

16<sup>th</sup> November 2009

**ASX Code: KSX**  
**Speculative Buy**
**Capital Structure**

Sector	Health Care Equipment
Share Price	A\$0.05
Fully Paid Ordinary Shares	560.8m
Options (ex \$0.05,30/06/10)	10.6m
Options (ex \$0.25, 30/10/09)	10.0m
Options (ex \$0.05, 12/14, 6/15)	1.8m
Options (ex \$0.05, 15/12/15)	13.0m
Options (ex \$0.05, 30/06/12)	29.74m
Partly Paid Shares (0.2 cents)	27.46m
Redeemable Con Prefs	0.64m
Market Capitalisation (undiluted)	\$28.0m
Share Price Year High-Low	\$0.285-0.01

**Directors**

Mr Peter Marks	Executive Chairman
Prof. N Intrator	Non Executive Director
Henry Pinskiar	Executive Director
Prof. N Gavriely	Executive Director,CEO

**Major Shareholders**

Karmel Medical Acoustic	14.21%
Renlyn Bell Investments	8.36%

**Analyst**

Guy Le Page +61 8 9321 3277

**Share Price Performance**


# KarmelSonix Limited

## FDA Approvals...WheezoMeter™ sales commenced

**Investment Highlights**

- **KarmelSonix** is a developer, manufacturer and supplier of innovative and leading edge non-invasive acoustic tools for the management of asthma and related pulmonary disorders. The Company provides the only known tools that are capable of testing nocturnal wheezing and cough in the home environment.
- In less than 3 years the company has developed a first generation product suite which over 2008 and 2009 has received FDA (US), CE (Europe) and TGA (Australia) approval for the **PulmoTrack®** and the Personal **WheezoMeter™**. The **WHolter™** will soon be submitted for CE and then TGA and FDA approval. The **Personal WheezoMeter™** and the **WHolter™** recently had a very positive reception at the American Thoracic Society conference in San Diego, California and at the recent European Respiratory Congress in Vienna in September 2009.
- The recent grant (24/09/2009) of marketing clearance 510k (k090863) for the **WheezoMeter™** by the US FDA represents an important milestone for the Company and opens the door for introduction of the **WheezoMeter™** to the general patient population. In May 2009, the **Personal WheezoMeter™** also received Therapeutic Good Administration (TGA) approval in Australia and earlier in 2009, CE Mark was granted which opens up the European market and permits worldwide sales.
- The **PulmoTrack®** technology will facilitate the analysis of wheezing and coughing. Distribution agreements for **PulmoTrack**, **WHolter™** and **WheezoMeter™** were also executed during the 4Q 2008 with Italian based company Sensor Medics Italia Ltd and S-Med, a leading distributor for PFT and sleep equipment in the UK. Initial orders for both the **PulmoTrack®** and **WheezoMeter™** have been received from these distributors.
- **KarmelSonix** now has distribution channels into US, Canada, Asia (China, Taiwan, Korea and Singapore), Europe (Italy, UK, Germany, Romania and Greece) and the Benelux countries. Further distribution appointments are likely in the near term. **PulmoTrack®, WHolter™** and **WheezoMeter™** orders have also been received in South Korea. **Patent No** GB2330466 has recently been granted (May 2009) – a technology that is included in **PulmoSonix's** AirwayClear device that utilises active acoustics to assist in diagnosing Obstructive Sleep Apnea, Asthma and Upper Airway Obstruction.
- Management has been boosted with the appointment of sales and marketing executives in the US and Australia including Larry Murdoch over 20 years working in senior roles in multinational respiratory device companies and Paul Eisen – former Australia/Asia Pacific Sales and Marketing Manager RESMED.

