ISSYS: Improving the world one small piece at a time

Executive Summary

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ISSYS

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Actual results might differ materially from these statements due to risks and uncertainties, including the uncertainties relating to clinical trials, the requirement for regulatory approval of products by the FDA and other regulatory agencies, impact of competitive products and pricing, market acceptance of new products, market conditions, enforcement of ISSYS intellectual property rights, and access to and enforcement of the intellectual property rights of others.

ISSYS disclaims any intent or obligation to update these forward-looking statements.
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Integrated Sensing Systems Inc. (ISSYS) mission is to design, develop, manufacture, and market advanced sensing products. ISSYS targeted markets provide a desirable balance between stability and market expansion that includes three large and rapidly-expanding, multi-billion-dollar markets:

1. **Wireless, batteryless, miniature implantable sensors for cardiovascular and intracranial applications** (congestive heart failure is the largest emerging medical device market in the world);

2. **Advanced Drug Delivery Products** (a viable solution for one of the biggest safety problems facing the health care industry: tremendous human and financial losses due to drug delivery errors);

3. **Fluidic Sensors** (a large, established market).

ISSYS Preferred Stock Round C was authorized for $20M and today only $1.3M is available for investment. Recently ISSYS’ Board of Directors approved the issue of Series D Preferred Stock ($20M) to be invested by medical companies as our strategic partners. Series D is priced at about 45% higher value than Series C and will be mostly used to perform the FDA-required clinical studies for ISSYS wireless, batteryless implantable products. As a result, ISSYS can only offer this $1.3M Series C until Series D is issued for strategic partners.

Series C is a great opportunity since an investor gets the lower risk of the Series D and the lower price of Series C. A fast investor exit (within 2-3 years of investment) and high Returns on Investment (ROI) are expected, through acquisition (all or partial) by a large company or via Initial Public Offering (IPO), depending on the market conditions.

ISSYS provides a great investment opportunity due to its high-growth markets, world-class people, proprietary and enabling technologies, great IP protection, comprehensive manufacturing facility, potential for a high ROI, and short-term investor exit. The investor risk is further reduced, first, by providing anti-dilution provisions for the preferred stock owners in order to protect them against unlikely future investment rounds at valuations below the current company valuation. Second, we offer a compounded dividend of 7% of the original purchase price per annum which provides a safety net for a minimum profit of compounded 7% per annum in an unlikely case of liquidity.

ISSYS’ core technology platform is MEMS (MicroElectroMechanical Systems) which plays two major roles in the company’s marketing strategy: (1) to provide competitive advantages to enter and dominate its selected markets, and (2) to create effective barriers against competition.

ISSYS’ attractiveness for investment is enhanced by its strategy of establishing a single flexible technology platform to support all of its products and markets. This flexible technology platform is very comprehensive and includes proprietary intellectual properties, know how, development, prototyping, and manufacturing. This strategy significantly reduces the investment risk while increasing its ROI.
ISSYS’ technology platform covers two major fields: medical and industrial. Within these two fields, ISSYS is introducing three product families selected for their market pull, growth potential, maximum leverage of ISSYS’ core technology, its installed manufacturing base, accessibility through strategic partnerships, and profitability. ISSYS’ selected markets are discussed next.

Market #1: ISSYS’ most exciting market relates to **miniature, wireless, batteryless, implantable sensors designed for Congestive Heart Failure (CHF) disease**. Many experts have identified CHF as the single largest emerging medical device market in the world. NIH has announced CHF as the new epidemic in the U.S., affecting over 5 million U.S. patients and causing 300,000 deaths annually. It accounts for 978,000 annual admissions or 5-10% of all hospitalizations, and costs the U.S. nearly $38 billion annually, making it a major national health problem. There are about 500,000 new CHF patients per year in the U.S., 24% of whom have severe dysfunction. The fatality rate for CHF is very high (more than cancer), with one in five persons dying within 1 year, more than half of the CHF patients dying within 5 years, and sudden death occurring at a rate of six to nine times that of the general population. One in five of all discharged patients age 65 and older has CHF as a primary or secondary diagnosis. A person age 40 or older has a one-in-five chance of eventually developing congestive heart failure.

