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# THE WALL STREET TRANSCRIPT

Questioning Market Leaders For Long Term Investors

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**THE WALL STREET TRANSCRIPT**

## COMPANY INTERVIEW

**CÉSAR M. GARCÍA**  
IRIS International, Inc.

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# IRIS International, Inc. (IRIS)



**CÉSAR M. GARCÍA** is President and Chief Executive Officer of IRIS International, Inc. He joined IRIS International, Inc., in January 2002 as Corporate Executive Vice President and was elevated to President in June 2003. Mr. García has nearly 30 years of experience in medical device manufacturing. Prior to joining the company, Mr. García was Senior Vice President, Operations and Program Management for Cytometrics Inc. of Philadelphia, Pennsylvania, 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. of Mahwah, New Jersey, which manufactures medical devices for interventional cardiology, anesthesiology and critical care monitoring. From 1974 through 1994, Mr. García worked with Bayer, assuming positions of increased responsibility including General Manager of Technicon Electronics Corp., a subsidiary of Bayer USA and Director Worldwide Hematology Manufacturing and Cellular Diagnostics Research and Development. Mr. García earned his BS in Industrial Engineering (cum laude) at the University of Puerto Rico and received an Advanced Management Certificate from Pace University, Pleasantville, New York.

## SECTOR – MEDICAL DEVICES

**(YAR617) TWST: Would you begin with a brief historical sketch of IRIS International and a picture of the things you're doing now?**

**Mr. García:** IRIS International was established in 1979 and our principal business is in the in-vitro diagnosis market. Our IRIS Diagnostics Division represents 80% of the business, and our StatSpin<sup>®</sup> subsidiary, which makes small medical devices, accounts for the other 20%. Our third group is Advanced Digital Imaging Research, which is the company's imaging research and development group. ADIR does not recognize revenue because most of the work that it performs is either financed internally or by the federal government through grants.

IRIS Diagnostics is presently concentrating most of its efforts on marketing its new product platform, the iQ<sup>®</sup>200 System, which was rolled out on August 5, 2003. The iQ200 System is a unique integration of two modalities — chemistry and microscopic urinalysis. Urinalysis traditionally has been performed only addressing urine chemistry. With the new iQ200 System, we perform both urine chemistry and urine microscopy at the touch of a button.

The iQ200 System consists of two different modules. The first is a benchtop unit, the iQ200 Automated Urine Microscopy Analyzer, which is designed and manufactured by IRIS. The second module is an Automated Urine Chemistry Analyzer manufactured by ARKRAY, our

Japanese business partner. ARKRAY, which is based in Kyoto, is an established medical device company and sells urine analyzers in more than 80 countries. We sell their unit under the name ARKRAY AX-4280. When the two units are combined, the result is the iQ200 System. What we sell is automation, workflow, and high accuracy of results and consistency. The iQ200 System performs the entire chemistry panel for urinalysis, but it also performs a complete microscopic analysis of urine, which consists of 12 different particles that are used to diagnose kidney disease, bladder disease and urinary tract infection. On the chemistry side, the results are used for diabetes, infection and preliminary indications of urinary track disorders.

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We have been developing and manufacturing urinalysis workstations since 1982. However, until now, those workstations were very large and expensive. The major market entry barrier was the cost of acquisition. This held true particularly in the European market, which is rental-based. Hospitals and laboratories in Europe generally do not buy the instruments; they pay on a fee-per-test basis. So it is very difficult for them to justify buying expensive instruments because when amortized over a long period of time, they are still significantly expensive.

With the iQ200 System, we have a new platform that we sell domestically for approximately 60% of the list price of the predecessor product. Internationally, we sell the less expensive iQ200 automated urine microscopy analyzer separately through distributors which, in turn, rent or lease them to our clients. ARKRAY markets its AX-4280 chemistry analyzer independently in the rest of the world. When customers choose to buy each item separately, we provide software that links the two units together, creating the iQ200 System. We recently gave ARKRAY distribution rights to our iQ200 microscopy analyzer in Japan, where it has an established base for the AX-4280. This opens up a whole new market for our product.