**Outlook**

**KarmelSonix** have successfully raised approximately A\$4.0 million over the last 12 months with the monthly burn rate reduced from A\$520K to A\$250k/month. We believe the **WheezoMeter™**, has the potential to move the Company into a cashflow positive position by CY 2010 with commercial sales now likely to commence shortly on the back of recent TGA and FDA approvals. The **WheezoMeter™** alone has potential to generate net revenues in the Australian market in excess of A\$7.0 million within three years. The Company remains focussed on further product development (**WHolter™**, **Wireless PT™**, and **WIM-GER™**), expansion of its distributor network and the reduction of manufacturing costs. By way of comparison, ASX Listed RESMED has annualised revenues in excess of A\$900m from their sleep disordered products that affects around 5% of the population compared to Asthma which effects up to 15% of the population. Food for thought!

## Company Overview

### Simple Business Model

KarmelSonix Limited (“KarmelSonix” or “the Company”) is the parent company of KarmelSonix Israel Ltd, (KSI) from Haifa, Israel and PulmoSonix Pty Limited (KSA) from Victoria, Australia.

The Company’s strategy is to provide innovative access to acoustic-based clinical solutions for non-invasive monitoring of cardio-pulmonary patients in the medical market and to implement these cutting edge technologies in specific lines of devices that cover the entire span of disease management: at homes, in clinics, at hospitals and during convalescence and long-term care.

**RM Research** envisages a three pronged approach to marketing in coming months;

- Development of cost-effective, sensitive and simple-to-use clinical solutions focused on specific market needs.
- **KarmelSonix** positioning themselves as a leader in the provision of non-invasive patient monitoring providers.
- Direct market visibility as well as collaboration with market leaders who are currently catering to the needs of cardio-pulmonary patients.

**KarmelSonix** will use three products to achieve this strategy;

- **Personal and Clinical WheezoMeter™** Home and clinical use.
- **WHolter™** Ambulatory testing device.
- **PulmoTrack®** Hospital device.

**Figure 1: WheezoMeter™**



**Source:** KarmelSonix Ltd

### Regulatory Approval Overview

The **WheezoMeter™** (figure 1) was recently granted (24/09/2009) marketing clearance 510k (k090863) by the US Food and Drug Administration (FDA). The product received the CE mark in January 2009 and from the TGA in May 2009 and in October 2009, Canadian approval.

In late July 2009, KarmelSonix also announced that R&D and engineering work for the **WHolter™** and **Wireless PulmoTrack®** was near completion with a submission to FDA, CE Mark and TGA imminent. The **WHolter™** unit provides a diagnostic tool for overnight study of nocturnal asthma and other respiratory conditions.

The **PulmoTrack®** Acoustic Respiratory Monitor has received FDA clearance (Class II 510K), Canadian registration, CE Mark and TGA approval in Australia and Israel. Registrations are pending in China and Taiwan, Registration has been received in Korea.

In late July 2009, the Company also received receipt of the CE Mark for the **PulmoTrack® 3010 Cough Count™ (CC)** and recently TGA (Aust) approval has also been granted. This technology has been submitted for FDA (US).

“In excess of 16 million  
Americans have Asthma...

..over 300 million with  
respiratory problems  
worldwide”

Until KarmelSonix...no tools  
for effort independent  
monitoring of asthma have  
existed

“Three Product Approach”

Recent FDA marketing  
clearance represents a major  
breakthrough for the personal  
**WheezoMeter™**

## Recent history of Commercial & Development Agreements

Over CY 2009, the Company has been focused on the initial commercialisation of its product suite of which a key element has been the appointment of distributors in various markets which now include North America (US, Canada), Asia (China, Taiwan, Korea and Singapore), Europe (Italy, UK, Greece, Germany, Czech Republic, Spain and Romania) and the Benelux countries. Highlights over the last 12 months have included:

