ASX ANNOUNCEMENT
13 October 2025

PainChek Secures First US Customer Following Landmark FDA De Novo Clearance

- **Initial agreement completed within days of receiving FDA De Novo clearance**
- **Agreement is for an initial three-year period with upfront payment - training and implementation to be completed this week**
- **Establishes PainChek in the US market with a leading reference center**
- **PainChek's first sale into the world's largest aged care market – 3 million long-term care beds & USD $100m per annum initial addressable market opportunity**
- **PainChek fast tracking US market penetration through attendance at major US long-term care conferences in October and November**
- **PainChek has established Business Development and Operations functions in North America**
- **Strategic integration partnerships established with PointClickCare and Eldermark – covering a combined ~60% of the 3 million bed US long-term care market – providing broad access to the large North American market**

Sydney, Australia, 13 October 2025 – PainChek Ltd (ASX: PCK) ("PainChek" or "the Company"), developer of the world's first AI-powered pain assessment and monitoring application, is pleased to announce its **first US customer**, **Jewish Home Family**[1], a leading senior care organisation in New Jersey. This milestone follows PainChek's recent **FDA De Novo clearance**, announced only days ago on the October 8 2025,officially recognising its Adult App as the **first and only regulated medical device for pain assessment** in the United States and solidying a first to market competitive advantage .

Jewish Home Family will deploy PainChek at its flagship location to enhance pain detection and management for residents living with moderate to severe dementia. This marks the beginning of PainChek's commercial rollout in the US, unlocking an initial **addressable market of over US$100 million annually** across 3 million long-term care beds.

"This is a transformative moment for PainChek," said **Philip Daffas**, CEO of PainChek. "FDA De Novo clearance validates our technology and opens the door to the world's largest aged care market. Partnering with Jewish Home Family, an organisation known for its innovation and quality of care, sets a strong precedent for our US expansion and provides PainChek an important and influential reference center."

PainChek's AI-driven solution uses facial recognition and behavioural analysis to assess pain in individuals unable to self-report, providing caregivers with real-time, objective data to guide treatment. The FDA's De Novo classification also created a new product code (SGB), establishing PainChek as a **category-defining technology**.

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Jewish Home Family President and CEO **Carol Silver Elliott** commented: "PainChek's technology aligns with our mission to deliver elder-directed care. It empowers our clinical teams with better insights and supports our residents with more responsive, dignified treatment."

The agreement term is for three years for the single facility in New Jersey, with the total $26,200 USD fees being paid upfront to PainChek. Training and Implementation will commence on Monday 13 October 2025.

As part of the plan for rapid US market penetration, PainChek is attending, exhibiting and also presenting outcomes data from the US FDA clinical study at the AHCA/NCAL convention and expo (Las Vegas, 19-22 October) and the 2025 LeadingAge Annual Meeting & Global Ageing Network Conference (Boston, 2-5 November). These two major US conferences attract the leading US long-term care providers, and Ms Silver Elliot will also be attending the Boston event to support PainChek with US client engagement.

PainChek has recently recruited Heads of Business Development in both the US and Canadian markets, and a US Operations Manager. The Company is also in the final stage of negotiations with additional Business Development Managers to fast-track direct sales and implementations across the US and Canada.

PainChek is supported by strategic integration partnerships with **PointClickCare** and **Eldermark**, who combined service approximately 60% of the US and Canadian long-term care market. A reseller agreement with Eldermark will accelerate deployment across skilled nursing and residential care facilities.

The US environment is primed for PainChek, with regulators seeking better pain assessment and management. This is driven by Medicare and Medicaid reimbursement and minimum data set requirements focused on pain management, factors expected to boost demand for PainChek's technology.

With operations already live in over 1,900 aged care facilities globally and more than 12 million pain assessments conducted, PainChek is scaling its US commercial team and preparing for broader market penetration, including home care and hospital sectors.

The Company is unable to provide an estimate for the additional revenue to be derived from these direct sales and partnership initiatives. The actual revenues will be disclosed in future quarterly cash flow reports.

[1] https://jewishhomefamily.org/

This announcement has been approved for release by the Board.

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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 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, USA, Canada, the European Union, New Zealand, Singapore, Malaysia, and the United Kingdom.

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