

ASX Release

NOVITA RECEIVES U.S. FDA CLASSIFICATION FOR TALI TRAIN ALLOWING RELEASE INTO THE MAJOR U.S. MARKET

KEY POINTS

- **Novita Healthcare has received classification from the U.S. Food and Drug Administration (FDA) for TALI Train, opening the door for the product to be launched in the major market of the United States**
- **Class 2 classification, exempt from 510k process means immediate marketing of TALI without requirement for further clinical trials**
- **Delivers a complimentary, safe and proven early intervention option for those millions of children on ADHD medication and the 1 in 6 children with a developmental disability¹**
- **Provides foundation for Commercial launch in the U.S. from 2019 - Novita will now progress discussions with identified potential U.S. partners to assist in direct marketing campaigns to parents and for rollout of TALI Train to clinicians and educators**

Melbourne, Australia - 10th September 2018: Novita Healthcare Limited (ASX: NHL), (“Novita” or the “Company”) today announced it has received classification as a “COMPUTERIZED COGNITIVE ASSESSMENT AID, EXEMPT”, Device Class 2 (medical device) from the U.S. Food and Drug Administration (FDA) for TALI Train.

TALI Train is the Company’s lead digital therapeutic delivered as a drug free tool to assist in childhood development. Designed for children aged 3-8 years of age with attention difficulties, both clinical (e.g., children with autism spectrum disorder or ADHD), and non-clinical, as an early intervention with *attention problems being the most commonly reported childhood difficulty*².

The FDA has classified TALI Train as a Class 2 medical device, exempt. This means the treatment can now be sold in the U.S. without the need to conduct further clinical trials or submit a 510k application.

Novita Healthcare Managing Director Glenn Smith said the regulatory classification marked a major milestone and that the Company will move quickly to advance discussions with identified potential partners to support launch in the USA.

“Attention disorders and difficulties among children are a major issue across the world and the U.S. is no exception. Given early intervention therapies have demonstrated value in treating children and improving attention, concentration and learning outcomes, we believe there is a significant market opportunity in the U.S. for a validated treatment like TALI Train,” Smith remarked.

TALI Train is owned by TALI Health, a subsidiary of Novita. TALI Train is designed as an early intervention treatment option for clinicians, educators and parents whilst being complimentary to existing treatments, including psychostimulants such as methylphenidate (sold under various trade names,

¹ CDC: Autism Spectrum Disorder (ASD) (<https://www.cdc.gov/ncbddd/autism/data.html>)

² Kirk, H, 2018: Monash Institute of Cognitive and Clinical Neurosciences (MICCN)

Ritalin® being one of the most commonly known). The USA Centers for Disease Control and Prevention (CDC) report that number of children diagnosed with ADHD is **6.1million** (2016 figure). And that 69% of children that are 6, 7 and 8 years of age were taking ADHD medication³.

While psychostimulants are a popular treatment for attention difficulties, the majority of evidence suggests drugs can only treat the symptoms and not the core underlying causes. And, there are ongoing concerns over the long-term impact, adverse side effects and its limited options as an early intervention treatment given it is not typically administered to children under the age of 5.

TALI Train is now commercially available in Australia and is delivered via a Software as a Service (SaaS) model direct to parents, via schools or for those with a clinical diagnosis, providers who specialise in this sector such as Psychologists and Paediatricians. Interest to date from overseas has been strong with TAL Health setting up an initial clinic in Singapore and an initial early childhood centre in Hong Kong.

“We are pleased that in the space of a few months TALI Train has received both U.S. FDA and Australian TGA (ARTG) inclusion. Both are regulatory milestones which provide access to important markets. TALI Train can be delivered as a digital therapeutic and provides access to non-drug additional treatment options for attention disorders,” Sue MacLeman, Chair of Novita stated.

THE TALI TECHNOLOGY

TALI is a platform technology and digital application. The lead solution TALI Train, strengthens core attention in children via an adaptive and fun game-based interface. The solution is a scientifically and clinically validated digital therapeutic for both clinical (e.g., children with autism spectrum disorder or ADHD), and non-clinical populations, making it ideal for clinical, school or at home use.

Designed as a 5-week intervention (results evident within 5 weeks), TALI Train can be accessed by any tablet device making unique as an in clinic, school or telemedicine option. Lack of attention has a detrimental impact on many areas such as education, social inclusion and general wellbeing. Without effective early treatment attention difficulties can have lifelong consequences.



Image: A child in the “Selection Attention” module of TALI Train

³ CDC: Attention-Deficit / Hyperactivity Disorder (ADHD) (<https://www.cdc.gov/ncbddd/adhd/data.html>)

In development is TALI Detect which will leverage the platform technology and be delivered (in 2019) as a game-based assessment of attention skills in early childhood. This screening tool will be applicable to all children and will provide a non-invasive and engaging method to assess attention skills in childhood.

ABOUT NOVITA HEALTHCARE

Novita Healthcare is an emerging health sector technology company targeting ATTENTION in children through its breakthrough technology TALI. TALI Train uses proprietary algorithms inside a game-based learning application to improve core attention skills in early childhood (www.talihealth.com).

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ADDITIONAL INFORMATION

For further information on how Attention-Deficit / Hyperactivity Disorder (ADHD) diagnosis occurs in the USA please see: <https://www.cdc.gov/ncbddd/adhd/diagnosis.html>

For further information on how Autism Spectrum Disorder (ASD) diagnosis occurs in the USA please see: <https://www.cdc.gov/ncbddd/autism/data.html>

