

# March 2021 Quarterly Update

# PainChek delivers 4<sup>th</sup> consecutive quarter of double digit RAC bed growth and UK sales and market activity increases

### **HIGHLIGHTS**

Increases in all sales and project related KPI's across the business for the quarter:

- Residential Aged Care: 993 Residential Aged Care (RAC) facilities and 80,037 approved beds are under annual PainChek® license as at 31 March 2021, representing 69% and 61% growth respectively over the previous year and 35%+ domestic market share. Minimal churn as clients transition to PainChek standard contracts post 12-month government trial. More than 350,000 PainChek clinical assessments have been conducted in aged care to date.
- **Contracted Annualised Recurring Revenue (ARR):** Contracted ARR (normalised post government trial) increases 14% for the guarter to \$3.5M.
- PainChek Universal Solution: Product received CE Mark and was TGA cleared during March and is being released as an App and system upgrade to all existing clients. The Universal App has been shown to broaden existing market potential, accelerate new take up and support ongoing retention in all market segments.
- PainChek Infants: PainChek clinical data receives positive peer review feedback and remains on track for Q2 2021 TGA and CE Mark clearance and subsequent market launch into Australian and European markets.
- Home Care market: Australian pilots completed in Q2 2021 domestic and overseas home care market launches scheduled for in Q3 C2021 in line with PainChek Universal Home Care version availability and new Federal Government funding for Home Care packages.
- Partnerships: MOU signed with nViso for new product development with social robotics in Japan.
- Overseas: UK market new sales achieved in England and Scotland as market re-opens in line with COVID-19 vaccinations. Canadian market access building through local partnership with AlayaCare
- **FDA clearance:** Feedback received from FDA on de-Novo study plan clinical protocol being updated prior to commencing US based study work in 2021.
- **Organisation update:** Iain McAdam came on board as CFO based in Sydney. The UK team is in the process of expansion to meet local market growth opportunities.
- Cash balance: PainChek's consolidated cash balance at 31 March 2021 was \$11.9M.

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 report continued growth in aged care and initial entry into the hospital, home care and disability markets during the quarter ended 31 March 2021.

### **Core Aged Care market:**

PainChek continued to deliver sales growth within Australian residential aged care in the past quarter. Sales growth in the quarter resulted in total global licenses covering 80,037 beds, which is 12% growth compared to the prior quarter and 61% growth year on year. These domestic sales represent more than 36% of the Australian Residential Aged Care (RAC) market. PainChek now has 288 Aged Care providers as clients, managing more than 1,000 aged care facilities, which is 65% growth year on year. This equates to contracted forward-looking annualised recurring revenue of \$3.5M (normalised post the government grant and assuming full implementation and contract renewal).

In the last quarter PainChek continued its growth contracting a net additional 8,719 Residential Aged Care beds. This is across 42 different Aged Care providers who operate 109 Residential Aged Care facilities. This included providers such as Anglican Community Services (23 RACs) and Darling Downs (11 RACs).

We have continued discussions on several large provider agreements which were delayed by the re-emergence of COVID outbreaks in December. PainChek has a strong pipeline of Aged Care beds to support continued growth in 2021.

In March 2021, the Department of Health, in line with the initiative, conducted an email distribution to all Aged Care facilities in Australia to promote the further take up of the PainChek solution, resulting in a large uplift in inbound enquiries and sales leads for the Company. This is being repeated in late April/early May 2021, which management believes will further stimulate the sales pipeline.

During COVID-19 restrictions, the PainChek clinical team has successfully delivered training remotely, having conducted more than 3,000 virtual workshops to Aged Care providers across Australia. Combined with the PainChek online learning curriculum, more than 4,400 aged care clinicians have been trained and conducted a PainChek assessment in the field. In addition, more than 350,000 PainChek clinical assessments have now been conducted in aged care, reflecting 219% growth year on year and the growing client acceptance and clinical utility.

