



**Pioneering the
development of novel
immunotherapies for
patients with blood
cancers and B-cell
disorders**

HaemaLogix

Newsletter February 2024

CEO Update



I am pleased to share this latest update on all the exciting news and achievements from the team at HaemaLogiX.

It's been a very productive period since I stepped into the CEO role in November.

We have leveraged several opportunities to expand HaemaLogiX's reach by meeting with industry leaders at Australian and international conferences, including those held recently by the American Society of Hematology (ASH) and JP Morgan, both in the US. I was also pleased to meet with key representatives from Myeloma Australia and Rare Cancers Australia; the opportunity to discuss the current landscape with leading advocacy groups not only brings invaluable insight to HaemaLogiX's work but also forges stronger relationships with Key Opinion Leaders.

With the company's keen focus on commercialisation, it continues to be a priority to present HaemaLogiX to both the medical and science communities, as well as current and prospective investors. It is evident that there is great interest in HaemaLogiX's portfolio by the calibre of events the company is invited to speak at or attend. These include the recently held [International Myeloma Society's Annual Meeting](#) in Athens, and [Cell and Gene Therapy World](#) in Singapore at which Dr Rosanne Dunn (CSO) was invited to present the KMA.CAR-T data. It also includes the upcoming [Australia Biologics Festival](#), of which HaemaLogiX CMDO Tertia Dex was invited to present as a keynote speaker.

We'll continue the momentum we've gained in recent months by ensuring strong representation of HaemaLogiX at key events throughout 2024.

Upcoming roadshow

Key milestones planned for Q1 and Q2 reflect the company's commercialisation focus; following a shareholder meeting on 6 February, we'll kick off a nation-wide roadshow to support a private placement led by MST Financial Capital Markets. The placement will fund a pivotal phase 2b for our lead asset KappaMab and a proof-of-concept Phase 1 trial in AL amyloidosis, which we anticipate will expedite commercialisation opportunity.

The placement will open preferentially to HaemaLogiX's current shareholders and concurrently to MST associated investors and a small group of professional investors introduced by the company.

Company transformation continues: New leadership appointments

HaemaLogiX appointed Non-Executive Director Dr. John Cullity as Chairman effective 4 January. Dr. Cullity has been on the HaemaLogiX board since 2014 as a founding shareholder and brings 20+ years of industry and commercial markets experience. Outgoing Chairman Bryce Carmine remains active in the company in his role of Non-Executive Director.

I would personally like to thank Bryce for his many years of service to the company and welcome his continued support and experience moving forward as he continues on with us as a Non-Executive Director.

I'm also pleased to announce that Dr. Laurence Turka has joined the HaemaLogiX board as a Non-Executive Director. Dr Turka is renowned in the field of immunology, having led a number of notable discoveries and breakthroughs.

I'm also pleased to announce that Professor Angela Dispenzieri has

joined the HaemaLogiX Scientific Advisory Board. Dr Dispenzieri is a Professor of Medicine and of Laboratory Medicine at the Mayo Clinic with extensive experience in the blood cancers that HaemaLogiX is currently focused on treating.

We are delighted for the opportunity to work with Dr. Turka and Dr. Dispenzieri.

Increasing our US presence

From constructive conversations over the last month, the board is completing a deep exploration into how it might most pragmatically increase the company's US presence. We consider that greater presence in the US could enhance our commercial position, which could in turn lead to a faster development process, and increased global advocacy across both our clinical program and investment options.

We see this as leveraging the best of both worlds for deeper technical and clinical expertise, an improved global regulatory position and greater access to open-ended financing, which will all return significant value for our Shareholders.

KMA.CAR-T Phase I collaboration agreement

Our collaboration agreement with the Peter MacCallum Cancer Centre (Peter Mac) to conduct the first in-human Phase I trial of KMA.CAR-T is progressing steadily.

The agreement, entered into in July, sees HaemaLogiX and Peter Mac continue to co-develop KMA.CAR-T following a collaborative preclinical research project that demonstrated compelling proof of concept.

The CAR-T cell GMP manufacturing and processing optimisation has been initiated to support TGA regulatory applications, and the development of a clinical trial protocol is now underway.

Thank you for your continued support of HaemaLogiX.

Kind regards,

Damian Clarke-Bruce
Managing Director and
Chief Executive Officer



Q&A with HaemaLogiX Chairman Dr John Cullity

HaemaLogiX has welcomed Non-Executive Director Dr. John Cullity to the position of Chairman.

