CANARY CAPITAL

Equity Research

Healthcare and Life Sciences

Initiation of Coverage | 12 Oct 2026

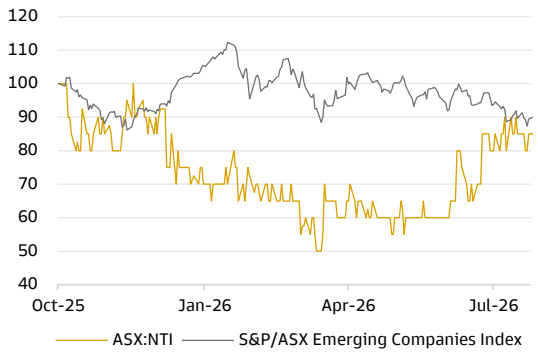
Key metrics

Rating	**Strong Buy**
Intrinsic value per share	A$0.155
Current share price	A$0.013
Potential upside	1,093%
Market cap	A$21.01m
Ordinary shares outstanding	1,616m
Diluted shares outstanding	1,706m
52-week range	A$0.010-0.029
30-day average daily volume	5.4m

Key financials (A$m)

	FY26A	FY27E	FY28E	FY29E
Revenue	-	-	-	-
EBITDA	(6.6)	(6.6)	(5.6)	(6.7)
EBIT	(6.6)	(6.6)	(5.6)	(6.7)
NPAT	(6.5)	(6.6)	(5.5)	(6.7)
CFO	(4.2)	(6.6)	(5.7)	(6.1)
FCF	(4.2)	(6.6)	(5.7)	(6.1)
Cash	2.4	1.9	1.9	1.9
Net cash/(debt)	2.4	1.9	1.9	1.9

Share price performance



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Neurotech International (ASX:NTI)

Phase III-stage neuroinflammation platform approaching a key ASD readout; initiating coverage at Strong Buy with a DCF-derived A$0.155 intrinsic value per share estimate.

Neurotech International is entering the value-defining stage of development for NTI164, its proprietary oral cannabinoid formulation targeting neuroinflammation across paediatric neurological and neurodevelopmental disorders. Autism Spectrum Disorder (ASD) is the lead indication, with the company now enrolling its 200-patient Beyond Harmony Phase III study following positive Phase II/III data.

The clinical evidence to date provides a credible foundation for the Phase III program. In the placebo-controlled Phase II/III NTIASD2 study, NTI164 produced a substantial improvement in overall illness severity, with mean CGI-S falling from 5.54 to 3.77 over eight weeks, effectively moving patients from markedly-to-severely ill to mild-to-moderately ill, while placebo was largely unchanged. NTI164 also delivered a materially greater improvement in adaptive functioning and social responsiveness.

The Australian commercial opportunity is substantial, with the NDIS reporting 350,651 active participants with autism as their primary diagnosis and A$11.2bn of payments to autism participants in FY26. Given that NTI164 is the most advanced pharmacological candidate targeting ASD's core symptoms in Australia, NTI's strategy is to commercialise in Australia initially while pursuing licensing opportunities in larger offshore markets. NTI also retains significant pipeline optionality in Rett syndrome, PANS/PANDAS and cerebral palsy, none of which is included in our valuation.

We utilise a discounted cash flow methodology with an EV/EBITDA exit multiple to value NTI at A$0.155/share on a probability-weighted basis, based on A$0.259/share in our success scenario and nil in failure. Our base case values only Australian ASD, assumes 10% peak penetration and A$15,000 annual pricing. Key risks to our thesis include clinical execution, PBS reimbursement, regulatory approval, intellectual property, competition, and reliance on a key partner and raw material supply. These risks predominantly reflect NTI's single-asset profile. The Beyond Harmony Phase III readout therefore represents the key near-term catalyst.

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Executive Summary

Company Overview

Neurotech International (ASX:NTI) is a Melbourne-based, clinical-stage biopharmaceutical company developing NTI164. NTI164 is an orally administered cannabinoid formulation high in cannabidiolic acid (CBDA) and low in THC (<0.3%). It is designed to modulate activated microglia, the brain's resident immune cells, whose chronic activation has been linked to several paediatric neurological and neurodevelopmental disorders. Neurotech has been a pure-play developer of NTI164 since divesting its legacy device business in 2025. Fenix Innovation Group runs clinical development and manufactures NTI164 under an exclusive collaboration agreement. The formulation is licensed from Dolce Cann Global in return for a 2.5% royalty on NTI164 revenue. NTI164 is in development across four indications. ASD is the lead program and the only one in a registrational study (Exhibit 1).

Exhibit 1: ASD is the only NTI164 indication in a registrational study

Indication	Most advanced study	Status
Autism spectrum disorder	Phase III Beyond Harmony (up to 200 patients aged 6-25)	Phase II/III met primary and key secondary endpoints; Phase III first patient dosed 21 Sep 2026; FDA IND cleared Jul 2026
Rett syndrome	Phase I/II NTIRTT1 (n=11)	Met primary endpoint; US and EU orphan drug designations held; randomised NTIRTT2 registered but not yet recruiting
PANS/PANDAS	Phase I/II NTIPANS1 (n=14)	Met primary endpoints, with improvement sustained to 52 weeks; no randomised study announced
Cerebral palsy	Phase I/II	No patient dosed; program effectively on hold

Source: Company Data, Canary Capital Equity Research

ASD is the commercial focus of the business. There are currently no FDA-approved therapies for ASD's core symptoms, with risperidone and aripiprazole approved only for associated irritability and aggression and carrying side effects including weight gain and sedation. Australia represents a potentially attractive initial market, with the NDIS recording 350,651 active participants with autism as their primary diagnosis and A$11.2bn in payments to this cohort in FY26.

Valuation

We initiate coverage with a Strong Buy rating and a probability-weighted intrinsic value of A$0.155 per share, 1,093% above the last close of A$0.013.

Methodology. We apply a discounted cash flow valuation to Australian ASD earnings over FY30-FY39, using EBITDA as a proxy for free cash flow. EBITDA margin rises from 5% in FY30 to 22.5% in FY39, when revenue of A$390.4m gives EBITDA of A$87.8m. Applying a 19.9x exit multiple, the average of ten profitable specialty pharmaceutical peers, gives an FY39 enterprise value of A$1,747m. We discount that value and FY30-FY39 EBITDA to FY27 at a 13.8% WACC.

Key assumptions. The target population is 219,714 NDIS participants aged 6 to 25 with medium or high function, matching the Beyond Harmony population. Uptake follows a Bass

diffusion curve towards a 10% penetration ceiling, reaching 26,029 patients in FY39. We hold the annual price flat at A$15,000 and assume commercial launch in FY30.

Scenario weighting. Our success scenario of A$0.259 per share (equity value A$417.8m) is weighted at 60%, and failure at nil is weighted at 40%. The 60% probability of success sits ~8 percentage points above the 52.4% Phase III-to-approval base rate. We justify the premium by the placebo-controlled data already in hand at the Phase III doses and endpoints.

Conservatism and sensitivity. Our valuation excludes Rett syndrome, PANS/PANDAS, cerebral palsy and all offshore markets, and prices NTI164 at the bottom of our A$15,000-25,000 achievable range. Across a 50-70% probability of success and a 16.9x-22.9x exit multiple, value ranges from A$0.114 to A$0.202 per share. Even the lowest point in that range is more than eight times the current price.

Investment Thesis

Clear business strategy. Neurotech has sequenced each NTI164 study to de-risk the next. An open-label study established tolerability and dose. The 61-patient Phase II/III NTIASD2 study then met its primary endpoint and key secondary endpoints, with mean CGI-S falling from 5.54 (markedly-to-severely ill) to 3.77 (mild-to-moderately ill) over eight weeks while placebo was largely unchanged. Beyond Harmony now tests the same doses on the same clinician-rated endpoints. It is designed as a single registrational study for both TGA and FDA submissions. Neurotech plans to commercialise in Australia first, where the NDIS spends an average of A$31,965 a year on each autism participant against our assumed A$15,000 annual price. Offshore, the company intends to license NTI164 instead of funding its own US launch.

Scalable business model. NTI164 is a single formulation across the whole pipeline, with all programs sharing the same manufacturing process and safety database. Success in ASD therefore lowers the cost of entering adjacent markets such as Rett syndrome. Unit economics also improve with scale. We model manufacturing cost per annual dose falling from about A$5,000 to A$4,000, lifting gross margin from 64.2% to 70.8% over our forecast period, net of the Dolce Cann Global royalty. We expect Australian prescribing to be concentrated among paediatric neurologists and developmental paediatricians, and offshore distribution would sit with licensees. We therefore expect revenue to grow well ahead of operating costs.

IP protection and barriers to entry. NTI164's clinical data package is its most durable barrier. NTI164 is the only cannabinoid-based ASD candidate to reach Phase III, while comparable programs remain at Phase II or earlier. Repeated late-stage failures in ASD make a positive placebo-controlled dataset scarce and costly to reproduce. On 2 July 2026 the USPTO issued Notices of Allowance for two NTI164 applications covering the reduction of neuroinflammation and the treatment of ASD. Once granted, these patents are expected to protect NTI164 in the US through 2042. The Rett syndrome orphan drug designations could also add market exclusivity on approval.

Successful management. Neurotech's board is weighted towards capital markets expertise, which suits a company entering the capital-intensive Phase III and potential licensing stages. Executive Chairman Mark Davies brings more than 20 years of investment banking and corporate advisory experience. Non-Executive Director Andrew Chapman has more than 25 years in financial services, including advising biotechnology companies on capital raisings. The board has no dedicated drug development specialist. Neurotech instead relies on Fenix, its strategic development partner, for preclinical, clinical and regulatory expertise. Fenix is led by Dr Esra Isikgel, who has taken products through FDA and TGA registration.

Significant investment upside. Our probability-weighted intrinsic value of A$0.155 per share is 1,093% above the last close of A$0.013, and every layer of the valuation is conservative. The success scenario covers one indication in one country with penetration capped at 10%, and we weight it at only 60%. Rett syndrome, PANS/PANDAS, cerebral palsy and all offshore markets sit outside our numbers. We expect positive Phase III data to drive a re-rating towards our intrinsic value.

Investment Risks

Clinical and single-asset risk. NTI164 is Neurotech's only drug candidate and Beyond Harmony its only registrational study. An unsuccessful or inconclusive readout would leave no recoverable equity value in our valuation. ASD has a poor late-stage record, with MapLight's ML-004 missing its Phase II endpoint in June 2026, and large placebo responses are common in paediatric neuropsychiatric trials. The risk is reduced by NTIASD2, which met its primary and key secondary endpoints in a randomised, placebo-controlled study using the same doses and clinician-rated measures as Beyond Harmony.

Regulatory and reimbursement risk. The TGA has never approved a therapy for autism's core symptoms, and cannabinoid medicines face added scrutiny on quality and consistency. At A$15,000 a year, our forecasts depend on a PBS listing, and a PBAC rejection or a restricted listing would cut adoption well below our model. However, our forecasted price sits well below the A$31,965 the NDIS already spends on the average autism participant each year. A therapy with placebo-controlled gains in severity and adaptive functioning would therefore enter the cost-effectiveness assessment from favourable ground.

Competition risk. Yamo Pharmaceuticals plans to start registrational Phase III trials of L1-79 in the US in early 2027 and could reach the US market first, which would weigh on licensing upside. Our base case is insulated from this risk, as it values only the Australian market, where no competing ASD program is in a registration pathway.

Intellectual property risk. NTI164's plant-derived, full-spectrum formulation limits the composition-of-matter protection available to novel synthetic molecules. Enforcement could also strain a company of Neurotech's size. However, Neurotech's position strengthened in July 2026, when the USPTO allowed two NTI164 applications that point to US protection through 2042 once granted. The Rett syndrome orphan drug designations would also add market exclusivity on approval.

Key partner risk. Neurotech relies on Fenix Innovation Group to sponsor and manage NTI164's clinical trials and manufacture the drug under an agreement terminable by either party with 90 days' notice. Losing Fenix as CRO and manufacturer could materially delay NTI164's development, as qualifying a replacement CRO and manufacturer capable of reproducing a standardised botanical formulation would be time-consuming and costly. The risk is partly mitigated by Neurotech retaining the underlying IP, clinical data and drug master file, which should facilitate the transfer of trials and manufacturing to alternative providers. Fenix's shareholding in NTI and its performance rights, which lapse upon termination, also provide alignment with Neurotech.

Raw material and scale-up risk. Commercial launch would require cultivation and extraction of NTI164's CBDA-rich strain at volumes far above clinical trial needs, and a feedstock shortfall could delay launch or cap early sales. However, Fenix plans to build a multi-regional supply base, retaining Australia as a growing site while developing large-scale cultivation offshore. It is also assessing multiple extraction sites in Australia and overseas, which would limit the impact of a disruption at any single site.

