



ASX ANNOUNCEMENT ASX: RSH
11th July 2022

New £2 Million NIHR-Funded UK Paediatric Asthma Clinical Trial with wheezo®

Highlights:

- National Institute for Health Research (NIHR) funded clinical trial with leading UK clinicians
- Trial to assess the impact of introducing Remote Patient Monitoring (RPM) technology to paediatric patients with asthma using wheezo® for wheeze
- Benefits of improving asthma control are substantial with UK asthma costs of £2.3 billion annually
- Respiri to provide wheezo® units and data management/support as part of the clinical trial
- Highly cost-effective trial for Respiri, with the potential to change the current standard of care for asthma management in the UK upon clinical success, including National Health Service (NHS) funding
- Respiri granted perpetual, royalty-free, exclusive worldwide research license for internal research development with sublicensing rights associated with the research data and outcomes

Respiri Limited (ASX:RSH) ("Respiri" or the "Company"), an eHealth SaaS Company supporting respiratory health management, today announces a £2 million NIHR-Funded UK paediatric asthma clinical trial awarded to King's College, London that will assess the impact of the wheezo® when combined with a standard integrated care approach for asthma (the control arm), for their effectiveness and cost-utility.

The **Technology Enhanced Integrated asthma care (TEAM-care)** trial is a three arm, randomised, 30-month, 1,464 patient clinical trial that aims to assess outcomes for children with asthma using a technologically enhanced integrated care pathway to address an unmet clinical need by building the clinical and health economic evidence base for NHS adoption of new technologies for asthma self-management, treatment optimisation, and monitoring. The primary endpoint of the TEAM-care trial is unscheduled health service use (consultation in primary, secondary, or out-of-hours care where a participant presented with symptoms or signs consistent with acute asthma) versus control. Key secondary endpoints include child-health related quality of life, asthma control, use of medicines and primary or secondary healthcare services use. The trial is expected to commence in Q4 2022, with results expected by the end of 2023 and interim data available for analysis as the trial progresses. See Appendix 1.

The co-principal investigators of the study are Dr Ingrid Wolfe, Director, Institute for Women and Children's Health, Reader in Paediatrics and Child Health at King's College, London, Consultant in Paediatric Population health at Evelina London Children's Hospital, and Professor Jonathan Grigg, Professor of Paediatric Respiratory and Environmental Medicine, Centre for Genomics and Child Health, Queen Mary University of London. After a rigorous selection criterion, wheezo® was selected by the study investigators as the preferred intervention for remote asthma monitoring.

