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**Quarterly Update: December 2018** 

# PainChek® Transforming Pain Management

The company and technology have progressed from a concept to a market reality in less than two years, generating rapid initial sales and receiving market acceptance as a new solution for a large, global unmet clinical problem. In the process, we have validated the initial enterprise (B2B) business model in Australia, built a strong sales pipeline for 2019 and established a base for international expansion during the next 12 months. In parallel, new projects including the children's App continue to make positive progress.

PainChek's initial market entry has been focused on dementia care within the Australian Residential Aged Care (RAC) market. In Australia, there are 950 RAC operators who manage a total of 2,700 facilities with 210,000 resident beds. There are 400,000 people living with dementia in Australia of which 115,000 are within Residential Aged Care<sup>(1)</sup>.

The following is a summary of the B2B Australian sales and market development during CY2018.

Summary of Agreements	Cumulative No. of Contracted RAC Customers	Cumulative No. of Contracted RAC's	Cumulative No. of Contracted Beds	Cumulative No. of Assessments (Active Clients)	Monthly Recurring Revenue (MRR) <sup>(2)</sup> as at quarter end	_
5 1 2 1 1 1 1 2 2 2 2			65	420	2.450	25.000
For the 3 months ended 31 Mar 2018	2	2	65	129	2,150	25,800
For the 3 months ended 30 Jun 2018	5	5	338	680	3,552	42,620
For the 3 months ended 30 Sept 2018	15	21	1,485	4,776	10,582	126,990
For the 3 months ended 31 Dec 2018	18	26	1,789	9,788	11,982	143,790

- All key measures continue to increase positively with revenue, contracted beds and assessments growing significantly through the year and quarter on quarter.
- The mix of RAC clients is well balanced between large, mid and small sized RAC's and the pipeline for new clients continues to increase. In addition, the two annual contracts that were up for renewal during the past quarter were both renewed for a further year under the same terms.
- The December 31<sup>st</sup> Annualised Recurring Revenue (ARR) of \$143,790 excludes the proposed Allity Aged Care full roll out planned for CY2019 (see ASX joint release January 16<sup>th</sup> 2019) which will increase the number of contracted beds to more than 5,000 and, when implemented, increases ARR to approximately \$310,000. This will represent 2.5% penetration of the beds in the Australian RAC market.

<sup>(1)</sup> Australian Government Dept of Health data at June 2015

<sup>(2)</sup> Monthly Annualised Revenue (MRR) includes subscription revenue on contracts of 12 months and longer and excludes one off fees for support and training. MRR and ARR are both calculated on the basis of contracts signed as of quarter end,

and include the one non-RAC contract for DSA. As such, MRR and ARR do not represent revenue recognised in the accounts for the periods ending on those dates.

- Sales in Q4 CY2018, in comparison to the previous quarter, were impacted by seasonality and
  the end of year reporting demands of the Royal Commission from the top 100 Aged Care
  Providers. We believe the Commission will endorse the importance of improved pain
  assessment, which results in improved pain medication, within Aged Care and this is reflected
  in our growing number of trials within the sector.
- In the past quarter we on-boarded 6 new Aged Care Providers covering 10 facilities and more than 600 beds all under one-year license agreements. The on-boarding process will be fast tracked in future through our collaboration with Dementia Training Australia and the development of the on-line training modules which are now both available for healthcare professionals and home carers, including family members.
- We have increased our contracted clinical assessment numbers from a total of 38 assessments in the month of January 2018 to a cumulative number of 9,800 for the full calendar year 2018 and more than 10,000 assessments since we commercialised the technology. These numbers reflect strong uptake and perceived value of the PainChek® App and the metric is an indicator of positive referrals to new clients and future contract renewals.
- We continue to be recognised and supported as a new standard in pain assessment by healthcare professionals including Pain Australia, Dementia Support Australia and Dementia Training Australia and have received strong press coverage during the past quarter including a Channel 9 news article (see PainChek® website).
- These results have been achieved maintaining a low operating cost base reflecting the cost
  effective "software as a service" subscription business model that has similar economies of
  scale at a global level.

