

30 Oct 2023 | Melbourne, Australia

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# Event Handbook

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# Victoria, where government is your partner for success

Melbourne, Victoria is a highly sought-after destination by global and local medical technology and pharmaceutical companies.

We offer a cost-competitive environment, access to specialist R&D and manufacturing capabilities, strong collaborative networks and an innovation culture, supported by government and private investment making it an ideal location for companies working to scale their innovation to global growth markets — all in one of the world's most liveable cities.

Together with our mature investment ecosystem and experience in working with early stage and commercial companies, the Victorian Government is keen to facilitate opportunities to drive investment in translation, research, innovation and commercialisation outcomes.

Find out how the Victorian Government can work with you to transform your idea or discovery into a market-ready product.



# Welcome

On behalf of AusBiotech, your proud host, I warmly welcome you to AusBioInvest 2023, Australia's leading investment and partnering conference for the life sciences sector.

As the peak body for Australia's biotech industry, AusBiotech represents and advocates for organisations doing business in and with the global life sciences economy.

We foster meaningful connections between the investment community and investment-seeking life sciences companies, enabling great ideas to attract risk-tolerant capital while assisting investors to connect with innovative, Australian companies that offer high-value return-on-investment.

Australia is a hotbed for innovation, and the influence of the domestic biotech industry on Australia's economic, enterprise and healthcare sectors is palpable.

As Australia's flagship life science investing event, AusBioInvest 2023 is the leading forum to inform your life science investment decisions within Australia. Today's programme features thought-provoking keynote and panel sessions with leading investors and business leaders, in addition to the 26 Australian biotech companies, spanning early- to late-stage, that are actively seeking investors or partners to support their funding and co-development.

Each year, biotech continues to break records in capital raising, indicating investors' increasing appetite for IP-based and impact-driven investments. To understand the capital flowing into the sector, AusBiotech established its process for tracking foreign direct investment into Australian life science companies. AusBiotech's inaugural foreign direct investment snapshot released in August this year, quantifying the amount of US-originated capital flowing into Australia's life science companies between 2018-2022, revealed that US investors invested US\$642.34 million into Australian biotechs during 2022, more than four times the amount invested during 2018. The increasing investor interest in our industry companies is demonstrative of the high-quality R&D undertaken in Australia.

#### To AusBioInvest 2023

Access to capital remains one of the most significant drivers of growth and sustainability for Australia's life sciences sector. In recognition of this, AusBiotech has bolstered its investment attraction programme to increase investor awareness and understanding of our unique sector, while enabling Australian life science companies to connect with international capital markets and empowering them to be competitive on a global scale. As part of this programme, AusBiotech launched A Practical Guide to ESG for Australian Life Sciences Companies (the Guide) this year to support life science companies on their 'environmental, social, and governance' (ESG) journeys, with the aim of increasing the attractiveness of Australia's business environment to international and local investors and collaborators. AusBiotech also facilitates national and international opportunities for investment discussions, collaborations, and partnerships.

AusBiotech would like to take this opportunity to thank the Victorian State Government as our Host State Partner, in addition to our event partners, presenting companies and speakers for contributing to the success of this conference.

I would also like to sincerely thank the AusBiotech Investment Advisory Group: a group of experts at the forefront of life sciences investment and partnering in Australia who are providing AusBiotech with guidance and advice on our current and future investment programmes and events.

We hope that AusBioInvest 2023 provides you with valuable insights and helps you build partnerships that will greatly benefit your business.

Warm regards,



Lorraine Chiroiu
Chief Executive Officer
AusBiotech

# 2023 Programme

### Monday 30 October 2023

#### 9:00am - 9:20am

#### **WELCOME & OFFICIAL OPENING**

Welcome to country

The Hon. Tim Pallas, Treasurer, Victorian Government Lorraine Chiroiu, Chief Executive Officer, AusBiotech

#### 9:20am - 9:40am

#### KEYNOTE - What biotech investors consider when evaluating a deal; a how-to for non-specialist investors

In traditional biotech investing, investors bet on the company's technology or its understanding of disease. But with roughly only 10 per cent of clinical-stage assets making it to market, it's difficult for investors to know which investments will succeed and what will fail. For non-specialist investors wanting to dip their toes into biotech investing, this can be a daunting prospect.

North America boasts a large pool of sophisticated life science investors with successful track records in venture creation, commercialisation and M&A. Experienced US investor, Kanishka Pothula, will share insights on how US investors operate, factors US investors consider when making a deal such as evaluation drivers, investment rights, round sizes, and company management, and why this model is successful.

Ending with a Q&A, this fireside chat will compare methods used by US and Australian investors, and why it's important to know what drives US investors when seeking seed and expansion capital offshore.

CHAIR: Lawrence Gozlan, Chief Investment Officer, Scientia Capital

· Kanishka Pothula, Partner, Nextech Ventures (USA)

#### 9:40am - 10:35am

#### **COMPANY PRESENTATIONS**

CHAIR: Stephen Earl, Managing Director, Acuity Capital

- Dr Michael Baker, Chief Executive Officer & Managing Director, Arovella Therapeutics (ASX:ALA)
- Dr Paul Gavin, Chief Executive Officer, Avecho Biotechnology (ASX:AVE)
- Dr Nina Webster, Chief Executive Officer & Managing Director, Dimerix Limited (ASX:DXB)
- Steven Lydeamore, Chief Executive Officer, Immuron (ASX:IMC)
- Thian Chew, Executive Chair, Invion (ASX:IVX)

#### 10:35am - 10:40am Capital markets update for listed companies

Challenging times and managing through the cycle by using the right tool for the right job at the right time.

Stephen Earl, Managing Director, Acuity Capital

#### 10:40am - 11:05am MORNING TEA

#### 11:05am - 12:00pm COMPANY PRESENTATIONS

CHAIR: Sarah Meibusch, Partner, One Ventures

- Dr Deborah Rathjen, Chief Executive Officer, Carina Biotech
- Dr Brenton Hamdorf, Chief Executive Officer, Celosia Therapeutics
- Dr Christian Toouli, Chief Executive Officer & Managing Director, FivepHusion
- A/Prof Anthony Sasse, Founder & Managing Director, Snoretox
- Dr Sam Costello, Chief Executive Officer & Co-Founder, BiomeBank

#### 12:00pm - 12:20pm KEYNOTE - ASX market update

Providing an overview of ASX as a capital raising platform, outlining the benefits of listing on ASX, including a brief update on ASX IPO and capital raising activity for FY23 and focusing on the performance of the Healthcare sector.

CHAIR: Serg Duchini, Non-Executive Director, Enlitic Inc

· Ajita Tynan, Manager, Listed Company Services, ASX Limited



#### 12:20pm - 1:20pm COMPANY PRESENTATIONS

CHAIR: Sarah Meibusch, Partner, One Ventures

- Zahangir Alam, Chief Executive Officer & Co-Founder, Genofax
- Brent Barnes, Chief Executive Officer & Managing Director, LBT Innovations (ASX:LBT)
- Dr Chris Barbe, Chief Executive Officer, EncapSolutions
- Dr Christos Papadimitriou, Chief Executive Officer, Tessara Therapeutics
- Dr Isaac Bright, Chief Executive Officer, Imagion Biosystems (ASX:IBX)
- Vanessa Waddell, Interim Chief Executive Officer, PolyActiva

#### 1:20pm - 2:10pm

LUNCH

#### 2:10pm - 3:05pm

#### **COMPANY PRESENTATIONS**

CHAIR: Michael Molinari, Managing Director, IP Group

- Andrew Maxwell, Chair, Cyban
- Darryl Davies, Chief Executive Officer, InhaleRx (ASX:IRX)
- Brian Leedman, Director, Respiri (ASX:RSH)
- Dr Beata Edling, Chief Executive Officer, TruScreen (ASX:TRU)
- David Hoey, Chief Executive Officer, Vaxxas

Q&A

#### 3:05pm - 3:35pm

#### PANEL DISCUSSION - How does Australia build the ecosystem to the next stage?

Australia's life science ecosystem has seen exponential growth in the past decade, from the number of companies operating in the sector, to individuals employed, patents logged, and therapies commercialised, all of which has a significant and positive impact on Australia's health and economic wealth. Australia is well-known for its world-class scientific capabilities and research translation, and focus has turned to building a late-stage ecosystem that allows technologies to be wholly developed and manufactured onshore, in turn creating an end-to-end value chain entirely in Australia. Achieving this will require strategic foresight, dedicated capital and innovative thinking from industry and policy makers alike.

Australia boasts the world's second largest superannuation fund with a reported US\$2568 billion (2022) in assets, sitting just behind the United States with a report US\$2619 (2022) in assets. Several Australian superannuation funds  $are \ actively \ contributing \ to \ the \ sector \ through \ their \ investments \ into \ PE \ and \ VC \ firms \ which \ invest \ in \ Australian \ biotech.$ 

In this panel discussion, experts will discuss investment approaches to building Australia's ecosystem, how to unlock the funds already in Australia (such as superannuation capital) to increase access to capital, and why it is critical to attract offshore investors to Australia.

CHAIR: Dr Amanda Gillon, Senior Partner, Bioscience Managers

- Dr Gurkeerat Singh, Associate Vice President, Lilly Ventures Venture Investing Asia, Lilly Research Laboratories, Eli Lilly and Company
- Dr Megan Baldwin, Chief Executive Officer & Managing Director, Opthea
- Neil Stanford, Executive Director, Venture Capital, Breakthrough Victoria

#### 3:35pm - 4:00pm

#### **AFTERNOON TEA**

#### 4:00pm - 4:55pm

#### **COMPANY PRESENTATIONS**

CHAIR: Victoria Durrans, Partner, Bioscience Managers

- Professor Trent Munro, Senior Vice President Therapeutics, Microba Life Sciences
- Dr Gisela Mautner, Chief Executive Officer & Managing Director, Noxopharm (ASX:NOX)
- Steven Yatomi-Clarke, Chief Executive Officer & Managing Director, Prescient Therapeutics (ASX: PTX)
- Penelope Lane, Chief Executive Officer, Esfam Biotech
- Andrew Shute, Senior Vice President Business Development, EBR Systems (ASX:EBR)

Q&A

#### 4:55pm - 5:25pm

#### **KEYNOTE - Global capital markets**

The biotechnology industry relies on steady, patient capital in order to innovate and succeed. With a limited pool of dedicated capital available in Australia, the global capital markets are an attractive place for life science companies to seek investment.

The capital markets Australian biotech companies usually look to have been severely impacted by the post-pandemic macroeconomic turbulence meaning companies must deploy new strategies or look elsewhere to raise capital.

Australia's most senior woman on Wall Street and Global Chairman of Investment Banking J.P. Morgan, Jennifer Nason, will shed light on the latest shifts and trends in the global capital markets and what that means for the biotech sector both globally and in Australia.

CHAIR: Dr Chris Smith, Partner, Brandon Capital

• Jennifer Nason, Global Chair, Investment Banking, J.P. Morgan

J.P.Morgan

#### 5:25pm - 5:30pm

#### WRAP UP & CLOSING REMARKS

Scott Power, Senior Analyst, Morgans

#### 5:30pm - 6:30pm

#### **NETWORKING RECEPTION**

Foyer, Park Hyatt Hotel Melbourne

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#### 6:30pm - Late

#### **CEO & INVESTOR DINNER**

Invitation only - details available on application

Programme current at 20 October 2023

For more information, please visit: ausbiotechinvestment.com.au

# Speaker Spotlight



Megan Baldwin
Chief Executive Officer
& Managing Director,
Opthea Limited



The Hon. Tim Pallas
Treasurer,
Victorian Government



Lorraine Chiroiu
Chief Executive Officer,
AusBiotech



Scott Power
Senior Analyst,
Morgans



Serg Duchini
Non-Executive Director,
Enlitic Inc



Kanishka Pothula Partner, Nextech Ventures USA



**Stephen Earl**Managing Director,
Acuity Capital



Dr Gurkeerat Singh
Vice President,
Eli Lilly & Company USA



**Dr Amanda Gillon**Senior Partner,
Bioscience Managers



**Dr Chris Smith**Partner,
Brandon Capital



Lawrence Gozlan
Chief Investment Officer,
Scientia Capital



**Neil Standford**Executive Director, Venture Capital,
Breakthrough Victoria



Jennifer Nason Global Chair, Investment Banking, J.P. Morgan USA



**Ajita Tynan**Manager, Listed Company Services,
ASX Limited

# **Host Industry Body**



Website: ausbiotech.org

Phone:

+61 (0) 437 126 843

Email:

admin@ausbiotech.org

AusBiotech is Australia's biotechnology industry organisation, working on behalf of members for more than 37 years to provide representation and services to promote the global growth of the Australian life sciences industry. AusBiotech is a well-connected network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), digital health and agri-biotech sectors.

We have representation in each Australian state, providing a national network to support members, and promote the commercialisation of Australian life science in national and international marketplaces.

#### Strengthening the Australian life sciences

AusBiotech is dedicated to the development, growth and prosperity of the Australian biotechnology industry, by providing initiatives to drive sustainability and growth, outreach and access to markets, and representation and support for members nationally and around the world.

