

## iSonea Limited (ASX: ISN)

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Research Abstract

Healthcare Research

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### Company Description

iSonea Ltd. (formally KarmelSonix) engages in the development, manufacture, and sale of asthma monitoring products. The company sells its products through independent third-party distributors and strategic alliances in the United States, Australia, Israel, Europe, among others. ISN has been listed on the Australian Securities Exchange (ASX) since 2000. However, the recruitment of new CEO Michael J. Thomas in June 2011 represented a new strategic direction for the company, focused on improved reimbursement, clinical data, and strategic partnerships. ISN is headquartered in Annapolis, Maryland.

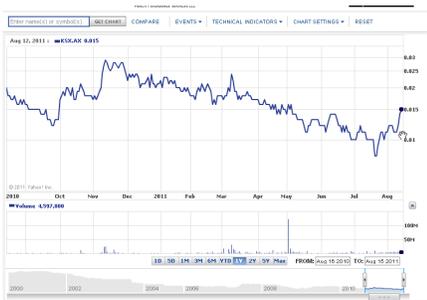


Chart Source: Yahoo!  
Finance

### HIGHLIGHTS

- iSonea (ISN) is an emerging medical technology company with new and innovative products for continuous asthma monitoring, which address an unmet medical need in the growing US asthma market.
- The company has already received a number of regulatory approvals, and is seeking more. All of ISN's products are cleared by the US FDA, the Australian TGA, and carry the European Union's CE Mark. ISN is also seeking additional regulatory clearances in China, Japan, and Korea.
- ISN patent portfolio and regulatory approval successes have attracted interest from large companies in the respiratory device and services market. We would expect to see significant strategic partnership deals announced over the next 12 months.
- ISN is planning near term clinical studies to confirm efficacy and improve reimbursement. ISN's large scale clinical study will provide data for a potential upgrade to a Category I CPT code (from its current level III CPT code), which carries with it improved reimbursement. The data from this clinical study will also be leveraged to solidify reimbursement in other countries around the world (e.g. the UK, Germany, France, Australia, Japan, China and India).
- ISN could be a potential take out target. As management executes on its new strategy, we believe ISN could become an attractive candidate for an acquisitive large device company looking to leverage ISN's unique technology. Consequently, at this stage we expect ISN's value to be viewed more accurately through the lens of an acquisition vs. a multiple of future revenue or earnings.

## Executive Summary:

iSonea (ISN) is an emerging medical technology company focusing on the US asthma market. In the US, the Centers for Disease Control (CDC) estimates that over 25MM people have asthma and that this number continues to rise (21% increase from 2001 to 2009). The ISN technology, which is built around proprietary algorithms to detect and quantify breathing and lung sounds, offers a solution to an unmet medical need: all US and global asthma treatment guidelines require continuous asthma monitoring, but very few patients/physicians actually adhere to this requirement because of inadequate technology. We believe that over the next twelve months ISN will launch a cost effective, easy to use technology to enable physicians and patients to comply with these guidelines. We note that ISN is an early stage medical device story and, as such, an investor is buying the management, technology, and the product potential, not near term earnings.

To date, the company has already achieved substantive milestones, such as:

- Securing 510(k) clearance from the US Food and Drug Administration (FDA) for all of its current products
- Consummating distributor agreements in the US and around the world
- Receiving approval from the US Centers for Medicare and Medicaid Services (CMS) for reimbursement under the American Medical Association's (AMA's) Category III (emerging technology) code in its "Current Procedural Terminology (CPT®)

Catalysts that might drive the stock going forward include:

- Initiate and complete clinically significant "economic outcome" studies to establish the cost-effectiveness and clinical utility of using ISN technology to manage asthma
- Use that data to file for a Category I (standard of care) CPT code, leading to more consistent reimbursement from healthcare payors
- Execute strategic partnership deals with 1-2 global companies in the respiratory medical device and healthcare services sectors to accelerate adoption rates by physicians for ISN products

We note that all early stage investments carry substantial risks, but for the more risk tolerant investor, ISN may provide an attractive risk/reward premium over the next twelve months.

## **Key elements of the ISN story:**

- *Large market.* The CDC has clearly documented that in the US alone more than 25 million people have asthma. The CDC also warns that this population is growing at around 2%-3% a year. We believe that this market will continue to grow due to macrodemographic factors such as: obesity, poor air quality, and an aging population.
- Unmet clinical need – first products to provide objective, passive, validated, patient friendly monitoring to achieve asthma management. The Global Initiative for Asthma (GINA) first recommended chronic monitoring of asthma patients in its 1993 guidelines.

Despite this global clinical mandate, very few physicians and their patients follow these guidelines because existing technologies (e.g. peak flow meters) are cumbersome, uncomfortable, and often unreliable. We believe that ISN' Personal WheezoMeter™ and 24hr WHolter™ monitor represent viable solution to address this costly and unmet medical need.

