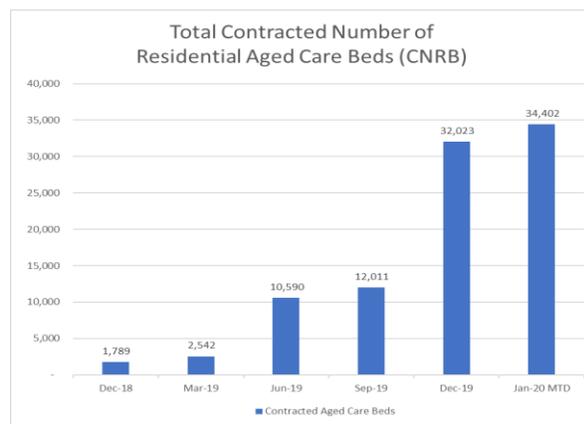
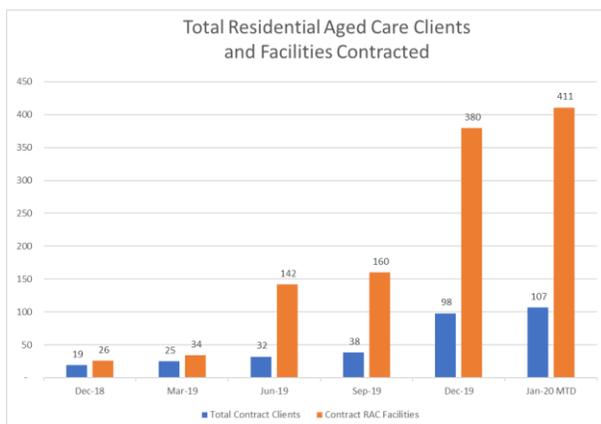


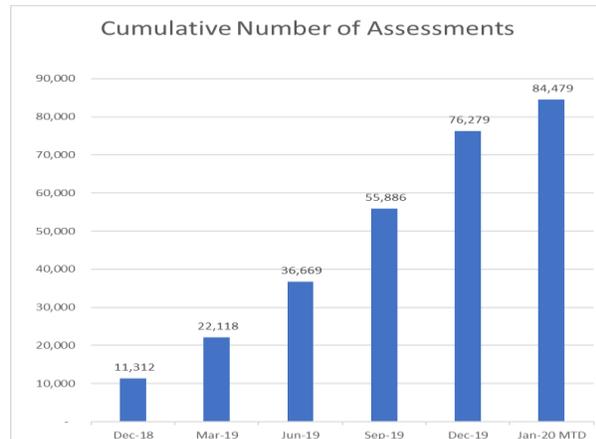
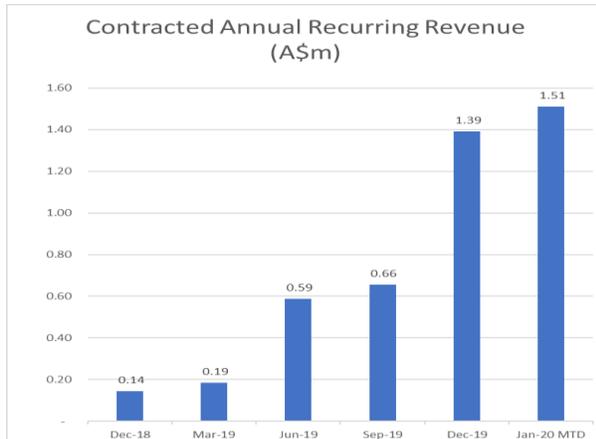
## December 2019 Quarterly Update

### PainChek® continues excellent progress with significant contract uptake in the residential aged care market

- In the quarter ended 31 December 2019, PainChek® increased contracted clients from 38 to 98 (+236%), contracted RACs from 160 to 380 (+238%), and total contracted beds from 12,011 to 32,023 (+267%) across Australia, NZ, Singapore and the UK. The majority (31,564 beds or 98.6%) of these contracted beds are in Australia, representing a 15% penetration level of the Australian Residential Aged Care (RAC) Market.
- Of these, 215 RACs and 18,604 approved places were contracted by 58 new clients (and 3 existing clients) under the Federal Government funded trial during the December quarter.
- From 1 January 2020 to to 24 January 2020, we signed an additional 9 clients, increasing total contracted clients to 107, total contracted RACs to 411, and total contracted beds to 34,402.
- Company is on target to achieve delivery of PainChek® to 100,000 people living with dementia as part of the rollout of the \$5M Government funded trial during 2020.
- The Children’s App trial continues in Melbourne, with completion expected by Q3 2020.
- First license agreement signed in UK with Person Centered Software and offshore pipeline accelerating.
- Discussions with Philips regarding global collaborations continue to progress.
- FDA pre-submission on track for Q1 2020.