- Our global investment programme promotes investment in the Australian life science industry, including events around the globe and resources for investors and companies.
- We advocate for policy reform in tax, clinical trials, intellectual property, regulation, and more, to sustain Australia's global competitive advantage in the life sciences.
- The Australian Life Science Innovation Directory contains a database of companies to inform global potential partnerships.

#### AusBiotech's mission

AusBiotech's mission is to foster a growing, strong and profitable biotechnology and life science industry in Australia through representation, advocacy and the provision of services and benefits to its members to help the industry realise its nationally important economic potential.

#### **AUSBIOTECH INVESTMENT ADVISORY GROUP**

The Investment Advisory Group (IAG) is made up of a group of experts at the forefront of life sciences investment and partnering in Australia, and provides AusBiotech with guidance and advice on our current and future investment programmes and events.

#### The IAG is chaired by:

Dr Amanda Gillon, Senior Partner, Bioscience Managers

#### **Advisory Group members:**

- · Sarah Meibusch, Partner, One Ventures
- · Michael Molinari, Managing Director, IP Group Australia
- · Dr Chris Nave, Managing Director, Brandon Capital
- · Scott Power, Senior Research Analyst, Morgans Financial
- Steven Yatomi-Clarke, Chief Executive Officer and Managing Director,
   Prescient Therapeutics Limited

# **Host State Body**



Victoria has one of the largest, most innovative, and globally connected biomedical ecosystems in the world. It is home to a range of globally connected health technology companies and world-leading biomedical integrated precincts and 22 medical research institutes. It offers a cost-competitive environment, access to specialist R&D and manufacturing capabilities, strong collaborative networks and a culture of innovation.

Victoria's expertise in health technologies has been supported by its experienced talent pool, favourable regulatory and R&D environment, world leading infrastructure, private investment and the long track record of the State Government of Victoria's investment into the sector.

Since 2014 the Victorian Government has invested more than \$1.3 billion into medical research - making it a leading location for companies taking their innovation to global markets.

The State Government of Victoria has a well-established strategy to help companies become part of the global supply chain in knowledge creation, product development and commercialisation. With a global network of 23 international business offices the Victorian Government is a dedicated partner for Victorian companies going global and international companies developing breakthrough products and treatments entering the Victorian market.

https://djsir.vic.gov.au/priorities-and-initiatives/health-technologies

# **Event Partners**



Company:

**Acuity Capital** 

Website:

acuitycapital.com.au

Phone:

1300 180 979

Email:

info@acuitycapital.com.au

Acuity Capital is the leading provider of At-the-Market (ATM) funding solutions to ASX-listed companies. We were the first to develop and introduce ATMs into Australia, and since our founding in 2012 we have:

- 1. Established over 60 ATMs with Australian listed companies, including a number in the life sciences sector
- 2. Made over \$800 million of standby capital available
- $3. \ \ Provided over \$130 \, million \, in \, equity \, capital$

ATMs are an integral part of the capital raising landscape in the United States where they have been available to listed companies for more than two decades. In 2022 alone, 491 ATMs were established in the U.S. with a total ATM facility size of over US\$80 billion, down from a peak of US\$140 billion in 2021. Of these, nearly half were established by companies in the healthcare sector (243 of 491).

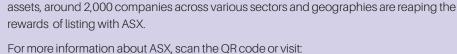
#### What is an ATM?

ATMs offer an additional source of equity capital that is often more efficient and lower cost than traditional capital raising methods. Importantly, ATMs place no restrictions on accessing other forms of capital and can be used as part of a diverse capital management toolkit to complement traditional capital raising methods. With an ATM in place, a company can:

- Reduce its cost of capital: ATMs broaden the capital raising options available to a company.
   They reduce reliance on any one source of capital and help to lower the cost of capital across all sources.
- 2. **Take advantage of market opportunities:** the ability to quickly activate an ATM allows a company to take advantage of favourable short-term market conditions such as spikes in share price. This is often not possible using traditional capital raising methods.
- 3. Maximise capital and reduce dilution: by giving companies control over the timing, minimum issue price and maximum number of shares to be issued, ATMs help maximise the capital raised while minimising dilution.

# **Event Partners**





ASX is one of the world's leading financial market exchanges, consistently ranked in the top ten globally for capital raising. With access to the world's fifth largest pool of pension

For more information about ASX, scan the QR code or visit asx.com.au/why-list-on-asx



# J.P.Morgan

#### Company:

J.P. Morgan

#### Address:

Level 31, 101 Collins Street, Melbourne VIC 3000

#### Website:

jpmorgan.com.au

#### Phone:

+61396334000

#### Email:

seth.h.schwartz@jpmorgan.com

JPMorgan Chase is a leading financial services firm based in the United States of America, with operations worldwide. JPMorgan Chase had U.S.\$3.9 trillion in assets as of September 30, 2023. The Firm is a leader in investment banking, financial services for consumers and small businesses, commercial banking, financial transaction processing and asset management. Under the J.P. Morgan and Chase brands, the Firm serves millions of customers predominantly in the U.S., and many of the world's most prominent corporate, institutional and government clients globally.

J.P. Morgan is committed to providing insights into investment banking and the wider world of finance, economics and markets. Within investment banking, the firm works with a broad range of issuer clients, including high growth companies, corporations, institutions and governments, to deliver comprehensive strategic advice, capital raising and risk management expertise that match their scale and needs, including:

- Mergers & Acquisitions: Advising corporations and institutions of all sizes on mergers and acquisitions, meeting the most complex strategic needs in local markets as well as on a global scale.
- Capital Markets: Serving clients holistically in partnership with the Industry Coverage and M&A groups. The firm offers a wide range of global services, from origination and structuring to financing and syndication.
  - Equity Capital Markets: Raising capital while offering origination, structuring and distribution capabilities across diverse markets.
  - Debt Capital Markets: Combining debt origination and structuring expertise with exceptional distribution capabilities.

Through in-depth, industry-specific expertise and regional market acumen, J.P. Morgan's industry coverage of the healthcare sector, including healthcare services, pharma, biotech, medtech and health IT/digital, serve the evolving needs of our clients.

J.P. Morgan's greatest asset is the breadth and depth of its client base. The firm's approach to serving clients has always centred on doing first-class business in a first-class way. Striving to build trusted, long-term partnerships, J.P. Morgan takes a holistic and forward-looking view of relationships, identifying ways to help clients accomplish their most important business objectives.

# **Event Partners**



Company:

Tenmile Ventures Pty Ltd

Address:

171-173 Mounts Bay Road Perth WA 6000

Website: tenmile.com

Phone:

+61864604949

Email:

ksewell@tenmile.com

Tenmile is a dedicated health technology investment business set up in July 2022 with an initial capital allocation of \$250 million. It invests in health technology companies and solutions that deliver life-changing ideas and better health outcomes for all.

The company is backed by Tattarang, one of the largest diversified private investment groups in Australia, owned by Andrew and Nicola Forrest. By applying Tattarang's responsible investment framework, including backing female-founded and female-led health businesses, Tenmile is focused on investing in products and solutions addressing unmet medical needs that support sustainable and equitable healthcare. Its remit is broad, spanning all health technology and life sciences, but with some specific areas of interest in digital health, immunology, oncology, microbial resistance, and the microbiome.

Headquartered in Perth, with team members in Sydney and San Francisco, Tenmile is well positioned to support and build early-stage companies throughout their journey with evergreen seed and expansion capital without the constraints of typical closed-end funds.

Tenmile is named after a permanent and reliable pool of clean water on the Ashburton River, in Western Australia, which has supported people and wildlife for millennia: an appropriate name for a new business that supports Australia's most innovative entrepreneurs and impactful health ideas with reliable capital.

### Other Event Partners





# Connecting companies with investors everywhere

Well-informed investment decisions call for in-depth research and understanding.

At ASX, we provide investors with opportunities to delve beyond annual reports and hear directly from the CEOs, CFOs, and founders of our listed companies.

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# >>> Presenting Companies

# **Arovella Therapeutics**





#### **CONTACT DETAILS:**

Name: Dr Michael Baker

Position:

Chief Executive Officer & Managing Director

Company:

Arovella Therapeutics

Address: Level 3, 62 Lygon Street Carlton VIC 3053

Website: arovella.com

Email:

investor@arovella.com

#### **COMPANY DESCRIPTION:**

Arovella Therapeutics Ltd (ASX: ALA) is a biotechnology company focused on developing its invariant natural killer T (iNKT) cell therapy platform from Imperial College London to treat blood cancers and solid tumours.

Arovella's lead product is ALA-101, which consists of CAR19-iNKT cells that have been modified to produce a Chimeric Antigen Receptor (CAR) that targets CD19. CD19 is an antigen found on the surface of numerous blood cancer types. iNKT cells also contain an invariant T cell receptor (iTCR) that targets  $\alpha$ -GalCer bound CD1d, another antigen found on the surface of several cancer types. ALA-101 is being developed as an allogeneic cell therapy, which means it can be given from a healthy donor to multiple patients.

#### **PIPELINE AND DEVELOPMENTS**

ALA-101 is being progressed to phase I first-in-human clinical trials, expected to commence in 2024. During the remainder of calendar 2023 the Company will complete process optimisation and scale-up preparation in preparation for cGMP manufacture and finalise its clinical trial plan for the Phase 1 study. In H1 2024 Arovella expects to complete cGMP manufacture for the trial as well as preparatory activities including the submission of its regulatory dossier.

For Arovella's iNKT cell therapy platform, the Company is focused on confirmation of the activity of CAR19-iNKT cells when combined with its partner company Imugene's onCARlytics to target solid tumours in animal models. It will also analyse additional CARs to add to the platform. During early 2024 the Company will then initiate proof-of-concept testing for novel CARs, and/or the cytokine technology Arovella currently has under option, for treatment of solid tumours.

#### **KEYINVESTMENT HIGHLIGHTS**

- Arovella is developing off-the-shelf iNKT cell therapies to target blood cancers and solid tumour cancers
- Its lead product, ALA-101, is a potential treatment for CD19expressing blood cancers
- Arovella's iNKT cell platform is well positioned to solve key challenges that hamper the cell therapy sector
- Arovella is among few companies globally developing an iNKT cell therapy platform
- Arovella's leadership team and its Board have proven experience in drug development, particularly cell therapies
- Arovella is focused on acquiring innovative technologies that strengthen its cell therapy platform and align with its focus areas

#### **INVESTMENT OPPORTUNITIES**

Arovella completed a capital raising in July 2023 which gave it pro-forma cash of \$7.38m. The Company continues to entertain any opportunities for strategically advantageous funding.

# **Avecho Biotechnology**





#### **CONTACT DETAILS:**

**Name:** Dr Paul Gavin

Position:

Chief Executive Officer

Company:

Avecho Biotechnology Limited

Address: Unit A8, 2A Westall Road Clayton VIC 3168 Website: avecho.com

Phone:

+61390025000

Email:

info@avecho.com.au

#### **COMPANY DESCRIPTION:**

Avecho Biotechnology develops and commercialises innovative Human and Animal Health products using its proprietary drug delivery system called Tocopheryl Phosphate Mixture (TPM®). TPM® is derived from Vitamin E using patented processes and is proven to enhance the solubility and oral, dermal and transdermal absorption of drugs and nutrients.

Avecho's lead asset is a proprietary oral cannabidiol (CBD) capsule with increased absorption for greater therapeutic effect. It is targeting over-the-counter registration in Australia, followed by rest-of-world. The product is about to commence a pivotal Phase III clinical trial. If successful, it will be amongst the first registered CBD products for insomnia anywhere in the world.

The company has developed a range of further cannabinoid products with increased absorption, including topical gels and gummies, that are the focus of development programs and licensing discussions. In addition, Avecho has partnered with US pharmaceutical companies for the development of non-cannabinoid pharmaceutical products.

#### **PIPELINE AND DEVELOPMENTS**

Cannabinoids (the active molecules in cannabis) are oil soluble molecules with poor oral absorption. Only ~6% of cannabinoids ingested in oral dosage forms are absorbed into the bloodstream to exert any therapeutic effect, limiting the value of existing medicinal cannabis products. Avecho has used its TPM technology to develop a range of dosage forms with increased cannabinoid absorption. These have been developed as pharmaceuticals for future FDA/TGA registration but can also be leveraged into the lucrative consumer cannabis markets overseas.

Avecho's lead asset is a proprietary oral cannabidiol (CBD) capsule enhanced using TPM for increased absorption and greater therapeutic effect. It is targeting over-the-counter registration in Australia with the TGA, followed by rest-of-world. The product is about to commence a pivotal Phase III clinical trial for insomnia. If successful, it will be amongst the first registered CBD products for insomnia anywhere in the world.

The Company has also completed its first clinical trial testing the effectiveness of a topical TPM CBD gel for arthritis. The initial study, conducted in partnership with the Lambert Initiative, demonstrated that daily applications of topical TPM CBD reduced pain and increased grip strength in patients suffering osteoarthritis of the fingers and hands. The product is now being prepared for a larger Phase II clinical trial.

Avecho has completed the development of first generation TPM gummies containing cannabinoids. Gummies are chewable, jelly-like preparations that can incorporate a range of medications or nutraceutical ingredients. The inclusion of TPM produces cannabinoid gummies that act faster with a larger magnitude of effect

Avecho is currenty in active discussions with multiple potential partners to support the commercialisation of several of its enhanced cannabinoid dosage forms.

