ASX Release

TALi signs strategic licensing agreement with milestone payments plus royalties for US-market with global leader Akili Interactive

Key highlights

- **Significant expected milestone and royalty payments:** TALi will receive estimated total milestone payments up to AU$51M (US$37.5M) assuming satisfaction of all milestones with an initial milestone payment of US$2m upon FDA[1] clearance (estimated in FY23). In addition, royalties are payable on future sales. See Table 1 for summary of key milestones.
- **Access to large and growing US market for cognitive therapeutics:** The Attention Deficit Hyperactivity Disorder ("ADHD") therapeutics market in the US is estimated at US$10B p.a. with over 6M children aged 8-18 in the US diagnosed with ADHD[2].
- **Akili is a global leader in digital therapeutics:** Akili commercialised the first FDA-cleared and CE-marked video game treatment, EndeavorRx™, as a prescription digital therapeutic (PDT) to improve attention function in children aged 8-12 with ADHD. Akili recently completed a US$160M funding round led by top-tier global investment management group, Neuberger Berman Funds.
- **Validation provides foundation for additional global partnerships:** This transformational deal validates the first-to-market TALi technology platform and opens up the potential for long-term sustainable revenues from the US, and other key global markets where strategic discussions are also progressing.

TALi Digital Ltd (ASX:TD1, "TALi" or "the Company"), a leading digital health business is pleased to announce that it has entered a Strategic Licensing Agreement ("Agreement") with Akili Interactive Labs, Inc. ("Akili"), a global leader in digital therapeutics. Under the Agreement, Akili will hold an ongoing license to TALi's market-leading technology to become the exclusive commercialisation partner for all paediatric cognition products in the US. The binding agreement is in full effect as of 17 August 2021.

Partnering with a global pioneer and leader in digital therapeutics

Akili has commercialised the first FDA-cleared and CE-marked video game treatment, EndeavorRx®, as a prescription digital therapeutic (PDT) to improve attention function in

[1] U.S. Food & Drug Administration (FDA)
[2] Global Attention Deficit Hyperactivity Disorder (ADHD) Market: Industry Analysis & Outlook (2018-2022), Koncept Analytics

children aged 8-12 with ADHD. The TALi platform builds on Akili's product portfolio and complements its flagship product EndeavorRx®.

Akili is a private company backed by leading venture capital firms and recently completed a US$160 million equity and debt raise in May 2021. Participants included top-tier global investment firms and leading global pharmaceutical players, including Shionogi & Co. Ltd, a multi-billion dollar Japanese-listed healthcare and medical company.

The Agreement is transformational and highly strategic for TALi, and is estimated at AU$51 million (US$37.5 million) in total future contingent milestone payments plus royalties on potential revenues (see table 1 for summary of key milestones). Payments and royalties are not guaranteed under the agreement and are contingent on achievement of milestones. It is also structured to leverage each organisation's expertise. TALi will lead the clinical and regulatory clearance, while Akili will lead commercialisation of paediatric cognition digital solutions in the US with an initial milestone payment to TALi of US$2m upon FDA clearance (estimated in FY23).

Market-leading, clinically validated, TALi technology platform

TALi's platform technology initially targets attention in early childhood (children aged 3-8 years) through its evidence and video game-based TALi screening ("DETECT®") and training ("TRAIN®") product.

This first-to-market and user-experience focused technology is complementary to existing diagnosis and therapy placing TALi at the forefront of patient experience and early intervention. This positions TALi as an ideal partner in the global digital health sector.

The technology combines 25+ years of research in developmental psychology and cognitive neuroscience to deliver easy-to-use, video game-based programs to assess and strengthen attention early in life as a means of promoting learning and childhood development.

TALi TRAIN® has been proven, through scientifically validated trials, to improve attention by strengthening underlying attentional processes over 25 sessions (or a five-week period). Multiple peer-reviewed published papers report significant benefits of TALi TRAIN® for both neurodiverse and neurotypical children. In clinical trials, TRAIN® has demonstrated benefits for clinical and non-clinical early childhood populations, specifically improvements in numeracy skills, gains in selective attention skills, and behavioural improvements in a classroom setting. Learning and behavioural improvements are significant positive influences on childhood self-esteem.

