

## COMPANY ANNOUNCEMENT

### KarmelSonix Receives TGA Approval for its Personal Wheezometer™ Device

#### HIGHLIGHTS

- TGA Approval for Personal Wheezometer™ represents an important milestone for Company.
- Process of securing FDA Approval for Clinical Wheezometer™ currently underway
- Widespread interest in both WHolter™ and Personal Wheezometer™ shown at ATS Conference in U.S. highlighting commercial potential for both products

**28<sup>th</sup> May 2009** : The Directors of KarmelSonix Limited (the Company or KSX) are pleased to announce that its Australian subsidiary, PulmoSonix Pty Ltd has received Therapeutics Goods Administration (TGA) approval for its novel, Personal Wheezometer™ device. The TGA approval which is effective immediately permits KSX to market and sell the Personal Wheezometer™ to all segments of the market, i.e. professional to personal.

Achievement of TGA approval represents an important milestone in the Company’s commercialisation program and builds on the previously achieved European approval process granted on the same basis.

The process of obtaining FDA approval is currently being undertaken in a 2 step process, firstly, seeking approval for medical profession usage in the USA followed by approval to be sold as an OTC product. The approach adopted in the USA differs necessarily from elsewhere due to the different requirements imposed by the FDA.

Receipt of the TGA approval for the Personal Wheezometer™ is important as Australia represents a market that has a substantial asthma population, where asthma is one of the national health priorities and where the market in terms of the funders both private and public has been relatively consistent. Furthermore, these factors will help KSX advance and develop its educational, marketing and business development plans across the health sector and broader community.

KSX Chairman, Mr Peter Marks stated today: “The achievement of the TGA approval together with the plans currently being developed in Australia for the release of the Personal Wheezometer™ as well as the upcoming launch of the WHolter™ monitor for up to 24 hour wheeze recording and monitoring will provide the market with what the Company calls its H to H (Hospital to Home) solution.”

***“Wheeze Rate – A New Paradigm in Asthma Management”***

The news of the TGA approval follows on from the very positive reception that both the WHolter™ and Personal Wheezometer™ received at the ATS Conference in San Diego, USA, last week. There was widespread interest in both these products, their utility and problems they addressed from a variety of health professionals involved with respiratory disease management as well as from other companies operating in this space. Further updates on progress are expected in the coming weeks.

For additional information please contact:

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KarmelSonix Ltd. focuses on supplying innovative non-invasive acoustic tools for disease management of asthma and related pulmonary disorders. Asthma affects 6-16% of the population in developed countries with a cost exceeding \$US15 billion in the US alone.

Acoustic Asthma Management is a breakthrough in monitoring of the asthmatic patient of all ages, including the very young, very old and others who cannot perform currently available tests. The technology that comes from extensive R&D and clinical validation in the US, Israel and Australia, facilitate continuous monitoring of patients at home, in the ICU and even during sleep. The company is focusing its efforts on the commercialization of its innovative product range with special emphasis on the European and North American markets.

***“Wheeze Rate – A New Paradigm in Asthma Management”***