

RESPIRI LIMITED

CEO OPERATIONAL REVIEW

The company is pleased to provide an Operational Update on its progress towards reaching its stated commercialisation strategy milestones for our breakthrough Gen II asthma monitoring solution.

Strengthened cash position

Respiri successfully conducted a \$3.0 million capital raising to provide the financial capacity to progress development of our Gen II product in readiness for launch targeted for Q3 FY19 (Q1 CY19). Further, and as noted in today's quarterly Appendix 4C announcement, we anticipate our cash position in Q1 and Q2 FY19 to benefit from the refundable R&D tax offset consistent with prior periods as well as other government grants such as export market development and accelerating commercialisation that are available as we are nearing commercial launch.

CXO appointment to drive launch plans

We are also pleased to announce the appointment of Wani Wall as Chief Customer Experience and Communications officer (CXO). Wani has been with the company since 2014, driving the redevelopment of AirSonea as consulting Product Manager, working closely with our partners Grey Innovation and Two Bulls as well as our Chief Research Officer, Dr Samaneh Sarraf on the foundation science.

Having overseen the company's most recent consumer research and clinical activities to inform product development based on the 'customer experience', the time is right for Wani to increase her commitment to full time in order to deliver our 'Direct to Patient' (DTP) launch strategy. With a deep understanding of the product and its potential to fill an unmet need for asthma families, Wani brings years of strategic and creative experience in consumer marketing communications and brand building using traditional media and digital marketing channels across a variety of sectors including education and health.

Completion of finished-quality medical device prototype

Engineering partner, Grey Innovation is in the process of finalising the breath sensor design building on learnings from 'pressure testing' of the Design Verification Test prototype (DVT1) released for marketing purposes on 20 April. The DVT2 prototype is planned to be ready for a limited production run and commencement of the verification and validation process in Q1 FY19 (Q3 CY18). We look forward to sharing images of the final design and further technical details when we reach this exciting milestone.

Prototyping	Status
Initial functioning demonstration quality prototype for technology demonstration purpose with partner & investors	Done
Fully functional medical device quality prototype with design completed	FY19 Q1 (CY18 Q3)

Appointment of contract manufacturer

Another major milestone is close to finalisation, as scheduled, with the imminent appointment of our contract manufacturer (CM). Respiro requires a CM partner with extensive experience across the full range of supply chain management, superior quality electronic manufacturing capabilities and the necessary experience in 'New Product Introduction' to support the company's ambitious plans to help millions around the world better manage their asthma. Full details will be provided in future announcements.

Contract manufacturing	Status
Initial manufacturing package and limited production of verification units by contract manufacturer	FY19 Q1 (CY18 Q3)
Final design updates and verification testing and ideally handover to preferred manufacturing partners in key target regions	FY19 Q2 (CY18 Q4)

Android development and engaging new app

Our software engineering team at Two Bulls is making significant progress on the development of the Android platform to be at parity with our iOS platform in readiness for product validation and verification. This effectively doubles our potential market reach and makes our product available across the most popular smartphones in the market today.

In parallel, the scope of Two Bulls' work has expanded with the development of a new user interface (UI) targeting our primary audience of children and their caregivers. Under our CXO's guidance and designed by an award-winning team with production credits for brands such as PBS Kids, ABC Kids, Disney and Sesame Street, the new app housing Respiro's ARM™ algorithm, is an engagement tool unlike anything else available in the marketplace for people with asthma. Our objective is to provide an irresistible educational experience that encourages daily use to help families reduce anxiety, avoid exacerbations and hospitalisation, and ultimately, improve quality of life.

Respiro's asthma management ecosystem powered by Amazon Web Services, provides a platform for the collection of big data and with the utilisation of AI can provide invaluable insights for people with asthma, healthcare professionals, health authorities, researchers, insurers/healthcare funders and others. Over time, as we gather more and more data around the world, Respiro will help provide data and insights to help better manage and find answers to questions that cannot be answered today.