The 20-minute TALi DETECT® assessment consists of seven tests of cognitive attention to build a profile of the attention capabilities of a child. Reports generated by TALi DETECT® assist in screening for attention difficulties (deficits), providing the potential to assist in clinical

decision-making. Quantitative indexing of improvements in attention skills make the test ideal as a pre-and post-therapy assessment aid.

An IP portfolio delivering immense near-term and long-term value to shareholders

TALi has invested in a significant and sustainable IP portfolio as part of its global channel partner strategy. Patents related to the TALi technology platform include, but are not limited to, United States (no. 10,621,882), Australia (no. 2015389150) and Japan (no. 2018-502292). This is complemented by TALi trademarks in multiple jurisdictions including the US, China, Japan India and the EU with this strategy pivotal in delivering the agreement with Akili and placing the companies at the centre of the digital therapeutics sector as a key ecosystem participants.

The Company is currently negotiating further potential partnerships arrangements in key global markets including (but not limited to) South Korea and Japan, and additional commercial relationships in India to continue layering new potential revenue streams for the business.

Large and fast- growth market opportunity

The ADHD therapeutics market in the US is estimated at US$10 billion, with over 6 million children aged 8-18 in the US diagnosed with ADHD[3]. It is estimated that around 50% of ADHD paediatric patients are willing to try non-pharmacological treatments.[4]

This "willingness to adopt" non-pharmacological treatments is driving the rise in digital health adoption in developing economies. Additionally, the emergence of evidence-based therapy for cognitive/mental health issues particularly in a COVID and post-COVID world, coupled with the bundling of telemedicine and telepharmacy products places digital therapeutics[5] at the centre of the US$11.4 billion (projected by 2025) cognitive assessment and training market. This market is forecast to grow at a CAGR of 29.3% p.a. between 2020-2025[6].

Significant expected milestone and royalty payments

The terms of the deal estimated at AUD$51 million (US$37.5 million) in total future contingent milestone payments plus royalties on potential revenues, are structured to leverage each organisation's expertise. TALi will bring the TALi TRAIN® and TALi DETECT® products through additional clinical and regulatory clearance in partnership with Akili, and will draw on Akili's

[3] Global Attention Deficit Hyperactivity Disorder (ADHD) Market: Industry Analysis & Outlook (2018-2022), Koncept Analytics
[4] Source: CDC, Attitude, Akili Market Research
[5] Source: Digital Therapeutics Market Size, Share & Trends Analysis Report By Application (Diabetes, Obesity, CVD, CNS Disease, Respiratory Diseases, Smoking Cessation), By End-use (Patients, Providers, Payers, Employers), And Segment Forecasts, 2021 - 2028
[6] Cognitive Assessment and Training Market by Component, Organization Size, Application (Clinical Trials, Learning, and Research), Vertical (Healthcare and Life Sciences, Education, and Corporate), and Region - Global Forecast to 2025

important experience in the commercialisation of EndeavorRx™. Akili will lead the commercialisation in the United States. Upon commercialisation, Akili will pay royalties (over and above milestones payments) on future sales to TALi.

Underpinning this process will be the clinical development and trials collecting US based paediatric data facilitated by Duke Clinical Research Institute (DCRI). DCRI and TALi have an existing collaboration (refer announcement dated 22nd June 2020) and protocols for the trials that are being prepared by DCRI. Trial commencement is projected to occur in 2021. TALi will follow a submission process with the FDA (not yet defined) but following a pathway as outlined here: https://www.fda.gov/patients/device-development-process/step-3-pathway-approval to achieve clearance as a prescription treatment.

Once cleared this has the potential to lead to a multi-decade annuity revenue stream for TALi as no additional regulatory approvals in the US will be required for this paediatric ADHD product (based on current US legislation/regulations).

