ASX ANNOUNCEMENT
29th October 2024

Positive validation study results pave way for PainChek Adult App FDA De Novo submission

- **Positive validation study results – FDA submission expected November 2024**
- **Results are consistent with other previous observational pain tool studies**
- **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 announce positive results from its US validation study, allowing it to progress with FDA De Novo submission for the PainChek Adult App.

This places PainChek's US market entry strategy on track, with the preliminary results from the recent US clinical validation study and statistical analysis including positive performance results in a paired study with the Abbey Pain Scale. PainChek can confirm that these validation study results are also consistent with other previous studies of evaluating the psychometric properties of observational pain assessment tools.

The PainChek FDA validation study recruited a total of 105 residents living in nursing homes in five sites in Iowa and New York who were assessed for pain in a comparative study with the Abbey Pain Scale.

PainChek is now in the process of submitting the results of the validation data along with the other required documentation to FDA for De Novo regulatory clearance. PainChek expects to complete this submission in November 2024.

PainChek will also be submitting the validation data for peer-reviewed journal publication and for presentation at US medical conferences in 2025 as part of the US market entry strategy.

"We are very pleased with the results from the validation study. Having now reviewed the data with our independent Clinical Research Organization we are compiling the clinical evaluation report along with the other required documentation to submit to FDA for regulatory clearance in the coming weeks. 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

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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 US patent that will remain in place until 2038."

The FDA states that De Novo application decisions typically require up to 150 days. PainChek has worked closely with the FDA with two previous pre-submissions to clarify the desired end points, which should contribute to a timely response from FDA.

The Company is also 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 1,600 aged care facilities, with more than 7,000,000 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

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- 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

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