Cartherics Pty Ltd
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By online submission: consult.treasury.gov.au

Dear Treasury,

Re: Treasury Laws Amendment (Tax Reform No. 5) Bill 2026: Better Targeting the Research and Development Tax Incentive – Exposure Draft

1. Introduction

Cartherics Pty Ltd is a biotech company developing off-the-shelf, stem cell derived, immune cell therapies for high-impact women's diseases, with lead programs in ovarian cancer and endometriosis.

Cartherics recently invested in a new cleanroom facility to manufacture product for its upcoming clinical trial in ovarian cancer and future pipeline candidates. In addition to constructing, equipping, commissioning and validating its clinical manufacturing facility, Cartherics has hired and trained specialist manufacturing, QA, QC and support staff, as well as establishing a quality management system. This has been a multi-year and multi-million dollar investment, funded solely from the Company's own cash reserves. The Company has now commenced manufacture of the first batch of product for clinical trials.

This is a major achievement for Cartherics and establishes it as the only company in Australia that is able to go from starting stem cell, through gene editing and characterised master cell bank, and into manufacturing for clinical trials of CAR-iNK cells (a particular type of genetically modified immune cell) – an important sovereign capability.

This investment reflects the reality of cell and gene therapy development in Australia: it is capital-intensive, requires highly specialised infrastructure, and typically takes well over a decade from foundational research to first regulatory approval and commercial revenue.

We welcome the opportunity to respond to the exposure draft legislation for Treasury Laws Amendment (Tax Reform No. 5) Bill 2026: Better Targeting the Research and Development Tax Incentive (the Exposure Draft), and to contribute the perspective of an Australian cell therapy biotech company to this reform process. The R&D Tax Incentive (RDTI) has been, and remains, critical to our ability to fund the long, high-risk research and manufacturing development that underpins our work. We support the Government's objective of better targeting the RDTI towards genuine, high-impact R&D, and offer the comments below in support of that objective.

2. Summary of key points

- We recommend Treasury use this consultation - which explicitly invites feedback on the treatment of clinical manufacturing R&D expenditure - to confirm that process development, scale-up and validation activities necessary to manufacture novel cell and gene therapies to clinical and regulatory standard are R&D activities in their own right, and are not excluded by the removal of the "supporting R&D activities" category. We further recommend that Treasury recognises that the cost of manufacturing product for clinical trials is essential to the conduct of clinical trials and is therefore a legitimate R&D expense for the purposes of the RDTI.
- We welcome the proposed 15-year refundability period for entities undertaking R&D related to therapeutic goods as an improvement on the standard 10-year period but note that both timeframes remain arbitrary cut-offs. We recommend the "start day" be measured from first R&D registration only, and that Treasury address how the window applies to companies that have invested in building a technology and infrastructure platform that provides for sequentially developed product candidates. This reflects the greater time and investment required to build a fully integrated company with the team and platform needed to develop multiple products, compared with a company developing a single product candidate (and often operating under a virtual or semi-virtual business model). Platform companies are significantly disadvantaged and discouraged under an arbitrary time limit for the rebatable RDTI, meaning that the proposed changes will be a disincentive for the emergence of fully-integrated biotechnology companies to underpin a biotechnology sector that is viable over the long term.
- We recommend Treasury make the discretionary Board finding required to access the 15-year window - based on the "dominant purpose" of an entity's R&D activities - more predictable for genuine therapeutic goods developers, given the compliance and timing risk this discretionary, activity-specific test creates.
- We welcome the increase in the refundable offset turnover threshold from $20 million to $50 million but note this does not protect pre-revenue biotechnology companies from the separate, age-based cutoff that converts the offset from refundable to non-refundable once an entity passes its tenth (or fifteenth) anniversary, regardless of turnover.
- We support the Government's decision to set the minimum R&D expenditure threshold at $50,000 rather than the higher amount canvassed in the Ambitious Australia report, as this better protects early-stage biotech ventures.
- We recommend early and detailed guidance, with worked examples for cell and gene therapy manufacturing, well ahead of the 1 July 2028 commencement date, given the long lead times involved in R&D and capital planning in our sector.

3. Recognising the realities of cell and gene therapy R&D and manufacturing

3.1: Manufacturing and process development should be recognised as core R&D

We note that the consultation materials specifically invite feedback on the appropriate treatment of clinical manufacturing R&D expenditure, and we welcome the opportunity to respond to this directly.

Unlike more established manufacturing sectors, cell and gene therapy manufacturing is itself an area of active experimentation. There is no settled, “off-the-shelf” process for manufacturing an iPSC-derived, gene-edited cell therapy product like CTH-401 at clinical scale. Each step - from cell expansion and differentiation protocols, to closed processing systems, to bioreactor and

cryopreservation methods - must be developed, tested and validated specifically for the product candidate. This is fundamentally different from the routine, repeatable manufacturing of an already-approved product.