Company Overview

Neurotech International Limited (ASX:NTI) is a Melbourne-based, clinical-stage biopharmaceutical company developing NTI164, its sole drug candidate for paediatric neurological and neurodevelopmental disorders driven by neuroinflammation. NTI164 is an orally administered, proprietary cannabinoid formulation designed to modulate microglial activation and reduce inflammatory signalling. The company is developing the therapy across four indications: Autism Spectrum Disorder (ASD), Rett syndrome, Paediatric Acute-onset Neuropsychiatric Syndrome (PANS/PANDAS) and cerebral palsy. ASD is the lead indication and the subject of the company's only Phase III registration study.

Neurotech has reported statistically significant, clinically meaningful results for NTI164 across completed clinical trials in ASD, Rett syndrome and PANS/PANDAS, and the Rett syndrome program holds orphan drug designation in both the US and Europe. Neurotech transitioned from a medical device company to a pure-play biotechnology company in 2020 and, following the divestment of its legacy device business in 2025, is now entirely focused on advancing NTI164. The formulation was originally developed by Dolce Cann Global, which licenses it to Neurotech in return for a 2.5% royalty on NTI164 revenue. The company's investment thesis is primarily driven by clinical and regulatory milestones, particularly the Phase III ASD trial, alongside potential licensing opportunities. The company remains exposed to the funding and single-asset risks typical of clinical-stage biotechnology.

Pathophysiology of Neuroinflammation

Growing evidence suggests that abnormal microglial activation and chronic neuroinflammation contribute to the development and progression of several paediatric neurological disorders, including ASD, Rett syndrome, cerebral palsy and potentially PANS/PANDAS.

Microglia: The Brain's Immune Cells

Microglia are the brain's resident immune cells and play a vital role in maintaining normal brain function. In their healthy, surveillant state, they continuously patrol the brain, clearing away cellular debris, defending against pathogens such as viruses and bacteria, and pruning weak or unused synaptic connections to support healthy brain development and efficient neural communication.

When the brain detects injury, infection, cellular stress or other harmful stimuli, microglia transition into an activated state. This is a normal and essential immune response that helps protect and repair brain tissue. Activated microglia migrate towards the site of damage and engulf pathogens, dead cells and debris. They also signal to surrounding cells to coordinate the wider immune response.

Role of Microglia in Neuroinflammation

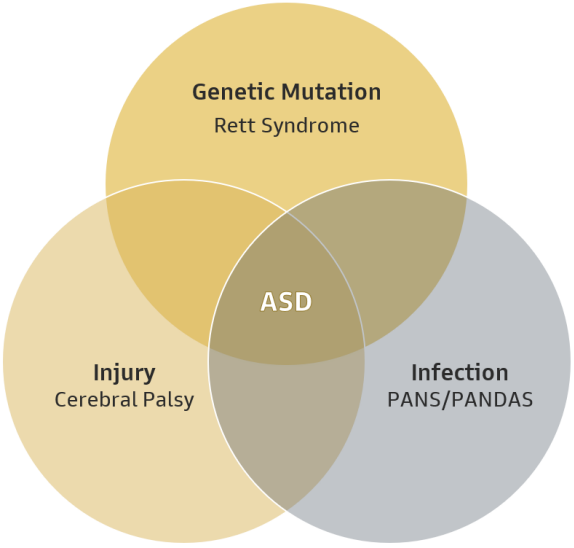
When microglia become activated, they switch on NF-κB, a protein that triggers the production of inflammatory signalling molecules such as tumour necrosis factor-α (TNF-α), interleukin-1β (IL-1β) and interleukin-6 (IL-6), as well as chemokines. These signals attract

other immune cells, strengthen the immune response and help the brain clear pathogens and damaged tissue. Normally, anti-inflammatory mechanisms keep this response under control. One of these is PPAR-γ, a receptor that helps suppress NF-κB activity and so restrains inflammation in the brain. However, if the underlying trigger persists, this balance can break down, leaving microglia continuously activated and driving ongoing, or chronic, neuroinflammation.

Potential Triggers of Neuroinflammation

ASD, Rett syndrome, cerebral palsy and PANS/PANDAS have each been associated with microglial activation and neuroinflammation, although the underlying triggers and strength of evidence vary across conditions. Research suggests that infections, genetic abnormalities and brain injury can contribute to microglial activation, depending on the condition (Exhibit 2). This provides a potential common pathway through which diverse underlying factors may contribute to neuroinflammation and, in turn, disease symptoms.

Exhibit 2: Triggers of neuroinflammation differ by condition, but converge in ASD



Source: Canary Capital Equity Research

Infections. Infections are the most prominent proposed trigger in PANS/PANDAS, where symptoms are often associated with preceding infections, particularly streptococcal infections. Proposed mechanisms include bacterial products that activate the immune system, immune cross-reactivity in which antibodies may mistakenly target neuronal structures, and recurrent infections that repeatedly stimulate immune activation.

Genetic mutations. Genetic factors are particularly well established in Rett syndrome, which is most commonly caused by mutations in the methyl-CpG binding protein 2 (MECP2) gene. Across these conditions, researchers are also investigating other genetic contributors, including variants affecting synaptic function, immune signalling and pathways involved in innate immune responses.

Brain injury. Brain injury is particularly relevant to cerebral palsy, which can result from injury to the developing brain before, during or shortly after birth. Potential contributors include perinatal hypoxia-ischaemia, intraventricular haemorrhage and disruption of the blood-brain barrier, all of which may promote inflammatory responses within the brain.

Intersection of Genetic, Immune and Injury-Related Triggers. ASD sits at the intersection of these potential pathways, with research investigating genetic, immune and environmental contributors. These include maternal immune activation during pregnancy, genetic variants affecting immune signalling, and perinatal complications such as hypoxia. Other factors under investigation include oxidative stress, altered cortisol signalling and maternal psychosocial stress, although the extent to which these factors contribute to ASD and neuroinflammation remains uncertain.

NTI164 Composition and Mechanism of Action

A Full-Spectrum Cannabinoid Formulation Designed for Broad Biological Activity

NTI164 is a proprietary, plant-derived cannabinoid formulation characterised by high levels of cannabidiolic acid (CBDA) and low levels of THC (<0.3%), alongside smaller quantities of cannabidiol (CBD), cannabichromene (CBC), cannabidivarin (CBDV), cannabigerolic acid (CBGA) and other minor cannabinoids and terpenes. Neurotech positions NTI164 as a full-spectrum formulation, meaning it contains multiple naturally occurring constituents rather than a single purified cannabinoid. This composition is intended to generate complementary biological effects through multiple molecular targets, with the potential for greater therapeutic activity than CBD alone.

NTI164 Targets Neuroinflammation Through Microglial Modulation

The mechanism of action of NTI164 centres on modulating activated microglia. Preclinical studies found that NTI164 significantly reduced several inflammatory markers in activated microglial cell models, including TNF-α, inducible nitric oxide synthase (iNOS), GM-CSF and COX-2. Some of these effects were greater with the full NTI164 extract than with CBD alone, which supports the case for the formulation's broader cannabinoid profile.

Multi-Pathway Activity May Provide Neuroprotective Effects

In addition to its anti-inflammatory effects, NTI164 has demonstrated anti-oxidative and neuroprotective activity in preclinical models. In neuronal cell experiments, NTI164 improved neuronal survival under excitotoxic stress, which suggests its effects may extend beyond suppression of inflammation to protection of neuronal function. Together, these anti-inflammatory and neuroprotective properties provide the biological rationale for developing NTI164 across neurological disorders in which neuroinflammation is implicated.

Fenix Innovation Group: Neurotech's Development and Manufacturing Partner

A Specialist Drug Development Partner

Fenix Innovation Group is a Melbourne-based private contract research organisation (CRO) and biotech advisory firm providing integrated drug development services across regulatory strategy, preclinical research, clinical development, manufacturing and commercialisation. The company has particular expertise in complex paediatric clinical trials and is also a strategic partner of Pharmaron, a global contract development and manufacturing organisation.

Fenix Runs NTI164's Clinical, Regulatory and Manufacturing Work

Fenix is responsible for a substantial portion of the development infrastructure supporting NTI164. Its role spans clinical trial protocol development, site and data management, regulatory support and study sponsorship. Fenix also manufactures NTI164 at its GMP facility and supports Neurotech's regulatory engagement with both the TGA and FDA, including the IND application cleared by the FDA in July 2026. The arrangement gives Neurotech access to clinical, regulatory and manufacturing capabilities without having to build these functions internally. This supports a relatively lean corporate structure while allowing Neurotech to outsource specialised activities to an established development partner.

An Exclusive and Incentive-Aligned Relationship

The relationship was formalised through a Strategic Collaboration Agreement executed on 3 June 2024. Under the Agreement, Fenix works exclusively with Neurotech in the medicinal cannabis field. In consideration, Fenix received 10 million Neurotech shares, subject to a 12-month escrow period, together with 50 million performance rights in five tranches linked to NTI164 regulatory and commercial milestones. Neurotech has since met the vesting conditions for the first three tranches, resulting in the vesting of 20 million rights held by Fenix. These were US orphan drug designation for Rett syndrome in November 2024, EU orphan drug designation in 2025 and FDA clearance of the NTI164 IND in July 2026. The remaining 30 million rights vest on a licensing transaction and TGA approval respectively.

The structure aligns a significant portion of Fenix's potential economic return with NTI164's development and commercial progress. This provides Fenix with a direct financial incentive to advance the program while limiting Neurotech's need to replicate Fenix's specialist capabilities internally.

Autism Spectrum Disorder

Indication Overview

Autism spectrum disorder is a lifelong neurodevelopmental condition that affects social communication, behaviour and interaction with the surrounding environment. ASD is Neurotech's primary indication and its most advanced clinical development program. The causes of ASD are complex and heterogeneous, with genetic susceptibility interacting with

environmental and developmental factors rather than a single underlying cause. Increasing evidence also implicates abnormalities in immune signalling and microglial function in at least a subset of patients, although the precise causal role of neuroinflammation remains under investigation. These biological disturbances may contribute to altered neuronal development and signalling, which can manifest as the disorder's core symptoms.

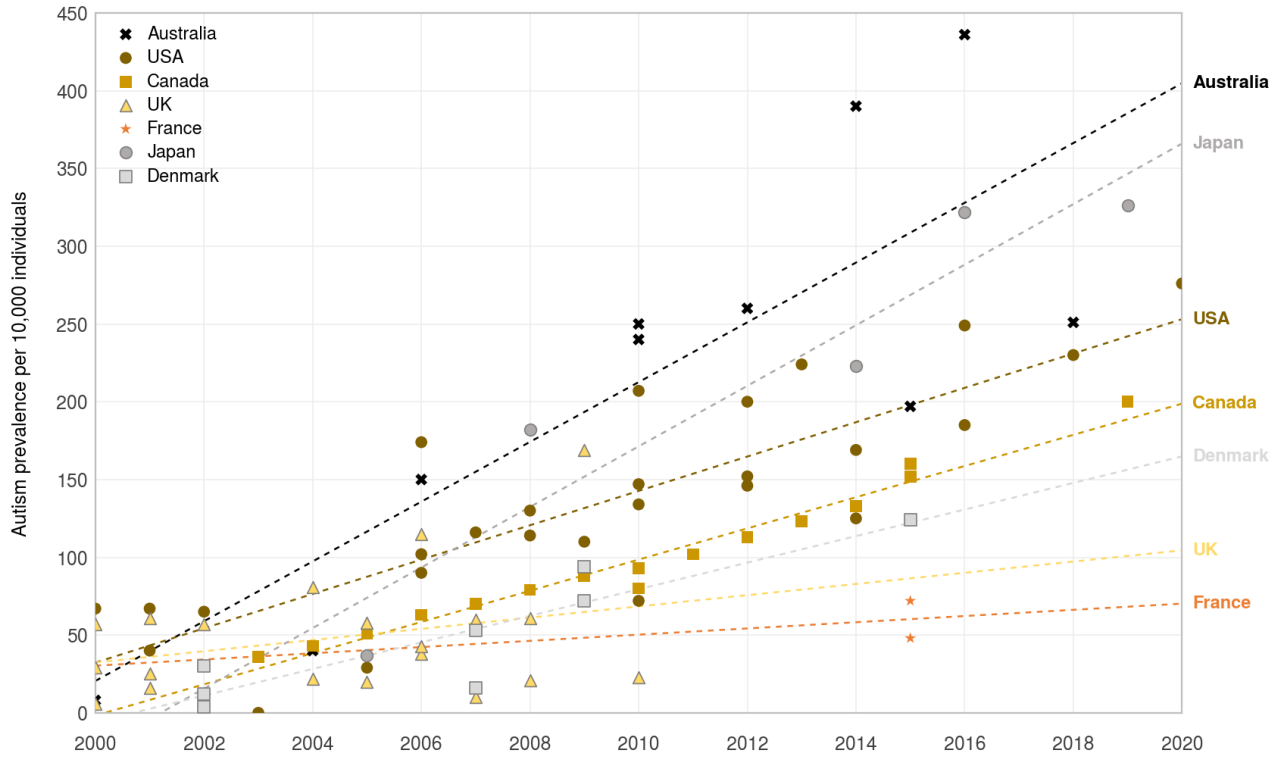
Core vs Associated Symptoms

ASD is characterised by two core symptom domains: persistent difficulties with social communication and social interaction, and restricted or repetitive behaviours, interests and activities. These features form the basis of the clinical diagnosis and include challenges with social reciprocity, communication, relationships, repetitive behaviours, insistence on sameness and sensory responses. By contrast, associated or non-core symptoms are clinically important problems that commonly occur alongside ASD but are not required for diagnosis, including irritability, aggression, self-injurious behaviour, anxiety, sleep difficulties and hyperactivity.

