Aide-Mémoire

Meeting with BioOra

Date due to MO:	10 February 2026	**Date of Meeting**	12 February 2026
Security level:	IN CONFIDENCE	**Reference:**	H2026078233
To:	Hon Simeon Brown, Minister of Health		
Consulted:	Health New Zealand: ☐		
Proactive release:	This **title** is proposed by the Ministry of Health for proactive release: ☒		

Contact for telephone discussion

Name	Position	Telephone
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About the Meeting

Purpose of Meeting	For BioOra, a leading New Zealand biotech company to provide you an udate on its operational and strategic direction to increase wider public access of their CAR-T therapy in 2027.	
Details of Meeting	**Date:**	12 February 2026
	Time:	11.10-11.30am
	Venue:	EW 6.6
Attendees	John Robson, CEO, BioOra Dr. Peter Crabtree, Board Chair, BioOra Sofie Parker, Head of Patient Access, BioOra	
Organisation	BioOra	
Ministry representatives	Not currently attending – officials can attend at your request	

Comment/ Summary:

- BioOra are developing a CAR-T product in collaboration with the Malaghan Institute. The product is currently being evaluated in a Phase 2 clinical trial involving 60 patients in New Zealand.
- The clinical trial will end in late 2026 and following this BioOra will apply to Medsafe for approval to use the product for patients with large B-cell lymphoma. Between 45 and 60 patients a year with this blood cancer could be eligible for treatment.
- Alongside product approval, BioOra will apply to Pharmac for assessment and funding. Delivering CAR-T as standard of care will require significant service investment beyond funding of the product.
- The Cancer Control Agency is working with the cancer sector to develop a national strategy for access of CAR-T treatments in New Zealand. This will be completed by the end of 2026, ahead of funding applications for specific CAR-T products expected in 2027.

Background on CAR-T

1) Chimeric Antigen Receptor T-cell (CAR-T) therapy involves collecting a patient's T-cells, genetically modifying them to target cancer cells, and re-infusing them to treat blood cancers. A one-off treatment can be curative for some patients.

2) CAR-T is recognised as standard of care for several blood cancers in Australia, the UK, the EU and the US. These health systems operate multiple accredited centres, national referral pathways, and public funding mechanisms.

3) CAR-T is one of a broader pipeline of advanced cellular therapies that New Zealand will need to consider for future funding and service delivery. These products extend beyond blood cancers into other cancers and in some cases autoimmune disorders.

Local clinical trial and product development

4) In New Zealand, local access to CAR-T is only available via the phase 2 clinical trial (ENABLE) being led by the Malaghan Institute (with BioOra as a partner). This trial plans to treat a total of 60 patients and will conclude in late 2026.

5) The Malaghan Institute has partnered with BioOra, which leads manufacturing and commercialisation of the New Zealand-developed CAR-T product.

6) Following trial completion, BioOra plans to apply to Medsafe in early 2027 for product approval. They have already engaged with Medsafe regarding this application. In parallel, BioOra will apply to Pharmac for funding, which will be considered as part of Pharmac's standard processes.

7) Patients who are ineligible for the local clinical trial may seek CAR-T treatment overseas. This is typically privately funded and costs between $300,000 and $2.3 million per patient. Some paediatric patients have received funded CAR-T treatment overseas via the High-Cost Treatment Pool.

8) It is likely that there will be approval and funding applications for multiple CAR-T products over time. The BioOra/Malaghan product is unique as it is locally developed in partnership with a registered charity, supported by philanthropic, government and corporate funding.

Funding requirements extend beyond the CAR-T therapy

9) Between 45 and 60 patients annually could be eligible for treatment with the BioOra product when this is commercially available. s 9(2)(b)(ii)

10) BioOra are planning for additional clinical trials for a range of CAR-T products that will treat blood cancers and immune disorders, expanding access to other patient groups over time.

11) Delivering CAR-T as a standard of care will require significant service investment in addition to funding of the medicine. This includes:

a. patient eligibility protocols, including genomic testing to identify those most likely to benefit

b. upgrading existing stem cell transplant centres

c. expanding laboratory and manufacturing capacity

d. training multidisciplinary teams in CAR-T-specific protocols; and,

a) establishing national referral pathways and patient monitoring systems, including robust data management.