- *The company has a number of regulatory approvals and is seeking more.* All of ISN's products are cleared by the US Food & Drug Administration (FDA), the Australian Therapeutic Goods Administration (TGA) and carry the European Union's CE Mark. ISN is seeking additional regulatory clearances in China, Japan, and Korea.
- *US reimbursement.* ISN has successfully achieved a Category III CPT code from the US AMA's CPT Editorial Panel. A Category III CPT code enables Medicare to track usage of emerging technologies prior to awarding full reimbursement and pricing approval for that new technology. ISN is currently designing a large-scale clinical study that will provide data for the Editorial Panel to consider an upgrade to a Category I CPT code which, in turn, will enable physicians using and/or prescribing technology to be reimbursed by all institutional healthcare payors in the US. The data from this clinical study will also be leveraged to solidify reimbursement in other countries around the world (e.g. the UK, Germany, France, Australia, Japan, China and India).
- *Strategic Partnerships.* ISN patent portfolio and regulatory approval successes have attracted interest from several large companies in the respiratory device and services market. ISN has signed one distribution agreement with Omron as a major distributor of its products in Japan and other foreign markets. As the company entertains additional inquiries from large pharmaceutical and medical device conglomerates, we would expect to see additional strategic partnership deals announced over the next 12 months.
- *Potential take out target.* As management executes on its new strategy, we believe ISN could become an attractive candidate for an acquisitive large device company looking to leverage ISN's unique technology for asthma management. Consequently, at this stage we expect ISN's value to be viewed more accurately through the lens of an acquisition vs. a multiple of future revenue or earnings.

### **Outlook on the Asthma Treatment Market:**

Market outlook. The asthma treatment market offers substantial potential as more than 300 million people in the world and more than 25 million in the US suffer from asthma. Furthermore, the CDC reports that the asthma treatment market has grown over 21% during the past decade. As with all paradigm shifting technologies, the potential for growth extends beyond traditional approaches as the technology enables new products and services not presently available. In addition to traditional asthma medical device sales, ISN estimates that the technology can provide solutions such as cost effective, objective, and easy to use monitoring services that are currently not available. Also, longer-term ISN expects to offer a consumer version of its WheezoMeter™ that leverages smartphones (e.g. iPhone, Android, BlackBerry) via a software application.

While ISN is positioned to generate revenue via agreements with distributor organizations around the world, the company plans to focus the majority of its efforts over the next few years on the US asthma market. According to the CDC, the direct and indirect asthma costs exceed \$56 billion per year in the US, or \$3,250 per person. Improving patient outcomes and reducing asthma costs has been a primary focus of third party payors (e.g. managed care organizations or MCOs), employers, disease management firms (e.g., Alere, Healthways), and Medicare over the past decade. We believe that obesity, poor air quality, and an aging “baby boomer” population will continue to drive market growth for the next decade, representing a strong macro-demographic tailwind for ISN products.

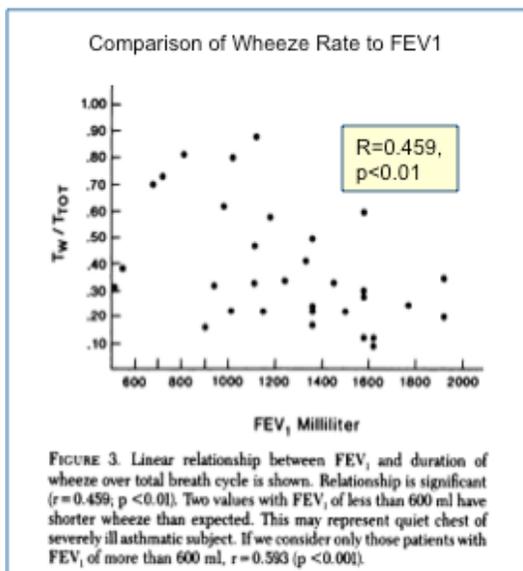
### **Technology and Products:**

**The technology.** Currently available technology, such as spirometry, use a metric called Forced Expiratory Volume in one second (or FEV<sub>1</sub>) to demonstrate the severity of asthma in a patient. The patient must breathe as hard as possible into a machine, which a snapshot of the patient’s breathing disorder severity. The ISN technology uses a completely different, noninvasive, passive approach to measuring asthma severity which the company calls the “wheezeRATE™.” Using wheezeRATE™ instead of FEV<sub>1</sub> allows ISN to provide physicians with a more patient friendly, passive, objective measurement that doesn’t cause patient discomfort, is easy to use on children and the elderly, and also allows for chronic monitoring, as recommended by The American Thoracic Society (ATS) guidelines.