Dr Cullity is also Managing Director at BioSynergy Partners (a New York based advisory spun out of Torrey). He brings to the role more than 20 years' industry and commercial experience, including positions held with Sanofi Pharmaceuticals, The World Bank and the World Health Organization.

What appealed to you about HaemaLogiX when you became a founding shareholder in 2014?

Having been exposed to the scientific story as an investment banker, I didn't hesitate when the opportunity came to secure the underlying IP and so form HaemaLogiX. This technology has the capacity to transform myeloma and amyloidosis therapeutics. The promise of HaemaLogiX was entirely compelling then but is all the more apparent now.

What are you most excited about for your new role as Chair?

We're coming into a dynamic phase at HaemaLogiX. I'm driven by transactions, and our capacity to maximize those on behalf of investors. I look forward to combining my financial credentials with the operational expertise that exists within our Company. Plainly, our core objective is to return outsized value to investors.

What motto or philosophy guides your decisions and ways of working?

Two principles underlie everything that I do. "Good ethics and good business go hand in hand" and "The world belongs to finishers." In short, we will run a focused commercial enterprise with combined intensity and integrity.



Professor Angela Dispenzieri joins our Scientific Advisory Board

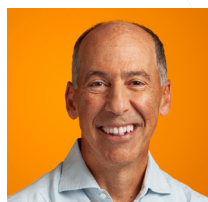
Prof. Dispenzieri is currently Professor of Medicine and of Laboratory Medicine at the Mayo Clinic in Rochester.

Prof. Dispenzieri earned her B.S. in biology at the Massachusetts Institute of Technology and her M.D. at Albert Einstein College of Medicine. She subsequently completed a residency and a fellowship in Hematology and Oncology at Mayo Clinic. Prof. Dispenzieri joined the staff of Mayo Clinic in 1998 and served as Chair of Hematology Research from 2014 to 2022. She currently chairs the Mayo Clinic Amyloid Interest Group. She has been an author or co-author on over six hundred manuscripts and book chapters in the field

of plasma cell disorders, including multiple myeloma, immunoglobulin light chain amyloidosis, POEMS syndrome, Castleman Disease, and mass spectrometry techniques.

"As an expert in the treatment of patients with AL amyloidosis, multiple myeloma and POEMS syndrome, we look forward to working closely with Professor Angela Dispenzieri on the clinical development of our immunotherapies for these diseases."

– Dr Rosanne Dunn, HaemaLogiX Director and Chief Scientific Officer



Q&A with Dr. Laurence Turka who joins our board as Non-Executive Director.

Dr. Turka was Co-Director of the Center for Transplantation Sciences at Massachusetts General Hospital where he led a number of notable discoveries including novel approaches to transplantation tolerance, the role of Toll-like receptors in T-cells, and pathways required for the maintenance of regulatory T-cell function.

What piqued your interest in HaemaLogiX?

As a physician, I was well aware of the devastating toll that multiple myeloma takes on patients.

Additionally, a close professional colleague and friend of mine died of myeloma a few years ago. The novel, and potentially transformative approach, that HaemaLogiX is taking has the potential to be a

game-changer and I am excited to be part of it.

What of your experience in biotech are you most excited about bringing to HaemaLogiX?

Helping to build early stage biotech companies is incredibly rewarding. There is nothing like the challenge and thrill that accompanies the potential for a new approach to cure disease. I am very excited about helping HaemaLogiX, and their terrific management team, to develop the company and realize the full potential of the pipeline.

How do you like to spend your leisure time?

I have a lot of hobbies, probably too many (!), but top of the list are sailing, hiking, and reading.

KMA.CAR-T: Collaboration with Peter Mac for Phase I Clinical Trial

KMA.CAR-T will be subject to its first in-human trial later this year under a co-development agreement between HaemaLogiX and the world-leading Peter MacCallum Cancer Centre (Peter Mac).

The Phase I proof of concept trial will be conducted initially in six patients, with the possibility of expanding to twelve patients.

Progress on KMA.CAR-T Phase I Clinical Trial



Clinical trial recruitment and trial start, targeting late 2024 pending TGA approval



Ethics submission and approval



TGA regulatory submission and approval



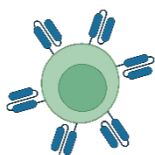
Clinical trial protocol is underway



CAR-T cell GMP manufacturing and processing optimisation initiated to support TGA regulatory applications



Collaboration agreement signed and joint steering committee kick-off meeting completed



KMA.CAR-T is a novel immunotherapy that targets a receptor called Kappa Myeloma Antigen (KMA) found only on the surface of myeloma cells in kappa-type multiple myeloma patients and not on normal immune cells, which means normal immune cells are not damaged by the treatment.