In addition, we have an excellent consumables business that presently makes up more than half of our revenues. We are in the “razor/razor-blade” business. We can count on recurring revenues from urine test strips and fluids required to operate and maintain our analyzers.

**TWST: What are some of the marketing factors that you take into consideration?**

**Mr. García:** One of the issues in the clinical laboratory sector is a shortage of medical technologists at a time when there is a significant increase in the aging population. The combination of these two factors makes it absolutely necessary to bring automation to urinalysis. Believe it or not, urinalysis is probably the last remaining test to be fully automated in the clinical laboratory, and up until now, it has largely been performed by manual microscopy. The iQ200 brings an excellent market opportunity. Domestically, the market has about 2,500 sites that qualify for automation. Internationally, there are about 4,000 sites for a worldwide total of 6,500 laboratories that could be automated. Previously, IRIS was able to compete only in the high-end domestic market, which is

very small. We have placed approximately 400 units domestically, which represents about 80% market share in the US, out of a total available market of only about 800 potential sites. So we went from 800 potential sites to 2,500 potential sites domestically. Internationally, we basically did not compete at all because in the history of the company we only placed about 50 systems overseas. Now with the less expensive iQ200, we can really compete in a significant international market where 4,000 laboratories qualify for automation.

A point that I need to clarify again is that internationally we only sell the iQ200 microscopy analyzer, and most of those laboratories have a clinical chemistry analyzer provided by others, or they can connect to our Japanese partners' chemistry analyzer, the ARKRAY AX-4280, which is distributed through ARKRAY's distribution network.

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**TWST: What are the advantages of a combined urine microscopy and chemistry system?**

**Mr. García:** When you have an independent urine chemistry analyzer and an independent urine microscopy analyzer, there is no communication between the two systems; there is no integration of results. There is also a significant increase in sample handling. For example, the technician has to load the specimen in the chemistry system and when that chemistry analysis is finished, they have to transfer those specimens into the urine microscopy machine, and lastly,

they have to combine the results for diagnostic interpretation. In the iQ200 System, it's all connected. The technician loads the specimen in the urine chemistry analyzer and a small sampler transfers the specimen from one system to the next. Then the data is consolidated using the proprietary IRIS software that combines the urine chemistry results from both the chemistry component and the microscopy component. The advantage we have over the competition is that the iQ200 is fully automated. You just press a button and walk away. In addition, the iQ200 performs a dozen different analysis parameters while the competition's analyzer performs five parameters. We have full integration between chemistry and microscopy, they don't.

In our system we actually present concentrations and images. Our proprietary Flow Imaging Technology and Automated Particle Recognition software enables technicians to actually see the size, shape and texture of the particles being analyzed. In the case of the competition's microscopy implementation, they provide only scattergrams and sediment concentrations. They cannot edit their results or see the image. One of the features that really sells the iQ200 is the vast amount of information encrypted in the images. This is very significant for the medical technologist, the nephrologist or the urologist.

**TWST: Do you think that at some point you'll be able to persuade the European laboratories to take both components?**

**Mr. García:** We believe so. A problem that we have in the European market is that we do not have distribution rights to the ARKRAY AX-4280 Chemistry Analyzer as we do in the US. But in terms of the need, it is there, and what we have been doing to facilitate that is aligning our distribution network with the ARKRAY distribution net-

work and vice versa. So if the distributors can provide both the AX-4280 and the iQ200, then naturally most of the iQ200 automated urine microscopy analyzers we sell will be fully integrated into iQ200 Systems by the distributors. In addition, there is already a large installed base of ARKRAY AX-4280 chemistry analyzers in Europe representing a significant readily available market for IRIS' iQ200 microscopy analyzer.