### Performance Summary (all countries)





\* Contracted ARR for the quarters to 30 September 2019 were calculated on the basis of contracted MRR x 12 months, as subscription contracts were on PainChek®'s normal commercial terms to that point in time. Contracted ARR for the quarter ending 31 December 2019 and later are presented on a normalized basis post completion of the Government trial reflecting contracted pricing on completion of the trial assuming the contracts are not terminated after the initial 12-month term.

As disclosed in the Appendix 4C, the Company received the first \$500,000 under the Federal Government grant in December 2019. The 31 December 2019 financial statements, which are currently subject to audit review, will be released at the end of February 2020 and will account for the grant revenue in relation to the trial. Subsequent payments by the Federal Government against specified milestones (see below) will also be recognized as and when the milestones are reached.

All existing PainChek® clients prior to the government grant period will be opting into the grant over the next calendar year, as their current contracts come up for renewal. The key recurring revenue measure that PainChek® will continue to report is the normalized contracted ARR that represents annual recurring revenue for all contracted clients post completion of the Government grant period. Normalized contracted ARR as of 24 January 2020 is \$1.51m. In addition, PainChek® will record grant revenue and report progress in the quarterly updates for the Australian market, and it will commence reporting on MRR and ARR for overseas business when it becomes material.

### **Australian Government Funded Trial:**

As announced to ASX on 6 December 2019, the Federal Government signed an agreement to provide funding of \$5M for the national trial of PainChek® in Australian residential aged care. The funding under the grant has been allocated as \$3m in FY2020 and a further \$2m in FY2021.

The funding makes provision for a PainChek® license to all the Residential Aged Care Providers in Australia and their 100,000 residents living with dementia or cognitive impairment for a one-year period. There are around 1,000 registered Residential Aged Care providers in Australia who manage close to 2,000 Residential Aged Care facilities (RAC's) where there are 200,000 resident beds in total. It is estimated that around 50% of these beds are occupied by people living with dementia or cognitive impairment and it is for these people that the PainChek® license is available for a one-year period through the grant.

In the quarter ended 31 December 2019, we signed 58 new clients to the government trial and three existing clients signed for additional beds under the trial. These clients comprise a total of 215 RACs and 18,604 beds. These agreements are typically commitments for a 2 to 3-year period combining the government funded dementia bed program for the first year and our standard approved beds terms for the additional years.

These contracts, together with two new overseas contracts, increased the total number of contracted aged care beds from 12,011 to 32,023 and the number of contracted RAC facilities from 160 to 380. In addition, the number of PainChek® clinical assessments on a cumulative basis has grown from approximately 56,000 to just over 76,000, reflecting continued strong take up and clinical use of PainChek®.

Of the clients acquired during the quarter, the more significant ones include the following:

- Aegis Aged Care – 29 RACs, 1,500 beds
- Summitcare – 9 RACs, 969 beds
- Bethanie – 11 RACs, 900 beds
- OzCare – 12 RACs, 1476 beds
- Fresh Hope – 13 RACs, 900 beds
- Juniper – 25 RACs, 1500 beds

All of contracted bed numbers referred to above include the total number of approved places for all clients who have agreed to participate in the trial. The Government however is funding only dementia specific and cognitively impaired beds. We are currently gathering this information from all of the RAC's participating in the trial. For the purposes of reporting this quarter against the trial milestones, we estimate that the dementia specific and cognitively impaired beds will be 50% of the total approved places. Both the approved places and estimated number of dementia specific and cognitively impaired beds are reflected in the table reflecting progress against FY2020 milestone below.

