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ASX ANNOUNCEMENT
30 OCTOBER 2020

PainChek™ Intelligent Pain Assessment

September 2020 Quarterly Update

PainChek continues to deliver growth in aged care, expanding into home care, hospital and disability segments as well as further establishing itself in international markets

HIGHLIGHTS

Increases in all sales related KPI's across the business for the quarter ended 30 September 2020:

- $750K revenue recognized during the quarter out of the $1.25M received in June 2020 in relation to the second quarterly license milestone as per the government funded licenses grant.
- 795 Residential Aged Care (RAC) Facilities and 66,887 approved beds are under annual PainChek® license as at 30 September 2020, representing a 10% and 9% increase respectively over the previous quarter and 397% and 457% growth over the previous year.
- Total beds under license as at 30 September 2020 equates to $2.79M in normalized contracted Annualized Recurring Revenue (ARR) in Year 2 of the client contracts (post government funded licenses) representing 323% growth over previous year.
- There have now been more than 190,000 clinical pain assessments conducted by clients, a 41% growth in the quarter and 241% growth over the previous year, demonstrating the App's strong clinical utility and uptake in the residential aged care market.
- Three pilots in the $2 Billion Australian Home Care market now underway with leading Australian Home Care providers to support the increasing demand for home care service and packages.
- New Hospital research commercial agreement in place with Ramsey Hospital Research and Cowan University for frail patient pain management.
- New Disability commercial agreement with Nulsen Group, opening access to the large NDIS market.
- Canada regulatory clearance pending and commercial partnership now in place with AlayaCare, the leading Home Care software care management system provider in Canada.
- Positive progress in revised Children's App clinical study – targeting 2021 TGA and CE Mark clearance.
- Pre-submission supplement application with FDA completed.
- The Company raised $10M in August 2020 via a private placement with professional and sophisticated investors at $0.11 per share. The funds will be used to accelerate international growth opportunities and to develop new products.
- As a result of the capital raising, PainChek's consolidated cash balance at 30 September 2020 increased to $13.8M

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 expansion into the hospital, home care and disability markets during the quarter ended 30 September 2020.

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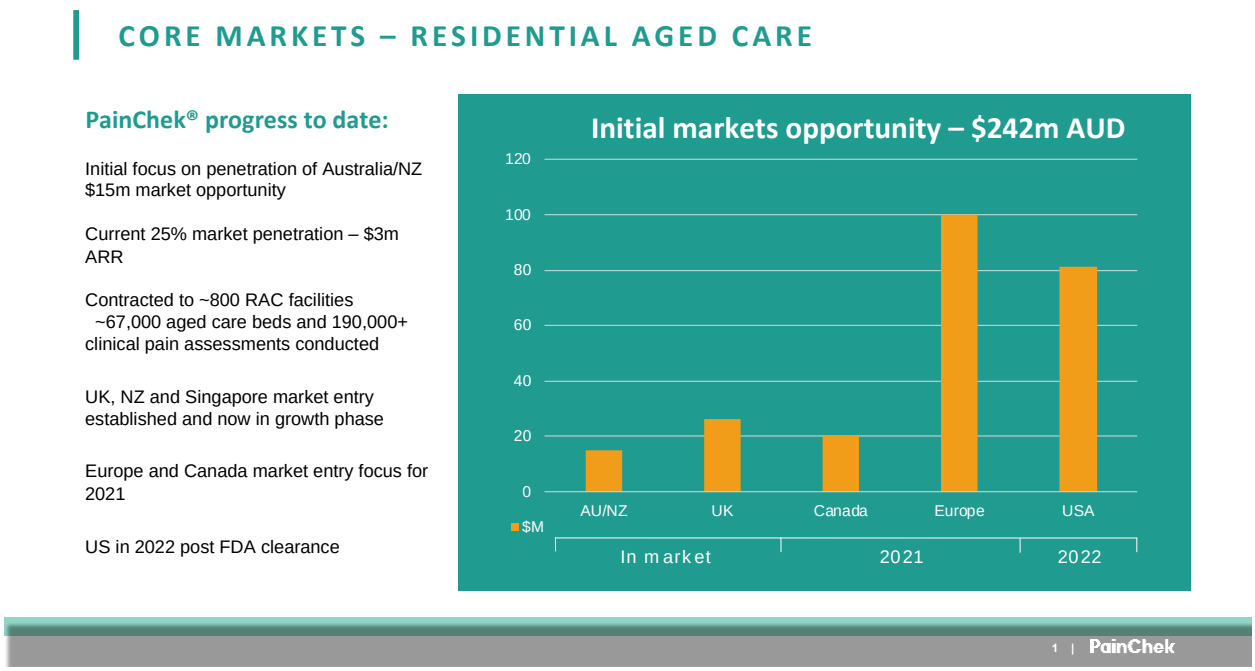
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PainChek's core markets, trends & progress

