuticals.com

COMPANY PROFILE

If you hear the word 'viral', the mind generally jumps to viral videos or memes that are seen by millions of people across the internet.

But while in clinical stage, drug repurposer Island Pharmaceuticals hopes its name will soon go viral in such a way, its interpretation of the word has a far more consequential meaning.

Island is driving the development of its lead drug asset, ISLA-101, in the hope it can be used to treat some of the world's most dangerous viral diseases, including dengue fever, Zika virus and Japanese encephalitis.

"As the world continues to emerge from the COVID-19 pandemic, we are as committed as ever to contributing to a new paradigm in antiviral drug development in which we can rapidly develop antivirals against known viral threats or viral threats yet to be identified," says Dr Paul MacLeman, Chairman of Island Pharmaceuticals.

"According to the World Health Organisation, around 390 million people contract dengue fever each year, with about 500,000 of those cases being severe and 25,000 people dying per year from the disease.

"Through the past year, we've seen other mosquito borne diseases, like Japanese encephalitis, feature more in the Australian news, with cases and deaths reported as far south as Victoria and South Australia. The same mosquitoes which carry this can carry dengue.

"Equally, we've seen dengue itself travel to parts of the world where we wouldn't usually expect to see it.

"As global temperatures warm, migratory birds are travelling further from their historic regions, bringing these diseased mosquitoes with them.

"The statistics underscore the need for preventatives and therapeutics for dengue fever, our core focus, and other mosquito borne diseases."

ISLA-101 was initially developed by Island's wholly-owned subsidiary Isla Pharmaceuticals, and has a well-established safety profile.

It is now being repurposed for the prevention and treatment for dengue fever and other mosquito or vector-borne diseases, although the immediate focus is on dengue fever.

"Dengue fever is the very definition of an unmet medical need," explains CEO, Dr David Foster.

"It is thought that around 30% - 50% of people with the disease do not present with symptoms, enabling the virus to spread within communities.

"Warming global climates are accelerating the presence of mosquito-borne viruses that can cause death to the US, Europe and Australia

"There is no specific pharmaceutical treatment and the two vaccines that exist are only available to a highly restricted audience."

Island has made significant progress with ISLA-101, which is heading into Phase II clinical trials. The clinical site has been secured, as have the regulators of the study, and most recently it engaged a Florida-based company, Sofgen, to manufacture the clinical product to be used in the upcoming clinical trial.

The next steps are to file an Investigational New Drug (IND) application with the FDA, on track for the coming months, and to commence with patient screening and enrolment, expected by the end of the calendar year.

The company's strategy was recently further validated through the appointment of accomplished virologist and pharmaceutical executive Dr Amy Patick to its scientific advisory board.

"We are delighted to have such an experienced virologoist as Dr Patick bringing her depth of scientific knowledge and leadership to our advisory board, at such a pivotal time in our drug repurposing program," Dr David Foster says.

ISLAND PHARMACEUTICALS
Antiviral therapeutics

KEY INVESTMENT HIGHLIGHTS

JANUARY 31, 2022: Island signs clinical trial support services agreement for ISLA-101 Phase 2a PEACH study with ICON Government and Public Health Solutions.
JUNE 15, 2022: Accomplished virologist and pharmaceutical executive Dr Amy Patick appointed to ILA Scientific Advisory Board.
JULY 28, 2022: New manufacturing partner, Sofgen Pharmaceuticals is appointed for the supply of ISLA-101 clinical trial study drug.

DR JAMES GARNER
CEO & MANAGING DIRECTOR

KAZIA THERAPEUTICS

(ASX:KZA)

- **Company Name:** Kazia Therapeutics
- **Company ASX code:** KZA
- **Key areas:** Biotech - oncology
- **Key Personnel:** Dr James Garner, CEO & Managing Director | Dr John Friend, Chief Medical Officer | Karen Krumeich, Chief Financial Officer
- **Locations:** New South Wales, Australia
- **Market Cap as of 15/09/22:** $35.16M
- **52 Week share price as of 15 September:** $0.195 - $1.650
- **Company Website:** kaziatherapeutics.com

COMPANY PROFILE

Kazia is a late-stage oncology company, with two potential cancer drugs in human trials.

Their lead program is paxalisib, a brain-penetrant inhibitor of the PI3K/Akt/mTOR pathway, which is being developed to treat several forms of brain cancer, including glioblastoma and the rare and aggressive childhood brain cancer, diffuse intrinsic pontine glioma (DIPG).

Despite all efforts, the prognosis for patients with brain cancer has improved little in the past two decades.

For glioblastoma, the most common and most aggressive form of brain cancer, average life expectancy from diagnosis is around 15 months, and less than 5% of patients are still alive after five years.

Not only is it a huge unmet clinical need – glioblastoma affects approximately 130,000 patients per annum worldwide – it is conservatively estimated to represent a US$1.5 billion annual commercial market.

If paxalisib can also be approved for other forms of brain cancer, that is expected to create additional opportunities for the product.

Kazia is casting a wide net in its clinical trials to explore the potential for the drug in a range of treatment areas – unlike the majority of biotech players who tend to put all their eggs in one basket.

The company currently has eight clinical trials underway, including GBM AGILE, a pivotal study in glioblastoma, which is due for completion in another 12 months' time.

The company also recently announced positive interim results from a phase I clinical trial of paxalisib in combination with radiotherapy for the treatment of brain metastases – namely a 100% overall response rate which means every evaluable patient has had some meaningful response.

That particular trial could lead to a potentially huge opportunity for Kazia and treat an enormous unmet need, with around 200,000 patients diagnosed with brain metastases each year in the United States alone. The next step is for the study to recruit another 12 patients, with final data expected in 2023.

A clinical trial of the combination of paxalisib with ONC201 (Chimerix, Inc) in the treatment of DIPG and diffuse midline gliomas (DMGs) commenced recruitment in November 2021 under the sponsorship of the Pacific Pediatric Neuro-Oncology Consortium (PNOC), with initial data anticipated in in the first half of 2023.

It remains very clear the company has plenty of opportunities in the pipeline for paxalisib. The drug was granted Orphan Drug Designation for glioblastoma by the US FDA in February 2018, and Fast Track Designation for glioblastoma by the US FDA in August 2020.

It was also granted Rare Paediatric Disease Designation and Orphan Designation by the US FDA for DIPG in August 2020, and for AT/RT – another childhood brain cancer - in June 2022.

Kazia is also developing EVT801, a small-molecule inhibitor of VEGFR3, which was licensed from Evotec SE in April 2021. Preclinical data has shown EVT801 to be active against a broad range of tumour types and has provided compelling evidence of synergy with immuno- oncology agents.

A phase I study for EVT801 commenced recruitment in November 2021, with interim data expected in 2H CY2022 or 1H CY2023.

The company launched a new Scientific Advisory Board (SAB) in July 2022, comprising four leading experts in brain cancer which it says reflects the late stage of development of paxalisib in brain cancer and has been designed to support imminent initiation of pre-commercial activities for the drug.

KAZIA THERAPEUTICS

KEY INVESTMENT HIGHLIGHTS

JUNE 12, 2022: Compelling preclinical data supporting the efficacy of paxalisib with ONC201 in the treatment of DIPG leads to new clinical trial.

JULY 6, 2022: Paxalisib awarded Rare Pediatric Disease Designation (RPDD) by US FDA for treating rare, aggressive childhood brain cancer, atypical rhabdoid/teratoid tumors.

AUGUST 8, 2022: Phase I clinical trial of paxalisib in combination with radiotherapy shows a complete/partial response rate of 100%.

BRENT BARNES
CEO & MANAGING DIRECTOR

LBT INNOVATIONS

(ASX:LBT)

- **Company Name:** LBT Innovations
- **Company ASX code:** LBT
- **Key areas:** Medical devices, diagnostics
- **Key Personnel:** Brent Barnes, CEO & Managing Director | Ray Ridge, Company Secretary & CFO
- **Locations:** Adelaide, South Australia, United States, Europe
- **Market Cap as of 15/09/22:** $26.97M
- **52 Week share price as of 15 September:** $0.064 - $0.158
- **Company Website:** lbtinnovations.com

COMPANY PROFILE

LBT Innovations uses disruptive artificial intelligence (AI) and intelligent imaging technology to automate the imaging, analysis, and interpretation of culture plates for busy microbiology laboratories.

Currently, around 70% of clinical decisions are based on in vitro diagnostic lab results and thousands of plates are assessed each day by busy microbiologists for the presence of clinically significant bacterial colonies, which can result in human error and extensive delays.

The company's Automated Plate Assessment System (APAS) Independence automatically screens, interprets and sorts these plates, overcoming the bottleneck in lab workflows and freeing up microbiologists' time. And the AI tech has been clinically proven to go beyond being purely assistive.

Through extensive clinical trials, LBT has demonstrated the system's ability to accurately detect the presence of significant disease-causing pathogens on a variety of culture mediums.

This means major time savings for busy laboratories and microbiologists, along with faster, more accurate results for doctors and their patients.

