ASX ANNOUNCEMENT
2nd October 2024

PainChek Adult app FDA De Novo submission update

- **Majority of requirements for submission complete – Clinical Evaluation Report in final stages**
- **PainChek expects to provide a further update this month regarding the submission**
- **US Aged Care market is the world's largest – 1.7 million people long-term aged care**
- **Potential FDA clearance for the Adult app would be a major milestone for the Company and provides a predicate for PainChek's use with infants and in other market segments**

PainChek® Ltd (ASX: PCK) ("PainChek®" or "the Company"), developer of the world's first smart phone-based pain assessment and monitoring application, is pleased to provide an update on its progress with FDA de Novo submission for the PainChek Adult App.

In July 2024 the PainChek US-based clinical validation study data collection, spanning five Aged Care homes in Iowa and New York, was completed. PainChek can now report the data sets have been locked down, performance data analysis of the 105 participating subjects has been completed by the Company's Clinical Research Organization (CRO) partners, and the preliminary statistical analysis is in the process of being finalised for incorporation into the final Clinical Evaluation Report.

The US FDA submission process is highly regulated, and PainChek cannot provide detailed comments on the specific contents or outcomes of the CRO's Clinical Evaluation Report at this stage.

In parallel, the Company has completed the majority of the other FDA submission requirements including US cyber security, software documentation and device labelling requirements that are to be submitted with the Clinical Evaluation Report.

PainChek will announce further key developments, including the final timeline for FDA de Novo submission, either at or before the Appendix 4C due at the end of October.

"The US Aged Care market is the largest in the world where 1,700,000 people reside in these long-term care facilities, with a potential gross annual recurring revenue value of around $85,000,000 USD for PainChek based on our projected US pricing[1]," said Philip Daffas, CEO of PainChek.

"The FDA De Novo is a marketing pathway to classify novel medical devices[2]. Should PainChek Adult successfully obtain FDA clearance, PainChek® would be the first of its kind FDA-cleared pain assessment tool in the USA specifically designed for aged care residents with moderate to severe dementia who are unable to self-report their pain," added Daffas. "This clearance would also provide an important predicate for the PainChek® Infant App and support the expansion of the Adult App into larger US markets, including home care and hospitals. Additionally, we hold a granted U.S. patent that will remain in place until 2038."

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The Company is currently well placed to rapidly penetrate the US and Northern American market given existing partnerships, including PointClickCare, who provide integration access to 1,000,000 aged care beds across USA and Canada.

1. Reference PCK quarterly June 2024 and FY23/24 Annual Report
2. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request

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 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 1,000 aged care facilities, with more than 4,000,000 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