

# KarmelSonix Ltd

## (ASX: KSX)

Maiden sales... FDA approval and CE Mark received

14h January 2008

### Recommendation:

SPECULATIVE BUY

**GICS Industry:** Health Care Equipment & Services

### Capital Structure:

Share price	A\$0.165
Fully paid ordinary shares	250.52
Options (ex \$0.10, 30th June 2008)	129.25m
Performance shares Class D	30.0
Performance shares Class E	30.0
Performance shares Class G	12.5
Performance shares Class H	12.5
Market Capitalisation-undiluted	41.25m

### Directors:

Executive Chairman	Peter Marks
Executive Director	Noam Gavriely
Executive Director	Reuven Regev
Executive Director	Henry Pinskiier

### Top Shareholders:

Entity	Shares(m)	%
KarmelSonix Medical	30.0	11.97
Medic Vision Limited	13.0	5.19
Citicorp Nominees	10.0	3.99
Walthamstow Pty Ltd	9.30	3.59
Mr Ian Murie	7.42	2.96
Peregrine Corporate	5.0	2.00
Guina Nominees Pty Ltd	4.49	1.80

### Share Price History:



### Breaking News

- Regulatory approval has been received from the US Food and Drug Administration (FDA) together with CE-Mark approval for the WIM-PC. This represents a key milestone for the commercialisation of the WIM-PC product globally.
- First sales of the WIM-PC are likely to commence in Q2 of CY 2008. Agreements with first distributors are likely to be signed in coming months.
- KarmelSonix has successfully commissioned the production line for the WIM-PC. Production has commenced for an aggressive sales ramp up in 2008.
- Commercial Agreement signed for the development and distribution of the WIM-GORD monitor.

### Investment Highlights

- KarmelSonix Ltd is a supplier of innovative and leading edge non-invasive acoustic tools for management of asthma and related pulmonary disorders.
- Burgeoning market- Asthma affects 6-16% of the population in developed countries. The cost of Asthma in the U.S exceeds \$US 15 billion.
- KarmelSonix Limited has brought together a skilled and experienced international commercial and scientific team.
- RM Research considers that the home based wheezometer can be fast tracked through to commercialisation over the next twelve months with first commercial sales to commence in the second half of 2009.
- The WIM-PC was successfully demonstrated in April 2007 at the Queen Silvia Children's Hospital in Gothenburg, Sweden.

### Outlook

- KarmelSonix Limited has been awarded a US \$425,000 VISTECH Research Grant to develop a non-invasive monitor for continuous monitoring of severe asthma patients. VISTECH is a combined technology development fund established between Victorian and Israeli governments to provide funds for joint Victorian and Israeli projects.
- The R&D team is accompanied by regulatory procedural experts engaged to make sure all products reach the requirements of jurisdictions in which they are intended to be sold.
- KSX has brought in an expanded development team of 5 people to ensure all development timeframes are achieved and has also established an Electronic-Acoustic laboratory equipped with state of the art medical device equipment and hardware.
- The WIM-PC technology has the ability to quantify wheezes as inspiratory or expiratory and can correlate timing of events. The technology can be used in allergy and asthma clinics, primary care physicians, pediatricians and pulmonary function testing labs.
- First sales for clinical trials of the Wheezometer, a stand alone miniature are likely to commence by the middle of next year. The Wheezometer, a new portable device allows for easy to use monitoring of a patients Asthma.
- Solid management team- includes Noam Gavriely an international authority in Pulmonary Acoustics. Mr Gavriely has commercialised multiple medical devices with world-wide distribution.

**Cost effective, simple-to-use clinical solutions**



**Market size of GORD is substantial**

## Company Profile

KarmelSonix Ltd. ("KSX" or "Company" is the parent company of KarmelSonix Israel Ltd., (KSI) from Haifa, Israel and PulmoSonix Pty Ltd. (KSA) from Victoria, Australia. These both are wholly owned subsidiaries of KarmelSonix.

The Company's strategy is to provide 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;

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

KarmelSonix's target market consists of patients inflicted with prevalent cardio-pulmonary disorders which includes;

- i) Asthma,
- ii) Congestive Heart Failure (CHF),
- iii) Acute Respiratory Distress Syndrome (ARDS),
- iv) Obstructive Sleep Apnea (OSA),
- iii) Emphysema,
- iv) Chronic obstructive pulmonary disease (COPD).