Plus, the APAS platform is the only United States Food and Drug Administration (FDA)-cleared AI technology for automated imaging, analysis and interpretation of culture plates following incubation.

Last year, LBT's joint venture company (which it now owns 100%) Clever Culture Systems (CCS) received 510(k) clearance for the APAS Independence with MRSA analysis module as a Class II medical device.

MRSA – which stands for Methicillin-resistant Staphylococcus aureus – is one of the leading causes of multi-drug resistant infections, with patients suffering from MRSA infections around 64% more likely to die than people with drug sensitive infections.

The company now has regulatory cleared analysis modules covering the largest two specimen types by volume – Urine and MRSA – meaning they are able to sell the modules commercially to customers in the United States.

Each analysis module is sold to customers under a separate software licence and is available to customers as a software upgrade, which enables laboratory customers to customise the configuration of the APAS Independence for their laboratory workflow and range of specimens – as well as increasing the revenue opportunity for each APAS instrument sold.

Pursuing FDA clearance was widely considered to be a smart move, especially since the United States has over 5,000 clinical laboratories, representing the single largest market in the world for the LBT's product.

In fact, the company estimates that the addressable market for the platform in the United States is over 1,500 laboratories – and it's already making sales.

During the June Quarter 2022, four APAS Independence instruments were sold following shipment to Thermo Fisher, with a fifth instrument scheduled for shipment in August.

LBT says commercial activities have continued to accelerate under the expanded sales reach of Thermo Fisher – who have an existing portfolio of microbiology products in the US and an established network of sales representatives with existing customer relationships across several large clinical microbiology laboratories.

In Europe, LBT's channel partner is Beckman Coulter, Inc, and the aim is to advance sales opportunities following recent evaluations completed by customers in the UK, Germany and France.

LBT is confident that APAS's revolutionary platform technology for intelligent image interpretation also offers potential for multiple applications across all of microbiology, including both clinical and non-clinical applications, such as, food, water and pharma, just to name a few.

LBT INNOVATIONS

KEY INVESTMENT HIGHLIGHTS

JANUARY 4, 2022: Completed acquisition of remaining 50% shareholding of the Clever Culture Systems joint venture, expected to accelerate time to breakeven for the Company.

AUGUST 10, 2022: Exciting new product pipeline increases market opportunity, including expansion into Pharma industry vertical with major multinational partner.

AUGUST 31, 2022: 7 sales completed so far in CY2022 (worth >US$350k per instrument). Market traction building follows appointment of Thermo Fisher, exclusive US distributor.

DR SEAN HALL
CEO

MEDLAB CLINICAL
(ASX:MDC)

- **Company Name:** Medlab Clinical
- **Company ASX code:** MDC
- **Key areas:** Biotechnology, drug enhancement and delivery technologies, new drug development with primary focus on pain, depression and stress.
- **Key Personnel:** Dr Sean Hall, CEO | Kerem Kaya, CFO
- **Locations:** Sydney, Australia
- **Market Cap as of 15/09/22:** $28.08M
- **52 Week share price as of 15 September:** $6.450 - $30.000
- **Company Website:** medlab.co

COMPANY PROFILE

Ensuring the active pharmaceutical ingredient (API) of medicines is delivered effectively and absorbed by the human body has been a major challenge throughout medical history.

In a traditional pill, around 80-90% of the API (Active Pharmaceutical Ingredient) is often lost through digestion, however one Aussie biotech has a market-ready solution; the NanoCelleTM technology of Medlab Clinical which is changing the way medicine is delivered for better patient outcomes.

It has potential to replace injections, rejuvenate existing medicines, improve the delivery and effectiveness of new drugs and vaccines utilising the NanoCelle chemical shrinking process to reduce the molecular size of the API to nanoscale.

A NanoCelle enhanced particle is 200 times smaller than a red blood cell, which is ~7.5 to 8.7um in diameter and ~1.7 to 2.2um in thickness. At such small scale, the API can be administered in a range of different ways, including application as a spray inside the cheek, under the tongue, as a nasal spray, lotion, or skin patch.

In bypassing the gut and liver, less active ingredient is required to reach the desired target, which can also lead to other benefits such as fewer side effects, lower toxicity and more rapid absorption particularly useful for acute pain.

Medicines that would traditionally take up to an hour to take effect do so within a few minutes the company says, adding that the NanoCelle-enhanced medicines have been clinically proven to have up to 5 times superior bioavailability over other drug delivery methods at equivalent doses, and are also ideal for those with difficulty swallowing, injecting or with gastro-intestinal complications.

But where the patented NanoCelle process stands out commercially is its ease of adaptability, making it highly scalable and cost effective. NanoCelle adds just three additional chemistry steps to existing drug manufacturing processes.

Furthermore, no additional equipment beyond that found in a modern liquid pharmaceutical manufacturing facility is required to make thousands of litres of liquid NanoCelle-enhanced medicines every few hours – stable-at-room-temperature solutions which optimise delivery of medicines and vaccines, with greatly reduced transport and storage temperature requirements.

Proof of concept has been shown for a needle-free NanoCelle nasal spray for insulin, and for enhancement of generic drugs such as statins (cholesterol) and loratadine (antihistamines).

Successful PI/P2 clinical trials of a NanoCelle cannabis product (NanaBis) for pain relief have already proven safety, efficacy and potential for opioid sparing or replacement.

The NanoCelle tech underpins Medlab's current products and research, such as programs for pain and stress (NanaBis and NanoCBD), depression (MDC2000) and the Australian government sponsored mRNA Covid nasal vaccine research.

Medlab currently has three TGA listed products that use NanoCelle, with NanoCelle D3, NanoCelle Activated B12, and NanoCelle D3+K2 available for consumer purchase.

NanaBis and NanoCBD are also available under the Special Access Scheme, pending P3 clinical trials and FDA/TGA approval. Over 350,000 doses of NanoCelle products have been safely delivered to patients.

2022 has been a milestone year for Medlab, which has established research collaborations with leading Australian universities, clinically validating and patent protecting NanoCelle in all Western territories.

KEY INVESTMENT HIGHLIGHTS

- NanoCelle® drug enhancement and delivery technology now patent protected in all Western territories, independently validated for superior bioavailability, and approaching diverse partnering deals on multiple drugs.
- Lead pain management drug candidate NanaBis™ entering final clinical stages to support FDA New Drug Applications and subsequent commercial sales.
- Medlab Clinical shareholders have approved the company's proposal to dual list on the NASDAQ later this year, providing access to the deep pool of biotech-savvy investors and capital in the world's largest market.

ROBY ZOMER
CEO & MANAGING DIRECTOR

MGC PHARMACEUTICALS

(ASX:MXC)

- **Company Name:** MGC Pharmaceuticals
- **Company ASX code:** MXC
- **Key areas:** Focused on the production of plant-based medicines for diseases including epilepsy, dementia and alzheimer's, COVID-19
- **Key Personnel:** Roby Zomer, CEO & Managing Director | Dr. Nadya Lisodover, Chief Medical Officer | Robert Clements, Chief Commercial Officer
- **Locations:** United Kingdom, Slovenia, Israel, Malta
- **Market Cap as of 15/09/22:** $45.61M
- **52 Week share price as of 15 September:** $0.015 - $0.066

COMPANY PROFILE

MGC Pharmaceuticals is a global biopharma company, focused on developing and supplying high-quality plant inspired medicines to patients in Europe, Australasia, and North America.

According to co-Founder, MD and CEO Roby Zomer, MGC's vision is "to have a global impact on undertreated medical conditions and diseases, using the power of plant-based medicine in novel combinations by using technology to harness knowledge and science to achieve our "Nature to Medicine" strategy.

That vision is underpinned by its drive to create sustainable and affordable treatment options, which MGC says are designed to work with patients' internal systems, ease symptoms and facilitate lifestyles that are "empowered by medication as opposed to limited by it".

Currently, MGC Pharmaceuticals has three main avenues of study and development in its phytomedicine range CannEpil, CogniCann and CimetrA.

CannEpil is an orally administered medical cannabis treatment for drug-resistant (or refractory) epilepsy, which involves frequent and severe seizures that are difficult to treat.

According to the World Health Organisation (WHO), there are roughly 50 million people in the world with some form of epilepsy, and of those 50 million, 30% have refractory epilepsy, a solid global market for the drug.

CannEpil has been made available since 2019, and ongoing trials into the drug's safety and efficacy for use in adolescents and children are currently underway in Israel, CannEpil was approved as part of the early access scheme in Ireland.

MGC signed a distribution agreement with Sciensus Rare meaning patients across the EU will also now be able to be prescribed the drug where there is an unmet medical need.

The company recently announced a concluded study into the effects of the drug on critical motor skills involved in driving a vehicle found that the drug was safe for post-treatment driving activities.

MGC has also developed CogniCann, a treatment to improve quality of life in dementia patients, which is currently in Phase II clinical trial stage at the University of Notre Dame in Perth, Western Australia.

The CogniCann trial was delayed by several months due to disruptions caused by COVID-19, which itself is the focus of MGC's third current development focus CimetrA, which is currently in Phase III clinical trials.