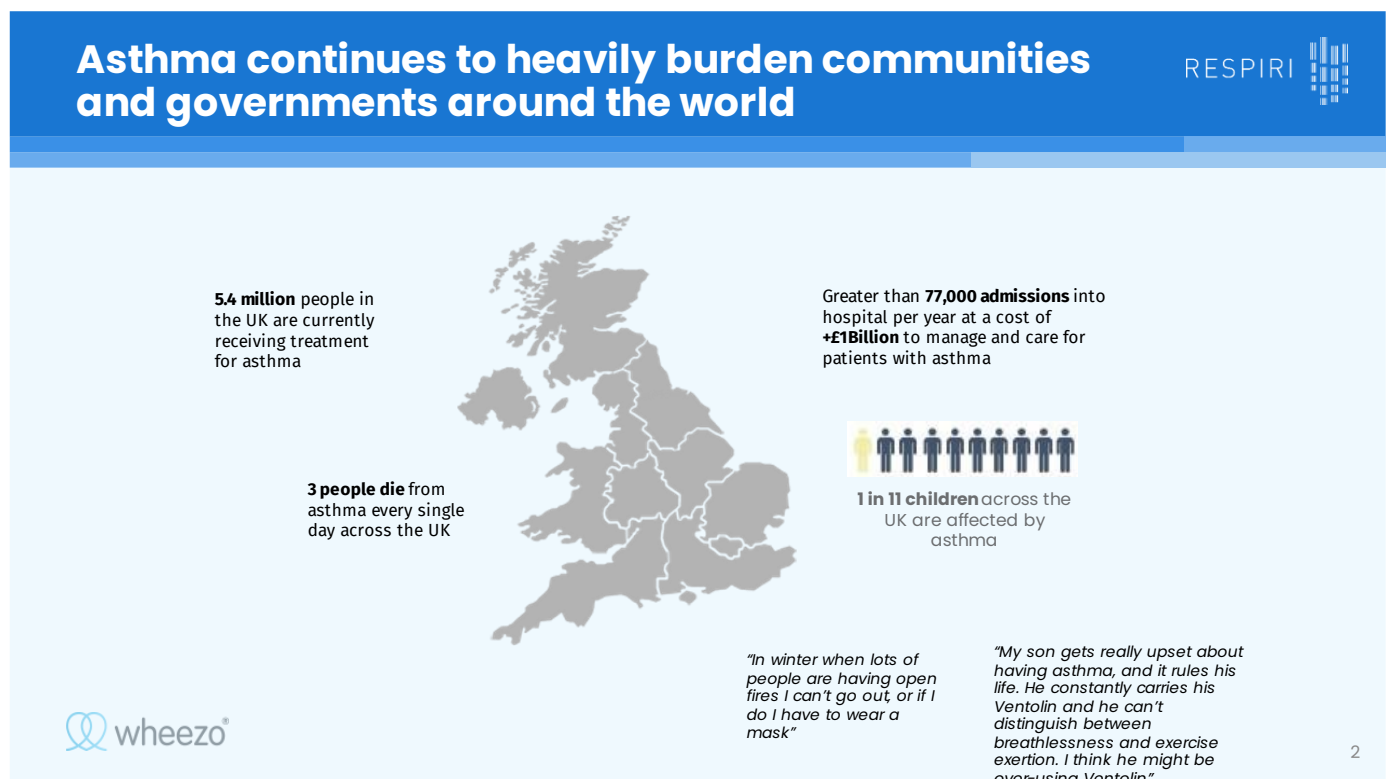
Dr Ingrid Wolfe/Jonathan Grigg said "We are delighted to be awarded this grant to test the benefits and value of technologies to improve asthma outcomes for children. There is real potential for improving asthma outcomes for children through this work."

Mr Marjan Mikel, CEO and Managing Director of Respiri said "The world class key opinion leaders who have successfully been awarded this grant, fully understand the importance of RPM solutions in respiratory medicine, especially in children, as does the NIHR given the significant cost of asthma to the UK healthcare system. It is pleasing the NIHR have funded this trial, as the TEAM-care trial will provide robust health economic evidence for potential NHS adoption of new RPM technologies like wheezo®, which we believe will show positive health outcomes for asthmatics and a lower the cost burden for government funded health systems with this major trial."

Mr Mikel added, “We are excited to be part of this study. For too long asthmatics and healthcare professionals have lacked the tools to better manage and monitor asthma to improve health outcomes. Technology has been available in the market for the two largest chronic disease states, being heart disease and diabetes to help with measuring and monitoring their conditions. It’s pleasing to finally see that asthmatics can also reap the benefits of new technologies just like other chronic disease sufferers and we are now at an exciting phase to deliver this with this clinical trial. Not only is this the NIHR funded study a great vindication of the wheezo[®] device but it also provides a funded study that enables RespiRI accelerate the process to get this new technology into patient hands faster.”

The Cost to the UK health System is Substantial

The potential benefits of improving asthma control are substantial, with the annual cost of asthma in the UK of £2.3 billion. The costs of an asthma attack in children with well controlled asthma is 3.5 times lower than those with uncontrolled asthma; and the cost of caring for a child with asthma is higher than cost of an adult¹. In the UK, 1 in 11 children suffer from asthma.



In choosing wheezo[®] from many other available technologies, the trial aims to investigate better solutions for patients with asthma. It is evident in recent studies that asthma is the most common long-term condition among children, yet outcomes are often poor, with preventable exacerbations and avoidable mortality.

Adoption of new technologies by the NHS does require rigorous evidence of clinical effectiveness and health economics are required. As RespiRI has an exclusive, perpetual and royalty-free license to use the outcomes of the TEAM-care study, the Company believes the significant size and breadth of the study, when measured against the best available standard of care, will provide the necessary level 1 evidence to support clinical adoption and NHS support, if successful.

¹ Environmental Audit Committee. Written Evidence (AQ29). 2010.