Preclinical data shows the anti-KMA CAR-T cells selectively killed KMA-expressing myeloma cell lines and demonstrated potent anti-myeloma activity in a mouse model.

Under the collaboration, HaemaLogiX provides its patented KappaMab technology, while Peter Mac will develop the technology, method of manufacturing and conduct the trial.

Professor Simon Harrison, Director of the Peter Mac Centre of Excellence in Cellular Immunotherapy, said: "CAR-T cell therapy is a game-changer in the treatment of certain blood cancers, such as multiple myeloma. We are delighted to continue our project with HaemaLogiX to translate the preclinical potential of KMA.CAR-T into a novel first-in-human clinical trial therapy."



Explore Peter Mac's new industry-leading GMP facility, where KMA.CAR-T is being manufactured.

"CAR-T cell therapy is now a realistic option for myeloma patients who have failed standard of care treatments. We're excited to progress KMA.CAR-T to the clinic in collaboration with Peter Mac, a renowned Australian cancer hospital and research institute that has been involved in the development of many of the CAR-T therapies now approved as treatments."

– Dr Rosanne Dunn,
HaemaLogiX Director
and Chief Scientific
Officer

Israeli and South Korean patents issued for KMA. CAR-T

HaemaLogiX's patent "Kappa Myeloma Antigen Chimeric Receptors and Uses Thereof" was granted in Israel on 2 August 2023 and South Korea on 16 January 2024.

The patent covers compositions and methods for treating KMA-expressing malignancies, including chimeric antigen receptors (CARs) and T cells containing CARs (CAR-T cells). The patent also covers methods and compositions comprising CAR-T cells co-expressing other anti-tumoral agents including cytokines and antibodies.

This patent has also been granted in Australia, USA, China, Russia and Japan and is under review in other jurisdictions.

Key Opinion Leaders

Share their views on the HaemaLogiX portfolio



Professor Andrew Spencer sits on the HaemaLogiX Scientific Advisory Board.

Professor Spencer is Head of the Malignant Haematology and Stem Cell Transplantation Service at The Alfred Hospital, Professor of Haematology at Monash University and Head of the Myeloma Research Group and Co-Director of the ACRF Blood Cancer Therapeutics Centre at the Australian Centre for Blood Diseases, all in Australia.

On the clinical relevance of our targets:

"I've reflected upon the fact that there's a lot of activity in the immunotherapy space in myeloma, but there's a very limited range of targets. The holy grail is to find myeloma specific targets for immune therapies. Unlike any of the other targets in myeloma being evaluated at the moment, KMA and LMA are really very, very tumour specific. That to me provides a very intriguing option therapeutically because the on-target effects are going to be on-target on tumour, and not on-target on other tissues."

On HaemaLogiX broadening its portfolio to CAR-T and bispecifics:

"The biological variation [of multiple myeloma] is immense, and to suspect that just one particular strategy will mitigate against that is somewhat naive.... combinatorial therapy with antibodies maybe a strategy in those older frailer patients, whereas the more aggressive bispecific / CAR-T strategies in the younger patients may be the way to go."



"The patients benefit hugely from this technology and it's transforming people's lives in front of our eyes."

Professor Simon Harrison is Director of The Centre Of Excellence for Cellular Immunotherapy at the Peter MacCallum Cancer Centre, the Director of Clinical Apheresis at the Royal Melbourne Hospital, and a leading myeloma doctor and a clinical scientist in the Sir Peter MacCallum Department of Oncology at Melbourne University.

Prof. Harrison said his interest in HaemaLogiX was piqued when his patient had an exceptional response to a single dose of KappaMab.

"The HaemaLogiX platform is a relatively unique offering to pharma because it allows the products to target the malignant population very specifically and leave alone the normal immune cells that are there to protect us from infection," he said. "And because you've covered both Kappa and Lambda, you've covered the whole of the myeloma and amyloid field to allow that balance to occur."

CAR-T therapy, he said, has "changed the field of cancer therapy".