CHF is primarily treated with medication in a very delicate manner to provide a balance between two competing parameters: to maximize cardiac output (CO) yet maintain a reasonable cardiac pressure, the left ventricular end diastolic pressure (LVEDP). Errors in either side (low CO or high LVEDP) can be deadly. The major problem facing the effective treatment of CHF via ongoing tailored medication is the lack of a safe, low cost and easy method to regularly collect patient’s cardiac pressure data in order to maintain this balance over time. The difficulty in achieving this delicate balance as it changes with time is the main reason for the current high mortality, morbidity and treatment cost of CHF.

ISSYS’ novel cardiac pressure monitoring system provides safe, chronic, fast, detailed, real time and continuous cardiac pressure measurements in order to enable the effective tailored treatment of CHF disease over time. This product supports the trend towards home health monitoring, with the potential to revolutionize the way CHF patients are treated. The pressure monitoring system consists of two major parts: an implantable, batteryless, telemetric sensor and a companion hand-held reader. The miniature sensor is implanted in a minimally invasive, outpatient procedure. Using electromagnetic telemetry, the reader transmits power to the sensor and the sensed cardiac pressure is in turn transmitted back to the reader. Data collected by the sensor will be used by physicians to tailor CHF treatment. Such data collection can be performed at the doctor’s office, or at home by the patient and submitted over the telephone or internet.

ISSYS’ target CHF market is over $10 Billion. There exists a tremendous potential for expanding the benefits of ISSYS’ wireless products to enhance the treatment of other cardiac diseases (e.g., hypertension and aortic aneurysms), and non-cardiac health problems such as brain injuries and...
hydrocephalus (excess of cerebrospinal fluid in the brain, which is among the most common birth defects in the U.S., affecting 1 in 1000 babies, as well as many adults). ISSYS plans to enter into strategic partnerships with major cardiac medical device partners to access the CHF market. At present, ISSYS has been closely observed by many large medical device companies and has established a great rapport with them.

**ISSYS plans to start its first clinical study in Q2 of 2013, to monitor 200 adult CHF patients.** This clinical study is performed in collaboration with Linkoping Hospital in Sweden and covers 200 patients: 100 with ISSYS implant and 100 patients in the control group. This is a significant milestone for ISSYS and the commercialization of its wireless implants. ISSYS expects to get the CE Marking approval for this implant family in 2015.

**ISSYS plans to start its second clinical study in Q3 of 2013, to monitor patients with congenital and structural heart diseases.** This clinical study is performed in collaboration with the University of Michigan Hospital and will be conducted in 3 major centers in the US (Boston, Pittsburgh, and Ann Arbor). These implants are qualified for FDA humanitarian exemption commercialization procedure which is much shorter than standard FDA-PMA path. ISSYS expects to get the FDA approval for this implant family in 2015.

**Market #2:** One of ISSYS’ major selected markets is **advanced drug delivery/infusion products.** Errors in medication delivery cause hundreds of thousands of deaths and injuries per year that cost U.S. between $76 and $136 billion annually and a great deal of human suffering. The probability that an American is harmed by a drug delivery error in a hospital is 2.5 times that of injury in a car accident. While reducing drug delivery errors is becoming a major issue in the health care industry, there is currently a critical lack of a cost-effective way of detecting drug delivery errors. ISSYS’ products offer unprecedented capabilities to detect and prevent major sources of infused liquid drug delivery errors, including:

- Whether the correct medication and concentration are actually being administered
- Whether the correct dose, dose rate, and volume are actually being administered
- Detection of air bubbles in the IV line
- Detection of occlusions in the IV line
- Detection of retrograde infusion (back flow from patient to the IV line)

