CEO CFO

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Leading Global In Vitro Diagnostics Company, IRIS International, Inc. is Focused on Advancing and Leveraging their Successful Business in Urinalysis and Sample Processing to Fund Expansion into Hematology and Personalized Medicine

Technology
Scientific & Technical Instruments
(IRIS-NASDAQ)

César M. García
Chairman, President and CEO

BIO:
César M. García has been a Director since November 2003 and Chairman of the Board since November 2007.

He joined IRIS in January 2002 as our Executive Vice President and was appointed President in June 2003 and Chief Executive Officer in November 2003. Mr. García has over 30 years of experience in design, manufacturing and commercialization of medical devices. From 1998 through 2001, Mr. García was Sr. Vice President, Operations and Program Management for Cytometrics Inc., an early stage manufacturer of non-invasive, photonics-based medical devices. From 1994 to 1998, he was Vice President of Operations and Engineering at Datascope Corp., manufacturer of medical devices for interventional cardiology, anesthesiology and critical care monitoring. From 1974 to 1994, Mr. García worked with Bayer Diagnostics (now Siemens Healthcare Diagnostics) assuming positions of increased responsibility including General Manager of Technicon Electronics Corp., a subsidiary of Bayer USA and Director of Worldwide Hematology Manufacturing and Cellular Diagnostics Research and Development. Mr. García earned his B.S. in Industrial Engineering (Cum Laude) at the University of Puerto Rico and received an Advanced Management Certificate from Pace University. Mr. García brings to the Board diversified experience in general management, operations, strategic planning and in the conceptualization, development and commercialization of complex diagnostic products and services for the global markets. In 2009 he earned the Certificate of Director Education from the University of California, Los Angeles, John E. Anderson Graduate School of Management.

Company Profile:
IRIS International, Inc. is a leading global in vitro diagnostics company focused on products that analyze particles and living cell forms and structures, or morphology of a variety of body fluids. The Company's products leverage its strengths in flow imaging technology, particle recognition and automation to bring efficiency to hospital and commercial laboratories. The initial applications for its technology have been in the urinalysis market and the Company is the leading worldwide provider of automated urine microscopy and chemistry systems, with an installed base of more than 3,700 systems in more than 50 countries. The Company is expanding its core imaging and morphology expertise into related markets, including applications in hematology and body fluids. In addition, the Company's personalized medicine group has a high complexity CLIA-certified laboratory for the further development and commercialization of the Company's NADiA ultra-sensitive nucleic acid detection immunoassay platform, with applications in oncology and infectious disease. For more information, please visit www.proiris.com.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Garcia, what is IRIS all about?

Mr. Garcia: IRIS International is a dynamic company with three divisions. Our principal business is urinalysis through our Iris Diagnostics Division. Our second business unit is the Iris Sample Processing Division and the third business unit is our Personalized Medicine Division, which is developing, and commercializing

NADiA® assays. IRIS International is probably the most successful automated urinalysis equipment company in the whole world. We sell more automated urinalysis solutions than any of our competitors, including some of the largest in-vitro diagnostics companies.

CEOCFO: What makes the IRIS urinalysis technology better?

Mr. Garcia: During the conceptualization of our iQ200 urine microscopy product in 2001, we realized that there was a significant need for automating urine microscopy. There are two different test modalities in urinalysis: urine microscopy and urine chemistry. Before the release of the iQ200 in 2003, urine microscopy was traditionally performed by reviewing slides under a microscope. The reviewer would have to spin the urine sample, re-suspend it, prepare a slide, etc – this is a tedious process that took about 5 minutes per sample. In addition to manual observation under a microscope, the morphological review is subjective and prone to error. We realized that we could automate the entire process using our proprietary flow microscopy technology, our image recognition software and other core technologies that we had developed. In our digital imaging instrumentation, we capture digital images as the urine samples pass through a proprietary fluidic system. Using our pattern recognition capabilities, the instrument characterizes and quantifies sediment in urine. Because of these capabilities, we offer the most comprehensive urine microscopy menu and software for the automated characterization of these sediments. As a result of this innovation becoming available, our customers adopted the automation of urine microscopy very rapidly. We realized then that automating urine microscopy was only the first step, and we could capture meaningful market share by automating the entire urine analysis testing process. Therefore, we added a urine chemistry machine from a partner and we integrated this into what has become the first fully automated urinalysis workstation. With this, a urine test tube is loaded into a rack and the workstation sequentially performs the urine microscopy and chemistry analysis and consolidates the results including editable images for the urine microscopy analysis. At the release of this product in late 2003, it was the first fully automated, walkaway urinalysis workstation and has resulted in a predominant market share position for IRIS. Today this product has 75% market share in the US and approximately 50% in developed countries with a growing position in China.