Domestically that has been a very successful tactic. More than 90% of the domestic placements are for complete systems. The cost of the complete system is approximately \$120,000. Internationally, we sell through distributors and we sell to the distributors at a transfer price, and they dictate their own terms of sale. But, as I mentioned before, most of those are rented on a fee-per-test basis. They're not actually sold.

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**TWST: Are there any other products that are very important to you?**

**Mr. García:** Yes. In addition to IRIS Diagnostics, we have two other companies. StatSpin, our subsidiary in Norwood, Massachusetts, is the world leader in rapid separation of blood-through centrifugation. StatSpin has placed more than 45,000 small centrifuges that are used in emergency rooms and in laboratories. Another significant market for StatSpin is veterinary applications. About 15,000 of the 45,000 have been placed through the veterinary distribution channel or as an OEM com-

ponent for veterinary diagnostics manufacturers. StatSpin is a significant part of our business that last year represented approximately \$6.1 million of our \$31 million in revenue.

Our Houston-based ADIR subsidiary performs contract research and also provides the technology underpinning the Automated Particle Recognition capabilities of the iQ200. ADIR does not have a product at this point, but we have redirected ADIR to focus their research efforts on products and technology that have significant market potential. ADIR, of course, has a group of scientists who specialize in image analysis. And I'm pleased to report that ADIR was recently awarded a \$2 million US government grant by the National Institute of Science and Technology to develop a 3-D face recognition system based on biometric measurements.

Our plan is to use some of the art and the science that we have developed over the last 10 years and apply it to the security business. As you know, national security is one of the major priorities now, and although face recognition has been difficult, we believe we have a unique opportunity to develop a product that could be used in airports, seaports, high security areas, and other areas where access control is important. For example, there are more than 6,000 military bases that could benefit from a face recognition product and there are significant commercial applications in the US and abroad.

**TWST: Is there any way that you can explain in layman's terms what the potential of the ADIR system is versus competing systems?**

**Mr. García:** Most of the systems in the market are based on two-dimensional analysis of photographs. The system that we're proposing is three-dimensional. We actually would take a three-dimensional picture and when enabled by software

it would do the face construction first. Then we're developing the software for second step, the face recognition. So the challenge is matching the pictures of known criminals or terrorists in a database to the pictures taken on the spot. That's a very difficult problem, but we believe that we have the technical competence and resources to approach it.

To minimize risk in the development program, we're approaching it from two angles — site access control and national security. Let's say that you want to use the technology for security in a building with 1,000 people. You have pictures of those 1,000 individuals in a database. When someone comes through the door, the system will capture the individual's face and compare it to the database. That is the first product and we hope to have a prototype in about a year.

The second product, which has the larger potential, is the one that I mentioned before, concerning national security, the largest market opportunity. There are 6,000 military bases, there are 100 nuclear plants and more than 5,000 airports in the US alone, in addition to more than 300 international ports of entry, both airports and seaports. And there are more than 2,500 security officers in the US who control at least one building, and many of them control multiple buildings. There is a very significant market opportunity for a face recognition system.

**TWST: How long do you think it would take you to develop the face recognition system in all its potentialities?**

**Mr. García:** I would say it would take about three years to develop the system to its full potential. But I don't want to overemphasize the face recognition program, because that is not our core business at this point in time. We have presented our company and dedicated our energy and resources over the last few years on redeveloping

the core business, tooling Iris Diagnostics with the release of the iQ200 urinalysis system. Additionally, we have redirected research and development funds into our StatSpin division so that it can develop modern versions of its product. Most recently StatSpin also developed the *ThermoBrite™*, a small DNA processing workstation. Those are the types of products that we would like to develop at StatSpin. This is the first example of how we can bring value to the specimen handling and processing marketplace.

