ASX ANNOUNCEMENT
08 October 2025

Landmark FDA De Novo Grant received for PainChek's Pain Assessment App which opens up initial US$100 million per annum addressable market opportunity in the US

- **Establishes PainChek as the first and only regulated medical device for pain assessment in the US and with a novel De Novo classification granted and new FDA product code SGB created for this first-of-its-kind medical device**
- **Provides PainChek with access to commence sales in the world's largest aged care market – 3 million long-term care beds & USD $100 million per annum initial addressable market opportunity**
- **Strategic integration partnerships established with PointClickCare and Eldermark – covering a combined ~60% of the US and Canadian long-term care market**
- **Business development underway with first sales expected in the near term**
- **Excellent regulatory and reimbursement landscape for pain management in the US**
- **Streamlined pathway for rapid regulatory clearances in additional market segments including home care, and hospitals**
- **With FDA De Novo classification granted, PainChek is positioned for a potential expedited approval in Japan, and other global markets**
- **Key US and Canadian business development team established**
- **Patent protected in major international markets (US, EU, UK, Japan, China)**

Sydney, Australia, 08 October 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 been granted a De Novo classification by the US Food and Drug Administration (FDA) for its PainChek® Adult App. The FDA De Novo Grant number is **DEN240073**.

As part of the granting decision, the FDA has created a new product code "SGB" – formally recognizing PainChek as a unique, first-of-its-kind medical device for pain assessment.

This is a major milestone as PainChek Adult App becomes the first and only regulated medical device available to assess pain people who cannot reliably verbalize within the US nursing home and long-term care market.

With its FDA De Novo grant, PainChek is recognized as a unique medical device, with no regulated competitive product, addressing critical unmet needs in pain management, especially within the substantial US aged care market, PainChek's initial addressable market in US aged care comprises over 3 million long-term care beds and represents a commercial opportunity exceeding USD $100 million

annually. The PainChek clinical trial conducted in the US during the past 2 years also provides local clinical data to address US market acceptance.

This streamlines a pathway for rapid regulatory clearances in additional market segments including home care, and hospitals, which are estimated to take the total US aged care market opportunity to $582m.

PainChek is strongly positioned for immediate commercial rollout in the US, bolstered by strategic partnerships with leading healthcare software providers PointClickCare and Eldermark. Additionally, a reseller agreement with Eldermark is in place to accelerate market entry and sales growth.

Through resellers and direct channels, PainChek is already active in pursuing business development opportunities in the US, and this will be accelerated following the FDA De Novo clearance.

PainChek is also booked to attend, present and exhibit at US local aged care conferences this year including AHCA/NCAL convention and expo, taking place in Las Vegas from October 19–22, and the 2025 LeadingAge Annual Meeting & Global Ageing Network Conference, taking place from November 2–5, 2025, at the Boston Convention & Exhibition Center.

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.

Philip Daffas, CEO of PainChek, commented: "This FDA De Novo clearance is a transformative achievement for PainChek, uniquely positioning us to enhance pain assessment and management in the world's largest healthcare market. It validates our innovative technology and provides the foundation for accelerated US market growth, building off our established success in Australia and the momentum we've recently achieved in the UK. I also want to thank the FDA for their continuous guidance through this unique DeNovo regulatory classification grant and to my team and our research collaborators for their outstanding efforts"

The FDA De Novo classification not only validates PainChek's innovative approach and clinical efficacy but also supports accelerated approval pathways for PainChek's expansion into other US market segments, notably home care, and hospitals.

Furthermore, the FDA De Novo classification and new product code SGB substantially increases the potential for expedited regulatory approval in Japan, the second-largest global market for long-term care, comprising approximately 1.1 million beds and other global markets such as Brazil and UAE that accept FDA approval to facilitate abbreviated market entry.

As recently announced, PainChek is growing its US commercial team with the appointment of Nick Garofoli as Head of Business Development, and David Allsopp has relocated from Australia to North America to

lead Canadian operations, ensuring the Company is well-positioned to maximise on this growth potential and market penetration. Nick and David are actively recruiting key staff to fast-track direct sales and implementations across the USA and Canada.

PainChek's strategic position is backed by patent protection in the major world markets including the USA, EU, UK, Japan and China.

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, 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