The following is a summary of PainChek's core markets, trends in the industry and the Company's business progress:

1. **Aged care facilities**: Have introduced restrictive visitation policies and shifted to operating and working with suppliers remotely using digital services. This is a new global normality, based on the risks associated with COVID-19 and is projected to be here to stay for the future. Companies that can deliver and operate this way are meeting these new needs, ensuring safety for the residents and their carers is the key focus.

PainChek progress: The Company's digital capability has proven to be very successful in both the sales and training delivery while also being seen as a safe and clinically valid solution within aged care. Today, there are more than 67,000 aged care beds under license across nearly 800 aged care facilities and more than 190,000 clinical assessments now completed. PainChek is now aged cares' most common clinical software in Australia. The Company also remains well positioned to continue to grow in our other existing markets including the UK and NZ with local partners and well positioned to move into mainland Europe in 2021 with the CE mark clearance in place.



Market size data is information provided in PainChek's June 2020 quarterly

2. **Home Care:** Increasingly, people want to stay at home for the duration of life to maintain independence and minimise risks associated with a residential aged care facility. It can also be more cost effective for the person and their family. This is driving global government policy to provide same care levels as expected in aged care through home care packages including the right to good pain management. This is not limited to people living with dementia or who are cognitively impaired but also includes people with disabilities, being cared for through NDIS and other government funded programs. There are more than 900 NDIS providers in Australia.

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PainChek progress: Three new Australian home care pilots sites have completed online training and onboarding, and due to commence live in November. These will conclude by January 2021 and provide the basis for a broader market launch in Australia and UK/Europe.

In addition, the Company has finalised an agreement with AlayaCare, a leading home care software provider, to collaboratively enter the Canadian home care market in early 2021, post anticipated Health Canada regulatory clearance. This agreement can extend to AlayaCare US clients post FDA clearance.

PainChek also finalised a first commercial agreement in the disability sector with the Nulsen Group in Australia, for a pilot programme assessing pain in people living with disabilities and communication difficulties. This agreement is PainChek's first with a National Disability provider (NDIS) and opens up an additional large new market for the Company.

CORE MARKETS - HOME CARE DEMENTIA(includes Direct to Consumer)

PainChek® progress to date:

Initial focus on Australia/NZ markets $35m market opportunity AU/NZ

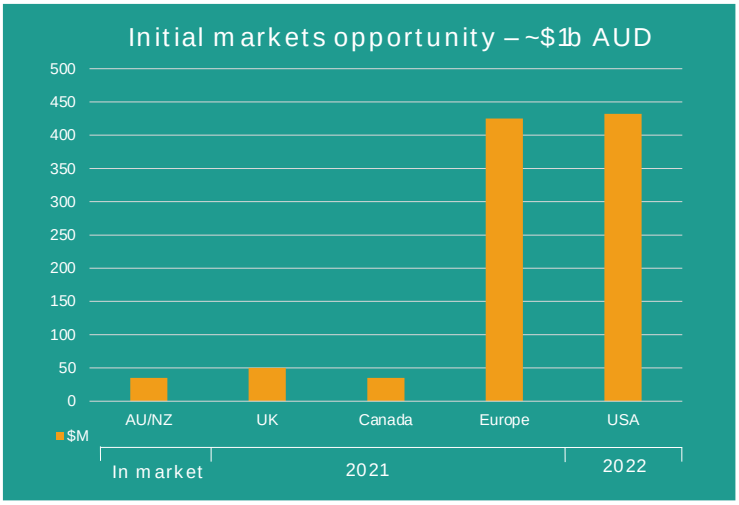
3x pilot programs in Australian Home Care – broader market launch in Q1 2021

Canada agreement with AlayaCare for Q1 2021 start post Canada Health clearance

UK and European market entry scheduled for 2021

US entry in 2022 post FDA clearance

Disability agreement with Nulsen Group is a new additional market



Market size data is information provided in PainChek's June 2020 quarterly

3. **Hospitals:** Hospitals are admitting and treating an increasing number of patients with communication difficulties, such as dementia, those otherwise cognitively impaired and post-surgery patients who are temporarily unable to verbalise their pain. These patients are at an increased risk of a delirium if pain is not managed effectively. It is estimated up to one third of patients in hospital are impacted by these conditions. Therefore, there is a growing recognition of the need for better pain assessment tools for this vulnerable population as they pass through the hospital sector.