The UK market returned to a level of stability following 10 million second dose COVID-19 vaccinations being delivered, and the sales pipeline is expanding as a result. New agreements are now in place with Erskine Homes in Scotland) and Orchard Care homes and a 3-month pilot agreed with Community Integrated Care. In addition, there is a new lead generation agreement with WELL Pharmacy, the third largest pharmacy operator in the UK that provides pharmacy services to care homes. The UK team is also well positioned to support broader European market entry.

# **New Market Expansion Developments:**

PainChek has also taken the opportunity to work with existing clients in the development of new PainChek initiatives including entering new larger healthcare market segments and the development of new PainChek products. These are core to the Company's business growth over the next 12 months. These new initiatives include:

#### 1. PainChek Universal Pain Assessment Solution:

PainChek Universal App, combining the PainChek App with the Numeric Rating Scale (NRS), is now CE mark and TGA cleared for commercial use and has commenced roll out to existing clients in Australia commencing in April 2021 with large Aged Care provider Allity.

P: +61 8 9388 8290 E: info@painchek.com W: painchek.com The combination of PainChek and the NRS in one point-of-care PainChek application allows carers to assess pain for those who cannot verbalise their pain, and to also document the pain score of those who can self-report their pain. PainChek is rapidly evolving to become the Universal Pain Assessment Solution for all people in all environments.

This means PainChek can now become the sole solution for multiple healthcare professionals in assessing and documenting pain across all their patients, making PainChek even stickier with existing clients and having far greater potential to attract new clients.

More information can be found in the attachment and at <a href="https://painchek.com/latest-publications/">https://painchek.com/latest-publications/</a>.

#### 2. Home Care and Disabilities market – market entry:

The PainChek pilots with Home Care providers in Australia were completed during Q1 CY21. The pilots confirmed the fit and market need for PainChek in the home environment and has provided the basis for the product positioning and business model for this sector. In parallel the Morrison government has indicated clear commitments to expand the home care packages to support the long-term strategy of allowing people to remain at home for as long possible, with additional funding projected in June 2021. This may include a potential level 5 package for people living with severe dementia. We are now working to launch the PainChek Universal Home Care system into the Australian and overseas markets (including UK and Canada) with our direct sales teams and international partners in H2 CY21.

In the Disability (NDIS) sector there is a clear need for better pain assessments. The Nulsen agreement in WA now includes the provision of a clinical study to be conducted with the support of Curtin University entitled "Implementation and user acceptance of PainChek® Pain Management Tool with people living in supported accommodation who have complex needs". The goal of the six-month study is to provide published clinical data that validates the utility of PainChek for this vulnerable group of people and provide a platform for broader use of PainChek within the NDIS sector — both in Australia and overseas.

# 3. Hospital Market – new applications and market entry:

The Ramsay Hospital Research Foundation research program to assess pain management for frail patients commenced at the Hollywood Hospital in WA during March. The nursing staff have been trained and are now using PainChek Universal within the Hollywood Hospital as the standard tool for pain assessment. The results will be used to review hospital patient pain management within the Ramsay Hospital Group.

The Philips Healthcare European research collaboration on pain management for patients at risk of a delirium has been delayed due to the 3rd wave of COVID-19 in Europe. PainChek remains in close contact with the Philips team and both parties are committed to commencing the project post COVID-19 vaccination roll out for healthcare professionals in Europe.

There are a number of other ongoing partner negotiations in place in multiple markets for hospital access and distribution.

#### 4. PainChek Infant:

Having successfully completed the PainChek Infant Face-Only study, PainChek has now also received positive feedback from a peer-reviewed scientific journal. The findings support the use of PainChek Infant for procedural pain assessment with infants.

**P:** +61 8 9388 8290 **E:** info@painchek.com

PainChek remains on schedule to achieve Australian (TGA) and European (CE Mark) regulatory clearance for the Infants App in Q2 CY21 and subsequent market launch in 2H CY21

PainChek expects to broaden the applications of PainChek Infant through additional clinical studies in 2021 at the Royal Children's Hospital (RCH) in Melbourne.