- Launch of **PulmoTrack®**, **WHolter™**, **PulmoTrack® Cough Counter**, and **Personal WheezoMeter™** (Clinical and Personnel) at the American Thoracic Society conference in San Diego, California and more recently, the European Respiratory Society Conference.
- **PulmoTrack®** has received Australian approval from the TGA. Inclusion of **PulmoTrack®** on the Australian Register of Therapeutic Goods which allows for first Australian sales to commence in the near term.
- Completion of R&D and development of the **WHolter™** and **Wireless PulmoTrack®** near completion prior to regulatory submission (FDA, CE, TGA).
- In May this year, the **Personal WheezoMeter™** received TGA approval which permits OTC and health sales in Australia. In January this year, the CE Mark was granted for the **Personal WheezoMeter™** which allows for OTC and health sales. FDA approval was granted in September 2009 for health professionals as first step prior to OTC granting and similarly just granted in Canada.
- Initial sales of **Personal WheezoMeter™** anticipated this month in Europe.
- Australian Private Health Insurer GMHBA to provide benefits for the purchase of the **Personal WheezoMeter™** later in CY 2009. Other Australian Private Health Funds anticipated to provide benefits for the **Personal WheezoMeter™**.
- First sales of **PulmoTrack®** to the Royal Melbourne Hospital Department of Respiratory and Sleep Medicine took place in Q3 2009.
- Distribution agreements for **PulmoTrack®** were executed in 4Q 2008 with Italian based company Sensor Medics Italia Ltd and S-Med, a leading distributor for PFT and sleep equipment in the UK. Initial orders for both the **PulmoTrack®** and **WheezoMeter™** have been received from these distributors.
- In July this year, agreements were executed with Newmedics to distribute the **WheezoMeter™** in Germany and Romania and initial orders received for the suite of products.
- Production of the **Personal WheezoMeter™** has commenced with initial production run completed and second run in process.
- First commercial sales of Personal Wheezometer announced to Doctors in Australia.

**2009 has been a productive year for KarmelSonix as it sets a platform for commercialisation**

## Product Portfolio

### Personal WheezoMeter™

The **WheezoMeter™** (figure 2) is a palm sized device which allows for patients and health professionals to assess wheeze activity over a short span of time (30 sec) (**WheezeRATE™**). The product can now be sold for use by all healthcare professionals in the US. The **WheezoMeter™** has previously been cleared for use in Europe (CE Mark) and Australia (TGA). The Company plans to seek FDA clearance for use of the **WheezoMeter™** by patients and parents (home use) by purchase over the counter (OTC) in due course.

Sales of the **WheezoMeter™** to the professional markets in the US will be through US national distributor(s) that specialize in sales to the hospital-based practitioners, RTs, EMS personnel as well as to doctors' offices and community-based allied healthcare personnel. Currently there is no competition in the market place for this type of device.

**Figure 2:** WheezoMeter™ (Source: KarmelSonix Annual Report 2008)



**The personal WheezoMeter™ is currently KarmelSonix's flagship product**

**Commercialisation of PulmoTrack® commenced in May 2008**

### PulmoTrack®

The **PulmoTrack®** device based on patented technology detects and quantifies sounds from the thorax, trachea and the patients' environment, accurately identifying the presence of wheeze and cough. The device is the first FDA approved Pulmonary Acoustic diagnostic tool in the market and the only device that has the ability to accurately monitor children, elderly and disabled patients day or night.

The **PulmoTrack®** comprises two contact sensors, pneumogram belt, signal conditioning electronics, algorithms and ambient noise rejection technology with data collected on a laptop computer. ISO 13485 status was granted in January 2008. The **PulmoTrack®** is derived from the WIM-PC™ platform and can be used in clinics, hospitals, military installations and research institutes.

Commercialisation of the **PulmoTrack®** was initiated in May 2008 with sales commencing in Q3 2008. Competition for the **PulmoTrack®** includes the companies Deep Breeze and Stethographics. **PulmoTrack®** has distinct advantages over its competition. Spirometry, the current gold standard can not be used with young children, elderly or disabled unlike the **PulmoTrack®**. Spirometry is also effort dependent and can not monitor nocturnal asthma.