Mark Henderson, CEO of Myeloma Australia

"Innovation - and bringing innovation to market quickly - is really important. The truth be told in the Australian context, our treatment protocols in some parts are lagging [behind] some of our international counterparts. The innovation and the technologies just haven't landed yet on our shores. So we are really keen for more organisations to put their hat in the ring to test their products with our patient community and to bring about what is again, our reason for being. And that's a cure for myeloma."

Clinical relevance of our data reinforced by **strong interest at international conferences**



HaemaLogiX's Chief Manufacturing and Development Officer, Tertia Dex, to speak at the 2nd Annual Australia Biologics Festival 2024

The [festival](#), held February 20-21, 2024 in Melbourne, recognises Australia and New Zealand as biopharma powerhouses, giving the region's thought leaders a platform to showcase current trends, opportunities and challenges. As a keynote speaker, Tertia will speak on 'Ensuring cGMP Compliance in a Global Supply Chain'.

"Having over 20 years' experience with international CDMO's, I have overseen the production of biologics in all major regions, including the North Americas, Europe, UK, China and the wider APAC

region," Tertia said, [in an interview with the festival's organisers](#). "As manufacturing choice becomes more complicated, it is difficult to decide who to partner with to ensure your precious product is in the right hands. In my presentation, I will share some of the key focus areas for CDMO selection, insights for when to manufacture overseas and how to ensure regulatory compliance when you choose a global supply chain."



International Myeloma Society, Athens
Presented by Professor Simon Harrison

HaemaLogiX had two abstracts accepted for poster presentation at the annual [International Myeloma Society Meeting and Exposition](#), held in Athens on 27-30 September.

Prof. Simon Harrison, Director of the Centre of Excellence in Cellular Immunotherapy at the Peter MacCallum Cancer Centre, presented the poster '[A Novel CAR-T cell therapy targeting kappa myeloma antigen for the treatment of multiple myeloma](#)'.

HaemaLogiX Chief Scientific Officer Dr. Rosanne Dunn presented the abstract '[Novel antigens LMA and KMA are expressed on malignant bone marrow plasma cells from patients at all stages of multiple myeloma and in other plasma cell dyscrasias](#)'.



Cell and Gene Therapy World 2023, Asia
Presented by HaemaLogiX
Chief Scientific Officer Dr Rosanne Dunn

HaemaLogiX Chief Scientific Officer, Dr. Rosanne Dunn, was invited to present at [Cell and Gene Therapy World Asia](#), held on 14-15 September, 2023 in Singapore. Dr. Dunn spoke on the specificity of KMA. CAR-T cells against a novel B cell target called kappa myeloma antigen (KMA), drawing on recent preclinical in vivo studies and clinically proven safety data on our other immunotherapy assets.

MST appointed to secure further investment



HaemaLogiX's therapies have a unique place in a fast-growing and commercially attractive market segment. HaemaLogiX has retained MST Financial Capital Markets to deliver a private placement to finance a pivotal trial of our lead asset, KappaMab, positioning HaemaLogiX to capitalise on this market and expedite commercialisation deals.

The placement led by MST will be used to expand the already compelling KappaMab data package and demonstrate its clinical relevance as an efficacy-boosting adjunct to standard of care.

A Phase II KappaMab dose optimisation study will flow on to a combination trial with pomalidomide and dexamethasone in patients who have relapsed or become refractory to other standard of care treatments.

HaemaLogiX expects the study to show that a higher dose of KappaMab could improve the depth and length of responses while continuing to be safe and well-tolerated, and that KappaMab could improve the efficacy of the standard of care for patients on third line treatment.

The trial is pivotal to demonstrating the commercial potential of KappaMab as a combination therapy with the immunomodulating drugs that form standard of care for all eight lines of treatment for multiple myeloma.

Trial preparatory work is progressing well; KappaMab is being stored at Cryosite in Sydney, the clinical trial protocol has been reviewed by the HaemaLogiX Scientific Advisory Board and is now final, and a Clinical Research Organisation that will monitor the trial has been identified.

Funds will also support KappaMab manufacturing, preparatory work for a clinical trial of KappaMab in AL amyloidosis patients, and to further the development of HaemaLogiX's LMA-targeting assets, particularly an LMA-targeting CAR-T.

HaemaLogiX's KMA.CAR-T, LMA.CAR-T and Bi / Tri Specific programs are funded off balance sheet, offering parallel value enhancements for shareholders.

A compliant Private Placement Memorandum will be made available to all investors from mid-February.