## 2019 Growth Initiatives:

2018 was the year in which we established a solid base and validated the business model for the PainChek® Adult App in Australia. The following are key initiatives in place that will accelerate the both the Enterprise (B2B) business and the Home Carer/Consumer business in Australia and overseas.

#### 1. Personalised Pain Management

In January 2019 (refer ASX release 16<sup>th</sup> January 2019) we announced the partnership with Allity Aged Care and Ward Medication Management (Ward MM) to deliver personalised pain management for aged care residents. This new partnership will see the technology used by Allity in combination with Ward MM's Thrive service, to deliver Personalised Pain Management to Australians living in aged care.

In this new initiative, Allity caregivers will use PainChek® to assess and document a resident's pain severity scores at the point of care and then share these pain scores with Ward MM's clinical pharmacist's team in real time. Through the Thrive service, Ward MM will also match residents' medication to their DNA to create an ongoing highly personalised medication management plan. This partnership will provide rapid, personalised and ongoing pain treatment for the Allity residents.

The program commences in January 2019 in three Allity Residential Aged Care homes in NSW and Victoria. Allity will roll the program out nationally across their 44 residential aged care homes and 3,500 residents during 2019.

This initiative is transferable across the broad Aged Care community in Australia and overseas and can help address the Australian Royal Commission issues within Aged Care.

This initiative is also transferable across a range of healthcare sectors including hospital settings such as the Emergency room, Surgical and Geriatric care and will support our strategies extending into the broader healthcare sector.

## 2. Home carer/Consumer market entry:

The development of the Home Carer/Consumer version of the App and service fits in with the Government's "Consumer Directive Care" (CDC) initiative launched in April 2018. The CDC initiative empowers consumers to take control of their home care packages and support the general drive to keep elderly people at home for as long as possible – reducing the burden on Hospitals and Residential Aged Care. The majority of people with dementia in Australia (around 300,000) live at home and many of them have access to these HCO packages.

We finalised the Home Carer/Consumer version of the App during the past quarter. The market strategy is based on ensuring all home carers are suitably trained on pain assessment prior to home use. Therefore, we are taking a 2-step approach to entering the market during 2019 and extending to overseas markets.

- The initial market entry has commenced through Australian Home care Operators (HCO's), many of whom are owned by RAC clients. The HCO's will use the PainChek® App during their home visits and can provide access to PainChek® for selected home carers during a home visit. This will ensure home carers are trained effectively by a healthcare professional and familiarise themselves with the App for a period of time. On familiarisation, the home carer will then have the opportunity to purchase their own license directly through the Apple or Google Play Store to ensure continuity of care.
- The second phase will be to open access to all home carers via the App Stores in conjunction with the Dementia Training Australia on-line training module. The service is scheduled to start in Q2 CY2019.

### 3. PainChek® Integration with Aged Care Third Party Care Management Systems (CMS):

The goal of integration is to ensure PainChek® assessments are automated and documented within Aged Care CMS systems for both regulatory and revenue reassurance (ACFI) purposes. Other benefits are single handling of data and driving cost efficiencies for pain management. Integration with these CMS companies will accelerate PainChek® take up, especially for the larger RAC providers.

- The integration developments with HealthMetrics and LeeCare are scheduled to go live with the initial RAC clients in February 2019 and in total these two agreements will provide access for up to 100,000 RAC beds in Australia and potential overseas access.
- Negotiations with six other CMS providers based in Australia, New Zealand and the UK are
  in advanced stages of negotiation. Completing these agreements will extend access to
  CMS systems that cover the full Australian RAC market and provide access to further
  penetration into the UK, Singapore and New Zealand markets.

#### 4. The Australian Aged Care Royal Commission:

In September 2018 the Australian government called for a Royal Commission on Aged Care. The need of more effective pain assessment and ongoing management in Aged Care is well documented. The top 100 Aged Care groups (by the Commission's definition) had to submit a significant set of documentation prior to the end of 2018 as part of the Royal Commission review process. While this did impact on our ability to close new agreements during the last quarter, the positive news is this has resulted in a growing demand for new PainChek® trials in order to pre-emptively address the current and future standard requirements.