### The WHolter™



**Figure 3:** WHolter™ (Source: KarmelSonix Ltd)

The **WHolter™** (figure 3) is an ambulatory acoustic recorder for continuous data collection based on the **PulmoTrack®** technology. It is the world's first device to provide physicians with accurate and quantitative measurement of the patients respiratory condition in his/her own environment. Commercialisation is likely to occur in Q4 2009.

**WHolter™ has no competition in the market place**

No competition currently exists for the **WHolter™**. To date physicians have made use of questionnaires for adults in testing the conditions of the patient's environment. This has proved to be largely ineffective as most patients fail to properly identify symptoms of respiratory distress. This method of testing is highly ineffective with children as they can not usually respond to questionnaires. There is currently no device in the market which can continually track a child's respiratory condition. For respiratory physicians the ability to be able to analyse exactly what is happening to a patient in their own environment and assess if they are wheezing, when they are wheezing, how much they are wheezing and the same for analysis of cough opens up a completely new area of diagnostic capability for the respiratory health providers and a significant commercial opportunity for **KarmelSonix**.

## Directors and Management

### **Mr. Peter Marks – Executive Chairman – Australia**

A venture capitalist and an investment banker, with years of experience in financing and assisting innovative biotechnology and medical device companies. Formerly Head of Corporate Finance at Baring Securities, Head of the Melbourne Companies Department at the Australian Stock Exchange, and a Director of Corporate Finance at KPMG Australia. Currently an Executive Director of a boutique corporate advisory and investment bank.

### **Prof. Noam Gavriely - Founder, Director, CEO, M.D. and Ph.D. from Technion Institute in Israel, and CMO**

Founder and former CEO of KMAT. Prof. Gavriely is an international authority in Pulmonary Acoustics, and holds multiple patents on phonopneumography. He has extensive entrepreneurial experience, and has commercialized several medical devices and has been responsible for development of new and innovative products.

### **Prof. Nathan Intrator – Non Executive Director,– Israel**

Widely recognized as a world expert in the field of signal processing (an area critical to the work of KSX), Prof. Intrator has over 100 peer reviewed publications in major journals and conferences. He is also the Founder of two technology start-up companies, including one in the field of Cardio Pulmonary Interactions – an area complimentary to that of **KarmelSonix**.

### **Dr. Henry Pinskier - Executive Director**

Dr. Pinskier is an experienced Health Sector operator at General Practice and Hospital Sector, and Health Sector entrepreneur. He assists in interfacing with healthcare professionals who deal with asthmatic and COPD patients on a daily basis, government relations and communications.

### **Mr. Paul Eisen - VP Sales & Marketing for Australia and Asia Pacific**

Paul Eisen has operated as a senior executive in the Medical device and Healthcare industry across Australia and Asia Pacific for the last 20 years. Paul holds a degree in Diagnostic Radiography from Sydney Technical Institute and a Graduate Diploma in Marketing from the University of Technology, Sydney (UTS).

### **Mr. Larry Murdock – Manager Director of USA Marketing and Sales**

25 years experience in global medical device marketing and product launches, particularly within respiratory care

### **Mr. Amir Ohad – Financial Manager**

CFO and CEO - Israeli and international medium size and start-up companies. Leader of execution of 3 M&A deals with strategic partners

### **Mr. Isaac Kroin – CTO**

Experienced EE and MBA executive. Instrumental in advancement of Acoustic Asthma Management technology over the past 10 years.

**One of KarmelSonix's core strengths is the assembly of professionals with extensive experience in the distribution of medical devices**