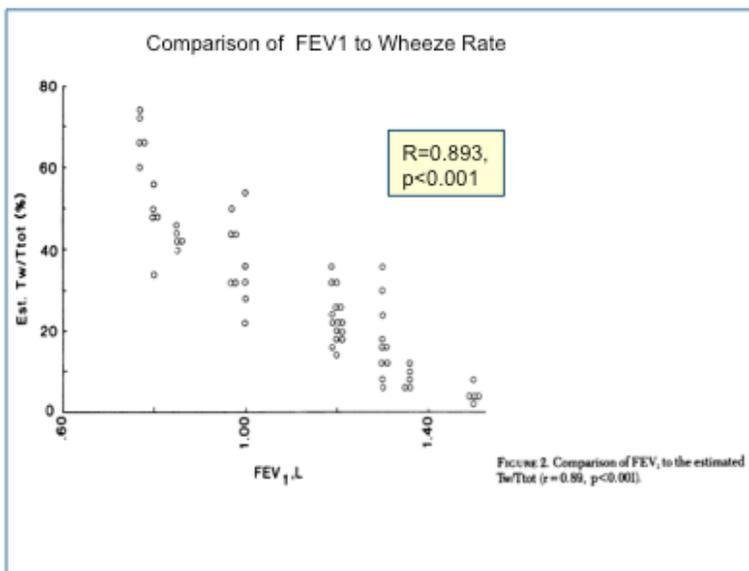
ISN technology works by using sensors applied directly to patient’s throat or through a set of well placed electrodes, depending on the product. Measurements from these sensors are then recorded. The recording can provide either a quick snapshot or chronic monitoring of the patient’s condition. In either case, what the doctor receives is an easy to read summary explaining the current state of the patient’s breathing.

The diagnostic precision of wheezeRATE has been illustrated in several scientific posters, which have compared the accuracy of using wheezeRATE vs FEV<sub>1</sub>; early data indicates that wheezeRATE has a linear correlation to FEV<sub>1</sub> at the moderate and severe levels (see Exhibits 1 and 2 below). The company plans to run pivotal trials, with the help of select strategic partners, over the next 12 months to validate the efficacy of its technology and use the data to move its Category III CPT code to a Category I code (see R&D section later on for more details).

**Exhibit 1: Baugh & Louden studies indicate statistically significant correlation between wheezeRATE and FEV<sub>1</sub>**



CHEST 1984; 86: 718-722



CHEST 1985; 88: 364-368

Source: Company reports

**Exhibit 2: WheezeRATE™ versus FEV<sub>1</sub>**

WheezeRATE	FEV1.0
Measured during tidal breathing	Measured during forced maneuver
Neutral lung volume history	Measured after TLC maneuver
Measured during expiration and inspiration	Measured during expiration
Effortless	Requires active patient cooperation
Can be done in preschool children, elderly and infirm	Patient must have technical capability and comprehension of test requirements
Continuous	Not continuous
Can be monitored during sleep	Cannot be performed during sleep
Can be monitored in a ventilated patient	Not done on ventilated patients
No predicted values. WheezeRATE above 5% indicates airway constriction	Needs predicted value to assess wellness and pathology

Source: Company reports.

**The products.** ISN has a portfolio of several products that help physicians and patients improve asthma management at a lower cost and at a greater ease of use/convenience to the end users. The current standard of care for asthma diagnosis or severity measurement is spirometry. This product is expensive (ASP at \$2,200), uncomfortable, difficult for patients to use and is not easily portable. The peak flow meter, which is often used in the patient's home, is inexpensive, but very unreliable and the values are difficult for the physician to interpret. Most importantly, *all* of the current technologies fail to enable patients and physicians to meet The American Thoracic Society clinical guidelines requiring monitoring.

ISN currently offers four products: the Clinical WheezoMeter™, Personal WheezoMeter™, WHolter™, and Pulmotrack®.

The Pulmotrack® is a hospital based product, that may help the company to seed key opinion leaders KOLs at tertiary care centers. The company has been successful in its early efforts attracting KOLs, mostly pulmonologists, to test and purchase small numbers of ISN products. If the company is successful in leveraging the sales force of strategic partners, ISN will have an opportunity to not only increase its penetration into the pulmonary market, but also later on may be able to make cost effective inroads into the primary care market. Successful placement of devices at these institutions leads to rapid adoption by private practice specialists and primary care doctors.

**The WheezoMeter.** The WheezoMeter is a hand-held device that can be used in the physician's office or patient home. Unlike spirometers or peak flow meters, it requires no uncomfortable coordinated heavy breathing by the patient. Instead the sensors of the machine are placed over the patient's throat, and in 30 seconds the WheezoMeter measures the occurrence and duration of wheezing. This product is light, battery operated, and easily portable. As with the spirometer and peak flow meter, it provides a "snap shot" of the patient's condition at that specific moment. However, given its portability and ease of use, we believe that it is likely to be used more frequently than current products such as the spirometer and peak flow meter. If the company is successful in demonstrating that patient use of the WheezoMeter leads to a meaningful improvement in an asthma patient's adherence to pharmaceutical therapies, reduction in emergency room (ER) visits, or overall improvement in the patient's quality of life, we believe that the company will have a compelling case to third party insurers and Medicare for reimbursement of a service fee for the chronic monitoring of the patient's asthma.

