IRIS INTERNATIONAL INC
Form 10-K
March 16, 2011

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2010

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to .

Commission File No. 1-11181

IRIS INTERNATIONAL, INC.

(Exact name of Registrant as Specified In Its Charter)

Delaware	**94-2579751**
(State or other jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*

9158 Eton Avenue, Chatsworth, California 91311
(Address of principal executive offices) (Zip Code)

(818) 709-1244
(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.01 per share	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes o No þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o	Smaller reporting company o
		(Do not check if a smaller reporting company)	

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act. Yes o No þ

The aggregate market value of the shares of common stock held by non-affiliates of the Registrant on March 7, 2011 was approximately $166 million based upon the closing price of $9.30 per share of its common stock as reported on the NASDAQ Global Market on such date.

The registrant had 17,802,163 shares of common stock outstanding on March 7, 2011.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement for the 2011 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission, or SEC, pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered on this Form 10-K are incorporated by reference into Part III, Items 10-14 of this Form 10-K.

IRIS INTERNATIONAL, INC.

ANNUAL REPORT ON FORM 10-K
Fiscal Year Ended December 31, 2010

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PART I

Forward-Looking Statements

This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statement of the plans and objectives of management for future operations, any statements concerning proposed new products or strategic arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, estimates, potential, intends , or continue or the negative thereof or other comp terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the Risk Factors set forth under Item 1A, and for the reasons described elsewhere in this report. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

Item 1. *Business*

Company Overview

We are a leading manufacturer of automated *in-vitro* diagnostics, or IVD, systems and consumables for use in hospitals and commercial laboratories worldwide, and a provider of high value personalized diagnostics testing services through a high complexity molecular diagnostics laboratory. We offer products that analyze particles and living cell forms and structures, or morphology of a variety of body fluids. Our IVD products leverage our strengths in flow imaging technology, particle recognition and automation to bring efficiency to the hospital and commercial laboratories, where a shortage of qualified laboratory technicians and labor-intensive processes result in significant cost and workflow challenges for our customers. The initial applications for our technology have been in the urinalysis market and we are the leading worldwide provider of automated urine microscopy systems, with approximately 3,000 systems sold in over 50 countries. In this market, we also provide integrated solutions comprising urine microscopy and urine chemistry products as well as consumable supplies, system support services and sample preparation products. We intend to expand into related market segments that can clearly benefit from automated morphology solutions, including hematology. Also, we have an active research and development platform in molecular diagnostics based on our Nucleic Acid Detection Immunoassay, or NADiA®, platform, which we are developing for various applications in personalized diagnostics for oncology. In July 2010, we acquired a high complexity CLIA-certified molecular pathology laboratory offering differentiated, high value molecular diagnostic services in the rapidly growing field of personalized medicine with emphasis in cancer diagnostics. In addition to its current testing services, the laboratory, Arista Molecular, Inc. (Arista or Arista Molecular), will provide a direct commercial channel for our NADiA platform.

Historically, we have predominantly focused on developing, manufacturing and commercializing *in vitro* diagnostics instruments and consumables for urinalysis, including our flagship iQ® analyzers, a family of fully-automated, image-based bench-top analyzers for urine microscopy. Urine microscopy is the visualization and identification of

cells and other sediments in urine. The iQ analyzer uses proprietary flow microscope and image-analysis software that captures the morphology of cells and sediments in urine and serous fluids, and assists in their identification and classification. Our systems are designed to provide users with faster, more complete and more consistent results, while substantially reducing hands-on time spent by laboratory technicians and turnaround time, as compared to traditional manual methods.

The iQ analyzer can be seamlessly integrated with an automated urine chemistry analyzer to simultaneously perform urine microscopy and chemistry testing in a fully automated manner. In September 2008, we released our

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proprietary iChem®VELOCITY™ automated urine chemistry analyzer and a fully integrated urine microscopy and urine chemistry work-cell, called the iRICELL in some international markets. We plan to begin selling these instruments in the United States contingent upon attaining clearance from the U.S. Food and Drug Administration (FDA) on our 510(k) application. Historically in the US, we sold our family of iQ analyzers integrated with an automated chemistry analyzer, the AUTION MAX AX-4280, which we sourced from a Japanese manufacturer.

We intend to solidify our leadership position in the urinalysis market, as well as enter into several adjacent markets with our product pipeline under development. To maintain our market position in urinalysis, we continue to implement improvements to our existing product lines, including enhancing our data analysis and productivity tools for the iQ analyzer, such as Edit Free Release Technology to improve turnaround time and iWare to enhance the laboratory information system s, or LIS, communication protocol for more effective management of resources and costs in the screening for negative urine cultures.

We are also developing our 3GEMS (Third Generation Morphology) platform, which will serve as the basis for our next generation products in urinalysis and an emerging pipeline of hematology products. These 3GEMS hematology products, currently in feasibility testing, use image-based technology to automate the identification and characterization of blood cells, in particular, abnormal white blood cells. We believe an automated hematology analyzer using our proprietary imaging technology and software recognition capabilities will provide improvements in the identification of abnormal blood cells, including an automated, image-based expanded white blood cell differential analysis. Like our urine microscopy products, these new hematology products by virtue of IRIS s inherent capabilities to capture and analyze images are expected to significantly reduce the need for manual slide preparation and reviews, increasing the efficiency of what is currently a highly labor-intensive process.

We believe a significant driver in the future growth of diagnostics will be in personalized medicine, meaning the ability to analyze the molecular make-up of an individual patient s cancer and assess disease progression in order to more precisely prescribe appropriate treatment. In order to be in a position to realize the potential of this segment, in July 2010 we acquired a high complexity CLIA certified molecular pathology laboratory, renamed Arista Molecular, to complement our active research and development program for our proprietary molecular diagnostics platform called NADiA.

NADiA has the ability to measure proteins below the detection thresholds of current immunoassay and molecular diagnostic methods. We believe our proprietary diagnostic products will address the need for increased sensitivity in the monitoring of disease enabling personalized treatment of cancers. Our first product pending regulatory clearance, NADiA ProsVue™, is an ultra-sensitive, blood-based test designed to be a prognostic indicator by using a threshold based on the slope of three successive test measurements of residual amounts of prostate specific antigen, or PSA, in prostate cancer patients following radical prostatectomy. In April 2010, we submitted our NADiA ProsVue 510(k) pre-market notification application to the FDA requesting clearance of the product with a prognostic claim. In February 2011, we submitted additional data requested by the FDA for this 510(k) application.

Our Arista Molecular laboratory is oncology focused and offers differentiated, high value molecular diagnostic services in the rapidly growing field of personalized medicine. With a comprehensive test menu, we believe Arista is able to meet the evolving needs of pathologists and cancer-focused physicians. In addition, the laboratory will provide us more control over the commercialization of our NADiA pipeline products, including sales, marketing and communications programs and value-based pricing strategies. Further, the laboratory should accelerate the development efforts of NADiA-based products and enable more direct access to the clinical end-users. Recently, Arista Molecular expanded its solid tumor test menu for breast, lung and colorectal cancer adding flow cytometry for detection and monitoring of leukemia and lymphoma and fluorescence *in situ* hybridization, or FISH, testing for certain cancers. We believe a broad menu of high value tests along with the additions of proprietary NADiA assays will provide Arista Molecular with a significant competitive advantage in the marketplace.

Our Sample Processing group markets and develops centrifuges, semi-automated DNA processing workstations and sample processing consumables. Our StatSpin brand bench-top centrifuges are used for specimen preparation in coagulation, cytology, chemistry and urinalysis. Our worldwide markets include medical institutions, commercial laboratories, clinics, doctors offices, veterinary laboratories and research facilities.

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Market Overview and Opportunity

The global market for IVD in 2010 is estimated at approximately $44 billion and is expected to grow in the mid-single digits annually. IVD manufacturers provide products and services to the clinical laboratory industry, which is confronted with significant challenges in the current market. Healthcare professionals are demanding improved turnaround time for diagnostic tests, greater sensitivity and lower costs. To improve accuracy, productivity and efficiency, many laboratories are turning to automated methods to perform these tests. Moreover, automated testing solutions better position laboratories to cope with the declining number of certified medical technologists available to perform tests.

Currently, we participate primarily in the urinalysis segment of the IVD market which we estimate is approximately $650 million. With our expansion into molecular diagnostics, we have the opportunity to participate in the personalized medicine market. PricewaterhouseCoopers estimates the market for esoteric services and test sales was $11 billion in 2009, including $3 billion related to the molecular diagnostics market with a 15% growth rate. We believe we are well positioned to experience growth in this segment with our focus on a personalized medicine test menu at Arista Molecular, which will include our proprietary molecular tests utilizing our NADiA technology platform.

Urinalysis

Urinalysis is performed as part of most routine medical examinations and is necessary for the diagnosis and monitoring of conditions such as urinary tract infection, and kidney and bladder disease. Traditionally, urinalysis comprises urine chemistry and urine microscopy tests, while urine cultures are considered part of microbiology. We believe that the advancement of automated technologies will blur this distinction, with urine cultures being performed increasingly in the same laboratories as urine chemistry and urine microscopy tests and eventually becoming part of the urinalysis market.

Urine Chemistry and Microscopy Market Overview

Urine chemistry consists of a panel of tests that identifies various chemical analytes in urine, while urine microscopy analyzes the microscopic solid particles and cells suspended in urine. Urine chemistry comprises the majority of the urinalysis market and is broadly used, with limited differentiation between products. Traditional urine microscopy is used less routinely because as a manual process it is time consuming and requires a trained medical technician to characterize particles and cells based on their morphology. In order to reduce costs, many laboratories perform manual urine microscopy only in response to results from an initial urine chemistry test despite evidence that urine microscopy can provide a more reliable clinical diagnosis. The commercial success of our iQ analyzer is attributable to its capability to image and accurately identify particles and cells suspended in urine in a time-efficient manner eliminating manual microscopic examination.

Of the $650 million urinalysis segment, urine chemistry represented approximately $490 million and automated urine microscopy represented approximately $160 million, but growing at a much faster rate than the other urinalysis sub-segments. We estimate there are 13,200 sites performing greater than 40 microscopy tests per day on a global basis including approximately 6,000 in China. These higher volume sites represent a significant opportunity for us, because they would benefit from the automation and consolidation of their urine chemistry and microscopy procedures. We believe the full automation and integration of results brought by the iQ product platform has accelerated the adoption of automated urine microscopy as a routine test. We believe approximately 40% of these targeted domestic sites continue to perform manual microscopy procedures. The penetration of automated urine microscopy analyzers varies significantly from country to country.

Limitations in Urine Chemistry and Microscopy

Current manual testing of urine and body fluids requires the clinical laboratory to split samples, perform automated and manual procedures and consolidate the separate results into one report. Moreover, the manual procedure for microscopy requires a qualified medical technician to accurately categorize particles and cells observed under the microscope. Therefore, these tests represent both time and cost intensive procedures for the clinical laboratory. Further, the inherent variability in sample preparation limits the quantitative and qualitative

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accuracy of the diagnostic result. The manual nature of performing urine microscopy and the lack of qualified personnel represents a significant opportunity. However, the challenge remains to compete for capital for urinalysis automation versus other disciplines of the laboratory.

Laboratories typically perform microscopy and chemistry tests separately and generally perform microscopy only in the case of an abnormal chemistry result because urine microscopy is a very tedious process. If both tests are performed, the separate results must then be manually consolidated into one report or file. Without the automatic integration of both the microscopy and chemistry results, valuable clinical information may be overlooked. By reducing the amount of manual labor spent conducting these tests and by automatically integrating the chemistry and microscopy results, we believe we can improve the consistency, reliability and value of the combined results and improve specimen turnaround time.

Hematology

Hematology Market Overview

The enumeration of the various cellular components of blood is an essential part of routine medical examinations. A complete blood count, or CBC, is the most common type of blood test performed and measures the number of specific types of blood cells, including red blood cells (RBC), white blood cells (WBC), platelets, and other blood components, such as hemoglobin. In most instances, a white cell differential count, which measures the percentage of five types of white blood cells, is added to the CBC test. Variations from concentration, size, or maturity of the blood cells can be used to indicate an infection or illness. CBC tests and differential WBC counts are performed primarily in hospitals and clinical reference laboratories.

According to industry sources, the hematology market is approximately $2.1 billion and growing approximately 4% per year driven primarily by system replacement sales and a small increase in test volume. Over the past 15 years, innovation within this market has been limited to automation of slide making and staining and algorithmic improvements to aid in the interpretation of results.

Limitations in Hematology

Traditional CBC test instruments use indirect means to measure the type and number of blood cells rather than direct observation of the blood cells. Despite the high number of these automated CBC analyzers in use, a significant percentage of the samples require a manual cell differential count of the blood specimen under a microscope. Frequently, a manual count is required due to the inability of automated CBC and differential analyzers to discriminate the complex morphology, especially the shape, of abnormal cells, such as immature white blood cells, or the presence of diseased cells, as in the case of sickle-cell anemia. The presence of immature white blood cells is often associated with conditions such as leukemia, infection, inflammation or tissue injury. However, a manual differential count of a blood specimen must be performed by a medical technologist trained in cytology or a pathologist under a microscope a time consuming and subjective process, resulting in longer specimen turnaround times and higher cost.

According to a 2006 study conducted by the College of American Pathologists, of the 263 US laboratories surveyed, an average of 29% of automated CBCs required a manual review, scan or differential and this percentage dramatically increased depending on the pathology of the patient population. IRIS has recently confirmed this manual review rate, independently. Since the hematology market is dominated by a few large companies that typically compete on their ability to marginally reduce manual review rates, we believe there is significant opportunity to offer an automated image-based instrument that has the ability to identify immature white blood cells and other anomalies in a systematic fashion and to reduce significantly the number of manual reviews performed.

Personalized Medicine

Personalized medicine may be defined as giving the right treatment to the right patient at the right time. The implementation of personalized medicine has been made possible by state of the art molecular diagnostic testing. By examining the molecular make up of an individual patient s cancer, therapy can be tailored for that specific patient, rather than blindly treating all patients with one size fits all drug cocktails. This leads to better

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management of the individual patient s cancer, with fewer potentially ineffective drugs, reduced incidence of side effects, and overall cost savings for the healthcare industry.

With the advancement in genomics and proteomics, there is an accelerating offering of better targeted diagnostics and therapeutics to aid clinicians in patient management, which is improving health outcomes. PricewaterhouseCoopers estimates the market for esoteric services and test sales addressing this segment was $11 billion in 2009 and is expected to grow to $21 billion in 2015 with an 11% annual growth rate.

The acquisition of our cancer focused CLIA-certified laboratory, Arista Molecular, provides us with differentiated, high value molecular diagnostic services in the rapidly growing field of personalized medicine. Our menu includes tests for solid tumor cancers such as lung, colon, breast and prostate, as well as hematological cancers such as leukemia and lymphoma. According to the American Cancer Society, there were an estimated 752,210 cases of these solid tumor cancers and approximately 137,260 cases of hematological cancers in 2010 in the US. The number of these cases is expected to increase due to the growth and aging of the population and the increase in unhealthy lifestyle behaviors.

Many smaller community-based pathology groups, hospitals and laboratories are unable to offer molecular diagnostics as they lack the required technical expertise, financial resources to fund the high costs of equipment, and sufficient test volume necessary to justify their investment in this high complexity test modality. As a result, the majority of these laboratories in the US do not offer molecular diagnostic services. Consequently, this provides a significant opportunity for our laboratory to offer these complementary high value tests to broaden these groups menu.

Molecular Diagnostics Market Overview

Molecular diagnostic tests examine nucleic acids, including DNA and RNA, and protein biomarkers, to identify a disease, determine prognosis, monitor its progression and response to treatment, or predict individual predisposition to a disease or genetic disorder. These biomarkers can also provide information in drug discovery, preclinical drug development and patient monitoring during clinical trials. Currently, the clinical market for molecular diagnostics is primarily nucleic acid testing performed by real-time polymerase chain reaction, or PCR, instruments that amplify and detect nucleic acid targets for diseases or infections. These tests require a high-complexity CLIA (Clinical Laboratory Improvement Act) license and are generally performed in commercial reference laboratories and large academic and research hospital laboratories due to the complexity and cost of the tests. It is expected that as more highly automated solutions become available, these tests may migrate to smaller laboratories and potentially even to point-of-care sites.

The analysis of DNA expression, presence of cell surface receptors, or the production of specific proteins in cells, provides the ability to characterize diseases, such as cancer and infectious diseases. As a result, the detection and identification of DNA and proteins can provide physicians with a means to tailor therapy, monitor disease progression and detect relapse.

Currently, the ability to detect specific proteins in cells is limited by sensitivity. We believe that development of an ultra-sensitive detection method for proteins with the capability to measure concentrations hundreds of times below the detection limits of currently available immunoassays, may provide a reliable method to detect disease at an earlier stage, which may result in improved patient care.

According to PricewaterhouseCoopers, the worldwide molecular diagnostics market in 2009 was approximately $3 billion and growing at 15% annually. We believe growth in the market is being driven primarily by an increase in the number of personalized diagnostic tests available to treat cancers and infectious diseases.

Limitations with Current Methods

Proteins are critical to understanding diseases and current testing methods lack the degree of sensitivity necessary to detect minute amounts of protein and the precision to monitor serial determinations for disease progression. Traditional methods to detect proteins, including enzyme-linked immunosorbent assay (ELISA) and chemiluminescence immunoassay (CIA), are unable to quantify protein biomarkers in extremely low concentrations. These methods become effective only after a disease has progressed to a more advanced stage and the

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concentration of the protein biomarker has increased to reach the lower limit of detection of those conventional methods. We believe there is a significant market opportunity for an ultra-sensitive detection technology that measures concentration as low as one femtogram per milliliter (10^{-15} gram/milliliter) compared to today s technologies that are limited to measuring concentrations of greater than 50,000 femtograms per milliliter.