Separate to the cannabinoid portfolio, Avecho is currently developing a topical ibuprofengel with NYSE-listed global consumer packaged goods business Perrigo Company for US registration and a range of oncology products with The Arthur Group.

#### **INVESTMENT OPPORTUNITIES**

Avecho has raised a total of \$8 million during 2023 to fund its pivotal Phase III clinical trial. This will be a key inflection point for Avecho with significant news flow. In addition, the company is approaching several additional milestones as it progresses further clinical trials, development programs and licensing discussions with partners for a range of products and markets. The company is excited for the opportunity to engage with range of future potential investors and corporate partners as the program moves forward.

## **BiomeBank**





#### **CONTACT DETAILS:**

Name: Dr Sam Costello

Position:

Chief Executive Officer & Co-Founder

Company: BiomeBank Address:

2 Ann Nelson Drive Thebarton SA 5031 Website:

biomebank.com

Phone:

(08) 7223 0075, 0413 311 793

Email:

scostello@biomebank.com

#### **COMPANY DESCRIPTION:**

BiomeBank is a commercial stage microbiome therapeutics company. Our mission is to restore human gut microbial ecology. Our first product, BIOMICTRA™, is the first approved donor derived microbiome therapy in the world (approved by TGA in Australia in 2022 for *C.difficile* infection). We have leveraged BIOMICTRA to generate clinical data and revenue used to develop second generation cultured microbiome therapies.

BiomeBank has developed an advanced drug development platform, BBOS™ to accelerate the development of microbial therapies by obtaining human data early in drug development to create therapies custom-built to treat the specific underlying causes of diseases.

BiomeBank's CONSORTIOME™ contains > 120 of the most prevalent species in the human bowel co-cultured into one drug substance. It contains > 97% of the known gene families in a healthy human gut microbiome.

This solves two critical problems for the microbiome therapy field simultaneously.

- Enhanced potential efficacy by:
   a. broadly restoring lost microbiome function
   b. enriching for specific patented function
- Dramatically improving the cost of production by limiting the number of bioreactors required for production (100x drop in cost)

BiomeBank has used studies of BIOMICTRA (FMT) to identify organisms and mechanisms of action associated with therapeutic benefit and have enriched the CONSORTIOME community for patented specific function. Our first such therapy, BB265, is designed to treat ulcerative colitis and will enter a phase 1b human study in 2024. Due to similar disease mechanisms, BB265 is expected to also have efficacy in treating Crohn's disease. In addition, BIOMICTRA is being positioned for orphan drug and rare paediatric disease designation for an undisclosed indication.

#### **PIPELINE AND DEVELOPMENTS**

BIOMICTRA: Donor derived "full spectrum" microbiome therapy approved for recurrent or refractory *C. Difficile* infection in Australia. Supplied to over 40 hospital networks in Australia. BIOMICTRA has been reformulated into a capsule and is being positioned for FDA orphan drug and rare paediatric disease designation for undisclosed disease.

Microbiome Drug Discovery Platform BBOS: Drug discovery platform that leverages human clinical and microbiome data from BIOMICTRA use and BiomeBank's unique ability to co-culture the most prevalent bacteria in a healthy human microbiome. Consotrium of >120 species that have 97% of the know gene families in a healthy human microbiome.

BB265: Co-cultured consortium of > 120 species with patented mechanisms of action targeting ulcerative colitis. Entering phase 1b human trial in 2024 and also positioned for treatment of Crohn's disease.

#### **KEYINVESTMENT HIGHLIGHTS**

- World's most advanced microbiome drug discovery platform with unique ability to co-culture the most prevalent bacteria in a healthy human microbiome, containing over 97% of know gene families in a healthy human microbiome.
- 2. Highly differentiated microbiome therapy for ulcerative colitis (BB265) entering phase 1b human trial in 2024
- World's first approved donor derived microbiome therapy for C.difficile infection that is also being positioned for FDA orphan drug and rare paediatric disease designation for undisclosed disease.

#### **INVESTMENT OPPORTUNITIES**

BiomeBank is raising capital to fund:

- 1. Phase 1b trial of BB265 for ulcerative colitis
- 2. Single pivotal trial for BIOMICTRA for orphan disease indication
- 3. Further development of BBOS platform and CONSORTIOME co-culturing technology

## **Carina Biotech**





#### **CONTACT DETAILS:**

Name:
Dr Deborah Rathjen
Position:

Chief Executive Officer

Company:

Carina Biotech Limited

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#### **COMPANY DESCRIPTION:**

Carina Biotech is a private Australian immunotherapy company established to research and develop chimeric antigen receptor T cell (CAR-T) therapies to treat solid cancers. CAR-T therapy is a revolutionary treatment option that uses a patient's immune system to fight their cancer. Carina has a pipeline of novel CAR-T programs for the treatment of a range of solid cancers, with the lead program targeting LGR5, a cancer stem cell marker in Phase 1 for the treatment of metastatic colon cancer.

The company has also developed a proprietary multi-functional chemokine receptor platform to enable CAR-T cell arming, homing and access to tumours and an efficient CAR-T cell manufacturing platform to increase efficacy through serial cancer cell killing and persistence within tumours.

#### **PIPELINE AND DEVELOPMENTS**

Lead pipeline asset, LGR5 CAR T cell therapy CNA3103 for treatment of advanced colorectal cancer has advanced to clinical trial after receiving approval to proceed from the FDA. Other solid tumour indications will be considered for CNA3103, including ovarian, gastric and pancreatic cancers.

Beyond CNA3103 Carina has focused pipeline of cancer stem cell targeting CAR-T assets in preclinical development.

#### **KEY INVESTMENT HIGHLIGHTS**

- Focused pipeline of pipeline of CAR-T cell therapy assets supported by a industry-leading, rapid, high yield manufacturing process and a proprietary multi-functional chemokine receptor platform to enable CAR-T cell arming, homing and access to tumours.
- IND clearance for a Phase I/II clinical trial of LGR5 targeted CAR-T CNA3103 in patients with metastatic colorectal cancer.
- Strong support from existing shareholders including Ten Mile Ventures and Minderoo Foundation Impact Fund.

#### **INVESTMENT OPPORTUNITIES**

Carina Biotech is currently seeking:

- Investment for CNA3103 clinical trials and pipeline development;
- Strategic partnerships and collaborations to further develop the Carina CAR product portfolio;
- · CAR co-development opportunities.

# **Celosia Therapeutics**





#### **CONTACT DETAILS:**

Dr Brenton Hamdorf PhD MBA

Position:

Chief Executive Officer & Executive Director

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#### **COMPANY DESCRIPTION:**

Celosia Therapeutics is a spin-off from Macquarie University (Sydney) arising from two research groups and more than 20 years of combined research into neurodegenerative diseases. Whilst the company itself has just celebrated its first year of operations, the company has been in active development for more than two years.

Celosia Therapeutics is a late discovery / early pre-clinical phase company, developing gene therapies for neurodegenerative disease. Celosia's initial target indications is Amyotrophic Lateral Sclerosis (also known as Motor Neuron Disease or Lou Gehrig's Disease).

Amyotrophic Lateral Sclerosis (ALS) is a terminal motor neuron disease for which there remains no effective treatment. The gene therapy targets pathogenic TDP-43 aggregates in the cytoplasm restoring cellular proteostasis and preventing neuronal cell death, and thus disease progression.

In ALS, 90% of cases occur sporadically with 10% genetically inherited. ALS is a devastating disease for both patients and their families and a lack of effective treatment options drives continued interest in new therapies. Celosia Therapeutics aims to provide a disease modifying treatment capable of halting the progression of the disease and significantly improving patient outcomes.

ALS is generally regarded as a rare disease and ALS is on the disease spectrum with Frontotemporal Dementia (FTD) and both can co-exist. In ALS, most patients progress rapidly, passing away from respiratory failure or respiratory complications of the disease within 27 months of diagnosis. The US incident and prevalent population (~5,800 and ~17,300 respectively in 2020) is expected to grow at a CAGR of 0.8% from 2019-2028. It is estimated that in Australia, at any one time, around 2,100 people are living with ALS. Most therapies available or in development target the 10% of cases with a genetic origin. Celosia Therapeutics is primarily focussed on the 90% of sporadic occurrences of the disease.

Through the Motor Neuron Disease Research Centre at Macquarie University, Celosia Therapeutics has access to a team of around 80 researchers, animal facilities, biobanking facilities containing in excess of 900 patients consisting of tissue / DNA / clinical data covering familial, sporadic and discordant twin cases. Dementia research expertise of a similar scale is accessed through Dementia Research Centre also based at Macquarie University.

The licensed gene therapies have arisen from Professors Chung and Ittner, both with exceptional reputations in their fields, who both remain actively involved in company activities. An ALS advisory panel has also been assembled with clinical, clinical trial and research expertise and we expect this to expand as the company grows.

An intentionally small management and governance team continues to evolve but presently consist of individuals with experience in investment, governance, technical and commercial skills.

#### **PIPELINE AND DEVELOPMENTS**

In 90% of ALS patients and 50% of FTD patients TDP-43 is mislocated and accumulates within the cytoplasm. TDP-43 is a known cause of ALS and Celosia Therapeutics is using a genetic approach to achieve targeted protein degradation of this toxic protein. We have two therapies in development, both targeting TDP-43, each with a slightly different approach. The aim is to clear pathogenic TDP-43 from the cytoplasm, restore normal nuclear TDP-43 function and prevent neuronal death.

We have validated our gene therapies using multiple animal models (including zebrafish and mice) and demonstrated a significant reduction in ALS symptoms. To do this we have developed a novel gene cassette consisting of our gene of interest driven by a neurone specific promotor, included a disease regulated switch of gene expression, and a synthetic biomarker (capable of indicating when disease and gene therapy are active).

Discussions with several potential partner companies and investors are also underway.

Our immediate future aims include finalisation of the discovery work, commencement of a pre-clinical program, securing a pharmaceutical partner / collaborator and securing a Seed B

Longer term (within 5 yrs) we aim to see our life-changing therapeutic successfully administered and working in multiple ALS patients.

#### **INVESTMENT OPPORTUNITIES**

We are introducing Celosia Therapeutics to the world and are seeking the opportunity to engage with a range of future potential investors and corporate partners. The next investment will be sufficient to complete the pre-clinical work and place Celosia Therapeutics in a position to commence a Phase 1 study. The final amount required will vary depending on grant and other funding

We have a very clear plan to improve our gene cassette, develop and/or validate new delivery vectors, and continue refinement of disease specific biomarkers in preparation for a comprehensive pre-clinical program. Don't hesitate to reach out if you would like to learn more.

# Cyban





#### **CONTACT DETAILS:**

Name:

Andrew Maxwell

Position:

Chair

Company:

Cyban P/L

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#### **COMPANY DESCRIPTION:**

Cyban is advancing the way brain injuries are detected and managed.

Our mission is to change the survival statistics for people that suffer traumatic and acquired brain injury.

Our Brain Pulse Monitor provides non-invasive, continuous measures of intracranial pressure, oxygen saturation and cerebral perfusion that are accurate relative to the existing "gold standard" invasive probes.

The Brain Pulse Monitor enables early detection and treatment of brain hypoxia for unconscious and intubated patients in Intensive Care Units and the Operating Theatre.

We help clinicians:

- minimise the likelihood of misjudging the risk of brain tissue injury;
- minimise the time it takes to determine how the brain injury will impact the treatment being considered or provided;
- minimise the risk of further brain injury and infection inherit in the current invasive monitoring standard of care; and
- reduce the cost of care in high value ICU and Operating Theatre settings.

#### **PIPELINE AND DEVELOPMENTS**

- FDA clearance for our first indication, oxygen monitoring, in April 2024.
- FDA clearance for our second indication, ICP monitoring, in September 2024
- · US commercial launch into the ICU market in early 2025.

#### **KEYINVESTMENT HIGHLIGHTS**

#### ~\$24B+ Diagnostic platform for neurocare and large organs

- ~\$4.3B TAM first entry in the U.S. traumatic brain injury market.
- Clear unmet need current standard of care leads to mortality rates of 50%, for traumatic brain injury, with 67% of survivors being diagnosed with serious long-term disability.<sup>1</sup>
- Clinical data demonstrates a correlation with current "gold standard" invasive probes.
- FDA pivotal study completed with the required endpoint met.
- · Clear path to FDA clearance in 2024.
- Established payment pathway via existing DRG codes.
- Tier 1 Clinical KOLs support Cleveland Clinic, Johns Hopkins, Duke University, UT Southwestern, Royal Edinburgh Infirmary, The Alfred and Royal Melbourne Hospitals.
- Two granted patents.
- Maloney-Wilensky E, Gracias V, Itkin A, et al. Brain tissue oxygen and outcome after severe traumatic brain injury: a systematic review. Crit Care Med 2009;37:2057

#### **INVESTMENT OPPORTUNITIES**

- \$5m+ in March 2024 for pre-commercial launch activities
- \$15m in September 2024 to fund commercial launch in the US ICU market

## **Dimerix Limited**





#### **CONTACT DETAILS:**

Name: Dr Nina Webster

Position:

Chief Executive Officer & Managing Director

Company:

**Dimerix Limited** 

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#### **COMPANY DESCRIPTION:**

Dimerix (ASX:DXB) 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 with first interim analysis expected in March 2024. 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, which is a rare kidney disease with no approved treatment anywhere in the world. The encouraging DMX-200 Phase 2 clinical data announced in 2020 demonstrated a strong safety and efficacy profile.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000, and worldwide about 220,000. Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX-200 in the US, UK and Europe for FSGS. Orphan Drug Designation is granted to support the development of products for rare diseases and qualifies Dimerix for various development incentives.

