

ASX Announcement  
(ASX:RSH)  
29 January 2018

## SHORT CEO UPDATE AND REAFFIRMATION OF 2018 PLANS AND MILESTONES

Dear Respiri Shareholders,

On 14 December 2017, at the Annual General Meeting, our Chairman Leon L' Huillier updated you all on the status of our company and priorities for 2018. Just over a month later, it should come as no surprise that the strategy and plans we are executing against remain unchanged. Please refer below to the relevant slide from the Chairman's address that captures the major milestones we intend to deliver against in 2018.

## MAJOR MILESTONES & INFLECTION POINTS

AirSonea Generation II	2018
Initial functioning demonstration quality prototype for technology demonstration purpose with partner & investors.	Q2
Fully functional medical device quality prototype with design completed	Q3
Attend major industry tradeshows and healthcare conferences to showcase and generate interest for AirSonea Gen II with investors, customer and potential partners	ongoing
Initial manufacturing package and limited production of verification units by contract manufacturer	Q3
One or more Memoranda of Understanding (MOU) or Letters of Intent (LOI) for collaboration will be established with targeted development & commercialisation partners to advance AirSonea Gen 2	Q3
Final design updates and verification testing and Ideally handover to preferred manufacturing partners in key target regions	Q4
Finalise planning and launch a significant pilot program in a major market (e.g. UK, Germany, USA) to establish value proposition of AirSonea Gen II	Q4
Regulatory approvals processes	Q3/Q4
Develop broader Respiri portfolio and roadmap including consumer overnight monitoring and the clinical PulmoTrack & WHolter products.	2018/2019

In this announcement, I wanted to expand a little on the milestones highlighted and reaffirm their importance to our future success.

### 1. Functional marketing Prototype (Q2 2018)

- The breath sensor upgrade (commencement announced to the market on 12 September) is on track for completion in Q2 2018.
- This is the **highest priority** for the company right now and the bulk of our resources, both human and capital, are being channelled into this work.
- Working closely with our development suppliers, (Grey Innovation and Two Bulls) to deliver the AirSonea Generation II sensor combined with state of the art real time smart app capabilities featuring our proprietary Acoustic Respiratory Monitoring algorithm with Artificial Intelligence or machine learning technology.

- This “functional prototype” milestone will allow us to finally demonstrate the innovation we are bringing to market for both investors and potential commercialisation partners. They will be able to touch it, use it, see first-hand what it can do and how it will address the major unmet needs in self-management and understanding for asthma sufferers.

## **2. Finished quality medical device Prototype Design Complete (Q3 2018)**

- After further ‘pressure testing’ and refinement this should be the fully functional finished product ready for a limited production run.
- Assembly and manufacturing standard operating procedures will be comprehensively defined by development suppliers.

## **3. Manufacturing Package and limited production of verification units by contract manufacturer (Q3 2018)**

- Manufacturing Dossier finalised for handover to contract manufacturer. We must demonstrate we can manufacture a significant quantity while maintaining quality and functionality standards. This is typically called batch testing.
- It will provide invaluable experience and information on the manufacturing process (e.g. level of automation versus human assembly, failure rates and causes, time to manufacture, refine quality management procedures etc.)

## **4. Final design updates and verification complete and ideally handover to manufacturing partner/(s) (Q4 2018)**

- Final design updates and verification complete based on findings and refinement from limited production run
- Medical device quality measures applied to comply with standards for regulatory approval by major global authorities (CE, FDA, TGA)
- Certified manufacturing sites in multiple geographies / regions identified and contracted as needed to support larger production runs for a significant pilot program in a major market to establish our value proposition

## **5. Obtain Regulatory Approval for Air Sonea Generation II by major global authorities to allow commercialisation and further de-risk the opportunity for potential commercialisation partners / investors**

- We approach this task with justified confidence given the previous generation device was approved in Europe and Australia – our wheeze detection technology works!
- AirSonea Generation II will represent a major innovative advance over that model in terms of the breath sensor and real time smart app capabilities featuring our proprietary Acoustic Respiratory Monitoring algorithm with Artificial Intelligence or machine learning technology
- Target first wave approvals will be Europe, USA and Australia which represent some of the most demanding regulatory authorities and processes. Approval by these authorities will be positively influential for other markets we plan to launch into (e.g. key Asian markets)

Our Board believes achievement of these stated milestones in 2018, either as independent events or cumulatively, will have the potential to be significant share price re-rating catalysts – enhancing shareholder return and in turn, company enterprise value.