Sample Processing

Sample Processing Market Overview

Nearly every sample presented to a clinical laboratory for testing requires some sort of sample processing before analysis. These samples include blood, urine and other body fluids, tissue, stool and other materials which may need to be separated into its different constituents. In the United States, there are over 180,000 testing sites where sample processing occurs, including hospital laboratories, independent laboratories, doctor s offices, health maintenance organizations and community clinics.

Although testing is performed on many different types of samples, most tests are performed on blood specimens that require separation in a centrifuge. The centrifuge market comprises five segments including non-refrigerated bench-top, refrigerated bench-top, floor, high-speed and ultra-centrifuges. According to Strategic Directions International, the worldwide market for sample processing centrifuges in 2010 is estimated at $660 million, of which the market for non-refrigerated bench-top centrifuges, the market segment we serve, is estimated at approximately $100 million. To improve laboratory productivity and sample turnaround time, the current trend is toward smaller and faster bench-top models and away from large capacity floor models which have longer processing time per batch. This represents a significant opportunity for our Express line of bench-top centrifuges.

Limitations with Current Sample Processing Methods

The time it takes to process a sample is critical for clinical laboratories as the volume of samples to be tested increases. Each day, laboratory technicians are expected to handle thousands of samples with minimal error in a defined amount of time with limited laboratory space. In most laboratories, sample processing occurs in a central location where blood specimens are sorted and centrifuged in batches. The entire process can take up to an hour and requires dedicated resources to manage the sample flow. Once processed, the samples are often split and then sent to the various stations within the laboratory for analysis. The centralized processing of samples is thus quite inefficient as samples wait to enter the floor model centrifuge in large batches followed by long centrifugation times. In fact, many sample processing procedures create significant delays in specimen turnaround time.

Our Products

Our commercialized products and product pipeline comprise three main categories: morphology, personalized medicine and sample processing. Our morphology category includes all urinalysis and hematology products consisting of our commercialized urine chemistry and microscopy products, as well as our development-stage products such as our 3GEMS urinalysis and hematology analyzers. Our personalized medicine category consists of our development-stage products that utilize our NADiA technology for ultra-sensitive detection of proteins for monitoring cancer and infectious disease applications and our recently acquired CLIA-certified oncology laboratory. Our sample processing category develops and markets small centrifuges and other processing equipment and accessories for rapid specimen processing. The table below is a summary of our major commercialized and in-development products:

Major Products	Status	Description

Morphology and Related Products		
iQ analyzers (200, Sprint, Elite, Select, Pro and Plus)	Marketed	Fully-automated urine microscopy and body fluids analyzer
iQ Body Fluids Module	Marketed	
Optional iWare Software	Marketed	

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Major Products	Status	Description
iChemVELOCITY	Launched internationally: 3Q2008 U.S.: pending 510(k) clearance	Fully-automated urine chemistry analyzer
iRICELL	Launched internationally: 3Q2008 U.S.: pending 510(k) clearance	Integrated iQ and iChemVELOCITY workcell
3GEMS Urinalysis and Body Fluids	In feasibility	Next generation urine microscopy and body fluids analyzer
3GEMS Hematology	In feasibility	Complete blood count, white blood cell count with expanded differentials and red blood cell and platelet morphology
Personalized Medicine		
Arista Molecular Tests Molecular pathology	Marketed	Application of molecular biology and molecular genetics at the level of basic molecules such as DNA, RNA, and proteins, to aid in the diagnosis and prognostication of pathologic entities
Flow cytometry	Marketed	A cell analysis platform using fluorescence tagged antibodies for enumeration & characterization of cells for diagnosis of hematological disorders
FISH	Marketed	An enhanced molecular cytogenetic method using fluorescent probes for detection of DNA on chromosomes in the intact cell (in-situ)
NADiA ProsVue	510(k) submitted 2Q2010	Prognosticate stable patients after radical prostatectomy
NADiA HIV	Feasibility complete Pursuing licensing partners	Monitoring HIV viral load during anti-retroviral therapy
NADiA CECs	In feasibility	Detect circulating epithelial cells to monitor cancer progression
Sample Processing		
Express centrifuge line	Marketed	Centrifuges for clinical diagnostic market
ThermoBrite	Marketed	DNA workstation for FISH procedures
Cytofuge 2	Marketed	Centrifuge used for thin layer cell preparation
Cytofuge 12	Marketed	12 placement centrifuge used for thin layer cell preparation
IDEXX Drive	Marketed	For internal use in IDEXX chemistry analyzers
IDEXX whole blood separator	Manufacturing rights licensed to IDEXX	Consumable used in IDEXX chemistry analyzers
OvaTube	Marketed	Ova and parasite testing for veterinarian market
Slide based sample preparation system	In development	Benchtop platform for automating slide based procedures including FISH testing

Morphology and Related Products

Cell morphology is the science of cell form and structure. Our morphology segment utilizes our proprietary imaging technology to identify cells and particles in a fully automated manner. In the urinalysis market, we offer urine microscopy analyzers and related urine chemistry instruments. As part of our 3GEMS Third Generation Morphology program, we are developing a next-generation urine microscopy analyzer and an image-based hematology analyzer.

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Automated Urine Microscopy Analyzers

Our flagship product is the family of iQ urine microscopy analyzers, which was first launched in 2003. Our iQ technology platform utilizes proprietary image flow cytometry and software to achieve significant reductions in cost and processing time as compared to manual urine microscopy. Our technology enables high speed digital processing to classify and display images of microscopic particles in an easy-to-view graphical user interface. We believe our iQ product line has numerous benefits over competing products, including increased accuracy, digital imaging of particles and fully automated analysis of urine and body fluids and lower manual review rates of abnormal samples.

The iQ microscopy product line comprises the iQ SELECT, a fully-automated instrument capable of analyzing 40 samples an hour and enabling partial automation at laboratory sites with lower test volumes; the iQ ELITE, a fully-automated instrument capable of analyzing 70 samples an hour that is appropriate for mid-sized hospital laboratories; and the iQ SPRINT, a fully-automated instrument capable of analyzing 101 samples an hour that is appropriate for large volume hospital and commercial laboratories. By utilizing our urinalysis system, we believe the average laboratory, which we define as those laboratories that typically perform 60 microscopy tests per day, can re-assign one medical technician currently performing these tests to another function, with a payback period of approximately two years. We also offer the iQ Body Fluids Module as an addition to the iQ urinalysis test menu, which enables the rapid diagnosis for the presence of nucleated cells, red blood cells, bacteria and crystals in body fluid samples. In 2010, we attained 510(k) clearance for the synovial fluid application and added it to this optional software module.

In 2010, we also introduced the iRICELL®Plus and the iRICELL® Pro which we believe delivers significant workflow enhancements and productivity to the laboratory. In addition, we launched iWARE™, an optional, expert software product that further enhances laboratory productivity by enabling real-time patient validation based on lab-defined verification rules for urine chemistry and microscopy results. The iWARE product includes an enhanced LIS communication protocol allowing for direct electronic communication between urinalysis and microbiology laboratories for more effective management of resources and costs in the screening for negative urine cultures.

Urine Chemistry Analyzers

We market our proprietary fully-automated urine chemistry analyzer, the iChemVELOCITY, which can be seamlessly connected to the higher throughput iQ automated urine microscopy analyzers and provide laboratories with walk-away solutions for chemistry and microscopy urinalysis with results combined and displayed in a single report. The iChemVELOCITY is designed for medium to high volume laboratories that typically process more than 100 urine chemistry samples per day. We offer the iChemVELOCITY as a stand-alone analyzer or as part of our integrated urinalysis workcell solution, the iRICELL.

Internationally, we began selling the iChemVELOCITY in September 2008 following CE Mark certification. In the United States, sales of our iChemVELOCITY chemistry analyzer and iRICELL workstations will be contingent upon clearance of our 510(k) application with the FDA. Historically in the U.S., we sold a fully-automated urine chemistry analyzers manufactured by ARKRAY, a Japanese IVD company. Our agreement with ARKRAY allows us to sell consumable strips for our existing installed base of AX-4280 analyzers through 2013. We plan to continue to support and service these instruments through the life of the customers contracts.

Consumables and Service

We generate significant revenue from the sale of consumables and service contracts for our urine microscopy and urine chemistry analyzers. For the year ended December 31, 2010, revenue derived from consumables and service contracts accounted for 57% of our total consolidated revenues and 66% of our IDD urinalysis segment s revenue.

Consumables include urine and body fluids reagents, calibrators and controls for our microscopy systems and test strips, calibrators, controls, and other solutions for the urine chemistry analyzers we manufacture and distribute. After the initial year of sale, which is covered by product warranty, we offer annual service contracts for our domestic and other direct customers in select international markets. To our distributors, we offer spare parts who in turn service the end-use customer.

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3GEMS Platform

Our 3GEMS platform combines our core imaging technology with improved software and sample processing to enhance the identification of various cell types and particles found in urine, blood and other body fluids. We believe the increased sensitivity and specificity, reliability, ease of use and improved imaging of our 3GEMS platform will increase the clinical utility of our diagnostic tests and allow physicians and other caregivers to make more informed treatment decisions. The 3GEMS Platform will be the basis for our next generation urine microscopy analyzer and improved body fluids module and a new hematology analyzer product line. The following describes our 3GEMS products under development:

Next Generation Urine Microscopy Analyzers. Our next generation urine microscopy analyzer will include advances in electronics and optics, including very high speed color cameras with higher resolution. We anticipate these advances will improve the clinical utility of the instrument as a greater number of cell types will be able to be identified with greater precision.

Next Generation Body Fluids Module. We currently offer products that utilize our proprietary technology for morphology analysis of other body fluids, including cerebrospinal, synovial and serous fluids. We are developing a next generation body fluids module that we believe will possess improved diagnostic capabilities relative to our current product offering.

Hematology Analyzers. We are developing a portfolio of hematology analyzers to automate the identification and characterization of cells in blood. Our initial hematology analyzer will conduct a complete blood count, or CBC, the most common type of blood test, as well as automatically complete an expanded white cell differential analysis. This differential analysis will identify the presence and quantity of immature white blood cells, whose presence is often associated with conditions such as leukemia, infection, inflammation or tissue injury. Importantly, the automation of the white cell differential will eliminate the need for a medical technologist trained in cytology or pathologist to manually identify and count cells under a microscope a time consuming and subjective process. Finally, since our analyzer captures digital images of individual cells, the creation of slides to enable the review of a blood smear under a microscope and to retain physical evidence of a particular sample would be significantly reduced. Our virtual slides will be stored digitally and transmitted electronically between laboratories or healthcare providers.

Personalized Medicine

NADiA (Nucleic Acid Detection Immunoassay) Platform

Our Personalized Medicine category is leveraging our proprietary NADiA technology platform to develop ultra-sensitive and precise diagnostic tests. NADiA technology has the ability to measure proteins in extremely low concentrations below the detection thresholds of current immunoassay and molecular diagnostic methods. NADiA combines immunoassay and PCR methodologies, or Immuno-PCR, with the potential to detect proteins with femtogram/milliliter sensitivity (10^{-15} gram/milliliter). The Immuno-PCR approach is similar to that of an enzyme immunoassay, which makes use of antibody binding reactions and washing steps, but in the NADiA method, the enzyme label is replaced with a double-strand of DNA which is used to detect and quantify the target protein using PCR amplification. We believe diagnostic tests that utilize our NADiA technology will aid in the early detection of disease relapse and potentially provide better therapeutic outcomes for patients. Our molecular diagnostics pipeline includes the following products under development:

Prostate Cancer: NADiA ProsVue. PSA, or prostate-specific antigen, is the most widely used cancer marker for the diagnosis and clinical management of prostate cancer in men. We have developed an ultra-sensitive

blood-based diagnostic test, called NADiA ProsVue, designed to be a prognostic indicator by taking the slope of three successive test measurements of residual levels of PSA that currently are undetectable with current testing methods, in men with prostate cancer who have undergone radical prostatectomy, or removal of the prostate gland. In April 2010, we submitted our NADiA ProsVue 510(k)

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pre-market notification application to the FDA requesting clearance of a prognostic claim. At the American Society for Clinical Oncology (ASCO) 2011 Genitourinary Cancers Symposium, the results of a multi-center clinical study were presented. The study s results demonstrate a negative predictive value (NPV), or the proportion of patients correctly identified as stable, of 95.2% and a positive predictive value (PPV) of 81.4%. We believe the data supports our hypothesis that NADiA ProsVue can contribute useful information as a prognostic indicator in identifying post-prostatectomy patients with low risk of cancer recurrence.

HIV: Viral Load Test. Current HIV viral load tests measure the quantity of HIV RNA in the blood of an individual infected with HIV. The presence of RNA indicates that the virus is actively replicating and increasing levels of RNA can indicate more serious or advanced disease. Viral load testing is one of the most valuable measures for predicting HIV disease progression and gauging how well anti-retroviral treatment is working. Effective anti-retroviral treatment can often reduce RNA viral load to levels that are undetectable by current diagnostic tests. Unlike current tests measuring HIV RNA, our NADiA technology measures a specific HIV viral protein, p24, which is present in greater numbers relative to HIV RNA. Specifically, per unit of sample, there are 3,000 p24 molecules while only two copies of HIV RNA. We have developed an experimental blood-based HIV viral load p24 assay utilizing NADiA technology that achieved a sensitivity of one femtogram/mL, which is below the limit of detection of the most sensitive FDA cleared HIV RNA-based assay. As a result of our decision to focus on cancer diagnostics, we are currently pursuing a development and commercial partner for our NADiA HIV assay.

Cancer Progression: Circulating Epithelial Cells. In addition to our NADiA technology, we have a novel cell isolation technology that makes it possible to isolate rare cells in the presence of billions of non-target cells using antibody-coated albumin micro-bubbles to bind to target cells. We believe our albumin bubbles have significant competitive advantages in terms of affinity. In addition, the albumin bubbles can easily collapse and disappear without the cumbersome step of separating glass bubbles or magnetic beads from targeted cells, as is necessary with current commercial isolation technologies. Utilizing our bubble isolation technology and NADIA, we are developing a test method to identify, quantify and characterize circulating epithelial cells present in blood to aid in monitoring cancer progression.

Arista Molecular

In July 2010, we acquired a high complexity CLIA-certified molecular pathology laboratory, renamed Arista Molecular, in order to provide a direct commercial channel for NADiA. The laboratory is oncology focused and offers differentiated, high value molecular diagnostic services in the rapidly growing field of personalized medicine. With a comprehensive test menu, we believe Arista is able to meet the evolving needs of pathologists and cancer-focused physicians. In addition, we believe the laboratory will provide us more control over the commercialization of our NADiA pipeline products, including sales, marketing and communications programs and value-based pricing strategies. Further, the laboratory should accelerate the development efforts of NADiA-based products and enable more direct access to the clinical end-users. We anticipate that ProsVue will be the first NADiA test offered by Arista Molecular following FDA 510(k) clearance.

We are expanding Arista s test menu to provide a broader menu of diagnostic panels useful for the diagnosis, disease characterization, treatment and monitoring of cancer. Currently, Arista Molecular offers companion molecular tests used to characterize and tailor cancer therapy for solid tumors, including lung, colorectal, breast and prostate cancer, flow cytometry for detection and monitoring of leukemia and lymphoma and FISH testing for certain cancers. We believe having a broad menu of high-value tests along with the additions of our proprietary NADiA assays will provide Arista Molecular with a significant competitive advantage in the marketplace.

In addition to its menu of high-value tests, Arista Molecular is striving to differentiate itself in the marketplace by providing industry-leading turnaround times of less than 72 hours for these test results, exceptional service to clients and competitive pricing. By providing valuable diagnostic information in a rapid manner, the laboratory is able to aid clinicians in improving patient care. In addition, upon request the laboratory has the ability to provide pathology consultation and pathology-guided diagnostic services.

Arista s primary customers include anatomic pathology groups, hospitals and regional and community laboratories, many of which are unable to integrate molecular diagnostics into their test menu as they lack the

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required technical expertise, financial resources to fund the high costs of equipment, and sufficient test volume necessary to justify the investment in this high complexity test modality. As a result, the sales strategy of the laboratory is to become partners with these pathology groups and community-based hospitals and laboratories by providing complementary high value services to their current offering. These groups benefit by being able to broaden their test menu with specialized tests, without the investment in equipment and technically skilled personnel necessary to perform the tests.

Arista Molecular continues to build a national sales force to offer high value testing services directly to our customers. Our sales people typically have experience in the laboratory services market focusing on molecular diagnostics with strong technical backgrounds.

Sample Processing

Our sample processing group markets and develops centrifuges, semi-automated DNA processing workstations and sample processing consumables. Our StatSpin brand bench-top centrifuges are used for specimen preparation in coagulation, cytology, chemistry and urinalysis. Our worldwide markets include medical institutions, commercial laboratories, clinics, doctors offices, veterinary laboratories and research facilities.

With our sample processing products, we believe we offer laboratories the ability to increase their efficiency by processing samples as they arrive rather than in a batch mode. Our bench-top centrifuges offer a significant advantage with two to three minute cycles compared to conventional centrifuges taking up to 15-30 minutes, depending on batch size. Further, our bench-top models are small enough to sit along side an analyzer eliminating the need for a separate central sample processing area.

Our Express 4 centrifuge employs a unique high speed horizontal rotor for separating samples and replaces larger and slower batch centrifuges by reducing sample preparation time and streamlining laboratory workflow. This product platform enables us to serve the high-volume chemistry market.

In November of 2010, we acquired the assets of a multi-purpose, bench-top instrument platform for automating highly repetitive, manual laboratory protocols for FISH (fluorescence *in-situ* hybridization) testing and other slide-based cytogenetic applications. The product acquisition is a natural extension to our successful ThermoBrite® DNA Hybridization System and consistent with our entry into personalized medicine with emphasis on cancer diagnostics. The new product platform will be integrated into our Iris Sample Processing Division and it is expected to position us as a major competitor in the high growth cytogenetic instrumentation market.