Platform development	Status
Development of Android platform to parity with existing iOS platform	FY19 Q1 (CY18 Q3)

Regulatory approvals

We have appointed George Loizou and Compliance Management Solutions (CMS), a highly experienced quality assurance and regulatory management consultant to oversee our local ISO 13485 certification, the international quality management standard for medical devices, required to facilitate the regulatory approvals process. We are on schedule with our submission and anticipate obtaining CE mark approval for over-the-counter sale of Gen II in UK/Europe during Q3 FY19 (Q1 CY2019). TGA approval for sales in Australia are expected to follow 8 to 10 weeks following CE certification. Thereafter, the focus will shift to FDA clearance and approvals in key Asian markets where asthma is a growing concern for health authorities.

Regulatory approvals	Status
Regulatory approvals – UK/Europe	FY19 Q3 (CY19 Q1)
Regulatory approvals – Australia	FY19 Q3/4 (CY19 Q1/2)
Regulatory approvals – FDA (US) and select Asian markets	TBC

Clinical studies

There is no gold standard¹ for the diagnosis of asthma and healthcare professionals encourage parents/caregivers to ‘listen’ for the typical symptom of wheeze by putting their ear to the chest of the child with asthma². Our consumer research tells us that parents suffer from acute anxiety as they simply don’t know what they’re listening for. Smarter than a doctor’s stethoscope, Respiro’s breakthrough technology addresses the unmet need for easy detection and measurement of wheeze in the home, along with the added value of correlating this data to the patient’s individual triggers, symptoms and use of medication.

There have been numerous clinical papers* published on Respiro’s clinical wheeze detection products over the last decade, with the most recent research study at the University of Chicago concluding AirSonea Gen I successfully detects and quantifies wheeze, but more work is needed as we go to market. Endorsement by healthcare professionals is important and asthma experts have advised that further clinical studies are required to demonstrate the usefulness of wheeze monitoring as part of a diagnosed asthmatic’s Asthma Action Plan.

To that end, Respiro has gained the support of some of the UK’s most influential respiratory experts to conduct the research studies. A long time supporter of the company’s technology, we are pleased to announce that Dr Mark Levy has been engaged to lead the efforts to evaluate our technology and is currently designing a study protocol using the Gen II device for execution in the UK and Australia prior to product launch in these markets. Dr Levy holds a number of posts including Respiratory Clinical Lead at Harrow and Clinical Lead Northwest London Asthma Radar. He is the author of numerous books, chapters and publications in peer reviewed journals and is the lead author of *Why Asthma Still Kills; the National Review of Asthma Deaths (NRAD) Confidential Enquiry Report Royal College of Physicians London 2014*.³

It is important to note that we are working with leading institutions and researchers and as such, a strict process is followed when developing study protocols and gaining ethics approvals. We look forward to announcing the details of additional observational community-based studies, as discussed with leading respiratory experts during the CEO’s visit to the UK in May, as soon as they are finalised. These studies are also planned for parallel execution at a prominent Australian hospital.

Building on the relationships Respiro has forged with key opinion leaders with significant research and clinical experience both in Australia and overseas, we are now focused on establishing a new Scientific and Clinical Advisory Board and look forward to announcing the distinguished names in the coming weeks.

Clinical studies	2018
Finalise planning and launch a significant pilot program in a major market to establish value proposition of Gen II (Observational community-based studies compared to current practice).	FY19 Q2 (CY18 Q4)

Stakeholder management and business development, UK

Respiri has engaged highly experienced consultants to assist with our UK launch plans. Origin Health Group brings best practice lobbying and stakeholder management services. Well connected with key decision makers in the National Health Service (NHS) and with experience in the respiratory field, the Group is charged with conducting a thorough stakeholder analysis and communications strategy recommendation for each of the target groups (e.g. government/policy makers, clinical, NHS, Asthma UK, health media, spokespersons/brand ambassadors).

Respiri are seeking to conduct a stakeholder identification/analysis programme to:



Industry experienced board

Recent board changes have added significant industry and early stage medical device experience and capabilities to the board at a critical stage as the company positions itself for commercialisation of its technology solutions. The new directors are fully supportive of the company’s commercialisation strategy and product development plans as it moves towards launch with the ultimate objective of growing investor returns while improving the quality of life for millions of people with asthma.