## FDA approval and CE Mark received

Regulatory approval has been received from the US Food and Drug Administration (FDA) for the WIM-PC. The approval allows KSX to market the WIM-PC in the U.S and is a key milestone for the successful commercialisation of the product. We consider the FDA approval of WIM-PC is a positive sign for further commercialisation of KarmelSonix's additional products which include the Personal Wheezeometer and WHolter. The WHolter unit provides a diagnostic tool for overnight study of asthma- nocturnal asthma including other ambulatory applications. The Personal Wheezeometer will be a home-based asthma diagnostic tool.

KarmelSonix Ltd has also received CE Mark for WIM-PC which will allow entry to the European Market. This is a significant milestone which has been achieved by KSX since the receipt of FDA approval in late 2007. In addition to this KSX is moving forward to achieve TGA approval for the Australian market and the commencement of an approval process for Asian markets. 2008 will see KSX move from product development to a sales and distribution focus with significant reach in global markets.

## Commercial & Development Agreement

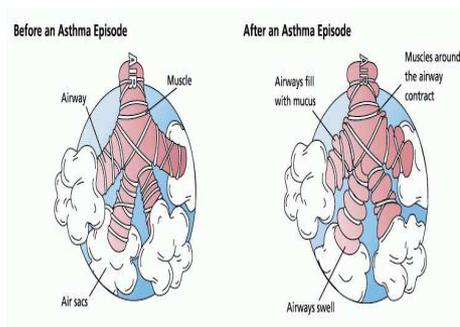
KarmelSonix has signed a commercial agreement for the co-development and distribution for a WIM-GORD Monitor. The market size of GORD is substantial and affects 50 million patients in the Western World. KarmelSonix has initiated a three phase plan leading to a product for monitoring relationships between asthma and gastro-esophageal reflux. Clinical studies will commence immediately in Leuven, Belgium and Bordeaux, France with WIM-PC™. Sandhill Scientific is a Denver Colorado based leader in the manufacturing and sales of monitoring and diagnostic devices for gastro-esophageal reflux disease. Management has indicated that the agreement is likely to lead to a long term commercial relationship between KSX and Sandhill.

## WIM-PC Production Line Commissioned

The company's production line for the WIM-PC has successfully been commissioned and has started to produce WIM-PC units for sale in 2008. First units of the WIM-PC will be available for sale in Q2 CY08. KarmelSonix has received strong interest from participants at the European Respiratory Society Meeting which was held in Stockholm.

## What is Asthma?

- Asthma is a chronic disease of the respiratory system in which the airway occasionally constricts, becomes inflamed, and is lined with excessive amounts of mucus;
- Episodes may be triggered by exposure to an environmental stimulant cold air, warm air, moist air, exercise or exertion, or emotional stress.
- In children common triggers are viral illnesses such as those that cause the common cold.
- Airway narrowing causes symptoms such as wheezing, shortness of breath, chest tightness, and coughing.
- Airway constriction responds to bronchodilators. Between episodes, most patients feel well but can have mild symptoms and they may remain short of breath after exercise for longer periods of time than the unaffected individual.



A typical inhaler, of Serevent (salmeterol), a long-acting bronchodilator

## The WIM Platform

KarmelSonix aims to be a leader in Acoustic Asthma Management to the clinical market. It does so by providing a simple, yet highly accurate and relevant measure of asthma – the Wheeze Rate (Wz %). When coupled with measuring the Cough Count, the Wz % is an objective and quantitative indicator of the extent of the airway narrowing at any given moment.

It is calculated as the duty cycle of wheeze activity as a % of the elapsed time and as such should be controlled at nearly zero by proper treatment during day and night. Obtaining the Wz % only requires that the patient will breathe at the rate and depth of convenience. No imposition is made on the patient and no cooperation is needed.

The Company has set forth a product development pipeline which will provide a full range of products, all based on its core technology, but implemented in the configuration that is most appropriate for its use – from the patient's home all the way to the Intensive Care Unit.

Applications of WIM include assistance in case of accidents and emergencies, assistance and monitoring in a home-care setting, monitoring of chronically ill patients, patient involvement in setting diagnosis, medicine dosage adjustment, physical state monitoring in sports, monitoring of irregular symptoms and emergency alarms.