#### PainChek CEO Philip Daffas commented:

"The positive acceptance of the PainChek Universal Pain Assessment Solution has been outstanding. Our goal is to make PainChek the Universal pain assessment system for all people – adults and kids – and useable by every healthcare professional in all locations. We are on our way to achieving our ultimate goal – making pain a new healthcare vital sign.

We have validated, within our domestic market, a novel product that delivers on a real market need and a business model that has significant long-term value. We have also successfully continued to deliver with significant, double digit sales growth for four consecutive quarters during a global pandemic that has significantly impacted access to aged care. This includes pivoting to a fully digital sales and delivery model that meets the immediate needs of our clients, as well as establishing a new cost-effective global go-to-market model.

PainChek is a global business and our long-term business growth is overseas, we have already seen green shoot opportunities in the UK and New Zealand in the past month, and this should accelerate on an international basis as the COVID-19 vaccination programs are completed worldwide.

In our domestic Australian market, we've now penetrated more than 35% of the aged care market and reached the point where the earliest RAC adopters of the Government initiative are coming off the 12-month trial period. We remain very confident of the vast majority of RACs continuing as fully paying clients of PainChek, and currently this is estimated to translate into \$3.5m of annual recurring revenue, a number we expect to continue to grow as we move forward.

We continue to listen to client feedback to continually improve our product and service delivery and commenced entry into new larger markets including home care, hospitals and the disability sector."

P: +61 8 9388 8290
E: info@painchek.com
W: painchek.com

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# Below is a summary of key measures for the past year on a quarterly basis.

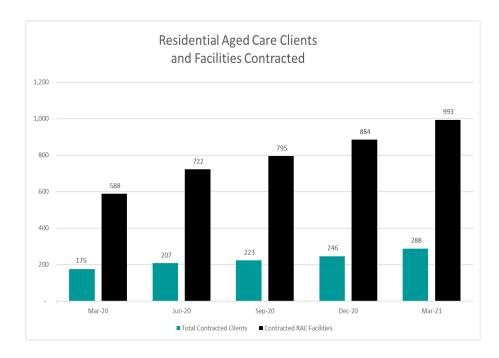


Table 1 above reflects PainChek's total contracted Residential Aged Care (RAC) clients and RAC facilities globally as at the end of each quarter. Contracted clients and RACs have grown to 288 and 993 respectively at 31 March 2021, a 17% and 12% increase respectively over the previous quarter.

In the last quarter PainChek continued its growth, contracting a net additional 8,719 RAC beds. The net increase (after non-renewals and adjustments) is 42 Aged Care providers who operate 109 Residential Aged Care facilities. This included providers such as Anglican Community Services (23 RACs) and Darling Downs (11 RACs).

We have continued discussions with several large providers which were delayed by the re-emergence of COVID outbreaks in December. PainChek has a strong pipeline of Aged Care beds to support continued growth in 2021.

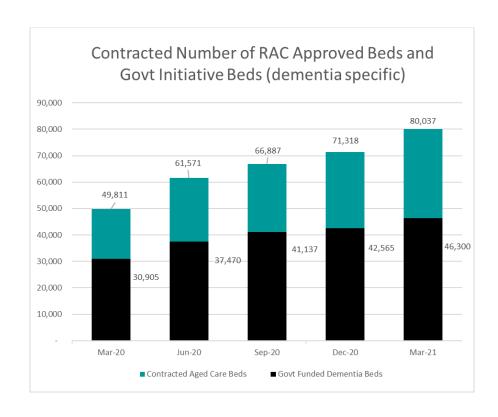


Table 2 above reflects the total approved beds contracted in all markets at the end of each quarter, including the dementia specific beds signed and funded under the government initiative.

