ASX ANNOUNCEMENT
21 July 2025

Final US FDA De Novo Clearance Submission Completed

Key Highlights:

- **Final US FDA Submission completed for clearance of the PainChek Adult App, which will allow sales in the long-term care US market**
- **Final decision on regulatory clearance expected within 75 days, being late September to early October or sooner**
- **US Partner Agreements already in place to support rapid commercialisation of the PainChek App, with potential for early revenues from the world's largest healthcare market**

Sydney, Australia, 21 July 2025 – 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 announce it has completed its final submission to the US FDA for De Novo regulatory clearance for the PainChek Adult App as a medical device in the USA.

PainChek now expects a final decision on the De Novo regulatory clearance within 75 days, giving a projected potential clearance date of between late September to early October 2025, if not sooner.

Following a meeting with the FDA in early June 2025, the final submission provides additional information collected from PainChek's recent US clinical trial that addresses specific feedback from the regulator.

The US is the largest healthcare market in the world with 2,900,000 people living in its skilled nursing and assistive living sectors,[1,2] where currently there is no regulatory cleared pain assessment medical device for people living with moderate to severe dementia.

Based on projected PainChek pricing this initial market opportunity exceeds $100M USD per annum. On successful receipt of the initial De Novo clearance, the Company's intent is to pursue additional clearances to also enter the larger US home care, hospital and infant markets.

"We're pleased to have submitted this final documentation to the FDA after the productive discussions we've had recently, which again gives us confidence on the pathway to selling the PainChek Adult App in the US market this year. We're continuing to lay the groundwork via our established US client relationships, our recently appointed US Head of Business Development and the major integration and reseller partner agreements we've established in the region. Combined these will provide us an excellent springboard for rapid US market commercial success upon FDA clearance." said PainChek CEO Philip Daffas.

[1] https://www.ahcancal.org/Assisted-Living/Facts-and-Figures/Pages/default.aspx
[2] https://data.cms.gov/provider-data/dataset/4pq5-n9py

This announcement has been approved for release by the Board.

For more information:

Natalie Climo
Company Secretary, PainChek
natalie.climo@boardroomlimited.com.au
02 8016 2875

Philip Daffas
CEO, PainChek
philip.daffas@painchek.com
0406 537 235

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 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 1,900 aged care facilities, with more than 12,000,000 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