That trial is looking into the efficacy and safety of CimetrA as a treatment for hospitalised patients diagnosed with COVID-19, and to provide additional data for claims on the product as an Investigational Medicinal Product.

To provide the necessary active ingredient, MGC has established licensed operations in Malta and Slovenia; an IMP production plant in Slovenia, and a manufacturing site co-funded by the Maltese government.

Further to the development of its three drugs, MGC is heavily involved in finding new ways to utilise its product and provide avenues to build on its history of positive reports.

In June 2022, the company reported that a 3-year preclinical in-vitro research into the use of cannabinoids in the treatment of Glioblastoma – a rapid and aggressive form of brain tumour, demonstrated that MGC Pharma's proprietary Cannabidiol (CBD) and Cannabigerol (CBG formulations were cytotoxic to Glioblastoma tumour and stem cells, reducing the cells' viability and inducing caspase-dependent cell apoptosis (or cell death).

mgc pharma

KEY INVESTMENT HIGHLIGHTS

JUNE 17, 2022: MGC celebrates success in an in-vitro preclinical study into cannabinoids treatment on glioblastoma multiforme cells.

JULY 15, 2022: MGC announces successful clinical study into the influence of ArtemiC Support on patients with Long Covid.

AUGUST 3, 2022: MGC snaps up strategic 40% stake in ZAM Software, owner of proprietary Artificial Intelligence (AI) data gathering platform, ZAM.

DR LUKE REID
CEO

MICROBA LIFE SCIENCES
(ASX:MAP)

- **Company Name:** Microba Life Sciences
- **Company ASX code:** MAP
- **Key areas:** Microbiome testing, drug discovery
- **Key Personnel:** Dr Luke Reid, CEO | Pasquale Rombola, Chairman | Prof. Ian Frazer (AC), Deputy Chair
- **Locations:** Australia
- **Market Cap as of 15/09/22:** $54.87M
- **52 Week share price as of 15 September:** $0.190 - $0.450
- **Company Website:** microba.com

COMPANY PROFILE

With world-leading technology for measuring the human gut microbiome, Microba Life Sciences is driving the discovery and development of novel therapeutics for major chronic diseases and delivering gut microbiome testing services globally to researchers, clinicians, and consumers.

Microba provides testing and data analysis for a fee and through these insights, develops novel monoclonal microbial cell therapies for a range of different diseases.

To date, the company's proprietary databank holds around 15,000 samples, 1.2 million genomes and 11.7 million genes which reveal disease signatures, and have already led to the production of novel therapeutic leads across 18 diseases.

The microbiome sector, an emerging market flagged at around US$4.89 billion this year, represents one of the biggest untapped opportunities to improve human health, with microbiome testing and therapeutics set to become a routine part of future healthcare.

The theory holds water, particularly since there's a growing body of evidence that modifying the gut biome plays a role in resolving chronic diseases including cancer, diabetes, and inflammatory conditions

And when 6 in 10 people in the US have a chronic disease like cancer or diabetes, it represents a significant market opportunity for Microba, which is why the company recently executed three major international agreements.

The first deal is with Genova Diagnostics, a US-based gastrointestinal pathology company; the second with G42 Healthcare, a health-tech company in the United Arab Emirates (UAE) targeting the Gulf Cooperation Council (GCC); and a third with Ginkgo Bioworks (NYSE:DNA) which invested US3.5m in Microba's ASX IPO.

With Ginkgo, the aim is to target the development of novel microbiome-based therapies for three major autoimmune disorders: lupus, psoriatic arthritis and certain autoimmune liver diseases.

Microba plans to leverage Ginkgo's high-throughput anaerobic culturing, multi-omics data collection and analysis, functional bioassay screening, and its media and fermentation optimisation capabilities to generate datasets that characterise potential therapeutic strains for the disorders.

Other notable partners for Microba include International Flavors & Fragrances (NYSE: IFF), Europe's largest pathology company Synlab (GR:SYAB) and digital healthcare company Midnight Health, backed by nib Holdings Limited (ASX:NHF), to deliver a personalised consumer health service to the Australian market.

Microba even has a partnership with the Australia Department of Defence, using its dataset to link gut microbiome and cognitive performance in soldiers, which could have therapeutic applications in anxiety and depression.

The company's current focus however is its inflammatory bowel disease (IBD) program with a Phase 1 trial for its drug candidate planned for FY2023, targeting the roughly 55% of US residents who suffer from IBD, a market worth around US$19.2 billion with a compound annual growth rate (CAGR) of 4.8%.

Microba is also working on its cancer program to develop a microbiome-derived cancer immunotherapy, a target market flagged to be worth more than $50 billion by 2025. Added to this, autoimmune diseases represent a US$53 billion market with a 11.2% CAGR.

Microba has the team with the knowledge and experience to use this data to secure its market foothold, and its scientific co-founders are in the top 1% of cited researchers globally.

The company boasts some big names including Professor Ian Frazer, current Chair of the Australian Medical Research Advisory Board and inventor of the Gardasil vaccine for the Human papillomavirus.

MICROBA™

KEY INVESTMENT HIGHLIGHTS

JUNE 8, 2022: Autoimmune Disease program commences, with the first strains from Microba's biobank supplied to development partner, Ginkgo Bioworks.
JUNE 28, 2022: G42 Healthcare's first microbiome reports, powered by Microba's Analysis Platform, delivered to users in the United Arab Emirates.
JUNE 30, 2022: First microbiome tests in recently signed partnership with Genova Diagnostics made available to health practitioners in the United States.

PAUL ANDERSON
CEO & MANAGING DIRECTOR

ORTHOCELL
(ASX:OCC)

- **Company Name:** Orthocell
- **Company ASX code:** OCC
- **Key areas:** Regenerative medicine
- **Key Personnel:** Paul Anderson, CEO & Managing Director | Alex McHenry, Chief Operating Officer | Dr Stewart Washer, Chairman of the Board
- **Locations:** Perth, Australia
- **Market Cap as of 15/09/22:** $76.90M
- **52 Week share price as of 15 September:** $0.300 - $0.590
- **Company Website:** orthocell.com

COMPANY PROFILE

Orthocell is a world-leader in regenerative medicine – a powerful discipline representing a paradigm shift to smarter, more targeted and efficient treatments.

The relatively new field has enormous potential, leveraging the body's ability for self-repair to reduce pain and return functionality.

Orthocell is dedicated to development of breakthrough regenerative products for the treatment of musculoskeletal disorders. The Company is currently developing and commercialising two regenerative medicine platforms – collagen scaffold medical devices and cell therapies.

Orthocell has established a quality-controlled facility at its Perth headquarters. The facility is licensed by the Therapeutic Goods Administration (TGA) for the manufacture of human tendon cells (tenocytes) and cartilage cells (chondrocytes) for the regeneration of damaged tendon and cartilage.

The facility is also certified to ISO 13485 for the manufacture of CelGro™ medical devices including Striate+™ and Remplir™. Orthocell is equipped to manufacture, scale up and export products around the world.

Orthocell recently secured a 25-year exclusive patent and trademark licence deal with BioHorizons for the manufacture of its Striate+™ product for dental and oral-maxillofacial procedures. Striate+™ is a resorbable collagen membrane used in guided bone and tissue regeneration.

Under the deal, US-based BioHorizons has agreed to pay Orthocell US $16 million ($23.1 million) in return for the granting of an exclusive licence of intellectual property (IP) for Striate+™.

This was a landmark deal for Australia's biotechnology sector, contributing undiluted capital to back the Company's most progressed platform product into key global markets, at scale.

Orthocell is also on track to disrupt the global nerve repair market with its trademarked product Remplir™, giving hope to sufferers of nerve injury.

Every year, millions of people globally sustain peripheral nerve injury as the result of motor vehicle, sporting, work-related or other accidents, resulting in pain, numbness, burning or tingling, or in extreme cases paralysis.

Surgery to repair damaged nerves is delicate and complicated, and not always successful. Remplir™ assists in re-joining severed or severely damaged peripheral nerves to restore function and sensation.

This unique collagen scaffold provides a non-adhesive barrier structure to protect the nerve and create an ideal microenvironment for the regeneration of damaged peripheral nerves. Remplir™ reduces the need for suturing, is easy to use and results in consistent and predictable return of muscle function to paralysed limbs.

Orthocell's final data read-out of all patients in its nerve reconstruction trial has shown encouraging results. The follow-up data at 24 months post treatment showed that 85% (23 of 27) of nerve reconstructions resulted in functional recovery of target muscles closest to the reconstruction site.

Patients in the clinical trial had suffered traumatic nerve injuries, resulting in partial or total loss of use of their arms and, in more severe cases, their legs and torso (quadriplegia).

In the Company's cell therapies division, Orthocell's OrthoATI™ is a novel Injectable cell therapy addressing tendon damage, which replenishes degenerative tissue with healthy mature tendon cells, reducing pain and returning function with extensive validation of more than 1000 patients treated to date.

OrthoATI™ has significant market potential with currently no non-surgical treatments available to treat chronic tendon injury.