In November of 2009, we initiated shipments of our StatSpin Ovatube System for use in veterinary hospitals, clinics and reference laboratories to process fecal samples for the detection of ova and parasites. Based on our research, there are some 20 million ova parasite tests performed on animals each year in the U.S. alone, with some 15 million of these tests being performed in 25,000 veterinary clinics.

We have been collaborating with Becton Dickinson, or BD, in their Lean-Six Sigma initiatives with our Express 3 centrifuge utilizing BD s blood collection tubes. Our collaboration study showed numerous benefits from utilizing our combined products in the laboratory including decreased turn-around time, increased productivity and decreased costs. As a result in 2008, our sample processing group and BD entered into a three-year distribution agreement. The agreement provides for BD distributing Express 3 centrifuges on a co-branded basis for use with its tubes in certain international markets.

Our Strategy

Our goal is to maintain our leadership position in automated *in vitro* diagnostics for urinalysis and sample processing while becoming a global leader in hematology and molecular diagnostics by offering products and solutions that increase laboratory productivity and efficiency and diagnostic tests that improve patient care. To achieve this goal, we intend to:

Increase the market adoption of the automated urinalysis platform in the in vitro diagnostics market. We strive to develop automated diagnostic instrumentation and solutions that enable increased laboratory productivity and efficiency. As we continue to market the clinical value of urinalysis, specifically in microscopy, we expect to

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increase market awareness and demand for our automated urinalysis products. In addition, we continue to pursue large multi-unit, multi-site contracts with large volume laboratories and to invest in emerging markets to increase our installed base of instruments.

Broaden our product offerings in the urinalysis IVD market. We intend to broaden our offerings in the urinalysis IVD market by developing and commercializing new products and solutions that improve laboratory efficiency and provide healthcare providers with more timely and more valuable information. The iChemVELOCITY, an automated urine chemistry analyzer, and iRICELL workstation represent key new product offerings that we launched in the international market in 2008 and for which we will launch domestically contingent upon attaining FDA clearance. The iChemVELOCITY, when linked with our iQ microscopy analyzer, allows us to offer an integrated system, called the iRICELL. In addition, we are leveraging our 3GEMS imaging technology to develop next-generation urinalysis instruments to provide our customers with innovative products.

Use our imaging technology expertise to enter the automated hematology in vitro diagnostics market. We intend to leverage our imaging technology, which forms the basis of our market-leading urinalysis products, into other IVD markets where customers will value automation and increased efficiency. We are developing a hematology product portfolio that utilizes our next-generation 3GEMS imaging technology to reduce the need to prepare manual slides and perform subjective assessments of those slides under a microscope. We believe our product, by using a digitally-imaged virtual slide, will significantly decrease labor spent in laboratories by reducing the manual examination of abnormal blood samples while improving standardization.

Enter higher value segments of the market focused on personalized medicine. We believe that NADiA, our proprietary molecular diagnostic technology, has the potential to improve patient care management by allowing for earlier monitoring of disease and detection of relapse and to improve patient outcomes due to its ultra-sensitive detection of proteins. Our portfolio of emerging molecular diagnostic tests for cancer is designed to provide physicians and patients with more valuable information that may impact the treatment decision in managing the course of disease. As a result, we believe our NADiA platform is well-positioned for growth with the advent of personalized medicine utilizing genomic and molecular data to better determine targeted therapies for patients. With the recent acquisition of our Arista Molecular diagnostics laboratory focused on oncology, we have a direct commercial channel for our NADiA products starting with our ProsVue test as a prognostic indicator for prostate cancer. Currently, the laboratory provides customers a broad menu of high value tests focused on personalized medicine, which will be supplemented with products from our NADiA pipeline.

Pursue selective acquisitions and technology in-licensing. We will continue to pursue selective acquisitions to augment our organic growth. Our acquisition strategy is to target companies and product lines that complement our business and provide additional infrastructure necessary for the commercialization of our pipeline. In 2010, we closed three acquisitions. We acquired a CLIA-certified laboratory to provide a direct commercial channel for our NADiA product pipeline. Our Sample Processing division acquired an automated bench-top instrument for FISH testing. Lastly, our Iris Diagnostics division acquired the assets from our European distributor relating to its distribution of IRIS products in Germany and the UK to provide for an expanded international direct sales channel for current and future products.

Competition

Competition in the IVD industry is intense. Many of our competitors are substantially larger than we are and have greater financial, research, manufacturing, marketing, sales and other resources than we do. As a result, our competitors may develop technologies or products that could render our products or products under development obsolete or noncompetitive.

Urinalysis

The principal competitive factors in the urinalysis market are cost-per-test, ease of use and quality of results. In the automated urine microscopy segment, Sysmex Corporation markets its automated non-imaging urine sediment analyzers globally and remains our principal competitor in the urine microscopy segment. Elektronika 77, a Hungarian company, offers a slide-based automated microscopy analyzer that can be run as stand-alone or in combination with a urine chemistry system. In the urine chemistry segment, Siemens Healthcare Diagnostics,

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ARKRAY and Roche Diagnostics are our principal competitors selling urine analyzers and test strips used in determining the concentration of various chemical substances found in urine. We believe our systems provide the highest level of integration of urine chemistry and microscopy and the broadest menu available to provide digital images of urine and other body fluids particles, which provides significant competitive advantages.

We are experiencing increased domestic and international pricing pressures in the urinalysis market due to the ongoing consolidation of both hospitals and medical device suppliers, increasing competition and decreasing reimbursement. Competitors are attempting to offer one-stop shopping for a variety of laboratory instruments, supplies and service with price discounts based on the hospital s aggregate volume of business. We have been successful in countering this type of strategy by our large competitors by negotiating contracts with group purchasing organizations, or GPOs, in the United States allowing GPO members to purchase our products at competitive pricing.

Hematology

Hematology is a mature segment of the *in vitro* market in which there are a number of large competitors who already have an established market presence and significantly greater resources than we have. The major competitors in the hematology market include Abbott Laboratories, Beckman Coulter, Inc., Siemens Healthcare Diagnostics, Sysmex Corporation and Horiba ABX. Our hematology analyzer currently under development represents a significant advancement in this market by combining an automated instrument with image-based expanded white cell differentials with complete blood counts. We believe this differentiates us from currently existing products, and will allow us to make a strong entry into the hematology testing market.

Personalized Medicine

In the ultra-sensitive protein detection market, we may experience competition from companies that utilize enzyme-linked immunosorbent assay, or ELISA, chemiluminescence and fluorescence technologies, including Abbott Diagnostics, Beckman Coulter, Inc., Ortho-Clinical Diagnostics, Inc., Roche Diagnostics and Siemens Healthcare Diagnostics. Our technology detects proteins at lower concentrations, which we believe will enable earlier detection of relapse of disease. Many of these companies market instruments and reagents for measuring serum markers in concentrations greater than 50,000 femtograms per milliliter, while we believe our technology detects concentrations as low as one femtogram per milliliter.

Arista Molecular participates in the significantly competitive medical testing laboratory segment. There are several factors driving competition in the industry including breadth of test menu, accuracy of results, turnaround time, reputation of laboratory, quality of service including analysis and pricing. The segment is dominated by two large national laboratories, Laboratory Corporation of America and Quest Diagnostics that have significant market share and resources. There are many other laboratories competing in the molecular and genetic testing segment of the market including academic institutions and specialized laboratories, with new competitors expected to enter the market.

Sample Processing

The primary competitive factors in the centrifuge market include speed, ease of use, size and cost. The major competitors in the bench-top centrifuge market include the Drucker Company, LW Scientific and Hettich. With the industry trend moving away from bulky floor models to smaller, faster, more efficient bench-top models, we are facing competition from a number of U.S. and foreign competitors. We believe our products are differentiated due to innovative design, single push button operation, small footprint, quiet cycle and rapid separation time.

Intellectual Property

We have a long history of innovation. Our diversified core technology spans through a number of scientific endeavors, which include IVD, immuno-assay, rare cell separation technology, specimen processing and handling, pattern recognition and image analysis. Our commercial success depends on our ability to protect and maintain our proprietary rights. We protect our proprietary technology by filing various patent applications domestically and in

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many foreign countries. We own various active patents and have pending patent applications for our technologies domestically and internationally.

These patents cover developments in imaging analysis and processing software, blood processing, digital refractometers, fluidics, centrifuges, immuno-PCR processes, rare cell separation, automated slide handling and disposable urinalysis products sold by us. In addition, we have various patents related to products of our sample processing business segment. These patents have various useful lives ranging from five to 15 years with expirations ranging from one to 15 years. Our core IVD patents in the United States will start to expire in 2017.

For our molecular platform technologies, we have a license for three patents from the University of California that cover the use of nucleic acid labeled antibodies in immunoassays. In addition, we filed a patent on the improved use of DNA labeled antibodies and obtained patents covering NADiA and our bubble isolation technology methods. In October of 2010, Iris Molecular Diagnostic was granted a patent by the European Patent Office, which covers important aspects of the NADiA technology. This patent will be effective until November of 2024 and will be in force in numerous countries throughout Europe. In addition to this patent, Iris Molecular Diagnostics has also applied for numerous other patents throughout the world to obtain additional patent protection for our NADiA platform.

We have trade secrets, unpatented technology and proprietary knowledge about the sale, promotion, operation, development and manufacturing of our products. We have confidentiality agreements with our employees and consultants to protect these rights.

We claim copyright in our source code and have a patent in the ways in which our software displays images, and have filed copyright registrations with the United States Copyright Office. We also own various federally registered trademarks, including IRIS , iChem , iQ , NADiA , ThermoBrite , and StatSpin. We own other registered and unregistered trademarks, and have certain trademark rights in foreign jurisdictions. We intend to aggressively protect our patents, copyrights and trademarks.

Third-Party Payor Reimbursements

Successful sales of our products in the United States and other countries will depend on the availability of reimbursement from third-party payors such as private insurance plans, managed care organizations, and Medicare and Medicaid. In the United States, the American Medical Association assigns to diagnostics tests specific Current Procedural Terminology, or CPT, codes, which are necessary for reimbursement of those tests. Once the CPT code is established, the Center for Medicare and Medicaid Services, or CMS, establish reimbursement payment levels and coverage rules under Medicaid and Medicare, and private payors establish rates and coverage rules independently. Our urinalysis tests are covered by established CPT codes and are therefore approved for reimbursement by Medicare and Medicaid as well as most third-party payors.

However, we may develop tests in the future that do not relate to previously established CPT codes and we may need to obtain new CPT codes in order to obtain reimbursement. Reimbursement by a third-party payor depends on a number of factors, including the level of demand by health care providers and the payor s determination that the use of the product represents a clinical advance or a reduction in the overall cost of treatment. In addition, in the United States, third-party payors and state governments routinely review reimbursement coverage for diagnostic tests considering budgetary constraints vis-à-vis demonstrated clinical efficacy. Also, outside of the United States, health care reimbursement systems vary from country to country, and to the extent we sell our products outside the United States, we may not be able to obtain adequate reimbursement coverage, if any, for our products.

Arista accepts assignment for Medicare patients as payment in full on Medicare covered tests. Reimbursement under the Medicare program for most of our laboratory testing is subject to the national Medicare clinical laboratory fee

schedule. Payment under the clinical laboratory fee schedule has been limited from year-to-year by Congressional action such as imposition of national limitation amounts and freezes on the otherwise applicable annual consumer price index, or CPI, updates. Reimbursement from third-party insurance companies varies widely, even from a single payor in a given geographic area and population. Insurance companies often follow the lead of Medicare in determining whether a clinical laboratory test is covered and reimbursable. The amount that we are able to be reimbursed from private health insurers is based on several factors, including the type of health insurance

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coverage (for example, health maintenance organization or preferred provider organization), whether the services are considered to be in network or out of network by the health insurance provider, and the amount of any co-pays or deductibles for which the patient is responsible.

Depending on our billing arrangement with each third party payor and applicable law, we are often obligated to bill in the specific manner prescribed by the various payors, such as private insurance companies, managed care companies, governmental payors such as Medicare and Medicaid, physicians, hospitals and employer groups, each of which may have different billing requirements. Additionally, the audit requirements we must meet to ensure compliance with applicable laws and regulations as well as our internal compliance policies and procedures add further complexity to the billing process.

Government Regulations

Our products are subject to stringent government regulation in the United States and other countries. These laws and regulations govern product testing, manufacture, labeling, storage, record keeping, distribution, sale, marketing, advertising and promotion. The regulatory process can be lengthy, expensive and uncertain, and securing clearances or approvals often requires the submission of extensive testing and other supporting information. If we do not comply with regulatory requirements, we may be subject to fines, recall or seizure of products, total or partial suspension of production, withdrawal of existing product approvals or clearances, refusal to approve or clear new applications or notices and criminal prosecution. Further, any change in existing federal, state or foreign laws or regulations, or in their interpretation or enforcement, or the enactment of any additional laws or regulations, could affect us both materially and adversely.

In the United States, the FDA regulates medical devices under the Food, Drug, and Cosmetics Act. Before a new medical device can be commercially introduced in the United States, the manufacturer usually must obtain FDA clearance by filing a pre-market notification, or PMA, under Section 510(k) of the Food, Drug, and Cosmetics Act, or obtain FDA approval by filing a PMA application. The PMA application process is significantly more complex, expensive, time-consuming and uncertain than the 510(k) notification process. To date, we have cleared all of our regulated products with the FDA through the 510(k) notification process. We cannot guarantee that we will be able to use the 510(k) notification process for future products. Furthermore, FDA clearance of a 510(k) notification or approval of a PMA application is subject to continual review, and the subsequent discovery of previously unknown facts may result in restrictions on a product s marketing or withdrawal of the product from the market.

We are also required to register as a medical device manufacturer with the FDA and comply with FDA regulations concerning good manufacturing practices for medical devices, or GMP Standards. In 1997, the FDA expanded the scope of the GMP Standards with new regulations requiring medical device manufacturers to maintain control procedures for the design process, component purchases and instrument servicing (Quality System Regulation or QSR). The FDA biannually inspects our manufacturing facilities for compliance with GMP Standards. We believe that we are in substantial compliance with the QSR.

Labeling, advertising and promotional activities for medical devices are subject to scrutiny by the FDA and, in certain instances, by the U.S. Federal Trade Commission. The FDA also enforces statutory and policy prohibitions against promoting or marketing medical devices for unapproved uses.

Clinical laboratory diagnostic tests that are developed and validated by a laboratory for use in testing that the laboratory performs itself are called home brew or laboratory developed tests (LDT). Like many other laboratories, Arista has developed and validated certain home brew tests. The FDA maintains that it has authority to regulate the development and use of home brews as diagnostic medical devices, but historically has elected not to exercise its enforcement authority with regard to most home brew tests. The FDA indicated in June 2010 that it is considering

exercising greater oversight of laboratory developed tests using a risk-based approach, but has taken no further action at this time.

Many states have also enacted statutory provisions regulating medical devices. The State of California s requirements in this area, in particular, are extensive, and require registration with the state and compliance with regulations identical to the GMP Standards established by the FDA. While the impact of such laws and regulations

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has not been significant to date, it is possible that future developments in this area could affect us both materially and adversely.

In addition to domestic regulation of medical devices, many of our products are subject to regulations in foreign jurisdictions. The requirements for the sale of medical devices in foreign markets vary widely from country to country, ranging from simple product registrations to detailed submissions similar to those required by the FDA. Our business strategy includes expanding the geographic distribution of these and other products, and we cannot guarantee that we will be able to secure the necessary clearances and approvals in the relevant foreign jurisdictions. Furthermore, the regulations in certain foreign jurisdictions continue to develop and we cannot be sure that new laws or regulations will not have a material adverse effect on our existing business or future plans. Among other things, CE Mark certifications are required for the sale of many products in certain international markets such as the European Community. We have secured CE Mark certification for our existing product lines.

We have obtained European Norm ISO 13485:2003 certification for our manufacturing facilities and are subject to surveillance by European notified bodies. In addition, our Chatsworth manufacturing facility is certified to ISO 13485:2003 with the Canadian Medical Devices Conformity Assessment System, or CMDCAS, which is the regulatory protocol used by Health Canada to certify manufacturers.

Our products are also subject to regulation by the U.S. Department of Commerce export controls, primarily as they relate to the associated computers and peripherals. We have not experienced any material difficulties in obtaining necessary export licenses to date.

Federal and State Clinical Laboratory Certification and Licensing

Our Arista laboratory, similar to almost all clinical laboratories operating in the United States, is required to maintain federal certification pursuant to the Clinical Laboratory Improvement Act, as amended, commonly known, together with its implementing regulations, as CLIA. The CLIA regulations have established three levels of regulatory control based on test complexity: waived, moderate complexity and high complexity. Arista has staffed and organized its San Diego, California clinical laboratory facility to meet the standards for a high complexity test laboratory, the most rigorous level of quality. CLIA imposes requirements relating to test processes, personnel qualifications, facilities and equipment, record keeping, quality assurance and participation in proficiency testing, which involve comparing the results of testing of specimens that have been specifically prepared for our laboratory to the known values of those specimens. Compliance with CLIA standards is verified by periodic on-site inspections. CLIA accreditation is maintained through regular inspections by the College of American Pathologists, and therefore, subject to its requirements and evaluation. The CLIA requirements also apply as a condition for participation for clinical laboratories in the Medicare and Medicaid programs.