Current Unmet Medical Need

The ASD market is underpinned by rising prevalence. A 2022 global systematic review (Zeidan et al., *Autism Research*) put median prevalence at 1 in 100 children, yet Australia has among the highest paediatric diagnosis rates in the world (Exhibit 3). The National Disability Insurance Scheme (NDIS) data released in December 2025 show 1 in 27 children accessing the scheme with an autism diagnosis. The ABS's 2022 Survey of Disability, Ageing and Carers puts the number of Australians with ASD at ~291k.

Exhibit 3: Australia's diagnosed paediatric autism population has grown faster than any comparable market



Source: Ranjan (2023), ANU TTPI Working Paper 17/2023, Canary Capital Equity Research

Significant Economic Burden Creates a Large Market Opportunity

ASD imposes a substantial economic burden, and effective treatments remain an unmet need. In the US, Leigh and Du (2015, *Journal of Autism and Developmental Disorders*) forecast annual societal costs, spanning medical care, non-medical services and lost productivity, of US$461bn in 2025 (range US$276bn–1.0tn). In Australia, a Synergies Economic Consulting study (2011) cited by the Senate Select Committee on Autism put annual economic costs at A$8.1–11.2bn (in 2010 dollars), while NDIS payments to participants with a primary disability of autism reached A$11.2bn in FY26 alone. Lifetime costs are similarly large: Cakir et al. (2020, *Research in Autism Spectrum Disorders*) estimate ~US$3.6mn per individual in the US (2019 dollars), and the Senate Select Committee on Autism (2022) cites lifetime NDIS support costs of A$6.7mn per participant to age 70. These figures point to the economic value of therapies that improve long-term outcomes and reduce support requirements.

NTI164 Clinical Progress in ASD

NTI164 has advanced through three sequential ASD studies and commenced Phase III dosing in September 2026. The two completed studies were run at the Paediatric Neurology Unit at Monash Medical Centre and Monash Children's Hospital under principal investigator Professor Michael Fahey, Head of Paediatric Neurology and Director of Neurogenetics, who also leads the Phase III study. The sequence consists of the completed Phase I/II open-label study (NTIASD1), the completed Phase II/III randomised placebo-controlled study (NTIASD2), and the Phase III registrational study, Beyond Harmony, which received Human Research Ethics Committee (HREC) approval on 2 February 2026, initiated its first clinical site on 17 March 2026 and dosed its first patient on 21 September 2026. Neurotech has described Beyond Harmony as the final clinical study required before submitting NTI164 for market authorisation.

The Phase I/II study established tolerability and produced improvement that persisted beyond two years. NTIASD1 was a single-arm, open-label dose-escalation study in 14 paediatric patients aged 8 to 17 with Level 2 or Level 3 ASD, with dosing underway by April 2022. Patients received NTI164 across four dose levels from 5 to 20 mg/kg/day. Efficacy was assessed using the Clinical Global Impression-Severity (CGI-S) scale, a standard clinician-rated measure in psychiatric and neurodevelopmental trials. The clinician rates the patient's overall illness from 1 (normal, not at all ill) to 7 (among the most extremely ill), judged against their experience of other patients with the same diagnosis (Exhibit 4).

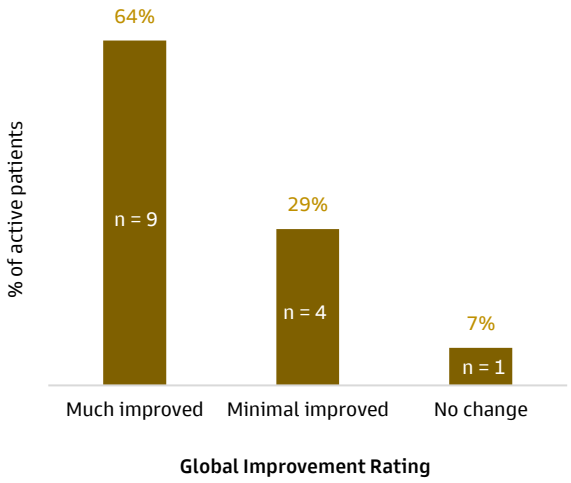
Exhibit 4: Lower CGI-S scores indicate less severe illness on a seven-point clinician-rated scale

Source: Guy (1976), ECDEU Assessment Manual for Psychopharmacology; Canary Capital Equity Research

On 8 July 2022, Neurotech announced the initial 28-day results. On the Clinical Global Impression-Improvement (CGI-I) scale, 93% of patients improved, with 64% rated much improved and only one patient unchanged (Exhibit 5). Clinicians rated the therapeutic effect as marked in 14% of patients and moderate in 72% (Exhibit 6). Mean CGI-S fell from 4.4 at baseline, in the moderately ill range, to 3.6 after 28 days, moving towards mildly ill. This is a statistically significant mean reduction of 0.7 points (p=0.027) (Exhibit 7). The treatment was also well tolerated, with no serious adverse events reported and no clinically significant changes in blood or liver function tests.

Exhibit 5: NTI164 delivered a Much Improved rating in 64% of patients, with only one non-responder

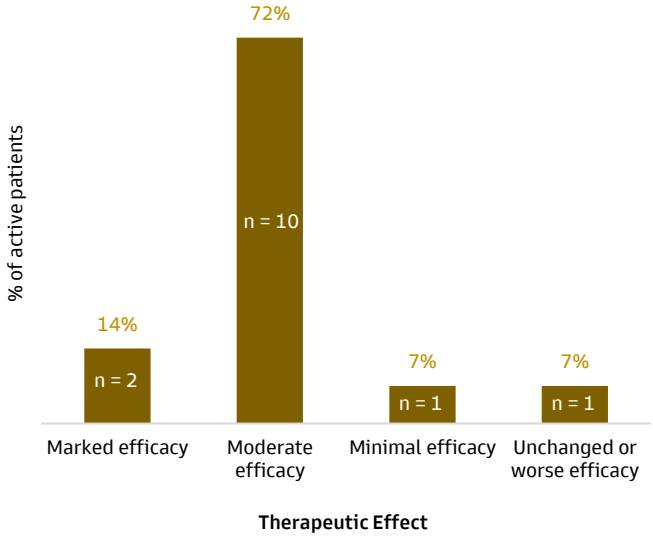
CGI Global Improvement at 28 days of NTI164 treatment



Source: Company Data

Exhibit 6: 86% of patients recorded a moderate or marked therapeutic effect, with only one patient unchanged

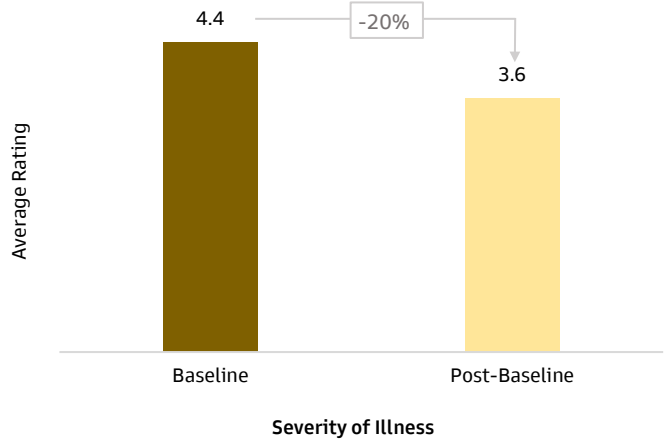
CGI Therapeutic Effect Index after 28 days of NTI164 treatment



Source: Company Data

Exhibit 7: Mean CGI-S fell 18% over 28 days, from 4.4 (moderately ill) to 3.6, moving towards mildly ill

CGI-S Severity of Illness after 28 days of NTI164 treatment



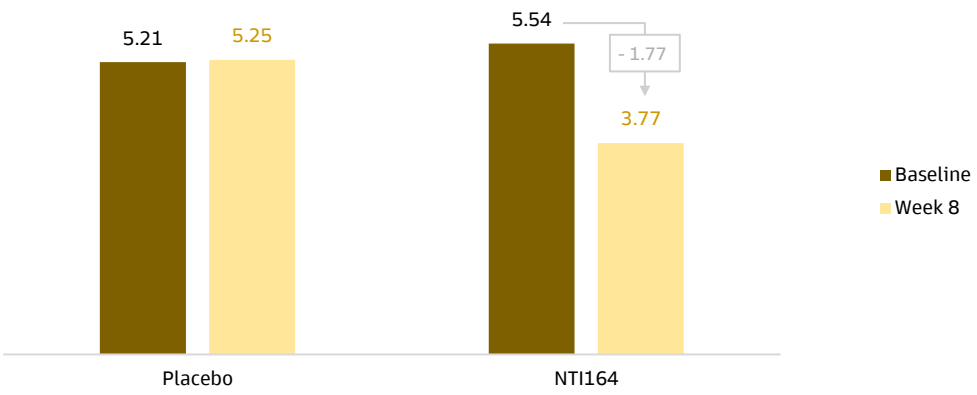
Source: Company Data

Following the positive initial results, the study was extended beyond its original 28-day design to assess longer-term safety and efficacy. On 17 March 2023, Neurotech reported the 52-week results from 11 continuing patients, with mean CGI-S improving from 4.3 to 3.0, a 30.2% reduction. None of the approximately 40% of participants classified as markedly or severely ill at baseline remained in either category from week 4 onwards. The 11 continuing patients subsequently transitioned to daily treatment under the Special Access Scheme Category B pathway, and in June 2024 the company reported that the cohort had surpassed two years of continuous dosing, with no reportable serious adverse events and no discontinuations due to safety concerns or loss of benefit.

The placebo-controlled Phase II/III study met its primary endpoint and key secondary endpoints. The NTIASD2 trial commenced on 19 December 2022 with the first patient randomised and treated, ultimately enrolling 61 paediatric patients with Level 2 and Level 3 ASD, of whom 54 completed the randomised period. Patients received NTI164 at up to 20 mg/kg/day or placebo for eight weeks in a double-blind period, followed by open-label maintenance and an optional extension for up to 54 weeks. On 17 April 2024, Neurotech announced positive top-line results. The primary endpoint, severity of illness, was met, with mean CGI-S improving from 5.54 at baseline, indicating markedly-to-severely ill, to 3.77 after eight weeks, versus no meaningful change on placebo ($p<0.001$) (Exhibit 8). Peer-reviewed results published in *Neurotherapeutics* in August 2026 showed a placebo-adjusted CGI-S reduction of 1.65 points, more than one and a half categories on the seven-point scale. The trial was powered to detect a 0.9-point difference, making the observed effect almost twice the anticipated magnitude. Key secondary endpoints were also met. On CGI-I, NTI164 produced a 1.38-point greater improvement than placebo at eight weeks ($p<0.001$) (Exhibit 9). Vineland-3 adaptive functioning also improved significantly ($p=0.021$), alongside social cognition and restricted and repetitive behaviours on the Social Responsiveness Scale. The largest effects were observed in mood and anxiety, with caregiver-rated Anxiety, Depression and Mood Scale (ADAMS) improving by 18.47 points more than placebo ($p<0.001$). Caregivers also reported significantly better family quality of life on the Autism Family Experience Questionnaire (AFEQ) ($p=0.008$). Tolerability remained consistent with the earlier study, with no new safety concerns. These results provided the first placebo-controlled evidence that NTI164 can meaningfully improve ASD severity and related functioning, supporting the Phase III study and the company's ongoing regulatory discussions with the TGA and FDA.