We continue to work closely with the Commission, the Federal Minister for Senior Australians and Aged Care and our Residential Aged Care clients to be part of the solution for the future of Aged Care in Australia.

### 5. Overseas Opportunities:

At a global level there are 50 million people living with dementia with numbers estimated to grow to 75 million by 2025. It is estimated there are on average three carers for each person with dementia and it is the carers who would be the primary users of the PainChek® App. Dementia is currently the second major cause of death globally (after cardiovascular disease) and it is projected to become the leading cause of death during this period.

In December 2018, we received a UK Department of International Trade Rocketship Award that provides financial support and local know how to set up a PainChek® operation in the UK. Initial business meetings are scheduled for February 2019 in London and across the UK that will include potential UK RAC clients and business partners. This fits perfectly with our original strategy of UK market entry in 2019 as well as providing a geographical base for mainland European entry.

We have also Singapore and New Zealand business opportunities which continue to progress positively, and we are working with the German Pain Society to assess market entry into the German market.

## 6. FDA Adult App submission:

During the past quarter we completed the de-novo FDA pre-submission documentation, with guidance from the FDA regulators and our regulatory consultants. This documentation is being submitted to the FDA in late January/early February 2019. We continue to anticipate an FDA clearance during 2020 for the Adult App.

### 7. PainChek® Children's App:

It is estimated there are 400 million pre-verbal children worldwide between the ages of 0-3 years. This figure is four times the dementia market opportunity. We believe the children opportunity will be both a healthcare professional App – for the neonatal, special baby care and maternity units – and an even larger home care opportunity for parents of young children.

PainChek® has developed a novel approach to the development of the Children's App using deep-learning algorithms to conduct automated facial analysis for infants. The new algorithm employs an adaptive video mode capability to capture facial micro-expressions indicative of the presence of pain in infants. The algorithm allows the capture and analysis of an infant's face even when excessive head movements, partial obstruction, or non-frontal face view impacts part of the video being assessed.

These are challenging problems for automated facial analysis in infants which we believe we have now addressed.

Preliminary results from beta testing of the algorithm revealed excellent performance. A PainChek® Children's App version incorporating the technology will be used in the forthcoming clinical study in a children's hospital based on the east coast of Australia.

We have finalised the clinical trial protocol with the children's hospital and are expecting ethics approval during Q1 CY2019 and trial commencement in Q2. Commercial availability of the Kids App is slated for late CY2019.

#### 8. Trademarks and Patents:

We have received the registered Trade Mark for the PainChek® name and branding/logo in Australia and progressed positively with Trade Mark approvals in other jurisdictions. Our patent application continues to progress positively through each national filing.

### 9. PainChek® Team Development:

The company now has seven full time employees including a "go to market" team comprising of sales, clinical and technical support. We retain a number of part time consultants that provide specialised services including finance, digital marketing, regulatory affairs and PR and a strong ongoing relationship with our technology partners nViso and Darwin Digital.

During the past quarter we on-boarded local internal software development capability for strategic projects and to fast track new developments.

On October 1<sup>st</sup> 2018 Mustafa Atee joined PainChek® as Senior Research Scientist and State Account Manager for Western Australia and South Australia. Mustafa was a founding member from the Curtin University research team and the original ePAT company, and as such, he brings a deep understanding of the product and the sector. Joining PainChek® full time reflects his continued commitment to the company.

We plan to extend sales capability in Australia and overseas during Q3 and Q4 FY2019 as part of our sales ramp up.

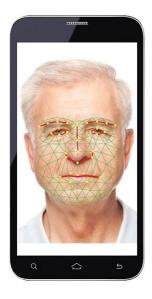
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#### **About PainChek:**

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.





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

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

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 home-based family carers for ongoing pain assessments or clinical data review.

To find out more, visit www.painchek.com