12) Funding decisions must therefore address both the medicine and the service investment. Service investment is currently Health New Zealand-led via the Health Technology Evaluation Pathway (HTEP), with Pharmac assessing clinical value, cost-effectiveness and budget impact of medicines through its standard processes.

Compassionate access funding

13) Compassionate access refers to a manufacturer supplying a medicine at no charge before regulatory approval and public funding decisions. This is usually done on an exceptional, case-by-case basis to ensure patients with urgent unmet clinical need can access therapy.

14) In New Zealand, where a company offers compassionate supply, clinicians may request named patient use under existing legal pathways (e.g. Section 29 of the Medicines Act).

15) In the case of CAR-T, if the manufacturer was to supply the medicine at no charge, Health New Zealand would need to consider the associated clinical costs and hospital care (e.g. apheresis, admission, administration and monitoring).

16) s 9(2)(b)(ii) we assess there may be interest in a public/private compassionate funding programme with contributions from both the manufacturer and Government.

17) We are not aware of any previous compassionate access funding arrangements that have involved public funding and there is no dedicated public fund to purchase therapies as part of these agreements.

Development of a CAR-T strategy

18) Given the potential complexity associated with the delivery of personalised medicines such as CAR-T, the Cancer Control Agency, Te Aho o Te Kahu, has established a cross agency Steering Group to develop a national strategy for public access to CAR-T.

19) The strategy will include processes for both New Zealand manufactured and internationally available products.

20) The Steering Group membership includes Health New Zealand leadership, clinicians, Medsafe, Pharmac, and New Zealand Blood Service representatives.

21) The strategy will define a range of operational requirements including stakeholder responsibilities, timeframes for implementation, national referral pathways, centre readiness and data and monitoring requirements.

22) The strategy will incorporate Medsafe and Pharmac timelines for product approval and funding, considering the role of Health NZ through the Health Technology Evaluation Pathway (HTEP). This will ensure that public service delivery planning is fully informed.

23) The strategy will be completed by the end of 2026, ahead of decisions on funding specific CAR-T products.

Likely requests from BioOra

24) While BioOra hasn't tabled a formal 'ask' in the agenda for this meeting, public statements published today (February 10th, 2026 – see Appendix 2) indicate that BioOra may seek:

a) Assurance of a coordinated, timely pathway that aligns with Medsafe approval after the clinical trial alongside Pharmac assessment and service delivery planning from Health NZ to enable public access to their CAR-T therapy in Q1 2027.

b) Active support for service readiness, including Health NZ service upgrades, workforce training and data infrastructure so implementation can proceed as soon as funding is in place.

c) Willingness to explore an interim access model (e.g. compassionate access or public-private arrangements) to avoid a gap between trial completion and potential public funding

