

Ethos Laboratories distribution agreement set to fast-track PainChek US market entry strategy

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 an update to its market entry strategy for the US after signing a key distribution agreement with pain diagnostic specialist Ethos Laboratories (Ethos).

Under the agreement Ethos will act as a non-exclusive distribution partner of PainChek’s technology into its network of healthcare clients, initially targeting aged care and long-term care facilities throughout the US. In the agreement Ethos will sell and market the PainChek Adult App for day-to-day pain assessment and monitoring and as a complementary product to the existing Ethos pain biomarkers.

Founded in 2010 and accredited by the College of American Pathologists, Ethos is a high complexity laboratory focused on pain diagnostic biomarkers, clinical toxicology, pharmacogenomics, and infectious disease testing. Its mission is to help more people live pain-free by developing novel diagnostic tools to illuminate the biochemical underpinnings of chronic pain.

Headquartered in Newport, Kentucky with over 150 sales and field support employees located geographically across the US market. Ethos provides a range of services to facilitate improved diagnosis and medication compliance. In 2021 Ethos commercialized the world’s first biochemical pain index known as Foundation Pain Index® (FPI). FPI is a multi-biomarker assay which identifies underlying, biochemical determinants of pain. This innovative diagnostic, which has been the focus of a growing number of peer-reviewed studies has been shown to improve diagnosis accuracy, reduce unnecessary imaging associated with back pain, and provide novel, non-opioid treatment options for patients with chronic pain.

Ethos becomes the third key partner for PainChek in the US, alongside the partnership with InterSystems focused on expansion into the global hospital market, and the agreement with PointClickCare targeted at its 1 million aged care beds under management in the US and Canada.

Upon FDA clearance for PainChek in the US, targeted for Q1 C2024, these core market partnership agreements are expected to provide rapid entry for PainChek into the vast US market, which includes more than 2 million aged care beds.

Although the Company is unable to quantify the revenue impact at this stage, the new distribution agreement is considered to be strategically material as it seeks to grow its footprint rapidly in the US market once the Company has FDA clearance which is targeted for Q1 2024.

PainChek CEO Philip Daffas said: “We’re pleased to be able to continue expanding our network in the US with proven, high-quality partners such as Ethos, a group with which we share similar goals and values, while having remarkable complementary product offerings. This comes just as we have made our first sales and implementation in the Canadian Residential Aged Care market.”

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“As we continue to reinforce our technology in Australia and grow our presence in the UK as one of a number of new target markets, it provides an excellent basis ahead of an expected US launch in 2024 following submission of our FDA clearance files by the end of this calendar year.”

Ethos President and CEO Brian Kincaid said: “We welcome PainChek as a complementary technology into our portfolio offering as part of Ethos’ mission to help more people. This agreement marks the first step in Ethos’ strategic direction to expand equitable access to more advanced insights meant to improve the lives of the chronic pain patient. The combination of technology like the PainChek App for day-to-day pain monitoring and biomarker diagnostics will further drive personalized pain management for millions of people suffering with chronic pain.”

This release has been authorised for release by PainChek CEO Philip Daffas.

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About PainChek®

PainChek® Ltd is an Australian based company that develops pain assessment technologies.

Pain often goes unrecognised and under-treated in people with communication difficulties. PainChek Universal is a clinically validated smartphone-based medical device that enables best practice pain assessment for all people, everywhere.

PainChek Universal is a complete point-of-care solution that combines the existing PainChek® App with the Numerical Rating Scale (NRS). This enables best-practice pain management for all residents living with pain in any environment — from those who cannot verbalise pain to those who can, and those who fluctuate between the two.

The PainChek® App uses artificial intelligence and facial recognition to detect pain in those who cannot self-report. This gives a voice to those who cannot verbalise pain, whilst also driving objectivity and consistency in all assessments. For those who can self-report, PainChek Universal also includes access to the Numerical Rating Scale, a well-established standard used to document pain levels amongst these individuals. PainChek Universal also supports pain assessment using both tools at the point of care, for those people whose ability to communicate fluctuates.

PainChek® is being rolled out globally in two phases: first, PainChek® for adults who are unable to effectively verbalise their pain such as people with dementia, and second, PainChek® for infants who have not yet learnt to speak. Both the adult and infants products have received regulatory clearance in numerous markets including Australia, Europe, UK, NZ, Singapore and Canada.

The PainChek® Shared Care Program is a PainChek® licensing model which enables a professional carer to share their resident or patient data securely with other healthcare professionals or designated homebased family carers for ongoing pain assessments or clinical data review.

To find out more, visit www.painchek.com

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About Ethos Laboratories

Ethos Laboratories is a CAP-accredited, CLIA-certified, high-complexity laboratory that specializes in providing diagnostic testing to inform treatment approaches for patients suffering with chronic pain. The company's Chronic Pain Intelligence Portfolio includes clinical toxicology, pain biomarker testing, pharmacogenetics and serology. Ethos holds itself to the highest standards for quality, accuracy and efficiency and offers the fastest turnaround times in the industry. The company strives for superior customer service and transparency with employees, customers and patients.

Ethos is committed to continued innovation driven by its passion to help more people and continually invests in R&D and strategic partnerships to provide more value to its customers and the patients they serve. Ultimately, the company's goal is to ensure more people can live fully without the constraints of chronic pain.

To find out more, visit <https://www.ethos-labs.com>