- Total approved beds contracted have increased from 71,318 at 31 December 2020 to 80,037 at 31 March 2021, a 12% increase for the guarter.
- Under the government funded initiative, the Federal Government is funding a subset of the total
  approved contracted beds, in that the grant is funding the use of PainChek for those people living with
  dementia or cognitive impairment. PainChek had achieved a total of 46,300 dementia specific beds
  reported to the government under the funded initiative as at 31 March 2021, representing a 9% increase
  for the quarter.

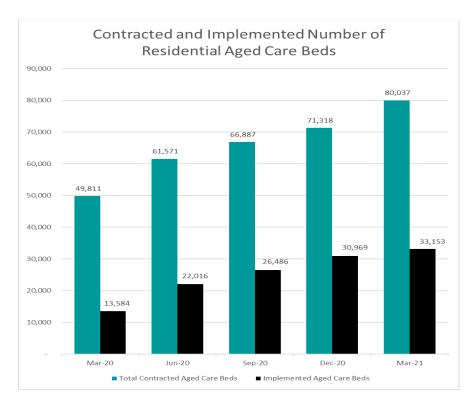
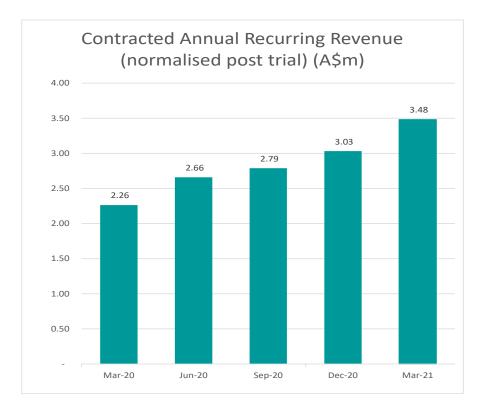


Table 3 above reflects total contracted and implemented beds at each quarter end across all markets. Implemented beds were 41.4% of total contracted beds at 31 March 2021. There is a lag in implementing the bed licenses for the following reasons:

- There is a time differential between signing up the client and scheduling implementation of PainChek® across a client's multiple aged care facilities, which has been exacerbated by the pandemic and the issues it created in aged care.
- Large clients can take a number of months to implement due to the large number of facilities to be covered in the roll out.
- The continuing impact of COVID-19 in terms of staff availability to attend training and implement change in clinical practices.

To improve customer implementations the Company has increased the resources delivering training both on site and virtually, continued to improve the quality and quantity of the on-line training tools and successfully transitioned to provide this service to clients through the remote digital delivery platform.



\* Contracted ARR figures are presented on a normalized basis post completion of the Government grant reflecting contracted pricing on completion of the trial, and assumes the contracts are fully implemented and not terminated after the initial 12-month grant period

Table 4 above reflects the increase in contracted Annualized Recurring Revenue (ARR) for the quarters to 31 March 2021.

- ARR measured on this basis provides an indication of the Company's future revenue, as PainChek's normal
  commercial pricing will apply to total approved beds across all existing RAC's in year two of the contract,
  on the assumption that the clients do not terminate their contracts after the initial 12-month grant
  period.
- For the 80,037 approved beds contracted as at 31 March 2021, the contracted Annualized Recurring Revenue on a normalized basis in year 2 of the contract is \$3.48M, a 15% increase for the quarter.

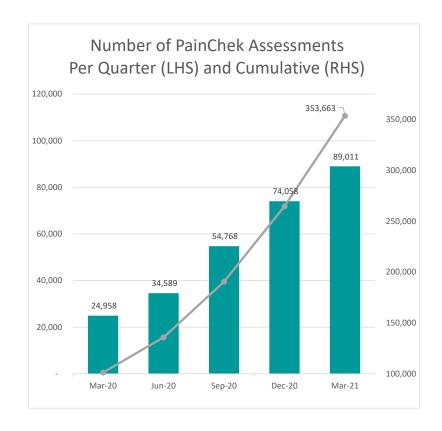


Table 5 above reflects the quarterly number of PainChek assessments up to 31 March 2021. There have now been more than 350,000 clinical pain assessments conducted by clients, demonstrating the App's strong clinical utility and uptake in the residential aged care market.

