



## Investor Update and Quarterly Report – 31<sup>st</sup> March 2012

Melbourne, Australia, 30 April 2012:

Australian medical technology company iSonea Limited (ASX: ISN; OTC: ISOAY) provides the following report on its progress for the third quarter of its fiscal year, the three month period ending 31 March 2012.

### Highlights:

- **New Directors appointed to Board**
- **US pediatric wheeze clinical study initiated**
- **OTC WheezoMeter™ submission to US FDA on track**
- **AsthmaSense™ v1.0 smartphone application readied for commercial release**
- **New consumer education website launched - [www.SoundAsthma.com](http://www.SoundAsthma.com)**
- **Qualcomm 2Net™ Hub technology development project underway**
- **Second generation WheezoMeter™ prototype developed to lower Cost of Goods Sold (COGS)**

We are pleased to announce that we have accomplished several crucial milestones in the strategic plan to produce and launch a suite of new products to bring more efficient asthma monitoring to patients and physicians alike.

Progress achieved on key milestones will be discussed below.

### **New Directors appointed**

Significant changes occurred within the iSonea Board of Directors in March 2012. On 20 March, Dr. David R. Dantzker, MD, a specialist in Pulmonary and Critical Care medicine and an expert on medical technology and venture capital investment, joined the Board.

On 31 March, both Mr. Paul Hopper and Mr. Fabio Pannuti stepped down from their Director positions. Subsequently, iSonea appointed Dr. Ross Macdonald and Dr. Stewart Washer to fill the Director vacancies and appointed Mr. Donal O'Dwyer as a special advisor to the Board.

All bring extensive experience in development, commercialization, and growth of companies in the pharmaceutical and medical device sectors on a global basis.

Mr. Ross Haghighat remains as Chairman of the Board and Mr. Jerry Korten also remains as Director.

- ***Dr. David Dantzker, MD:***

Dr. Dantzker brings more than 10 years of medical technology portfolio management and corporate board experience to iSonea. As a general partner at Wheatley Partners, LP, Dr. Dantzker manages the medical technology portfolio of investments for the US-based \$250 million venture capital fund.

Dr. Dantzker also brings extensive pulmonary medicine experience to iSonea's BOD. Before joining Wheatley Partners, Dr. Dantzker held several executive positions at some of the country's most prestigious medical institutions, including president of North Shore-Long Island Jewish Health System; vice chairman of the Department of Internal Medicine and director of the Pulmonary and Critical Care Medicine division at the University of Texas Health Science Center; and chairman of the American Board of Internal Medicine as well as its subspecialty board on Pulmonary Disease. Dr. Dantzker has authored 68 peer reviewed articles and edited five books.

- ***Dr. Stewart Washer:***

Dr. Washer has 15 years of senior executive and board experience at medical device, drug development and agrifood companies. He was a venture partner with Inventages (a Nestlé fund) and is currently Investment Manager with IB Managers, which manages Australian life-science funds.

Dr. Washer was previously the CEO of Calzada Ltd. (ASX: CZD); the founding CEO of Phylogica Ltd. (ASX: PYC); CEO of Celentis; and managed the commercialization of intellectual property from AgResearch in New Zealand. He has held a number of board positions, including Chairman of Resonance Health Ltd. (ASX: RHT) and Hatchtech Pty Ltd.; and Director of iCeutica Pty Ltd. and AusBiotech Ltd. He was also a Senator with Murdoch University and is currently a Director of Healthlinx Ltd. (ASX: HTX) and Immuron Ltd. (ASX: IMC).

- ***Dr. Ross Macdonald:***

Dr. Macdonald brings extensive biomedical experience in general management, technology commercialization, capital raising and business development, including licensing, mergers and acquisitions. He was formerly Managing Director and CEO of Living Cell Technologies Ltd. (ASX: LCT; OTCQX: LVCLY), a development stage biotechnology company focused on therapeutics for type-1 diabetes, Parkinson's disease and stroke. Dr. Macdonald is currently a Member of the Investment Committee of Uniseed Management Pty Ltd., a venture fund established to commercialize research outcomes from the Universities of Queensland, Melbourne and New South Wales, and serves as a Director for pharmaceutical development companies Telesso Technologies Ltd (ASX: TEO) and Hatchtech Pty Ltd.

Dr. Macdonald was previously the Vice President, Business Development for Sinclair Pharmaceuticals Ltd., Vice President of Corporate Development for Stiefel Laboratories, Inc., and was Vice President of Business Development for Connetics Corporation when it was acquired by Stiefel. He was also Vice President of Research & Development for F.H. Faulding & Co, Ltd., Australia's largest and oldest pharmaceutical company.