For those diagnosed with FSGS the prognosis is not good. The average time from a diagnosis of FSGS to the onset of complete kidney failure is only five years and it affects both adults and children as young as two years old. For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney. At this time, there are no drugs specifically approved for FSGS anywhere in the world, so the treatment options and prognosis are poor.

Dimerix is the only company with a potential drug candidate in Phase 3 clinical stage for FSGS and more notably, the first interim data is expected from the study in March 2024.

#### **PIPELINE AND DEVELOPMENTS**

#### **FSGS PHASE 3 STUDY**

The Phase 3 study, which is titled "Angiotensin II Type 1 Receptor (AT1R) & Chemokine Receptor 2 (CCR2) Targets for Inflammatory Nephrosis" – or ACTION3 for short, is a pivotal (Phase 3), multicentre, randomised, double-blind, placebo-controlled study of the efficacy and safety of DMX 200 in patients with FSGS who are receiving a stable dose of an angiotensin II receptor blocker (ARB). Once the ARB dose is stable, patients will be randomized to receive either DMX-200 (120 mg capsule twice daily) or placebo.

The single Phase 3 trial in FSGS patients has two interim analysis points built in that are designed to capture evidence of proteinuria and kidney function (eGFR slope) during the trial, aimed at generating sufficient evidence to support accelerated marketing approval. A successful outcome in the first interim analysis outcome, expected on or around 15 March 2024, would see the Company announce a clinically significant and statistical meaningful improvement in proteinuria in patients on DMX 200 vs placebo and that the trial is continuing to Part 2.

The primary endpoints for potential Accelerated Approval (the second interim analysis) are the percent change in protein in the urine (proteinuria) and its relationship to change in eGFR from Baseline to Week 35 following treatment with DMX-200 compared with placebo. Accelerated Approval is marketing approval for serious conditions that fill an unmet medical need based on a surrogate or an intermediate clinical endpoint, much like emergency use approvals.

In addition to the granted patents in all key territories, 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 generics may not enter the market and the patents may not be challenged. This may be extended by a further 2 years in Europe and 6 months in US for paediatric indications.

Further information about the study can be found on Clinical Trials.gov (Study Identifier: NCT05183646) or Australian New Zealand Clinical Trials Registry (ANZCTR) (Study Identifier ACTRN12622000066785).

#### **INVESTMENT OPPORTUNITIES**

Dimerix has no plans to take drug to market itself, and will ultimately commercialise with a partner. Our preference is to work with partners that have strong sales and marketing infrastructure and experience. As part of Dimerix' active business development program, meetings are being held with representatives from multiple pharmaceutical and biotechnology companies, including with those companies who have submitted offers for the asset, to increase and progress interest in Dimerix' DMX-200 program.

# **EBR Systems**





#### **CONTACT DETAILS:**

Name: Andrew Shute

Position:

Senior Vice President (Business Development)

Company:

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#### **COMPANY DESCRIPTION:**

EBR Systems (ASX: EBR) is dedicated to superior treatment of cardiac rhythm disease by providing more physiologically effective stimulation through wireless cardiac pacing. The WiSE® CRT System was developed to eliminate the need for cardiac pacing leads, historically the major source of complications and reliability issues in cardiac rhythm disease management.

WiSE is the world's only wireless, endocardial (inside the heart) pacing system in clinical use for stimulating the heart's left ventricle. WiSE enables cardiac pacing of the left ventricle with a novel cardiac implant that is roughly the size of a large grain of rice.

EBR Systems released their positive pivotal SOLVE-CRT trial results in May 2023 which showed the trial meeting its safety and efficacy endpoints with a 16.4% improvement in heart function and an absence of device and procedure related complications in 80.9% of patients. EBR expects full FDA approval by the end of 2024.

#### **PIPELINE AND DEVELOPMENTS**

Supporting the ACCESS-CRT and Totally Leadless CRT (TLC) clinical studies to support therapy expansion.

Developing a new rechargeable battery that will support the WiSE CRT System in becoming a first-line therapy option and treat a broader suite of patients.

#### **KEYINVESTMENT HIGHLIGHTS**

Unique Solution: EBR participates in a market dominated by three large players, yet it is complimentary to them, not competitive.

Large Market: Initial addressable market of US\$2.6bn, with an expansion opportunity up to US\$9.6bn.

Positive Results: Met safety and efficacy endpoints for the SOLVE-CRT study.

Focused Strategy: clear pathway to FDA approval and progressing commercialisation plans for first sales.

Expert Leadership: experienced management team with significant clinical, development and commercial expertise.

Well-Funded: strong cash position of US\$84.8 / A\$128.1m (as off 30 June 2023).

#### **INVESTMENT OPPORTUNITIES**

EBR is participating in the AusBioInvest event to engage with current and potential shareholders, with the goal of building greater awareness of their investment thesis.

# **Encapsolutions Pty Ltd**



#### **CONTACT DETAILS:**

**Name:** Dr Chris Barbé

Position:

Chief Executive Officer

Company:

Encapsolutions Pty Ltd

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capsolutions

#### **COMPANY DESCRIPTION:**

Encapsolutions is an innovation-driven, drug delivery company based in Sydney. It offers truly novel and customised solutions to deliver active substances using its proprietary encapsulation technology.

The Encapsolutions team has developed a ground-breaking patch technology, to produce highly efficient patches that can deliver effective analgesia with zero waste. This technology is based on the production of a nanofibrous polymeric mat which dissolves completely in contact with moist skin, releasing the drug on the skin. Over 95% of the drug is released, in contrast to traditional patches where 50-95% of the payload is discarded after use. These dissolvable patches are exceptionally efficient, using up to 30x less drug for the requisite delivery. Drug-encapsulation inside the polymeric fibres enhances its bioavailability and provides protection during storage.

Encapsolutions development is motivated by a strong commitment to provide patients with safe and efficacious pain relief options, including a tangible alternative to opioids.

#### **PIPELINE AND DEVELOPMENTS**

The proof of concept of Encapsolution's zero-waste patch technology has been demonstrated in preclinical studies using traditional analgesics i.e. Lidocaine and Fentanyl.

Encapsolutions has decided to focus its product development on CBD patches for complementary medicine. The strategy is to generate revenue, validate the platform for commercial-scale manufacturing, and at the same time gather consumer data specifically targeting pain relief. The target is to launch a product in the North American market by June 2024.

In parallel, over the next 3 years, Encapsolutions will clinically validate the technology for safety and test the efficacy of our cannabinoid patches for the management of chronic pain.

#### **KEYINVESTMENT HIGHLIGHTS**

A seed funding of \$1.3 millions was secured in June 2022 to cover initial set-up cost, equipment for pilot patch production and prototyping, R&D staff and lab equipment and securing IP rights.

#### **INVESTMENT OPPORTUNITIES**

Encapsolutions is seeking a total funding of AUD 8.5 millions over 3 years. This is to fund the expansion and GMP certification of their production capability as well as to conduct early phase clinical trials to test safety and efficacy against chronic pain.

## **Esfam Biotech**





#### **CONTACT DETAILS:**

Name: Penelope Lane Position:

Chief Executive Officer

**Company:** Esfam Biotech

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#### **COMPANY DESCRIPTION:**

Esfam Biotech is a biopharmaceutical company, spun out of The University of Melbourne, developing novel therapeutics addressing globally significant medical conditions with limited treatment options.

Esfam Biotech's novel approach is focused on tetraspanins as druggable targets for common cancers and viral infections.

With a structure-based drug design approach, in silico screening of small molecules predicted to bind to bioactive regions of tetraspanins, we have developed high-affinity analogues. We have discovered over 80 small molecule new chemical entities (NCEs) that have selective in vitro and in vivo activity against the tetraspanins CD81 and CD151.

Lead candidates from Esfam's development programs target inhibition of viral entry, replication and tumour progression and growth. The lead candidates possess favourable pharmacokinetics, safety pharmacology, cytotoxicity, genotoxicity and safety against cardiac channels.

Esfam Biotech has two globally registered core compounds and will progress these three lead candidates to internationally compliant, two-species animal toxicology testing, followed by first-in-human studies.

#### **PIPELINE AND DEVELOPMENTS**

Esfam Biotech has globally two patented drugs and is progressing to toxicology testing; followed by first-in-human studies across three indications. Esfam has a professionally targeted pipeline of 15 additional assets that it plans to develop with strategic global partners.

#### ESFAM 269 - Cancer

ESFAM 269 – Cancer, shown to act against prostate cancer and indicated to do the same against a broad range of other cancers, is a first-in-class, small molecule inhibitor of CD151, a newly revealed oncogenic driver of cancer progression, which has in vitro and in vivo activity against advanced human prostate cancer which has escaped the effects of anti-androgen treatment (castrate-resistant prostate cancer, CRPC), a commonplace clinical scenario. This is achieved by ESFAM 269 working through an androgen-independent process. In addition, other solid tumours that overexpress the target tetraspanin (CD151), including *breast, lung, pancreatic,* and *colon* cancers, are being studied.

#### Esfam 289 - Respiratory disease

Human applications: our anti-viral treatment is a novel treatment against respiratory diseases, including *coronaviruses, with* a targeted approach of long-covid. Esfam 289 in vitro and in

vivo results show complete inhibition of SARS-CoV-2 infection (including the Omicron variant) by blocking viral entry, leading to a reversal of lung inflammation in a Syrian hamster model of COVID-19 infection. A direct-to-lung dry powder inhaler system has been developed for human trials. Esfam 289 is also active against other coronaviruses involved in human infections, which should facilitate future pandemic preparedness. We have shown efficacy against *cytomegalovirus* (CMV) infection, a significant cause of morbidity and organ rejection post-transplantation. Maternal CMV infection during pregnancy has also been implicated in cerebral palsy in newborn infants.

A pre-IND package proposed pre-clinical and clinical programs in SARS-CoV-2. The FDA has approved our approach.

A direct-to-lung dry powder inhaler system has been developed for delcetravir in human trials. Esfam 289 is clinically positioned as a treatment for acute COVID-19 and post-exposure prophylaxis (a treatment for long-term COVID-19). Esfam 289 is also active against other coronaviruses involved in human infections, which should facilitate future pandemic preparedness.

Animal applications: Esfam 289 is a world-first treatment and preventative for the porcine reproductive and respiratory syndrome virus (PRRSV). We have shown inhibition in multiple strains of PRRSV, addressing significant global unmet needs. It is a disease requiring management and containment by the Animal World Health Organisation.

The Foot and Mouth Disease (FMD) virus shares a related viral entry pathway to the PRRSV. Esfam-289 is likely to have an anti-viral effect against FMD. The market size for these viral infections is significant, and the tetraspanin mode of action is a target-rich therapeutic domain with a strong future pipeline.

#### **KEY INVESTMENT HIGHLIGHTS**

Spun out of The University of Melbourne, who remain invested.

- · Esfam Pty Ltd owns all IP.
- Two globally patented core compounds with two drugs globally registered to target three specific diseases in development.
- · Founding Professor Dr. Albert Frauman
- Globally recognised SAB board Inc. Professor Sharron Lewin and Dr Anne Phillips (US advisory).
- Multiple Novel Global Market Solutions, Targeting Billion Dollar Markets.
- · Exit opportunities in under four years.
- An extremely robust strategically developed pipeline.

#### **KEYINVESTMENT HIGHLIGHTS**

#### Esfam 269 Late-Stage Cancer

Esfam 289 active in human and animal health

- Long Covid (and respiratory disease) with Pre FDA Ind-Approval (animal studies: cessation of disease growth and reversal of lung damage).
- PRRS Animal Health Market Porcine Reproductive Respiratory Syndrome, WHO list of significant diseases impacting food bowl. Pre- or post-outbreak treatment: This is a world-first treatment.

Esfam has been awarded a \$1m MRFF grant from the Commonwealth government to continue the research and commercialisation of Esfam 289 for respiratory diseases, including Long-COVID. For which Esfam have received Pre IND FDA-Approval.

#### **INVESTMENT OPPORTUNITIES**

Following strong data in animal studies, Esfam has undertaken the identification and engagement of an investable executive team and built out a biotechnology commercial experienced board to take Esfam through the stages of commercialisation, growth and expected multiple exit opportunities.

Minimum investment of A\$250k (US\$160k at current FX rate of A\$0.64)

Preferred terms are available for investors willing to support the First Round raise of A\$3-4M and follow on to the Second Round raise of A\$20M for toxicology.

The company is currently pre-money valuation of A\$95 M (based on a USD rate of 75 cents to A\$1),

- The current valuation is A\$3.75 per share based on an exchange rate of A\$0.75 to USD, so the current rate exchange rate of A\$0.64 cents offer a further discount for USD investors.
- Preferred terms for early & AusBiotech investors: 20% discounted price of A\$3.00 (pre-money valuation of A\$75M) for all investors in the first round of A\$3-4M.
- First Round investors of A\$1M or more will also be eligible for the discounted A\$3.00 price in the Second Round for up to 5 times their investment in the First Round

Multiple exits and strategic partnering opportunities.