**The WHolter.** This product also helps patients and physicians meet the ATS guideline of "assessment, treatment, and monitoring." The WHolter is a small device (not much larger than the first blackberries) that is attached with a pair of electrodes to the patient's body. It can be used for 24-hour monitoring in any situation, including when the patient is working or sleeping. As with the WheezoMeter, the WHolter uses ISN proprietary technology to measure the presence of wheeze in a passive manner for optimal patient comfort. The WHolter may be used for hours or days. At the completion of each testing period, the physician is provided with a short, easy-to-read report summarizing the patient's overall condition and the key areas of concern regarding his or her wheeze. It is the first chronic monitoring tool available to physicians and can be used on patient groups with challenging conditions or situations, such

as patients with nocturnal asthma, patients with occupational asthma, young children (infants and toddlers), and the frail or elderly.

**Competitive Landscape/ Intellectual Property:**

The company’s primary product competitors are spirometers and peak flow meters. These products are manufactured by a large number of both pharmaceutical and medical device companies. The spirometer is expensive, and sells for around \$2,200. Peak flow meters are inexpensive (about \$10 per single use), but are considered a commodity in a declining market due to their issues of reliability and dependency on patient effort. There are no significant competitive products that we are aware of on the horizon. A few other companies market sound technologies for other medical monitoring applications. It is also possible that other companies that specialize in the disordered breathing area could be working developing asthma monitoring products. However, ISN has broad patent claims, which could provide barriers to entry for future competitors.

**Business Model/ Reimbursement status:**

Reimbursement for treatment using ISN technology occurs in two ways: through physician prescribed device sales (WheezoMeter, Pulmotracks and WHolters), and for diagnostic service, such as sleep studies. Comparable services are reimbursed between \$60 and \$250 per study in certain developed markets. As mentioned, the ISN near term strategy is to focus on the US market. All of ISN’s products are cleared for use by the US FDA. Category III CPT codes have been granted for the company’s technology in intermittent and continuous use, but reimbursement for Category III codes vary by payor. Therefore, the company is actively working on converting these codes to Category I. When the company receives a Category I CPT code, the Company expects the reimbursement rate to improve. We believe that the US rates could be similar to those listed under “report reimbursement” in Exhibit 3.

**Exhibit 3: Expected US Reimbursement, for ISN Devices**

	Spirometer	Peak Flow Meter	WHolter	WheezoMeter
ASP of Device	\$1500-\$2,200	NA	\$1,500	\$1,000
Disposable	\$2.50	\$10 (one time use)	NA	NA
Report Reimbursement	\$98.62	NA	\$207.62	\$98.62

Source: Company reports

**Financials:**

- *Revenue.* ISN is in the planning and data gathering stage and as such we do not expect significant revenue until late FY12. After that, we expect revenue growth may be choppy on a quarter-to-quarter basis until the company begins to ramp up. The company believes that with a reasonable level of execution it should be able to reach

sales of \$10M by FY2013 and could see steady growth well in excess of 50% per annum for the next few years.

- *Margins/Expenses.* In ISN's latest available financial statement (FY 2010 ending 30 June 2010) the company had a gross margin of just 22%. This is largely because the company has only modest products sales and has not officially launched any of its products. By FY2015 the company expects to see a gross margin closer to 65%-70%. Longer term, the company believes that they could achieve gross margins in the mid 70% range. SG&A, which is also currently very high, could get to the mid to high 40% over that same time frame.
- *Earnings.* The company is unlikely to reach EBITDA profitability until at least FY2014. Right now, the stock is less of an earnings story and more of a technology story. Therefore, we believe that releasing any detailed earnings projections at this time would be premature.
- *Cash burn & capital needs.* Cash on hand is around \$1M and ISN's operating expenses are in the range of \$500K per month. The company is working to reduce the burn rate to around \$350K per month. ISN will need to raise funds in the near term.

### **Operational Abilities/Manufacturing:**

ISN utilizes contract manufacturing in Israel. Its contract manufacturer is described as a high quality, low volume facility. Given the low cost of materials involved in the production of ISN products, we believe that, with enough volume, the company should be able to meet its high gross margin manufacturing goals (70%+), which are above the medical technology industry average.

### **Sales Model/Sales Force:**

The company has chosen not to have an internal sales force at this time. We believe that this is a prudent choice given the company's limited funds and early stage of development. Based upon the early promise of this technology the company plans to establish strategic relationships with distribution partners and large multinational companies that desire to drive this technology into their channels.

### **New Product Development/R&D:**

The bulk of the company's development efforts for its technology are complete. Existing funds will be utilized for product iteration, scaling in response to market, customer feedback and clinical trials. The company is planning a large clinical trial that will demonstrate clinical utility. This U.S. clinical trial will enlist more than 100 patients and is focused chiefly on clinical and economic outcomes (patient adherence to pharma therapies, reduction in ER visits, reduction in hospitalizations, and reductions in unscheduled physician office visits). This trial is expected to start in Q4 2011 and should take about 6-9 months.