## Benefits of WIM

- ❑ Asthma/respiratory patient: Parameters like blood oxygen levels and respiratory rate can be monitored which aids physicians in setting diagnosis.
- ❑ Heart condition patients: Heart parameters like ECG and blood pressure can be closely monitored which aids physicians in diagnosis and treatment of heart patients.
- ❑ Diabetes patients: Blood glucose levels or insulin levels can be monitored which aids physicians in diagnosis and treatment of diabetes and its symptoms.

## Core Technologies

KarmelSonix has developed extensive knowledge and technology in Pulmonary Acoustics. KarmelSonix is a leader in detection and signal processing of normal and pathological breath sounds which include wheezes and cough.

KarmelSonix's proprietary core technology is comprised of the introduction of custom designed sound structures into the mouth or nose and the detecting of its transmission to the chest surface.

The attenuation of the sound and its filtration by the thorax and lungs indicates the health of the structures beneath. Novel sensors and advanced algorithms are the foundation of the patented technologies for KarmelSonix. KarmelSonix owns the IP in this area which includes granted patents in the U.S and other important countries.

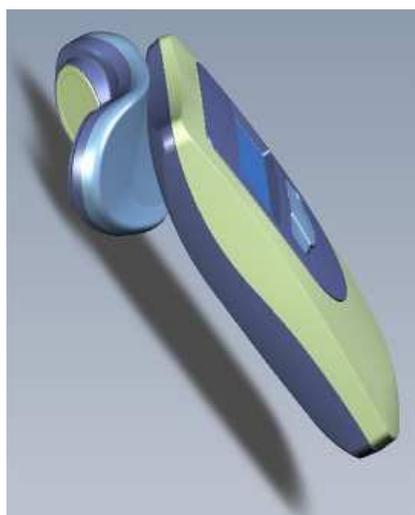
There are three products in KarmelSonix's pipeline which are based on the WIM Platform. These consist of a small pod containing the signal conditioning electronics and an ambient noise microphone. This is an essential component in the defense against environmental noise interferences. Two Phonopneumography (PPG) breath sounds sensors and a chest expansion belt for monitoring the breathing activity connects the patient to the pod. The signals are then digitized into a computer and the rest of the analysis is performed by calibrated algorithms that automatically detect wheezes, cough and respiration.



The WIM family of products includes the WIM-PC for use in primary care, pediatric, asthma and allergy and occupational clinics and in pulmonary function testing (PFT) laboratories. The second product is the Spiro-WIM, a combination of a Spirometer and the WIM technology. This product is specifically intended for the assessment and management of Vocal Cord Dysfunction, a wheezing disorder that is of emotional origin and must be sharply distinguished from Asthma.

### Leading clinical sites undertaking WIM-PC clinical studies

### Asthma affects 20 million in the U.S



Personal Wheezometer prototype

The third product is the WIM-Nocturnal, a wheeze, cough and respiration monitor for home and sleep-lab evaluation of asthma activity during a night sleep. It has the ability to collect data for up to 8 hours and is equipped with wireless technology to avoid the need for dealing with the sensor wires during a sleep study.

## The WIM-PC

FDA approval and CE mark have been received and set the stage for maiden sales by Q2 CY 2008. The WIM-PC production line has also been successfully commissioned.

WIM-PC has received strong feedback from leading international clinicians. In excess of 10 leading clinical sites have agreed to undertake WIM-PC clinical studies.

The WIM-PC technology represents an underlying platform which will be rolled out as suite of products over the next twelve months. A series of clinical studies will be conducted in the USA, Europe, UK, Israel and Australia. We consider that the clinical trials have the potential to generate a substantial amount of buy-in interest in the technology from the clinical market.

The WIM-PC has been exhibited as at a recent annual meeting of the American Thoracic Society. Other conferences attended by KarmelSonix executives include, the European Society of Allergy and Asthma in Sweden (within the nSpire booth), the First American Conference on Cough in New York, The American Society for Sleep Pathologies (ASSP) in Minneapolis and the World Asthma Meeting in Istanbul.

## Market Potential & Statistics

- ❑ Australian population estimated at 20 million and US population estimated at 300 million.
- ❑ Number of asthma and COPD affected people estimated at 2 million in Australia (16%) and 20 million in US (approx 7%).
- ❑ Asthma costs Australia in excess of \$700 million every year.
- ❑ Over 1 million school days are lost in Australia every year.
- ❑ Australia has the 3<sup>rd</sup> highest occurrence of childhood asthma in the world.
- ❑ Total number of separations with a principal diagnosis of asthma and COPD assumed at 100,000 in Australia (Source Australian Hospital Statistics) and 10.5 million in USA (Source: [www.aafa.org](http://www.aafa.org))
- ❑ Market size of medical equipments and devices for asthma and COPD diseases in Australia estimated at A\$100 million in Australia and A\$10.5 billion in the USA.