APPENDIX 1 – TEAM-care Clinical trial summary

Title	<u>T</u> echnology <u>E</u> nhanced integr <u>A</u> ted asth <u>M</u> a care (TEAM-care)
Investigated devices	wheezeo [®] , Propeller Health smart inhalers
Study Design	<p>Randomised Control Trial of component parts of technologically enhanced integrated care pathway</p>
Study Objectives	<ul style="list-style-type: none"> - To assess the outcomes for children (under the age of 16 years) with asthma using a technology enhanced integrated care pathway. - To assess the effectiveness and cost-utility of integrated care for asthma (control) augmented with remote wheeze monitoring (trial arm 1). - To assess the effectiveness and cost-utility of integrated care for asthma (control) augmented with remote treatment monitoring (trial arm 2) - To model the long-term cost-utility - To assess acceptability of the technologically enhance care pathway - To assess implementation processes - To assess behavioural change associated with the use of the intervention.
Primary Endpoints	Change in unscheduled health services use (consultation in primary, secondary, or out of hours care where a participant presented with symptoms or signs consistent with acute asthma.
Secondary Endpoints	<ol style="list-style-type: none"> 1. Child health: Health-related quality of life (PedsQL, CHU-9D) & Asthma Control Test (ACT) 2. Rates of primary and secondary care health service use, and medicine use 3. Parental wellbeing (Warwick Edinburgh Mental Wellbeing Score) 4. Child wellbeing and mental health (Strengths and difficulties Questionnaire) 5. Missed days of school and parental missed days of work.
Number of Subjects	1,464 children under the age of 16 years equally randomised across three trial arms in the United Kingdom.
Condition	Children with confirmed asthma diagnosis.

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wheezo® is a registered trademark of Respiri Limited.

This ASX announcement dated 5th July 2022 has been authorised for release by the Board of Directors of Respiri Limited.

About Respiri Limited

Respiri is an e-Health SaaS company supporting respiratory health management. Its world-first technology detects wheeze, a typical symptom of asthma, COPD and respiratory disease to provide an objective measure of airway limitation. wheezo®, Respiri's innovative technology, comprises an eHealth app combined with a simple, easy to use, handheld device. wheezo® is the first smart device to help improve asthma management by monitoring wheeze and documenting symptoms, signs, triggers, weather conditions and medication use. The asthma management platform also facilitates the sharing of data with caregivers, physicians, and other health care professionals.

Respiri's mission is to help improve quality of life for hundreds of millions of children and adults around the world and dramatically reduce hospital admissions and the economic burden of asthma. Respiri Limited's operations are based in Melbourne, Australia.

For additional information about Respiri and its products, please visit www.respiri.co

About wheezo®

Developed in Australia, with the support of respiratory specialists and other healthcare professionals, the innovative wheezo® device analyses breath sounds for wheeze, and the eHealth App assists patients with managing their asthma by tracking symptoms, triggers, medication use and geo-specific weather conditions. The platform has been designed to extend asthma management beyond the clinic and make it easy to share information with doctors and make appropriate adjustments to asthma action plans. Better active management may lead to better outcomes and improved quality of life for the asthma patient.

About National Institute for Health Research (NIHR)

The NIHR was established in 2006 in the United Kingdom to "create a health research system in which the National Health Services (NHS) supports outstanding individuals, working in world-class facilities, conducting leading-edge research focused on the needs of patients and the public". Since that time, it has transformed research in and for the NHS and helped to shape the health and social care research landscape more broadly. Working in partnership with the NHS, universities, local government, other research funders, patients and the public, NIHR fund, enable and deliver world-leading health and social care research that improves people's health and wellbeing and promotes economic growth. NIHR are funded by the Department of Health and Social Care. Work focuses on early translational research, clinical research and applied health and social care research. NIHR are centred on England but collaborate closely with the devolved administrations in Scotland, Wales and Northern Ireland. We are also a major funder of applied health research in low and middle income countries, work that is principally funded through UK aid from the UK government.

Forward Looking Statements

Certain statements made in this announcement are forward-looking statements. These forward looking statements are not historical facts but rather are based on Respiro current expectations, estimates and projections about the industry in which Respiro operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates", "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties, and other factors, some of which are beyond the control of Respiro, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward looking statements. Respiro cautions shareholders and prospective shareholders not to place undue reliance on these forward looking statements, which reflect the view of Respiro only as of the date of this release. The forward looking statements made in this announcement relate only to events as of the date on which the statements are made. Respiro will not undertake any obligation to release publicly any revisions or updates to these forward looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