- ***Mr. Donal O'Dwyer:***

Mr. Donal O'Dwyer brings extensive worldwide sales, marketing, product development and manufacturing operations experience in the healthcare products and medical device industries. He was formerly Worldwide President of Cordis Cardiology, a Johnson & Johnson Company, during which time he re-established their position as a leader in international cardiology with the development and launch of the revolutionary Cypher coronary stent. He oversaw the growth of that business from USD500M per annum to over USD2B per annum.

Mr. O'Dwyer is currently Deputy Chairman of the Board at Mesoblast Limited (ASX: MSB; OTC ADR: MBLTY), the world's leading developer of biological products for regenerative medicine. He is also a member of the Board at Cochlear, the leading global hearing solution company. Previously, he was President of the Cardiovascular Group, Europe, for Baxter Healthcare. He was chairman of the Board of AtCor Medical and has served as Director on the Boards of Angioblast Systems and Sunshine Heart.

#### **US pediatric wheeze clinical study initiated**

This multi-site study will involve 95 children in the asthma patient and control groups. Institutional Review Board (IRB) approvals for the study sites were obtained in Q3 and the physicians and nursing staff were trained on the study protocol. Sites are now actively accruing patients and the first patients have been enrolled. The study is expected to require 3 to 4 months for completion. The primary objective of this study is to establish correlation between wheeze monitoring via Acoustic Respiratory Monitoring and other conventional methods of assessing lung function in the diagnosis and management of asthma in children. It is expected that the data provided by this study will support future regulatory submissions and adoption of Acoustic Respiratory Monitoring (ARM™).

#### **OTC WheezoMeter™ submission on track for US FDA**

The 510(k) dossier for an over-the-counter version of the company's WheezoMeter™ device, to be called the SonoSentry™, is nearing completion and is on schedule for submission to the US FDA in Q4 FY 2012. FDA clearance of this device will provide access to ARM devices for daily monitoring of wheeze without requiring a prescription in the US. This level of accessibility, coupled with a lower cost, higher margin monitoring device, will allow promotion to and penetration of the US asthma consumer market, as well as providing a competitively priced device to meet the needs of key markets in the rest of the world.

#### **AsthmaSense™ v1.0 mobile health app beta tested in preparation for commercial launch**

A major component of the new strategy for iSonea is the integration of our proprietary Acoustic Respiratory Monitoring sensory technology and diagnostic algorithms into smartphone platforms. The universal proliferation and availability of Apple iPhones and Android-based smartphones provides an ideal platform for asthma monitoring – over 500 million of these devices are being sold every year. These devices are perpetually present with their owners, meaning that the hardware needed for frequent daily monitoring will already be in our customers' hands. Harnessing the mobile health (mHealth) platform also provides lower cost product development, a more efficient market penetration model (than traditional physician promotion), and a quicker path to revenue generation for the company.

In the third fiscal quarter, v1.0 of the AsthmaSense™ mobile health application (app) entered the programming phase for both Apple and Android devices. The app has undergone beta testing and is nearing design completion in preparation for a commercial launch in the coming quarter. The initial version offers a comprehensive journaling app with active reminders for medication and testing, as well as an alert system to

notify when an individual's trends indicate that, according to standardized guidelines, their asthma status may be changing. Utilizing this app daily will provide users with tools to better manage their asthma.

AsthmaSense Cloud™ is also in development, which will integrate enhanced environmental risk data into the management tools and will allow physicians, patients and families to track and trend asthma symptoms, events, and response to medications.

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#### **Consumer education website launched**

Creating awareness and demand for a better way to monitor asthma is a crucial goal for market penetration in the US. A key part of the strategy to reach asthma consumers is to utilize social media sites and a consumer-oriented website to introduce Acoustic Respiratory Monitoring, the WheezoMeter™ and its evolutionary successors, and the AsthmaSense™ mobile health apps. In Q3 FY2012, we completed and launched a new consumer-oriented website, [www.SoundAsthma.com](http://www.SoundAsthma.com), and linked it to Facebook, Twitter, and You Tube sites under the SoundAsthma™ brand.

Through the social media channels, we have introduced a weekly blog written by a young mother who is struggling with the challenges of caring for a toddler with asthma, and we have developed a supportive network of asthma bloggers, physicians and consumers who are interested in new approaches to better monitoring and management of the disease. This network will provide an efficient means of announcing commercial availability of our products.

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#### **Qualcomm technology collaboration initiative underway**

In Q3, we developed a prototype of the second generation WheezoMeter™ technology with Bluetooth® output to link up with the Qualcomm 2Net™ Hub, in order to collect asthma monitoring data for transmission to a back-end cloud-based service. We have qualified the hardware vendor and are finalizing the service agreement. This project is on schedule to meet original expectations for Q2 FY2013.