ISSYS achieved a major milestone and **received FDA approval** for its first drug delivery products. Second–generation products are being developed for successful commercialization. The estimated U.S. market size for advanced drug delivery products is over $3.5 Billion annually and it covers a full spectrum of products: disposable parts, pumps, monitors, and high-end syringes. ISSYS disposable drug infusion products are accretive and thus represent a continuous cash flow resource to the company, its medical partners, and its investors. ISSYS' innovative products are currently the only technology that is able to detect such a wide variety of drug delivery errors. As a result, ISSYS is not anticipating any viable competing technologies. Our immediate objectives are to reduce the manufacturing costs and to perform the required regulatory studies. A portion of the requested investment will be used to achieve these
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**Market #3:** While a relatively slow expanding market, the fluidic sensors represent a well-established, large market ($7 Billion in 2006) that ISSYS can easily penetrate. Furthermore, due to the lack of any FDA requirements, ISSYS selected the fluidic sensor markets as its early-entry applications. ISSYS fluidic sensors have allowed it to build infrastructure, to optimize product design, and to develop the necessary capacity to access the larger lucrative markets. The commercialization of ISSYS’ advanced fluidic sensors has played a crucial role in the introduction of ISSYS enabling technology into other markets, including fuel cells and fuel custody transfer. Product sales projections are attractive due to the great performance to price ratio that ISSYS’ technology offers, as well as providing new enhanced functionalities. Two spill over markets for ISSYS fluidic sensors are: fuel custody transfer and fuel cell sensors.

ISSYS fluidic sensing products can be used for quality control during fuel production, as well as fuel custody transfer in both industrial and military applications. Petrochemicals-based fuels and biofuels can be monitored for concentration, purity, water content, and grade using fuel’s physical properties such as density and viscosity. ISSYS’ products offer desired additional features such as temperature measurement, data logging (up to 3 years), and detection of whether fuel is actually flowing through the sensor. Rising oil and gas prices as well as increased energy demands worldwide, has given fuel quality monitoring and custody transfer issues an even greater importance. Having accurate, reliable, and low cost methods for fuel density and flow measurements become an important tool in fulfilling the needs of producers as well as customers. For the US military, fuel quality control enhancements may have even greater importance, especially for units stationed in unstable countries around the world, where lower quality fuels or even in some cases tampered fuel can have disastrous consequences on personnel, assets and military operations. A high quality, lightweight, low-cost, and portable fuel quality monitoring unit that can be easily used by military personnel during custody transfer will be of great benefit to the US military.

**ISSYS is one of the oldest independent MEMS-based companies in the U.S.** (founded in January 1995). Over 17 years and $45 million of funding, the company has evolved as a manufacturer of advanced medical and industrial sensing products. ISSYS is located in a suburban industrial park within the Ann Arbor (Michigan) metropolitan area. Unlike many fab-less competitors, ISSYS is one of the few companies managing its own in-house MEMS manufacturing facility that is ISO-13485, ISO- 9001and ISO-13980 qualified for both medical device and intrinsically safe manufacturing. Currently, ISSYS is capable of producing a few hundred thousands of MEMS devices that can be upgraded to millions of units per year. ISSYS’ single technology/manufacturing platform allows all of ISSYS’ sensor chips to be manufactured using the same infrastructure, tools, personal, material, and quality control standards. This is an important strategic issue that may not be obvious by solely examining ISSYS’ product portfolio. By following this strategy, ISSYS has achieved a great focus on its core manufacturing infrastructure while simultaneously supporting all of its products.
ISSYS has a comprehensive IP protection portfolio, including 41 issued patents and over 40 pending and provisional patents, and a significant amount of manufacturing and technology know-how and trade secrets.

One of the strongest assets of ISSYS is its people that include world-renowned experts both from industry and academia. The company founders, Dr. Nader Najafi, Dr. Ken Wise, and Dr. Khalil Najafi, are recognized world leaders in the highly-complex technical field of MEMS. These technical leaders combine 100+ years of continuous industry and academic hands-on-experience in producing working MEMS devices and integrated systems, particularly in the Bio-MEMS field. The founders have generated more than 500 technical publications. ISSYS has assembled a world-class team with diverse expertise that covers all of the required areas to commercialize high-performance, innovative medical products.