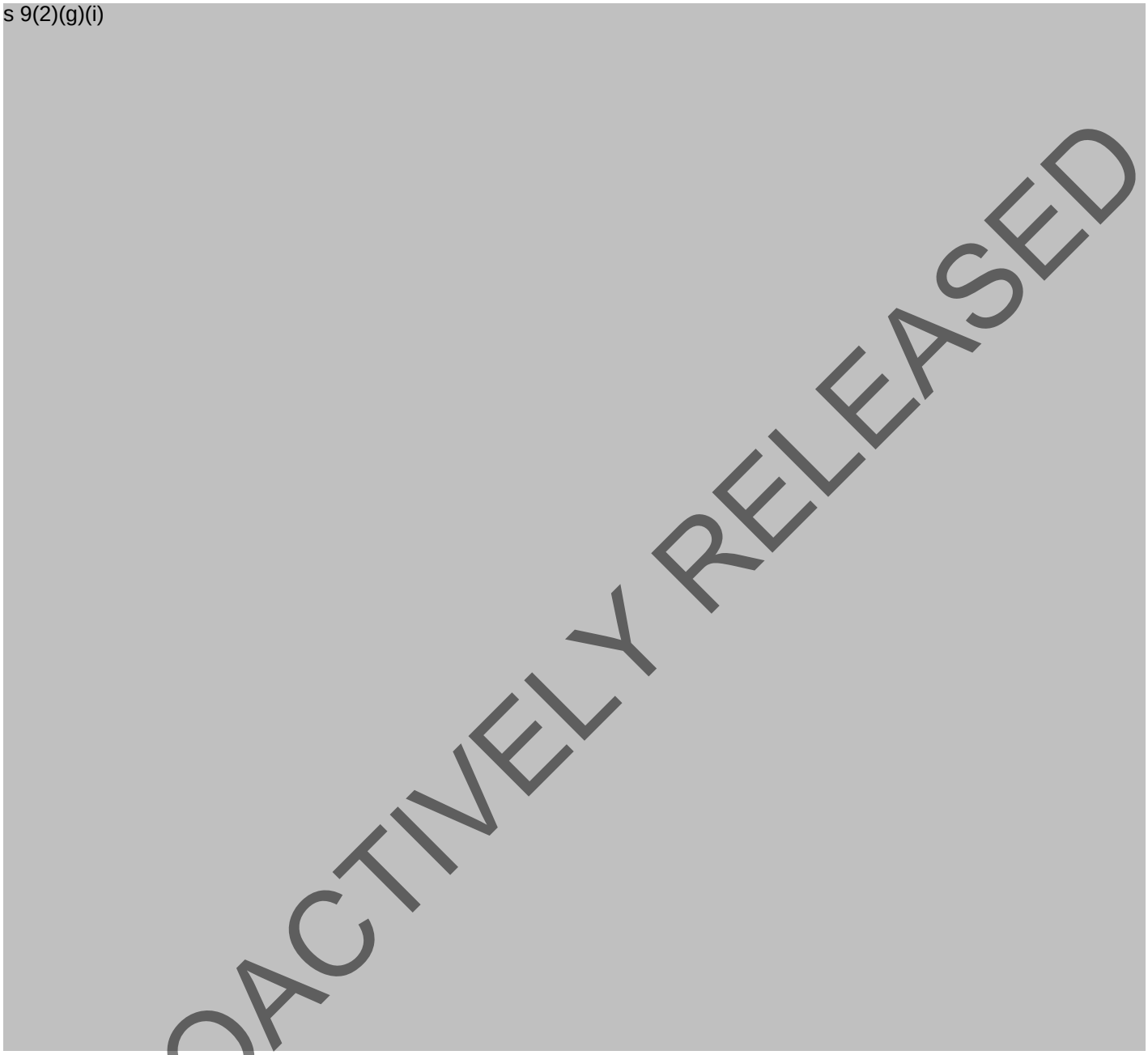
Risks and sensitivities

25) Any endorsement of their requests could create a perception of pre-commitment and pre-judge Medsafe/Pharmac process.

26) There are multiple CAR-T products available internationally and once the CAR-T strategy is developed additional companies may wish to apply for Medsafe approval and Pharmac funding.

27) Beyond the funding of the CAR-T product itself, there are significant non-drug service costs that must be sequenced and funded. This requires consideration by Health NZ and HTEP alongside assessment by Pharmac for funding.

s 9(2)(g)(i)



James Oughton
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Appendix 1: Profiles of attendees

John Robson, CEO, BioOra

John initially oversaw BioOra as the General Manager of Bridgewest Ventures New Zealand before officially joining the team in 2024.

John's background is in the oversight of early-stage tech and life science investments in New Zealand. He has worked closely with founders and management teams to help them operationalise and scale their companies.

In addition, John is a board member for several start-ups including life science companies Avasa, Macso, and Precision Chromatography. As a seasoned finance and investment professional, John has been involved with tech start-ups in New Zealand since 2008. His expertise includes finance, risk & compliance, business strategy, venture capital, and technology strategy.

Dr. Peter Crabtree, Board Chairman, BioOra

Dr. Crabtree is Board Chairman of BioOra and is leading the team's vision for revolutionary cancer immunotherapies through BioOra's automation of CAR T-cell manufacturing.

Dr. Crabtree has extensive expertise in science, business and government and strategic innovation. Throughout his career he has held leadership roles at the New Zealand Ministry of Business, Innovation and Employment. As Head of the New Zealand Space Agency, GM of Science Innovation and International Branch, and Chair of New Zealand Covid-19 Vaccines Taskforce, he has been a pivotal driving force for transformational change.