Exhibit 8: Mean CGI-S fell from 5.54 to 3.77 on NTI164 while placebo was unchanged, markedly-severely ill down to mild-moderately ill

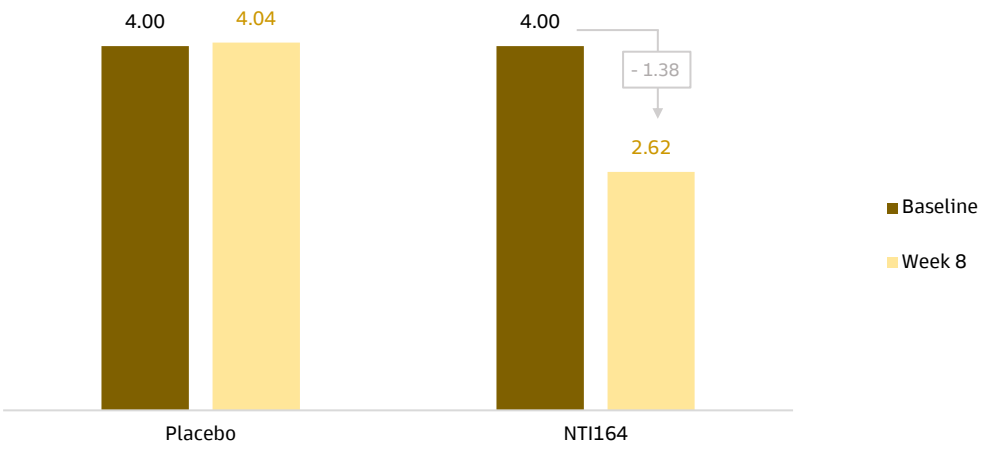
Mean severity of illness



Source: Company Data

Exhibit 9: NTI164 delivered a 1.38-point improvement in CGI-I at 8 weeks versus no change on placebo

CGI-I



Source: Company Data

Beyond Harmony is structured as a single registrational study intended to support both TGA and FDA submissions. Following HREC approval in February 2026, Neurotech initiated the first clinical site at Monash Children's Hospital in March 2026, opening the study to patient screening and recruitment. On 21 September 2026, the company announced that all six sites, located across Victoria, Queensland, New South Wales, Tasmania and Western Australia, had been initiated and that the first patient had been dosed, which formally commenced the study. The trial is a multi-centre, randomised, double-blind, placebo-controlled study in participants aged 6 to 25 with Level 2 and Level 3 ASD, again led by Professor Fahey, with up to 200 patients planned for enrolment. The adaptive design permits pre-specified modifications at interim analysis without compromising statistical validity, and the study targets core ASD symptoms alongside the underlying neuroinflammatory mechanism. Following media coverage of the trial, the company has received more than 300 enquiries from parents and caregivers seeking information about participation and considers this level of interest sufficient to recruit the required number of participants within the planned time frame.

The non-clinical package supported FDA review, resulting in IND clearance in July 2026. In the March 2026 quarter, Neurotech reported results from a 90-day GLP repeat-dose oral toxicity study in animals, conducted to give the FDA the non-clinical safety data required for the planned US clinical study. NTI164 was tolerated at 216 mg/kg/day, roughly ten times the highest human dose evaluated to date on a mg/kg basis, or approximately six times on a human equivalent dose (body surface area) basis, with no dose-limiting toxicity and only mild findings at higher doses that reversed within a 14-day recovery period. Enhanced brain sectioning and analysis, incorporated after FDA Type C and Type D meeting interactions, identified no safety concerns. On 14 July 2026, the FDA cleared the company's IND application for NTI164. The clearance permits a US population pharmacokinetic study to run alongside Beyond Harmony to generate US-specific exposure data, while the broader Phase III program is intended to provide a common efficacy and safety dataset for both jurisdictions. The approach avoids separate registration trials in Australia and the US and could allow NTI164 to support submissions in both markets from a single registrational program and readout.

ASD Drug Development Landscape

Limited pharmacological options leave core ASD symptoms largely untreated. There are currently no approved therapies that treat the neuroinflammation underlying ASD. The only FDA-approved pharmacological treatments, the atypical antipsychotics risperidone and aripiprazole, were originally developed to treat schizophrenia and primarily target irritability and aggression rather than ASD's core symptoms. However, both medications carry significant side effects, including weight gain and sedation. This leaves a substantial patient population without an effective, well-tolerated option. To address this gap, a number of companies are developing candidates against different biological pathways, including dopamine and serotonin signalling, cannabinoid pathways and the gut microbiome (Exhibit 10). Cannabinoid-based candidates are currently the only approaches that target neuroinflammation as a potential mechanism for addressing the core symptoms of ASD.

Exhibit 10: NTI164 is the most advanced clinical asset targeting autism's core symptoms

ASD clinical development pipeline, selected companies

Company	Drug	Target / Mechanism	Main Symptoms being Targeted	Pre-Clinical	Phase I	Phase II	Phase III	FDA Approval
Janssen Pharmaceutica	Risperidone	Dopamine and serotonin receptor antagonist	Irritability					1993
Otsuka Pharmaceutical	Aripiprazole	Dopamine partial agonist and serotonin antagonist	Irritability					2009
Curemark	CM-AT	Enhanced protein digestion	Irritability					
Neurotech International*	NTI164	Neuroinflammatory modulation	Core symptoms				◊	
Yamo Pharmaceuticals	L1-79	Tyrosine hydroxylase inhibitor	Core symptoms					
Sci-Sparc*	SCI-210	Enhanced endocannabinoid signalling	Core symptoms			◊		
DeFloria*	AJA001	Endocannabinoid system modulation	Core symptoms					

(1) * denotes a cannabinoid-based candidate (2) ◊ denotes an on-going trial

Source: Company Data, Canary Capital Equity Research

NTI164 maintains a clinical lead among cannabinoid-based ASD therapies. The most direct comparables for NTI164 are DeFloria's AJA001 and SciSparc's SCI-210, given their cannabinoid-based formulations. However, the two programs employ meaningfully different approaches. SCI-210 combines CBD with palmitoylethanolamide (PEA), which is intended to enhance endogenous cannabinoid signalling through the proposed "entourage effect". SciSparc is evaluating SCI-210 against CBD alone in 60 children and adolescents with ASD, although the study is not formally assigned a clinical phase and efficacy data have not yet been reported. AJA001 is a full-spectrum botanical formulation containing CBD and other cannabinoids, which DeFloria believes may act across multiple signalling pathways involved in neuronal and immune function. AJA001 completed Phase I in 2024 in 70 healthy adults, demonstrating acceptable tolerability and dose-proportional pharmacokinetics, and received FDA clearance to proceed to Phase II. DeFloria's latest update indicated that it planned to commence its 60-patient, 12-week Phase II study in mid-2026. Against these programs, NTI164 holds a clear development lead as the only cannabinoid-based ASD candidate to have progressed into Phase III.

Non-cannabinoid mechanisms target narrower aspects of ASD. Beyond cannabinoid-based competitors, several programs employ substantially different mechanisms and demonstrate the breadth of the ASD development landscape. Curemark's CM-AT is a pancreatic enzyme replacement therapy designed to improve protein digestion and amino acid availability through the gut–brain axis. Its Phase III Blum Study in 190 children aged 3–8 produced a statistically significant reduction in irritability and agitation on the Aberrant Behavior Checklist (ABC) but failed to demonstrate a significant improvement in lethargy or social withdrawal. Yamo Pharmaceuticals' L1-79 is an oral tyrosine hydroxylase inhibitor designed to modulate catecholamine synthesis and primarily address the social and communication deficits of ASD. Following its 58-patient Phase II study that produced a statistically significant improvement in social functioning versus placebo, Yamo plans to commence registrational Phase III trials in early 2027. These programs point to the differentiation of NTI164, which is being developed to address both core and associated ASD symptoms rather than a single symptom domain.

ASD Drug Development Remains Highly Challenging

The ASD drug development landscape remains characterised by significant efficacy and regulatory risk, with several high-profile programs failing to demonstrate meaningful benefit despite progressing into late-stage clinical development.

Efficacy risk persists despite advances into late-stage development. In June 2026, MapLight Therapeutics' Phase II IRIS trial of ML-004 failed to meet its primary endpoint for improving social communication deficits. The failure illustrates the difficulty of demonstrating efficacy against ASD's core symptoms. While a prespecified subgroup of adolescents with higher baseline irritability showed a positive signal, the overall study did not support the primary objective. Several earlier programs provide further evidence of this risk. Roche's balovaptan, which had received FDA Breakthrough Therapy Designation, failed to improve socialisation and communication in its Phase III V1aduct study; the trial was terminated early for futility after placebo outperformed treatment on the Vineland-II composite measure. Servier's bumetanide similarly failed in two large Phase III SIGN studies involving 422 children and adolescents, with no significant improvement versus placebo on the primary CARS2 measure or secondary endpoints, and the program was discontinued. Novartis' mavoglurant failed to demonstrate efficacy in two Phase IIb studies in adolescents

and adults with Fragile X syndrome, a related neurodevelopmental condition, and development was discontinued in 2014.

Regulatory approval remains an additional hurdle even after positive clinical data. Astrogen's AST-001 illustrates the challenge of translating positive clinical data into approval. Its Phase II study reported statistically significant improvements in adaptive behaviour and certain communication and motor-skill measures, and Astrogen submitted an NDA to Korea's Ministry of Food and Drug Safety (MFDS) in June 2025. More than a year later, the program remains under regulatory review, with the company seeking approval for paediatric treatment of core ASD symptoms.

Rett Syndrome

Indication Overview

Rett syndrome is a progressive, X-linked neurodevelopmental disorder associated with severe physical and cognitive disability. The disease triggers developmental regression, typically after a period of normal early growth. Manifestations are wide-ranging and include the loss of acquired language and purposeful hand use, intellectual disability, seizures and severe anxiety.

The underlying cause is a random mutation in the MECP2 gene on the X chromosome. The MECP2 gene encodes a protein vital for normal brain development and the maintenance of mature biochemical communication between neurons. In over 99% of cases, Rett syndrome is not inherited; the mutation arises sporadically at conception. Because the mutation is carried on the X chromosome, Rett syndrome primarily affects females, as males, who have only one X chromosome, typically do not survive to birth or beyond early infancy.

Current Unmet Medical Need

Rett syndrome is a rare disease, affecting approximately 1 in 10,000–15,000 females (Samanta, *Frontiers in Neurology*, 2026), with a global patient population of ~350k according to the company. Most cases are caused by loss-of-function mutations in the MECP2 gene, yet management has historically been limited to symptomatic and supportive care. Trofinetide (Daybue) remains the only FDA-approved therapy, and gene therapies aimed at restoring MeCP2 function are still in development. This leaves considerable room for a therapy that targets neuroinflammation and helps young patients build functional skills and independence.

NTI164 Clinical Progress in Rett Syndrome

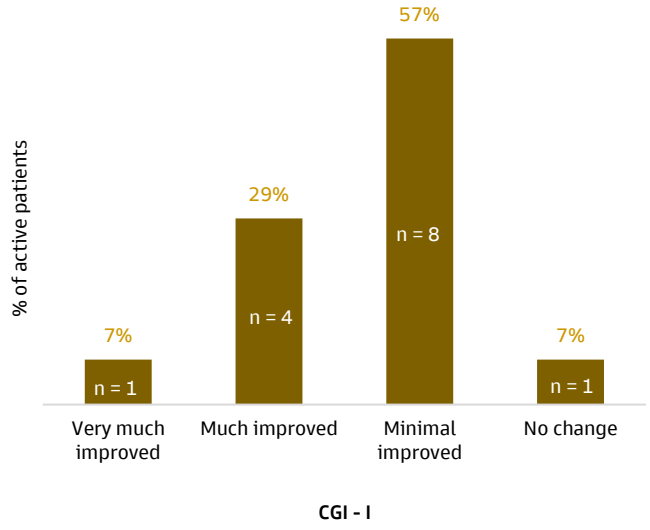
Rett syndrome is the second most advanced indication and carries the strongest regulatory designation package in the portfolio. The program consists of a completed Phase I/II open-label study (NTIRTT1, also designated FENRTT1) conducted at The Children's Hospital at Westmead under Associate Professor Carolyn Ellaway, and a randomised placebo-controlled follow-on study (NTIRTT2 / FENRTT2, NCT07257978) that is registered but has not begun recruiting. The Phase I/II results have been published in a peer-reviewed journal, and NTI164 holds US Orphan Drug Designation, European Commission Orphan Drug Designation and US Rare Pediatric Disease Designation in this indication.

The Phase I/II study met its primary endpoint at 12 weeks in a cohort of 11 patients. NTIRTT1 received HREC approval and TGA Clinical Trial Notification (CTN) clearance on 10 July 2023, with the first patient enrolled and treated on 1 August 2023. The study was a single-arm, open-label trial in female patients aged 5 to 11 with classical Rett syndrome confirmed by a pathogenic MECP2 variant, dosed twice daily at up to 20 mg/kg/day over a 12-week treatment phase following a four-week up-titration. Recruitment of all 11 patients was completed on 26 September 2023, and all participants subsequently elected to continue treatment under a 52-week extension.

