ASX ANNOUNCEMENT
5th June 2025

PainChek has a productive meeting with FDA agreeing a revised timeline for US De Novo regulatory clearance decision

Sydney, Australia, 5th June 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 a successful final feedback review meeting with the US FDA as the Company targets De Novo regulatory clearance with the US regulator.

The meeting, held on 3rd June 2025 AEST, was the follow up to a previous face-to-face meeting on 19 May 2025.

The latest meeting was focused on addressing the FDA's final questions related to PainChek's recent US clinical trial results conducted in New York and Iowa. The meeting was a positive two-way conversation providing feedback and clarity for both parties.

Based on the meeting discussions, PainChek is now compiling additional information collected from the completed clinical study that addresses the FDA feedback and aligns with the agreed actions concluded during the meeting. This submission is expected to be the final step in PainChek's US De Novo marketing clearance application and will be submitted prior to the end of June 2025.

On receipt of the final PainChek submission, there is a commitment by FDA for a final decision on De Novo regulatory clearance within 75 days, giving a projected potential clearance date of mid-to-late September 2025 or sooner.

"We appreciate the positive communications with the FDA over the past two months, the feedback has been helpful in providing PainChek with a clear route to US market entry based on the US regulatory requirements and patient's clinical needs. The De Novo clearance route is relatively complex as it is designed for novel and unique technologies such as the PainChek Adult App. Based on these recent FDA meetings and ongoing communication with FDA, we remain confident that we will be in a position to launch a first version of the Adult App designed for the US market later this year." said PainChek CEO Philip Daffas.

In parallel, PainChek has recently recruited a local Head of Business Development for the US market, established integration and reseller agreements with PointClickCare and ElderMark that cover more than 60% of the 3,000,000 long term beds, and have identified early clients in the USA to ensure a rapid commercial market entry post FDA clearance.

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 1,800 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