- Toxicology Results 1 2 years
- Phase One Clinical Trials 3 4 years
- · Phase Two Clinical Trails 4 5 years

# **FivepHusion**





#### **CONTACT DETAILS:**

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Position:

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Company: FivepHusion

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#### **COMPANY DESCRIPTION:**

FivepHusion is a clinical-stage biotech company focused on improving patient treatment outcomes and quality of life for cancers with significant unmet needs.

FivepHusion is addressing the safety and efficacy limitations of standard of care solid tumour therapy via the development of Deflexifol™, a novel, enhanced drug formulation enabling the codelivery of 5-fluorouracil (5-FU) chemotherapy with its biomodulator leucovorin (LV) at a physiological pH. Deflexifol™ offers superior safety, tolerability, and anti-tumour activity over standard treatment for various solid tumour indications, including colorectal, breast, pancreatic, and other gastrointestinal cancers.

FivepHusion is seeking to develop Deflexifol™ through to registration as the new Gold Standard of Care™, facilitated by collaborative deals with Treehill Partners (USA) and Syneos Health. FivepHusion is also collaborating with Allarity Therapeutics (NASDAQ:ALLR), enabling potential precision oncology strategies, and with Pfizer CentreOne for GMP scale-up manufacture of Deflexifol™ in preparation for global registration trials and commercial launch.

#### **PIPELINE AND DEVELOPMENTS**

FivepHusion is developing Deflexifol™ as a superior replacement of standard of care 5-FU/LV in all indications for which they are routinely used, with a global incidence exceeding 6 million patients. FivepHusion is additionally leveraging the proven cytotoxicity of 5-FU and the unique attributes of Deflexifol™ for its development in new indications with significant unmet needs, including paediatric brain cancers. Priority pipeline indications are metastatic colorectal cancer (mCRC) and paediatric ependymoma.

Deflexifol™ is eligible for immediate development into first-line mCRC via the 505(b)(2) regulatory pathway, as recently confirmed by the US FDA. Safety and efficacy has been demonstrated across two phase 1b/2a trials in hard-to-treat patients with advanced tumours. A near-term phase 1b/2a dose confirmation trial is planned prior to initiation of a global phase III pivotal trial by the end of 2024. A phase 1b/2a trial in paediatric brain cancers, including ependymoma, is underway across all paediatric oncology centres nationally.

#### **KEYINVESTMENT HIGHLIGHTS**

FivepHusion is entering 2024 with strong momentum into de-risked, advanced clinical-stage development of Deflexifol™. Late-stage development has been designed according to feedback from the FDA and expert KOLs to facilitate Deflexifol™ registration as a superior replacement of standard of care therapy for various solid tumours, offering near-term entry into established and substantial global markets.

Deflexifol™ is positioned to enhance and replace the backbone of therapy for mCRC, a significant market of US\$12.6B (2021, + 2.6% CAGR), and to become one of few treatment options available for paediatric brain cancers (US\$1.65B market in 2023 + 4.1% CAGR).

FivepHusion is led by an experienced and dedicated Board, management team and advisors, and is supported by strategic, world-class drug development and commercial organisations, including Syneos Health and Pfizer CentreOne.

#### **INVESTMENT OPPORTUNITIES**

FivepHusion is seeking investment and further strategic global and regional partnerships to support rapid development and commercialisation of Deflexifol $^{\infty}$ .

## Genofax





#### **CONTACT DETAILS:**

Name: Zahangir Alam

Position:

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Company:

Genofax

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#### **COMPANY DESCRIPTION:**

Genofax is a microbiome science company that combines the power of targeted science, a diverse data set and artificial intelligence to personalise wellbeing and, ultimately, healthcare.

Our research is focused on the gut microbiome, because every human has trillions of microorganisms in their gut that play an integral role in managing wellbeing and health. Our research targets healthy ageing, neuronal disorders and phage therapy and benefits from the use of *C. elegans* as an efficient model organism.

We are also focused on proactively addressing the need for new data sets upon which to base microbiome research. Existing data sets are dominated by adults from wealthy, urban locations, we are building new and diverse datasets that will allow us to develop microbiome solutions for all of humanity.

Our first products are a test and report kit and probiotics. The test kit is an at home self-test which the consumer sends to a sequencing facility in their home country. We analyse their sequencing data using our proprietary platform and provide a report with personalised recommendations. This is the first step in allowing every individual to have more control over their health. Our test kit and probiotics are the first in our range of products made possible by combining new microbiome discoveries, improvements in artificial intelligence and increasing demand for personal wellbeing and health solutions.

#### **INVESTMENT OPPORTUNITIES**

Genofax is a privately held business established by Co-Founders Zahangir Alam and Dr Abed Chaudhury in 2021.

Genofax is looking for investors or strategic partners for our next stage of growth, which will focus on accelerating novel research and new product development.

This is the first time Genofax has considered external investment.

# **Imagion Biosystems**





#### **CONTACT DETAILS:**

Name: Dr Isaac J. Bright, MD Position: Chief Executive Officer

**Company:** Imagion Biosystems Limited Address: 5601 Oberlin Drive Suite 100 San Diego CA 92121 Website: imagionbiosystems.com Email:

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#### **COMPANY DESCRIPTION:**

Imagion Biosystems is developing new ways, based on their proprietary nanoparticle technology, to allow physicians to identify the presence of cancer sooner and more specifically than current methods. Imagion uses MagSense® technology, using molecularly targeted magnetic nanoparticles for precise cancer detection via Magnetic Resonance Imaging (MRI). Nanoparticles are attached to targeting molecules like antibodies, binding specifically to cancer tumour cells expressing the target molecule, such as HER2 breast cancer (Imagion's first clinical indication).

In Imagion's recently completed HER2 Breast Cancer Phase 1 Study potential utility was shown with a change in MRI image contrast in lymph nodes highly suspicious for tumour being distinctly different from the image contrast seen in non-involved nodes. The assertion that the MagSense® imaging agent provides new information for the radiologist not available through ultrasound, which is currently used as the standard of care, has been corroborated by an independent panel of expert radiologists.

#### **PIPELINE AND DEVELOPMENTS**

Imagion Biosystems is currently in the clinical development phase for its lead product, designed to detect nodal diseases in HER2 breast cancer patients. Phase 1 has recently been completed and the Company will use the data in support of an Investigational New Drug (IND) filing to the US FDA expected late in 2023 or early in 2024.

Imagion also has several pipeline projects in pre-clinical research including imaging agents for other cancer indications including ovarian, prostate, brain, and pancreatic cancer. Additionally, the company is also researching a 'non-targeted' imaging agent (a potential alternative to gadolinium-based contrast agents) for MRI, allowing the potential visualization of vascular and structural anomalies associated with cardiovascular diseases.

#### **KEY INVESTMENT HIGHLIGHTS**

Today's medical imaging technologies are still not sensitive enough to detect small tumours and often require exposing patients to radiation. MagSense® technology is bio-safe and uses magnetic nanoparticles coated with targeting molecules to enable radiation-free cancer detection, addressing the global need for earlier diagnosis.

Imagion Biosystems has multiple revenue opportunities. The MagSense® imaging agent will have a high gross margin enabling strategic partnering to out-license the technology as each cancer indication is developed. The ability of the MagSense® imaging agent to locate cancerous tumors gives rise to other opportunities for the technology as a drug delivery vehicle. As well as manufacturing nanoparticles for its own clinical and research use, Imagion is also a manufacturer of choice for third-party providers with one currently using Imagion's nanoparticles in clinical development. The Company believes there are further third-party revenue opportunities in this area.

#### **INVESTMENT OPPORTUNITIES**

Imagion Biosystems, listed on ASX since June 2017, is seeking equity investments to continue to fund its research, development, and clinical advancement. Imagion's market valuation has tracked alongside many micro-cap biotech stocks in the Australian listed landscape in recent history where there has been a widespread decline in valuations. This potentially represents a good opportunity for a re-rate when sector sentiment improves, combined with Imagion on the cusp of value inflection points, such as an IND filing and advancing partnership opportunities.

Some current collaborations include an agreement with Patrys Limited researching brain cancer imaging via sponsored research with the University of Sydney; establishment of a strategic partnership via an MOU with Prestige Biopharma (listed in South Korea) to research the non-invasive early detection of pancreatic cancer; and a research collaboration with Siemens Healthineers to assist with the optimization of MRI protocols for clinical studies.

### **Immuron**





#### **CONTACT DETAILS:**

Name: Steven Lydeamore

Position:

Chief Executive Officer

Company:

Immuron Limited

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#### **COMPANY DESCRIPTION:**

Incorporated under the laws of Australia, Immuron Limited is listed on the Australian Securities Exchange (ASX) with ordinary shares trading under the symbol "IMC.". Immuron also has American Depositary Shares and warrants listed on NASDAQ under the symbols "IMRN" and "IMRNW", respectively. Each ADS represents 40 of our ordinary shares, no par value.

Immuron Limited is a commercial and clinical stage publicly listed Australian biopharmaceutical company with a proprietary technology platform focused on the development and commercialization of a novel class of specifically targeted polyclonal antibodies that we believe can address significant unmet medical needs.

Our validated technology platform can produce orally active polyclonal antibodies which offer targeted delivery within the gastrointestinal ("GI") tract and do not cross into the bloodstream. We believe that our lead drug candidates, currently in clinical development, have the potential to transform the existing treatment paradigms for moderate to severe Campylobacteriosis, Clostridioides difficile infections, Enterotoxigenic Escherichia coli (ETEC) infections and travellers' diarrhoea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce.

Immuron's products are a subset of the global digestive health market, which a multi-billion-dollar market. 30% - 70% of traveller's experience travellers' diarrhea which is a billion dollar market. Clostridioides difficile infections are the leading cause of gastroenteritis-associated mortality in USA; the therapeutic market is expected to grow to over \$1.7 billion by 2026 In addition to gastrointestinal drug development capability, Immuron actively markets and distributes product including lead product Travelan® in Australia, Canada, and USA.

#### **PIPELINE AND DEVELOPMENTS**

Immuron has two therapeutic drug candidates in clinical development and two partnered clinical programs.

Since AusBioInvest+2022 Immuron has achieved the following:

- FDA IND approval for and initiation of a Phase 2 clinical trial for IMM-124E in a controlled human infection model (CHIM) clinical study (ETEC);
- FDA IND approval for our partner, Naval Medical Research Command therapeutic to conduct Phase 2 clinical trials for CampETEC in controlled human infection model studies: campylobacter and ETEC;

Our partner, Uniformed Services University enrolled 347 of 868 participants in a field clinical trial of Travelan® against placebo in travellers' diarrhoea

#### **KEY INVESTMENT HIGHLIGHTS**

In the period ending June 2024, Immuron anticipates:

- · Continued strong growth in commercial sales of Travelan®;
- Reporting topline results for IMM-124E Phase 2 clinical study in a controlled human infection model study (ETEC);
- Our partner, Naval Medical Research Command initiating a Phase 2 clinical study for CampETEC in a controlled human infection model study;
- Our partner, Naval Medical Research Command reporting topline results for a Phase 2 clinical study for CampETEC in a controlled human infection model study;
- Our partner, Uniformed Services University completing the in-patient phase of a field clinical trial of Travelan® against placeboin travellers' diarrhoea;

Submitting a pre-IND to the FDA for IMM-529 in Clostridioides difficile.

#### **INVESTMENT OPPORTUNITIES**

Immuron is seeking:

- access to investors to share the Immuron story, to inspire buying on market and interest in future capital raises;
- partners to expand geographical sales of Travelan® (travellers' diarrhoea) and Protectyn® (gut and liver health); and investment/ development/marketing partners for IMM-529 (clostridioides difficile).

## **InhaleRx**





#### **CONTACT DETAILS:**

Name:
Darryl Davies
Position:
Chief Executive Officer

Company: InhaleRx Ltd Address: Level 16, 414 La Trobe Street Melbourne VIC 3000 Website: inhalerx.com.au Email: Info@inhalerx.com.au

#### **COMPANY DESCRIPTION:**

InhaleRx Limited (ASX: IRX) ("InhaleRx" or "the Company") is an Australian healthcare company developing unique drug-device combination products to address unmet medical needs in both pain management and mental health sectors.

The Company's overarching goal is to develop U.S. Food & Drug Administration ("FDA") registered therapies, targeting anxiety and pain-related indications via the rapid and capital conserving regulatory pathways, such as 505(b)(2). A 505(b)(2) application is an New Drug Approval ("NDA") that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies available in the public domain.

Current therapeutic treatments for the chosen indications are limited and are often accompanied by significant side effects and abuse potential. Addressing these unmet needs present significant economic opportunities for InhaleRx's shareholders.

InhaleRx holds innovation and provisional patents for the technology and nominated indications which the Company plans to build a portfolio on to strengthen its core value creation platform.