Orthocell is helmed by a world-leading team of experts in medical research, clinical practice, and commercialisation – primed and ready to bring these innovative products to the world.

ortho·cell
pioneering innovative technologies for tendon regeneration

KEY INVESTMENT HIGHLIGHTS

JUNE 7, 2022: Final data read-out of all patients in Orthocell's nerve reconstruction trial shows return of function to paralysed upper limbs.

JUNE 28, 2022: Orthocell shares up 35% after securing an exclusive global patent and trademark licence deal with BioHorizons for the manufacture of Striate+™.

SEPTEMBER 7, 2022: Device Technologies appointed distributor for Remplir™ nerve repair device, after approval for inclusion on the Australian Register of Therapeutic Goods (ARTG).

MARK LEONG
EXECUTIVE CHAIRMAN

OSTEOPORE
(ASX:OSX)

- **Company Name:** Osteopore
- **Company ASX code:** OSX
- **Key areas:** Natural tissue regeneration, bone cartilage, tendon, 3D printing
- **Key Personnel:** Mark Leong, Executive Chairman | Goh Khoon Seng, CEO | Lim Jing, COO & CTO
- **Locations:** Australia, Singapore
- **Market Cap as of 15/09/22:** $32.83M
- **52 Week share price as of 15 September:** $0.100 - $0.345
- **Company Website:** osteopore.com

COMPANY PROFILE

Natural tissue regeneration company Osteopore is transforming the way many surgical procedures are performed leading to better patient outcomes, less complications and consequently reduced medical costs.

Osteopore is commercialising a range of bespoke products engineered to harness the body's regenerative capacity to rebuild lost tissue and facilitate bone healing across multiple therapeutic areas.

The company's tech fabricates specific micro-structured scaffolds for bone regeneration through 3D printing and bioresorbable – absorbed naturally by the body over time – material.

Osteopore's patent-protected scaffolds are made from proprietary polymer formulations that naturally dissolve to leave natural, healthy bone tissue.

Osteopore's history dates back to 1996, when inventors from the National University of Singapore, National University Hospital and Temasek Polytechnic commenced research to identify bioresorbable material, microarchitecture, and manufacturing techniques.

Following the first-in-human procedure for burr hole cover in 2002, the research team founded the company in 2003 and listed on the ASX in 2019 and has over 60,000 successful cases with superior results over traditional procedures.

Osteopore has been involved in several world-firsts using its implants including in skull replacement surgery on a motorcycle accident patient and regenerative matching axial vascularisation, involving printing a 3D scaffold of the patient's tibia bone, wrapping it in their tissue from a donor site providing blood supply to re-grow their own bone.

While craniofacial was one of the first areas the company concentrated, its implants are proving adaptable and particularly useful for other areas including orthopaedics and large bones such as the tibia.

While concentrating on the low-hanging fruit over time it is working to expand into other applications including cartilage, tendons, and ligaments in the orthopaedic realm.

The company also secured a $19 million partnership with world-leading institutions the National Dental Centre Singapore and the Agency for Science, Technology and Research (A*STAR), to co-develop the next generation of dental implant technology.

Beyond human health, Osteopore's tissue regenerative technology has applications in the lucrative animal health sector, including thoroughbred racehorses, who face dire consequences from leg injuries.

The company's transformative bone regeneration products with low risk profile are ticking all the boxes for growth, having gone through research and development, clinical trials, key regulatory approvals, commercialisation and sales.

The company has sales on every continent as it continues to drive uptake among surgeons worldwide globally, with faster adoption from clinical cases and published case studies.

Osteopore is an example of the growing theme among the healthcare sector of personalised medicine with scaffolds being designed which are patient specific, as well as a reduction in post-surgical complications and long-term patient outcome improvements.

Currently complex bone surgeries are undertaken with open reduction and internal fixation (ORIF), involving special screws, plates, wires, or nails to position bones in place so they don't heal abnormally.

However, with Osteopore's technology, a combination of microstructure on the device as well as it being 3D-printed allows for infiltration of cells and blood vessels to the point where bone can regrow.

In turn this leads to improving health economics by leading to faster patient recovery times, reduction in post-op complications and less medical costs.

Osteopore®

KEY INVESTMENT HIGHLIGHTS

JULY 25, 2022: Osteopore records its best quarterly result in history, marking the third consecutive quarter of revenue growth.
AUGUST 4, 2022: Osteopore's US distributor secures a key agreement which will see its FDA-cleared products sold to healthcare facilities operated by the US federal government.
AUGUST 23, 2022: Osteopore signs a distribution agreement with Kontour (Xi'an) Medical Technology to market and sell Osteopore products within China.

DR JAMES CAMPBELL
CEO & MANAGING DIRECTOR

PATRYS

(ASX:PAB)

- **Company Name:** Patrys
- **Company ASX code:** PAB
- **Key areas:** Novel antibody therapeutics for oncology
- **Key Personnel:** Dr James Campbell, CEO & Managing Director
- **Locations:** Melbourne, Australia
- **Market Cap as of 15/09/22:** $49.36M
- **52 Week share price as of 15 September:** $0.019 - $0.047
- **Company Website:** patrys.com

COMPANY PROFILE

Patrys' deoxymab technology platform opens up new ways that antibodies can be used to treat cancer. This is because, unlike other antibodies, Patrys' deoxymabs are able to enter cells and the cell nucleus where they can block the repair of damaged DNA.

Deoxymabs can also cross the blood-brain barrier, a major advancement for antibody therapeutics. These properties enable deoxymabs to be used either alone or in conjunction with DNA damaging therapies (chemo drugs or radiation) to treat cancer.

It also allows deoxymabs to be used to target the delivery of various chemical payloads (drugs, imaging agents or oligonucleotides) across the blood-brain barrier or into the cell nucleus.

Patrys is currently developing two different forms of its deoxymabs. PAT-DXl, a small antibody fragment, has completed commercial scale manufacturing which is a key step for any antibody development program.

In coming months Patrys will complete the remaining preclinical studies required before PAT-DXl starts human clinical trials in patients in H2 of 2023.

Patrys' second deoxymab, PAT-DX3, is a full-sized antibody which is more typical of therapeutic antibodies. Patrys has established a cell line that can be used to manufacture PAT-DX3 and is currently developing a production process for this deoxymab.

The larger size of PAT-DX3 results in it having different pharmaceutical properties to PAT-DXl which, in turn, means it can be used for different clinical applications. Furthermore, its larger size means that there are more places to attach various drugs or imaging agents that can then be delivered across the blood-brain barrier or into the cell nucleus.

Such constructs are called Antibody Drug Conjugates (or ADCs) and these are rapidly becoming one of the most commercially active areas in biopharmaceuticals.

Patrys' deoxymabs have potential to be used in the clinic in three different ways: 1) as a stand-alone therapy in cancers that have pre-existing mutations in their DNA repair systems, 2) in conjunction with other agents that cause DNA damage such as chemotherapy and radiation therapy, or 3) as agents to deliver drugs across the blood-brain barrier or into the cell nucleus.

In preclinical studies Patrys has demonstrated that all three approaches appear to be viable opportunities. On their own or in combination with DNA-damaging therapies, deoxymabs have been able to significantly inhibit tumour growth and improve survival in animal models of human brain cancer, metastatic breast cancer, colon cancer, and pancreatic cancer.

Also in an animal model, PAT-DX3 successfully delivered a potent anticancer drug to tumour tissue where it significantly improved survival.

The unique properties of Patrys' deoxymabs have attracted the interest of researchers, funding agencies and companies around the world.

Patrys has an ongoing collaboration with researchers at Yale University where the technology was developed, and across Australia.

The company also has a collaboration in place with ASX-listed company Imagion Biosciences to develop new imaging agents for brain cancer. Recently the Cure Brain Cancer Foundation Clinical Accelerator awarded $250,000 to researchers at the Telethon Kids Institute to study deoxymabs in brain cancers and researchers at the Olivia Newton-John Cancer Research Institute received $100,000 to study the use of deoxymabs to treat breast cancer.

Patrys has the expertise and the vision to successfully develop its deoxymab technology with a highly skilled team led by Dr James Campbell who has over 20 years of executive-level international biotech development and deal-making experience with transactions and capital raisings worth more than $400M.

patrys

KEY INVESTMENT HIGHLIGHTS

AUGUST 10, 2022: Study shows PAT-DX1 combined with radiation therapy significantly improves survival in animal models of brain cancer.

AUGUST 26, 2022: Olivia Newton-John Cancer Research Institute awarded $100k grant to support investigation of Patrys' deoxymab technology in controlling breast cancer tumour growth and metastasis.

AUGUST 30, 2022: PAT-DX1 meets all specification tests, putting Patrys on a solid trajectory to initiate the planned phase 1 clinical trial in H2 CY2023.