The timing of this announcement represents two months into my journey with Respiri. I had the opportunity to meet with some of our shareholders at the recent AGM and really enjoyed that. Many of you have asked to hear more from me and I can guarantee you will.

Like any new CEO, I am in the process of thoroughly reviewing the business, defining both short and longer goals /objectives and developing the road map towards our ultimate success as a company. Typically, in my experience this is a 100 day or 3-month process, so I am targeting the end of February to complete this task and report back to shareholders and the broader investment community with a more detailed review and core presentation for discussion. Most likely we will set up a conference call, combined with a road show in order to provide increased access and the opportunity to engage with you directly as much as possible.

Having said that, in common with all our shareholders, I was attracted to the Respiri story from the start when I was being interviewed for the CEO role. Having had the opportunity to meet leading global clinical experts, better understand the fundamental dynamics of the huge asthma market and the real-life challenges asthma sufferers and carers are facing today, I like the company and what we are trying to accomplish even more.

### **Case in point: Lack of progress with Asthma care in the UK**

Just this week, Asthma UK released results of a 2017 survey (7,611 people) that concluded:

*“Nearly two-thirds of people with asthma are still not receiving the basic level of care despite claims it could prevent two out of three asthma deaths a year.”*

Further,

*“The study revealed a frustrating lack of progress in asthma care, following similar findings last year. Lack of basic care can be fatal with NHS data from the past 4 years showing, on average, someone is admitted to hospital for an asthma attack in the UK every 8 minutes.”*

It is alarming to see these headlines from an educated, developed and sophisticated market like the UK, highlighting the immediate need and frustrations that exist for asthma patients. I am sure the UK market is not unique, and you will hear the same thing around the world. Obviously, the approaches to managing asthma today are not working and this has disastrous consequences.

The timing for a new, innovative intervention like Respire's AirSonea Generation II and real time smart app capabilities featuring our proprietary Acoustic Respiratory Monitoring algorithm could not be better in a disease area that has sadly lacked true innovation for a long time. I am fully convinced about the positive impact our products will have on the lives of asthma sufferers, parents/carers and medical professionals alike, who are crying out for greater support.

I want to formally recognize all the work of others before me who achieved the substantial progress in the last few years, which provides a great foundation and legacy for me to build on, and our Chairman, Leon L' Huillier's tireless assistance in supporting my transitioning into the CEO role.

We just need to get on with it and ensure we deliver on that promise. The value of our company and what we are doing will be obvious.

**Mario Gattino**

CEO and Director

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#### **About Respire Limited (ASX:RSH)**

Respire is a health technology company leading the way in the development of innovative devices and mobile health apps to improve the management of chronic and costly respiratory disorders such as asthma and COPD. Building on decades of experience in the research and development of cutting-edge clinical products for hospitals, the company has first-mover advantage in providing broad access to its proprietary acoustic based clinical solutions for remote monitoring with the development of a suite of over-the-counter connected devices. Health authorities universally agree that mHealth solutions can transform asthma care and health conscious consumers are rapidly embracing patient self-management with the aid of smartphones, the growth engine for Respire's flagship product, AirSonea®. With the addition of new products, including a connected device for nocturnal monitoring in development, Respire has a captive market, globally, of parents and carers of young children who cannot perform lung function tests. Respire products have been cleared for use by the US Food and Drug Administration, the European Union CE, the Australian TGA and the commencement of an approval process for Asian markets has begun. Respire is especially proud of its recent de-risking of milestones. The substantial achievements over the past 18 months place Respire in a lower risk position and on the cusp of commercialisation compared to the vast majority of medical device and biotech companies.