#### **PIPELINE AND DEVELOPMENTS**

- InhaleRx's two lead candidates, IRX616 and IRX211, are currently in early phase clinical development, with the aim of addressing significant unmet medical needs in the therapeutic areas of mental health and pain, respectively.
- These drug-device combination products consist of pressurised metered dose Inhalers ("pMDI's") designed to disperse the respective drugs for efficient uptake via the lungs. The expected rapid therapeutic onset is purposefully aligned with health conditions where management of acute episodes is crucial.
- Both InhaleRx's lead candidates have gone through rigorous formulation work and been matched with device components to optimise performance suitable for manufacturing according to Good Manufacturing Practice.
- Both programs have involved consultations with the U.S. FDA via Pre-Investigational New Drug (PIND) meetings, which provided important insights and guidance with respect to identifying the drug development pathways and indications with the greatest chances of success.
- IRX211's (pain indication) safety and tolerability is currently being evaluated in a Phase 1 clinical trial, with two cohorts already having completed testing. Result have so far exceeded the Company's expectation in terms of tolerability, efficiency and overall performance.

 IRX616 (mental health indication) is slated to enter phase 2 of clinical development in a population of patients suffering with panic disorder (PD) within the next 6 months.

#### **KEY INVESTMENT HIGHLIGHTS**

- InhaleRx has a well-connected and industry leading management team and board of directors with 120+ years' experience across healthcare commercialisation, pain management and mental health.
- The team has significant FDA regulatory experience, most notably with navigating the 505(b)(2) pathway.
- Over the past 3 years, the Company has acquired real-world data from over 10,000 patients and physicians on inhaled cannabinoid products and has a good understanding of the unmet clinical needs which it continuously leverages to inform its commercialisation strategy.
- The Company has been granted an innovation patent and is continuously strengthening its position through provisional patents across different indications.
- Close partnerships with regulatory and contract research organisations have enabled the Company to progress its drug development activities in a capital conserving manner.

#### **INVESTMENT OPPORTUNITIES**

- The Company is inviting investment from investors who appreciate the dynamic nature of drug development and recognise the future value potential for the Company and its shareholders through the development of its drug-device combinations.
- Specifically, InhaleRx is looking to raise capital that will enable it to complete the IRX616 phase 2 trial and support the preparations for the phase 2 clinical trial of IRX211.
- The Company is focussed on developing quality speed to market drug-device development pathways, whilst also running a lean operation to maximise value for shareholders.

## Invion





#### **CONTACT DETAILS:**

Name: Thian Chew Position:

Executive Chairman & Chief Executive Officer

Company: Invion Limited Address: 100 Albert Road South Melbourne VIC 3205 Website: Inviongroup.com

Email:

brendon.lau@inviongroup.com

#### **COMPANY DESCRIPTION:**

Invion is a clinical stage life-science company that is leading the global research and development of the Photosoft™ technology for the treatment of a range of cancers, atherosclerosis and infectious diseases.

The Company is close to commencing clinical trials in cancer indications and is working with partners like the Peter MacCallum Cancer Centre, Hudson Institute and the University of Adelaide.

Results to date show Photosoft has the potential to regress multiple cancer types, impede metastatic cancers and stimulate the body's immune response.

Photosoft has also demonstrated effectiveness against bacteria, fungi and viruses, including MRSA, COVID-19 and dengue *in vitro*.

Invion holds the exclusive rights to Photosoft for most of Asia Pacific (APAC) for cancers, atherosclerosis and infectious diseases, plus the US and Canadian rights for infectious diseases indications.

Apart from multiple nearer-term milestones and large addressable markets, Invion's research and clinical cancer trials in Australia are funded by the technology licensor, RMW Cho Group Limited.

#### **PIPELINE AND DEVELOPMENTS**

Cancer is the key focus for Invion as it progresses towards clinical trials after completing the majority of the required pre-clinical and drug discovery work on its lead drug candidate, INV043.

Proof-of-concept studies on INV043 showed it completely regressed TNBC *in vivo*. The tumour mass was undetectable two weeks after initial treatment and no scarring was evident. Further, there was no recurrence of disease and a re-challenge with TNBC implant could not re-establish new tumours, indicating the development of protective immunity.

Separate proof-of-concept studies have also highlighted Photosoft's potential to be used in combination therapy with immune checkpoint inhibitors (ICI).

A new Australian patent for Photosoft, which includes INV043, was also recently granted. This patent builds upon previously granted patents to the technology in Australia and other territories that Invion has exclusive rights to and extends the intellectual property (IP) protection for Photosoft for around another two decades until at least late 2041.

Additionally, further pre-clinical work, including proof-of-concept studies, are currently being undertaken to better characterise Photosoft's impact on infectious diseases and atherosclerosis – both of which represent a significant and lucrative market opportunity for Invion.

#### **KEYINVESTMENT HIGHLIGHTS**

Photosoft has the potential to revolutionise the treatment of multiple cancer types as it has few side effects and a strong safety profile (non-toxic and well tolerated). This gives Photosoft an advantage over current treatments, which may be painful, have a harmful impact on healthy cells and disfiguring.

Invion's target markets are large and significant, particularly as there are limited treatment options and high mortality rates for some of the cancers it is targeting. For instance, the global market opportunity for anal cancers is estimated to be worth US\$1.3 billion by 2028 while the immune checkpoint inhibitors market (where INV043 may be used in combination therapies) is estimated to grow at 16.8% CAGR to US\$141 billion by 2030.

Outside of cancer, the global market for atherosclerosis treatments is forecast to hit US\$56.6 billion by 2027 with Asia Pacific tipped as the fastest growing market, and the global pandemic has also put the spotlight on infectious diseases.

#### **INVESTMENT OPPORTUNITIES**

Invion is expected to achieve several important milestones over the next year or two. In particular, the Company is expected to commence at least two human trials for skin cancer and an anogenital cancer.

Invion also continues to undertake further proof-of-concept studies in cancer and further pre-clinical work on atherosclerosis and infectious diseases that will assist it in identifying other indications to progress to clinical trials.

Research and clinical trials in Australia are funded by the technology's licensor. This provides Invion a balance sheet advantage, although a further capital contribution will enable Invion to accelerate the development of its non-cancer program. Additionally, Invion is open to partnership opportunities.

## **LBT Innovation**





#### **CONTACT DETAILS:**

Name: Brent Barnes

Position:

Chief Executive Officer & Managing Director

Company:

LBT Innovations Ltd

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#### **PIPELINE AND DEVELOPMENTS**

#### **Pharmaceutical Quality Control Market**

- Dec-22 \$0.6 million funding from Thermo Fisher to develop APAS PharmaQC solution for their culture media
- Jan-23 LBT secure \$1.1 million development partnership with AstraZeneca for APAS PharmaQC
- Aug-23 First APAS PharmaQC performance data released demonstrates 100% sensitivity for microbial growth detection

#### **Clinical Market**

- Dec-22 Thermo Fisher expand distribution partnership to Europe
- FY22-23 Growing customer installed base for APAS Independence 14 sales globally
- FY23 CE Mark for Urine and MRSA analysis modules under new in vitro diagnostic regulations

#### **Product Development**

 Nov-22 \$1.5 million funding awarded for new benchtop instrument - APAS Compact. MTPConnect CTCM Program

#### Corporate

- FY23 \$2.0m new funding raised through Shareholder rights issue and share placement agreement (Lind Partners)
- $\,$  Jul-23 Ms Rebecca Wilson joins the LBT Board as Chair

#### **KEYINVESTMENT HIGHLIGHTS**

# Novel platform technology for Microbiology culture plate reading

- · Traditional methods labour intensive and ripe for disruption
- · Best-in-class technology addressing unmet need
- · Validated hardware platform, multiple AI products
- APAS® Clinical + APAS® PharmaQC

#### APAS® PharmaQC ~\$2.8 billion global addressable market

- \$1.7m product development funded by AstraZeneca & Thermo Fisher
- First data released demonstrate exceptional performance 100% sensitivity for microbial growth detection
- Expect AstraZeneca roll-out and additional pharmaceutical manufacturer placements in 2024
- · Market dynamics point towards rapid adoption

#### APAS® Clinical ~\$1.1 billion addressable target market

- · Compelling value proposition, 18+ month sales cycle
- Exclusive distribution partnership with Thermo Fisher world leader in microbiology culture media
- Regulatory clearances in USA (FDA), Europe (CE Mark), Australia (TGA)
- · Key Opinion Leaders and Reference Sites established
- 14 sales achieved globally (US, UK, Germany, Australia)

## Microba





#### **CONTACT DETAILS:**

Name:

Professor Trent Munro

Position:

Senior Vice President Therapeutics

Company:

Microba Life Sciences

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microba.com

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#### **COMPANY DESCRIPTION:**

Microba Life Sciences is a commercial-stage diagnostic and clinical-stage drug development company, driven to improve human health through the microbiome. Established in 2017 utilising technology developed at The University of Queensland, Microba 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.

Over the last decade, a growing body of research has demonstrated that the gut microbiome plays a critical role in many aspects of human health and disease. However, current technology lacks the resolution required to accurately map these relationships. Microba has addressed this gap through development of world-leading technology for measuring the human gut microbiome.

Microba operates complementary business pillars; Microbiome Testing Services and Microbiome Therapeutics. Through partnerships with leading organisations, Microba is powering the discovery of new relationships between the microbiome, health and disease for the development of new health solutions.

Microba employs a human-first data-driven approach to identify therapeutic leads which are naturally derived from a healthy human gut. Leveraging a globally unique, proprietary databank, Microba has established a unique, repeatable Therapeutic Platform to develop multiple candidates to address large unmet clinical needs for chronic diseases.

#### **PIPELINE AND DEVELOPMENTS**

Microba operates in the emerging US\$4.89 billion gut microbiome sector impacting the chronic disease management market and is expected to grow to \$6.07 billion in 2023 at a CAGR of 7.5%.

- Publicly listed company on ASX with ~US\$68M market cap, ~70
   FTE and ~\$5.4M in FY23 revenue
- Partnerships established with market leaders incl. Sonic Healthcare (ASX: SHL), SYNLAB (GR:SYAB), Illumina (NASDAQ: ILMN), Ginkgo Bioworks (NYSE: DNA), Unilever (LON: ULVR), IFF: International Flavors & Fragrances Inc. (NYSE: IFF)
- · Microba has established a strong therapeutic pipeline:
  - Phase I Trial commenced for Inflammatory Bowel Disease Program
  - Cancer program initiated with leading cancer institutes
  - Discovery stage program in autoimmune disease in partnership with Ginkgo Bioworks
- Microba is expanding its testing services globally through a growing distribution partner network
  - Advanced microbiome tests launched in Australia during 2023; MetaXplore™ for gastrointestinal disorders; and MetaPanel™ for infectious diseases
  - 13 Countries operationalised with Microba's testing technology, access into 35 countries

# **Noxopharm**





#### **CONTACT DETAILS:**

Name: Dr Gisela Mautner

Position:

Chief Executive Officer & Managing Director

Company: Noxopharm Address: Suite 71 159 Ridgecrop Drive Castle Hill NSW 2154 Website:

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info@noxopharm.com

#### **COMPANY DESCRIPTION:**

Noxopharm Limited (ASX:NOX) is an innovative Australian biotech company discovering and developing novel treatments for cancer and inflammation, including a pioneering technology to enhance mRNA vaccines.

The company utilises specialist in-house capabilities and strategic partnerships with leading researchers to build a growing pipeline of new proprietary drugs based on two technology platforms - Chroma™ (oncology) and Sofra™ (inflammation, autoimmunity, and mRNA vaccine enhancement).

Noxopharm also has a major shareholding in US biotech company Nyrada Inc (ASX:NYR), which focuses on drug development for cardiovascular and neurological diseases.

The Noxopharm management team has over 100 years of combined pharma experience, 20+ drug launches in numerous therapeutic areas, 60+ years of academic research and 150+ peerreviewed publications. Skills include: research and development, drug discovery and development, regulatory matters, chemistry, manufacturing, creation and management of clinical trials, commercialisation, corporate finance, academic and industry partnerships, intellectual property law and medical marketing.

#### **PIPELINE AND DEVELOPMENTS**

Noxopharm has a strong product pipeline backed by its expert in-house team and world-class external partners such as UNSW Sydney and the Hudson Institute for Medical Research.

The corporate strategy focuses on the development of new and proprietary drug candidates from the Chroma and Sofra platforms. These include a novel preclinical drug to treat pancreatic cancer, as well as an mRNA vaccine enhancer. The latter mitigates vaccine side effects and can be used for current and future mRNA-based vaccines and medicines, for example most COVID vaccines.

The Sofra platform is also relevant for developing new treatments for autoimmune diseases such as lupus, and the company recently presented data showing reduced inflammation in preclinical models.

All these assets are supported by a robust intellectual property strategy, and represent a diverse portfolio designed to capture multiple opportunities while mitigating risk.

#### **KEYINVESTMENT HIGHLIGHTS**

Noxopharm is developing new drugs that respond to unmet needs and have clear commercial potential.

The SOF-VAC vaccine enhancer enters a market that will grow rapidly as mRNA technology's use progresses beyond COVID vaccines into other vaccine types, as well as drugs for various diseases. The mRNA market in 2021 was US\$42 billion and is expected to grow to US\$128 billion by 2030 at a compound annual growth rate of 13%.

Regarding pancreatic cancer, there is an urgent need to develop more effective treatments. It is set to become the second leading cause of cancer-related deaths in the US by 2030, with a five-year survival rate of just 9% from diagnosis. Only a few new treatment options have appeared over recent decades.