This near term trial is the focus for the company as data showing product efficacy and clinical utility will be key to ISN receiving both physician acceptance and a category I CPT code.

Longer term, the company is considering new indications for its products such as continuous monitoring of asthma and rapid daytime test for sleep apnea, among others.

### Valuation:

The shares appear to be undervalued considering ISN's potential growth profile and acquisition attractiveness. Successful emerging medical device companies with unique technologies designed to address unmet needs often trade at high revenue multiples based upon strategic partnership opportunities, patent portfolios, and clinical trial results (see Exhibit 4). As ISN positions itself as a technology leader in a large and growing market, and management executes its strategy (successfully concluding clinical trials, receiving Category I CPT codes, and engaging key strategic partnerships) shares should begin to trade in-line with peers over the coming 12 to 24 months.

### Exhibit 4: Valuation – The Emerging Medical Technology Group

#### Medical Device Companies - Trading Multiples Analysis

As of: 7/11/2011

(\$ in millions)

Market Capitalization > \$200MM										
Negative LTM EBITDA										
Company	Symbol	Mrk. Cap.	TEV	Total Assets	LTM		Total Enterprise Value (TEV) /		Price/BV	Price/TBV
					Revenue	EBITDA	Revenue	EBITDA		
Opko Health, Inc.	AMEX:OPK	\$1,158.5	\$1,091.3	\$176.3	\$87.6	(\$14.4)	29.0x	NM	9.4x	11.9x
Insulet Corporation	NasdaqGM:PODD	\$1,083.4	\$1,049.8	\$148.0	\$104.4	(\$25.0)	10.1x	NM	17.6x	17.6x
DexCom, Inc.	NasdaqGM:DXCM	\$1,037.6	\$1,000.6	\$66.6	\$53.3	(\$43.3)	18.8x	NM	18.1x	18.1x
Heartware International Inc.	ASX:HIN	\$990.7	\$862.5	\$262.8	\$62.4	(\$30.6)	13.3x	NM	5.9x	6.0x
OraSure Technologies Inc.	NasdaqGS:OSUR	\$463.6	\$398.8	\$119.2	\$74.5	(\$0.5)	5.4x	NM	4.6x	4.8x
Unilife Corporation	ASX:UNS	\$318.7	\$312.4	\$98.2	\$8.6	(\$37.0)	35.2x	NM	5.0x	6.4x
Cytori Therapeutics, Inc.	NasdaqGM:CYTX	\$282.3	\$259.7	\$57.2	\$8.8	(\$29.8)	29.5x	NM	22.7x	34.7x
DURECT Corporation	NasdaqGM:DRRX	\$177.3	\$138.9	\$59.9	\$32.5	(\$21.7)	4.3x	NM	16.6x	42.3x
<b>Median</b>		<b>\$727.2</b>	<b>\$630.7</b>	<b>\$108.7</b>	<b>\$45.4</b>	<b>(\$27.9)</b>	<b>16.1x</b>	<b>NM</b>	<b>13.0x</b>	<b>14.7x</b>

#### Respiratory / Sleep Disorder Medical Device Companies - Trading Multiples Analysis

As of: 7/11/2011

(\$ in millions)

Market Capitalization < \$200MM										
Company	Symbol	Mrk. Cap.	TEV	Total Assets	LTM		Total Enterprise Value (TEV) /		Price/BV	Price/TBV
					Revenue	EBITDA	Revenue	EBITDA		
Itamar Medical Ltd.	TASE:ITMR	\$74.9	\$85.4	\$20.5	\$11.8	\$0.0	7.2x	0.0x	NM	NM
Somnomed Ltd.	ASX:SOM	\$55.2	\$51.2	\$7.8	\$12.0	\$0.3	4.1x	NM - 142.0x	8.9x	9.3x
Compumedics Ltd.	ASX:CMP	\$14.1	\$15.5	\$21.7	\$32.9	\$0.1	0.4x	NM - 100.7x	NM - 78.6x	NM - 78.6x
KarmelSonix Ltd.	ASX:KSX	\$12.4	\$10.7	\$4.0	\$0.5	(\$6.8)	20.3x	NM	4.1x	8.1x
Dehaier Medical Systems Limited	NasdaqCM:DHRM	\$11.7	\$10.6	\$37.3	\$19.9	\$5.2	0.5x	2.0x	0.5x	0.5x
Pearl Healthcare Ltd.	ASX:PHL	\$1.3	\$3.1	\$4.0	\$14.1	\$0.8	0.2x	3.6x	4.2x	9.6x
<b>Median</b>		<b>\$13.2</b>	<b>\$13.1</b>	<b>\$14.2</b>	<b>\$13.0</b>	<b>\$0.2</b>	<b>2.3x</b>	<b>2.0x</b>	<b>4.2x</b>	<b>8.7x</b>