Under the Exposure Draft, the category of "supporting R&D activities" is removed altogether, rather than being retained at a different rate. The draft repeals the current supporting R&D activities test (section 355-30) and the definition of "supporting R&D activities," and inserts a new provision (proposed subsection 355-25(2A)) stating that an activity is not an R&D activity merely because it is directly related to, or undertaken for the purpose of supporting, another eligible activity. If clinical manufacturing process development were found to fall outside the narrower, post-reform definition of an R&D activity in its own right, companies like Cartherics could lose access to the incentive entirely for a substantial share of the R&D investment required to bring a cell therapy from the laboratory to a patient.

> **Recommendation:** Treasury should confirm, through the explanatory materials or joint ATO/Department of Industry, Science and Resources guidance, that manufacturing process development, scale-up and validation activities necessary to produce a novel biological product to clinical and regulatory standard - where the outcome cannot be known or determined in advance - are R&D activities in their own right under proposed section 355-25, and are not excluded by proposed subsection 355-25(2A) merely because they are connected to, or support, a broader program of work. Worked examples specific to cell and gene therapy manufacturing would give the sector confidence to continue investing in Australian-based manufacturing infrastructure, consistent with the Government's stated goals of encouraging R&D to be undertaken onshore and building sovereign advanced manufacturing capability. We further recommend that Treasury recognises that the cost of manufacturing product for clinical trials is essential to the conduct of clinical trials and is therefore a legitimate R&D expense for the purposes of the RDTI. For cell therapy products, the cost of product for clinical trials represents the largest single expense. No product means no clinical trial. If the cost of product is not an allowable R&D expense, then the cost of a clinical trial becomes significantly more expensive for the developing company. This will result in less clinical trials being conducted, resulting in reduced access for Australian patients to cutting-edge therapies.

3.2: The 15-year refundability period for therapeutic goods R&D is a welcome improvement, but remains an arbitrary cut-off that needs a clear start point

We welcome the Government's recognition, through the proposed 15-year (rather than 10-year) refundability period for entities undertaking R&D related to therapeutic goods, that therapeutics development takes materially longer than R&D in many other sectors. This is a welcome improvement on the standard 10-year period. However, both timeframes are ultimately arbitrary cut-offs that may not align with the actual, product-specific development timeline of any given therapeutic — which can vary significantly depending on modality, indication and regulatory pathway.

The Exposure Draft defines an entity's "start day" - the date from which both the 10-year and 15-year refundability windows are measured - as the earlier of the day it first started carrying on an enterprise

or the day it first registered for R&D activities under the Industry Research and Development Act 1986. For a company such as Cartherics, which was registered ~2 years before formally registering for the RDTI, this means the refundability clock runs from the earlier, less favourable of the two dates - effectively shortening the window available for R&D undertaken after registration, and penalising companies for time spent establishing their enterprise before their R&D program was mature enough to register. In the case of Cartherics, which was not spun out of an academic institution but created its own technology platform from scratch, it's first two years were spent raising seed capital to allow it to commence operations.

This entity-level, single start-day approach also creates a specific problem for platform biotechnology companies with multiple products in development, such as Cartherics. Because the 15-year window runs once from a single start day for the whole entity, it does not reset or extend for each new product candidate that enters development from the same underlying platform. A company's lead product may benefit from close to the full 15-year window, but a second- or third-generation candidate - built on the same technology but commencing pre-clinical and clinical development years later - inherits only whatever remains of that same clock, regardless of its own, independent development timeline. This has the perverse effect of penalising platform companies precisely for building a productive pipeline, and risks creating an incentive to establish new corporate entities for later-stage candidates purely to access a fresh refundability window, which does not appear to be consistent with the policy's intent.

> **Recommendation:** We recommend that, if it persists with an arbitrary cut-off date, Treasury measure the start day, for the purposes of the therapeutic goods window, from the date of first R&D registration only rather than the earlier of that date or the date an entity first started carrying on an enterprise. This will help ensure that genuine cell and gene therapy developers are not disadvantaged for pre-registration foundational activity. We further recommend Treasury consider how the 15-year window should apply to platform companies with multiple, sequentially developed product candidates - for example, by assessing refundability eligibility by reference to the registration date of each distinct product or R&D program, rather than a single entity-wide start day - so that genuine, ongoing pipeline development is not disadvantaged relative to a company with a single product. If the entity-level "earlier of" test is retained, Treasury should at minimum provide a transitional or grandfathering mechanism for existing long-tenured, pre-revenue biotechnology companies whose start day, as newly defined, would otherwise curtail their refundability window before their lead product reaches commercialisation.

3.3: Access to the 15-year window depends on a discretionary Board finding, not an automatic entitlement

The 15-year refundability window for therapeutic goods R&D is not automatic. Under proposed subsections 355-100(4) and (5), it applies only where the entity has been registered for the relevant R&D activities in the income year in which its start day occurred, or in one of the following nine income years, and only where those activities are found to have been conducted for the "dominant purpose" of generating new knowledge about therapeutic goods or their therapeutic use. This finding is made by the Industry Innovation and Science Australia Board under new section 28EA of the Industry Research

and Development Act 1986, which the Board may make on its own initiative, must make if requested by the Commissioner or applied for by the entity, and may decline to make "if justified in accordance with the decision-making principles." Applications for a finding must generally be made within 10 months of the end of the relevant income year.