CLIA does not preempt state laws that are more stringent than federal law. Therefore, similar requirements also apply to our laboratory under California s clinical laboratory licensure laws. The State of California Department of Health and Human Services Laboratory Field Services enforces the state s requirements to apply for and maintain licensure, CLIA certification, and proficiency testing. Our facilities have been inspected by these authorities and have been issued licenses to manufacture medical devices and provide laboratory diagnostic services in California. These licenses must be renewed every year. The State of California could prohibit our provision of laboratory services if we failed to maintain these licenses. Sanctions for failure to meet these certification, accreditation and licensure requirements may include suspension, limitation or revocation of certification, accreditation or licensure, civil penalties, criminal penalties, injunctive actions, and the imposition of plans of correction to remedy deficiencies. If a laboratory s CLIA certificate or California license is revoked or suspended, the laboratory must then cease performing testing, until licensure is reinstated.

Antifraud Laws/Overpayments.

Federal Medicare/Medicaid laws apply a wide array of fraud and abuse provisions to laboratories that participate in these programs. These laws include the federal False Claims Act, and prohibit, among other things: the submission of false claims or false information to government programs; deceptive or fraudulent conduct; and the provision and billing for excessive or unnecessary services. Federal law also prohibits fraud on private sector health insurers. Penalties for violating these laws may include exclusion from participation in the Medicare/Medicaid

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programs, asset forfeitures, civil penalties and criminal penalties. If an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from $6,000 to $11,000 for each separate false claim. While there are many potential bases for liability under the federal False Claims Act, such liability primarily arises when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. Submitting a claim or failing to repay an overpayment with reckless disregard or deliberate ignorance of its validity could result in substantial civil liability. Exclusion from the Medicare and Medicaid programs is mandatory for certain offenses, and regulators also have the authority to impose permissive exclusions from Medicare and Medicaid programs in response to a wide range of less serious misconduct. In addition, the CMS may suspend Medicare payments to any provider it believes has engaged in fraudulent billing practices. Because the financial consequences to a laboratory of exclusion from participation in federal health care payment programs would typically be devastating, fear of such exclusion has been a motivating factor in the settlement of many fraud investigations.

California law extends similar penalties beyond Medicare to punish laboratories engaged in conduct which defrauds the Medi-Cal program, private insurers or patients. California law also denies Medi-Cal enrollment to any provider that has entered into a settlement in lieu of conviction for fraud or abuse in any government program and further provides that a provider under investigation by certain governmental agencies for fraud or abuse will be subject to a temporary suspension from Medi-Cal pending investigation.

Independent of fraud allegations, Medicare and Medicaid programs and private payors may also retroactively determine that certain payments for services must be repaid due to failure of a laboratory to satisfy applicable payor requirements.

Federal and California Self-Referral Restrictions.

A federal self-referral law, commonly referred to as the Stark law, prohibits Medicare payments for laboratory tests referred by physicians who, personally or through a family member, have ownership interests in or compensation arrangements with the testing laboratory. Sanctions for violations of the self-referral prohibitions include denial of payment, refunds, civil money penalties of up to $15,000 for each service billed in violation of the prohibitions and exclusion from the Medicare program. In addition, claims submitted in violation of the Stark Law may also give rise to liability under the federal False Claims Act and its whistleblower provisions. Several states, including California, have enacted legislation that prohibits physician self-referral arrangements and/or requires physicians to disclose to their patients any financial interest they may have with a healthcare provider when referring patients to that provider. Some of these statutes, including California s, cover all patients and are not limited to beneficiaries of Medicare, Medicaid or other federal healthcare programs. Possible sanctions for violating state physician self-referral laws vary, but may include loss of license and civil and criminal sanctions.

Anti-Kickback Laws

Existing federal laws governing Medicare and Medicaid, and other similar state laws, impose a variety of broadly described restrictions on financial relationships among healthcare providers, including clinical laboratories. The Medicare/Medicaid antikickback statute prohibits laboratories from paying for patient or specimen referrals for testing paid for by Medicare or Medicaid. Violation of the Medicare/Medicaid antikickback statute can result in criminal penalties pursuant to the U.S. sentencing guidelines, civil monetary penalties of $50,000 per violation plus treble damages, and exclusion from Medicare and Medicaid participation. The OIG has criticized a number of additional business practices in the clinical laboratory industry as potentially implicating the antikickback statute, including providing phlebotomy staff to clients who perform clerical or other functions for the client which are not solely related to the collection or processing of laboratory specimens, providing computers or fax machines to clients which are not used exclusively in connection with performance of the laboratory s work, the lease of space in a physician s office for

rent which exceeds the fair rental value of such space, certain acquisition agreements where the sellers may make referrals to the buyer after the sale and various other compensation relationships between laboratories and entities from which they receive referrals, or to which they make referrals, if such relationships are intended to induce referrals. In addition, the OIG has indicated that discounts given by

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laboratories to clients concerning their private pay patients and/or HMO patients must not be intended to induce a client to refer Medicare or Medicaid patients to the laboratory.

Health Insurance Portability and Accountability Act and HITECH Act

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, protects the security and privacy of individually identifiable health information. HIPAA standards govern the conduct of certain electronic transmission of health care information and to protect the security and privacy of individually identifiable health information maintained or transmitted by health care providers. These standards include:

1) The Standards for Electronic Transactions establishes standards for common health care transactions such as claims information, plan eligibility, and payment information. It also establishes standards for the use of electronic signatures, unique identifiers for providers, employers, health plans, and individuals.

2) The Standards for Privacy of Individually Identifiable Information restricts the use and disclosure of certain individually identifiable health information. The HIPAA privacy and security regulations establish a uniform federal floor and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing patient/private health information (PHI). As a result, we are required to comply with both HIPAA privacy regulations and varying state privacy and security laws, which include physical and electronic safeguard requirements. These laws contain significant fines and other penalties for wrongful use or disclosure of PHI.

The federal Health Information Technology for Economic and Clinical Health Act, or HITECH, enacted in February 2009, strengthens and expands the HIPAA privacy and security rules and its restrictions on use and disclosure of PHI. HITECH includes, but is not limited to, prohibitions on exchanging patient identifiable health information for remuneration, restrictions on marketing to individuals and obligations to agree to provide individuals an accounting of virtually all disclosures of their health information. Violation of HITECH may result in penalties ranging from $100 $50,000 per violation depending upon the violation category, subject to a $1.5 million cap for multiple violations of an identical requirement or prohibition in a calendar year.

Other Regulatory Requirements

Our laboratory is subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood and bone marrow samples and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste. Historically, our costs associated with handling and disposal of such wastes have not been material.

The Occupational Safety and Health Administration, or OSHA, has established extensive requirements relating to workplace safety for healthcare employers, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

Summary of Revenues by Product Line

	Year Ended December 31,		
	2010	**2009**	**2008**

	($ in thousands)					
Revenues						
IDD instruments	$ 32,083	30%	$ 26,018	28%	$ 35,128	37%
IDD consumables and service	61,112	57%	52,213	56%	46,643	49%
Sample Processing instruments and supplies	14,408	13%	14,335	16%	13,731	14%
Personalized Medicine services	69	0%		0%		0%
Total revenues	$ 107,672	100%	$ 92,566	100%	$ 95,502	100%

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See Note 19 to the Consolidated Financial Statements, Segment and Geographic Information, for financial information regarding our operating segments and geographic areas.

Backlog

We did not have a material amount of backlog as of December 31, 2010. Our products usually ship within 30 to 60 days of receipt of sales orders. We do not believe that backlog is necessarily indicative of sales for any succeeding period.

Employees

At March 1, 2011, we had 377 full-time employees, including 329 in the United States and 48 internationally. We also use outside consultants and part-time and temporary employees in production, administration, marketing, research and development and engineering. None of our employees are covered by collective bargaining agreements. We consider our relations with our employees to be satisfactory.

Corporate Information

We incorporated in California in 1979 and reincorporated in Delaware in 1987. We currently have ten facilities, three in California, one in Massachusetts, one in Marburg, Germany, and sales offices in France, Germany, the United Kingdom, Japan and Hong Kong.

Available Information

We make available our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, along with any related amendments and supplements on our website as soon as reasonably practicable after we electronically file or furnish such materials with or to the Securities and Exchange Commission, or the SEC. These reports are available, free of charge, at www.proiris.com. Our website and the information contained in it and connected to it do not constitute part of this annual report or any other report we file with, or furnish, to the SEC.

Item 1A. ***Risk Factors***

We have identified the following additional risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment.

Risks Related to Our Business

Adverse conditions in the global economy and disruption of financial markets could negatively impact our customers and therefore our results of operations.

An economic downturn in the businesses or geographic areas in which we sell our products could reduce demand for these products and result in a decrease in sales volume that could have a negative impact on our results of operations. Volatility and disruption of financial markets could limit our customers ability to obtain adequate financing or credit to purchase and pay for our products in a timely manner, or to maintain operations, and result in a decrease in sales volume that could have a negative impact on our results of operations.

In the past few years, we have faced adverse macro economic forces, which have impacted our selling markets and the credit markets of our customers. At this point the impact from these forces are relatively mild, but in the future we may face the following challenges: deferrals of purchases due to decreases in capital budgets of our customers, delays in the purchasing cycle due to greater scrutiny of deals and increased internal competition for limited capital dollars, and a significant increase in requests for quotes for operating leases. The aforementioned

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factors may lead to a decrease in revenue, an increase of deferred revenue, or could lead to installment cash collection.

Our success depends largely on the continued acceptance of our iQ and iChem product lines.

Our current strategy assumes that our instrument platforms will be adopted by a large number of end-users. We have invested and continue to invest a substantial amount of our resources in promotion and marketing of the iQ and iChem product lines in order to increase their market penetration, expand sales into new geographic areas and enhance and expand the system features. Failure of our instrument operating platforms to achieve and maintain a significant market presence, or the failure to successfully implement our promotion and marketing strategy, will have a material adverse effect on our financial condition and results of operations.

If we fail to obtain, or experience significant delays in obtaining, regulatory clearances or approvals for our products or product enhancements, our ability to commercially distribute and market our products could suffer.

Our products are subject to rigorous regulation by the U.S. Food and Drug Administration, or FDA, and numerous other Federal, state and foreign governmental authorities. Our failure to comply with such regulations could lead to the imposition of injunctions, suspensions or loss of regulatory clearances or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities are possible. The process of obtaining regulatory authorizations to market a medical device, particularly from the FDA, can be costly and time consuming, and there can be no assurance that such authorizations will be granted on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new class II or III medical device only after the device has received 510(k) clearance or is the subject of an approved pre-market approval, or PMA, application. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The PMA approval process is more costly, lengthy and uncertain than the 510(k) clearance process. Introduction to the market of products we develop that require regulatory clearance or approval may be delayed. In addition, because we cannot assure you that any new products or any product enhancements we develop will be subject to the shorter 510(k) clearance process, the regulatory approval process for our products or product enhancements may take significantly longer than anticipated. There is no assurance that the FDA will not require that a new product or product enhancement go through the lengthy and expensive PMA approval process. To date, all of our class II or III products have been cleared through the 510(k) process. We anticipate several of our molecular diagnostics products under development will be reviewed by the FDA under a PMA filing.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent, and to the extent we continue to market and sell our products in foreign countries, we will be subject to rigorous regulation in the future. In such circumstances, we would rely significantly on our distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

There is no assurance that U.S. or foreign regulatory bodies will ultimately allow market clearance or approval for these products. Regulatory delays or failures to obtain clearances and approvals could disrupt our business, harm our reputation and adversely affect our sales.

Modifications to our products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until clearances are obtained.

Modifications to our products may require new 510(k) clearances or PMA approvals or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new

approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) is necessary. However, the FDA can review a manufacturer s decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and

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may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a PMA approval. Where we determine that modifications to our products require a new 510(k) clearance or PMA approval, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. For those products sold in the European Union, we must notify our E.U. competent authority by means of revision of our technical file, if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Any failure to introduce our future products and systems successfully into the market could adversely affect our business.

Our commercial success depends on the timely development of new products that are needed for future growth. These new products depend on our success in demonstrating technical feasibility and achieving cost targets and functionality demanded by the market. Even if our product development efforts are successful and even if the requisite regulatory approvals are obtained, our products may not gain market acceptance among physicians, healthcare payers and the medical community. A number of additional factors may limit the market acceptance of products including the following:

rate of adoption by healthcare providers;

rate of our products acceptance by the target market;

timing of market entry relative to competitive products;

availability of alternative products;

price of our product relative to alternative products;

availability of third-party reimbursement; and

extent of marketing efforts by us and third-party distributors or agents retained by us.

Failure to achieve clinical acceptance will adversely impact our financial condition and results of operations.

We face intense competition and our failure to compete effectively, particularly against larger, more established companies will cause our business to suffer.

The healthcare industry is highly competitive. We compete in this industry based primarily on product performance, service and price. Many of our competitors have substantially greater financial, technical and human resources than we do, and may also have substantially greater experience in developing products, obtaining regulatory approvals and manufacturing and marketing and distribution. As a result, they may be better able to compete for market share, even in areas in which our products may be superior. Further, our competitive position could be harmed by the

establishment of patent protection by our competitors or other companies. The existing competitors or other companies may succeed in developing technologies and products that are more effective or affordable than those being developed by us or that would render our technology and products less competitive or obsolete. If we are unable to effectively compete in our market, our financial condition and results of operation will materially suffer.

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If we choose to acquire new businesses, products or technologies, we may experience difficulty in the identification or integration of any such acquisition, and our business may suffer.

Our commercial success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and technologies. Accordingly, we may in the future pursue the acquisition of complementary businesses, products or technologies instead of developing them ourselves. We do not know if we will be able to identify or complete any acquisitions, or whether we will be able to successfully integrate any acquired business, product or technology or retain key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. Moreover, we may fail to realize the anticipated benefits of any acquisition. If we are unable to integrate any acquired businesses, products or technologies effectively, our business will suffer. In addition, any amortization or charges resulting from acquisitions could adversely affect our operating results.

If we do not establish strategic partnerships to commercialize our products under development, we will have to undertake commercialization efforts on our own, which could be costly and may ultimately be unsuccessful.

We may selectively partner with other companies to obtain assistance for the commercialization of certain of our products. We may enter into strategic partnerships with third parties to develop and commercialize some of our products that are intended for larger markets or that otherwise require a large, specialized sales and marketing organization, and we may enter into strategic partnerships for products that are targeted beyond our selected target markets. We face competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. If we are unable to negotiate strategic partnerships for our products under development, we may be forced to reduce the scope of our sales or marketing activities or undertake commercialization activities at our own expense. In addition, we will bear the entire risk related to the commercialization of these products. If we elect to increase our expenditures to fund commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all.

Changes in reimbursement fees or lower than anticipated reimbursement for diagnostics tests could reduce demand and the price at which we can sell our products.

Successful sales of our products will depend on the availability of adequate coverage and reimbursement from third-party payors both domestically and internationally. Healthcare providers that purchase medical devices generally rely on third-party payors to reimburse all or part of the costs and fees associated with the procedures performed with these devices. Both public and private insurance coverage and reimbursement plans are central to new product acceptance. Customers are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products.

To date, reimbursement has generally been available for the diagnostic tests that our products perform. However, all third-party coverage and reimbursement programs, whether government funded or insured commercially, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling healthcare costs through limitations on covered items and services, prospective reimbursement and capitation programs, group purchasing, redesign of benefits, second opinions required prior to major surgery, careful review of bills, encouragement of healthier lifestyles and exploration of more cost-effective methods of delivering healthcare. These types of programs and legislative changes to coverage and reimbursement policies could potentially limit the amount which healthcare providers may be willing to pay for medical devices.

We believe that future coverage and reimbursement may be subject to increased restrictions both in the United States and in international markets. Third-party reimbursement and coverage for our products may not be available or adequate in either the United States or international markets. Future legislation, regulation, coverage or reimbursement policies of third-party payors may adversely affect the demand for our existing products or our products currently under development, and limit our ability to sell our products on a profitable basis.

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If we fail to meet changing demands of technology, we may not continue to be able to compete successfully with our competitors.

The market for our products and systems is characterized by rapid technological advances, changes in customer requirements, and frequent new product introductions and enhancements. Our future success depends upon our ability to introduce new products that keep pace with technological developments, enhance current product lines and respond to evolving customer requirements. Our failure to meet these demands could result in a loss of our market share and competitiveness and could harm our revenues and results of operations.

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.

Our success depends significantly on our ability to protect our intellectual property and proprietary technologies. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

Our pending U.S. and foreign patent applications may not issue as patents or may not issue in a form that will be advantageous to us. Any patents we have obtained or do obtain may be challenged by re-examination, opposition or other administrative proceeding, or may be challenged in litigation, and such challenges could result in a determination that the patent is invalid. In addition, competitors may be able to design alternative methods or devices that avoid infringement of our patents. To the extent our intellectual property protection offers inadequate protection, or is found to be invalid, we are exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

In addition to pursuing patents on our technology, we have taken steps to protect our intellectual property and proprietary technology by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate.

In the event a competitor infringes upon our patents or other intellectual property rights, litigation to enforce our intellectual property rights or to defend our patents against challenge, even if successful, could be expensive and time consuming and could require significant time and attention from our management. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against challenges from others. Additionally, our earliest patents begin to expire in 2010, which may allow our competitors, many of which may have substantial resources and have made substantial investments in competing technologies, to develop technologies previously protected by these expiring patents

The medical device industry is characterized by patent litigation, and we could become subject to litigation that could be costly, result in the diversion of our management s time and efforts, require us to pay damages or prevent us from selling our products.

The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether or not a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Our competitors may assert that they own U.S. or foreign patents containing claims that cover our products, their components or the methods we employ in the manufacture or use of our products. In addition, we may become a party to an interference proceeding declared by the U.S. Patent and Trademark Office to determine the priority of invention. Because patent applications can take many years to issue and in many instances at least 18 months to publish, there may be applications now pending of

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which we are unaware, which may later result in issued patents that contain claims that cover our products. There could also be existing patents, of which we are unaware, that contain claims that cover one or more components of our products. As the number of participants in our industry increases, the possibility of patent infringement claims against us also increases.