As a consequence, PainChek now has a comprehensive and growing database of pain assessments for people living with dementia. This database represents a significant asset to the company, PainChek users at an organisational, facility and patient level, and for researchers. The data collected is being used to:

- Develop business intelligence tools
- Promote and monitor best practice
- Facilitate future App and web admin portal development
- Further the understanding of how pain is manifested in those living with dementia

### Australian Government funded sales activity this quarter

In the quarter ended 31 March 2021, the Company signed 48 new clients to the government trial, representing an additional 115 RACs and 9,081 approved beds. These figures represent the gross number of new contracts and exclude net non-renewals or adjustments during the quarter.

A number of the early adopters of the national trial have now reached the end of the 12-month trial. Some of these clients have successfully embedded PainChek as their pain assessment practice and have continued as contracted PainChek customers on standard commercial terms. There is also a cohort of Aged Care providers who undertook training, however due to COVID-19 outbreaks were unable to make use of PainChek during their 12-month trial period. This group mostly comprises small providers who do not have the same infrastructure or

resources as larger organisations. After consultation with the Department of Health, PainChek granted a short extension of their trial to provide an opportunity for staff to experience the benefits of the PainChek technology. A few small clients have not renewed at this stage, but PainChek management remains in contact and has the opportunity to re-engage post COVID pandemic.

As of 31 March 2021, the Company has delivered and fully implemented PainChek into 183 of the clients signed or who opted into the government trial, covering 472 residential aged care facilities.

## Federal Government / Department of Health Grant milestones

We continue to convert the strong sales pipeline to pursue the following milestones:

Milestone	Payment Amount (excl. GST)
Received prior to 30 June 2020	\$3,000,000
Provision of 75,000 cumulative licenses during FY2021 (Milestone 3: end date 31st May 2021)	\$950,000
Provision of 100,000 cumulative licenses during FY2021 (Milestone 4: end date 31 <sup>st</sup> May 2021)	\$950,000
Provision of evaluation report during FY2021	\$100,000
Total funding	\$5,000,000

At the date of this report, the cumulative dementia licenses total approximately 50,000. We have a strong sales pipeline and are working hard towards achieving the above milestones, targeting to achieve at least 75,000 cumulative licenses by 31 May 2021 which is the final date for sign up for the government grant. This would equate to approximately 120,000 approved beds or 55% market share in Australia, and a value of approximately \$5M per annum ARR on standard PainChek pricing terms. It is too early to predict the precise final number at this stage, however we will update the market once we are in a position to do so. All agreements signed after 31 May 2021 will be on standard PainChek pricing terms.

#### PainChek infant's App development

There are 400 Million pre-verbal children<sup>1</sup> in the world of which it is estimated 100 million are born to first time parents each year. This is a significantly large new market opportunity.

PainChek is pleased to report that the PainChek Infant Face-Only clinical study has been successfully completed and the manuscript outlining the findings from the study is currently in the final stages of peer review. Further, human factor validation testing has been completed on the App, which demonstrated good useability.

P: +61 8 9388 8290 E: info@painchek.com

PainChek remains on schedule for Australian and European regulatory clearance of the PainChek® Infant product, with submission planned for Q2 CY21 followed by market launch in these territories.

The PainChek Infant Face-Only study was developed to test the feasibility of using PainChek® Infant's face domain alone as an indicator of pain, and to evaluate it using video recordings of infants undergoing painful procedures. This study received ethics approval from Curtin University. The study involved PainChek infant face domain scores being compared with assessments conducted using the Revised Neonatal Facial Coding System (NFCS-R)3 and the Observer Visual Analogue Scale (ObsVAS). Both NFCS-R and ObsVAS are well known and validated scales used in assessing procedural pain in infants, such as vaccinations, finger and heel pricks, dressing changes or more invasive procedures such as biopsies. Assessment of procedural pain occurs in various settings, from hospitals to home care environments.