Did you know:

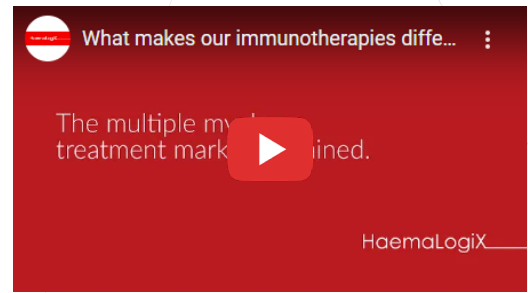
Two patients who participated in our KappaMab Phase 2b clinical study remain continuing to respond after four years?

When compared to outcomes for patients in the control group, the combination of KappaMab with Revlimid and dexamethasone demonstrated both significant efficacy (with an overall response rate of 82.5%) and a significant overall survival advantage (46% reduction in the risk of death). The median Overall Survival was not reached at study closure (June 2021) compared with 27.8 months in matched case control group.

The Phase 2b positive final results were published in the [British Journal of Haematology](#).

These results, along with several other preclinical and clinical findings across our novel targets and 7-strong portfolio of products, show compelling proof of concept, making HaemaLogiX an attractive commercialisation or partnering proposition right now, and discovery phase.

HaemaLogiX's therapies are poised to benefit multiple myeloma patients across all lines of therapy



Watch: What makes our immunotherapies different on the large and growing multiple myeloma treatment market

There is great unmet need for multiple myeloma treatments with improved efficacy, safety and tolerability. HaemaLogiX is developing a suite of immunotherapies with highly specific targets unlike others, giving our treatments a number of potential advantages and providing a novel mechanism of action for combination therapies.

Why we're developing CAR-Ts and bispecifics, as well as monoclonal antibodies to treat multiple myeloma.

While monoclonal antibodies have helped improve the survival rate for multiple myeloma patients since their advent, prognosis remains poor (> 5 years). Chimeric antigen receptor T (CAR-T) cells and bispecific antibodies represent new treatment options for patients, particularly relapsed refractory patients.

The key problem with most current treatments is that they target both cancer cells and normal immune cells, so they diminish the immune system's cancer-fighting ability and have greater potential for unwanted off-target side-effects. They may also leave residual treatment-resistant malignant cells behind. As a result, the response in patients is not long-lasting; Patients have a poor prognosis, repeatedly relapse, and eventually succumb to the disease.

Despite their promise as advanced treatments, CAR-T and bispecifics may present these same limitations depending on their targets.

HaemaLogiX's targets – Kappa Myeloma Antigen (KMA) and Lambda Myeloma Antigen (LMA) - exist only on cancer cells, not on normal plasma cells. Our treatments, including our CAR-Ts and bispecifics, have the potential to improve efficacy without compromising the patient's immune response. Their target-specificity also gives our treatments a good safety profile, which is clinically proven.

Our suite of immunotherapy platforms provides more treatment options for patients at varying stages of life and disease progression

Some modalities are more suitable to patients than others, depending on a patient's frailty, state of health and stage of disease progression. By having a suite of therapeutic

platforms to draw on, we're able to give treating practitioners more options in their artillery.

By 2040, the HaemaLogiX Multiple Myeloma portfolio may reach ~\$11B in worldwide revenue, including \$2.6B in KappaMab alone in the US.

HaemaLogiX commissioned Triangle Insights Group to undertake a primary research-led revenue forecast model for KappaMab in multiple myeloma in 2021. This model has since been updated annually.

The research finds that by 2024, KappaMab will drive around half of the revenue generated by our portfolio, with our CAR-T and bispecific therapies carrying a majority of the remaining share.


About Multiple Myeloma

- The 2nd most common blood cancer
- The average age of patients is 65
- Cyclical disease characterised by remission, relapse, re-treatment before patients inevitably stop responding.
- Poor patient prognosis; current overall five year survival rate of 51%*

* ASCO (via cancer.net May 2020)

The treatment landscape

- 60% of patients first treated progress to later lines of therapy
- 12% of patients discontinue treatment due to adverse effects
- Standard of care is combination therapy regimes including proteasome inhibitors (e.g., Velcade®), immunomodulatory agents (e.g., Revlimid®), corticosteroids, monoclonal antibodies (i.e., Darzalex®)
- Patients can receive up to eight lines of therapy, which are sequenced to extend treatment options and life, before they inevitably become resistant to the disease



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