In addition to Board Chair at BioOra, Dr. Crabtree is Managing Partner at Idé Partners, an innovation strategy consulting firm, and Board Chair at Zenno Astronautics.

Sofie Parker, Head of Patient Access, BioOra

Sofie leads BioOra's patient access initiatives, ensuring that patients can benefit from New Zealand's first homegrown CAR T-cell therapy. With over a decade of experience in corporate R&D and the pharmaceutical sector, Sofie has managed large-scale, international clinical trials, most recently leading CAR-T projects for Johnson & Johnson across Australia and New Zealand. Her expertise spans the entire therapy lifecycle, from early-stage research and manufacturing to clinical delivery and commercialisation. Sofie and her team works across clinical programs and operational pathways to accelerate the delivery of BioOra's transformative cell therapies to patients.

Appendix 2: Excerpt of recent media article

Why public access to a life-changing cancer treatment is 'on a knife edge

By Nicholas Jones (February 10 2026, 4:00am) – Retrieved from Stuff

A revolutionary cancer treatment developed in Wellington has put patients with only months to live into long-term remission, and could be ready for the public system by 2027. In a special series, senior reporter Nicholas Jones reports on the breakthrough, and what hurdles remain. This is part 3 - the Christchurch biotech with grand ambitions.

A game-changing cancer treatment could be available in the New Zealand health system as early as next year, experts say - but only if health officials approve special support.

BioOra Limited, a biotech company partly owned by the Malaghan Institute of Medical Research, is gearing up to quickly manufacture a cancer treatment called CAR T-cell therapy for either public or private healthcare systems, once a trial run by the institute finishes.

That would be a lifeline for desperate patients currently paying big money for treatment in countries like China.

The company - which has grand ambitions to become "the Rocket Lab of immunotherapy" - is building a high-tech manufacturing facility in Christchurch, which will use an automated system to produce the therapy at scale, precisely and free of the risk of contamination.

However, its managing director John Robson is worried the public system will be too slow to act - costing lives and also threatening to stall the fledgling company's momentum.

"We're kind of on this knife edge of, will they go fast enough for us? … quarter 1 of 2027 is a distinct possibility for public access, but it has to dovetail with a funding stream."

If that lags then the treatment could be provided in the private system instead, Robson says, with talks progressing with one interested provider.

What is the treatment?

CAR T-cell therapy involves the collection of a patient's immune cells, which are then genetically modified to recognise and kill their cancer, multiplied and then infused back into the patient's blood.

The therapy has become a standard of care for certain blood cancers overseas, including Australia, but isn't available privately or publicly here

The Malaghan Institute is aiming to change that. It has designed its own CAR T which in a phase 1 clinical trial produced strong results, with just over half of lymphoma patients - who had run out of other treatments and were extremely sick - cleared of cancer within months of treatment.

There were also much lower rates of serious side effects than leading commercial CAR T-cell therapies offered overseas. This means the homespun CAR T will likely be able to be given as an outpatient model - slashing the overall per patient cost.

Phase 2 of the trial aims to enrol its final patient with large B-cell lymphoma around October, with final results available after that for Medsafe approval.

BioOra is a spin-out company that was incubated at the Malaghan, to help take CAR T-cell therapy beyond the trial stage. It is currently making the CAR T for the trials from Wellington, but is raising tens of millions of dollars from private investors to build its new bespoke base in Christchurch.

The final designs and a lease on a St Asaph St building have been signed off, and early building work for the full commercial-grade GMP facility is underway.

GMP (good manufacturing practice) is an international standard set out by the World Health Organisation, which aims to make manufacturing medicines as safe as possible, and encompasses cleanliness, airflow and consistency.

"Our expectation is that that site is certified and operational at the very end of 2026, so that synchronizes with the end of the trial. It's about 45 to 50 jobs in Christchurch that we will be bringing into that site," Robson says.

The aim is to manufacture the engineered cells for 160 patients in the first year of operations, then more than 300 in year 2.

"You don't just turn it on. We'll have to hire people and train people," Robson says.

When could the public have access?