This creates meaningful compliance and timing risk for genuine cell and gene therapy developers. A company could fail to secure the 15-year extension - and default to the standard 10-year window - simply by not registering the relevant activities within the qualifying nine-year period, by an adverse or refused Board finding, or by missing the application deadline in a given year. For a company such as Cartherics, whose platform generates a sequence of product candidates over many years, this discretionary, activity-specific and time-bound test adds a further layer of uncertainty on top of the start-day and multi-product issues raised above. Further, biotechnology companies like Cartherics are absolutely dependent on long-term, patient investment to fund development and commercialisation of its product. Such capital is in very limited supply in Australia, providing an ongoing, existential challenge for these companies. Investors dislike uncertainty, and any uncertainty around a company's ability to obtain the refundable RDTI provides an additional hurdle for biotechnology companies to access capital. Long-term consistency in the RDTI policy is essential, particularly for capital-intensive industries in a capital-constrained environment.

> **Recommendation:** Treasury should consider whether the dominant-purpose finding required for the 15-year extension can be made more predictable for genuine therapeutic goods developers - for example, by allowing a single finding in respect of an entity's overall R&D program to extend to later-registered activities on the same platform, rather than requiring this to be re-established activity-by-activity, and by providing clear guidance on the decision-making principles the Board will apply in exercising its discretion to make or refuse a finding.

4. The turnover threshold does not protect pre-revenue biotech companies from the age-based refundability cutoff

We welcome the increase in the turnover threshold for the refundable offset from $20 million to $50 million, as it will allow more R&D-intensive companies to access cash-flow support during their growth phase.

However, we note this threshold offers no protection against the separate, age-based cutoff in proposed table item 1A, which converts the offset from refundable to non-refundable once an entity passes the tenth anniversary of its start day (or fifteenth, where the therapeutic goods extension applies) - regardless of whether its turnover remains well under $50 million. For a pre-revenue biotechnology company, the binding constraint on continued access to refundability is this age-based test, not the turnover threshold itself. A company that has raised substantial private investment capital but generated no product revenue could still lose refundable cash-flow support purely due to elapsed time, notwithstanding its turnover remaining well below the new threshold.

Recommendation: Treasury should recognise that, for pre-revenue R&D-intensive companies, the turnover threshold and the age-based cutoff operate independently, and that raising the former does not address the risk created by the latter. We reiterate our recommendations in section 3.2 regarding the start day and its application to companies with long foundational research phases and multiple pipeline products, as these - rather than the turnover threshold - are the provisions that determine whether a pre-revenue biotechnology company retains access to refundability.

5. Minimum expenditure threshold

We note that the Ambitious Australia report canvassed a minimum R&D expenditure threshold as high as $150,000, while the Exposure Draft proposes a more moderate increase, from $20,000 to $50,000. We support the Government's more moderate approach. A higher threshold risks excluding genuine early-stage research and university spin-out companies in their first year or two of operation, before they have scaled up their R&D spend - working against the broader goal of encouraging a pipeline of new Australian biotechnology companies of the kind Cartherics itself once was. However, we note that the combination of allowing for small R&D claims plus the arbitrary time-based cut-off for the rebatable RDTI creates an environment in which companies will be encouraged to "think small" in their early years and look for premature exits (licensing or selling their technology) prior to the 10 or 15 year deadline. This is contrary to the government's stated ambition to build a medical technology sector and encourage sovereign manufacturing capability.

6. Certainty and lead time for the sector

Cell and gene therapy companies make R&D and capital investment decisions years in advance of the outcomes being realised, informed in part by the settings of programs like the RDTI. Cartherics' decision to invest in a clinical-scale cleanroom manufacturing facility, for example, was made with a multi-year view of our clinical program and its funding requirements, and with the expectation that the rebatable RDTI would continue to be available to it. The announcement of the proposed changes was an unhelpful and unwelcome surprise to the Company. It required the Company to revise potential future capital requirements at a time when it was in active discussions with potential investors and created a situation where investors were not prepared to make any investment decisions until the situation was clarified.

Recommendation: We recommend that Treasury and the ATO issue detailed public guidance - including worked examples specific to cell and gene therapy manufacturing and R&D - well ahead of the 1 July 2028 commencement date, to give the sector the certainty needed to plan R&D programs, capital raising and facility investment with confidence.

7. Conclusion

Cartherics supports the Government's objective of ensuring the RDTI is well targeted, sustainable, and delivers genuine additional R&D investment and spillover benefits for Australia. As a Melbourne-based company developing world-first cell therapy technology, we have a direct interest in a scheme that continues to make Australia an attractive place to undertake high-risk, high-reward biotechnology R&D and manufacturing. We believe that Cartherics is exactly the type of company that should be

encouraged to develop and grow in Australia. The structure of the RDTI has a major impact on whether that will be the case.

We would welcome the opportunity to discuss any of the points raised in this submission further, and to contribute to the development of guidance material as the reforms progress towards the 1 July 2028 commencement date.

Yours sincerely,

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