CEOCFO: What do you sell in addition to the equipment?

Mr. Garcia: For diagnostics, our aftermarket consist of consumables and service, it is a razor/razor blade business. Therefore, for every workstation that we sell, we generate a significant recurring revenue stream. The sources of recurring revenue are the consumables for the urine microscopy, test strips for the urine chemistry and service for the instrumentation. The recurring business has proven to be successful and predictable. For every unit that we sell in the U.S., we generate roughly $45,000 per machine per year. In 2002, the company was still quite small, with revenue of approximately $28 million and unprofitable. Over the last eight years, Iris has been growing at double-digit rates. Our financial guidance for 2012 is between $127 and $131 million in revenue. In 2012, we expect IRIS to be approximately $100 million bigger than what it was in 2003.

The future of IRIS depends on sustaining, advancing and leveraging our successful business in urinalysis and sample processing to fund expansion into hematology and personalized medicine. Five years from now, I expect to have a company that would be significantly bigger, more profitable and much more diversified. - Cesar M. Garcia

CEOCFO: What is the barrier to entry for a competitive system?

Mr. Garcia: There are multiple barriers. One of them is our know-how on the core technology of image flow microscopy. The other barrier of entry is strategic; we are focused on niche market applications. There are other companies focusing on urinalysis, but many of these competitors lack the specialized product portfolio and they have not developed the core expertise in this segment. Separately, there are emerging competitors that have been trying to copy our technological approach, especially in developing countries, but their products do not have comparable quality and reliability, and their organizations have failed to provide our level of customer support. We compete both in terms of product functionality and in providing the most rewarding customer experience through our iCare program. Industry customer satisfaction surveys show that we provide the best customer support in the segments we serve.

CEOCFO: What is happening in Iris' other areas of business?

Mr. Garcia: Around 2005 we realized that although we were very successful in a profitable market segment like urinalysis; it was a niche market. The urinalysis market is about $600 million in annual sales and only about half of the market uses automated instruments. The rest is in the physician's office and point of care segment, however, we do not serve physician office laboratories. We realized that IRIS needed to diversify into larger markets and we opted to diversify into personalized medicine and hematology. The focus of personalized medicine is to determine which treatment is adequate for each patient individually. For example, in past times, doctors used to prescribe chemotherapy to a high number of patients with a certain disease, but only a small fraction benefited from that form of chemotherapy. The new personalized medicine solutions enable the identification of patients which have a high probability of benefiting from certain therapies or medications, thus avoiding unnecessary and/or ineffective treatment. There are a number of factors that need to be considered before initiating cancer treatments, such as the presence or absence of certain chro-