Table 1: Key Milestones

General terms	Overview	What it means for TALi
Milestone payments and royalties	Estimated AUD$51M (US$37.5M) plus royalties	Payments to TALi due upon satisfaction of the following milestones: **MILESTONE** • FDA Clearance: US$2 million milestone payment • First sale and subsequent revenue milestones up to revenues of US$150m in addition to royalty payments. For example, on achievement of cumulative revenue of US$10 million: US$1.5 million milestone payment plus royalties would be received by TALi. • Above US$150 million revenues royalty payments only. Timeframes of milestones vary with sales milestones initially dependent upon FDA clearance milestone being satisfied which is estimated to occur in FY23. There are no time limits on achieving sales milestones with Akili to make commercially reasonable efforts to make the first sale upon receiving FDA clearance. If achieved, the milestone and royalty payments deliver significant potential earnings for TALi in forward years. **ROYALTY** Royalty to be paid based on a range of factors, calculated on yearly sales and of a high single figure percentage.

General terms	Overview	What it means for TALi
Term	For life of the license, (effectively ongoing)	Ongoing royalty payments to TALi to potentially deliver a multi-decade annuity revenue stream.
Development of product	Both parties to contribute to development cost for product approval	TALi will receive payments from Akili with the payments for clinical development expected to commence in the second half of the current financial year. TALi will also contribute funds expected to be (and budgeted at) AU$500k for clinical development in the current financial year and has sufficient cash available to fund its obligations under the Agreement.
Responsibilities	TALi will lead clinical and regulatory clearance with Akili feedback and Akili will lead commercialisation in the US	TALi secures a global leader in digital therapeutics with established clinical sales channels. No market entry or significant ongoing marketing/sales costs to TALi is expected to ensure high margin return for shareholders. Revenues (royalties for TALi) expected from FY23.
Termination	Standard clauses in agreement	Akili has certain rights to terminate this Agreement without cause under specified conditions after completion of clinical study and both parties have the right to terminate upon written notice in the event of a material breach.

Delivering on the TALi growth strategy

This transformational deal with Akili represents the next step in TALi's growth strategy on the path towards sustainable long-term recurring revenues from key global markets. TALi has a market-leading, clinically-validated platform technology with applications in the fast-growing market for non-pharmaceutical treatments to assist cognitive impairments.

In December 2020, TALi established a strategic partnership with The Times Group of India to diversify and expand marketing activities to target the significant consumer market (non-medical use) in India for non-invasive enhancement of cognitive function and assist learning. Learning and behavioural improvements are significant positive influences on childhood self-esteem. Whilst the initial launch of TALi in India has been hampered by COVID-19, the Company remains confident that this strategy to deliver diversification in non-medical use target segments and generate revenue will deliver results over a medium to long term horizon.

With a scalable technology platform and validation from global leaders, TALi now has access to the world's largest market in the US through Akili to establish recurring revenues through royalties. This landmark deal and data collected from the clinical development phase will help to progress established plans by TALi in Australia such as the undertaking of a reimbursement submission (MSAC and/or PBS submission in Australia) for TALi to potentially be listed on the

Medicare Benefits Scheme (or other relevant scheme) in Australia as a reimbursable therapeutic. This would enable access to TALi products by all relevant healthcare providers and their patients without or with significantly rebated out-of-pocket expense. The Company will pursue this submission process and will continue to update shareholders.

TALi is also currently engaged in a evaluating a research program exploring the potential for its technology platform to be expanded to other cognitive decline indications, more common in populations with Mild Cognitive Impairment (MCI). MCI has been found to often been a precursor to recognising Alzherimer's disease and other forms of dementia. Many conditions associated with MCI are not able to be screened with conventional imaging , such as MRI scan, and require a functional test to assess the reduction in executive cognitive function.

"Akili is continuously seeking opportunities to expand our suite of targeted treatments for cognitive impairments, including through strategic collaborations with companies that share our commitment to delivering high-quality patient experiences built on scientific rigor," stated **Eddie Martucci, PhD, Akili's co-founder and CEO**. "Focused on early childhood intervention targeting attention, TALi's impressive technology is an ideal addition to Akili's portfolio. We are committed to changing the way people think about medicine, and strategic agreements like this will allow us to expand our vision to treat cognitive impairments in entirely new ways and usher in the next generation of digital therapeutics."