On 6 May 2024, Neurotech announced positive results from the 12-week treatment period. On the primary CGI-I measure, 93% of patients (Exhibit 11) improved from baseline across four core Rett domains, with 36% rated much improved or very much improved (p=0.001). On the Rett Syndrome Behaviour Questionnaire (RSBQ), the accepted symptom measure in the disease and a secondary endpoint in the study, the mean improvement from baseline tripled from -4.4 at week 4 to -13.4 at week 12 (Exhibit 12), a statistically significant (p<0.001) and clinically meaningful 30% reduction in mean RSBQ score. CGI-S, another secondary endpoint, improved by a statistically significant 0.4 points (8.7%) at 12 weeks versus baseline (Exhibit 13).

Exhibit 11: At 12 weeks, 93% of Rett patients improved on the four-domain CGI-I composite, with 36% "very much" or "much improved"

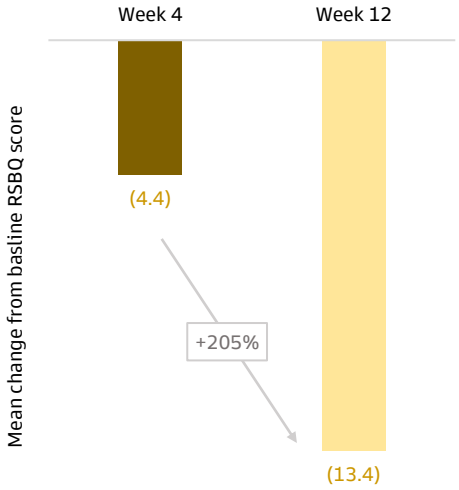
CGI



Source: Company Data

Exhibit 12: Mean RSBQ improvement tripled from -4.4 at week 4 to -13.4 at week 12

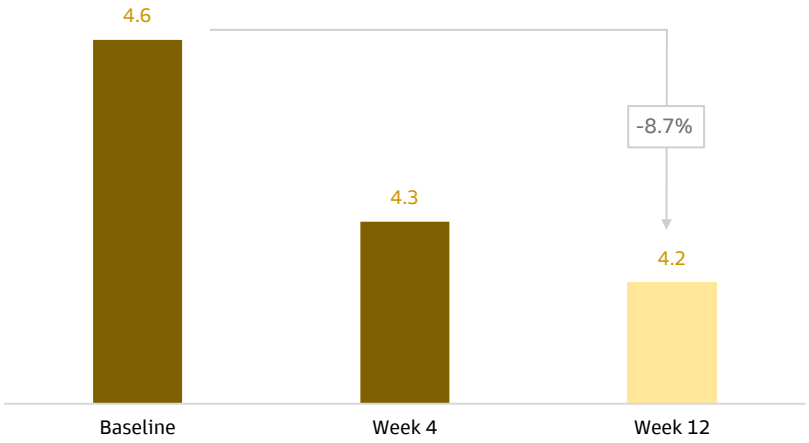
CGI Change in baseline RSBQ scores



Source: Company Data

Exhibit 13: Mean CGI-S improved 0.4 points (8.7%) to 4.2 at 12 weeks

Mean severity of illness



Source: Company Data

At 20 weeks, clinical improvements continued to deepen from the 12-week results. The proportion of patients showing improvement on CGI-I increased from 93% at 12 weeks to 100% at 20 weeks ($p<0.001$), while the proportion rated much improved or very much improved rose from 36% to 57%. No serious adverse events were reported during the 20-week treatment period.

The randomised follow-on study has been registered but is not yet recruiting. ClinicalTrials.gov lists NTIRTT2 as a Phase II/III, randomised, double-blind, placebo-controlled crossover study enrolling 40 female patients aged 4 to 25 years with a documented pathogenic MECP2 variant, a Rett Syndrome Clinical Severity Scale score of 10–36, and a CGI-S score of ≥4. The study is designed to run for 28 weeks, followed by an optional extension of up to 52 weeks, and will be conducted at Monash Health. According to the trial registration, the study was scheduled to commence on 1 July 2026, with estimated completion on 1 October 2028. However, as of October 2026, Neurotech has not provided an update on the timing of trial initiation.

A mechanistic collaboration runs alongside the clinical work without advancing the regulatory pathway. In February 2026 Neurotech announced a research program with The University of Sydney led by Professor Wendy Gold, using human-derived Rett neuronal models to examine how NTI164 acts on disease mechanisms associated with MECP2 deficiency. The work is preclinical and mechanistic, and we treat it as supporting evidence for the platform rather than as a step towards registration.

Rett Syndrome Drug Development Landscape

Daybue establishes a commercial benchmark but leaves significant room for safer alternatives. Daybue (trofinetide), developed by Neuren Pharmaceuticals and marketed in the US by Acadia Pharmaceuticals, became the first FDA-approved treatment for Rett syndrome in March 2023. Daybue is a synthetic analogue of glycine-proline-glutamate (GPE), a naturally occurring brain peptide, designed to repair neuronal connections while reducing inflammation. Daybue is being rolled out globally, with Acadia Pharmaceuticals currently awaiting European Commission approval and conducting accelerated clinical trials to support a regulatory application in Japan in 2027. However, Daybue has yet to enter the regulatory

approval pathway in Australia. In Q2 2026, Acadia generated US$125m in net Daybue sales, which indicates the scale of the still largely untapped Rett syndrome TAM.

Daybue nonetheless has several limitations that could constrain its long-term adoption. Tolerability and treatment persistence remain key concerns, with 85% of patients experiencing diarrhoea during the initial 12-week clinical trial, including 49% who experienced chronic diarrhoea. Other reported adverse events included vomiting (29%) and weight loss (12%). These tolerability issues contributed to 17.2% of patients discontinuing treatment during the 12-week trial, primarily due to gastrointestinal adverse events. Real-world data suggest that treatment persistence remains challenging over the longer term, with only 55% of patients remaining on therapy after 12 months, implying an attrition rate of approximately 45% as families manage the gastrointestinal side effects of twice-daily dosing.

Due to Daybue's significant tolerability challenges, there remains a clear unmet need for safer and better-tolerated treatment options, and this creates an opportunity for competing therapies to capture market share (Exhibit 14).

Exhibit 14: NTI164 is the sole cannabinoid-based drug candidate in development globally

Rett syndrome clinical development pipeline, selected companies

Company	Drug	Target / Mechanism	Pre-Clinical	Phase I	Phase II	Phase III	FDA Approval
Acadia Pharmaceuticals	Daybue (Trofinetide)	IGF-1 pathway modulation					2023
Anavex Life Sciences	Blarcamesine	Sigma-1 receptor agonist					
UCB	Fenfluramine	Serotonin receptor agonism					
Neurogene	NGN-401	MECP2 gene replacement					
Taysha Gene Therapies	TSHA-102	MECP2 gene replacement					
Minoryx Therapeutics	Leriglitazone (MIN-102)	PPAR-γ agonism					
Neurotech International*	NTI164	Neuroinflammatory modulation					
Unravel Biosciences	RVL-001	Histone deacetylase inhibition					

(1) * denotes a cannabinoid-based candidate (2) ◊ denotes an on-going trial

Source: Company Data, Canary Capital Equity Research

Emerging therapies are targeting Rett syndrome through multiple biological pathways. The pipeline includes SIGMAR1 activation (Anavex's blarcamesine), serotonergic modulation (UCB's fenfluramine), metabolic and anti-inflammatory modulation (Minoryx's leriglitazone), epigenetic regulation (Unravel's RVL-001) and potentially disease-modifying MECP2 gene replacement therapies from Neurogene and Taysha. Among these, the gene therapies represent the most direct attempts to address the underlying genetic cause of Rett syndrome, while most small-molecule therapies seek to improve downstream neuronal, behavioural or metabolic dysfunction. Although NTI164 trails competing drugs in clinical development, early Rett syndrome data have demonstrated statistically significant improvements in communication, mental alertness, socialisation/eye contact, and anxiety. Its low-THC, full-spectrum cannabinoid formulation also offers a potentially favourable tolerability profile relative to competing therapies, while its proposed ability to modulate neuroinflammation through activated microglia provides a differentiated mechanism.

PANS/PANDAS

Indication Overview

Paediatric Acute-onset Neuropsychiatric Syndrome (PANS) is a severe, childhood-onset neuropsychiatric condition marked by the sudden, dramatic emergence of obsessive-compulsive disorder (OCD) or severely restricted food intake. Onset is often encephalitic in nature and is hypothesised to reflect a misdirected immune response. Its principal clinical subcategory, Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS), is triggered specifically by a Group A Streptococcal infection.

Both syndromes present with a debilitating array of concurrent neuropsychiatric and somatic symptoms, including acute separation anxiety, extreme emotional lability, motor tics, sleep disturbance and a rapid decline in school performance. Symptoms flare abruptly and relapse with each subsequent immune activation or new infection. Clinical severity varies widely: milder cases allow children to continue attending school with accommodations, while severe presentations can become life-threatening through absolute food restriction or profound suicidality.

Current Unmet Medical Need

PANS/PANDAS is rare: a retrospective review of three US primary care populations (Wald et al., *Frontiers in Pediatrics*, 2023) estimated annual incidence at 1 in 11,765 children aged 3–12, with variation across sites. No therapy is currently approved for PANS/PANDAS. Treatment is largely off-label and may include antibiotics, corticosteroids, NSAIDs, intravenous immunoglobulin (IVIG) and, in severe cases, plasma exchange. These approaches primarily manage symptoms or broadly modulate the immune response rather than target the underlying disease process.

NTI164 Clinical Progress in PANS/PANDAS

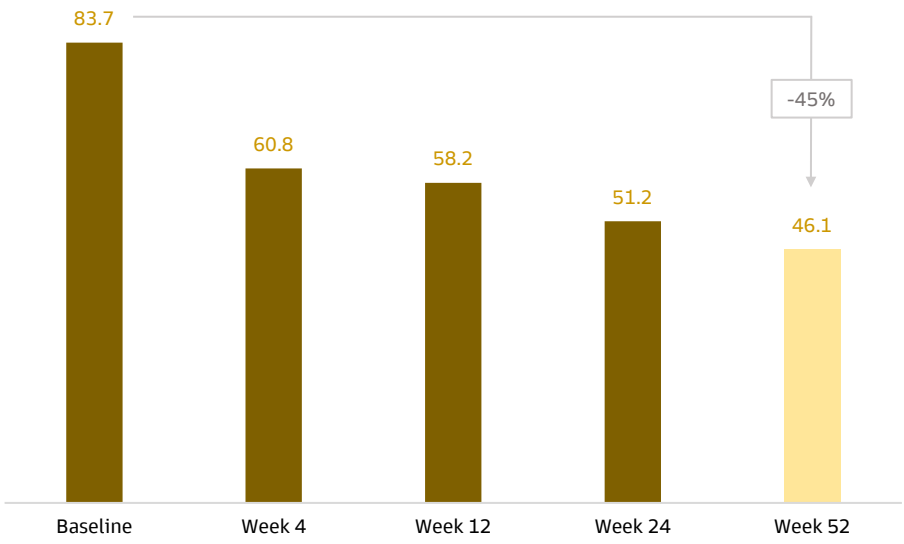
The PANS/PANDAS program consists of one completed Phase I/II study with no randomised follow-on announced. The study, NTIPANS1, was a single-arm, open-label trial in 14 paediatric patients, aged between 4 and 17, with moderate-to-severe PANDAS/PANS, run across The Children's Hospital at Westmead and the Paediatric Neurology Unit at Monash Medical Centre under co-principal investigator Professor Russell Dale. Patients received NTI164 at up to 20 mg/kg/day over an initial 12-week period, with an extension taking treatment to 52 weeks. Unlike ASD, where Phase III dosing is underway, and Rett syndrome, which has a registered randomised follow-on, there is no confirmed placebo-controlled study in this indication.

The study met its primary endpoints and reported deepening improvement through 52 weeks. Neurotech announced 12-week results on 6 October 2023 and the Revised Children's Anxiety and Depression Scale-Parent (RCADS-P) improved approximately 30% from baseline (p=0.016), with mean total T-score falling from 83.7 to 58.2 (Exhibit 15), and CGI-S improved from markedly ill (5.0) to moderately ill (4.1), an 18% improvement (p=0.0005) (Exhibit 16). At 24 weeks, reported in February 2024, RCADS-P improvement had reached 39%, with 32% of patients moving from markedly ill at baseline to mildly ill.

At 52 weeks, results reported in June 2024 showed further improvement, with CGI-S improving by 38% and RCADS-P by 45%. No serious or severe adverse events were recorded.