**Additional key sales and marketing staff have already been identified...**

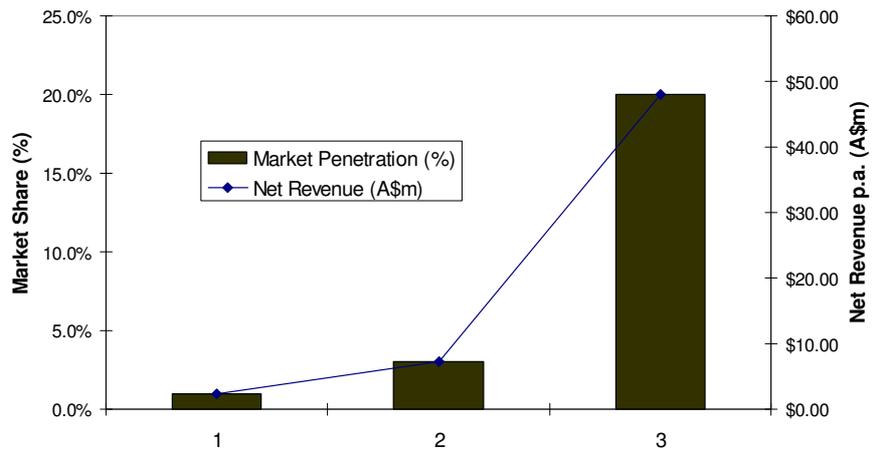
**...complimenting a world class technical team**

## Financial Overview

### Personal WheezoMeter™

Net Revenue outcomes (figure 4 and 5) are presented below for the **WheezoMeter™** alone. **RM Research** remain optimistic that the Company will be able to achieve a market penetration of in excess of 3% of the Australian market (assuming 2.5 million asthmatics) within the next three years which would potentially result in Net Revenues of approximately A\$7.0 million per annum to KarmelSonix.

**Figure 4: Personal WheezoMeter Australian Net Revenue Model**



**WheezoMeter™ alone has potential to generate substantial net revenues in the medium term**

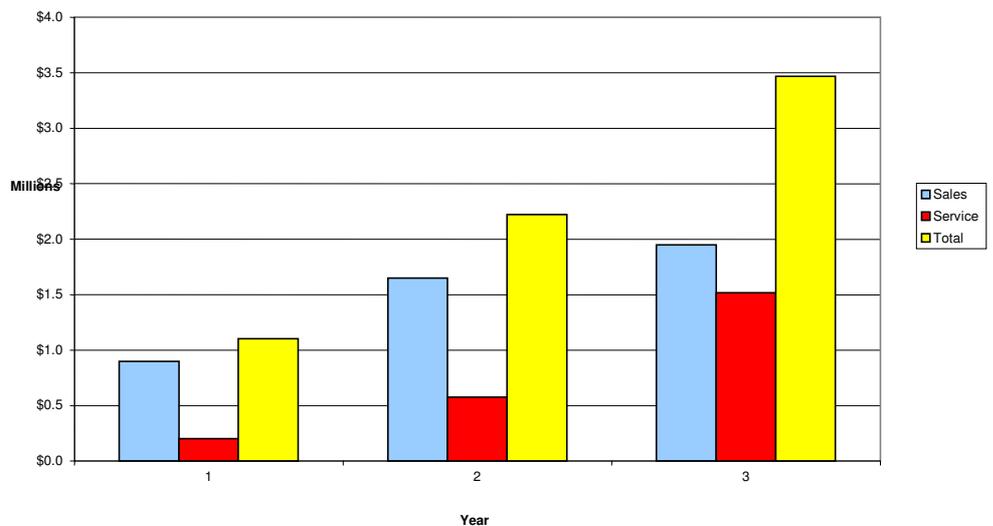
#### WHolter™ Assumptions

- 160,000 home based units p.a.
- 24,000 home based sleep studies p.a. rapid 0 – 2 yrs)
- Holters provided by 4 major pathology companies + Cardiologists
- Sleep studies provided by 5 companies
- Conservative 800 WHolter's required to meet market demand over 3 Years
- Respiratory Market at least 2-3 X size of sleep market. SDB prevalence 6.7%, asthma alone 15%
- Multiple conditions e.g. asthma, COPD

### WHolter™

Based on the assumptions opposite, the **WHolter™** (figure 5) has potential to generate Net Revenue of in excess of A\$3.0 million per annum within three years in the Australian market alone.