In essence, what we want is to develop Iris Diagnostics, our in-vitro diagnostics subsidiary, as the fastest growing urinalysis company, StatSpin as our specimen processing subsidiary, and then ADIR as our commercial imaging subsidiary. In the case of StatSpin, we believe that there are substantial opportunities that have not yet been exploited to facilitate many of the steps that are performed in the laboratory handling and processing specimens.

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***"StatSpin, our subsidiary in Norwood, Massachusetts, is the world leader in rapid separation of blood-through centrifugation. StatSpin has placed more than 45,000 small centrifuges that are used in emergency rooms and in laboratories. Another significant market for StatSpin is veterinary applications. StatSpin is a significant part of our business that last year represented approximately \$6.1 million of our \$31 million in revenue."***

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**TWST: Can you sketch out a timetable for each part of the company over the next three years?**

**Mr. García:** 2004 is a transition year for Iris Diagnostics. We are beginning to see the fruits of our hard work with the release of the iQ200. Early in 2003, we also launched the AX-4280

Automated Urine Chemistry Analyzer. Earlier this year, we launched a small urine chemistry machine manufactured by ARKRAY called the AJ-4270. Over the next year, the iQ200 will be expanded to include new functionality and increased throughput to address one of the most important market segments, the clinical reference lab. This is a market segment that requires higher throughput than the technology that we have today. We will also be releasing new applications. We have planned a release for body fluids diagnostics capabilities in the iQ200 and the higher throughput model. Both of them should materialize in early 2005. After that we will be looking into implementing other high-value applications in the iQ200 platform.

Our plans are to diversify the iQ200 specifically in the field of urinalysis to consolidate our position in that market. The urinalysis market is a \$550 million market. We believe that we can grow the market, but we could also capture a larger portion of the \$550 million market.

One of the things that we did effectively with our legacy products was to make ourselves the first company with U.S. Food and Drug Administration clearance on body fluids. In our legacy products we have eight different body fluids implemented, which are used for analyzing bleeding and infection in the abdomen, the chest, the lungs and joints, such as the knees and the wrists. These systems are also used in analyzing cerebrospinal fluid. Body fluids applications have higher reimbursements than urinalysis, and I think that this will help us to consolidate the iQ200 as the best system in the marketplace both in urinalysis and body fluids.

**TWST: What are your thoughts on mergers, acquisitions, partnerships and alliances?**

**Mr. García:** We are looking into selective acquisitions or partnerships to expand our market

participation and provide a more complete product to our customers. A year ago, we did not have the financial resources to do it, but today, the company is in a good financial situation. We have no debt, have about \$10 million in cash in addition to a credit facility of \$16 million. This provides a total liquidity of about \$26 million. Now we can begin to do something significant.

We want companies or products that are complementary to IRIS. We want to maximize the utilization of the distribution channel and maximize the synergies in service, manufacturing and research and development. We would try to make the acquisition transaction accretive to earnings.

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***“ADIR, of course, has a group of scientists who specialize in image analysis. And I’m pleased to report that ADIR was recently awarded a \$2 million US government grant by the National Institute of Science and Technology to develop a 3-D face recognition system based on biometric measurements.”***

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**TWST: You’re not quite at breakeven, right?**

**Mr. García:** Actually, we’re profitable. The company lost \$550,000 last year on total revenue of \$31.3 million but we incurred significant non-recurring expenses, about \$1.2 million. IRIS has been profitable since we released the iQ200. Before the iQ200 delay, the company was profitable for 13 consecutive quarters. Early in 2003, we had to drive the iQ200 to completion and stopped selling the legacy products. That resulted in two quarters of losses. We were profitable in the first quarter of this year and the second half of last year. In fact, the company achieved its highest quarterly revenue in the fourth quarter of 2003, with quarterly revenue exceeding \$10 million for the first time in the company history.

This is not a startup company. We have a significant application. The technology has been proven. Our major issue is rolling the technology into the global marketplace and this is what has been consuming most of our energies.