Glenn Smith, TALi's Managing Director said, "Akili is leading the digital therapeutics industry with its ability to dramatically scale into mainstream medicine while maximizing value to patients and to the business, making it an ideal partner for expanding the reach and impact of our technology," said Glenn Smith, Managing Director of TALi. "We're looking forward to working with the Akili team to provide solutions that deliver digital-first support to the millions of children living with attention issues."

The ongoing work by the Company combined with this transformational agreement with Akili, ensure that the Company is well positioned to deliver significant value to all stakeholders in the coming years.

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This announcement is authorised by the Board, TALi Digital Limited

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Understanding Prescription Digital Therapeutics (PDTs)

Prescription Digital Therapeutics (PDTs) are clinically validated software-based interventions that prevent, manage, or treat a medical disease or disorder. PDTs are approved by regulators and available by prescription for use alone or alongside other medications or medical devices.

EndeavorRx® Indication and Overview

EndeavorRx is the first-and-only FDA-cleared treatment delivered through a video game experience. Indicated to improve attention function in children with ADHD. EndeavorRx is indicated to improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue. Patients who engage with EndeavorRx demonstrate improvements in a digitally assessed measure Test of Variables of Attention (TOVA®) of sustained and selective attention and may not display benefits in typical behavioral symptoms, such as hyperactivity. EndeavorRx should be considered for use as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs, which further address symptoms of the disorder. EndeavorRx is only available by prescription in the US. It is not intended to be used as a stand-alone therapeutic and is not a substitution for a child's medication. To learn more about EndeavorRx, please visit www.EndeavorRx.com.

About Akili

Akili is combining scientific and clinical rigor with the ingenuity of the tech and entertainment industries to challenge the status quo of medicine. Akili is pioneering the development of digital treatments and care solutions to help people affected by cognitive impairments. Akili's treatments are designed to directly activate the networks in the brain responsible for cognitive function and have been rigorously tested in extensive clinical studies, including prospective randomized, controlled trials. Driven by Akili's belief that effective medicine can also be fun and engaging, Akili's treatments are delivered through captivating action video game experiences. For more information, please visit www.akiliinteractive.com.

About TALi

TALi [TALi Digital Limited (ASX: TD1)] is a digital health company delivering diagnostic and therapeutic solutions for cognitive function and behaviour. The Company has built a platform technology, the first iteration of which targets cognitive attention skills during early childhood through its evidence and video-gamed-based TALi screening (DETECT®) and training (TRAIN®). This first to market and user experience focused technology is complementary to existing diagnosis and therapy placing TALi at the forefront of patient experience and early intervention thus positioning the business as an ideal partner in the global digital health sector.

Innovations that target cognitive skills to deliver non-invasive early interventions underpin the TALi platform technology. This innovation focus is allowing the Company to deliver a series of product developments in ADHD (Attention Deficit Hyperactivity Disorder) and ASD (Autism Spectrum Disorder) for predictive diagnosis and treatment for all age groups along

with a core research program exploring applications for at populations afflicted with Mild Cognitive Decline (MCI has been found to often been a precursor to recognizing Alzheimer's disease and other forms of dementia). TALi solutions aim to deliver foundational advances in human cognitive function and behaviour only dreamt of a few short years ago.

At TALi, our vision is to create personalised game changing experiences to enhance cognitive function and behaviour from any digital device. Learn more at talihealth.com.au.

Forward-Looking Statements

Certain statements in this announcement are forward-looking statements. Forward-looking statements can generally be identified by the use of words such as "anticipate", "future", "contingent", "estimate", "expect", "project", "intend", "plan", "believe", "target", "may", "assume" and words of similar import. These forward-looking statements speak only as at the date of this announcement. These statements are based on current expectations and beliefs and, by their nature, are subject to a number of known and unknown risks and uncertainties that could cause the actual results, performances and achievements to differ materially from any expected future results, performance or achievements expressed or implied by such forward-looking statements.

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