Any interference proceeding, litigation or other assertion of claims against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of our management from our core business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to be infringing, we could be required to pay substantial damages and/or royalties and could be prevented from selling our products unless we could obtain a license or were able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may be unable to make, use, sell or otherwise commercialize one or more of our products. In addition, if we are found to willfully infringe, we could be required to pay treble damages, among other penalties.

We operate in a consolidating industry that creates barriers to our market penetration.

The healthcare industry in recent years has been characterized by consolidation. Large hospital chains and groups of affiliated hospitals prefer to negotiate comprehensive supply contracts for all of their supply needs at once. Large suppliers can often equip an entire laboratory and offer hospital chains and groups one-stop shopping for laboratory instruments, supplies and service. Larger suppliers also typically offer pricing discounts to their customers based on the customer s total volume of business with the supplier. The convenience and discounts offered by these large suppliers are administrative and financial incentives that we do not offer our customers. Our plans for further market penetration in the urinalysis market and penetration into the hematology and molecular diagnostics markets will depend in part on our ability to overcome these and any new barriers resulting from continued consolidation in the healthcare industry. The failure to overcome such barriers could have a material adverse effect on our financial condition or results of operation.

Changes in government regulation of the healthcare industry could adversely affect our business.

Federal and state legislative proposals are periodically introduced or proposed that would affect major changes in the healthcare system, nationally, at the state level or both. Future legislation, regulation or payment policies of Medicare, Medicaid, private health insurance plans, health maintenance organizations and other third-party payors could adversely affect the demand for our current or future products and our ability to sell our products on a profitable basis. Moreover, healthcare legislation is an area of extensive and dynamic change, and we cannot predict future legislative changes in the healthcare field or their impact on our industry or our business. Any impairment in our ability to market our products could have a material adverse effect on our financial condition and results of operation.

We may not be able to fully realize deferred tax assets.

As of December 31, 2010, we have deferred tax assets of approximately $5.8 million resulting from the differences between the financial statement and the tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Management believes it is more likely than not that the deferred tax assets will be realized through future taxable income or alternative tax strategies. However, the net deferred tax assets could be reduced in the near term if management s estimates of taxable income during the carryforward period are not realized or are significantly reduced or alternative tax strategies are not available. Although we believe that the deferred tax asset is recoverable, there is no assurance that we will be able to generate taxable income in the years that the differences reverse.

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We rely on independent and some single-source suppliers for key components of our instruments. Any delay or disruption in the supply of components may prevent us from selling our products and negatively impact our operations.

Certain of our components are obtained from outside vendors, and the loss or breakdown of our relationships with these outside vendors could subject us to substantial delays in the delivery of our products to our customers. Furthermore, certain key components of our instruments and consumables are manufactured by only one supplier. Because this supplier is the only vendor with which we have a relationship for a particular component, we may be unable to sell products this supplier becomes unwilling or unable to deliver components meeting our specifications. Our inability to sell products to meet delivery schedules could have a material adverse effect on our reputation in the industry, as well as our financial condition and results of operation.

We may not be able to maintain contracts with Group Purchasing Organizations, or GPOs.

A significant portion of our domestic sales are affected through agreements with participant members of GPOs. A failure to renew one or more GPO contracts may have a material effect on our domestic sales.

Our success depends on our ability to attract, retain and motivate management and other skilled employees.

Our success depends in significant part upon the continued services of key management and skilled personnel. Competition for qualified personnel is intense and there are a limited number of people with knowledge of, and experience in, our industry. We do not have employment agreements with most of our key employees nor maintain life insurance policies on them. The loss of key personnel, especially without advance notice, or our inability to hire or retain qualified personnel, could have a material adverse effect on our ability to maintain our technological edge and ultimately our financial condition and results of operations. We cannot guarantee that we will continue to retain our key management and skilled personnel, or that we will be able to attract, assimilate and retain other highly qualified personnel in the future.

The expense and potential unavailability of insurance coverage for us, our customers or our products may have an adverse effect on our financial position and results of operations.

Our products are used to gather information for medical decisions and diagnosis. Accordingly, a defect in the design or manufacture of our products, or a failure of our products to perform for the use that we specify, could have a material adverse effect on our reputation in the industry and subject us to claims of liability arising from inaccurate or allegedly inaccurate test results. Misuse of our products by a technician that results in inaccurate or allegedly inaccurate test results could similarly subject us to claims of liability. While we currently have insurance for our business, property, directors and officers, and products, insurance is increasingly costly and the scope of coverage is more narrow, and we may be required to assume more risk in the future. If we are subject to claims or suffer a loss or damage in excess of our insurance coverage, we will be required to cover the amounts in excess of our insurance limits. If we are subject to claims or suffer a loss or damage that is outside of our insurance coverage, we may incur significant costs associated with loss or damage that would have a material adverse effect on our financial position and results of operations. Furthermore, any claims made on our insurance policies may impact our ability to obtain or maintain insurance coverage at reasonable costs, or at all. We do not have the financial resources to self-insure, and it is unlikely that we will have these financial resources in the foreseeable future.

We have product liability insurance that covers our products and business operation, but we may need to increase and expand this coverage commensurate with our expanding business.

Any product liability claims brought against us, with or without merit, could result in:

substantial costs of related litigation or regulatory action;

substantial monetary penalties or awards;

decreased demand for our products;

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reduced revenue or market penetration;

injury to our reputation;

an inability to establish new strategic relationships;

increased product liability insurance rates; and

an inability to secure continuing coverage.

Furthermore, any impairment of our reputation could have a material adverse effect on our sales and prospects for future business. We have not received any indication that our insurance carrier will not renew our product liability insurance at or near current premiums; however, we cannot guarantee that this will continue to be the case. In addition, any failure to comply with FDA regulations governing manufacturing practices could hamper our ability to defend against product liability lawsuits.

Our facilities are located near known earthquake fault zones, and the occurrence of an earthquake or other catastrophic disaster could damage our facilities and equipment, which could cause us to curtail or cease operations.

Instruments for our diagnostics division are manufactured in a single facility in the San Fernando Valley, Arista Molecular is located in San Diego, CA and Iris Molecular Diagnostics is located in Carlsbad, California, all of which are near known earthquake fault zones and, therefore, are vulnerable to damage from earthquakes. We are also vulnerable to damage from other types of disasters, such as power loss, fire, and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We currently may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial condition and prospects.

If we are unable to manage our growth, our results could suffer.

We have been experiencing significant growth in the scope of our operations. This growth has placed significant demands on our management, as well as operational resources. In order to achieve our business objectives, we anticipate that we will need to continue to grow. If this growth occurs, it will continue to place additional significant demands on our management and our operational resources, and will require that we continue to develop and improve our operational, financial and other internal controls both in the United States and internationally. In particular, if our growth continues, it will increase the challenges in implementing appropriate control systems, expanding our sales and marketing infrastructure capabilities, providing adequate training and supervision to maintain high quality standards, and preserving our cultural values. The main challenge associated with our growth has been the management of our expenses. Our inability to scale our business appropriately or otherwise adapt to growth, could cause our business, financial condition and results of operations to suffer.

To market and sell our products, we depend on third-party distributors, and they may not be successful.

We currently depend on third-party distributors to sell our IVD products in most markets outside of the United States as well as all Iris Sample Processing products. The quarterly and yearly demand from distributors depends on factors such as buying patterns, cash availability, currency exchange rates, etc. If these distributors are not successful in

selling our products, we may be unable to increase or maintain our level of revenue. Our distributors may not commit the necessary resources to market and sell our products. If current or future distributors do not perform adequately or if we are unable to locate distributors in particular geographic areas, we may not realize revenue growth internationally. Over the long term, we intend to grow our business internationally, and to do so we will need to attract additional distributors to expand into new territories or to sell new products.

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Our sales in international markets are subject to a variety of laws and political and economic risks that may adversely impact our sales and results of operations in certain regions.

Our ability to capitalize on growth in international markets is subject to risks including:

changes in currency exchange rates that impact the price to international consumers;

the burdens of complying with a variety of foreign laws and regulations;

unexpected changes in local regulatory requirements; and

the difficulties associated with promoting products in unfamiliar cultures;

subject to general, political and economic risks in connection with our international sales operations, including:

political instability;

changes in diplomatic and trade relationships; and

general economic fluctuations in specific countries or markets.

Any of the above mentioned factors could adversely affect our sales and results of operations in international markets.

We are subject to currency fluctuations.

We are exposed to certain foreign currency risks in international markets where we source, produce, market or sell product. Some consumable chemistry strips and spare parts for our installed base of chemistry analyzers are sourced from ARKRAY, a supplier located in Kyoto, Japan. Our purchases from this supplier are denominated in Japanese Yen and any fluctuations in the U.S. Dollar/Japanese Yen exchange rate could result in increased costs for these key components. We anticipate the exposure to the Japanese Yen to decrease as we no longer source instruments from Japan. For consumables, the exposure will gradually decrease as we begin replacing AX-4280 machines with our iChemVELOCITY domestically, contingent upon us attaining FDA clearance.

We are also exposed to currency fluctuations with respect to the exportation of our products. With the exception of France, Germany and the United Kingdom where our operations are denominated in Euros and British Pounds, most of our sales are denominated in U.S. Dollars. Accordingly, any fluctuation in the exchange rate between the U.S. Dollar and the currency of the country with which we are exporting products could also affect our ability to sell internationally. To the extent we conduct operations abroad in non-local currency, fluctuations in the exchange rate between functional currency of those operations and the local currency may lead to significant increased costs and could negatively impact our profitability.

Risks Related to Our Laboratory Business

We have a limited operating history in our laboratory business and have experienced operating losses making it difficult to evaluate whether we will operate profitably.

Arista, formerly AlliedPath, was established in March 2008 and commenced operation of its clinical laboratory business in November of 2008. Arista began testing services in August 2009 upon receiving its CLIA license. Because Arista only recently commenced its principal operations, we do not have a meaningful historical record of sales and

revenues nor an established business track record. While we believe that we have the opportunity to be successful in the specialized, cancer-focused molecular diagnostics segment of the clinical laboratory industry, there can be no assurance that we will be successful in accomplishing our business initiatives, or that we will be able to achieve any significant levels of revenues or net income, from the sale of Arista s products and services.

Unanticipated problems, expenses and delays are frequently encountered in increasing marketing and sales efforts and developing new products, especially in the current stages of our business. Our ability to continue to

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successfully develop, produce and sell our products and to generate significant operating revenues will depend on our ability to, among other matters, successfully market and sell our services to medical providers.

Changes in healthcare laws, regulations or policies, or third-party payor policies could affect coverage or reimbursement for our specialized laboratory tests and adversely affect our financial results.

Government payors, including Medicare and Medicaid and third-party payors, such as insurance companies, have historically implemented measures to control the cost, utilization and delivery of healthcare services. In the past, Congress has implemented changes to healthcare laws, which have resulted in amendments to the Medicare fee schedule, new administrative requirements and added costs for healthcare service providers. In the future, additional Congressional intervention may results in further reductions of reimbursement rates and additional costs to operate clinical laboratories like Arista. These changes have, and in the future may have, adversely affected coverage for the specialized tests that we offer.

Any changes to the current healthcare laws and regulations may necessitate a change to our business model.

The clinical laboratory industry is a highly regulated industry. Our clinical laboratory is subject to numerous federal and state laws and regulations, including with respect to anti-kickback, billing and claims, privacy, security and electronic transactions (including HIPAA), and the regulation of laboratories, including CLIA. While we believe that we are currently in compliance with all of these laws and regulations, they may be, or the way the courts interpret these laws and regulations, may be, changed or amended at anytime. Any such changes may necessitate a change to our business model or result in increased costs of compliance, which may adversely affect our business, prospects and the results of our operations.

U.S. healthcare reform legislation may result in significant changes, and our business could be adversely impacted if we fail to adapt.

Government oversight of and attention to the healthcare industry in the United States is significant and increasing. In March 2010, U.S. federal legislation was enacted to reform healthcare. The legislation provides for reductions in the Medicare clinical laboratory fee schedule of 1.75% for five years beginning in 2011 and also includes a productivity adjustment that reduces the CPI market basket update beginning in 2011. The legislation imposes an excise tax on the seller for the sale of certain medical devices in the United States, including those purchased and used by laboratories, beginning in 2013. The legislation establishes the Independent Payment Advisory Board, which will be responsible, beginning in 2014, annually to submit proposals aimed at reducing Medicare cost growth while preserving quality. These proposals automatically will be implemented unless Congress enacts alternative proposals that achieve the same savings targets. Further, the legislation calls for a Center for Medicare and Medicaid Innovation that will examine alternative payment methodologies and conduct demonstration programs. The legislation provides for extensive health insurance reforms, including the elimination of pre-existing condition exclusions and other limitations on coverage, fixed percentages on medical loss ratios, expansion in Medicaid and other programs, employer mandates, individual mandates, creation of state and regional health insurance exchanges, and tax subsidies for individuals to help cover the cost of individual insurance coverage. The legislation also permits the establishment of accountable care organizations, a new healthcare delivery model. While the ultimate impact of the legislation on the healthcare industry is unknown, it is likely to be extensive and may result in significant change. Our failure to adapt to these changes could have a material adverse effect on our business.

We may incur substantial penalties including fines or possible debarment from Medicare or Medicaid if we violate certain government payor laws and regulations.

We are required to comply with a number of different government regulations relating to billing practices and relationships with physicians and hospitals. Violations of these regulations can lead to civil penalties, criminal liability and possible disbarment from participation in Medicare and Medicaid. If we were ever determined to be in violation of these regulations our relationship with many of our clients would be severely affected and we could face a material adverse effect to our financial condition or results of operations.

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Our laboratory business may be harmed if we are unable to comply with certain healthcare related laws and regulations, including the Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Improvement Amendments of 1988 (collectively, CLIA).

Arista is regulated and licensed by a number of federal and state statutes and regulations, including CLIA. If a clinical laboratory fails to comply with CLIA requirement or state healthcare and licensing laws and regulations, it can have its license suspended or revoked. At this time we believe that we comply with these laws and regulations. If these laws or regulations are amended, we may have to change the manner in which we conduct our laboratory business, which could lead to additional expenses in running our laboratory business. If we are unable to properly comply with these changes, we could have our licenses suspended or revoked, which would adversely affect our laboratory operations.

We face possible litigation, penalties and damage to our reputation with payors, physicians and patients if we are unable to properly protect customer-related information.

Arista receives a variety of personal information about our customers. We believe that we have a strong security system in place and that we comply with all federal and state laws and regulations relating to the protection of personal information (including HIPAA). However, if there was a breach of our security system or we inadvertently released protected patient information, we face possible monetary fines, litigation and damage to our reputation.

We face possible litigation, penalties and medical malpractice for errors in laboratory testing results.

Arista utilizes the best practices in quality assurance to avoid and prevent errors in test results. However, if the laboratory produces an inadvertent erroneous result, this can adversely affect a patient s diagnosis and treatment and may result in medical malpractice litigation for which fines and damages can be substantial and could exceed the limits of our medical malpractice insurance coverage, causing substantial damage to the our financial condition.

The nature of the testing performed in our laboratory is complex and often depends on our ability to obtain specialized reagents from a sole source provider. Any disruption of supply, or discontinuance of products by a sole source may severely impact Arista s ability to provide testing services.

Many of the tests performed by our laboratory are not commercially available and are laboratory-developed tests (LDT). Often LDTs rely on specialized reagents or products that are supplied by a single source. Any disruption in our ability to obtain these specialized reagents may result in the laboratory s inability to continue to perform such testing, or may require that the laboratory change its testing protocol to perform the testing using a different reagent. In either case, this can severely affect our financial performance or harm our relationship with our customers.

Federal, state and CLIA regulations define certain personnel standards that our laboratory must adhere to, including education, background and experience requirements. Our ability to attract, hire and maintain critical personnel may limit the testing our laboratory can perform.

The laboratory relies on its ability to attract, hire and keep certain critical personnel such as Medical Directors and Pathologists, and licensed laboratory personnel who have appropriate advanced degrees and years of experience necessary to satisfy CLIA requirements and certain state requirements. If the laboratory cannot attract, hire and maintain these critical employees, then the laboratory s ability to perform certain testing may be severely limited. This can damage the laboratory s reputation with its customers and severely impact our financial performance.

The laboratory industry is highly competitive and many other laboratories offer the same testing that our laboratory offers. Our ability to discriminate our laboratory in a cluttered marketplace may limit our ability to attract and maintain customers and will have a material adverse effect on our financial performance.

There are many competitors currently offering the same menu of testing and in some cases a larger menu of tests than Arista. We primarily compete with large national laboratories that have significant market share and

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resources. We also compete with many other laboratories, including academic institutions and specialized laboratories, with new competitors expected to enter the market. If we fail to compete effectively, our business could be adversely affected and our revenues and profitability could be damaged. Our ability to distinguish our laboratory from our competitors is critical to our financial performance.

Discontinuation or recalls of existing testing products or failure to develop, or acquire, licenses for new or improved testing technologies could adversely affect the Company s business.

From time to time, manufacturers discontinue or recall reagents, test kits or instruments used by the Company to perform laboratory testing. Such discontinuations or recalls could adversely affect the Company s costs, testing volume and revenue.

The clinical laboratory industry is subject to changing technology and new product introductions. The Company s success in maintaining a leadership position in genomic and other advanced testing technologies will depend, in part, on its ability to develop, acquire or license new and improved technologies on favorable terms and to obtain appropriate coverage and reimbursement for these technologies. The Company may not be able to negotiate acceptable licensing arrangements and it cannot be certain that such arrangements will yield commercially successful diagnostic tests. If the Company is unable to license these testing methods at competitive rates, its research and development costs may increase as a result. In addition, if the Company is unable to license new or improved technologies to expand its esoteric testing operations, its testing methods may become outdated when compared with the Company s competition and testing volume and revenue may be materially and adversely affected.