DR ROGER ASTON
EXECUTIVE CHAIRMAN

PHARMAUST

(ASX:PAA)

- **Company Name:** PharmAust
- **Company ASX code:** PAA
- **Key areas:** Clinical-stage biotechnology company that repurposes marketed drugs for other uses including anticancer, brain and antiviral diseases
- **Key Personnel:** Dr Roger Aston, Executive Chairman | Robert Bishop, Executive Director | Sam Wright, Finance Director
- **Locations:** Western Australia
- **Market Cap as of 15/09/22:** $25.35M
- **52 Week share price as of 15 September:** $0.065 - $0.120
- **Company Website:** pharmaust.com

COMPANY PROFILE

PharmAust is a clinical-stage biotech developing novel targeted cancer therapeutics for both humans and animals, specialising in repurposing marketed drugs, lowering the company's risks and costs of development in the process.

PharmAust's lead asset is monepantel (MPL), a repurposed drug from an animal antiparasitic, Zolvix, developed by Novartis, which blocks a receptor in parasites and kills them.

In mammals, MPL inhibits mTOR protein, which regulates metabolism – and a lower metabolism means slower growth of tumour cells and less production of misfolded proteins which cause brain disease.

By modulating metabolism, MPL does not damage the cells unlike aggressive treatment like chemotherapy, and MPL has also shown potential antiviral use by protecting against cell death from Covid-19.

PharmAust is engaged in clinical trials of three potential uses for MPL: canines with B-cell lymphatic cancer; people with motor neurone disease (MND) / Amyotrophic Lateral Sclerosis (ALS), otherwise known as Lou Gehrig's disease; and Covid-19.

Based on the results so far, PharmAust is confident of success in these trials and progressing them to Phase 2/3 in 2023.

In the Phase 2 trial of canine lymphoma, results have shown positive outcomes and are close to meeting its endpoints.

MPL is shown to double the life expectancy of dogs with lymphoma to about five months (compared to palliative care with prednisolone alone), and with high quality of life (compared to chemotherapy which may damage organs).

MPL tablets can be taken orally daily, so they are far more accessible and a lot cheaper than chemotherapy.

As it gears up for Phase 3, PharmAust is in confidential discussions with big pharma to co-develop and commercialise MPL for canine cancer, and there's a licensing deal in the works that will keep PharmAust fully funded for future human cancer trials.

Success in this Phase 2 canine trial allows rapid translation to human trial, creating interests from institutions in the US and EU for PharmAust to conduct trials in leukaemia, glioblastoma, oesophageal, gastrointestinal, ovarian and pancreatic cancers.

Meanwhile, the MND Phase 1 trial is currently enrolling patients. The trial is funded by Fight MND, the largest non-profit for MND research in Australia, however PharmAust will own all the intellectual property the trial generates.

MND is an incurable, rare and fatal brain disease. PharmAust is working towards determining if MPL can inhibit misfolded protein production, extending the life of patients and decreasing symptoms such as memory loss.

PharmAust will take the Phase 1 pharmacokinetic (PK) data from the MND trial for the Covid-19 trial, enabling it to go straight into a Phase 2 trial in Covid-19 instead of Phase 1.

The Covid-19 trial will determine the efficacy of MPL's antiviral effect, aiming to add to the very small number of approved antiviral drugs in the market for the virus.

PharmAust says it is progressing well on all three fronts, and as results start coming in the next 12 months, commercialisation potentials will become more apparent – and commercialisation success in just one area would be a gamechanger for PharmAust.

The company is led by executive chairman Dr Roger Aston, who brings more than 20 years' experience in pharmaceutical and healthcare industries in the UK, Asia Pacific and Australia. Prior to PharmAust, he has had experience on boards and as CEO of many biotechnology companies.

PharmAust LIMITED

KEY INVESTMENT HIGHLIGHTS

NOVEMBER 17, 2021: Phase 1 Covid-19 trial successfully completed primary diligence on potential trial sites with six centres expressing interest.

APRIL 8, 2022: Received first installment from FightMND amounting to $201,615 to commence Phase 1 trial of motor neurone disease (MND).

AUGUST 17, 2022: Canine cancer trial Phase 2 indicates a combination of MPL and standard of care can more than double the life expectancy of dogs with lymphoma.

STEVEN YATOMI-CLARKE
CEO & MANAGING DIRECTOR

PRESCIENT THERAPEUTICS

(ASX:PTX)

- **Company Name:** Prescient Therapeutics
- **Company ASX code:** PTX
- **Key areas:** Oncology, cell therapies (CAR-T cell therapy), targeted therapies
- **Key Personnel:** Steven Yatomi-Clarke, CEO & Managing Director | Dr Rebecca Lim, Senior VP of Scientific Affairs | Leanne West, Director of Clinical Operations
- **Locations:** Australia and United States
- **Market Cap as of 15/09/22:** $121.13M
- **52 Week share price as of 15 September:** $0.115 - $0.305
- **Company Website:** ptxtherapeutics.com

COMPANY PROFILE

When it comes to giving hope in finding a cure for cancer, global eyes are on Prescient Therapeutics (PTX) and its game-changing work in personalised cancer treatments.

Prescient is at the forefront of the personalised treatment revolution in oncology with a deep pipeline of innovative therapies.

Prescient has licensed technologies from and in collaboration with world-leading cancer centres in Australia and the US, such as Yale, Oxford, UPenn, MD Anderson and Peter Mac, with IP rights exclusively owned by Prescient.

Prescient is progressing clinical trials in two targeted therapies, PTX-100 and PTX-200, which are treating cancers of considerable unmet need.

PTX-100 is a first-in-class prenylation inhibitor that disrupts oncogenic Ras pathways in cancer cells, licensed from Yale. It is currently in a clinical trial in T cell lymphomas under the leadership of renowned haematologist, Professor Miles Prince, where it is demonstrating safety and exhibiting encouraging signs of efficacy in this difficult-to-treat patient population.

PTX-200 is a novel PH domain inhibitor that inhibits an important tumour survival pathway known as Akt, which plays a key role in development of many cancers, including breast and ovarian cancer, as well as leukaemia.

PTX-200 is currently in Phase Ib trial in relapsed and refractory Acute Myeloid Leukaemia – a disease with a grim prognosis. Four patients on the trial so far have had complete remissions with another patient experiencing a partial remission.

PTX-200 has also shown encouraging activity in a Phase 2a data in HER2-negative breast cancer, and Phase Ib in recurrent or persistent platinum-resistant ovarian cancer.

When it comes to the ultimate goal of curing cancer, and not just delaying its progression, medical science has made a major leap forward in recent years with development of Chimeric Antigen Receptor (CAR) T cell therapies.

The new form of personalised immunotherapy uses a patient's own T cells which are enhanced to enable them to seek and destroy cancer cells. Considered a game-changer, the treatment has shown exceptional promise as a cure with patients with certain blood cancers treated with CAR-T cell therapy remaining cancer-free for more than 10 years.

Prescient has two complementary, next generation cell therapy platforms capable of making next-generation CAR-T therapies safer, controllable, able to target any cancer and employ any immune cell. These platforms have yielded three in-house CAR-T therapies and presents a myriad of external partnering opportunities.

Prescient's OmniCAR platform is a universal CAR-T platform which employs technology licensed from UPenn, the pioneer and world leader in CAR-T, as well as Oxford University.

OmniCAR-T cells go a step further than current CAR-T cell approaches with a modular universal immune receptor that can bind with any separate targeting ligand to potentially combat any form of cancer.

Prescient is developing next-generation CAR-T therapies on the OmniCAR platform for Acute Myeloid Leukaemia (AML), Her2+ solid tumours including breast, ovarian and gastric cancers, and glioblastoma multiforme (GBM). In addition, Prescient recently unveiled its complementary cell therapy enhancement platform CellPryme-M, which produces superior cells during the CAR-T cell manufacturing process.

Simply put, the cells are fitter and less prone to exhaustion, enabling longer duration of cancer killing activity. Prescient's deep pipeline and scalable and diversified business model put it in a position to benefit from the current revolution in cancer cell therapy.

Prescient Therapeutics

KEY INVESTMENT HIGHLIGHTS

AUGUST 16, 2022: Prescient enters a manufacturing services deal with Q-Gen Cell Therapeutics to produce its OmniCAR. cell lines for upcoming clinical trials.

AUGUST 18, 2022: Prescient signs agreement to test automated, closed manufacturing solutions for OmniCAR platform.

SEPTEMBER 7, 2022: Prescient announces strategic collaboration with MD Anderson Cancer Centre to develop unique blood cancer binders for OmniCAR.

PHILLIP LYNCH
CEO & MANAGING DIRECTOR

RACE ONCOLOGY

(ASX:RAC)

- **Company Name:** Race Oncology
- **Company ASX code:** RAC
- **Key areas:** Anti-cancer drug Zantrene in multiple indications: breast cancer, melanoma, AML and MDS
- **Key Personnel:** Phillip Lynch, CEO & Managing Director | Dr Daniel Tillett, Chief Scientific Officer | Dr. John Cullity Non-Exec, Chairman
- **Locations:** Sydney, Australia
- **Market Cap as of 15/09/22:** $324.70M
- **52 Week share price as of 15 September:** $1.450 - $3.830
- **Company Website:** raceoncology.com

COMPANY PROFILE

Race Oncology is a precision oncology company with a late stage Phase 2/3 cancer drug called Zantrene which breakthrough preclinical research has shown protects hearts from anthracycline damage, while improving the killing of breast cancer cells.