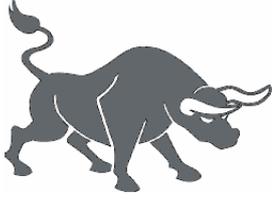
**Figure 5: WHolter Revenue Model - Australia**



Based on these assumptions, **RM Research** consider that **KarmelSonix's** Net Revenue potential based on the scenarios above in the Australian market alone could exceed A\$7.0 million in the next three years. Clearly the worldwide potential is a multiple of this.

## Bulls and Bears

### The Bulls Say

- 
- World's first non-invasive Asthma diagnosis and management solutions for the sick, elderly and children who do not have access to spirometry or other diagnostic tools.
  - The Company is in a strong position to capitalise on a burgeoning market which places great value on being able to effectively diagnose and manage Asthma. Costs of direct and indirect care of Asthma is in excess of US\$16 billion per year in the US and \$17 billion Euro per year in Europe.
  - Potential for numerous new products to be developed for other pulmonary ailments from core technology that provide a Hospital to Home solution.
  - Product suit should permit KarmelSonix to enter a market with no competition or competing technologies. In Australia alone (which represents 3% of the world market), some 15% of the population (22 million) suffer from respiratory ailments.
  - Testing of Lung functions (137,000 in 2006-2007 and 161,000 in 2008-2009) and sleep analysis (72,000 in 2006-2007 and 93,700 in 2008-2009) is trending up – take home point is that the **PulmoTrack®** and the **WheezoMeter™** are effective for those that cannot use spirometry while the **Wholter™** can perform lung testing as a home testing tool.
  - No regulatory hurdles. CE, FDA and TGA approvals have been received.
  - Very strong IP and Patent position
  - Recruitment of Paul Eisen - ex VP Australia and Asia Pacific for RESMED - has opened up the RESMED network (ie former staff and distributors) that have expressed interest in product distribution. This should accelerate the appointment of distributors and delivery of product into the market. He is also highly regarded by physicians.
  - Commercialisation in full swing from 2010 with distributors already appointed in key markets.

### The Bears Say

- 
- Potential for new competitors to enter market place.
  - The large number of options is likely to keep a lid on the share price until these are converted or unless sales ramp up exceeds expectations.
  - Potential ramp-up of new products may be slower than anticipated.

## Conclusion

**RM Research** believes the personal **WheezoMeter™** alone has the potential to be a “cash cow” and capture significant market share in a rapidly growing market. The **WheezoMeter™** is the only portable device in the world which can be used by asthma patients and their family to accurately assess wheeze activity. The product is to be sold in pharmacies and other health outlets as an OTC product with or without prescriptions. The product will also be sold to pharmaceutical companies in clinical studies to validate drugs and also to GPs, asthma nurses, paediatricians and emergency physicians.

The revenue model for the **WheezoMeter™** and **Wholter™** in the Australian market alone has potential to generate in excess of A\$7.0 million per annum within three years. Sales of **WheezoMeter™** could be substantial considering the captive market that exists globally from concerned parents and caregivers. By way of comparison RESMED have only one key product (compared to **KarmelSonix** 3 products) and generate annualised revenues in excess of A\$900 million and have returned 27% YOY since listing in 1995.

We consider the product offering offers plenty of leverage for investors into a market which has to date been neglected by major medical device companies. There is significant growth potential in the diagnosis and management of asthma through non-invasive means. **KarmelSonix's** product offering addresses the needs of a highly captive market which places great value on the ability to be able to effectively monitor and diagnose asthma in children, the elderly and disabled. **RM Research** rates **KarmelSonix** as a **Speculative Buy**.

## Research Analysts

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<b>Speculative Buy</b>	We forecast strong earnings growth or value creation that may achieve a return well above that of the broader market. These companies also carry a higher than normal level of risk.
<b>Hold</b>	A sound well managed company that may achieve market performance or less, perhaps due to an overvalued share price, broader sector issues, or internal challenges.
<b>Sell</b>	Risk is high and upside low or very difficult to determine. We expect a strong underperformance relative to the market and see better opportunities elsewhere.

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