## Medical Device Companies - Trading Multiples Analysis

As of: 7/11/2011

(\$ in millions)

Market Capitalization < \$200MM										
Negative LTM EBITDA										
Company	Symbol	Mkt. Cap.	TEV	Total Assets	LTM		Total Enterprise Value (TEV) /		Price/BV	Price/TBV
					Revenue	EBITDA	Revenue	EBITDA		
Cardiovascular Systems Inc.	NasdaqGM:CSII	\$245.3	\$240.0	\$43.7	\$75.1	(\$11.0)	3.2x	NM	14.5x	16.7x
AtrixCare, Inc.	NasdaqGM:ATRC	\$232.1	\$224.0	\$36.7	\$60.7	(\$0.6)	3.7x	NM	14.5x	14.5x
Uroplasty Inc.	NasdaqGM:UPI	\$182.9	\$166.8	\$25.7	\$13.8	(\$3.6)	12.2x	NM	8.1x	8.8x
Cutera, Inc.	NasdaqGS:CUZ	\$118.8	\$109.7	\$109.4	\$51.1	(\$12.3)	0.6x	NM	1.3x	1.3x
ImpediMed Limited	ASX:IPD	\$107.6	\$86.5	\$25.7	\$3.9	(\$13.9)	21.0x	NM	5.7x	4.2x
Trans51, Inc.	NasdaqGM:TSON	\$101.0	\$84.5	\$46.2	\$24.6	(\$18.3)	2.8x	NM	2.4x	2.4x
EnteroMedics, Inc.	NasdaqGM:ETRM	\$77.0	\$50.6	\$33.7	\$0.0	(\$16.3)	0.0x	NM	3.1x	3.1x
Cardica Inc.	NasdaqGM:CDXC	\$75.4	\$64.1	\$13.9	\$13.2	(\$3.0)	4.9x	NM	7.2x	7.2x
MELA Sciences, Inc.	NasdaqGM:MELA	\$63.9	\$37.9	\$28.8	\$0.0	(\$19.6)	0.0x	NM	2.4x	2.4x
Sunshine Heart Inc.	ASX:SHC	\$58.6	\$45.8	\$12.8	\$0.6	(\$9.1)	NM - 78.0x	NM	2.9x	2.9x
Oxygen Biotherapeutics, Inc.	NasdaqGM:OWBT	\$57.1	\$58.7	\$2.9	\$0.1	(\$10.0)	NM	NM	NM	NM
Lombard Technologies PLC	AJM:UMT	\$55.8	\$46.6	\$19.7	\$4.7	(\$13.5)	9.7x	NM	1.9x	2.5x
InVivo Therapeutics Holdings Corp.	OTCBB:NVIV	\$46.5	\$39.7	\$8.0	\$0.0	(\$4.4)	0.0x	NM	NM	NM
EDAP TMS SA	NasdaqGM:EDAP	\$44.5	\$54.1	\$0.0	\$34.4	(\$4.3)	1.8x	NM	3.5x	4.9x
DORR Corp.	AMEX:DRR	\$43.7	\$24.2	\$52.7	\$1.8	(\$6.2)	13.9x	NM	0.9x	0.9x
Neovasc Inc.	TSXV:NVC	\$42.6	\$41.8	\$3.8	\$4.6	(\$3.0)	9.0x	NM	16.8x	16.8x
CAS Medical Systems Inc.	NasdaqGM:CSGM	\$38.4	\$36.2	\$13.1	\$23.6	(\$2.1)	1.5x	NM	3.9x	4.2x
Cytosorbents Corporation	OTCBB:CTSO	\$35.1	\$35.2	\$2.9	\$0.0	(\$3.0)	0.0x	NM	26.2x	26.2x
MedPro Safety Products, Inc.	OTCBB:MPSP	\$32.5	\$48.9	\$28.6	\$0.2	(\$8.8)	NM - 163.1x	NM	NM	NM
Gabari German Company for Medical Device	DSM:GGMD	\$28.8	\$29.8	\$80.6	\$2.7	(\$0.5)	10.8x	NM	0.5x	0.6x
Luna Innovations Incorporated	NasdaqGM:LUNA	\$23.5	\$12.2	\$23.1	\$35.7	(\$0.5)	0.6x	NM	2.4x	2.6x
ArCor Medical Holdings Limited	ASX:ACG	\$20.1	\$17.8	\$6.9	\$9.4	(\$0.6)	1.8x	NM	3.3x	3.3x
ProUroCare Medical Inc.	OTCBB:PUMD	\$17.1	\$18.4	\$0.2	\$0.0	(\$1.9)	0.0x	NM	NM	NM
Misonix Inc.	NasdaqGM:MSDN	\$16.8	\$9.2	\$18.9	\$14.6	(\$2.3)	0.8x	NM	1.0x	1.3x
Analytica Ltd.	ASX:ALT	\$15.3	\$15.3	\$0.4	\$0.0	(\$0.9)	NM	NM	54.9x	54.9x
Urologix, Inc.	NasdaqGM:ULGX	\$14.3	\$10.5	\$8.1	\$12.9	(\$2.5)	0.8x	NM	2.3x	2.4x
SafeSitch Medical, Inc.	OTCFK:SFES	\$14.3	\$12.5	\$2.4	\$0.0	(\$5.8)	0.0x	NM	6.7x	6.7x