While it's been clear for decades that chemotherapy is highly effective in destroying tumorous cells, what many don't realise is that serious heart-related problems can arise during chemotherapy treatment.

A recent study showed that adult cancer survivors have a 42% greater risk of heart failure and other cardiovascular diseases later in life than those without cancer. Solving this opens a large addressable market for Zantrene that's estimated to reach into the billions of dollars.

Race has shown Zantrene combined with chemotherapeutic drug doxorubicin not only protects the heart, but is also more effective at killing cancer cells.

A mouse study completed in June further showed that Zantrene was able to protect the hearts of mice from the damaging effects of doxorubicin, without additional toxicity or bone marrow suppression.

In addition to its breast cancer research, Race is also currently pursuing two other opportunities with regards to Zantrene.

Firstly, Zantrene has been found to be a potent inhibitor of the 'Fatso' fat mass and obesity associated (FTO) protein. Overexpression of FTO has been shown to be the genetic driver of a diverse range of cancers.

The FTO protein is over-produced in approximately 50% of metastatic melanomas, which is one of the most lethal and treatment resistant cancers with a 5-year survival rate for advanced melanoma of only around 25%.

A pre-clinical mouse study showed that Zantrene, when combined with immunotherapy, shrinks melanoma tumours that do not respond to immunotherapy alone.

The third area where Race is exploring uses for Zantrene is as a treatment for leukaemia, with the drug currently being trialled in a Phase Ib/2 study in AML (Acute Myeloid Leukemia) and MDS (Myelodysplastic Syndromes).

This trial was expanded in June to include five additional trial sites in Europe and will recruit up to 60 patients in the near future.

In earlier mouse studies, Zantrene was found to kill a genetically diverse range of AML cells at low drug concentrations and AML tumours in mice. This research also found that low dose Zantrene in combination with another AML drug (decitabine) can better kill AML tumours.

Due to the multiple indications that Race is concurrently pursuing, combined with the extensive clinical history of Zantrene, Race believes it is a lower risk drug that presents a compelling investment for investors.

Race Oncology is managed by a team of pharmaceutical industry experts, including CEO Phillip Lynch, who brings more than 30 years' experience working in Asia Pacific markets with Johnson & Johnson.

Lynch is a highly-experienced Board Director with a diverse background across corporate development, strategy, financial performance, marketing and governance.

Chief scientific officer Dr Daniel Tillett was the founder and CEO of Nucleics, a private Australian biotechnology company producing and selling world leading DNA sequencing software to the genomics industry.

Tillett has extensive commercial experience over the last 20 years in the biotech industry in project management, sales and marketing, IP management, fundraising and start-up investing.

Race is chaired by Dr. John Cullity, who has previously held senior executive roles with Sanofi-Aventis and Schering-Plough in the US, and has consulted to the World Health Organization and the World Bank.

RACE ONCOLOGY

KEY INVESTMENT HIGHLIGHTS

MAY 12, 2022: Race expands its FTO-targeting clinical trial in extramedullary Acute Myeloid Leukaemia (EMD AML) and Myelodysplastic Syndromes (MDS). to Europe.

JUNE 22, 2022: Zantrene found to improve cancer immunotherapy in a mouse model of treatment resistant melanoma.

JUNE 30, 2022: Race's drug Zantrene found to protect the hearts of mice from the permanent damage caused by the commonly-used chemotherapeutic doxorubicin.

RICCARDO CANEVARI
CEO & MANAGING DIRECTOR

RADIOPHARM THERANOSTICS

(ASX:RAD)

- **Company Name:** Radiopharm Theranostics
- **Company ASX code:** RAD
- **Key areas:** Biotechnology / cancer radiotherapy
- **Key Personnel:** Riccardo Canevari, CEO & Managing Director | Paul Hopper, Chairman Professor | David Mozley Chief Medical Officer
- **Locations:** Australia, United States, European Union
- **Market Cap as of 15/09/22:** $42.14M
- **52 Week share price as of 15 September:** $0.130 - $0.495
- **Company Website:** radiopharmtheranostics.com

COMPANY PROFILE

Radiopharm aims to become a leader in the innovation and development of both diagnostic and therapeutic radiopharmaceuticals products for use in areas of high unmet medical needs, like oncological diseases – commonly known as cancer.

Radiopharmaceuticals are safe radioactive drugs that can be used as diagnostic or therapeutic tools.

In diagnostics, patients are given a very small amount of safe radioactive medication injected into the bloodstream.

Then low energy radioisotopes are used to allow physicians to see and measure disease within the body, via imaging.

In therapeutics, high energy radioisotopes are used to treat malignant tumours. This involves attaching a radioisotope to a targeting agent such as a small molecule or antibody which delivers a radioactive payload to tumour cells.

Recently the company signed an exclusive sublicensing agreement with NeoIndicate for the rights to develop the PTPμ-targeted radiopharmaceutical agent as an imaging diagnostic and as a targeted radiopharmaceutical theranostic as part of its clinical development pipeline.

When combined with low level radiation, the agent functions as a highly specific Positron Emission Tomography (PET) imaging agent - and when combined with high energy radiation, the agent works as a radiopharmaceutical theranostic to destroy tumours.

Basically, the PTPμ-targeted agent labels invading tumour cells far away from the main tumour mass, achieving specific recognition of the full extent of an invasive tumour. It also recognizes this fragment in multiple tumour types including brain tumours and gynaecological cancers.

The technology has shown encouraging pre-clinical data in human glioblastoma (GBM) tumour models, which have limited treatment options and poor prognosis, and represent an immediate, unmet need for targeted therapies with high sensitivity and specificity.

That's where Radiopharm comes in, with plans for the manufacturing of PTPμ to kick off in December 2022. The company has also worked to secure isotopes for the purpose of conducting clinical research, development, manufacture and early-stage commercialization of the company's diagnostic and therapeutic products.

In June, they reached an agreement with Isotopia Molecular Imaging for the supply of high-quality Lutetium-177 N.C.A – which has shown significant promise in treating a variety of late-stage cancers.

The company has also established relationships with some of the world's foremost cancer research organisations and suppliers, including a licensing agreement with the University of California Los Angeles Technology Development Group (UCLA-TDG) for its promising LRRC15 antibody DUNP19.

Currently available antibodies for cancer treatment omit tumour micro-environment (TME) cells, such as stromal and immune cells, which comprise >50% of tumour masses.

The DUNP19 antibody has a unique ability to effectively find, internalize and destroy both cancer and TME cells – and the agreement gives Radiopharm the rights to develop DUNP19 as an Antibody-Drug Conjugates (ADC) within radiotherapy as part of its clinical development pipeline.

Meanwhile in Australia, Radiopharm has extended its agreement with global oncology provider GenesisCare who will support a second clinical trial using the company's PSA targeting antibody to start a therapeutic Phase 1 in prostate cancer, with an expected commencement in the coming months.

Notably, the antibody can target free human prostate kallikrein (PSA) in prostate cancer cells, enabling radioimmunotherapy and diagnosis of advanced prostate cancer.

The company says this innovative approach and novel mode of action compared with other treatments under development make its technology highly prospective.

RAD
RADIOPHARM THERANOSTICS

KEY INVESTMENT HIGHLIGHTS

FEBRUARY 1, 2022: Signed a deal with TerraPower, a leading nuclear innovation company, to advance the next generation of radiopharmaceutical therapies for cancer treatment.

MARCH 23, 2022: Agreed on a Letter of Intent (LOI) with GenesisCare to start its first Phase 1 trial in Australia targeting the PDL1 expression in non-small cell lung cancer.

JULY 21, 2022: Extends agreement with global oncology provider GenesisCare, who will support a second Radiopharm clinical trial for prostate cancer in Australia.

PETER MALONE
CHAIRMAN

SKIN ELEMENTS

(ASX:SKN)

- **Company Name:** Skin Elements
- **Company ASX code:** SKN
- **Key areas:** Skincare, cosmetics, healthcare
- **Key Personnel:** Peter Malone, Chairman
- **Locations:** Perth, Australia
- **Market Cap as of 15/09/22:** $10.83M
- **52 Week share price as of 15 September:** $0.015 - $0.075
- **Company Website:** skinelementslimited.com

COMPANY PROFILE

There's no doubt that the world has changed since the emergence of the COVID-19 pandemic. How we interact and communicate with each other has been impacted.

While vaccinations have helped prevent severe illness and death, there remains concern about spread of the virus, particularly among vulnerable people such as the elderly or immunosuppressed.

But one ASX-listed company has been working to adjust to living with COVID-19 through the development of a hospital-grade disinfectant.

Known as SuprCuvr, Skin Elements has secured Therapeutic Goods Administration (TGA) registration for its 100% plant-based product, which has been confirmed by independent laboratory testing to be 99.99999% effective against COVID-19.

The registration has been crucial to the commercialisation of SuprCuvr for use in hospitals and aged-care homes, places that are restricted to using only TGA registered disinfectants.