PainChek progress: During the past quarter PainChek finalized a clinical study and commercial agreement with Ramsay Hospital Research group and Cowan University for the use of PainChek with frail patients in the Australian hospital sector. This first phase study can lead to a broader adoption of PainChek throughout the Ramsay hospital network if successful. In addition, the Company continues to remain in contact with Philips Healthcare for a potential global collaboration in the hospital market within critical care monitoring and reducing the risk of a post-operative delirium.

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CORE MARKETS – HOSPITAL

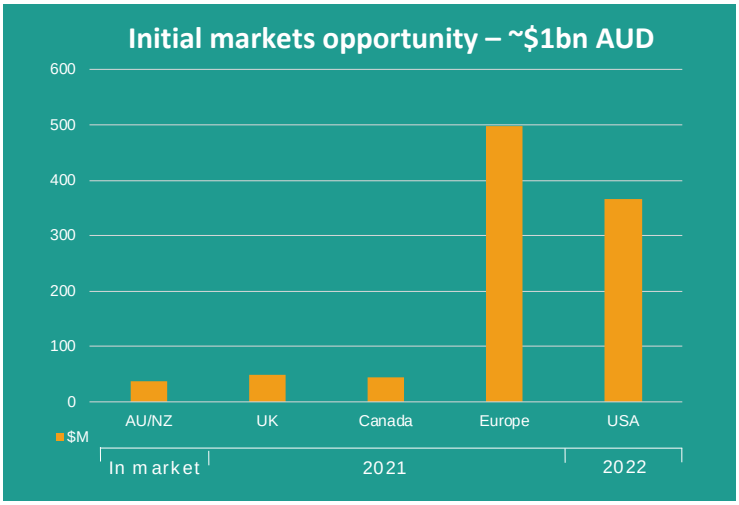
PainChek® progress to date:

Initial focus on penetration of Australia/NZ $36m market opportunity

Research agreement with Ramsay Research and Cowan University for pain assessment in frail patients.

Philips Healthcare communications ongoing global collaboration in research and integration opportunities.

Additional European Partner opportunities being explored in 2021



Market size data is information provided in PainChek's June 2020 quarterly

PainChek CEO Philip Daffas commented:

"During 2020 and the COVID-19 pandemic there have been major challenges to the healthcare market and specifically the revision of attitudes and policies to the delivery of healthcare in aged care, home care and hospitals globally. We have continued to significantly grow our business during this year without being able to visit a single aged care facility and with the well documented lock downs around the world. We envisage stronger growth over the next period in our local market as Victoria comes out of lock down and overseas as UK, European and North American markets now start to learn to live and manage ongoing business with the pandemic.

It is also well documented that elderly people living with dementia and cognitive impairment can rapidly move from home to an aged care facility and to hospital prior to returning home again. In addition, we now see carers and nurses transitioning between these three sectors and taking best practice across with them. We are experiencing this firsthand as PainChek has extended its business reach during the past quarter from aged care into the larger home care and hospital segments in Australia and international markets.

PainChek has taken the opportunity to proactively deliver on these changing market dynamics and client needs. The Company has fully pivoted to a new safe and cost-effective business model that can be used globally, leveraging our fully digital capability to meet the 'new norm' of our three core global market opportunities.

The additional benefits of this business model are significant as it provides the basis for rapid expansion into international markets without the need for significant cost development."

Below is a summary of the results for the past quarter and over the last year.