KarneSense Ltd.	ASX:KSK	\$12.4	\$10.7	\$4.0	\$0.5	(\$6.8)	20.3x	NM	4.1x	8.1x
Medical Australia Limited	ASX:MLA	\$10.7	\$11.7	\$7.6	\$8.2	(\$0.3)	1.4x	NM	2.1x	17.4x
NeuroMetrix Inc.	NasdaqGM:NURO	\$10.3	(\$4.8)	\$20.3	\$13.2	(\$12.5)	NM	NM	0.6x	0.6x
Antisense Therapeutics Ltd.	ASX:ANP	\$10.1	\$6.9	\$3.3	\$0.4	(\$2.1)	15.0x	NM	3.1x	3.1x
MedMira Inc.	TSXV:MIR	\$9.3	\$24.6	\$9.5	\$0.7	(\$2.2)	24.1x	NM	NM	NM
SpectraScience Inc.	OTCFK:SCIE	\$9.2	\$6.0	\$6.3	\$0.0	(\$2.8)	NM	NM	1.5x	2.7x
Escalon Medical Corp.	NasdaqGM:ESMC	\$8.9	\$11.3	\$19.0	\$30.6	(\$2.6)	0.4x	NM	1.0x	1.7x
Microcos Medical AB	OM:MPQS	\$8.7	\$7.7	\$3.7	\$0.2	(\$0.8)	47.1x	NM	2.6x	2.8x
BioElectronics Corporation	OTCFK:BIEL	\$8.2	\$13.0	\$1.6	\$0.9	(\$2.8)	14.2x	NM	NM	NM
Nephros Inc.	OTCBB:NEPH	\$7.6	\$5.4	\$3.6	\$2.6	(\$1.9)	2.1x	NM	2.7x	2.7x
Aethlon Medical Inc.	OTCBB:AEMD	\$6.7	\$6.5	\$1.0	\$0.0	(\$4.3)	0.0x	NM	NM	NM
Arbios Systems, Inc.	OTCFK:ARBI	\$5.0	\$0.0	\$0.5	\$0.0	(\$0.8)	0.0x	NM	NM	NM
Computer Vision Systems Laboratories Corp	OTCBB:CVSL	\$5.0	\$5.0	\$0.0	\$0.0	(\$0.2)	0.0x	NM	NM	NM
PLC Systems Inc.	OTCBB:PLCS.F	\$4.2	\$4.4	\$6.0	\$3.7	(\$0.8)	1.2x	NM	NM	NM
American Scientific Resources, Inc.	OTCFK:ASPK	\$4.0	\$6.6	\$1.0	\$0.8	(\$3.1)	8.5x	NM	NM	NM
Medgard Ltd.	ASX:MSZ	\$2.7	\$1.8	\$1.2	\$0.1	(\$0.8)	18.7x	NM	1.1x	1.3x
MIN Therapeutics Inc.	OTCFK:MINI	\$2.4	\$0.0	\$4.0	\$1.0	(\$13.5)	0.0x	NM	1.4x	34.8x
Urodynamic Technologies Ltd.	TSXV:URO	\$2.1	\$1.7	\$0.0	\$0.1	(\$0.7)	30.7x	NM	1.9x	1.9x
OMI Holdings Limited	ASX:OMI	\$2.1	\$0.9	\$1.7	\$0.0	(\$1.1)	NM - 67.7x	NM	1.2x	1.3x
Meridian Co., Ltd.	OTCBB:MRDALF	\$1.4	\$5.9	\$1.1	\$1.2	(\$1.7)	5.0x	NM	NM	NM
Encorium Group Inc.	OTCFK:ENCO	\$1.1	\$4.7	\$9.9	\$16.8	(\$4.5)	0.3x	NM	NM	NM
MedX Health Corp	TSXV:MDX	\$1.1	\$1.9	\$0.4	\$0.6	(\$0.9)	3.0x	NM	NM	NM
Victrom Human Bionics Inc.	TSXV:VHB	\$1.0	\$8.8	\$7.8	\$0.1	(\$4.0)	NM - 115.5x	NM	NM	NM
Cardima, Inc.	OTCFK:CADM.Q	\$0.7	(\$0.5)	\$5.1	\$3.0	(\$12.6)	NM	NM	0.2x	0.2x
<b>Median</b>		<b>\$14.3</b>	<b>\$13.0</b>	<b>\$6.3</b>	<b>\$1.0</b>	<b>(\$3.0)</b>	<b>1.9x</b>	<b>NM</b>	<b>2.5x</b>	<b>2.8x</b>

Source: Thompson Financial

**Management:**

The ISN management team has seen almost a complete turnover since CEO Michael J. Thomas took over in June of 2011. While Mr. Thomas has made great strides to restructure the ISN management team, there are still a number of positions he plans to fill over the next twelve months including: VP Sales, VP Marketing, VP Business Development, and VP systems and Engineering. Regarding management incentives and their alignment to stock holder goals, ISN has an executive compensation program, which links executive management's bonuses with company performance.