SuprCuvr has also been certified by NASAA certified organic as a 100% botanical-based organic input.

Earlier this year, the company signed a key distribution deal with major medical supplies distributor Pacific Health Care to distribute SuprCuvr in Australia and New Zealand.

SuprCuvr has been found not only to be effective against COVID-19 but also other pathogens such as E. Coli, Staph. aureus, Salmonella, and Pseudomonas.

However, SuprCuvr is only a small part of the work of Skin Elements. Founded in 2005 and listed on the ASX in 2017, the company is focused on developing natural, organic products that perform better than their chemical counterparts.

Skin Elements has four main product lines. It produces all natural sunscreen products under the Soléo Organics brand, therapeutic papaya skin treatment products under the PapayaActivs brand and cosmetic skincare products under the Elizabeth Jane brand.

Also, Skin Elements has the InvisiShield brand, which includes hand sanitisers.

All of Skin Elements' products are based on Naturopathic principles and use only organic and natural ingredients.

Through natural science and innovation, Skin Elements produces products that are leading the industry without harming the planet.

From non-whitening (micronised) zinc to botanically fortifying extracts with anti-oxidants, the company has spent more than 15 years and $35m researching and developing its formula and products.

The company's variety of products has been granted US Food and Drug Administration (FDA), plus TGA and other international approvals.

Skin Elements products now have a presence in the major markets of the Americas, Europe and Asia.

Importantly, Skin Elements is operating in a growing market as health conscious consumers increasingly prefer natural to chemical-based products.

Pitt Street research reported the global natural and organic cosmetics and personal care market is expected to grow from ~US$38bn in 2020 to ~US$55bn in 2027.

The market for hand sanitiser and disinfectant products is also forecast to grow significantly in coming years.

The company has a strong board and management team led by Peter Malone who has more than 30 years of experience in the global financial market and is passionate about commercialization of organic wellness and healthcare products.

skin elements
enhancing health + wellness naturally

KEY INVESTMENT HIGHLIGHTS

JANUARY 18, 2022: Skin Elements appoints major medical supplies distributor Pacific Health Care to distribute its hospital-grade disinfectant product SuprCuvr.

MARCH 17, 2022: Skin Elements delivers 120,000 litres of SuprCuvr, invoicing more than $1.4 million in its first major sales order with Pacific Health Care.

JUNE 22, 2022: Skin Elements set to capitalise on global demand (conscious consumer) for chemical-free, plant-based environmentally friendly products. SKN's disinfectant SuprCuvr protects against pathogens including COVID 19.

DR JACKIE FAIRLEY
CEO

STARPHARMA HOLDINGS

(ASX:SPL)

- **Company Name:** Starpharma Holdings
- **Company ASX code:** SPL
- **Key areas:** Health and medical products and pharmaceuticals
- **Key Personnel:** Mr Robert Thomas, Non-Executive Chairman | Dr Jackie Fairley, CEO | Mr Nigel Baade, CFO and Company Secretary
- **Locations:** Melbourne, Australia
- **Market Cap as of 15/09/22:** $236.80M
- **52 Week share price as of 15 September:** $0.550 - $1.495
- **Company Website:** starpharma.com

COMPANY PROFILE

Starpharma is an Australian biotechnology company focused on the development and commercialisation of medical products and pharmaceuticals based on its proprietary dendrimer technology.

The company has developed its core range of innovative products around highly branched nanoscale polymers called dendrimers, whose precise size and unique structural properties make them perfect for use in pharmaceutical and medical applications.

Starpharma's dendrimer technology plays a starring role in its marketed products, VIRALEZE™ nasal spray and VivaGel®, but SPL's "holy grail" is a range of dendrimer-delivered anti-cancer therapies aimed at providing improved efficacy and reduced toxic side effects for novel or existing drugs.

This dendrimer-enhanced product (DEP®) technology is highly promising in its potential to offer multiple commercial and therapeutic benefits.

Commercially, Starpharma is seeking to attract development and market partnerships, leveraging the flexibility of DEP® technology in a wide range of therapeutic areas, and how this opens up multiple revenue streams and potential for new intellectual property and patent extensions.

Starpharma has already secured partnerships with several of the world's largest pharmaceutical companies, including a multiproduct licence with AstraZeneca and research collaborations with Merck & Co., Inc., and Genentech.

On the therapeutic side, the potential upsides are enormous in terms of patient comfort and medical outcomes, particularly considering the role Starpharma sees DEP® technology playing in enhancing the efficacy and reducing the toxic side effects of conventional cancer treatments.

Because of the scale of the technology, Starpharma says it also has potential to help target the delivery of other drugs to organs, tissues or molecular receptors, with enhanced solubility.

Starpharma has developed four clinical stage dendrimer-based oncology drugs to aid in the fight against cancer. Three of the drugs are in Phase 2 clinical trials for the treatment of a range of cancers, including prostate, ovarian, pancreatic, colorectal, and oesophageal, with a fourth expected to enter the clinic later in CY2022.

Additionally, SPL has brought three products to market, built using its patented dendrimer, SPL7013, originally identified for its antiviral activity against sexually transmitted viral infections, including HIV, HPV, and genital herpes.

The products developed using SPL7013 are VIRALEZE™ nasal spray, VivaGel® BV, and VivaGel® condom.

VIRALEZE™ is a broad-spectrum nasal spray developed in response to the Covid-19 outbreak in 2020, to trap and block respiratory viruses in the nasal cavity.

Extensive testing at the renowned Scripps Research institute in the United States has clearly demonstrated strong antiviral effects of SPL7013 against multiple viruses, including multiple variants of SARS-CoV-2 and influenza, as well as RSV, MERS, SARS.

Starpharma has worked tirelessly to get VIRALEZE™ registered in more than 30 countries, and today it is available from a variety of retail outlets and pharmacies around the world, as well as online.

VivaGel® BV is a novel, non-antibiotic gel containing SPL7013 for the treatment of bacterial vaginosis (BV) and the prevention of recurrent BV.

Throughout the world, BV is the most common vaginal infection. It is caused by an imbalance of healthy and harmful bacteria in the vagina, and can lead to abnormal vaginal discharge and odour that are unpleasant and can interfere with a woman's relationships and general quality of life.

VivaGel® BV is registered in more than 45 countries.

starpharma

KEY INVESTMENT HIGHLIGHTS

JULY 20, 2022: Study finds VIRALEZE™ offers high protection against the SARS-CoV-2 Omicron variant.
AUGUST 10, 2022: Starpharma sign a new DEP® agreement with Merck, USA.
SEPTEMBER 12, 2022: Interim trial results presented at ESMO show efficacy signals in 100% of prostate cancer patients assessed following DEP® cabazitaxel treatment.

STEPHEN TOMISICH
CEO & MANAGING DIRECTOR

TRAJAN GROUP

(ASX:TRJ)

- **Company Name:** Trajan Group
- **Company ASX code:** TRJ
- **Key areas:** Medical devices
- **Key Personnel:** Stephen Tomisich, CEO & Managing Director | John Eales AM, Chair | Alister Hodges, Chief Financial Officer
- **Locations:** Australia, Germany, Japan, Malaysia, United Kingdom, United States
- **Market Cap as of 15/09/22:** $316.32M
- **52 Week share price as of 15 September:** $1.910 - $4.590
- **Company Website:** trajanscimed.com

COMPANY PROFILE

Trajan is a global developer and manufacturer of analytical and life sciences products and devices. With products and solutions used in the analysis of biological, food, and environmental samples, the company was founded to have a positive impact on human wellbeing through scientific measurement.

The company has more than 650 people and while headquartered in Ringwood, Australia, holds a truly global footprint, with seven manufacturing sites across the US, Australia, Europe, and Malaysia.

Servicing multiple areas in healthcare, ranging from pharmaceutical drug development and medical research to public health and remote patient monitoring, Trajan's purpose is to deliver science that benefits people.

Trajan aims to achieve this by building the capabilities to enable personalised, preventative, data-based healthcare for all.

And the company is putting its money where its mouth is, having made four acquisitions in Axel Semrau, Neoteryx, LEAP PAL Parts and Consumables, and Chromatography Research Supplies (and one strategic investment in Humankind Ventures Ltd) since listing on the Australian Securities Exchange in June 2021 – all of which have worked to expand its product, manufacturing, and geographic footprint.

German-based Axel Semrau, acquired by Trajan in November 2021, employs just over 50 staff in Europe and develops and manufactures laboratory automation and chromatography software and detection systems. It reported FY21 (year ended Sept '21) revenues of €14.9M and EBITDA of €1.46M (normalised EBITDA of €1.67M, unaudited).

Axel Semrau owns and develops the CHRONOS intelligent sequencing software platform upon which Trajan's automated workflows are built. Following the acquisition, Trajan plans to further invest in CHRONOS in line with its goal to simplify and automate complex analytical workflows. Axel Semrau's presence in chromatography and portable gas detection also aligns with Trajan's direction.