Timing that expensive scaling-up with demand for the therapy will be critical for the company, which is half owned by private investment firm Bridgewest Ventures and formed in 2021 with support from Callaghan Innovation, a government agency.

Information from the ongoing clinical trial will be sent to Medsafe in stages throughout the year, and the regulator will take three to six months to approve the therapy, or lodge objections.

Malaghan wouldn't discuss results of the phase 2 trial, but Robson says, so far, "everything is on par with phase 1 … but it is patient-by-patient data that we get that moves the needle".

There is a regulatory mechanism that means CAR T could be offered privately before Medsafe approval, Robson says, and BioOra is talking with an interested private health provider.

To get it into the public system around the same time would require special funding from the Government, Robson says. That could provide access until a more permanent funding arrangement, probably through Health NZ.

Robson would not be drawn on how much the per patient cost could be, but says it will be much lower than the $1m in Australia and the US, and not "massively different" to the roughly $200,000 charged in other markets such as China, while being much safer.

"The price becomes secondary to, 'Will I be in ICU, and is my life at risk?' … The global story for us is that this is a safer immunotherapy than anything else that's currently approved."

BioOra will return a large proportion of profits to Malaghan to research and develop further CAR Ts and immunotherapies. It also has its own research team.

Future therapies could treat a wide range of conditions, Robson says, including childhood acute lymphoblastic leukaemia, other blood and solid tumour cancers, and autoimmune diseases.

"Our goal is to be able to bring as many assets as effectively as possible into our manufacturing sites, off the back of the success of this one. This first asset really is a bootstrap for capability.

"The sovereign capability to manufacture immunotherapy is a game changer, because these therapies will challenge disease by disease by disease over the next five to 10 years. And if you can't make it, then you are going to be buying it."

Robson says BioOra has ambitions to become a global powerhouse of immunotherapy, with people travelling here for treatment.

"The more doses you make, the cheaper your average dose will be. So you would underwrite your country's sovereign cost through medical tourism.

"Our goal - and this is Malaghan's stated goal as well - is to have the lowest possible price point for public access. If we can do that through an underwrite with foreigners paying more, then that's the goal."

Examining how to tap into the Australian market is a particular focus for Sofie Parker, head of patient access for BioOra and who previously worked in the pharmaceutical industry there.

CAR T-cell therapy is already in the Australian public and private systems, she says, but once T cells are taken from patients' blood they must be sent to labs in the United States or Europe.

"To ship cells all that way, there and back, for these products adds so much time for patients. And these are patients who can't just wait around - there are many patients who die in that time or have poorer outcomes as a result."

BioOra is investigating possibly establishing a manufacturing facility in Australia.

The not-for-profit Malaghan Institute has this week launched a campaign to raise funds to cover the cost of the phase 2 trial, which will top $17m.

This is separate from the funding used by BioOra, which has been raised by private investors. A further $15m was raised in a capital funding round last year, with the next round aiming to raise $30-45m. Robson recently returned from pitching for investment in the US.

In terms of securing funding for public access here, Robson says doing so will save the country millions in health and productivity costs.

The upfront cost is relatively high, he says, but it is a one-off treatment, compared to years of hospital interactions and expensive and dangerous interventions like stem-cell transplants and chemotherapy.

"If you have a 20 or 30-year-old that's treated and they effectively go down this curative pathway, then their benefit and their input to New Zealand is huge, because they carry on working and they carry on being productive.

"The savings are significant … the question is, how quickly can you prove it and make a decision for compassionate access for a therapy? Our case would be that it would be abhorrent for it not to be immediately after the trial."

Health NZ referred questions to the Cancer Control Agency, Te Aho o Te Kahu, which is part of the Ministry of Health and leading the official response to CAR T-cell therapy, which includes the ministry, HNZ, Pharmac, Medsafe, and the Blood Service.

"This work will enable a streamlined approach for the agencies to identify the regulatory, health technology assessment and operational implications of technologies such as CAR-T cells, and will include identifying the impact on health services and associated requirements," the agency's acting chief executive Nicola Hill said.

New legislation, the Medical Products Bill, will be introduced this year and allow "flexible and risk-proportionate approval pathways" for treatments like CAR T-cell therapy, Hill said. However, the go-live date will be late 2030.