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#### **Development of a lower cost, higher margin WheezoMeter™**

In Q3, we engaged an engineering and design firm to work with iSonea to redesign the WheezoMeter™, replacing the obsolete processor with new, more cost efficient components that will include optional Bluetooth® communication. The first step in our 'costing down' strategy was achieved with the completion of a proof-of-concept build that will ultimately become the platform for both the WheezoMeter™ and SonoSentry™ devices. Our target of reducing the cost of goods sold (COGS) of production versions to approximately one-third of the current COGS is feasible with this proof of concept. The project is on track for Q2 FY2013 completion.

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### Looking forward:

In the quarter ahead, we expect to:

- Submit the 510(k) dossier for the SonoSentry™ OTC wheeze monitoring device to the FDA;
- Commercially launch our first AsthmaSense™ smartphone asthma management app;
- Complete development of a successor mobile health app with an enhanced feature set;
- Fully enroll the US pediatric clinical study;
- Continue significant product development progress toward the second generation WheezoMeter™ and its successors.

As is evident from our delivery of key milestones, iSonea is making substantial, step-by-step progress toward our goal of becoming the global leader in asthma monitoring and management technology. We have a vision for how our novel technology can better address the needs of physicians and consumers, who struggle to manage asthma in a more effective and successful manner, to improve long-term outcomes.

We have a robust development pipeline that encompasses more than 10 new products at this time, which can provide iSonea with a scalable, profitable pathway to a sustainable medical technology business, with footholds in the US and key respiratory markets worldwide.

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### Resources focused on commercial development of 2<sup>nd</sup> generation ARM™ products

As previously announced in the Q2 FY2012 and Half Year FY2012 reports, iSonea has focused current resources on development of new mobile health products and a lower cost, higher gross profit margin, over-the-counter version of WheezoMeter™ - the SonoSentry™ - aimed at the large and growing US asthma consumer market. A more competitively priced device will also increase access to wheeze monitoring in any key asthma market, such as Australia or the UK.

The first generation products proved the concept of Acoustic Respiratory Monitoring, mitigated the regulatory risk, and defined the value proposition of measuring symptomatic wheeze to physicians and patients. Our decision not to aggressively market the first generation technology was both practical (i.e. maximize shareholder value) and strategic, given the exciting potential for refining the technology and expanding the market to include consumers and third party payers for reimbursement.

FY 2012 is proving to be a productive year for shaping the new direction for iSonea Limited. We believe that the commercial progress made with new products over next 24 months will drive more personalized medical care, and therefore more successful outcomes, for asthmatics around the globe.

iSonea's innovative technology and mHealth apps are uniquely suited to the challenges of managing chronic asthma:

- It is a life-long problem, but one that can be effectively treated if triggers are identified and oncoming attacks are recognized early;
- iSonea's monitoring technology can help to alert patients to environmental factors such as pollen, air quality, weather, or exposure to other triggers, allowing for prompt action or avoidance of events;
- Long-term monitoring and recording of data helps physicians recognize patterns of illness and more effectively plan or adjust treatment regimens.

We want to personally thank our shareholders for your continued support and loyalty as we demonstrate progress toward the creation of a solid, profitable company with growing revenues.

**Mr. Michael Thomas**

Chief Executive Officer

iSonea Limited

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### About iSonea Limited

iSonea Limited (ASX: ISN; OTCQX: ISOAY) is an emerging medical technology company developing innovative, non-invasive devices and mobile health apps to improve the management of chronic, costly respiratory disorders such as asthma and COPD. By leveraging iSonea's proprietary Acoustic Respiratory Monitoring™ (ARM) technology with its AsthmaSense™ mobile applications, iSonea is turning smartphones into medical devices – enabling anyone, anywhere, at any time to monitor breathing distress symptoms, in order to take action. iSonea's ARM devices have been cleared for use by the U.S. Food and Drug Administration, the Australian TGA, and the European Union CE.

For more information, please visit [www.iSoneaMed.com](http://www.iSoneaMed.com).