We look forward to continuing to provide shareholders with ongoing communications on new developments and achievements over coming months as we execute and further develop our plans to bring our Gen II solutions to market.

Yours faithfully



Mario Gattino
CEO & Director

NOTES:

1. <http://www.astmahandbook.org.au>
2. <http://www.asthmauk.org.uk>
3. <https://www.rcplondon.ac.uk/projects/outputs/why-asthma-still-kills>

***PUBLISHED RESEARCH PAPERS**

1. Puder L., Fisher S., Wilitzki J., Usemann J., Godfrey S., Schmalisch G., Validation of Computerised wheeze detection in young infants during the first months of life. *BMC Pediatrics* 2014 14:257
2. Eising, J.b., Uiterwaal C.S., van der Ent C.K., Nocturnal wheeze measurement in preschool children *Pediatr. Pulmonol* 2014 49:257-262
3. Park H., Jang W., Nam H., Kang I., Seo S.C., Bauer S., Choi I.S., Choung J.T., Yoo Y., Validity of Cough-Holter Monitoring for the objective Assessment of Cough and Wheezing in Children with Respiratory Symptoms *Pediatr Allergy Respir Dis (Korea)* 2012 22: 344-353
4. Boner AL, Piacentini GL, Peroni DG, Irving CS, Goldstein D, Gavriely N, et al. Children with nocturnal asthma wheeze intermittently during sleep. *Journal of Asthma*. 2010 Apr;47(3):290-4.
5. Vigel E, Yigla M, Goryachev Y, Dekel E, Felis V, Levi H, et al. Validation of an ambulatory cough detection and counting application using voluntary cough under different conditions. *Cough*. 2010;6:3.
6. Godfrey S. The use of bronchial challenge to diagnose asthma in preschool children. *Primary Care Respir Journal* 2009 18(1):10-14
7. Gavriely N, Avrahami AN, Levy H, Vivat Y, Dekel S, Dekel E, et al. Wheeze Monitoring in Non-Asthmatic Pediatric Population. *American Journal of Respiratory and Critical Care Medicine*. 2009;179(1 Meeting Abstracts):A4430.
8. Proadhan P, Dela Rosa RS, Shubina M, Haver KE, Matthews BD, Buck S, et al. Wheeze detection in the pediatric intensive care unit: comparison among physician, nurses, respiratory therapists, and a computerized respiratory sound monitor. *Respiratory Care*. 2008 Oct;53(10):1304-9.
9. Beck R, Elias N, Shoval S, Tov N, Talmon G, Godfrey S, et al. Computerized acoustic assessment of treatment efficacy of nebulized epinephrine and albuterol in RSV bronchiolitis. *BMC Pediatrics*. 2007;7:1-6.
10. Bentur, L., Beck R., Berkowitz, Hasanin J., Berger I., Elias N., Gavriely Adenosine bronchial provocation with computerized wheeze detection in young infants with prolonged cough: correlation with long term follow-up. *Chest* 2004 126:1060-1065
11. Bentur L, Beck R, Irving CS, Godfrey S. Nocturnal wheeze measurement in young asthmatics. *Pediatric Asthma, Allergy and Immunology*. 2004;17(3):191-197.
12. Levy ML, Godfrey S, Irving CS, Sheikh A, Hanekom W, Bush A, Lachman P. Wheeze detection: recordings vs. assessment of physician and parent. *Journal of Asthma*. 2004;41(8):845-53.
13. Bentur, L., Beck R., Berkowitz, Hasanin J., Berger I., Elias N., Gavriely Pulmonary Acoustics and Esophageal pH Monitoring in infantile Nocturnal Cough *Pediatric Asthma, Allergy and Immunology*. 2004 17:262-27
14. Bentur L, Beck R, Shinawi M, Naveh T, Gavriely N. Wheeze monitoring in children for assessment of nocturnal asthma and response to therapy. *European Respiratory Journal*. 2003 Apr;21(4):621-6