The government grant documentation has set milestones of 25,000 activated licenses, against which payment under the contract terms will be made to PainChek® according to the following anticipated schedule:

Milestone	Payment Amount (excl. GST)
Upfront payment on contract execution (received Dec 2019)	\$500,000
Provision of 25,000 cumulative licenses during FY2020	\$1,250,000
Provision of 50,000 cumulative licenses during FY2020	\$1,250,000
Provision of 75,000 cumulative licenses during FY2021	\$950,000
Provision of 100,000 cumulative licenses during FY2021	\$950,000
Provision of evaluation report during FY2021	\$100,000
<b>Total funding</b>	<b>\$5,000,000</b>

Other key terms of the contract are:

- The number of activated licenses are based on the RAC facilities which have training on PainChek® made available, and for which RAC operators have reported the number of beds occupied by dementia or cognitively impaired residents at a point in time.
- The first two license milestone payments totaling \$2.5m are to be met by 30 June 2020 or the pro rata amount of licenses issued will be paid, and the final two license milestone payments totaling \$1.9m are to be met by 31 October 2020 or the pro rata amount will be paid.

Progress against the initial 25,000 license milestone as of 24 January 2020 is presented on a proforma basis in the table below:

Milestone under Federal Government Trial						25,000
No. of activated dementia beds Q3 FY2020						
	No. of Customers	No. of RAC's	No. of Approved Places	No. of Dementia Beds Estimated	As a % of Milestone	
New clients signed under trial	67	228	19,582	9,791		
Pre-existing clients opting into trial	11	55	4,170	2,085		
<b>Total for clients under the trial</b>	<b>78</b>	<b>283</b>	<b>23,752</b>	<b>11,876</b>	<b>48%</b>	

As we are in the process of confirming with the RACs the number of beds for those living with dementia or cognitive impairment, this number may increase. As of 24 January 2020 (seven weeks into the grant period), PainChek® estimates it has contracted almost 12,000 licenses or 48% of this initial milestone which are in the process of being activated. Given the strong sales pipeline and the range of training and implementation support available we believe we are on track to meet the 25,000 target this calendar quarter and achieve the overall 100,000 target by October 31<sup>st</sup> 2020.

**The benefit of the government funded contract is significant in that;**

1. It will fast track the take up of PainChek® across aged care in Australia, providing a high level of market penetration over a relatively short timeframe and providing the benefits of PainChek® to as many residents as possible. This program will also help refine how PainChek® becomes integrated into everyday clinical care in the aged care residential setting working with our current and future care management software system partners in Australia.
2. The government funding is for dementia beds and people with cognitive impairment which may result in a higher penetration than the 50% of the average care home than currently projected. Once the trial has completed and the utility of PainChek® proven, we anticipate that most clients who participate in the trial will continue their contracts. The second and third years of these contracts reflect our normal commercial terms and pricing.
3. We have taken the time prior to the grant commencement to ensure we are positioned to implement and activate PainChek® rapidly. We have established refined training programs (including a new simpler version of our online training programs) and recruited and trained an additional clinical trainer in Melbourne to provide extended presence in Victoria. Ward Medication Management have received extensive training (refer ASX release dated 17 October 2019) and will provide additional training resources nationwide to support the implementation.
4. PainChek® has developed a close working relationship with the Federal Minister for Health and Ageing and the Department of Health (DoH) which we believe will hold us in good stead for the future. We have engaged KPMG to conduct independent clinical outcomes studies to assess the impact PainChek® has on resident care within aged care and the impact on the use of medication in consultation with the DoH. This report will be supplied in two stages, first draft in Q4 2019 and second mid 2020 as part of the conclusion of the trial, to determine the long-term benefits of PainChek® and support the potential for long-term funding as part of the Government's strategic analysis of the Aged Care sector.

This significant investment is expected to trigger widespread and long-term use of PainChek® within Australian Residential Aged Care and it is already having a positive impact on our international expansion program.

### **Integration Partners:**

We now have integration agreements in place with the six major aged care management system providers in Australia, including Person-Centered Software, who also has a strong UK presence.

These agreements facilitate the automated documentation and data integration of PainChek® for more than 80% of the 220,000 Australian aged care beds and more than 40,000 beds in the UK. The benefit is rapid, point of care pain assessments that eliminate duplication of effort for carers giving them more time to focus on resident care.