Exhibit 15: RCADS-P anxiety/depression scores fell 45% over 52 weeks, taking patients from above the clinical threshold (83.7) to low severity (46.1)

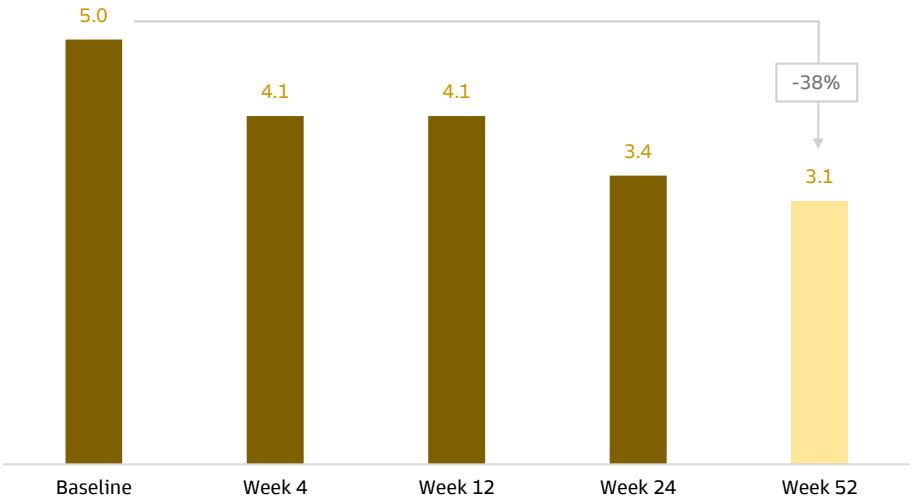
RCADS-P Scores



Source: Company Data

Exhibit 16: Mean CGI-S improved 38% over 52 weeks, re-classifying patients from markedly ill (5.0) to mildly ill (3.1)

Mean severity of illness



Source: Company Data

PANS/PANDAS Drug Development Landscape

NTI164 is the only candidate with an active clinical program in PANS/PANDAS. Octapharma's Panzyga, an intravenous immunoglobulin, was the most advanced program to date, but its 71-patient Phase III study missed its primary endpoint in May 2025, with a 31.1% improvement in obsessive-compulsive symptoms (Children's Yale-Brown Obsessive Compulsive Scale, CY-BOCS) against 12.1% on placebo falling short of significance (p=0.072). No follow-on study or PANS regulatory filing has been announced since. NTIPANS1, by contrast, met its primary endpoints with no serious adverse events, and NTI164 is the first cannabinoid-based candidate to report clinical improvement in the indication, with a non-invasive oral alternative to infusion-based therapy.

Cerebral Palsy

Indication Overview

Cerebral palsy (CP) is a group of permanent disorders of movement and posture attributed to a non-progressive disturbance in the developing foetal or infant brain, and the most common cause of lifelong childhood-onset physical disability, affecting approximately 1 in 500 newborns worldwide. It presents in four forms: spastic (stiff muscles and exaggerated reflexes, reflecting injury to the motor cortex and corticospinal tracts), dyskinetic (involuntary movements), ataxic (impaired balance and coordination) and mixed.

Neurotech will target spastic CP first, with the option to expand into the residual population later. Spastic CP is the dominant presentation at approximately 80% of diagnoses, and its

motor phenotype is the most readily measurable in a trial setting. Severity is graded by the Gross Motor Function Classification System (GMFCS), a five-level scale from independent ambulation to full dependence on assisted mobility. Most patients also carry associated conditions that are not required for diagnosis but drive much of the day-to-day burden, including epilepsy, chronic pain, sleep disturbance and intellectual disability. Existing therapy largely leaves these to supportive care, and Neurotech's planned secondary endpoints target them directly.

Current Unmet Medical Need

An estimated 17mn people live with CP worldwide, including ~34k in Australia (Cerebral Palsy Alliance), where around 1 in 715 babies is diagnosed with the condition (MCRI). Applying the share of spastic CP, we estimate an addressable domestic population of ~27k, with Neurotech's initial paediatric cohort smaller again. No approved therapy addresses the underlying brain injury, and the standard of care remains focused on symptom management and supportive interventions. The commercial opportunity is therefore driven less by population scale than by the high cost associated with each patient: Deloitte Access Economics (2019) estimated the total cost of CP in Australia at more than A$145k per person in 2018, including lost wellbeing. This points to the value of an effective disease-modifying treatment.

NTI164 Clinical Progress in Cerebral Palsy

The cerebral palsy program holds regulatory clearance and nothing beyond it. In January 2024 Neurotech received HREC approval and TGA clearance under the CTN scheme to commence a Phase I/II study of NTI164 in paediatric patients with spastic cerebral palsy. The approved design is a single-arm, open-label study in up to 14 paediatric patients with spastic diplegic CP at GMFCS levels II–III. The primary endpoint is the Caregiver Priorities and Child Health Index of Life with Disabilities (CPCHILD) at 12 weeks, with secondary endpoints covering safety, pain, sleep, seizure frequency, dystonia and spasticity.

The company has not announced trial registration, patient recruitment, first patient dosed, or any clinical result in the more than two years since. No patient has been dosed and no clinical data exist in this indication. We understand that Neurotech has deprioritised the cerebral palsy program in favour of ASD; the program is effectively on hold.

Cerebral Palsy Drug Development Landscape

Approved therapy is confined to symptom control, and none of it is oral, systemic and non-sedating. There is no cure for spastic CP, and protocols remain focused on symptom management through supportive care, physiotherapy, speech and language therapy, and muscle relaxants such as diazepam, baclofen and clonazepam (Exhibit 17). Only two targeted interventions carry FDA approval. Botox (botulinum toxin type A) is injected locally into overactive muscles from 18–24 months of age. Each cycle gives roughly three months of relief, and the approach works best where motor control is retained and target muscles are few. Baclofen, delivered by implantable pump into the cerebrospinal fluid, is reserved for severe spasticity unresponsive to oral medication. However, it carries drowsiness and infection risk, and pump failure can trigger life-threatening acute withdrawal.

Exhibit 17: NTI164 would be the only oral systemic candidate in spastic cerebral palsy

Cerebral palsy clinical development pipeline, selected companies

Company	Drug	Target / Mechanism	Pre-Clinical	Phase I	Phase II	Phase III	FDA Approval
Allergan (now part of AbbVie)	BOTOX (Botulinum Toxin Type A)	SNARE protein inhibitor					2020
Ciba-Geigy (now part of Novartis)	Baclofen	GABA-B receptor agonist					1992
Merz Therapeutics	XEOMIN (NT 201)	SNARE protein inhibitor					
Dompé Farmaceutici	Cenegermin-bkbj	Nerve growth factor agonist					
StemCyte	RegeneCyte (SCCP001)	Human umbilical cord blood infusion					
Neurotech International*	NTI164	Neuroinflammatory modulation					

(1) * denotes a cannabinoid-based candidate (2) ◊ denotes an on-going trial

Source: Company Data, Canary Capital Equity Research

Competition is advancing, but disease-modifying alternatives remain early stage. Merz Therapeutics reported positive Phase III ELLIE results for Xeomin (NT 201) in paediatric lower limb spasticity and filed for an EU/EEA label extension covering ages 2–17 in January 2026. Among emerging disease-modifying approaches, Dompé Farmaceutici is the closest comparator, with intranasal nerve growth factor (cenegermin-bkbj) designed to target underlying brain injury and its first Phase II patient enrolled in March 2026. Other candidates remain earlier stage, including StemCyte's RegeneCyte, an allogeneic cord-blood product in Phase II. However, each of these approaches involves localised injection, complex delivery or a direct muscle target, in contrast to an oral systemic therapy.

NTI164 is differentiated by its delivery and proposed mechanism but remains Neurotech's least advanced asset. If the Phase I/II study proceeds, NTI164 would offer a non-invasive, orally administered daily liquid formulation designed to achieve a systemic effect without the sedation associated with conventional muscle relaxants. Its proposed mechanism may also provide broader applicability than spastic presentations, as microglial over-activation is hypothesised to contribute to cerebral palsy across subtypes. However, unlike Neurotech's more advanced programs, NTI164 has yet to generate any clinical data in this indication.

Valuation

We value NTI at A$0.155 per share on a probability-weighted basis, 1,093% above the last close of A$0.013. Our success scenario, in which NTI164 completes the Beyond Harmony Phase III program, secures TGA registration and launches into the Australian ASD market, supports a value of A$0.259 per share. Our failure scenario carries nil value. Weighting the two outcomes at 60% and 40% produces our intrinsic value per share estimate. The valuation prices the Australian ASD opportunity alone: Rett syndrome, PANS/PANDAS, cerebral palsy and all offshore markets are excluded, so each successful step in those programs would add value that our numbers do not yet recognise.

Methodology

We value NTI on a discounted cash flow basis, using EBITDA as a proxy for free cash flow and an EV/EBITDA exit multiple for the terminal value. We forecast NTI164's Australian ASD revenue over the ten years from FY30 to FY39, a period we consider adequate for the drug to approach its estimated penetration potential. EBITDA margin starts at 5% in FY30 and rises in equal annual steps to a 22.5% target in FY39 as fixed costs are spread across a growing revenue base. In the terminal year we apply an exit multiple of 19.9x to FY39 EBITDA, with the target margin and the multiple each benchmarked against profitable specialty pharmaceutical peers, to derive an FY39 enterprise value of A$1,747m. We discount that value and each year's EBITDA from FY30 to FY39 back to FY27 at a WACC of 13.8%, deduct the present value of pre-launch cash burn, add cash on hand and divide by shares outstanding to reach our success scenario value. The model assumes Phase III completion and TGA registration support a commercial launch in FY30, following three years of pre-launch spending from FY27 to FY29.

Sizing the Target Patient Population

We size the addressable market from NDIS participation data rather than survey-based prevalence estimates. NDIS active participants are diagnosed and already receiving funded support, and the dataset is refreshed quarterly, which makes it a firmer commercial base than population surveys. On 30 June 2026 the NDIS recorded 350,651 active participants with autism as their primary diagnosis. From that base we include only the estimated number of participants aged 6 to 25 (272,249 people, or 77.6% of the total), consistent with the patient population being studied in NTI's Beyond Harmony trial, and only those with a medium or high reported level of function (80.7% of participants). Applying both filters produces a target population of 219,714, which we grow at 1.5% a year to 229,750 by the first year of sales and 262,694 by FY39.

Pricing Below the Current Cost of Support

We price NTI164 at A$15,000 per patient per year and hold that price flat across the forecast period, because price increases on PBS-listed medicines are difficult to obtain. The assumption sits at the bottom of the A$15,000 to A$25,000 range we consider achievable for an annual course of therapy. It is also well below what the system already spends on this population: NDIS payments to autism participants totalled A$11,208m over the year to 30 June 2026, an average of A$31,965 per active participant, before counting the informal costs carried by families who reduce or give up paid work to provide care. In randomised, placebo-controlled testing, NTI164 has delivered statistically significant improvements in clinician-rated severity and in adaptive functioning, and it targets core symptoms where risperidone

and aripiprazole address only associated irritability. We therefore expect the drug to screen well when the PBAC weighs additional health benefit per dollar against the current standard of care, and a listing recommendation would in turn support both subsidised access and uptake.

Adoption Follows an S-Curve Towards a 10% Ceiling

We model uptake with a Bass diffusion curve, an s-curve that captures the way prescribing of a novel paediatric therapy builds slowly at first and then accelerates as clinician experience spreads. Penetration starts at 0.1% of the target population in FY30 and approaches a 10% ceiling. Patient numbers build from roughly 230 in the first year of sales to 26,029 in FY39, by which point penetration reaches 9.9% and revenue growth has tapered to low single digits. The 10% ceiling is deliberately modest, implying one in ten eligible participants on therapy at maturity.

Manufacturing Costs Fall as Volumes Build

Manufacturing an annual dose of NTI164 currently costs about A$5,000. We forecast that cost declining to A$4,000 as production scales, and we phase the reduction in line with the adoption curve, so unit economics improve as volumes grow. Cost of sales also carries a 2.5% royalty on NTI164 revenue payable to Dolce Cann Global, from which Neurotech licenses the NTI164 formulation. Gross margin consequently expands from 64.2% in FY30 to 70.8% in FY39 (Exhibit 18).

