

R&D Tax Refund, FDA Review of Adult App advances & Infant App launched on Apple App Store

PainChek Ltd (ASX: PCK) (“PainChek” or “the Company”), developer of the world’s first smart device-based pain assessment and monitoring application, is pleased to provide the following updates on its recent activities.

Highlights

- **\$1.41 million R&D tax refund received for FY24 – provides PainChek further runway to complete upcoming key milestones**
- **US FDA review of PainChek Adult App advancing, with a meeting scheduled for April 2025 and regulatory clearance anticipated in H1 CY2025.**
- **PainChek Infant App launched on Apple App Store, with early feedback validating its value to parents; broader marketing rollout planned for Q2 CY2025.**

PainChek receives \$1.41m R&D Tax Incentive Refund

PainChek is pleased to advise that the Company has received a research and development (R&D) tax refund amounting to \$1,410,000 for the 2024 financial year.

The R&D tax incentive is an Australian Government program to support Australian companies to undertake R&D activities in Australia, under which eligible companies can receive cash rebates of to 43.5% of eligible expenditure on R&D activities.

The rebate, combined with the Company’s recent capital raising, provides PainChek with the cash runway to complete its upcoming key milestones.

US FDA review progressing for PainChek Adult App

Following PainChek’s submission in November 2024 to request De Novo regulatory clearance from the US Food and Drug Administration (FDA) for the PainChek® Adult App, the FDA has now reviewed the application and requested additional information for clarification. A meeting with the FDA is scheduled for April 2025 to discuss these details further.

Regulatory clearance would enable PainChek to enter the US healthcare market — the largest globally — with a potential opportunity valued at approximately USD \$100 million per annum in aged care alone. The FDA review is being led by the same FDA executive involved in earlier interactions with PainChek in 2019, prior to delays caused by the COVID-19 pandemic.

This continuity and constructive engagement provides added confidence that PainChek is well positioned to become the first and only FDA-regulated pain assessment app available in the US market.

Preparations for US commercialisation are well underway, with go-to-market partners already secured and further local partnerships currently being explored to support rapid market entry and expansion.

PainChek Infant App now available on Apple App Store

PainChek has officially launched its *PainChek® Infant* app on the Apple App Store, available to the public for \$99.99 per year in Australia only at this stage.

PainChek has implemented a controlled soft launch strategy for its Infant product, prioritising market learning over immediate scale. This measured approach allows the company to observe user behaviour, gather user feedback, test pricing models, and efficiently allocate resources before a widespread rollout. This strategy enables PainChek to optimise conversion rates based on real user engagement metrics before expanding to wider market adoption.

Feedback on the Infant App has been very positive. Parents value the app's "easy-to-use" and "simple" pain assessment technology that provides instant pain scores, offering reassurance, validation and "peace of mind" during stressful and uncertain moments. The app has primarily been used in situations when babies seem unwell, during teething, at night when children are fussy, inconsolable crying, or after exhausting other soothing methods. Users also appreciate the pain tracking and documentation features, which help identify patterns and inform treatment decisions.

PainChek is continuing to gather structured feedback through its partnership with parenting ecosystem Kiindred. Price sensitivity is also being tested more thoroughly, with alternative models like free trials and monthly plans under review.

With this foundation of user insight, marketing activity will ramp up in the coming months. This will include refreshed messaging, updated content, and strategic partnerships with parenting platforms and healthcare experts — all aimed at building awareness and trust to position PainChek Infant as an essential part of the toolkit for a baby's first year

This release has been authorized for release by PainChek CEO Philip Daffas.

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About PainChek®

[PainChek®](#) is the world's first regulatory-cleared medical device for the assessment of pain, enabling best-practice pain management for people living with pain in any environment, from those who cannot reliably self-report their pain, those who can, and for those whose ability to self-report their pain fluctuates.

The PainChek® app is available on smartphones and tablets and combines PainChek's AI pain assessment tool, which intelligently automates the multidimensional pain assessment process, with the Numerical Rating Scale (NRS). This hybrid functionality allows accurate, consistent pain

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assessment at the point of care, and for care to be considered in PainChek's detailed reporting suite, PainChek® Analytics.

Globally, PainChek® has attained regulatory clearance as a medical device in Australia, Canada, the European Union, New Zealand, Singapore, Malaysia, and the United Kingdom, with FDA review in the United States currently in progress.

PainChek® has contracts with over 1,800 aged care facilities, with more than 10,000,000 digital pain assessments conducted to date, and is trusted by thousands of nurses, carers, and clinicians.

Using PainChek®, facilities can:

- Ensure greater consistency, continuity, and diagnostic certainty in pain assessment and management by decreasing subjectivity and removing unintentional assessor bias
- Streamline the pain assessment process for time-poor carers, with access to the PainChek® tool, the NRS, pain trends, and charting in one solution
- Simplify record-keeping and documentation to demonstrate compliance and support funding claims, with all historical pain assessment data in one place
- Enhance engagement with GPs and allied healthcare professionals

Clinical studies conducted in Australian and UK residential aged care centres have been published in various peer-reviewed journals including the [Journal of Alzheimer's Disease](#). An article in [BMC Geriatrics](#) indicates that PainChek® is a valid and reliable instrument to assess the presence and severity of pain in people with moderate-to-severe dementia living in aged care. Further information on clinical studies can be found [here](#).

PainChek® has successfully supported accurate pain assessment and management for thousands of adults worldwide living with dementia, disability, or other conditions impacting their ability to self-report pain. Building on the success of this technology, the clinically validated [PainChek® Infant app](#) identifies and detects six facial action units indicative of pain in infants aged one month to 12 months.

The need for PainChek as a best-practice pain management solution also extends to older people living at home and with access to home care packages that enable long-term home living. PainChek is expanding into home care by partnering with home care and disability service providers.

For more information, visit: <https://painchek.com>