Our integration partners have completed their development and testing programs and have deployed the PainChek® integration into production. We now have residential aged care clients from all six of the integrated care management systems gaining the benefits of the PainChek® integration. The benefits of integration will be applicable to all aged care centers who participate in the Government funded trial.

### **PainChek® Clinical Outcomes:**

The Company has reached the stage where our growing base of RAC clients are now able to share the clinical benefits of the use of PainChek® and its impact to their residents' care. We have released five case studies from McLean Care Residential Home in Inverell, Queensland; Barossa Village for Aged Care in South Australia; and Regents Garden, Scarborough in Western Australia. The latest is from Allambie Heights Village, Northern Sydney, New South Wales.

These case studies confirm PainChek® has become a standard tool for assessing pain and evaluating pain management strategies in residents with dementia, helping to produce significant clinical benefits including:

- Reduced resident pain levels through better assessments and more accurate treatment.
- Significant improvement in pain management and residents' behaviours, together with significant reduction in psychotropic prescription and administration as a result of PainChek® assessments.
- An increase in staff awareness of pain management, and increased staff confidence when dealing with pain in residents with cognitive impairment or dementia.
- Ease of access and administration - with easier access to stored assessments and electronic charts, there has been increased and more effective input from GPs.

### **PainChek® and Delirium**

A new review published by the Journal of European Geriatric Medicine has revealed a potential role for PainChek® in the assessment and management of pain in patients with delirium. Delirium is a serious acute medical condition which affects a person's mental ability and results in confused thinking and reduced awareness.

According to the paper by Sampson et al., delirium affects people's ability to self-report pain and can make it more challenging for practitioners to recognise, assess and treat pain.

Professor Sampson, Marie Curie Palliative Care Research Department, University College London (UCLH), believes there should be more investigation into what tools practitioners are using to assess pain in people with delirium.

"Delirium can exacerbate movement-related pain but it can also alter how people perceive pain and reduce their ability to communicate their pain. PainChek® may have a useful role in detecting pain in people with delirium and we are currently running a research project to see whether it could be helpful," said Professor Sampson.

We are working with Prof Sampson and the UCLH team to assess PainChek® in the hospital setting and now as a new delirium patient management tool. There are more than 50 Million people living with dementia and around the world more than 1/3 of hospital beds are now occupied by dementia and cognitively impaired patients. These patients typically stay in hospital 18 days longer than the non-dementia patients, they have a 3 times greater risk of an in-hospital delirium and more than half receive anti-psychotic drugs

#### **International Expansion:**

The first 1,000 PainChek® license agreement was signed with Person Centered Software UK the last quarter which are being rolled out to the UK market. Person Centered Software is based in the UK and supplies Care Management systems to more than 1,200 aged care providers, servicing over 40,000 residents. PainChek® integration into Person Centered Software's industry leading product range has been completed. Under the agreement, Person Centered Software are distributing PainChek® to their UK client base through their sales, marketing and service capabilities.

The PainChek® UK team has expanded to 3 people and the first two direct aged care clients were signed up in December 2019. PainChek UK is now well placed to accelerate the take up with PCS UK and broaden its own direct UK sales, and the UK base will also provide a platform for European market entry during calendar 2020.

We completed our first direct license agreement into New Zealand for 300 beds with the Enliven Aged Care home on the South Island during the past quarter.

We continue to receive strong interest from other international markets, which will further expand our commercial progress and global market reach.

#### **Philips HealthWorks programme.**

PainChek® was selected from more than 2000 early stage healthcare companies to participate in the Philips HealthWorks 2019 Global Program focused on accelerating breakthrough innovation in Patient Monitoring and Patient Care Analytics.

Philips is a leading health technology company focused on improving people's health and enabling better outcomes across the health continuum from healthy living and prevention, to diagnosis, treatment and home care. Headquartered in the Netherlands, Philips is a leader in diagnostic imaging, image-guided therapy, patient monitoring and health informatics, as well as in consumer health and home care.

The Philips HealthWorks Program was designed to identify best in class new healthcare technologies that fit with the Philips' business and strategy. The program kicked off in September 2019 across four Innovation Hubs (Eindhoven, Bangalore, Shanghai and Cambridge, USA) and culminated in a Breakthrough day in Eindhoven, the Netherlands on 11<sup>th</sup> December 2019. PainChek® was one of seven companies chosen to attend and present on the joint collaborative opportunities on this final Breakthrough day. There were a number of strategic fits identified between PainChek® and Philips and we are now in contact to further those potential global collaborations.