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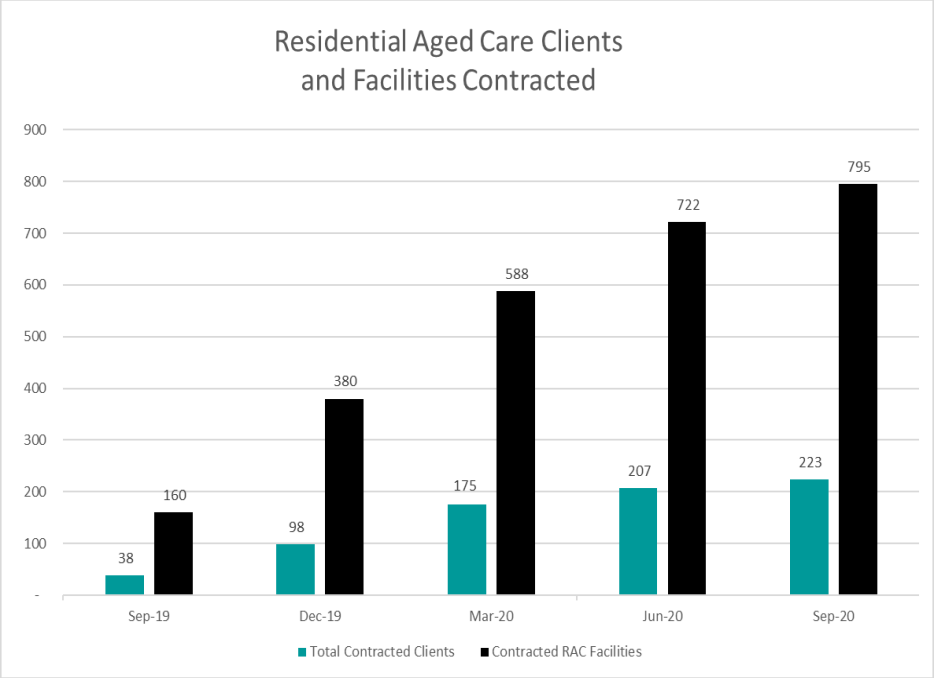
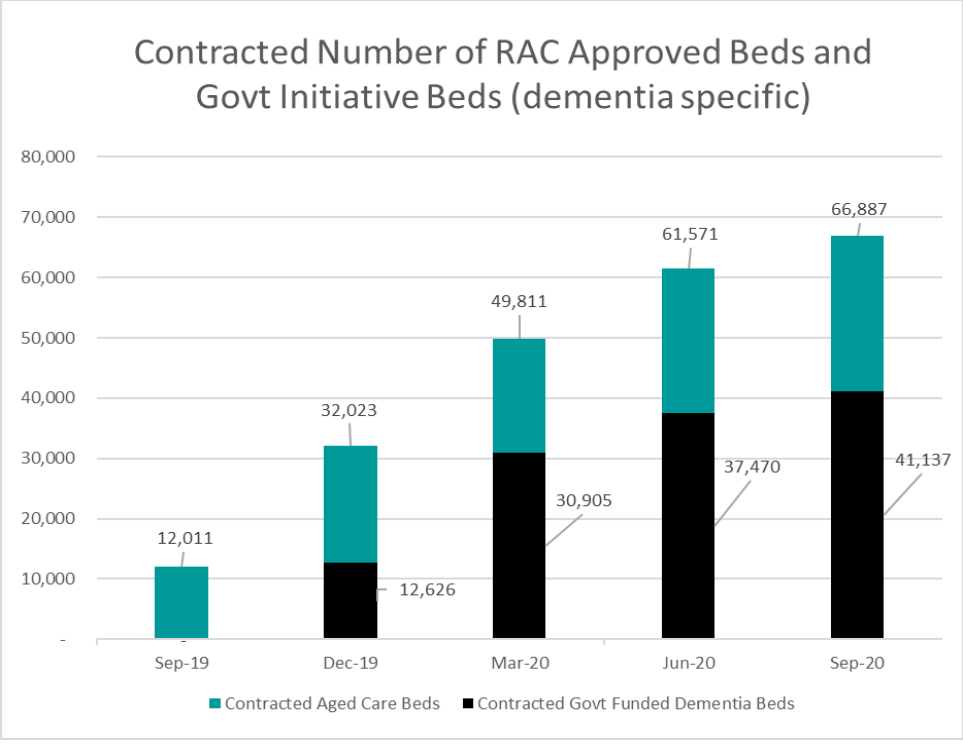


Table 1 above reflects PainChek's total contracted Residential Aged Care (RAC) clients and RAC facilities globally. Contracted clients and RACs have grown to 223 and 795 respectively at 30 September 2020, an 8% and 10% increase respectively over the previous quarter.



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

- Total approved beds contracted have increased from 61,571 at 30 June 2020 to 66,887 at 30 September 2020, a 9% increase for the quarter.
- 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. The data gathered from the RAC participants to date continues to support that this subgroup is on average 62% of the total approved beds. On this basis, PainChek had achieved a total of 41,137 dementia specific beds as at 30 September 2020, representing a 10% increase for the quarter.

