



**Focused on North America as Biggest Market Opportunity:  
Clinical Trial Process Begins**

1. AirSonea<sup>®</sup> device and app ready for trial
2. Clinical trial process begins
3. Strong IP portfolio for commercial partnerships
4. An “up-to-date” approach to the management of wheeze is recommended by global authorities
5. Poor asthma control remains a global problem

## 1. AirSonea® Device and App ready for trial

- The AirSonea Asthma Wheeze Monitor and Asthma Management App upgrades are ready for trials, recognising that app updates are a continuing process.
- Over the last three months, iSonea has developed a totally new software architecture to improve the performance of the device.
- Upgrades have provided a substantially faster analysis of breath recordings and a more engaging user app.
- The AirSonea product is now stable and robust to support large numbers of consumers and regular updates.

## 2. Clinical trial process begins

### Two external clinical trials

**Trial 1:** The objective is to show AirSonea® is at least as accurate as a consensus of a panel of physicians and trained experts in detecting and quantifying wheeze.

**Trial 2:** The objective is to study the efficacy of managing asthma in children during and after an acute attack using the AirSonea device to measure wheeze rate in an Urgent Care/Emergency Department setting.

The company expects Trial 1 to be completed by the end of October and Trial 2 by year end. However, the number of variables in clinical trials make it virtually impossible to accurately predict completion dates.

## Clinical trials process has begun in two countries: Israel and North America

- **The first trial** will be undertaken in Israel.
- The company's R & D headquarters are located in Haifa and Quality Assurance consultants are also based in Israel.
- Scientific advisors are resident in Israel and have long experience in running trials with leading hospitals and physicians.
- The algorithm technology was originally developed by Professor Noam Gavriely in Israel and he remains a consultant to the company.
- iSonea's subsidiary company, KarmelSonix, has a strong reputation for excellence in its Acoustic Respiratory Monitoring™ (ARM) devices in Israel.

## Trial Two

- **The second trial** will be conducted in the North America. It is the largest target market for the company with over **30 million asthma sufferers**.<sup>1</sup>
- North America has the best consumer appetite for innovative technology, especially in health devices and apps.
- iSonea has strong relationships with leading physicians at a number of sites in North America and is currently completing analysis on a study in nocturnal wheeze monitoring at the Children's Hospital of Chicago.
- Easier to run FDA and regulatory approvals thereafter.

**Many of the global respiratory companies have a large footprint in North America.**

## History of successful clinical trials

- In the last few years, 14 successful clinical studies have been conducted using iSonea's proprietary Acoustic Respiratory Monitoring (ARM™) technology in patients with obstructive airway disease.
- ARM™ technology has been applied to children from as young as 4 months of age to adults in various settings.

## United Kingdom

- Recent discussions have taken place with leading UK physicians who have published on wheeze detection using iSonea's ARM™ technology. Two of these globally recognised physicians were keynote speakers at recent asthma conferences in Australia.
- Evaluation reports on AirSonea® in nominated UK asthma clinics are under consideration.

### 3. Strong IP portfolio for commercial partnerships

Successful AirSonea® trials will broaden the company's IP portfolio of computerised wheeze detection products: AirSonea®, WHolter™, SonoSentry™, WheezoMeter™, PulmoTrack™, AsthmaSense™ and KlikSonea™.



And provide an attractive opportunity to develop partnerships that will monetize and commercialize the business.

#### 4. An “up-to-date approach” to the management of wheeze is recommended by global authorities

*The Global Asthma Report 2014* recommends: “As part of their asthma strategy, every country needs an **up-to-date approach** to the diagnosis and **management of wheezing in young children.**”<sup>2</sup>

Self-monitoring via traditional peak flow meters is outdated technology. Patient compliance and patient interpretation is poor, the meters require considerable patient effort and are not suitable for children.

#### **AirSonea® technology is leading edge in wheeze monitoring**

- AirSonea’s clinically proven wheeze monitoring technology and its smartphone app provides an objective WheezeRate™ measure, easy logging of triggers, symptoms and medication.
- The AirSonea product package is a much needed “asthma thermometer” and electronic diary to help patients, their family and their physicians better manage their asthma.
- The great advantage of the AirSonea wheeze monitor is that it provides immediate and objective real-time information on the presence of wheeze.

## 5. Poor asthma control remains a global problem

- Nearly half of adults with asthma had poor asthma control and 29% needed urgent health care for asthma in the previous year according to a recent study published in *Medical Journal of Australia*.<sup>3</sup>
- 49% of the people who had died in the UK from asthma in 2012 were being treated for mild or moderate asthma when it is likely that many of these patients had poorly controlled, undertreated asthma.<sup>4</sup>
- 48% of adults diagnosed with asthma who were taught how to avoid triggers did not follow most of this advice<sup>5</sup>.

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1. Centers for Disease Control and Prevention (CDC) : Asthma Statistics/Asthma Society of Canada
2. Global Asthma Network: Global Asthma Report 2014
3. Medical Journal of Australia 202 (9) 18 May 2015: Asthma control in Australia: a cross-sectional web-based survey in a nationally representative population
4. *Why Asthma Still Kills*, The National Review of Asthma Deaths (NRAD) May 2014
5. Centers for Disease Control and Prevention, *Vital Signs*, May 2011.

### Forward Looking Statements

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