

10 June 2020

### **PainChek plans Canadian regulatory clearance and market entry**

Listed Australian company PainChek Ltd (ASX:PCK) continues positive progress towards expanding global regulatory clearances and market presence for the PainChek adult medical app.

PainChek Ltd has submitted for regulatory clearance with Canada Health under the Canadian regulatory “Software as a Medical Device” (SaMD) category. The Company has applied for a Class 1 medical device clearance which is based on the PainChek App risk classification and in line with the existing CE Mark and TGA clearances.

Canada Health has estimated a 120-day review timeframe for PainChek’s application which, based on this timeline, would allow PainChek to enter the Canadian market as a cleared regulatory medical device as early as Q4 Calendar 2020.

Obtaining Canadian regulatory clearance is part of the Company’s global market entry strategy building on the existing presence in Australia, UK, New Zealand, and Singapore. It will also provide a geographical base for PainChek’s early entry into the North American market prior to our projected FDA clearance in the USA.

“Our goal is to establish a business presence in North America in line with the regulatory clearance. The Canadian market is an attractive market and has strong commonality with the Australian market in terms of care provision and the importance of pain assessment within aged care. There are more than 250,000<sup>1</sup> aged care beds across the country and a strong government funded home care market for those who want to receive their care in the home environment” commented Philip Daffas CEO, PainChek Ltd.

PainChek Ltd has an existing integration commercial agreement in place with the Canadian based company AlayaCare/Procura<sup>2</sup> for the Australian aged care market. “We are in discussions to extend this collaboration into the Canadian market, where AlayaCare also have a strong Home Care market presence, during 2020. This is consistent with our strategy of working with our integration partners in multiple markets to provide a fully automated and high quality of care service for our collective clients” added Daffas.

This ASX announcement has been approved for release by Philip Daffas, Managing Director.

<sup>1</sup>. [https://www.cma.ca/sites/default/files/2018-11/9228\\_Meeting%20the%20Demand%20for%20Long-Term%20Care%20Beds\\_RPT.pdf](https://www.cma.ca/sites/default/files/2018-11/9228_Meeting%20the%20Demand%20for%20Long-Term%20Care%20Beds_RPT.pdf)

<sup>2</sup>. <https://www.alayacare.com>

#### **For more information:**

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### About PainChek®

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

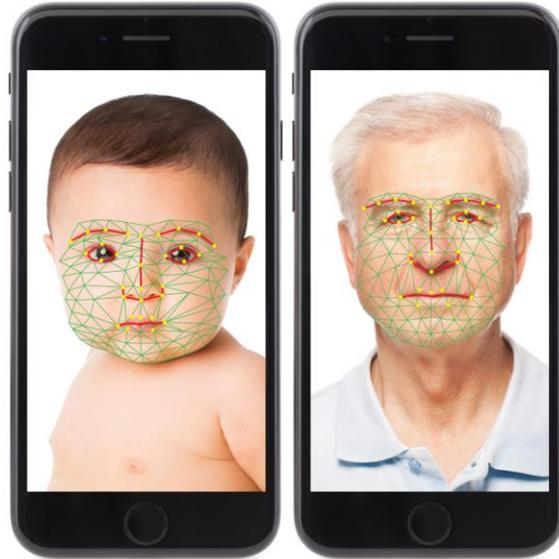
PainChek® is a smart-phone based medical device using artificial intelligence to assess and score pain levels in real time and update medical records in the cloud. PainChek® records a short video of the person's face and analyses the images that indicate pain and records them.

Next, the caregiver uses PainChek® to record their observations of other pain related behaviours that complete the assessment. Finally, PainChek® calculates an overall pain score and stores the result allowing the caregiver to monitor the effect of medication and treatment over time.

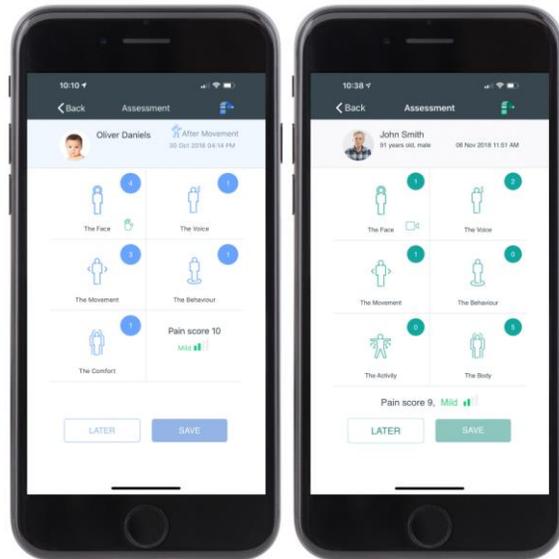
PainChek® is being rolled out globally in two phases: first, PainChek® for adults who are unable to effectively verbalise their pain such as people with dementia, and second, PainChek® for Children who have not yet learnt to speak.

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](http://www.painchek.com)



PainChek® artificial intelligence assesses facial micro-expressions that are indicative of the presence of pain.



PainChek® domains of pain assessment that calculates pain severity score.