Risks Related to Ownership of Our Common Stock

We have adopted a number of anti-takeover measures that may depress the price of our common stock.

Our stockholders rights plan, our ability to issue additional shares of preferred stock and some provisions of our certificate of incorporation and bylaws could make it more difficult for a third party to make an unsolicited takeover attempt of us. Additionally, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These anti-takeover measures may depress the price of our common stock by making it more difficult for third parties to acquire us by offering to purchase shares of our stock at a premium to its market price without approval of our board of directors. They could also have the effect of preventing changes in our management.

Our quarterly sales and operating results may fluctuate in future periods, and if we fail to meet expectations the price of our common stock may decline.

Our quarterly sales and operating results have fluctuated significantly in the past and are likely to do so in the future due to a number of factors, many of which are not within our control. If our quarterly sales or operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Factors that might cause quarterly fluctuations in our sales and operating results include the following:

- variation in demand for our products, including seasonality;
- our ability to develop, introduce, market and gain market acceptance of new products and product enhancements in a timely manner;
- our ability to manage inventories, accounts receivable and cash flows;

our ability to control costs;

the size, timing, rescheduling or cancellation of orders from consumers and distributors; and

our ability to forecast future sales and operating results and subsequently attain them.

The amount of expenses we incur depends, in part, on our expectations regarding future sales. In particular, we expect to continue incurring substantial expenses relating to the marketing and promotion of our products. Since

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many of our costs are fixed in the short term, if we have a shortfall in sales, we may be unable to reduce expenses quickly enough to avoid losses. If this occurs, we will not be profitable. Accordingly, you should not rely on quarter-to-quarter comparisons of our operating results as an indication of our future performance.

Item 1B. ***Unresolved Staff Comments.***

None.

Item 2. ***Properties.***

We lease all of our facilities. Our headquarters are located at 9158 Eton Avenue, Chatsworth, California 91311. The table below sets forth certain information regarding our leased properties as of March 1, 2011.

Location	Approximate Floor Space (Sq. Ft.)	Monthly Rent	Use
Chatsworth, CA	98,446	$ 74,725	Corporate headquarters and manufacturing (Corporate and Iris Diagnostics Division)
Westwood, MA	29,220	$ 34,967	Sample Processing division
Carlsbad, CA	14,941	$ 17,675	IRIS Molecular Diagnostic research division (Personalized Medicine)
San Diego, CA	12,716	$ 20,354	Arista Molecular laboratory and testing facility. (Personalized Medicine)
Marburg, Germany	8,539	$ 16,775	Urine chemistry strip manufacturing facility (Iris Diagnostics Division)
Marburg, Germany	4,844	$ 2,115	Urine chemistry strip manufacturing warehouse (Iris Diagnostics Division)
Marburg, Germany	953	$ 1,734	Urine chemistry strip R&D facility (Iris Diagnostics Division)
Paris, France	2,684	$ 3,117	Sales office (Iris Diagnostics Division)
Causeway Bay, HK	120	$ 1,744	Sales office (Iris Diagnostics Division)
Cologne, Germany	130	$ 2,520	Sales office (Iris Diagnostics Division)
Cambridge, UK	323	$ 1,452	Sales office (Iris Diagnostics Division)

We believe our facilities are adequate to meet our current and near-term needs.

Item 3. ***Legal Proceedings.***

From time to time, we are party to certain litigation arising in the normal course of business. Management believes that the resolution of such matters will not have a material adverse effect on our financial position, results of operations or cash flows. We are not currently involved in any litigation that requires disclosure in this report.

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PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.***

Our common stock is listed on the NASDAQ Global Market under the symbol IRIS. The closing price of our common stock on March 7, 2011 was $9.30 per share. The table below sets forth the high and low closing prices of our common stock on the NASDAQ Global Market for the periods ended:

	Price per Share	
	Low	**High**
Fiscal 2010:		
First Fiscal Quarter	$ 10.21	12.08
Second Fiscal Quarter	9.79	11.86
Third Fiscal Quarter	7.34	10.12
Fourth Fiscal Quarter	8.80	10.44
Fiscal 2009:		
First Fiscal Quarter	$ 8.60	13.33
Second Fiscal Quarter	10.03	12.94
Third Fiscal Quarter	9.50	11.81
Fourth Fiscal Quarter	9.99	12.62

As of March 7, 2011 we had approximately 1,914 holders of record of our common stock.

Dividend Policy

We have never paid any cash dividends on our common stock. We currently expect to retain any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Furthermore, we may not pay any cash dividends on the common stock without the written consent of our lender.

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FIVE-YEAR STOCK PRICE PERFORMANCE COMPARISON (1)

The following graph and table compare the cumulative total return on our common stock with the cumulative total return (including reinvested dividends) of the Standard & Poor s 500 Index (S&P 500), the NASDAQ Medical Devices, Instruments and Supplies, Manufacturers and Distributors Stocks Index and the Standard & Poor s HealthCare Equipment Index for the five years ending December 31, 2010, assuming that the relative value of the common stock and each index was $100 on December 31, 2005. Amounts below have been rounded to the nearest dollar. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

(1) This section is not soliciting material, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of IRIS International, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

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Item 6. ***Selected Financial Data.***

The following selected financial data should be read in conjunction with our consolidated financial statements. The information set forth below is not necessarily indicative of results of future operations, and should be read in conjunction with Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and notes thereto included in Item 8, Financial Statements and Supplementary Data of this Form 10-K in order to understand fully factors that may affect the comparability of the financial data presented below.

	Year Ended December 31,				
	2010	2009	2008	2007	2006
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenues	$ 107,672	$ 92,566	$ 95,502	$ 84,306	$ 72,067
Operating income	3,108	7,811	10,967	8,953	1,049
Other income	1,022	894	2,409	1,440	1,089
Net income (loss)	3,042	6,251	9,013	7,549	(175)
Basic net income (loss) per share	0.17	0.35	0.49	0.42	(0.01)
Diluted net income (loss) per share	0.17	0.35	0.48	0.40	(0.01)
Balance Sheet Data:					
Working capital	48,435	58,988	51,553	49,685	37,283
Total assets	106,609	97,790	90,638	86,390	74,317
Total debt					
Total liabilities	17,958	12,568	14,728	11,456	11,751
Stockholders equity	88,651	85,222	75,910	74,934	62,566

Our financial results for the years set forth above were impacted by the following events:

1. 2010 results include the operating losses, including acquisition related costs, of approximately $3.7 million related to our acquisition in July 2010 of Arista Molecular, Inc. In addition, we incurred $923,000 in CFO and related transition costs, $1.1 million unfavorable foreign currency fluctuation and losses and approximately $800,000 related to higher instrument cost of goods due to a price premium on our final purchase of automated chemistry analyzers from the Japanese manufacturer.

2. 2009 results include the following expenses totaling $1.1 million; an accrual of $475,000 for payroll taxes attributable to the exercise of stock options, $350,000 in start-up expenses for the initiation of direct sales operations in the UK and Germany and $250,000 for product retrofit costs related to the voluntary recall of approximately 1,565 StatSpin Express 4 Centrifuges.

3. 2008 results include the non recurring other income related to the $1.2 million net payment to us as part of the manufacturing transition rights agreement signed with IDEXX Laboratories in December 2008.

4. 2007 results include the effects of closing our Advanced Digital Imaging Research subsidiary s operations which resulted in a $163,000 write-off.

5. 2006 results include the effect of the acquisition in April 2006 of Leucadia Technologies, Inc. We recorded a $5.2 million charge for purchased in-process research and development. In addition we incurred additional research

and development expenses of $1.8 million as a result of the acquisition.

Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations.***

Overview

IRIS International, Inc. consists of three operating units in three business segments as determined in accordance with FASB ASC Topic 280, *Segment Reporting*. Our in-vitro diagnostics segment also called Iris Diagnostics Division (IDD), designs, manufactures and markets systems, consumables and supplies for urinalysis

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and body fluids. Our Personalized Medicine segment combines the research and development operations of our Iris Molecular Diagnostics and Arista Molecular, Inc. subsidiaries. Under this new segment we consolidate all operations for the development and commercialization of cancer diagnostic testing services and related products. Our Sample Processing segment markets small centrifuges and other processing equipment and accessories for rapid specimen processing, as well as, equipment for fluorescent in-situ hybridization (FISH).

Iris Diagnostics Division

Our core business is in the urinalysis market and we are the leading worldwide provider of automated urine microscopy systems, with more than 3,000 iQ microscopy analyzers shipped to date in over 50 countries. We generate revenues primarily from sales of instruments, consumables and service. Revenues from instruments include global sales of urine microscopy analyzers and sales of chemistry analyzers. In September 2008, we released our proprietary iChemVELOCITY automated urine chemistry analyzer and a fully integrated urine microscopy and urine chemistry work-cell, called the iRICELL in some international markets. We plan to commence selling the iChemVELOCITY and iRICELL in the United States contingent upon attaining clearance from the U.S. Food and Drug Administration (FDA) on our 510(k) application. Historically we sold our family of iQ analyzers integrated with an automated chemistry analyzer, the AUTION MAX AX-4280, which we have sourced from a Japanese manufacturer.

Our consumables offering includes products such as chemical reagents, urine test strips, calibrators and controls. Service revenues are derived primarily from annual service contracts purchased by our domestic customers after the initial year of sale, which is covered by product warranty, and spare parts purchased by international customers. Once the analyzers are installed, we generate recurring revenue from sales of consumables. Consumable and service revenue should continue to expand as the installed base of related instruments increases.

In the United States, France, Germany, the United Kingdom and Puerto Rico sales of our urinalysis systems are direct to the end-user through our sales force. All other international sales are through independent distributors. In January 2010, we completed the purchase from certain European distributors of assets relating to the distribution of products in the United Kingdom, Ireland and Germany. The purchased assets consisted primarily of installed instruments leased to customers and the related lease agreements and service contracts. Our incremental revenue relating to the acquired distributors businesses was $2.4 million for the year ended December 31, 2010. International sales represented 34% of consolidated revenues for the years ended December 31, 2010 and 2009. Since the majority of international sales are made through independent distributors, gross profit margin is lower than domestic sales of the same products, but we incur minimal sales and marketing costs for such sales.

Personalized Medicine

On July 28, 2010, we acquired Arista Molecular, a high complexity CLIA-certified molecular pathology laboratory offering differentiated, high value molecular diagnostic services in the rapidly growing field of personalized medicine. Pursuant to the terms of the merger agreement dated July 26, 2010, we acquired all the issued and outstanding stock for an amount in cash equal to $4.7 million less certain indebtedness existing at the closing, with an additional earn-out of up to $1.3 million subject to the achievement of specific sales and earnings targets through December 2013. We did not assume any outstanding options or warrants in connection with the acquisition. Arista will operate under the Personalized Medicine reporting segment of the consolidated financial statements.

At the time of acquisition, Arista Molecular was an early-stage laboratory with limited commercial operations. In 2010, we focused the laboratory s efforts to broaden its menu of diagnostic panels useful for the diagnosis, disease characterization, treatment and monitoring of cancer. We added testing for breast and prostate solid tumors beyond the existing lung and colorectal offering. In addition, we now offer flow cytometry for detection and monitoring of leukemia and lymphoma and FISH testing. Further, we are building the commercial infrastructure of the laboratory by

adding sales and marketing personnel. As a result, 2010 results included the dilutive impact from Arista of $3.7 million, or approximately $0.15 per share with negligible revenue. With the expansion of the test menu and sales force, we expect the revenue contribution from this segment to become more meaningful in 2011, but continue to have a dilutive impact for the year.

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Sample Processing

Our IRIS Sample Processing group markets and develops centrifuges, semi-automated DNA processing workstations and sample processing consumables. Our StatSpin® brand bench-top centrifuges are used for specimen preparation in coagulation, cytology, chemistry and urinalysis. Our worldwide markets include medical institutions, commercial laboratories, clinics, doctors offices, veterinary laboratories and research facilities. Our Sample Processing products are sold worldwide primarily through distributors and incorporated into our OEM partners products.

On November 22, 2010, we acquired the assets of a multi-purpose, bench-top instrument platform for automating highly repetitive, manual laboratory protocols for FISH (fluorescence in-situ hybridization) testing and other slide-based cytogenetic applications. The product acquisition is a natural extension to the successful ThermoBrite® DNA Hybridization System and in line with our entry into personalized medicine with emphasis on cancer diagnostics. The product prototypes and proprietary technology assets were purchased for $3.2 million in cash from BioMicro Systems, Inc. Although BioMicro Systems built and tested a working prototype, which proved the technical feasibility of the base technology, several elements of this technology platform requires continued development in order to reach salability for its stated purpose. Once development is completed, a useful life will be determined and the assets will be amortized over the useful life determined at that time.

Research and Development

We have invested significant capital to acquire technologies and to increase our investment in research and development both to sustain our technological leadership in our existing core product lines in urinalysis and sample processing and as part of our growth strategy to broaden our product pipeline into new high value platforms in hematology and molecular diagnostics. The decision to diversify into IVD market segments in which we do not presently participate has adversely affected our earnings growth over the last four years, as we have invested significantly in research and development without any corresponding revenues from new products still in development. Our investment in new product platforms, however, is of strategic importance and is necessary to position the company for significant revenue and earnings acceleration in future years. Research and development expense increased to $14.6 million, or 14% of revenue, in 2010 compared to $11.4 million, or 12% of revenue, in 2009. Of these expenditures, approximately $7.0 million and $6.0 million was invested in 2010 and 2009, respectively, in our NADiA and hematology platforms. For 2011, we anticipate that research and development expense will be approximately 14% of revenue.

The following table summarizes product technology expenditures for the periods indicated:

	2010	2009	2008
		(In thousands)	
Total product technology expenditures during year	$ 15,357	$ 12,331	$ 11,699
Less: amounts capitalized during year to software development costs as reported in the consolidated statements of cash flow	(754)	(835)	(1,178)
Less: amounts reimbursed through grants for government sponsored research and development	(41)	(85)	(164)
Research and development expense as reported in the consolidated statements of income	$ 14,562	$ 11,411	$ 10,357

Critical Accounting Policies

The preparation of financial statements and related disclosures in conformity with U.S. generally accepted accounting principles and our discussion and analysis of our financial condition and results of operations require us to make judgments, assumptions, and estimates that affect the amounts reported in our consolidated financial statements and accompanying notes. Note 2 of the Notes to Consolidated Financial Statements of this Form 10-K describes the significant accounting policies and methods used in the preparation of our consolidated financial statements. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying

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values of assets and liabilities. We regularly discuss with our audit committee the basis of our estimates. Actual results may differ from these estimates and such differences may be material.

We believe the following critical accounting policies, among others, affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Revenue recognition: IDD and Sample Processing Revenues are primarily derived from the sale of IVD instruments, sales of consumable supplies and services for IVD systems as well as sales of sample processing instruments and related supplies. Revenue is recognized once all of the following conditions have been met: (i) an authorized purchase order has been received in writing with a fixed and determinable sales price; (ii) customer credit worthiness has been established; and (iii) delivery of the product based on shipping terms.

Revenue is recorded in accordance with the provisions of FASB Accounting Standards Codification (ASC) Topic 605 Revenue Recognition , which generally require revenue earned on product sales involving multiple-elements to be allocated to each element based on the relative fair values of those elements if sold separately. Multiple elements of certain domestic product sales include IVD instruments, training, consumables and service.

Accordingly, we allocate revenue to each element in a multiple element arrangement based on the element s respective fair value, with the fair value determined by the price charged when that element is sold separately and specifically defined in a quotation or contract.

A portion of our revenues are derived from sales-type leases as we provide lease financing to certain customers that purchase our diagnostic instruments. Leases under these arrangements are classified as investment in sales-type leases. These leases typically have terms of five years. Revenue from sales-type leases is recognized when collectability of the minimum lease payments is reasonably predictable and no important uncertainties surround the amount of unreimbursable costs yet to be incurred by us as lessor under the lease. The minimum lease payments that accrue to our benefit as lessor are recorded as the gross investment in the lease. The difference between the gross investment in the lease and the sum of the present value of the minimum lease payments and unguaranteed residual value, accruing to our benefit as lessor, are recorded as unearned income.

We have certain government contracts with cancellation clauses or renewal provisions that are generally required by law, such as (i) those dependant on fiscal funding outside of a governmental unit s control; (ii) those that can be cancelled if deemed in the tax payers best interest; and (iii) those that must be renewed each fiscal year, given limitations that may exist on multi-year contracts that are imposed by statute. Under these circumstances and in accordance with the relevant accounting literature, as well as considering our historical experience, a thorough evaluation of these contracts is performed to assess whether cancellation is remote or whether exercise of the renewal option is reasonably assured.

We recognize revenues from service contracts ratably over the term of the service period, which typically ranges from twelve to sixty months. Payments for service contracts are generally received in advance. Deferred revenue represents the revenues to be recognized over the remaining term of the service contracts.

Revenue recognition: Personalized Medicine Revenues related to our Personalized Medicine segment are recorded in accordance with FASB ASC 605-10-S99-1, Revenue Recognition , when (i) the price is fixed or determinable, (ii) persuasive evidence of an arrangement exists, (iii) the service is performed and (iv) collectability of the resulting receivable is reasonably assured.