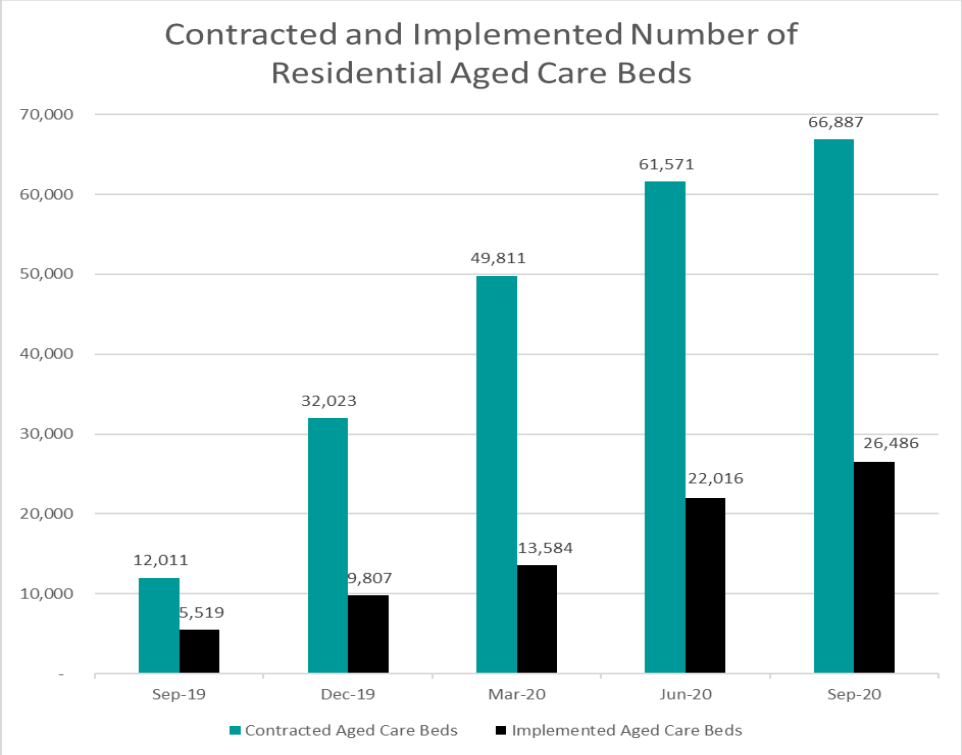


Table 3 above reflects total contracted and implemented beds at each quarter end across all markets. Note that the figure for implemented beds at 30 June 2020 was over-reported and has been adjusted from the 24,435 previously reported. As a result, the number of implemented beds increased by 20% this quarter.

There is a lag in implementing the bed licenses for the following reasons:

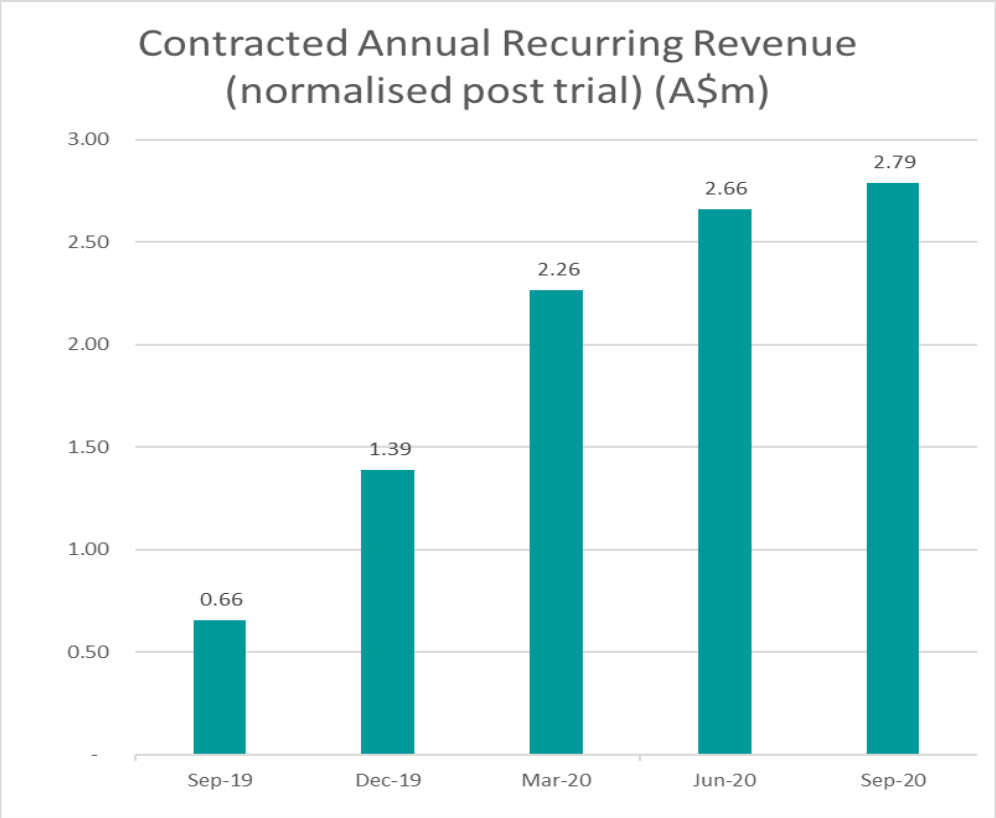
- There is a time differential between signing up the client and scheduling implementation of PainChek® across a client's multiple aged care facilities, which increases when there has been a large number of sign ups in a short period.
- Large clients can take a number of months to implement due to the large number of facilities to be rolled out to.