Both the Chroma and Sofra platforms are versatile core technologies from which the company can develop several distinct drug candidates, each with their own clinical and commercial relevance.

#### **INVESTMENT OPPORTUNITIES**

Noxopharm is seeking to identify potential investors and partners who have an interest in biotech and are prepared to make long-term investments in the company.

This could include focusing on one area of the portfolio, or general support for the company and its multi-platform strategy.

# **PolyActiva**



#### **CONTACT DETAILS:**

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Vanessa Waddell

Position:

Interim CEO

Company:

PolyActiva Pty Ltd

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**PolyActiva** 

Email:

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#### **COMPANY DESCRIPTION:**

PolyActiva is a venture capital funded clinical-stage ophthalmology company with the mission is to become a leader in ophthalmic sustained drug delivery to improve patient outcomes and quality of life.

Based in Melbourne, PolyActiva is developing a unique proprietary polymeric prodrug technology that provides precise and controlled drug delivery to the eye. PolyActiva's products are designed to replace topical eye drop therapy for a range of ocular diseases. The lead clinical candidate is a latanoprost ocular implant to treat open angle glaucoma and is being evaluated in a phase IIa clinical study here in Australia and in New Zealand to demonstrate safety and efficacy and ability to provide chronic therapy. We are preparing for US studies in 2024 with our pivotal registration trial to commence in 2025.

Our platform is broadly applicable to the delivery of a variety of small drug molecules to the eye and our pipeline includes antibiotic and steroid implants.

#### **PIPELINE AND DEVELOPMENTS**

PolyActiva's lead candidate (PA5108 - latanoprost ocular implant) for glaucoma is being evaluated in a phase 2a clinical trial. PolyActiva closed recruitment for this study in August 2023. A total of 37 participants have been recruited and 22 have exited the study. Positive results from the low dose cohort were reported in 2022 and data on the repeat dose cohort (subjects who have received two implants, 21 weeks apart) is being reported in October/November 2023.

PolyActiva has early clinical data of a second generation latanoprost ocular implant indicating the potential to provide 12 months therapy from a single implant.

PolyActiva has also demonstrated safety of its antibiotic implant for post-surgical care in a phase I IND study in 2022.

PolyActiva has a steroid implant in early-stage development, the implant is being developed as a treatment for aged macular degeneration.

#### **KEY INVESTMENT HIGHLIGHTS**

Feb 2022 - PolyActiva opens additional cohort to Phase 2a clinical trial of PA5108 (Latanoprost Ocular Implant), repeat dosing participants at 21 weeks to show that chronic use is safe.

April 2022 - PolyActiva reports successful phase I trial results for the levofloxacin antibiotic implant designed to prevent infection after ocular surgery.

May 2022 - PolyActiva presents data from first two dose cohorts of its Phase 2a clinical trial of PA5108 (Latanoprost Ocular Implant) as US Ophthalmology meetings.

August 2023 - PolyActiva closes recruitment of repeat dose cohort and Phase 2 a study.

November 2023 - PolyActiva reports interim data on repeat dose cohort demonstrating safety with administration of the second ocular implant.

#### **INVESTMENT OPPORTUNITIES**

PolyActiva is Australian based and locally funded. PolyActiva has been funded by Venture Capital since 2012, raising a total of A\$44m. The lead investors are Brandon Capital and Yuuwa Capital. Funding raised to date has supported the development of the technology, identification of a clinical candidates, preclinical animal testing, CMC and the conduct of three clinical trials in Australia (2 for the latanoprost implant and one for the antibiotic implant).

The company is seeking a further A\$30m to support its plans for a US based IND clinical trial with a Phase 2b trial planned in 2024. This study will be a dose confirmation study in 30 subjects. This will be followed by a Pivotal Phase 3 trial to start in 2025.

# **Prescient Therapuetics**



#### **CONTACT DETAILS:**

Name:

Steven Yatomi-Clarke

Position:

Chief Executive Officer & Managing Director

Company:

**Prescient Therapeutics** 

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ptxtherapeutics.com

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steven@ptxtherapeutics.com

#### **COMPANY DESCRIPTION:**

Prescient Therapeutics is a clinical stage oncology company developing personalised medicine approaches to cancer, including targeted and cellular therapies.

#### **Targeted Therapies**

PTX-100 is a first in class compound with the ability to block an important cancer growth enzyme known as geranylgeranyl transferase-1 (GGT-1). It disrupts oncogenic Ras pathways by inhibiting the activation of Rho, Rac and Ral circuits in cancer cells, leading to apoptosis (death) of cancer cells. PTX- 100 is believed to be the only GGT-1 inhibitor in the world in clinical development. PTX-100 demonstrated safety and early clinical activity in a previous Phase 1 study and recent PK/PD basket study of hematological and solid malignancies. PTX-100 is now in a Phase 1b expansion cohort study in T cell lymphomas, where it is showing encouraging efficacy and safety. The US FDA has granted PTX-100 Orphan Drug Designation for all T cell lymphomas.

PTX-200 is a novel PH domain inhibitor that inhibits an important tumour survival pathway known as Akt via a novel mechanism of action. This promising compound is currently in a Phase 1b/2 trial in relapsed and refractory AML, where it has resulted in 4 complete remissions so far. PTX-200 previously generated encouraging Phase 2a data in HER2-negative breast cancer and Phase 1b in recurrent or persistent platinum resistant ovarian cancer.

#### **Cell Therapy Platform Technologies**

**CellPryme-M:** Prescient's novel, ready-for-the-clinic, CellPryme-M technology enhances adoptive cell therapy performance by shifting T and NK cells towards a central memory phenotype, improving persistence, and increasing the ability to find and penetrate tumours. CellPryme-M is a 24-hour, non-disruptive process during cell manufacturing. Cell therapies that could benefit from additional productivity in manufacturing or increased potency and durability in-vivo, would be good candidates for CellPryme-M.

**CellPryme-A:** CellPryme-A is an adjuvant therapy designed to be administered to patients alongside cellular immunotherapy to help them overcome a suppressive tumour microenvironment. CellPryme-A significantly decreases suppressive regulatory T cells; increases expansion of CAR-T cells in vivo; increases tumour penetration of CAR-T cells. CellPryme-A improves tumour killing and host survival of CAR-T cell therapies, and these benefits are even greater when used in conjunction with CellPryme-M pre-treated CAR-T cells.

OmniCAR: is a universal immune receptor platform enabling controllable T-cell activity and multi- antigen targeting with a single cell product. OmniCAR's modular CAR system decouples antigen recognition from the T-cell signalling domain. It is the first universal immune receptor allowing post- translational covalent loading of binders to T-cells. OmniCAR is based on technology licensed from Penn; the SpyTag/SpyCatcher binding system licensed from Oxford University; and other assets.

The targeting ligand can be administered separately to CAR-T cells, creating on-demand T-cell activity post infusion and enables the CAR-T to be directed to an array of different tumour antigens. OmniCAR provides a method for single-vector, single cell product targeting of multiple antigens simultaneous or sequentially, whilst allowing continual re-arming to generate, regulate and diversify a sustained T-cell response over time.

#### **KEY INVESTMENT HIGHLIGHTS**

- Diversified pipeline of clinical stage and emerging assets with multiple shots on goal
- Well funded, with >\$20m cash to deliver value-creating milestones
- Assets from world leading institutes including Yale, Penn and Oxford
- PTX-100 showing potential in an area of unment need, T cell lymphoma, with the potential to leap into a Phase 2 registration study.
- Exhibiting excellent safety, as well as efficacy signals exceeding that expected from stand of care treatments
- Granted Orphan Drug Designation by US FDA
- Two cell therapy platform technologies that can enhance third party approaches to make cell therapies more efficacious

# Respiri





#### **CONTACT DETAILS:**

Name:
Brian Leedman, BEc, MBA (UWA)
Position:
Director

Company: Respiri Limited Address: Level 9, 432 St Kilda Road Melbourne VIC 3004 Website: respiri.co/au

#### **COMPANY DESCRIPTION:**

Respiri Limited (ASX:RSH, OTCQB:RSHUF) is a pioneering presence in the Remote Patient Monitoring (RPM) and MedTech sector. The company uses its innovative respiratory technology with a disruptive business model as an RPM provider to offer the only RPM program for respiratory disorders. As a differentiated RPM provider, Respiri's mission is to improve health outcomes for patients with chronic diseases from cardiovascular, diabetes, obesity and, exclusively, respiratory disease. Respiri's globally unique medical device and its Remote Patient Monitoring services empower healthcare organisations to take action from patient data when needed, not only when scheduled. Respiri is strategically positioned to revolutionise chronic disease management globally and is focused on the US market, where RPM services are reimbursed by Current Procedural Terminology (CPT) Code reimbursement. Respiri Limited is headquartered in Melbourne with offices in New York City and Miami.

#### **PIPELINE AND DEVELOPMENTS**

This year has seen Respiri accelerate from US market entry to revenue generating in under 12 months. The Company is building on a solid foundation of strategic 'Firsts'. Respiri is the first and only known Australian company to:

- gain FDA clearance for its unique WheezeRate Detector, Class II medical device - wheezo®
- successfully reimbursed for RPM by Centers of Medicare and Medicaid (CMS) in the USA
- deliver end-to-end RPM services to US health providers through newly acquired Access Managed Services LLC (Access Telehealth)

The recent acquisition of Access Telehealth, which operates as a subsidiary, is focussed on reshaping chronic care management in the US through best in class, reimbursed RPM solutions and advances remote care delivery by improving patient engagement and program efficiency and effectiveness.

A wearable prototype in development can provide multiple physiological parameters that has significant potential to reduce the burden on the US Health system.

#### **KEYINVESTMENT HIGHLIGHTS**

The Access Telehealth acquisition provides Respiri control of an established and scalable end-to-end RPM offering providing clinical solutions across all major disease states including Respiratory, Cardiovascular, Diabetes and Obesity. These are critical competencies that Healthcare Organisations want and need; with approximately 80% of Americans ≥ 55 years living with one or more chronic conditions and 60% living with at least two chronic conditions. Access also significantly increases monthly recurring patient revenues for Respiri from US\$10-\$20 to US\$70-\$100, reducing the projected monthly breakeven number of patients from 30,000 to 9,000 forecasted to be achieved in CY2024. With an addressable US market now more than three times larger than the original respiratory market (approximately 150 million patients) and a significant, advanced sales pipeline, Respiri is well placed to meet this target. With a growing established customer base and pipeline of opportunities, there is currently a contracted potential reach of 20,000+ patient lives.

#### **INVESTMENT OPPORTUNITIES**

The company is seeking strategic investors wanting exposure to the US healthcare market with an innovative, disruptive FDA approved technology that will significantly improve cost-savings to US healthcare providers. The acquisition of Access Telehealth further improves the Respiri offering by increasing monthly recurring patient revenues and bringing forward projected break-even revenues to CY 2024.

## **Snoretox**





#### **CONTACT DETAILS:**

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A/Prof Anthony Sasse

Position:

Founder & Managing Director

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Snoretox Ltd

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tony@snoretox.com

#### **COMPANY DESCRIPTION:**

"If it's a weak muscle, we can tone it up" | Winner MRFF Frontier Round 1

At RMIT University Australia, Snoretox have developed novel tetanus toxin based biotherapeutics for the treatment of muscle weakness conditions by the controlled increase of local muscle tone in target muscles, unlocking the immense therapeutic, cosmetic and veterinary potential of the tetanus toxin, through by-passing the vaccination induced antibodies.

Demonstrated to be highly effective in Bulldog BOAS Syndrome and will assist millions of BOAS afflicted dogs. Snoretox holds FDA Breakthrough Status for this indication. Around 3 years to market.

Other treatable conditions include:

- Snoring, Obstructive Sleep Apnoea
- · Ectropion and other floppy eyelid conditions
- · Cosmetic indications: chin lift, face lift
- · Anal incontinence, oesophageal reflux, pelvic floor weakness
- Neurological muscle disorders such as MS, MND and Myopathy (symptom relief, not a cure)
- · Muscle Rehabilitation and Injury recovery
- · Other Veterinarian indications includes pet incontinences

#### **PIPELINE AND DEVELOPMENTS**

For Bulldogs and other BOAS breeds: we have completed proof of concept trials with excellent results even in severe BOAS cases, videos available.

Completed Drug detection Assay, commencing PK study.

Completed manufacturing protocol.

Next in 2024 is commencing 100 Bulldog Field Study and 32 beagle MOS study for FDA CVM Approval.

For humans, next is safety studies in mice and pigs, then First-in-Human trials.

#### **KEYINVESTMENT HIGHLIGHTS**

Short time to market (3 years) for BOAS Syndrome and subsequent pet incontinence.

\$50 Million PIPE deal passed Due Diligence, now under final contract negotiation with GEM Capital New York USA. Funds accessible on floating.

Convertible Note Offer from Bridgewest Ventures San Diego USA to cover manufacturing at BioCina, Adelaide.

#### **INVESTMENT OPPORTUNITIES**

Asking \$7.5 Million for 15% equity.

This will complete the FDA Veterinarian Approval and enable cash flow from sales, as well as enable Phase 1 studies in humans in conditions such as Sleep Apnoea, ectropion and MND.