Our specialized diagnostic services are performed based on a written test requisition form and revenues are recognized once the diagnostic services have been performed, the results have been delivered to the ordering physician, the payor

has been identified and eligibility and insurance have been verified. These diagnostic services are billed to various payors, including Medicare, commercial insurance companies, other directly billed healthcare institutions such as hospitals and clinics, and individuals. We report revenues from contracted payors, including Medicare, certain insurance companies and certain healthcare institutions, based on the contractual rate, or in the case of Medicare, published fee schedules. For non-contracted payors, including certain insurance companies and individuals, we report revenues based on the amount which we expect to be collected. The difference between the amount billed and the amount expected to be collected from non-contracted payors is recorded as a contractual allowance to arrive at the reported revenues. The expected revenues from non-contracted payors are based on the

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historical collection experience of each payor or payor group, as appropriate. In each reporting period, we review our historical collection experience for non-contracted payors and adjust our expected revenues for current and subsequent periods accordingly.

Inventory valuation We value inventories at the lower of cost or market value on a first-in, first-out basis. Provision for potentially obsolete or slow-moving inventory is made based on management s analysis of inventory levels and future sales forecasts.

Goodwill and Intangible Assets Our intangible assets consist of goodwill and intangible assets with indefinite lives such as a CLIA license, which are not being amortized and intangible assets with a finite life, which are being amortized over useful lives ranging from 3 to 20 years. All intangible assets are subject to impairment tests on an annual or periodic basis. Goodwill and intangible assets with indefinite lives are evaluated in accordance with FASB ASC Topic 350, The Intangibles-Goodwill and Other , based on various analyses, including a comparison of the carrying value of the reporting unit to its estimated fair value and discounted cash flow. The analysis necessarily involves significant management judgment to evaluate the capacity of an acquired business to perform within projections. Intangible assets with a finite life are evaluated for impairment using the methodology set forth in FASB ASC Topic 360, Property, Plant and Equipment. Recoverability of these assets is assessed only when events have occurred that may give rise to a potential impairment. When a potential impairment has been identified, forecasted undiscounted net cash flows of the operations to which the asset relates are compared to the current carrying value of the long-lived assets present in that operation. If such cash flows are less than such carrying amounts, long-lived assets, including such intangibles, are written down to their respective fair values.

At December 31, 2010, we evaluated goodwill and intangible assets and determined that fair value had not decreased below carrying value and no adjustment to impair goodwill was necessary in accordance with ASC Topic 350. Substantially all of the goodwill resides in the Personalized Medicine reporting unit.

Capitalized software We capitalize certain software development costs in connection with our development of our urine analyzers in accordance with FASB ASC Topic 985, Software. We capitalize software development costs once technological feasibility is established and such costs are determined to be recoverable against future revenues.

Capitalized software development costs are expensed to cost of sales over periods of up to five years. When, in management s estimate, future revenues will not be sufficient to recover previously capitalized software development costs, we will expense such items as additional software development amortization in the period the impairment is identified. Such adjustments are normally attributable to changes in market conditions or product quality considerations.

Income taxes We account for income taxes in accordance with FASB ASC Topic 740, Income Taxes, which requires recognition of deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined based on the differences between the financial statement and the tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense represents the tax payable for the period and the change during the period in deferred tax assets and liabilities.

We account for uncertain tax positions in accordance with FASB ASC Topic 740-10 which prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return and also provides guidance on various related matters such as derecognition, interest, penalties and disclosures required. We recognize interest and penalties, if any, related to unrecognized tax benefits in income tax expense.

Stock based compensation The Company accounts for stock based compensation under FASB ASC Topic 718, *Compensation- Stock Compensation* (ASC 718) which requires compensation costs related to share-based transactions, including employee stock options, to be recognized in the financial statements based on fair value.

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Results of Operations

The following table summarizes results of operations data for the periods indicated. The percentages in the table are based on total revenues with the exceptions of percentages for gross profit margins, which are computed on related revenue, and percentages for income taxes, which are computed based on the relationship of income taxes to pre-tax income.

	Years Ended December 31,					
	2010		2009		2008	
	(In thousands)					
Revenues						
IDD instruments	$ 32,083	**30%**	$ 26,018	**28%**	$ 35,128	**37%**
IDD consumables and service	61,112	**57%**	52,213	**56%**	46,643	**49%**
Sample Processing instruments and supplies	14,408	**13%**	14,335	**16%**	13,731	**14%**
Personalized Medicine services	69	**0%**		**0%**		**0%**
Total revenues	107,672	**100%**	92,566	**100%**	95,502	**100%**
Gross Profit(1)						
IDD instruments	10,846	**34%**	9,240	**36%**	15,523	**44%**
IDD consumable and service	36,623	**60%**	32,055	**61%**	26,648	**57%**
Sample Processing instruments and supplies	7,789	**54%**	7,370	**51%**	6,868	**50%**
Personalized Medicine services	(372)			**0%**		**0%**
Gross profit	54,886	**51%**	48,665	**53%**	49,039	**51%**
Operating expenses						
Marketing and selling	19,829	**18%**	16,122	**17%**	15,706	**16%**
General and administrative	17,387	**16%**	13,321	**14%**	12,009	**13%**
Research and development, net	14,562	**14%**	11,411	**12%**	10,357	**11%**
Total operating expenses	51,778	**48%**	40,854	**44%**	38,072	**40%**
Operating income	3,108	**3%**	7,811	**9%**	10,967	**11%**
Other income	1,022		894		2,409	
Income before provision for income taxes	4,130	**4%**	8,705	**9%**	13,376	**14%**
Provision for income taxes(2)	1,088	**26%**	2,454	**28%**	4,363	**33%**
Net income	$ 3,042	**3%**	$ 6,251	**7%**	$ 9,013	**9%**

(1) Gross profit margin percentages are based on the related sales of each category.

(2) Income tax percentage is computed based on the relationship of income taxes to pre-tax income.

Comparison of Year Ended December 31, 2010 to 2009

Consolidated revenues for the year ended December 31, 2010 increased 16% over the prior year to $107.7 million from $92.6 million in 2009. International revenues accounted for approximately 34% of consolidated revenue in 2010 compared to 33% in 2009. Revenues in the IDD urinalysis segment increased 19% to $93.2 million in 2010, from $78.2 million in the prior year. The current year IDD revenues include approximately $2.4 million incremental revenue related to the acquisition of European distributor operations earlier in the year. Sales of IDD instruments increased 23% to $32.1 million from $26.0 million in the prior year. The continued increase in IDD instrument sales is primarily driven by strong domestic sales versus a year ago period due to new marketing and sales initiatives and improvement in the U.S. medical capital equipment market environment.

IDD consumables and service increased during the year to $61.1 million from $52.2 million, an increase of 17% over 2009, primarily due to the larger installed base of instruments both domestically and internationally and

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increased sales of iChemVELOCITY test strips due to increased placements of our iChemVELOCITY analyzer in the international market.

Revenues derived from Sample Processing instruments and supplies modestly increased to $14.4 million, a 1% increase over 2009 revenues of $14.3 million. Revenues were favorably impacted by the following factors: a) continued strong sales of our ThermoBrite line of instruments, b) introduction of our new Cytofuge 12 instrument and c) OvaTube consumables. Revenues were unfavorably impacted by the completion of the transition of the separator consumable business to IDEXX. We will receive royalties on these units beginning in 2014.

Personalized Medicine revenues in 2010 totaled $69,000.

Consolidated gross profit margin decreased to 51% in 2010 compared to 53% in 2009, primarily the result of higher cost of goods due to a price premium on our final purchase of automated chemistry analyzers from Arkray, the negative effect of foreign currency fluctuations, and increased service costs relating to our start up of direct commercial operations in Europe.

The gross profit margin of our IDD instruments was 34% in 2010 compared to 36% in 2009. Instrument gross margins were impacted by increased costs from foreign-sourced products due to the weakening of the U.S. dollar, in particular on our purchases of AUTION MAX AX-4280 chemistry analyzers which are denominated in Japanese Yen, partially offset by higher instrument volume and a greater mix of direct domestic sales versus international sales through distributors.

The gross profit margin of our IDD consumables and service decreased to 60% in 2010 compared to 61% in 2009, primarily the result of increased costs of foreign-sourced products due to the weaker U.S. dollar, increased service costs related to iChemVELOCITY and an increase in service costs related to our direct commercial operations in the United Kingdom and Germany, partially offset by the higher margins due to manufacturing efficiencies resulting from higher volume in consumables sold.

Gross profit margin for our Sample Processing instruments and supplies segment increased to 54% in 2010 from 51% in 2009 as a result of product mix, favorable purchase price discounts, and cost reduction initiatives such as lean manufacturing.

Marketing and selling expenses totaled $19.8 million, or 18% of revenues, in 2010 as compared to $16.1 million, or 17% of revenues in 2009. The increase primarily results from $1.3 million of expenses related to Arista s operations, additional personnel and related costs of $2.0 million related primarily to our direct operations in the United Kingdom and Germany, travel and entertainment, excluding UK and Germany of $192,000 as well as higher commissions and GPO fees of $210,000.

General and administrative expenses increased to $17.4 million, or 16% of revenues, in 2010, from $13.3 million or 14% of revenues in 2009. This increase primarily relates to $1.9 million in acquisition and operating expenses relating to Arista, $923,000 of CFO severance and related transition expenses, $796,000 of additional personnel and related costs in information technology, quality assurance and regulatory affairs and $455,000 of recruiting and relocation expenses.

Research and development expense increased to $14.6 million, or 14% of revenues, in 2010 from $11.4 million, or 12% of revenues in 2009. The increase was primarily attributable to $1.2 million in research materials, consulting, clinical development expenses, $1.6 million in personnel and related costs and other expenses of approximately $400,000 as we continue to invest heavily in research and development for the continued development of our diagnostics product pipeline, including our NADiA platform and 3GEMS urinalysis and hematology programs.

Interest income during 2010 amounted to $1.1 million, a $266,000 increase over 2009 mainly due to a higher cash balance through part of 2010 as well as an increase in in-house sales-type leases.

Income tax expense during the year amounted to 26.4% of pre-tax income as compared to 28% during the prior year. The decrease in the income tax provision resulted from an increase in research and development tax credits due to an increase in qualifying research and development expenses. We have federal and state research and development and other tax credit carryovers totaling $3.6 million.

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Comparison of Year Ended December 31, 2009 to 2008

Revenues for the year ended December 31, 2009 decreased by 3% over the prior year to $92.6 million from $95.5 million in 2008. International revenues accounted for approximately 33% of consolidated revenue for both 2009 and 2008. Revenues in the IDD urinalysis segment decreased 4% to $78.2 million in 2009, from $81.8 million in the prior year. Sales of IDD instruments decreased 26% to $26.0 million from $35.1 million in the prior year as a result of a significant shortage of capital in the global markets.

Sales of IDD consumables and service increased during the year to $52.2 million from $46.6 million, an increase of 12% over 2008, primarily due to the larger installed base of instruments and the success of converting expiring warranty agreements to service agreements.

Revenues derived from Sample Processing instruments and supplies increased to $14.3 million, a 4% increase over 2008 revenues of $13.7 million. This growth was driven by continued strong sales of our new Express 4 centrifuge along with an increase in orders from our international distributors, most notably our distributor in the United Kingdom.

Overall gross profit margins increased to 53% in 2009 compared to 51% in 2008. The gross profit margin of our IDD instruments was 36% in 2009 versus 44% in 2008.

As compared to the prior year period, IDD instrument gross margin in 2009 was impacted by $368,000 in sales promotions, $1,193,000 in costs related to the iChemVELOCITY, which included Velocity retrofit costs of $373,000, volume and other costs of $320,000, severance costs of approximately $40,000 with an offset of a reduction in employee bonuses of $76,000. In addition, our gross margins on IDD instruments were negatively impacted by foreign currency fluctuations on our purchases of AUTION MAX AX-4280 chemistry analyzers which are denominated in Japanese Yen.

The gross margin of our IDD consumables and service increased to 61% during 2009 compared to 57% in 2008, respectively, and included $501,000 in international sales discounts. The consumable gross margin improvement primarily resulted from economies of scale generated by our increasing volume of urine microscopy consumables and spare parts, improved efficiencies in our domestic service business, a reduction in unfavorable foreign currency fluctuations on purchases of dry chemistry strips denominated in Japanese Yen and a reduction of employee bonuses of $160,000.

Gross profit margin for our Sample Processing instruments and supplies segment increased to 51% in 2009 from 50% in 2008 as a result of product mix, price increases and reduced headcount related to the reduction in force in the second quarter of 2009. In addition, the gross margin was affected by our Sample Processing division s voluntarily recall of approximately 1,565 centrifuges, requiring a $250,000 accrual to cover the product retrofit costs during the fourth quarter of 2009.

Marketing and selling expenses totaled $16.1 million, or 17% of revenues, in 2009 as compared to $15.7 million, or 16% of revenues in 2008. The increase includes personnel and related costs of $967,000, partially offset by lower commission and GPO fees of $319,000, travel and entertainment of $198,000, a reduction of employee bonuses of $134,000 and professional fees of $151,000. Our $967,000 increase in personnel and related costs includes $350,000 in start-up expenses relating to the initiation of direct sales in the United Kingdom and Germany.

General and administrative expenses increased to $13.3 million, or 14% of revenues, in 2009, from $12.0 million or 13% of revenues in 2008. This increase includes additional personnel and related costs of $619,000, stock-based compensation expense of $804,000, professional fees of $108,000, board compensation expense of $64,000, an

accrual of $475,000 for payroll taxes attributable to the exercise of stock options, other corporate related expenses of approximately $300,000 and an offset of $541,000 for a reduction in employee bonuses.

Research and development expense increased to $11.4 million, or 12% of revenues, in 2009 from $10.4 million, or 11% of revenues in 2008. The increase includes research materials, consulting, clinical development expenses and software capitalization of $1.1 million as we continue to invest heavily in research and development for the continued development of our diagnostics product pipeline, including our NADiA platform

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and 3GEMS urinalysis and hematology programs. These costs were partially offset by a reduction in employee bonuses of $431,000.

Interest income during 2009 amounted to $857,000, a $323,000 decrease over 2008 mainly due to a lower interest rate environment on our cash balances, and in spite of a higher cash balance.

Income tax expense during the year amounted to 28% of pre-tax income as compared to 33% during the prior year. The decrease in the income tax provision resulted from an increase in research and development tax credits. At December 31, 2009 we had federal and state research and development and other tax credit carryovers totaling $5.3 million.

Contractual Obligations and Commercial Commitments

The following table aggregates our expected minimum contractual obligations and commitments subsequent to December 31, 2010:

Contractual Obligations	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
			(In thousands)*		
Operating lease commitments	$ 9,390	$ 2,358	$ 4,200	$ 2,718	$ 114

* Not included in the table above are normal recurring accounts payable or accrued expenses which are presented on the accompanying consolidated financial statements.

Off-Balance Sheet Arrangements

At December 31, 2010 and 2009, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

Liquidity and Capital Resources

Our primary source of liquidity is cash from operations, which depends heavily on sales of our IDD instruments, consumables and service, as well as sales of sample processing instruments and supplies. At December 31, 2010, our cash and cash equivalents amounted to $25.5 million compared to $34.3 million at December 31, 2009.

In the past few years, we have faced adverse macro economic forces, which have impacted our selling markets and the credit markets of our customers. At this point the impact from these forces are relatively mild, but in the future we may face the following challenges: deferrals of purchases due to decreases in capital budgets of our customers, delays in the purchasing cycle due to greater scrutiny of deals and increased internal competition for limited capital dollars, and a significant increase in requests for quotes for operating leases. The aforementioned factors may lead to a decrease in revenue, an increase of deferred revenue, or could lead to installment cash collection.

Operating Cash Flows. Cash provided by operations for the year ended December 31, 2010 was $8.8 million, which included net income of $3.0 million, a decrease in inventory of $0.5 million, an increase in operating liabilities of $3.6 million, depreciation and amortization of $4.2 million and stock based compensation of $4.2 million. Cash provided by operations was offset by an increase in accounts receivable of $3.1 million, an increase in investment in sales-type leases of $2.8 million and an increase in prepaid expenses and other assets of $0.8 million.

The number of days sales in accounts receivable remained at 70 days at the end of 2010 compared to the prior year end. The number of days sales in accounts receivable varies and extends due to extended payment terms for our international customers and the granting of an increased volume of extended payment terms for certain customers of our instrument sales and instrument, consumables and service mix.

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Our cash flow has been favorably affected by tax credit carryforwards. As of December 31, 2010, we had federal and state tax credit carryforwards of approximately $666,000 and $2.9 million, respectively. We continue to realize tax deductions from the exercise of certain stock options. During the year ended December 31, 2010, we realized tax deductions of approximately $201,000 relating to this item. During the year ended December 31, 2010, we paid federal and state taxes of $1.7 million and $820,000, respectively.

Investing Activities. Cash used in investing activities totaled $13.9 million in 2010 primarily as the result of the acquisition of Arista of $4.6 million, an increase in the purchase of assets from a European distributor of $0.7 million, an acquisition of product technology totaling $3.3 million, an increase in the purchase of property and equipment of $4.6 million and an increase in software development costs capitalized of $0.8 million.

Financing Activities. Cash used in financing activities totaled $3.2 million in 2010, which was related primarily to repurchase of common stock.

We currently have a credit facility with a commercial bank consisting of a $6.5 million revolving line of credit for working capital and a $10.0 million line of credit for acquisitions and product opportunities. The credit facility has variable interest rates, which will change from time to time based on changes to either the LIBOR rate or the lender s prime rate. As of December 31, 2010, there were no borrowings under the new credit facility. We are subject to certain financial and non-financial covenants under the credit facility with the bank and as of December 31, 2010, we were in compliance with these covenants.

In August 2010, the Company s board of directors authorized a share repurchase and retirement plan of up to $10 million of the Company s common stock over a 12-month period. During the year ended December 31, 2010, the Company repurchased 330,454 shares of common stock at an average price per share of approximately $9.10, for an aggregate amount of approximately $3.0 million.