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- The continuing impacts of COVID-19 in terms of staff availability to attend training and implement change in clinical practices.

To improve implementation rates the Company has significantly improved the quality and quantity of the on-line training and successfully transitioned to provide this service to clients through the remote digital delivery platform.

The proportion of implemented beds in relation to contracted beds at 30 September 2020 is 40%. The Company plans to accelerate the implementation of PainChek® as both the sector's management of the COVID-19 impact and staff availability improve.



* Contracted ARR figures 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 figures for the quarters ending 31 December 2019 and later 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 not terminated after the initial 12-month grant period.

Table 4 above reflects the increase in contracted Annualized Recurring Revenue (ARR) for the period covered by the chart, which correlates with the increase in PainChek® licenses.

- ARR measured on this basis offers insight to the Company's future revenue generation, 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.

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- For the 66,887 approved beds contracted as at 30 September 2020, the contracted Annualized Recurring Revenue on a normalized basis in year 2 of the contract is $2.79M (a 5% increase for the quarter).
- All Australian residential aged care clients acquired prior to the government trial, with the exception of a small number opted into the grant prior to 30 June 2020.

Government grant revenue

- The revenue generated under the Federal Government grant is subject to AASB 120 Accounting for Government Grants, and accordingly PainChek's revenue in relation to the trial is be recognized under that standard and is based both on the achievement of contractual milestones and the matching of expenditure to revenue.
- The upfront payment of $500k received in December 2019 and the first quarterly milestone payment of $1.25M received in March 2020 were recognized as grant revenue in the year ended 30 June 2020.
- The $1.25 million receipt in June 2020 was received in advance of the second license milestone being met. Of that amount, $750k was recognized in the quarter ended 30 September 2020 based on progress against the second quarterly license milestone.