- *Michael J. Thomas, CEO.* Mr. Thomas is a seasoned medical device executive with a documented track record of increasing shareholder value. Prior to joining ISN,

Mr. Thomas was the President & CEO of Sleep Solutions, a medical device company focused on developing and selling products/services for in-home patient self-administered sleep studies. Also pertinent in the case of ISN is his extensive experience in venture capital fundraising. Mr. Thomas has a proven track record of raising money for early stage companies. At Sleep Solutions, he raised more than \$50M in venture capital. He has 15 years experiences in devices and more than 22 years in the health care industry.

- *Stephen Tunnell, SVP of Operations.* Mr. Tunnell has more than 32 years in the health care industry. He is intimately familiar with the disordered breathing industry, beginning his career as a registered respiratory therapist in 1980. He was later promoted to Technical Director of Pulmonary Services at Sharp Health Care. During the 90's Mr, Tunnell served as General Manager at Nellcor Puritan-Bennett's Ventilator Systems Division of Mallinckrodt. In 2000, he co-founded, a life support company, eVent Medical Ltd., and as President and CEO led the company to a successful trade sale.
- *Jonathan Freudman, MD, Consulting Medical Director.* Jonathan Freudman has over twenty-five years of experience in healthcare, including 16 years of general practice medicine for Kaiser in California. Since 2002 he has been an industry consultant helping a variety of health care companies with both clinical and business challenges. His clients have included: venture capital, medical device and other biotechnology companies. Dr. Freudman specializes in planning and implementation of effective reimbursement strategies, which is a key goal for ISN over the next twelve months.

**Key Milestones/Catalysts:**

The company has a number of near term catalysts. We note some of the most important in below.

**Exhibit 5: ISN Key Catalysts**

Catalyst	Description	Timeframe
Partnerships	Company plans to sign partnership agreements with 1-3 device, distribution, and/or pharmaceutical companies	FY 2011 through FY 2012
Clinical trials	Company plans to conduct large (100+ patient) multicenter outcomes studies to demonstrate the clinical utility of the ISN products	FY 2011 through FY 2012
Category I CPT Code Filing	Following positive data results, the Company plans to file for Category I CPT Code	FY 2012
Category I CPT Code Approval	Approval of a Category I CPT code can take 6 to 12 months post submission	FY 2013

Source: Company reports.

**Potential Risks:**

- *Unproven product.* ISN is a first mover in the chronic monitoring and non-invasive asthma monitoring market. Because of this, it must convince doctors, hospitals, payors, and patients of the product's efficacy and clinical utility. Also, because the current

standard of care uses products that are fairly inexpensive commodities with long product life cycles, there is no real incentive for physicians to switch products unless efficacy and clinical utility can be demonstrated.

- *Data could fall short of expectations.* While there are several legs to the ISN story, the strategy works if and only if the data shows that the product can demonstrate equivalent or superior outcomes than current methods of diagnosis and monitoring products (spirometer and peak flow meter). The company is planning a sizable clinical trial over the next year. If these outcomes studies do not demonstrate equivalent or superior clinical or economic outcomes then we would expect a significant decrease in the value of ISN shares.
- *Physician acceptance of wheezeRATE™.* Even if the data indicate that ISN products are equally to or better at monitoring asthma than the current standard some physicians may remain skeptical. The main issue is that ISN not only has new products, but also that these products use a different statistic to evaluate asthma versus traditional products. As we described in the product section above the ISN technology does not use the current standard asthma monitoring static (FEV<sub>1</sub>), but instead uses a metric invented by ISN called wheezeRATE™. Delays in physician acceptance of wheezeRATE versus company expectations could affect ISN's value.
- *Reimbursement.* A key part of the ISN story is obtaining standard reimbursement, which is based on outcomes and clinical utility data that will allow ISN to receive a Category I CPT code. Receiving a Category I CPT code should lead to improved and more consistent reimbursement for ISN's products and services (in most cases) over what is currently be received by the Company. However, the approval process to receive a Category I CPT code can take six months to a year. A later than expected approval or a denial of a Category I CPT code could significantly depress share value.
- *Litigation risk.* Unfortunately, the medical technology industry is riddled with litigation risk, especially around patents. ISN does not have any active lawsuits at this time, but has said they will vigorously defend their patents so this could be an issue in the future.
- *Financial risk.* Given the company's burn rate, ISN will need to successfully raise funds in the near future.
- *Execution risk.* New management will need to continue to successfully execute on their strategy.

### **Disclosure:**

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