# **Tessara Therapeutics**





#### **CONTACT DETAILS:**

Dr Christos Papadimitriou

Position:

Chief Executive Officer & Managing Director

Company:

Tessara Therapeutics Pty Ltd

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#### **COMPANY DESCRIPTION:**

Tessara Therapeutics is a privately held, Melbourne-based biotechnology company that has developed the RealBrain® technology, a disruptive drug screening platform featuring human brain micro-tissues made from human neural stem cells. RealBrain® micro-tissues provide a more accurate representation of human neurophysiology, and therefore have the potential to outperform traditional animal models. Available through technology licensing to pharmaceutical companies and contract research organisations, RealBrain® technology enables drug developers competing in the multi-billion-dollar neurology market to identify drug candidates more likely to advance in clinical trials for the treatment of diseases such as Alzheimer's, Parkinson's, epilepsy, and many others.

#### **PIPELINE AND DEVELOPMENTS**

Tessara's RealBrain® drug screening platform offers a highfidelity, scalable solution for pharmaceutical research. Based on human brain micro-tissues, a.k.a "mini-brains" with functioning neural networks, our platform provides advanced modelling of human brain physiology in a range of normal and disease conditions. Automation, developed in partnership with leading robotics companies, enables consistent, rapid and reproducible manufacturing of micro-tissues. Furthermore, AI algorithms transform images of elaborate neural networks into digital 3D maps for automatic extraction of unprecedented insights about neurophysiology. Precise quantification of structural, cellular and molecular changes allows accurate assessment of drug effects on various cell populations and the dynamics of neural connectivity (neuroplasticity). Unique in its capability for high-throughput, highcontent analysis, the RealBrain platform combines sophisticated biology with user-friendly handling, accelerating drug discovery and early prediction of safe and effective treatments.

#### Game-changing product pipeline:

- Alzheimer's Disease (ADBrain™ model)
- Brain cancer / Glioblastoma (GBMBrain™ model)
- Mature, "healthy" brain (ArtiBrain™ model)

#### **KEY INVESTMENT HIGHLIGHTS**

- Revenue Growth: In Q2, 2023 Tessara achieved first revenues, having executed commercial contracts with prominent AU drug developers and a US-based, NASDAQ-listed pharmaceutical company.
- Global Market Penetration: Tessara recently signed our first licencing agreement with a US-based, neuro-specific Contract Research Organisation (CRO) in the midst of the increasing global commercial traction. Tessara is also in discussions around

licensing the RealBrain platform to other neurology-focused CROs across India, US, and Europe.

- 3. Validated Revenue Potential: The growing demand for the RealBrain® platform and executed commercial contracts validate our pricing strategy and revenue forecasts.
- 4. Significant market opportunity: After the passing of the FDA Modernization Act 2.0, human-relevant tissue models are of great interest to drug developers, driving a large and rapidly expanding global market. We are the first to deliver a scalable and predictive human brain model suitable for the pharmaceutical industry and we have a pipeline of more than 20 customers, highlighting our potential to become the gold standard in neuroscience drug discovery and development, with an addressable market estimated to exceed US\$ 2 billion.

#### Scalable business model:

- · License platform to CROs and pharmaceutical companies
- · Ongoing supply of biomaterials and cells
- · Pipeline of new CNS disease models
- · Drug discovery partnerships

#### Drug screening market opportunity:

- · Revenue generating, NASDAQ sales
- Minimum addressable market > US\$2b
- On track to be cash flow positive by 2026, projected > \$80 million p.a in ~5 years

#### **INVESTMENT OPPORTUNITIES**

Aiming to capitalise on significant market pull and accelerate our growth in revenue, Tessara is well positioned to raise additional capital to expand the capacity of our commercial operations and maximise the accessibility to our platform through a global network of CRO distributors.

Tessara is raising \$5 million to roll out the RealBrain platform globally.

We present a unique opportunity for investors seeking the right team, with the right technology, at the right time for success in the market. Our investors are also critical backers of our steadfast mission to break technological barriers for development of effective drugs to treat debilitating neurological diseases such as Alzheimer's.

## TruScreen



#### **CONTACT DETAILS:**

Name: Dr Beata Edling Position:

Chief Executive Officer

Company:

TruScreen Limited



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#### **COMPANY DESCRIPTION:**

TruScreen Group Ltd is an ASX and NZX dual listed manufacturer of class IIA medical device for primary cervical cancer screening. TruScreen technology is an Al-enabled device and consumable (Single Use Sensor, SUS) for detecting abnormalities in the cervical tissue in real-time via measurements of the low level of optical and electrical stimuli, without the need for collection of cervical tissue.

#### What problem are we solving?

TruScreen's cervical screening technology enables fast, painless and operator independent cervical screening. The technology does not need tissue or cell sampling and processing, and avoids failed samples, missed follow-up, and the need for costly, specialised personnel and supporting laboratory infrastructure. The results are available immediately. TruScreen's vision is "A world without the cervical cancer"©.

#### What have we achieved so far?

The TruScreen device, TruScreen Ultra®, is registered as a primary screening device for cervical cancer screening.

The device is CE Marked/EU certified, ISO 13485 compliant and is registered for clinical use with the TGA (Australia), MHRA (UK), NMPA (China), SFDA (Saudi Arabia), Roszdravnadzor (Russia), and COFEPRIS (Mexico). It has Ministry of Health approval for use in Vietnam, Israel, Ukraine, and the Philippines, among others and has distributors in over 20 countries. In 2021, TruScreen established a manufacturing facility in China for devices marketed and sold

In July 2023, TruScreen technology has been recognised and included in CSCCP's (Chinese Society for Colposcopy and Cervical Pathology) China Cervical Cancer Screening Management Guideline.

TruScreen is also recognised in a China Blue Paper "Cervical Cancer Three Stage Standardized Prevent and Treatment" published on 28 April 2023.

In financial year to 31 March 2023 alone, over 140000\* examinations have been performed with TruScreen device. To date, over 200 devices have been installed and used in China, Vietnam, Mexico, Zimbabwe, Russia, and Saudi Arabia.

The current financial year Q1 results showed fast post-Covid recovery with sales of devices soaring 100% over the same quarter year on year and a 73% growth in sales of Single Use Sensor (SUS) for the same period.

\*Based on Single Use Sensor sales.

#### **PIPELINE AND DEVELOPMENTS**

The recent inclusion of TruScreen technology in the CSCCP national screening guideline for cervical cancer screening and the recognition in the Chinese Blue Paper further opens the Chinese public and private health markets for TruScreen. The addressable market for cervical cancer screening is up to 400 million of women of screening age. With China committed to WHO strategy for the elimination of cervical cancer by the end of the century, the growth opportunity in China is exponential. In addition, TruScreen has been expanding to Africa, Middle East, Central and Easter Europe and Vietnam

TRU completed its first clinical evaluation in the Middle East. Private health services provider Dr. Sulaiman Al-Habib Medical Group (DSAMG) completed a screening of 507 women and analysis of the results showed that TRU's sensitivity was 83.3% and specificity was 95%, compared to 83.3% and 98% for the placebo Liquid Based Cytology (LBC) mechanism. This depicts that it is just as effective while providing real time results and resolving many of the issues faced with potential patient follow-up when using LBC. The clinical evaluation manuscript of the study is in submission for publication in the European Journal of Gynaecology. On the back of these positive results, the distributor in the Middle East has won the commercial tender at the DSAMG and commenced commercial operations.

In Vietnam, TruScreen has replaced liquid-based cytology as the primary screening method in the leading Hanoi OBGYN hospital. Two major hospitals have received the Ministry of Health approvals for use of the TruScreen technology. An additional 4 hospitals are seeking approvals from MoH to adopt TruScreen as the primary screening method. The authorities support the introduction of TruScreen in the region.

In Zimbabwe Masvingo province, the MOH and NAC continue the very successful screening program with over 14,000 women screened to date.

In Mexico, TruScreen's distributor has submitted request for access to public hospital system to Cofepris, the national regulator. If the decision is positive, TruScreen would become available to public hospitals and clinics. The Cofepris decision is expected in FY24.

Turning to Europe, TRU has been listed on the Innovation Register by the Polish Ministry of Health. This will increase awareness among specialists and clinicians in Poland. This country has an 'at risk' population of 17.1m and relatively high cervical cancer rates (3,515 cases and 1,858 deaths annually) due to the lack of a national screening or HPV vaccination program.

#### **PIPELINE AND DEVELOPMENTS**

#### Our short-term goals are:

- Seize the CSCCP national guideline window to grow sales in China
- Successfully expand markets in Zimbabwe, Saudi Arabia, and Vietnam.
- Grow commercial presence in Africa, Middle East, Central and Eastern Europe.
- · Improve the gross margin, reduce COGS.

#### Longer-term goals include:

- further expansion and adoption of technology in the screening cervical cancer guidelines world-wide, including USA, EU
- further development of technology toward diagnostics and treatment
- development of screening technology into other therapeutic areas.

#### **KEY INVESTMENT HIGHLIGHTS**

TruScreen is seeking Growth Capital to enable TruScreen technology to maximise the market opportunities as described above, in China, Vietnam, Saudi Arabia, Mexico and Poland.

Recent Pitt Street Research valuation of TRU at NZ\$0.065 per share base case and NZ\$0.133 per share bull case (Pitt Street Research Report - Truscreen: https://truscreen.com/pitt-street-research-report/)

#### **INVESTMENT OPPORTUNITIES**

TruScreen is currently looking to engage with investors and M&A candidates. The following funding needs have been identified:

Short-term goals: 3-5M AUD in 2023-2024

#### Vaxxas





#### **CONTACT DETAILS:**

Name: David Hoey

Position:

Chief Executive Officer

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#### **COMPANY DESCRIPTION:**

Vaxxas is a privately held biotechnology company focused on transforming vaccination globally by making vaccines more accessible and effective. With its proprietary needle-free vaccine platform technology, the high-density microarray patch (HD-MAP), Vaxxas is rethinking what's possible with vaccines.

The HD-MAP offers an alternative to traditional needle and syringe, and has the potential to improve vaccination by creating vaccine products that are easy to use (potentially enabling self-administration) and stable at room temperature, reducing the complexities and costs associated with refrigerated distribution required for many existing vaccines.

Vaxxas is partnering with leading global health, biomedical, pharmaceutical, industrial, philanthropic, and government organisations to develop its technology, including the World Health Organisation (WHO), the Bill and Melinda Gates Foundation, CEPI (Coalition for Epidemic Preparedness), the US Government, Merck and Harro Höfliger.

In June 2023, with support of the Queensland Government, Vaxxas opened its first manufacturing facility and global headquarters. From this facility, Vaxxas will produce millions of HD-MAPs for late-stage clinical trials and first commercial products.

Vaxxas was founded in 2011 based on research at The University of Queensland (UQ), coupled with an initial round of equity financing led by OneVentures with co-investors Brandon Capital and US-based HealthCare Ventures. Additional financing rounds have been led by OneVentures and UQ.

#### **PIPELINE AND DEVELOPMENTS**

Vaxxas is progressing eight programs including pre-clinical and clinical studies. Its pipeline includes commercial and philanthropic partners and diversity through, out-licensing, in-licensing and partnership opportunities.

- Vaxxas in-licensed COVID-19 vaccine (SARS-CoV2 spike HexaPro), Phase I safety \$3M (CRC-P), PoC results under review
- US Govt BARDA Pandemic Influenza Funded Phase I study \$30M - Project completion late 2025
- Merck & Co. Undisclosed vaccine in pre-clinical development prior to Phase I study \$2.9M (Merck has licensing options on an additional 2 vaccines)
- Partnership with large pharmaceutical company Seasonal Quadrivalent Influenza - Preclinical and Phase I study \$7.2M
- Bill and Melinda Gates Foundation Measles and Rubella Phase I and II studies \$10M
- Wellcome Trust V Typhoid Formulation development \$5.3M

- Internal immuno-oncology vaccine Research program to evaluate HD-MAP to deliver a DNA vaccine for a solid tumour cancer
- CEPI mRNA Preclinical project to demonstrate the stability of mRNA vaccines on a MAP \$6.4M.

#### **KEY INVESTMENT HIGHLIGHTS**

We are part of a large and growing market, forecast to reach \$128B by 2028. We have a vaccine delivery platform that has demonstrated superior immunological performance with reduced dosing and resulting cost benefits. Over 550 patients have been through our clinical trials with an additional 250 expected in the next 12 months. In addition, well over 100 participants have been involved in usability studies. A significant differentiator is our demonstration of both device and aseptic manufacture to deliver 10's of millions of units. We are due to launch the first patch product in three to five years. We have a growing product pipeline and a foundation of over 140 employees and have raised more than \$200M in non-dilutive and equity funding. Since our inception Vaxxas has invested over \$90M directly into the Queensland economy. This is the future of vaccinations.

#### **INVESTMENT OPPORTUNITIES**

We have a growth strategy that includes in-licensing for a Vaxxas product portfolio. We have a strategy that would see Vaxxas supply Governments around the world with a future pandemic solution, we have established partnering with major pharmaceutical companies and have engaged with organizations that can have a revolutionary impact on world health for those who really need it. In order to achieve this Vaxxas will require around \$250M to completely build out the manufacturing facility at Northshore, Brisbane and to conduct the clinical trials required to get the first commercial product to market.

# **Notes**

# **Notes**





Tuesday 29 Oct 2024

Melbourne, Australia

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