Neoteryx is a global leader in blood microsampling devices based in Torrance, California. Through the acquisition made in December 2021, Trajan's goal is to drive the global commercialisation and adoption of microsampling at scale – especially since remote sampling is an essential element in progressing personalised, preventative, and data-based healthcare. The company is also focused on building the tools around the entire workflow, from consumer portals to laboratory automation.

While not immediately EBITDA accretive, Trajan expects to see a meaningful acceleration of the microsampling portfolio's contribution to both its top line and EBITDA growth over the next 3-5 years.

Then there's LEAP Pal Parts and Consumables (LPP) which Trajan acquired in December 2021. LPP operates in the specialised parts of medical instruments business, which supports customers that operate automated laboratory workflows based on the PAL platform from CTC Analytics AG Switzerland.

Trajan also has high hopes for Chromatography Research Supplies (CRS), which is a leading global manufacturer of high-quality analytical consumables that's been in operation for over 25 years. The company and its products are highly complementary to Trajan's existing portfolio, which are used in analytical laboratories and various other industries worldwide and are known for their quality.

These recent acquisitions performed to plan for Trajan, contributing $22.7M to revenue and $2.1M to normalised EBITDA in FY22. The company's focus is now on fully integrating these businesses and capitalising on their synergies in FY23. And with a continued focus on its dual growth strategy of strong organic growth and strategic acquisitions and investments, Trajan won't be stopping there.

TRAJAN

KEY INVESTMENT HIGHLIGHTS

JUNE 27, 2022: Acquired 100% of CRS for US$43.3M (Trajan's fourth acquisition since its June 2021 IPO), funded partially by a fully underwritten $29.7M institutional placement.

JULY 15, 2022: Completed $4.7M Share Purchase Plan (SPP) to support further acquisition and organic growth objectives.

AUGUST 24, 2022: Released FY22 Full Year Results with net revenues of $107.6M, up 40.5% on PCP, and normalised EBITDA of $12.5M, up 26% on PCP.

MAURIE STANG
NON-EXECUTIVE DEPUTY CHAIRMAN

VECTUS BIOSYSTEMS

(ASX:VBS)

- **Company Name:** Vectus Biosystems
- **Company ASX code:** VBS
- **Key areas:** Drug development targeting fibrosis
- **Key Personnel:** Dr Ronald Shnier, Non-Executive Chairman | Maurie Stang, Non-Executive Deputy Chairman | Dr Karen Duggan, Executive Director & CEO
- **Locations:** Sydney, Australia
- **Market Cap as of 15/09/22:** $27.77M
- **52 Week share price as of 15 September:** $0.750 - $2.200
- **Company Website:** vectusbiosystems.com.au

COMPANY PROFILE

Sydney-based biotech Vectus Biosystems is a well-focussed operation, with an elegantly simple goal: research, development and licence its technologies.

The company's story begins with the realisation by Vectus Executive Director & CEO, Dr Karen Duggan, that a naturally occurring molecule in the human body (VIP) was capable of reversing damage to organs such as the heart and kidney due to chronic diseases such as diabetes and hypertension.

As a quick explainer, the damage to multiple organs is termed fibrosis and reflects replacement of the functional tissue of heart, lungs, liver or kidney by scar tissue.

Fibrosis tends to happen in areas of the body that are repeatedly exposed to toxins or put under pressure to the point where injuries occur.

When a significant part of an organ is replaced by fibrosis then symptoms and signs of heart failure, liver failure, kidney failure or respiratory failure occur.

Probably the most commonly recognised example is cystic fibrosis, a genetic disorder that is carried by 1 out of every 25 of the world's population and affects around 1 in every 3,000 people.

And although there are a number of treatments available to slow down the progression of the disease, life expectancy for people with cystic fibrosis is fleetingly short: around 37 years old for men, and about 40 years old for women.

Any form of fibrosis is extremely difficult to treat, and the lasting damage it causes is almost always permanent.

This is what makes the current focus for Vectus such an attractive avenue of development as the company has shown that its treatment can reverse what has long been considered a 'one way street'.

When Dr Duggan formed Vectus Biosystems, the aim was to take her discovery and develop a novel, orally-delivered drug treatment that would not only halt, but also turn back the incredible damage fibrosis is known to cause.

Since that time, the company has made some enormous leaps forward, developing a library of more than 1,000 small molecules with varying degrees of anti-hypertensive and/or anti-fibrotic properties.

In May of this year Vectus announced that the single ascending dose (SAD) Phase I study, where healthy volunteers received 2mg, 10mg, 30mg, 100mg or 300mg doses of its cardiovascular renal lead drug candidate VB0004, had been completed.

No adverse events occurred during the study.

Then in September, Vectus announced that the multiple ascending dose (MAD) component had also been completed, again with no adverse events.

Following completion of the Phase Ia Vectus will now embark on a Phase Ib study in patients with uncomplicated hypertension to provide efficacy data for VB0004.

KEY INVESTMENT HIGHLIGHTS

- Three first-in-class assets focused on major unmet therapeutic needs – lead program VB0004 continues positive. progress through Phase 1 clinical trial
- Exceptional patent protection across a library of more than 1,000 compounds.
- Significant interest from potential pharmaceutical partners.

TERI THOMAS
CEO

VOLPARA HEALTH TECHNOLOGIES

(ASX:VHT)

- **Company Name:** Volpara Health Technologies
- **Company ASX code:** VHT
- **Key areas:** Breast cancer detection and screening, artificial intelligence software
- **Key Personnel:** Teri Thomas, CEO
- **Locations:** Wellington, New Zealand and Seattle, Boston, United States
- **Market Cap as of 15/09/22:** $148.70M
- **52 Week share price as of 15 September:** $0.400 - $1.320
- **Company Website:** volparahealth.com

COMPANY PROFILE

Volpara Health Technologies has a simple vision: become the global leader in software for the early detection of cancer.

Truthfully, that vision probably undersells where Volpara, founded in 2009, is currently at.

The company provides clinically-validated software powered by artificial intelligence for the personalised screening and early detection of cancer, breast cancer in particular.

It is in that field that Volpara's name is well-known, being the preferred partner of thousands of leading clinical sites around the world, and backed up by more than 100 patents, over 200 peer-reviewed publications and a wealth of certifications, trademarks and regulatory registrations.

Volpara's software gives clinicians feedback on breast density, compression, dose, and quality, enabling them to offer their patients personalised breast care and enhanced risk assessment.

And the approach is working.

The company's latest quarterly results showed record cash receipts of $8.7 million, up 35 per cent year-on-year, and US$23.7 million in contracted annual recurring revenue.

The rapid uptake of Volpara's suite of products speaks to a concerning underlying need - that each year, despite huge advancements in technology, nearly 700,000 people lose their lives to breast cancer, out of 2.3 million diagnoses.

Even more concerning is that there are growing numbers of cases of breast cancer in women under 40.

"Young women are generally not part of the breast care conversation – it's thought of as an older women's concern," Volpara CEO Teri Thomas says.

"Nine per cent of breast cancers are diagnosed in women under age 45, and those cancers tend to be diagnosed at later stages and are usually more aggressive. Sadly, many of these cancers could have been caught earlier.

"Let us take the time now to make earlier risk assessments the standard of care. By catching these cancers early enough, we can prevent them from claiming more young lives."

Volpara's mix of world-leading AI-powered software, deep clinical knowledge and patient-focused care makes the company uniquely placed to drive down the statistics, Thomas says.

"Our strategy is to proactively identify women at higher risk and personalise their care pathway," she says.

"We increase physician and patient understanding of breast composition, cancer risk and imaging, improve the quality of every mammogram produced for more accurate detection and enable additional cancer risk modelling and genetic testing in streamlined workflows."

This rigorous, multifaceted approach to tackling breast cancer is embedded into Volpara's DNA.

Founded by Ralph Highnam following breakthrough medical physics and AI research at the University of Oxford, Volpara stands today as a leader in breast cancer risk assessment, volumetric breast density measurement, mammographic quality and AI and machine learning software.

A recent strategic review has further validated this model, and over the next two years the company will bring "more money in, less money out and protect and invest in our secret sauce".

"We have the most research-validated technology in the industry, a great reputation, rich data for ongoing development, and the expertise to execute on new innovation," Thomas says.

Volpara aims to be cash flow breakeven by the end of the FY24 financial year, and profitable by FY25; beyond that, it sees great opportunity to expand into new verticals in other cancers and diseases.

Volpara HEALTH

KEY INVESTMENT HIGHLIGHTS

APRIL 22, 2022: Highly experienced healthcare industry executive Teri Thomas named as VHT Group Chief Executive Officer.

JULY 4, 2022: VHT signs contract with the largest US outpatient imaging provider Radnet, for an initial contract period of 42 months plus mutual option to extend.

JULY 28, 2022: Volpara reports record quarter for contracted annual recurring revenue (CARR) at US$23.7M, up almost US$1.5M on end FY22, eyeing cash flow profitability by FY25.

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CROSS SECTOR CLIENTS

L1 CAPITAL	"Long-Short" LIC $1.35B IPO
HazerGroup™	$7M placement + $7M SPP
TRAJAN	$26M acquisition of Axel Semrau GmbH
ANTERIS	$15M exercise of listed options

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