mosomes. Now, you can pre-screen patients and identify which ones are better candidates for a certain type of therapy, and consequently achieve significantly higher success rates - 90% success rate instead of the 20% success rate of past times. We have a technology called Nucleic Acid Detection Immunoassay, or NADiA(R). The NADiA(R) technology is a clever approach to combining a traditional immunoassay with a double stranded DNA marker. Traditional immunoassay testing combines a "sandwich" antigen antibody complex with a fluorescent marker or an enzyme to measure the concentration of proteins. In our case, we attach the double stranded DNA to the antigen-antibody complex and we amplify the DNA to measure the target protein using polymerase chain reaction (RT-PCR). This approach benefits from a highly sensitive immunoassay and the high quantification power of RT-PCR resulting in an ultra-sensitive and precise assay such as our prognostic cancer marker, NADiA ProsVue. We have demonstrated the platform's capability to measure very low concentrations, down to the femtogram, which is 1 million times smaller than a nanogram. Low limits of detection are required to measure low concentrations of proteins, which in our current and future test applications, are used to identify potential cancer relapse. NADiA ProsVue was cleared by the FDA in September of 2011 as a prognostic marker to identify men that are at a reduced risk of relapse after a radical prostatectomy. NADiA ProsVue is a prognostic cancer marker based on three consecutive measurements of PSA in blood, over a ten-month period. We calculate the slope, and if the slope for that patient is rising at a rate of less than two picogram per milliliter per month, the patient is prognosticated to be at a reduced risk of relapse and is likely not to require further treatment. If the slope is rising at a rate higher than two picogram per milliliter per month, then that patient is not at a reduced risk and is likely to relapse. Currently, half of the men that are treated for prostate cancer receive a radical prostatectomy as part of their treatment. Many of these post-prostatectomy men receive radiation therapy, but a significant percentage do not need it because they are stable. Until now, there have been no reliable tools to differentiate stable versus non-stable patients with a high level of confidence. We believe that using NADiA ProsVue, urologists can significantly reduce the number of patients that are subject to adjuvant therapies such as radiation or hormone deprivation therapy. We are highly encouraged by our clinical results and expect ProsVue to be a major improvement in the treatment of post-prostatectomy patients. A clinician needs to feel confident when prescribing radiation treatment due to the associated morbidities such as urinary incontinence and sexual impotence. As for the health care system, it would avoid about $50,000 in treatment costs for every patient incorrectly categorized as relapsing without utilizing ProsVue as a confirmation.

CEOCFO: What is the third division?

Mr. Garcia: Our third segment is our Iris Sample Processing Division – this business unit manufactures table-top centrifuges and processing workstations for florescence in-situ hybridization (FISH). FISH is a technique to identify genetic aberrations that may affect the efficacy of certain therapies used for the treatment of cancer, predominantly breast, bladder and hematological cancers. Over the last 7 years, we have been successful selling over five thousand manual denaturation and hybridization stations called the ThermoBrite. We recently launched a new product called the ThermoBrite Elite, which is an automated version with expanded capabilities that reduces hands on labor by at least 50% in the most frequently performed FISH tests. Although our Sample Processing business is very profitable, it has not grown significantly in the last two years. We believe the ThermoBrite Elite should be a significant growth driver for this business.

CEOCFO: What is the rest of your strategy for the next year or two?

Mr. Garcia: Our strategy is to launch a pipeline of novel and cost effective products using the technology arsenal that we have been developing over the last five years. We are expanding the addressable market of our products from approximately $750 million to approaching $4 billion with our product pipeline by adding applications to our digital flow microscopy technology from urinalysis to hematology – the single largest *in vitro* diagnostic market segment. We are in the process of designing the next generation of instrumentation, which we call the 3GEMS program. The acronym stands for Third-Generation Morphology System. 3GEMS will be the common platform for urinalysis and hematology –using common components and imaging technology, we expect significant synergies in R&D spending, manufacturing and service, as well as optimal utilization of our distribution channel. Our products in development are expected to have the necessary innovation to reduce costs through automation and improve patient care. The future of IRIS depends on sustaining, advancing and leveraging our successful business in urinalysis and sample processing to fund expansion into hematology and personalized medicine. Five years from now, I expect to have a company that would be significantly bigger, more profitable and much more diversified. Today, our urinalysis business produces about eight-five percent of our revenue and most of the earnings. Five years from now, I expect that to change dramatically.

CEOCFO: What is the financial picture like today for the company?

Mr. Garcia: The Company has been profitable since 2003. The guidance for fiscal year 2012 is to achieve revenue between $127 and $131 million and $0.30-0.35 in earnings per share. The core business is producing solid earnings, but we are heavily investing in new technology that is not yet generating revenue and earnings. We have over $26 million in cash and our business is expected to continue generating sufficient cash to finance our extensive product pipeline in development.

CEOCFO: Why should potential investors pay attention?

Mr. Garcia: Investors should pay more attention to IRIS since the restructuring in late 2011 of our Personalized Medicine Division, which has and will continue to improve profitability. Over the last 15 months, the company has achieved significant product development milestones and our earnings have improved dramatically. We have launched three new products over this same period: our iChem Velocity automated chemistry analyzer, the ThermoBrite Elite and NADiA ProsVue. IRIS is a successful small company developing a multi-billion product pipeline. Based on our track record and recent technological achievements, we are confident in the execution of a well thought-out strategy that should result in significant advances in patient care, reduction in healthcare cost and higher returns to our shareholders.

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