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***“We want to develop Iris Diagnostics, our in-vitro diagnostics subsidiary, as the fastest growing urinalysis company, StatSpin as our specimen processing subsidiary, and then ADIR as our commercial imaging subsidiary.”***

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**TWST: What are the financial milestones or the possible financial milestones that potential investors should be looking for?**

**Mr. García:** We have not disclosed any financial projections beyond 2004. We provided guidance calling for a 20% increase in revenue for this year. In general terms, our goal with IRIS International is to achieve operating income of about 18%-20% of revenue within the next three years. The reason for forecasting increased future earnings (2005 and 2006) is our expectation that significant growth in recurring consumables revenue will begin to materialize later this year. As I noted, we are a classic razor/razorblade type business. Our system has a very significant recurring revenue component, but there is 4.5-month time lag between instrument placement and consumable generation. Consumables such as cleansing fluids, reagents and test strips and service represented 55% of our revenues in 2003. Let me give you a few of the data points.

An iQ200 sold to the high-end market, that's clinical laboratories performing about 150 urinalyses a day, we can expect that system to yield about \$30,000 in recurring consumables revenue per year from both the chemistry consumable and the microscopy consumable. We were selling

our legacy products to the tip of the market pyramid and now we're selling to the mid-range market — the number of sites is much bigger. But in the mid-range, although a much larger market segment, they perform less urinalyses per system per day. That's a market where they perform approximately 100 urinalyses per day. At 100 urinalyses a day, we estimate that each system is going to generate about \$24,000 in consumables per year in a domestic installation. Obviously, internationally, (because we only sell one component, the urine microscopy analyzer, and we do not sell the chemistry analyzer) those systems will generate only about \$8,000 per year in consumables business because they go through distribution.

The other source of recurring revenue is our service business. Domestically, we have a significant service business and most of that is driven by service contracts. After the expiration of the 15-month warranty period, we will begin to realize service revenues at a rate of \$13,000 per iQ200 system per year.

If you combine the service revenue with the consumable revenue market, (in the mid-range) you're talking about between \$30,000-\$37,000 per year per instrument. The basis for our projected increase in earnings is the realization of recurring revenue in 2005 and 2006.

**TWST: Are you at full strength or are you going to be adding people in certain areas to carry all this out?**

**Mr. García:** In 2002, we reorganized the company and we brought in some of the most successful managers that we knew of. We have the management staff to manage the expected growth. Our management team consists of former employees from Bayer, Datascope, Boehringer Mannheim, etc. These individuals had positions at the Director or Vice President level with those rep-

utable organizations. We have the management infrastructure in place.

We also have the manufacturing infrastructure. We invested more than \$2 million in upgrading our diagnostics manufacturing plant for the iQ200. We have significant capacity both in instruments and consumables.

We had three international distributors 18 months ago. Today, we have 39. There has been a lot of work done over the last two years to reposition the company for growth.

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***“Over the next year, the iQ200 will be expanded to include new functionality and increased throughput to address one of the most important market segments, the clinical reference lab. This is a market segment that requires higher throughput than the technology that we have today.”***

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**TWST: How long have you been with the company?**

**Mr. García:** Two and a half years. I joined the company in January 2002 as Executive Vice President, responsible for Iris Diagnostics and StatSpin. I was brought in to finish the iQ200 development. Beyond research and development, my assignments included all business aspects such as setting up the distribution network, restructuring the company, establishing pricing policies, etc. Basically, the entire business planning for the iQ200 was my primary responsibility within my first 18 months with the company. In June 2003, I was promoted to President and Chief Operating Officer and in November 2003, I was promoted to President and Chief Executive Officer.

**TWST: What are the elements in your background that led you to do what you’re doing now?**

**Mr. García:** I worked for 20 years with Bayer Diagnostics. I began in 1974 with Technicon, which was acquired by Bayer in 1989. I’ve been in the medical device business for nearly 30 years now. My background includes engineering, operations, marketing, business development and general management with three companies. After my 20 years with Bayer, I worked with Datascope for four years and three years for an early-stage company called Cytometrics.