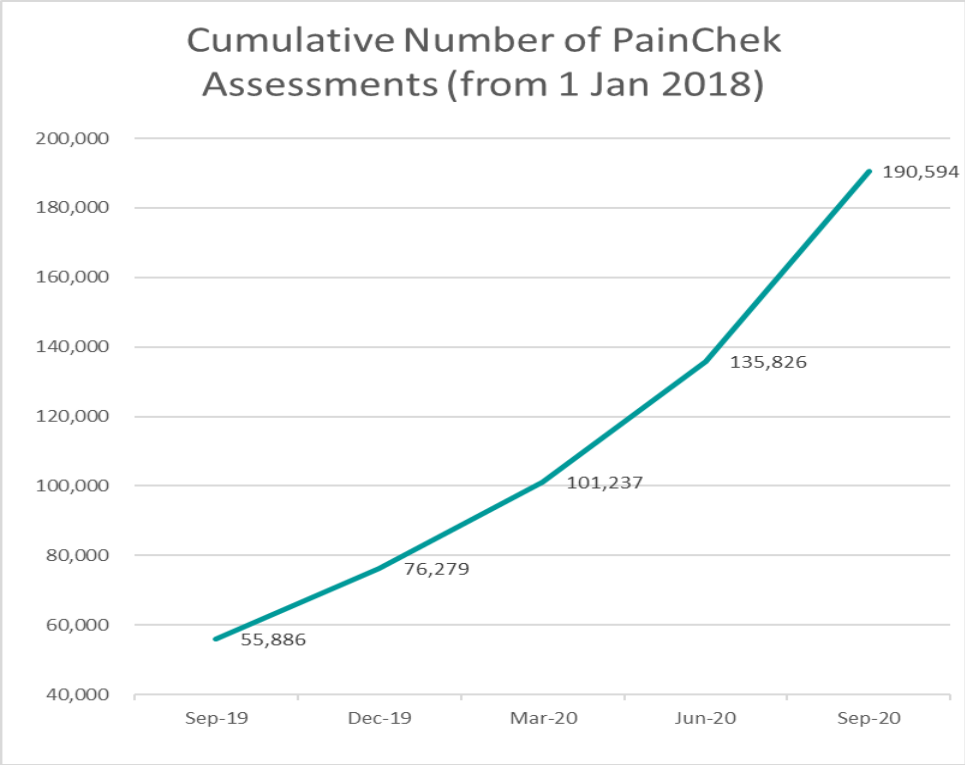


Table 5 above reflects the cumulative number of PainChek® assessments up to 30 September 2020. There have now been more than 190,000 clinical pain assessments conducted by clients, demonstrating the App's strong clinical utility and uptake in the residential aged care market.

Subsequent to the end of the September quarter the number of clinical pain assessments completed by PainChek® users surpassed 190,000. In doing so, this provides PainChek with one of the most, if not the most, comprehensive database of pain assessments in people living with dementia in the world.

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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 30 September 2020, the Company signed 21 new clients to the government trial, representing an additional 75 RACs and 5,605 approved beds. There were a small number of clients (comprising 6 RACs and 521 approved beds in total) who decided during the quarter not to proceed with the trial, for reasons primarily related to dealing with the challenges presented by the pandemic.

The agreements are for a two to three-year period, and combine the government funded dementia bed program for the first year and the PainChek standard approved bed terms for the additional years.

Significant clients acquired during the quarter, as well as the number of approved places, include:

- Blue Cross Community Care Services 2,700
- Australian Unity Care Services 786

As of 30 September 2020, the Company has delivered and fully implemented PainChek® into 123 of the clients signed to the government trial, covering 315 residential aged care facilities. The company plans to accelerate its implementation plans as the restrictions and constraints created by the pandemic start to lift in the coming months.

Federal Government / Department of Health Grant milestones

The following are the next milestones and related dates for which payments will be made under the contract terms to PainChek as part of the Federal Government initiative:

Milestone	**Payment Amount (excl. GST)**
Received prior to 30 June 2020	$3,000,000
Provision of 75,000 cumulative licenses during FY2021 **(Milestone 3 now March 2021 or sooner as achieved)**	$950,000
Provision of 100,000 cumulative licenses during FY2021 **(Milestone 4 now May 2021 or sooner as achieved)**	$950,000
Provision of evaluation report during FY2021	$100,000
Total funding	$5,000,000

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Australian Home Care Market Expansion

Home care packages account for more than $2 billion of federal funding per annum, with FY2019's mid-year fiscal review releasing a further half a billion dollars' worth of packages to meet need. Since deregulation there has been exponential growth in HCP providers, with the number of operators sitting at 925, almost double what it was in 2016. The top 25 providers control $1 Billion of funding and the majority of these are also large Residential Aged Care providers. With an increased demand for value-based services in a competitive market, PainChek is well placed to support innovative quality improvement for home care providers by effective and consistent measurement of pain. In addition, eight of the current top 25 home care providers are currently PainChek clients in the Residential Aged Care sector.

There are currently three PainChek Australian trials commencing with a mix of private and not-for-profit home care providers. These trials are targeted for completion in December 2020/January 2021. Early indications are that there is a clear need for increased pain assessment in this market and the rapid performance of PainChek provides a cost-effective solution to address the need. The overall trial goal is to collect consumer, provider and user data as a basis for the broader home care market launch in Australia and overseas market in early 2021. We have identified the top tier targets in the domestic market to underpin the subsequent local market roll out.

Initial market development activity is also underway in the adjacent disability (NDIS) sector, targeted towards the assessment and management of people with an intellectual disability. With challenging behaviors 3–5 times more common in the intellectually disabled population than in the general population, a critical aspect of assessment is to screen for physical causes and look for unrecognized pain. PainChek have successfully secured a first commercial agreement with NDIS disability services provider Nulsen, to further validate the application in this market and the use of PainChek to determine pain assessment indicators in people with intellectual disability.

