



Cover Story



KarmelSonix Limited is Strategically Positioned with a Suite of Commercially Developed Products, including its Flagship Personal WheezoMeter™ Device, to Capitalise on the Substantial Market Potential of the Products

KarmelSonix Limited (KarmelSonix) is an ASX listed (ASX:KSX) leader in developing and commercialising a range of acoustic respiratory monitoring devices. The Company's novel products are based on acoustic signal acquisition technology and advanced analysis capabilities.

KarmelSonix is dedicated to providing a full range of products, all based on its core technology, but implemented in the configuration that is most appropriate for its use and that of its patient – from a patient's home to the Intensive Care Unit.

Highlighting the value of the company's strategic position as an imminent portfolio performer, KarmelSonix has released a number of positive highlights for the first half of 2009, which advantageously position the group for potential rewards on the broader markets' road to recovery.

Specifically, KarmelSonix has had positive developments in terms of its flagship Personal WheezoMeter™ device. The product was recently launched at the American Thoracic Society Conference with an overwhelmingly positive response.

In addition to this, key milestones have also been achieved in relation to the Company's WHolter™ and PulmoTrack® products.

Mr. Peter Marks, Chairman of KarmelSonix Limited stated, "Formed about three and a half years ago, KarmelSonix is the unique combination of Israeli and Australian technology in the acoustic area focusing particularly on respiratory diseases.

"The primary focus of the company is bringing to market a range of innovative non-invasive devices for the improved monitoring and management of asthma, cough and other related diseases.

Mr. Marks highlighted a number of key developments for KarmelSonix for the half year to date, principally, "KarmelSonix has secured both the European CE Mark approval and Australian, Therapeutics Goods Administration (TGA) approval for its flagship WheezoMeter™ device. We are now in the process of securing USA, Food and Drug Administration (FDA) approval for the device."

The achievement of TGA approval represented an important milestone for KarmelSonix in its commercialisation program as Australia is a significant and growing asthma market.

It is expected that this approval will assist the Company advance and develop its broadly-based education, marketing and business development plans across the health sector and broader community.

The process of obtaining FDA approval is being undertaken in a two step process, initially seeking approval for medical professional usage in the US followed by approval to be sold as an OTC product.

Importantly, "KarmelSonix is also in the final stage of bringing its, up to 24 hour WHolter™ monitor to market as well as the wireless PulmoTrack® device. In addition, the commercial rollout of the current PulmoTrack® device is continuing in several markets," Mr. Marks told the Australian Investor.

The first placement of the PulmoTrack® system in an Australian sleep lab setting was the recent sale to the Royal Melbourne Hospital Department of Respiratory & Sleep Medicine. This sale is seen as significant as it opens up the sleep laboratory market to the Company's suite of wheeze and cough detection devices.

"There are several important and specific drivers which will help underpin the Company's success," in the future. "Firstly, there is a growing market in the area of asthma monitoring and management, at the same time there is an unmet need in that approximately 30 per cent of the population who suffer from asthma and related diseases are unable to undertake current testing, for example, standard spirometry tests.

"At the same time, KarmelSonix's devices are novel in that they are non-invasive and do not require patients to cooperate other than to sit quietly in order to take a reading.

"There has already been widespread interest from the pulmonary and respiratory community regarding the application and utility of devices," Mr. Marks explained.

In order to maintain its strong position KarmelSonix has several important strategies in place, "We will place units with key opinion leader - that is people who have strong international reputations and are seen as early adopters for new technologies with real utility.

"We will undertake outcome studies which demonstrate the real benefits of using our devices." The Company also aims to get "further publications in peer reviewed journals completed over the coming months and beyond, as this brings further professional recognition and validation of the Company's devices."

Finally, KarmelSonix is looking to extend its existing distribution channels to move its products from the professional markets, to the G.P. and at home markets.

According to Mr. Marks, KarmelSonix priorities for 2009 "span a number of key areas including product completion, registration and an accelerating commercial roll out of our three main products, PulmoTrack®, the Personal WheezoMeter™ and WHolter™."

In addition to this, the Company will commit to "ramping up manufacturing operations in appropriate, cost-effective jurisdictions and continuing to work on the important issues of reimbursement," Mr. Marks informed the Australian Investor.

"What KarmelSonix is bringing to market is a new approach to the way that asthma and related respiratory diseases are being managed.

"Asthma and related respiratory diseases are growing in prevalence and, while there are some good drugs on the market, the tools available for monitoring and managing diseases, haven't changed in decades."

He concluded, "Approximately 10 years of R&D has gone into the development of our technology and product suite. The Company is now poised to roll out the various products as part of its overall H2H – hospital to home solution."

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