Exhibit 18: NTI164 Australian ASD revenue and EBITDA build, FY30-FY39

	FY30E	FY31E	FY32E	FY33E	FY34E	FY35E	FY36E	FY37E	FY38E	FY39E
Target patient population ('000s)	229.8	233.2	236.7	240.2	243.8	247.5	251.2	255.0	258.8	262.7
Adoption rate (%)	0.1	1.6	3.4	5.3	7.0	8.3	9.1	9.6	9.8	9.9
Patients on NTI164	230	3,789	8,107	12,762	17,097	20,538	22,907	24,408	25,364	26,029
NTI164 revenue (A$m)	3.5	56.8	121.6	191.4	256.5	308.1	343.6	366.1	380.5	390.4
Manufacturing cost per annual dose (A$)	5,000	4,854	4,689	4,510	4,343	4,211	4,120	4,062	4,026	4,000
Gross margin (%)	64.2	65.1	66.2	67.4	68.5	69.4	70.0	70.4	70.7	70.8
EBITDA margin (%)	5.0	6.9	8.9	10.8	12.8	14.7	16.7	18.6	20.6	22.5
EBITDA (A$m)	0.2	3.9	10.8	20.7	32.8	45.4	57.3	68.1	78.2	87.8

Source: NDIS quarterly data (30 June 2026), Canary Capital Equity Research

Terminal Economics Benchmarked Against Profitable Peers

Terminal-year revenue of A$390.4m and a 22.5% EBITDA margin give FY39 EBITDA of A$87.8m (Exhibit 18). We benchmark the margin and the 19.9x exit multiple against ten listed specialty pharmaceutical companies selected on four criteria: revenue generation and sustainable EBITDA profitability; market capitalisation below US$50bn; approved products targeting CNS, neurodevelopmental or rare paediatric diseases overlapping NTI164's indications; and domicile in Australia, the United States, Canada, the United Kingdom or continental Europe. The peer set trades on an average trailing EV/EBITDA of 19.9x and earns

an average EBITDA margin of 23.0% (Exhibit 19). Our 22.5% target margin sits slightly below that average, which we consider prudent for a single-product, single-market company without the scale of the larger peers.

Exhibit 19: NTI comparable companies

Company	Ticker	Market Cap (A$ m)	Enterprise Value (A$ m)	TTM Margins			TTM Revenue Growth	Valuation Multiples	
				Gross Margin	EBITDA Margin	Net Margin		EV/EBITDA	P/E
Harmony Biosciences	HRMY	3,367.4	2,799.2	75.4%	26.7%	18.9%	24.3%	7.6x	12.9x
ACADIA Pharmaceuticals	ACAD	4,892.6	4,340.0	91.1%	8.7%	7.5%	11.8%	30.7x	40.1x
Neurocrine Biosciences	NBIX	20,785.1	20,307.9	98.0%	25.0%	20.9%	34.4%	16.8x	20.5x
Jazz Pharmaceuticals	JAZZ	20,354.1	24,275.4	88.4%	35.1%	20.4%	12.5%	10.5x	15.1x
BioMarin Pharmaceutical	BMRN	15,226.6	19,981.4	76.1%	8.9%	2.1%	11.1%	46.1x	145.3x
Alkermes	ALKS	9,780.2	11,203.6	84.6%	18.3%	4.0%	10.8%	25.6x	103.1x
Swedish Orphan Biovitrum	SOBI	22,069.3	24,391.1	77.8%	17.1%	4.5%	13.5%	32.3x	110.8x
H. Lundbeck	LUNB	9,752.0	11,206.0	82.1%	29.3%	15.2%	10.4%	6.9x	11.5x
Ipsen	IPN	19,225.7	16,057.9	81.0%	25.3%	11.9%	20.5%	9.2x	23.4x
Recordati	REC	17,816.5	20,900.4	69.1%	36.2%	18.4%	9.0%	13.3x	22.3x
Average				**82.4%**	**23.0%**	**12.4%**	**15.8%**	**19.9x**	**50.5x**

As of 9/10/2026

Source: Company Data, Bing Finance, Canary Capital Equity Research

Discount Rate, Cash Burn and the Equity Bridge

We discount at a WACC of 13.8%, built from a CAPM cost of equity of 8.8% (a 5.37% risk-free rate, a 4.14% equity risk premium and an unlevered industry beta of 0.84 for drug and biotechnology companies) plus a 5.0% small-cap risk premium. NTI carries no debt, so the WACC equals the adjusted cost of equity. Between FY27 and FY29 we forecast operating cash burn of roughly A$5.7m to A$6.6m a year as the company funds the Phase III program on research spending of A$7m to A$9m a year, offset in part by R&D incentive receipts equal to roughly 46% of research expenses. The present value of that burn, A$14.3m, is deducted from the combined present value of the FY39 enterprise value (A$323.7m) and FY30-FY39 EBITDA (A$106.0m) to reach an FY27 enterprise value of A$415.4m. Adding cash of A$2.4m, with no debt or minority interests to remove, gives an equity value of A$417.8m, or A$0.259 per share across 1,616.1m shares on issue (Exhibit 20).

Exhibit 20: NTI Equity Valuation Bridge

FY39 EBITDA margin (%)	22.5
FY39 EBITDA (A$m)	87.8
FY39 EV/EBITDA (x)	19.9
FY39 enterprise value (A$m)	1,747
Discount rate (%)	13.8
PV of FY39 enterprise value (A$m)	323.7
PV of FY30-FY39 EBITDA (A$m)	106.0
PV of FY27-FY29 cash burn (A$m)	(14.3)
FY27 enterprise value (A$m)	415.4
Cash and cash equivalents (A$m)	2.4
Equity value (A$m)	417.8
Success scenario value per share (A$)	**0.259**
Probability of success (%)	60.0
Failure scenario value per share (A$)	-
Probability-weighted value per share (A$)	**0.155**
Last close (A$)	0.013
Implied upside (%)	**1,093**

Source: Company Data, Canary Capital Equity Research

Probability of Success Set at 60%

We anchor our probability of success to the February 2021 study by BIO, Informa Pharma Intelligence and QLS Advisors, which covered 12,728 clinical phase transitions between 2011 and 2020 and remains the broadest published dataset of drug development outcomes. Across all indications, 57.8% of Phase III programs advanced to a regulatory filing and 90.6% of filings were eventually approved, a compound Phase III-to-approval rate of 52.4%; for psychiatry programs the equivalent figure was 51.4%.

We apply 60%, a premium of roughly eight percentage points to the base rate, for two reasons. First, NTI164 enters Phase III with randomised, placebo-controlled efficacy data already in hand at the same doses and on the same clinician-rated endpoints as the registrational study. In the Phase II/III study, the placebo-adjusted improvement in CGI-S was 1.65 points, almost twice the 0.9-point difference the trial was powered to detect. That gives the Phase III room to succeed even if the effect is smaller across a larger, multi-site population. NTI164 also carries a safety record built across completed trials in three indications and extended use under the Special Access Scheme. Second, Fenix has engaged with the TGA throughout the design and conduct of the NTI164 studies. The registration package should therefore be prepared to the regulator's known requirements, which reduces the risk of a rejection on data or format grounds.

The failure scenario carries nil value. We currently value NTI as a single-asset company, and we assume remaining cash is consumed by the trial, so a failed program would leave no recoverable equity value. Weighting A$0.259 at 60% and nil at 40% produces our intrinsic value of A$0.155 per share.

A Deliberately Conservative Base Case

Our valuation prices one indication in one country. It ascribes no value to Rett syndrome, where NTI164 holds orphan drug designation in both the US and Europe, none to PANS/PANDAS or cerebral palsy, and none to any market outside Australia despite the company's stated intention to pursue the US. A US licensing agreement struck after a successful Phase III readout would layer licensing income on top of an already attractive valuation, without the capital cost of a self-funded US launch, and none of that potential sits in our numbers. Pricing at the bottom of our achievable range and a 10% penetration ceiling add further conservatism.

Exhibit 21 shows how the intrinsic value per share responds to the two judgement calls with the widest error bars, the exit multiple and the probability of success; even the most cautious combination shown implies value more than eight times the current share price. The principal risks to our valuation are an unsuccessful or inconclusive Phase III result, reliance on future equity placements to fund the program, delay or failure in the PBS listing process, and the approval of competing ASD therapies.

Exhibit 21: Probability-weighted value per share (A$) across exit multiple and probability of success

	EV/EBITDA		
Probability of success (%)	16.9x	19.9x	22.9x
50	0.114	0.129	0.144
60	0.137	**0.155**	0.173
70	0.160	0.181	0.202

Source: Canary Capital Equity Research

Key People

Mark Davies, Executive Chairman

Mr Davies joined the board as a non-executive director in April 2019, was appointed Non-Executive Chairman on 15 August 2022 and became Executive Chairman on 17 August 2026. In the executive role, his responsibilities span corporate strategy, capital markets and funding initiatives, partnering and licensing activities, investor engagement, governance and strategic oversight of the clinical and regulatory programs. Mr Davies has more than 20 years' experience in investment banking and corporate advisory work, specialising in capital raisings for emerging Australian companies. He is Managing Director of 1861 Capital, co-founded the investment banking firm Cygnet Capital and holds a Bachelor of Commerce.

Gerald Quigley, Non-Executive Director

Appointed on 7 July 2022, Mr Quigley is a qualified pharmacist and one of Australia's most recognised consumer health commentators. His experience covers pharmaceutical and nutraceutical product development, dispensing and marketing, and product positioning within the TGA and FDA regulatory frameworks. For a company whose end users are children

and whose advocates are parents, his understanding of how paediatric therapies are dispensed and communicated to families complements the capital markets weighting of the rest of the board.

Andrew Chapman, Non-Executive Director

Appointed on 8 September 2026, Mr Chapman is the founder of Merchant Funds Management and has over 25 years' experience in the financial services industry, spent advising biotechnology companies on capital raisings and capital markets strategy and execution. He is a Non-Executive Director of Argent BioPharma (ASX: RGT) and Chairman of Cycliq Group (ASX: CYQ) and holds a Bachelor of Commerce and a Post Graduate Diploma in Finance and Investment. His appointment adds capital markets depth at the point in the company's development where the Phase III funding requirement and potential licensing negotiations dominate the agenda.

Investment Thesis

Clear Business Strategy

Neurotech's strategy concentrates all of the company's capital on the shortest, defensible path to registration for NTI164. Since divesting its legacy device business in 2025, the company has run as a pure-play developer of a single asset, and each clinical step has been sequenced to de-risk the next: an open-label study established tolerability and dose, a randomised placebo-controlled study then met its primary endpoint and every key secondary endpoint, and the Phase III program now underway tests the same doses on the same clinician-rated endpoints that succeeded under placebo control. Beyond Harmony is designed as a single registrational study capable of supporting both TGA and FDA submissions, with the FDA clearing an Investigational New Drug application in July 2026 and a US pharmacokinetic study running alongside the Australian trial. One dataset serving two regulators spares shareholders the cost and dilution of duplicate registration trials.

The commercial plan matches the company's resources. Neurotech intends to register and commercialise in Australia first, where the NDIS concentrates 350,651 diagnosed and funded autism participants within a single payer system, and where NTI164's proposed A$15,000 annual price sits below the A$31,965 the scheme already spends on the average participant each year. Offshore, the company intends to pursue licensing rather than a self-funded launch, so a successful Phase III readout could convert into licensing income without the capital cost of building a US commercial operation. For a company of Neurotech's size, we consider this the optimal strategy to realise the value of the NTI164 asset.

Scalable Business Model

NTI164 is a single formulation across the whole pipeline, so each clinical success adds value to an asset the company already owns. It has met its primary endpoint in completed studies in three indications, and every new program uses the same manufacturing process and the same safety database, which lowers the cost of entering each additional market. The adjacent markets are commercially meaningful. Acadia reported US$125m of net Daybue sales in a single quarter in Rett syndrome, where NTI164 holds orphan drug designations in the US and Europe and where our valuation includes nothing for the program.

Furthermore, we expect NTI164's unit economics to improve with volume. At an annual price of A$15,000, and with manufacturing cost per annual dose falling from about A$5,000 to A$4,000 as volumes build, gross margin rises from 64.2% to 70.8% over our forecast period, net of the 2.5% royalty payable to Dolce Cann Global. Each additional patient needs a prescription and product supply, with little incremental capital or headcount. We expect that prescribing in Australia will be concentrated among paediatric neurologists and developmental paediatricians, which keeps the domestic sales effort small, and offshore licensing would place manufacturing scale-up and distribution with partners. We therefore expect revenue to grow well ahead of operating expenditure.

IP Protection and Barriers to Entry

The most durable barrier around NTI164 is its clinical data package, which competitors are years away from replicating. NTI164 is the only cannabinoid-based ASD candidate to reach Phase III, while comparable programs remain in Phase II or earlier. This lead is particularly valuable given the high attrition in the field, as described in the earlier ASD drug development landscape section. A placebo-controlled dataset showing efficacy on clinician-rated ASD endpoints is therefore both scarce and costly to reproduce.

Neurotech's patent position has also strengthened materially. On 2 July 2026, the USPTO issued Notices of Allowance for two NTI164 applications. The allowed claims cover methods of reducing neuroinflammation and treating autism spectrum disorder. Once granted, the patents are expected to protect NTI164 in the US through 2042. While the patents are not enforceable until formally granted, the allowances provide meaningful evidence that Neurotech can secure IP protection around its plant-derived formulation.

NTI164's formulation and regulatory position provide further barriers. Its proprietary full-spectrum formulation has shown greater preclinical activity than CBD alone, while reproducing a standardised, GMP-grade botanical profile presents significant manufacturing and characterisation challenges. In Rett syndrome, US and European orphan drug designations could provide additional market exclusivity following approval, and US Rare Pediatric Disease Designation could make NTI164 eligible for a priority review voucher. In Australia, TGA registration and potential PBS listing would further strengthen NTI164's position through reimbursement, prescribing familiarity and clinician adoption.