### Forward Looking Statements

Certain statements made in this announcement are forward-looking statements. These forward looking statements are not historical facts but rather are based on iSonea's current expectations, estimates and projections about the industry in which iSonea operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "guidance" and similar expressions are intended to identify forward-looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors, some of which are beyond the control of iSonea, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. iSonea cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of iSonea only as of the date of this release. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. iSonea will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

# Appendix 4C – 3<sup>rd</sup> Quarter

## Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001

**Name of entity:**

iSonea Limited (ASX:ISN)

**ABN:**

98 009 234 173

**Quarter ended ("current quarter")**

31<sup>st</sup> March, 2012

### Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter \$A'000	Year to date (9 months) \$A'000
1.1 Receipts from customers	3	7
1.2 Payments for:		
(a) staff costs	(529)	(1,535)
(b) advertising and marketing	(105)	(280)
(c) research and development	(236)	(728)
(d) leased assets	(53)	(174)
(e) other working capital	(352)	(1,350)
1.3 Dividends received	-	-
1.4 Interest and other items of a similar nature received	27	39
1.5 Interest and other costs of finance paid	(1)	(4)
1.6 Income taxes paid	12	145
1.7 Other (R&D Tax Refund & Grants)	-	(8)
<b>Net operating cash flows</b>	<b>(1,234)</b>	<b>(3,888)</b>

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
1.8 Net operating cash flows (carried forward)	(1,234)	(3,888)
<b>Cash flows related to investing activities</b>		
1.9 Payment for acquisition of:		
(a) businesses (item 5)	-	-
(b) equity investments	-	(24)
(c) intellectual property	-	-
(d) physical non-current assets	-	-
(e) other non-current assets	-	(1)
1.10 Proceeds from disposal of:		
(a) businesses (item 5)	-	-
(b) equity investments	-	-
(c) intellectual property	-	-
(d) physical non-current assets	-	-
(e) other non-current assets	-	-
1.11 Loans to other entities	-	-
1.12 Loans repaid by other entities	-	-
1.13 Other (provide details if material)	-	-
<b>Net investing cash flows</b>	-	(25)
<b>1.14 Total operating and investing cash flows</b>	(1,234)	(3,913)
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	315	5,637
1.16 Proceeds from sale of forfeited shares	-	-
1.17 Proceeds from borrowings	-	-
1.18 Repayment of borrowings	-	-
1.19 Dividends paid	-	-
1.20 Other – (Capital Raising Costs)	(78)	(527)
<b>Net financing cash flows</b>	237	5,110
<b>Net increase (decrease) in cash held</b>	(997)	1,197
1.21 Cash at beginning of quarter/year to date	3,489	1,318
1.22 Exchange rate adjustments to item 1.21	(13)	(36)
<b>1.23 Cash at end of quarter</b>	<b>2,479</b>	<b>2,479</b>

+ See chapter 19 for defined terms.

**Payments to directors of the entity and associates of the directors**

**Payments to related entities of the entity and associates of the related entities**

		Current quarter \$A'000
1.24	Aggregate amount of payments to the parties included in item 1.2	84
1.25	Aggregate amount of loans to the parties included in item 1.11	-
1.26	Explanation necessary for an understanding of the transactions  Professional services and in lieu of cash payment for capital raising costs at normal commercial rates	

**Non-cash financing and investing activities**

- 2.1 Details of financing and investing transactions which have had a material effect on consolidated Assets and liabilities but did not involve cash flows

The following securities were issued to consultants in lieu of cash payment for services rendered:

- 13,300,000 Ordinary fully paid shares

- 2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

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**Financing facilities available**

*Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).*

		Amount available \$A'000	Amount used \$A'000
3.1	Loan facilities	-	-
3.2	Credit standby arrangements	-	-

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

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**Reconciliation of cash**

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.	Current quarter \$A'000	Previous quarter \$A'000
4.1 Cash on hand and at bank	2,479	3,489
4.2 Deposits at call	-	-
4.3 Bank overdraft	-	-
4.4 Other (provide details)	-	-
<b>Total: cash at end of quarter (item 1.23)</b>	<b>2,479</b>	<b>3,489</b>

**Acquisitions and disposals of business entities**

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1 Name of entity	N/A	N/A
5.2 Place of incorporation or registration	-	-
5.3 Consideration for acquisition or disposal	-	-
5.4 Total net assets \$A'000	-	-
5.5 Nature of business	-	-

**Compliance statement**

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.

Sign Here:   
Company Secretary

Date: Monday 30<sup>th</sup> April, 2012

Print Name: PETER VAUGHAN



**The CFO Solution**

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27.04.2012

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+ See chapter 19 for defined terms.

## Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
2. The definitions in, and provisions of, *AASB 1026: Statement of Cash Flows* apply to this report except for the paragraphs of the Standard set out below.
  - 6.2 - reconciliation of cash flows arising from operating activities to operating profit or loss
  - 9.2 - itemised disclosure relating to acquisitions
  - 9.4 - itemised disclosure relating to disposals
  - 12.1(a) - policy for classification of cash items
  - 12.3 - disclosure of restrictions on use of cash
  - 13.1 - comparative information
3. **Accounting Standards.** ASX will accept, for example, the use of International Accounting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

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+ See chapter 19 for defined terms.