## Earnings Model

- ❑ Strong margins- net profit margin (NPM) assumed at an industry average of 14.6% (Source: [www.investor.reuters.com](http://www.investor.reuters.com))
- ❑ Revenues are received directly from appointed distributors who will sell KarmelSonix products in appointed distributor regions.
- ❑ KSX aims to achieve margins of 65% of the selling price of the WIM-PC. It is also expected that the gross margin for the personal Wheezometer will be in the order of 70%.
- ❑ In addition it is expected that KSX will also receive licensing, sub-licensing fees and further revenues from sale of consumables and other services.
- ❑ After receiving the FDA and CE marks for the WIM-PC we envisage sales to commence by mid 2008.
- ❑ Wheezometer- The first prototype is planned for mid 2008. Post FDA approval sales are likely to commence in Q2 of CY 2009.

## Directors

### **Peter Marks** **CHAIRMAN, AUSTRALIA**

An experienced venture capitalist with a background in financing medical and innovative technology companies.

### **Noam Gavriely** **DIRECTOR, CSO, ISRAEL**

MD and PhD from Technion Institute in Israel. Founder and former CEO of KMAT. An international authority in Pulmonary Acoustics, and holds multiple patents on Phonopneumography. He has extensive entrepreneurial experience, and has commercialised multiple medical devices with world-wide distribution.

### **Reuven Regev** **DIRECTOR, CEO, ISRAEL**

Electrical Engineering BSc and MSc from the Technion Institute in Israel and MSc and PhD degrees in Management from Stanford University (USA). Held leadership positions in Israel's armament technology authority. In the mid 1990s, he became a CEO of a VC Fund.

### **Henry Pinski** **EXECUTIVE DIRECTOR,** **AUSTRALIA**

Experienced Health sector operator at General Practice and Hospital Sector. Health sector entrepreneur. He assists in interfacing with healthcare professionals who deal with asthmatic and COPD patients on a daily basis.

### **Mr Isaac Kroin EE, MBA** **CTO**

Seasoned technology leader in medical devices with BSc in Electronic Engineering and MBA. Has been the moving force behind the Acoustic Asthma Management Technology for the past ten years.

### **Israel Tal** **CORPORATE VP OF SALES**

Prior to his appointment with Karmel, Mr Tal served as Director of Business Development at S.H.L Telemedicine, a public healthcare company which specialises in home monitoring of cardiac patients together with sales of telemedicine systems. He also served as VP of Sales in Power Paper Ltd, a consumer skin care technology company.

### **Brad Sheehan** **ASIA PACIFIC GENERAL MANAGER**

Mr Brad Sheehan currently holds the position of Asia Pacific General Manager. Mr Sheehan joins KarmelSonix after a five year tenure at biotechnology company Clinical Cell Culture (C3) in the UK.

## Key Investment Risks

- ❑ **Regulatory Approval**  
The regulatory environment for biomedical devices is demanding, complex, time consuming and very expensive and as such there is no certainty that the applications for regulatory approval will be successful.
- ❑ **Market Acceptance**  
The global marketplace for most products is ever changing due to new technologies, new products, changes in preferences, changes in regulations and other factors influencing market acceptance or market rejection. This market volatility and risk exists despite the best endeavors of market research, promotion and sales and licensing campaigns.

## Outlook

- ❑ In the coming months KSX will establish internal and external sales infrastructure for the fast tracking of WIM distribution in selected regions through KarmelSonix appointed distributors.
- ❑ The company has indicated that they will also seek to initiate strategic contacts with NGOs such as the WHO, major domestic and international Asthma patient and advocate groups plus the establishment of strong relationships with relevant professional medical organisations.
- ❑ New management appointments have strengthened and broadened the management team. Appointments of Mr Brad Sheehan and Mr Israel Tal will add significant scope to regulatory and global distribution activities.
- ❑ CE and FDA approval of the WIM-PC have been received and set the way for the transition from a technology company to commercial sales phase for KarmelSonix.
- ❑ In August KarmelSonix completed a capital raising that raised in excess of \$5.5 million through a placement of new ordinary shares at 19 cents. KarmelSonix's cash position currently sits at around \$3.5m. The current level of cash burn is approximately \$250k-\$350k per month.
- ❑ KarmelSonix is operating in a market which has experienced exponential growth in recent years. Asthma currently affects 6-16% of the population in the developed world. Technology developments with the WIM platform will form the basis for a rollout of a number of products which will address numerous segments in the Asthma market. Initial sales in Europe and North America are to commence by mid next year for KarmelSonix's commercialised Wheeze and Cough Monitor (WIM). The management team has been strengthened and we consider it has the ability to secure market share in key segments during FY 07/08 and consolidate its position in the following year. We maintain our recommendation of Speculative Buy