People with cognitive impairment are eligible for the NDIS if they meet the age and residence requirements and either of the disability or early intervention criteria. The NDIS is a potentially high value market for PainChek with 392,000 active participants and $16.1 billion paid by the NDIS for participant supports in FY20.

PainChek infant's App development and research plans

The COVID-19 pandemic has seen clinical trials and research unrelated to the virus largely curtailed globally. As a result, the PainChek® Infant validation study due to commence in Q1 2020 at Royal Children's Hospital (RCH), Melbourne has had to be put on hold. The primary aim of this study is to evaluate the performance of PainChek® Infant compared to a standard paper-based pain assessment tool (FLACC). A secondary aim of the RCH study was to evaluate the feasibility of using the face domain score only as an indicator of the presence and intensity of pain.

Given the current hold on clinical trials, we have developed a study protocol to test the feasibility of using PainChek® Infant's face domain alone as an indicator of pain, and to evaluate it using pre-COVID-19 recorded videos of infants undergoing painful procedures (PainChek® Infant Face-Only study). Similar study protocols using pre-recorded videos to test pain scales in infants have been conducted and published previously (Crellin et al). This study received ethics approval from Curtin University, and PainChek® infant face domain scores are now being compared with assessments conducted using the Revised Neonatal Facial Coding System (NFCS-R)[3] and the Visual Analogue Scale (VAS). The PainChek Infant Face-Only study is expected to be completed in November 2020. The preliminary results from this study are encouraging. PainChek plans to use the results of this study to support its application for Australian and European regulatory clearance of the PainChek® Infant product, with submission planned for Q1, 2021.

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FDA regulatory clearance progress

PainChek has been made aware that the assigned reviewer has completed their assessment of its Pre-submission Supplement application, and it is awaiting internal FDA sign-off before it can be released.

In the meantime, PainChek already has TGA and CE mark clearance that covers approximately 40 percent of the market, and with FDA clearance the Company will effectively have access to more than 70 percent of the global medical device market.

UK market progress

The UK market progress has been significantly impacted by COVID-19 during 2020 and the range of lock downs through the country. The UK team continue to operate digitally whilst visitation to residential aged care facilities remains restricted. Medium sized aged care groups are in a more stable position, enabling them to engage and consider larger scale technology implementations.

The sales pipeline continues to grow in the small and medium tiers, in particular where facilities have a speciality in dementia care and recent new license agreements have been finalised with aged care facilities Notwen House, Grosvenor House, Early Bird and most recently with Orchard Care during October 2020.

PainChek UK has entered into working relationships with the National Care Association and a number of Regional Care Associations.

The collaboration with Person Centred Software UK has also seen the addition of new residential aged care clients and this demonstrates the strength in creating integrations with established technology providers. Monthly webinars are delivered to the Person Centred Software UK client base.

The UK market has adapted to the presence of COVID-19 and whilst there are regional concerns, the social care sector is better prepared this time around. Additional funding for residential aged care facilities for pandemic support from the UK Government has been provided.

The December quarter should see an increase in pipeline that should lead to spending decisions increasing into Q1 CY2021.

NHSX, the driver of digital transformation in the UK health and social care sector, has cited PainChek UK as an AI-driven case study. In addition, Digital Social Care has also approved and subsequently posted a PainChek UK case study on their website. There is a growing recognition by UK Government that digitisation of care is a key driver in effective social care management, and remote monitoring capabilities, coupled with good data remain a focus.

Philips Healthcare collaboration

The PainChek and Philips European 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 classic patient vital sign measures to pre-actively 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 their global pain management strategy continues and is expected to progress. The collective aim of the parties' is to progress and finalize these collaborations so that they are ready to jointly execute immediately following the easing of COVID-19 related measures.

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

Philip Daffas
CEO – PainChek Limited
30th October 2020

References

1. Crellin DJ, Babl FE, Santamaria N, Harrison D. The psychometric properties of the MBPS scale used to assess procedural pain. J Pain 2018;19:660-669.
2. Crellin DJ, Harrison D, Santamaria N, Huque H, Babl FE. The psychometric properties of the FLACC scale used to assess procedural pain. J Pai. 2018;19:862-872.
3. Kappesser J, de Laffolie J, Faas D, Ehrhardt H, Hermann C. Comparison of two neonatal pain assessment tools (Children and Infant's Postoperative Pain Scale and the Neonatal Facial Coding System-Revised) and their relations to clinicians' intuitive pain estimates. Eur J Pain. 2019; 23:708-718.

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