#### **Federal and Drug Administration (FDA):**

Following our meeting with FDA in Washington DC in June 2019 and confirmation of the De Novo regulatory classification, we have engaged with two North American agencies to conduct both the Human Factors and Clinical Study work required for the De Novo submission.

We are on track for the pre-submission request to FDA in the current quarter prior to initiation of the study work which is scheduled for Q2-Q3 calendar 2020. This cost of this work is budgeted and we anticipate completing the De Novo submission for FDA clearance for the PainChek® Adult App during calendar 2020, and FDA clearance expected during calendar 2021.

The PainChek® adult FDA De Novo submission is projected to act as a predicate for future PainChek® versions such as the Children's, and therefore provide a route to the US market through the 510K route which is a more rapid and cost effective route to FDA clearance.

#### **PainChek® Children's App:**

The PainChek® Children's App serves a potentially even larger market than the Adult App with a large hospital market and home care market opportunity.

Globally there are more than 400 million children at any one time between the age of 0-3 years. Due to the rapid changes and development in children's faces, the PainChek® Children's App is scheduled to be delivered in 3 age group versions, with the youngest Infant App (infants 0-1 years of age) being the first developed and now undergoing clinical research.

The research agreement with Melbourne's Murdoch Children's Research Institute (MCRI) was signed in June 2019. MCRI is the largest child health research institute in Australia, and one of top three worldwide and their campus partners include Royal Children's Hospital in Melbourne and the University of Melbourne's Department of Paediatrics.

The *PainFaces* study is being led by Professor Franz Babl and Associate Professor Di Crellin in the Emergency Department (ED) of the Royal Children’s Hospital. The clinical trial version of the PainChek® Infant App has been finalized for use in the study which is scheduled to commence in Q1 calendar 2020.

The pain scores derived using the PainChek® Infant App will be compared to those obtained using observational children’s pain assessment tools by independent assessors on 100 infants undergoing painful procedures within the ED. Completion is dependent on the recruitment of the 100 children and is currently projected for Q2/Q3 calendar 2020.

The results and learnings from the research will support applications for regulatory clearance of PainChek® Infant’s App with the Therapeutics Goods Administration (TGA), CE Mark, Europe, and FDA in the USA. We are planning for TGA clearance during Q4 calendar 2020.

### **Patents**

In 2020 PainChek® now has the following two granted patents:

- US patent by the United States Patent Office (Patent number US10398372)
- Japanese patent No. 2017-529115

These patents allow PainChek® to protect the intellectual property of its invention in the United States and Japan. It also provides PainChek with exclusive rights to exclude others from making, using, selling or importing the invention for 20 years from the filing date in the US (17 February 2017).

The US is the largest medical device market in the world and has more than six million people living with dementia. Establishing our intellectual property in the US is a crucial step forward as part of protecting and growing the PainChek® brand internationally.

In Japan recent estimates suggest that at least one in four residents is aged 65 years or older. Japan has a big population – around 126 million - and the number of elderly people is set to grow significantly in the future. This patent is an important step in opening up significant commercial opportunities for PainChek®, especially given the focus on quality aged care services in Japan. A separate regulatory approval process is required to sell PainChek® in Japan, and we plan to develop a strategy for this during 2020.

We continue to make positive progress with our national patent filings for the PainChek® App in all other jurisdictions including Europe, China and Australia.

### **Trademark progress:**

The PainChek® trademark has now been granted in Australia, US, Germany, UK, and the European Union. This provides the Company with the strategic advantage of building a global brand position and the right to exclusively use PainChek® as a company name in these key markets. These are key in establishing a long term successful global business.

**Summary:**

The Company progress and achievements to date are a reflection of the transformational impact PainChek® has on pain management and better medication treatment for people living with dementia and other communication difficulties.

The Company has now set its strategic priorities for 2020, and is set for an exciting year accelerating sales and broadening global market presence, and further establishing PainChek® as the new gold standard for pain assessment in multiple healthcare market segments.

**Philip Daffas**  
**CEO – PainChek Limited**  
**30<sup>th</sup> January 2020**

This announcement has been approved for release by Philip Daffas, managing director.