Successful Management

Neurotech's board is weighted towards capital markets expertise, which is well suited to the company's current stage as it enters the capital-intensive Phase III and potential licensing stages of NTI164. Executive Chairman Mark Davies brings more than 20 years of investment banking and corporate advisory experience, with responsibilities spanning funding, partnering and licensing. Non-Executive Director Andrew Chapman has more than 25 years of financial services experience, including advising biotechnology companies on capital raisings. Gerald Quigley, a qualified pharmacist and consumer health commentator, adds experience across pharmaceutical and nutraceutical product development, dispensing and marketing. The board does not include a dedicated clinical development or drug registration specialist, with Neurotech instead relying on Fenix for these functions.

Led by Dr Esra Isikgel, Fenix provides the scientific, clinical and regulatory expertise supporting NTI164. Dr Isikgel holds a PhD in molecular biology and biochemistry and an MBA and has experience taking products through FDA and TGA registration. Her involvement with NTI164 predates the 2024 Strategic Collaboration Agreement. She contributed to the preclinical study characterising NTI164's anti-inflammatory and neuroprotective activity and

is a co-author of the peer-reviewed Rett syndrome and ASD publications. During Fenix's involvement, NTI164 has progressed through clinical studies in three indications, secured US and European orphan drug designations for Rett syndrome, obtained FDA IND clearance and commenced the Beyond Harmony Phase III program.

Fenix's broader team provides complementary expertise across clinical development and study operations. Chief Scientific Officer Dr Brooke Keating has a research background in neuroimmunology, including work examining immune and epigenetic factors in children with neurodevelopmental disorders, and is lead author of the Harmony and Rett syndrome publications. Fenix's Chief Operating Officer, Yelda Ogru, has a background in clinical research and biostatistics and oversees the CMC and regulatory programs, while a clinical research manager, Deb Harris, with 18 years of paediatric nursing experience manages site recruitment and study operations. At the clinical level, the ASD program is led by principal investigator Professor Michael Fahey, Head of Paediatric Neurology at Monash Children's Hospital.

The combination of a capital markets-focused board and an external development partner with specialist clinical and regulatory expertise is central to Neurotech's current operating model. The structure provides the company with access to the capabilities required to fund, develop and potentially commercialise NTI164 without maintaining a large internal clinical development function.

Significant Investment Upside

Our probability-weighted intrinsic value of A$0.155 per share is 1,093% above the last close of A$0.013, and each layer of the valuation is conservative. The success scenario includes one indication in one country, caps penetration at 10% and uses the bottom of our achievable pricing range. We then weight that scenario at 60%, with the remaining 40% assigned to a nil-value outcome. Rett syndrome, PANS/PANDAS, cerebral palsy and all markets outside Australia are excluded from our numbers and represent upside the current share price does not reflect. Our most cautious sensitivity case, a 50% probability of success and a 16.9x exit multiple, still implies a value more than eight times the current share price (Exhibit 21). We expect positive data from the ongoing Phase III trial to provide a potential catalyst for a material re-rating towards our intrinsic value estimate.

Investment Risks

Clinical Development and Single-Asset Risk

Neurotech's value rests almost entirely on a single trial. NTI164 is its only drug candidate and Beyond Harmony its only registrational study, so an unsuccessful or inconclusive readout would remove the basis for registration and, in our valuation, leave no recoverable equity value. Base rates warrant caution: 52.4% of Phase III programs reached approval across 12,728 clinical phase transitions from 2011–2020, while ASD has proved particularly challenging. Roche's balovaptan and Servier's bumetanide both failed in Phase III, while MapLight's ML-004 missed its Phase II endpoint in June 2026. Large, unpredictable placebo responses in paediatric neuropsychiatric trials add further uncertainty to a study of up to 200 patients.

The key mitigant is the evidence already in hand. NTIASD2 met its primary and key secondary endpoints in a randomised, placebo-controlled study using the same doses and clinician-rated measures as Beyond Harmony. The NTIASD1 open-label cohort has also passed two years of continuous dosing without a reportable serious adverse event. This lowers, but does not eliminate, translational risk. We therefore apply a 60% probability of success, modestly above the historical base rate, and assign nil value to failure.

Regulatory Approval and Reimbursement Risk

A successful trial would not guarantee registration or reimbursement. The TGA has never approved a therapy for autism's core symptoms, meaning NTI164 would establish a precedent, while cannabinoid medicines face additional scrutiny around quality and consistency. Astrogen's AST-001 illustrates that regulatory risk persists after positive data, with its application having remained under Korean regulatory review for more than a year despite statistically significant results.

Reimbursement is the second and commercially decisive gate. At A$15,000 a year, NTI164 is beyond the reach of most families without subsidy, so our forecasts depend on a PBS listing. A PBAC rejection or a materially restricted or repriced listing would cut adoption and revenue well below our model, and listings for novel therapies frequently take multiple PBAC cycles to secure. However, the mitigants to this risk are structural. Autism is among the most visible cost pressures in Australian public policy, with NDIS payments to autism participants of A$11.2bn in FY26 and an average payment of A$31,965 per participant, so a therapy that improves core symptoms and daily functioning at A$15,000 a year enters the cost-effectiveness discussion from favourable ground. NTI164's placebo-controlled evidence covers clinician-rated severity and adaptive functioning, and the Phase II/III study also showed a statistically significant improvement in family quality of life on the Autism Family Experience Questionnaire (p=0.008). The family result gives a health-economic assessment evidence of benefit to caregivers as well as patients, which matters in a condition where families carry much of the cost of care. Our valuation also absorbs part of this risk through the 60% probability weighting and a launch assumption no earlier than FY30.

Competition Risk

Approved competitors could reshape the commercial landscape, most likely overseas first. Yamo Pharmaceuticals plans to initiate registrational Phase III trials of L1-79 in the US in early 2027, while DeFloria's cannabinoid candidate is expected to enter Phase II. Earlier approval of either would confer first-mover advantage in the world's largest market. In Australia, competition is more subtle: risperidone and aripiprazole are already established for irritability, and clinicians may adopt a novel therapy only gradually after registration.

This risk is mitigated by geography and our valuation approach. No competing ASD program is currently advancing through an Australian registration pathway, and the Beyond Harmony trial is being conducted at Australian sites specifically for TGA submission. In our view, this positions NTI164 with the clearest path to the Australian market among candidates in development. Our valuation reflects only the Australian opportunity. Therefore, a US competitor approval would not directly impact our base-case numbers, though it could soften the licensing upside we currently exclude. Given the heterogeneous nature of ASD, no single mechanism is likely to address all patients, allowing an underserved market to support multiple products with meaningful share. NTI164's neuroinflammation-targeting mechanism and established tolerability further differentiate it from both approved antipsychotics and other candidates in development.

Intellectual Property Risk

NTI164's plant-derived, full-spectrum formulation limits conventional patent protection. Naturally occurring substances are harder to claim than novel synthetic molecules, preventing the broad composition-of-matter protection typical of new chemical entities. Enforcement could also be challenging for a company with limited resources for prolonged litigation.

However, NTI's intellectual property position strengthened on 2 July 2026, when the USPTO issued Notices of Allowance for two NTI164 patent applications covering the reduction of neuroinflammation and the treatment of ASD in paediatric patients. Once granted, these patents are expected to provide US protection through 2042, although they will not be enforceable until formal issuance. We believe that securing these US patents will also strengthen the company's corresponding applications in Australia. In addition, the Rett syndrome program holds US and European orphan drug designations, which would confer market exclusivity upon regulatory approval.

Key Partner Risk

Neurotech is highly dependent on Fenix Innovation Group, which is the CRO and study sponsor for NTI164's clinical trials and manufactures the drug at its GMP facility. A capacity constraint, GMP issue, commercial dispute or change of control at Fenix could disrupt the entire development program, and the Strategic Collaboration Agreement is terminable by either party on 90 days' notice. Manufacturing is the more significant exposure, as qualifying an alternative manufacturer able to reproduce NTI164's standardised GMP-grade botanical profile would likely be a lengthy and costly process.

The risk is partly mitigated by Neurotech retaining ownership of the IP, clinical data and drug master file, which would allow trial management to be transferred to another CRO if required. Fenix is also economically aligned with Neurotech through 15.2 million shares and 30 million performance rights linked to licensing and TGA milestones, with the rights lapsing on termination of the Agreement. The partnership has supported all NTI164 studies to date without any reported interruption.

Raw Material Supply and Scale-Up Risk

Commercial supply of NTI164 depends on cultivating and extracting sufficient volumes of the CBDA-rich cannabis strain from which the drug is derived. Commercial volumes would be well above clinical trial requirements, and meeting launch demand would require a substantial increase in both cultivated area and extraction throughput. Concentrating cultivation or extraction in a single region would expose supply to crop failure, site-specific disruption or regulatory change in that jurisdiction. A feedstock shortfall at launch could delay commercialisation or constrain sales in the initial years.

The risk is mitigated by Fenix's planned multi-regional cultivation strategy, which retains Australia as a growing base while developing large-scale cultivation offshore to support commercial volumes. Fenix is also assessing multiple extraction sites in Australia and overseas to build redundancy into the downstream supply chain, reducing reliance on any single facility. Diversifying both cultivation and extraction across jurisdictions limits the impact of a disruption at any one site.

Projected Financials

Income statement (A$'000s)

	FY26A	FY27E	FY28E	FY29E
Revenue	-	-	-	-
Cost of sales	-	-	-	-
Gross profit	**-**	**-**	**-**	**-**
Professional consultant and advisory expenses	(372)	(386)	(386)	(386)
Professional legal expenses	(44)	(74)	(74)	(74)
Corporate and administration expenses	(576)	(651)	(651)	(651)
Depreciation and amortisation expenses	-	-	-	-
Advertising and marketing expenses	(3)	-	-	-
Employee benefits expense	(678)	(420)	(452)	(485)
Share based payments expense	(612)	(210)	(226)	(243)
Research expenses	(9,047)	(9,000)	(7,000)	(9,000)
Other expenses	(14)	-	-	-
Operating income	**(11,346)**	**(10,741)**	**(8,788)**	**(10,839)**
Finance costs	-	-	-	-
Other income	4,807	4,161	3,241	4,157
Loss before income tax expense	**(6,539)**	**(6,579)**	**(5,547)**	**(6,682)**
Income tax expense	-	-	-	-
Loss after income tax	**(6,539)**	**(6,579)**	**(5,547)**	**(6,682)**

Cash flow statement (A$'000s)

	FY26A	FY27E	FY28E	FY29E
Net (Loss) after income tax	(6,539)	(6,579)	(5,547)	(6,682)
Share based payments	612	210	226	243
Forex gain/(loss)	3	-	-	-
Depreciation and amortisation	-	-	-	-
(Increase)/decrease in trade and other receivables	(254)	14	65	(65)
(Increase)/decrease in prepayments	102	19	-	-
(Increase)/decrease in Inventories	-	-	-	-
Increase/(decrease) in trade and other payables	1,851	(266)	(411)	411
Increase/(decrease) in provisions	-	(10)	0	0
Net cash (outflow) from operating activities	**(4,224)**	**(6,613)**	**(5,667)**	**(6,093)**
Payments for plant and equipment	-	-	-	-
Net cash (outflow) from investing activities	-	-	-	-
Proceeds from issue of shares, net of costs	3,580	6,122	5,667	6,093
Net cash inflow from financing activities	**3,580**	**6,122**	**5,667**	**6,093**
Net (decrease) / increase in cash	**(645)**	**(491)**	**-**	**-**
Cash at the end of the financial year	2,386	1,895	1,895	1,895
Free cash flow	(4,224)	(6,613)	(5,667)	(6,093)

Balance sheet (A$'000s)

	FY26A	FY27E	FY28E	FY29E
Cash and cash equivalents	2,386	1,895	1,895	1,895
GST/VAT/Sales tax receivable	342	329	264	329
Prepayments	19	-	-	-
Inventories	-	-	-	-
Total current assets	**2,747**	**2,224**	**2,159**	**2,224**
Property, plant and equipment	-	-	-	-
Total assets	**2,747**	**2,224**	**2,159**	**2,224**
Trade payables	2,065	1,800	1,400	1,800
Accrued expenses	57	56	45	56
Provisions for annual leave	14	4	5	5
Total liabilities	**2,136**	**1,860**	**1,450**	**1,861**
Contributed equity	52,494	58,616	64,283	70,376
Reserves	6,812	7,022	7,248	7,490
Accumulated losses	(58,695)	(65,274)	(70,821)	(77,503)
Total equity	**611**	**364**	**709**	**363**

Disclosures and Disclaimers

Disclosure of Interests

Neurotech International is a Canary Capital-mandated company. Canary Capital Pty Ltd, its directors and associates own ordinary shares and options in Neurotech International.

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