Findings from the study support the use of PainChek Infant for procedural pain assessment. This was achieved by the automated assessment of facial expressions alone. The paper-based NFCS-R also assesses pain based on facial expression. When compared to the NFCS-R and ObsVAS, PainChek Infant (Face Only) demonstrated good to excellent validity, reliability and internal consistency. Detailed results of the study will be made available following their publication in a peer-review scientific journal. Procedural pain represents a significant problem as it can have both short-term and long-term negative consequences on children's health if not managed effectively.

PainChek continues with next steps to broaden the clinical applications of PainChek Infant, including research at the Royal Children's Hospital (RCH) in Melbourne, which was put on hold due to COVID-19.

## FDA regulatory clearance progress

PainChek has received the reviewers' feedback on its pre-submission Supplement application and met with FDA to discuss this. The Company is now in the process of amending the protocol for its pivotal trial, which will be submitted for FDA in Q2 CY21.

In the meantime, PainChek already has TGA, CE mark, HSA Singapore and Health Canada clearances that covers approximately 40% of the global market. With FDA clearance the Company will effectively have access to more than 70% of the global medical device market.

#### **UK market progress**

PainChek UK adapted well to the challenges of the second COVID-19 wave during Q1 CY21. Whilst January and February were challenging for many reasons, March saw an uplift in sales. Confidence returned toward the end of the quarter as the aged care sector adapted and vaccination rollout success continued. Lock down restrictions have been relaxed in April and this, along with the 10 million second vaccine doses being delivered, should continue to boost confidence.

A medium size operator, Erskine Hospitals Care Group, provides a strong footprint for PainChek in Scotland. Orchard Care, a large UK care operator, is also continuing to rollout to the rest of the group following a successful pilot in four homes.

Integrations with UK care management software companies progressed well in Q1. In addition, a partner arrangement has been agreed with WELL, the third largest pharmacy operator in the UK that provides pharmacy services to care homes.

As market stability increases through Q2 2021, and integrations expand, we expect an uplift in sales, both direct and via partners. The focus remains to establish and capitalise on integrations that subsequently present an active prospect base for sales growth

# **Philips Healthcare collaboration**

The PainChek and Philips Europe-based research study plan is still delayed due to the COVID-19 impact in the Netherlands. The focus of the study is around combining PainChek facial pain indicators with other patient vital sign measures to proactively assess the risk of a delirium for a patient in hospital care.

Communications between the two parties around the fit of PainChek pain assessment technology within the Philips vital signs monitoring platform and its global pain management strategy continues. The collective aim of the parties' is to progress and finalise these collaborations so that they are ready to jointly execute immediately following the easing of COVID-19 related measures.

#### Japan / NVISO MOU

PainChek signed a Memorandum Of Understanding (MOU) with nViso to investigate the potential combination of PainChek's pain assessment and nViso's emotion sensing AI technology to increase the overall functionality of personal robots in Japan's aged care sector. Switzerland-based nViso has a Smart Health & Living division and is currently engaged in the development of personal/companion robots with a major robotics manufacturer in Japan.

The collaboration concept was displayed at the artificial intelligence conference AI Expo Tokyo [Spring] event in Tokyo from 7-9 April 2021, where nViso presented its solutions for personal robots and the PainChek Universal pain assessment solution as part of its "Smart Living" sector offering.

This MOU may lead to a definitive partnership agreement

In accordance with ASX Listing Rule 4.7C.3, the amount of \$103,000 stated in section 6.1 of the Appendix 4C paid to related parties and their associates related to director fees and salaries for the quarter.

This release has been authorized for release by the Company's board.

Philip Daffas CEO – PainChek Limited 29<sup>th</sup> April 2021

# References

1. See PainChek ASX release Company presentation 28<sup>th</sup> November 2019