**TWST: What was it about IRIS that made you want to work for them?**

**Mr. García:** I realized that IRIS had a technology that was way ahead of its time. When it was introduced in 1980, the technology was really revolutionary. Still today, the technology that we have is leading edge in many aspects and its value resides on the imaging technology platform, the high level of systems integration and the knowledge base that this team has to implement very clever solutions to significant customer problems.

I saw a diamond in the rough and I felt that because of my strong background in in-vitro diagnostics in particular, I could really make a significant contribution to the company in difficult times.

**TWST: Do you feel that you’ve done a good job in getting the story out to the investment community?**

**Mr. García:** I think that we have. If you look into what has happened with the appreciation of our stock, the increase in trading volume and market capitalization, etc., we believe that the message is out there. It’s never easy for a small company like ours to get institutional support, but over the last 12 months we have seen a significant increase in the number of high-quality long-term institutional firms who have invested in our company. One of the most challenging jobs of a small public

company CEO is that you have to be supporting day to day internal efforts of the company, while personally supporting the investor relations side.

I have been investing a significant amount of time talking to our shareholders and educating them, while at the same time listening to them. I believe that when you go out on an investor relations trip, it's a two-way street. You give and you take. One of the things I'm very appreciative about is the significant contribution of our Board of Directors and also our shareholders.

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**TWST: What would be the three or four best reasons for the long-term investor at this time to take a very good look at IRIS International?**

**Mr. García:** I think that the most salient point in terms of the financial highlights is that you have a company with a completely new product platform in a market that is large and there is significant recurrent revenue trail. We have a highly experienced management team in place to grow the company. We have two divisions that are in a growth phase right now. With the planned increased penetration, the consumables will materialize because once you place the units, the consumable annuity will begin to be realized.

In addition to that, we have a new business opportunity, at ADIR, with their development of a 3-D face recognition system. This new opportunity, face recognition, is out there but it hasn't yet been priced into our stock value. Although it is too

early to know whether or not it would be successful, we feel confident about it.

IRIS has a simple business model supported by strong management in a large market with significant geographic expansion. We believe that we will be realizing the growth in revenues and earnings that we are projecting for 2005 and 2006.

**TWST: Do you see any need at this time to improve the company's capital structure?**

**Mr. García:** Not at this time. As I mentioned before, the company has \$10 million in cash. We have warrants that are due at the end of July that will bring another \$1.7 million to the company.

I want to point out that the company has significant tax loss carry forwards. We do not pay taxes at this point in time. So we are factoring our tax burden when in reality, the tax is applied to loss carry forwards and we will begin to generate more cash.

**TWST: Is there anything you'd like to add, particularly with regard to the company's long-term objectives?**

**Mr. García:** I think it's very important to remember that the company is in the penetration phase at this point in time. 2004 is the year to penetrate the market. 2005 and 2006 will be the years of increased earnings, and that's a very important message to our shareholders.

**TWST: Thank you. (MC)**

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the Company's forward-looking statements include, among other things, the following: the acceptance by customers of our new iQ<sup>®</sup>200 product platform, our substantial expansion of international sales and our reliance on key suppliers, the potential need for changes in long-term strategy in response to future developments; future advances in diagnostic testing methods and procedures, as well as potential changes in government regulations and healthcare policies, both of which could adversely affect the economics of the diagnostic testing procedures automated by the Company's products; rapid technological change in the microelectronics and software industries; and increasing competition from imaging and non-imaging based in-vitro diagnostic products. The Company refers interested persons to its most recent Annual Report on Form 10-K and its other SEC filings for a description of additional uncertainties and factors that may affect forward-looking statements. The Company assumes no duty to update its forward-looking statements.

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