# RM CAPITAL GROUP DIRECTORY

## REGISTERED OFFICE

1175 Hay Street  
West Perth WA 6005  
AUSTRALIA

## CONTACT DETAILS

Telephone +61 8 9321 3277  
Fax +61 8 9321 8399  
Website: [www.rmresearch.com.au](http://www.rmresearch.com.au)

## ADMINISTRATION

Karla Pavlinovich + 61 8 9321 3277 [jbrich@rmcapital.com.au](mailto:jbrich@rmcapital.com.au)  
Carol Oakley + 61 8 9321 3277 [caz@rmcapital.com.au](mailto:caz@rmcapital.com.au)

## WEALTH MANAGEMENT

James Richardson + 61 8 9321 3277 [jbrich@rmcapital.com.au](mailto:jbrich@rmcapital.com.au)  
Kim Leunig + 61 8 9321 3277 [kleunig@rmcapital.com.au](mailto:kleunig@rmcapital.com.au)  
Martin Wiedemann + 61 8 9321 3277 [martin@rmcapital.com.au](mailto:martin@rmcapital.com.au)  
Brendan Atkinson + 61 8 9321 3277 [batkinson@rmcapital.com.au](mailto:batkinson@rmcapital.com.au)

## Corporate Finance

James Richardson + 61 8 9321 3277 [jbrich@rmcapital.com.au](mailto:jbrich@rmcapital.com.au)  
Guy Le Page + 61 8 9321 3277 [gtlepage@rmcapital.com.au](mailto:gtlepage@rmcapital.com.au)

## CORPORATE AUTHORISED REPRESENTATIVES

### Agudo Pty Ltd

Colin Barboutis +61 8 9485-0140 [cb@westernventures.com.au](mailto:cb@westernventures.com.au)

### Mainbreak Securities Pty Ltd

Mark Swan 1-800-195-859 [markswan@mainbreaksecurities.com.au](mailto:markswan@mainbreaksecurities.com.au)

### Triple C Consulting & Financial Services

Peter Sheppard +618 9480 0447 [peter@tripleccc.net.au](mailto:peter@tripleccc.net.au)

## RESEARCH

Dennis Trlin + 61 8 9321 3277 [dennis@rmcapital.com.au](mailto:dennis@rmcapital.com.au)  
Guy Le Page + 61 8 9321 3277 [gtlepage@rmcapital.com.au](mailto:gtlepage@rmcapital.com.au)  
Richard Monti + 61 8 9482 0502 [rmonti@ventnorcapital.com.au](mailto:rmonti@ventnorcapital.com.au)  
Terry Butler-Blaxell + 61 8 9321 3277 [tbutler@rmcapital.com.au](mailto:tbutler@rmcapital.com.au)  
Michael Mech + 61 8 9321 3277 [mmech@rmcapital.com.au](mailto:mmech@rmcapital.com.au)

## Symmetry Financial Consultants

Brent Coxon +61-8 6380 1400 [brent@symmetrygroup.com.au](mailto:brent@symmetrygroup.com.au)  
Megan Hinchliffe +61-8 6380 1400 [meqan@symmetrygroup.com.au](mailto:meqan@symmetrygroup.com.au)  
Michael Bower +61-8 6380 1400 [michael@symmetrygroup.com.au](mailto:michael@symmetrygroup.com.au)

## Ventnor Capital Pty Ltd

Richard Monti +61 8 9482 0502 [rich@ventnorcapital.com.au](mailto:rich@ventnorcapital.com.au)  
John Hannaford +61 8 9482 0502 [john@ventnorcapital.com.au](mailto:john@ventnorcapital.com.au)  
Morgan Baron +61 8 9482 0502 [morgan@ventnorcapital.com.au](mailto:morgan@ventnorcapital.com.au)

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