In 2008, our board of directors authorized two stock repurchase plans, which resulted in our purchase of an aggregate of 983,579 shares of our common stock for approximately $11.9 million during 2008, and an additional 250,800 shares of our common stock for approximately $2.5 million during 2009.

We believe that our current cash on hand, together with cash generated from operations and cash available under the credit facility with the bank will be sufficient to fund normal operations for the foreseeable future. However, additional funding may be required to fund expansion of our business. There is no assurance that such funding will be available on terms acceptable to us.

Recent Accounting Pronouncements

In December 2010, the FASB issued Accounting Standards Update (ASU) ASU 2010-29, *Business Combinations-Disclosure of Supplementary Pro Forma Information*, which specifies that if a public entity presents comparative financial statements, the entity should disclose revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only.

ASU 2010-29 is effective on a prospective basis for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010 with early adoption permitted. We are currently evaluating both the timing and the impact of the adoption of the ASU on our consolidated financial statements.

In July 2010, the FASB issued ASU 2010-20, *Disclosures about the Credit Quality of Financing Receivables and the Allowance for Credit Losses* which amends ASC Topic 310, *Receivables*. ASU 2010-20 requires disclosures about the nature of the credit risk in an entity s financing receivables, how that risk is incorporated into the allowance for credit losses, and the reasons for any changes in the allowance. Disclosure is required to be disaggregated, primarily at the level at which an entity calculates its allowance for credit losses.

ASU 2010-20 is applicable to both private and public companies, and will affect any entity that has financing receivables on its balance sheet, not including short-term trade accounts receivable. Public entities must apply the disclosure requirements applicable to period-end balances beginning with the first interim or annual reporting period ending on or after December 15, 2010 (December 31, 2010 for a calendar year-end entity). The adoption of this guidance resulted in additional disclosures (see Note 7 in the Notes to Consolidated Financial Statements) but did not have an impact on our consolidated financial statements.

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In October 2009, the FASB issued Accounting Standards Update ASU 2009-14, *Certain Revenue Arrangements That Include Software Elements*, now codified under FASB ASC Topic 985, *Software*. ASU 2009-14, removes tangible products from the scope of software revenue guidance and provides guidance on determining whether software deliverables in an arrangement that includes a tangible product are covered by the scope of the software revenue guidance. ASU 2009-14 is to be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with early adoption permitted. We are currently evaluating both the timing and the impact of the adoption of the ASU on our consolidated financial statements.

In October 2009, the FASB issued Accounting Standards Update (ASU) 2009-13, *Multiple-Deliverable Revenue Arrangements*, which amends ASC Topic 605, *Revenue Recognition*, to require companies to allocate revenue in multiple-element arrangements based on an element s estimated selling price if vendor-specific or other third-party evidence of value is not available. ASU 2009-13 is effective for fiscal years beginning on or after June 15, 2010. Earlier application is permitted. The adoption of ASU 2009-13 did not have a material impact on our consolidated financial statements.

In December 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-28 *When to Perform Step 2 of the Goodwill Impairment Test for Reporting Units with Zero or Negative Carrying Amounts.* This update provides amendments to ASC Topic 350 Intangibles, Goodwill and Other that requires an entity to perform Step 2 impairment test even if a reporting unit has zero or negative carrying amount. Step 1 tests whether the carrying amount of a reporting unit exceeds its fair value. Previously reporting units with zero or negative carrying value passed Step 1 because the fair value was generally greater than zero. Step 2 requires impairment testing and impairment valuation be calculated in between annual tests if an event or circumstances indicate that it is more likely than not that goodwill has been impaired. ASU 2010-28 is effective beginning January 1, 2011. As a result of this standard, goodwill impairments may be reported sooner than under current practice. We do not expect ASU 2010-28 to have a material impact on our financial statements.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk.***

Market Risk

Our business is exposed to various market risks, including changes in interest rates and foreign currency exchange rates. Market risk is the potential loss arising from adverse changes in market rates and prices, such as interest rates and foreign currency exchange rates. We do not invest in derivatives, foreign currency forward contracts or other financial instruments for trading or speculative purposes. We had no debt at December 31, 2010, thus were not subject to market risk for changes in interest rates on debt obligations. We are subject to market risk for changes in interest rates on our short-term investment portfolio. We invest our excess cash in certificates of deposit and the market value of these investments fluctuate based on changes in interest rates.

Foreign Currencies

We conduct business in certain foreign markets, primarily in the European Union and Asia. Our primary exposure to foreign currency risk relates to investments in foreign subsidiaries that transact business in a functional currency other than the U.S. Dollar, primarily the Euro. We are also subject to certain foreign currency risks in the importation of goods from Japan and as a result of commercial operations in Europe and Asia. Our purchases from a major Japanese IVD supplier are denominated in Japanese Yen. These components represent a significant portion of our material costs, but our Yen exposure should decrease with the discontinuation of Japanese-sourced instruments beginning in January 2011. All of our sales are denominated in U.S. Dollars with the exception of France and Germany, where sales are denominated in Euros and the United Kingdom, where sales are denominated in British Pounds. Fluctuations in the U.S. Dollar exchange rate for Japanese Yen and Euros could result in increased costs for our key components

and increased costs for commercial operations in Europe.

To mitigate the potential impact of adverse fluctuations in the U.S. Dollar exchange rate for these currencies, we have periodically purchased foreign currency forward contracts in the past for Euros and Japanese Yen. During the years ended December 31, 2009 and 2010, we did not enter into any such contracts, and no such contracts existed at December 31, 2010.

Item 8. ***Financial Statements and Supplementary Data.***

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Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders of IRIS International, Inc.
Chatsworth, California

We have audited the accompanying consolidated balance sheets of IRIS International, Inc. s as of December 31, 2010 and 2009 and the related consolidated statements of operations, shareholders equity, cash flows and other comprehensive income for each of the three years in the period ended December 31, 2010. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of IRIS International, Inc. at December 31, 2010 and 2009, and the results of its operations, cash flows and its other comprehensive income for each of the three years in the period ended December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), IRIS International Inc. s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 16, 2011, expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Los Angeles, California
March 16, 2011

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of IRIS International, Inc.
Chatsworth, California

We have audited IRIS International, Inc. s internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). IRIS International, Inc. s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management s Report on Internal Control over Financial Reporting . Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, IRIS International, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of IRIS International Inc. as of December 31, 2010 and 2009, and the related consolidated statements of operations, shareholders equity, cash flows and other comprehensive income for each of the three years in the period ended December 31, 2010 and our report dated March 16, 2011 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Los Angeles, California

March 16, 2011

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IRIS INTERNATIONAL, INC.

CONSOLIDATED BALANCE SHEETS

	At December 31,	
	2010	2009
	(In thousands, except per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,531	$ 34,253
Accounts receivable, net of allowance for doubtful accounts and sales returns of $453 and $417 at December 31, 2010 and 2009, respectively	20,733	17,715
Inventories	10,310	10,866
Prepaid expenses and other current assets	1,661	1,045
Investment in sales-type leases, current portion	3,578	3,397
Deferred tax asset	3,135	4,238
Total current assets	64,948	71,514
Property and equipment, net of accumulated depreciation of $14,491 and $11,713 at December 31, 2010 and 2009, respectively	12,035	9,667
Goodwill	3,957	2,450
Intangible assets, net of accumulated amortization of $529 and $336 at December 31, 2010 and 2009, respectively	9,345	1,454
Software development costs, net of accumulated amortization of $4,226 and $3,365 at December 31, 2010 and 2009, respectively	2,637	2,534
Deferred tax asset	2,615	1,898
Investment in sales-type leases, non-current portion	10,002	7,441
Other assets	1,070	832
Total assets	$ 106,609	$ 97,790
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 5,795	$ 4,479
Accrued expenses	7,513	5,761
Deferred service contract revenue, current portion	3,205	2,286
Total current liabilities	16,513	12,526
Deferred service contract revenue, non-current portion	71	42
Other long term liabilities	1,374	
Total liabilities	17,958	12,568
Commitments and contingencies		
Stockholders equity:		
Common stock, $0.01 par value		

Authorized: 50 million shares; Issued and outstanding: 17,791 shares and 18,111 shares at December 31, 2010 and 2009, respectively	178	181
Preferred Stock, $0.01 par value; Authorized 1.0 million shares: Callable Series C shares issued and outstanding: none		
Additional paid-in capital	89,703	87,692
Other comprehensive income	140	560
Accumulated deficit	(1,370)	(3,211)
Total stockholders equity	88,651	85,222
Total liabilities and stockholders equity	$ 106,609	$ 97,790

The accompanying notes are an integral part of these consolidated financial statements.

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IRIS INTERNATIONAL, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,		
	2010	2009	2008
	(in thousands, except per share data)		
Revenues			
IDD instruments	$ 32,083	$ 26,018	$ 35,128
IDD consumables and service	61,112	52,213	46,643
Sample processing instruments and supplies	14,408	14,335	13,731
Personalized medicine services	69		
Total revenues	107,672	92,566	95,502
Cost of Revenue			
IDD instruments	21,237	16,778	19,605
IDD consumables and service	24,489	20,158	19,995
Sample processing instruments and supplies	6,619	6,965	6,863
Personalized medicine services	441		
Total cost of revenue	52,786	43,901	46,463
Gross profit	54,886	48,665	49,039
Marketing and selling	19,829	16,122	15,706
General and administrative	17,387	13,321	12,009
Research and development, net	14,562	11,411	10,357
Total operating expenses	51,778	40,854	38,072
Operating income	3,108	7,811	10,967
Other income (expense):			
Interest income	1,123	857	1,180
Interest expense	(10)	(21)	(11)
Manufacturing transition rights			1,232
Foreign currency transaction (loss) gain and other	(91)	58	8
Income before provision for income taxes	4,130	8,705	13,376
Provision for income taxes	1,088	2,454	4,363
Net income	$ 3,042	$ 6,251	$ 9,013
Net income per share basic	$ 0.17	$ 0.35	$ 0.49
Net income per share diluted	$ 0.17	$ 0.35	$ 0.48

Weighted average common shares outstanding	basic	17,903	17,727	18,246
Weighted average common shares outstanding	diluted	18,019	17,874	18,728

The accompanying notes are an integral part of these consolidated financial statements.

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IRIS INTERNATIONAL, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Common Stock Shares*	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
			(In thousands)			
Balance, January 1, 2008	18,601	$ 186	$ 84,289	$ 345	$ (9,886)	$ 74,934
Common stock issued on exercise of options	369	4	1,808			1,812
Restricted stock grants to employees	119	1	(1)			
Tax benefit from stock option exercises			760			760
Translation adjustment, net of tax				70		70
Stock based compensation expense			2,467			2,467
Purchase of common stock for retirement	(1,051)	(11)	(5,655)		(7,458)	(13,124)
Settlement on restricted stock tax withholding	(2)		(22)			(22)
Net income for year					9,013	9,013
Balance, December 31, 2008	18,036	180	83,646	415	(8,331)	75,910
Common stock issued on exercise of options	221	2	1,448			1,450
Common stock issued on exercise of restricted stock units	17					
Restricted stock grants to employees	113	2	(2)			
Tax benefit from stock option exercises			416			416
Translation adjustment, net of tax				145		145
Stock based compensation expense			3,729			3,729
Cancellation of restricted stock	(9)					
Purchase of common stock for retirement	(251)	(3)	(1,366)		(1,131)	(2,500)
Settlement on restricted stock tax withholding	(16)		(179)			(179)
Net income for year					6,251	6,251
Balance, December 31, 2009	18,111	181	87,692	560	(3,211)	85,222
Common stock issued on exercise of options	22		31			31

Common stock issued on exercise of restricted stock units	10					
Restricted stock grants to employees	23					
Tax shortfall from stock option exercises			(61)			(61)
Translation adjustment, net of tax				(420)		(420)
Stock based compensation expense			4,157			4,157
Cancellation of restricted stock	(15)					
Purchase of common stock for retirement	(330)	(3)	(1,801)		(1,201)	(3,005)
Settlement on restricted stock tax withholding	(30)		(315)			(315)
Net income for year					3,042	3,042
Balance, December 31, 2010	17,791	$ 178	$ 89,703	$ 140	$ (1,370)	$ 88,651

* Shares outstanding (does not include unvested restricted stock units or vested restricted stock units which have not been settled)

The accompanying notes are an integral part of these consolidated financial statements

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IRIS INTERNATIONAL, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Cash flows from operating activities:			
Net income	$ 3,042	$ 6,251	$ 9,013
Adjustments to reconcile net income to net cash provided by operating activities:			
Loss on disposal of fixed assets	41	74	185
Loss on foreign currency remeasurement	155		
Deferred taxes	(217)	(182)	2,158
Tax benefit from stock option exercises	(99)	(416)	(760)
Depreciation and amortization	4,164	3,523	3,127
Stock based compensation	4,157	3,729	2,467
Changes in operating assets and liabilities:			
Accounts receivable	(3,062)	2,546	(4,186)
Inventories	512	(909)	(71)
Prepaid expenses and other assets	(779)	1,280	(1,890)
Investment in sales-type leases	(2,790)	(1,677)	112
Accounts payable	1,100	(1,820)	2,010
Accrued expenses	1,593	(713)	762
Deferred service contract revenue	938	373	500
Net cash provided by operating activities	8,755	12,059	13,427
Cash flows from investing activities:			
Acquisition of business	(4,630)		
Purchase of assets from European distributor	(660)		
Acquisition of property and equipment	(4,564)	(2,905)	(3,588)
Purchase of core technology	(3,284)		
Software development costs capitalized	(754)	(835)	(1,178)
Purchase of short-term investments in marketable securities			(1,857)
Sale of short-term investments in marketable securities		2,157	
Net cash used in investing activities	(13,892)	(1,583)	(6,623)
Cash flows from financing activities:			
Issuance of common stock and warrants for cash	31	1,450	1,812
Settlement on restricted stock tax withholding	(315)	(179)	(22)
Repurchase of common stock	(3,005)	(2,500)	(13,124)
Tax benefit from stock option exercises	99	416	760
Net cash used in financing activities	(3,190)	(813)	(10,574)

Net foreign currency translation adjustments	(395)	145	70
Net increase (decrease) in cash and cash equivalents	(8,722)	9,808	(3,700)
Cash and cash equivalents at beginning of year	34,253	24,445	28,145
Cash and cash equivalents at end of year	$ 25,531	$ 34,253	$ 24,445

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IRIS INTERNATIONAL, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

	For the Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Supplemental schedule of non-cash investing and financing activities:			
During the year ended December 31, 2010, the Company disposed of property and equipment with a cost and accumulated depreciation of $666 and $625, respectively.			
Fair value of contingent consideration in connection with business acquisition completed in the year ended December 31, 2010 was $1.2 million			
During the year ended December 31, 2009, the Company disposed of property and equipment with a cost and accumulated depreciation of $122 and $48, respectively.			
During the year ended December 31, 2008, the Company disposed of property and equipment with a cost and accumulated depreciation of $957 and $773, respectively.			
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ 2,523	$ 2,729	$ 2,200
Cash paid for interest	$ 9	$ 21	$ 11

The accompanying notes are an integral part of these consolidated financial statements.

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IRIS INTERNATIONAL, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	For the Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Net income	$ 3,042	$ 6,251	$ 9,013
Foreign currency translation, net of tax	(420)	145	70
Comprehensive income	$ 2,622	$ 6,396	$ 9,083

The accompanying notes are an integral part of these consolidated financial statements.

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

IRIS International, Inc. (the Company) was incorporated in California in 1979 and reincorporated in 1987 in Delaware. IRIS International, Inc. consists of three operating units. Our in-vitro diagnostics segment also called Iris Diagnostics Division (IDD), designs, manufactures and markets systems, consumables and supplies for urinalysis and body fluids. Our Sample Processing segment markets small centrifuges and other processing equipment and accessories for rapid specimen processing, as well as, equipment for fluorescent in-situ hybridization (FISH). Our Personalized Medicine segment combines the research and development operations of our Iris Molecular Diagnostics and Arista Molecular, Inc. subsidiaries. Under this new segment we consolidate all operations for the development and commercialization of cancer diagnostic testing services and related products.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. The significant estimates in the preparation of the consolidated financial statements relate to the assessment of the carrying allowance for doubtful accounts, inventory reserves, the useful lives, fair value and recoverability of carrying value of long-lived and intangible assets, including goodwill, unearned income on sales-type leases, estimated provisions for warranty costs, laboratory information system implementations, currency hedges for foreign purchases and deferred tax assets. Actual results and outcomes may differ from management s estimates and assumptions.

Principles of Consolidation

The Company s consolidated financial statements include the accounts of IRIS International, Inc. and its wholly-owned subsidiaries. Inter-company accounts and transactions have been eliminated in the consolidated financial statements.

Cash Equivalents

The Company considers highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents. These investments are carried at cost, which approximates fair value.

Investments in Marketable Securities

In 2008, the Company adopted FASB ASC Topic 820, Fair Value Measurement and Disclosures (ASC 820), for assets and liabilities measured at fair value on a recurring basis. ASC 820 defines fair values as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a fair value hierarchy, which prioritizes the inputs used in measuring fair value into three broad levels as follows:

Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 inputs include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability and inputs that are derived principally from or corroborated by observable market data by correlation or other means.

Level 3 inputs are unobservable inputs for the asset or liability

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accounts Receivable

The Company sells predominantly to entities in the health care industry. The Company grants uncollateralized credit to customers, primarily hospitals, clinical and research laboratories, and distributors. The Company performs ongoing credit evaluations of customers financial condition before granting uncollateralized credit. Although the Company generally does not require collateral, letters of credit may be required from its customers in certain circumstances. No single customer accounts for 10% or more of the Company s consolidated revenues or 10% or more of the Company s accounts receivable at the balance sheet date.

Accounts receivable are carried at original invoice amount less allowances made for sales markdowns, returns and doubtful accounts. Accounts receivables are customer obligations due under normal trade terms. Despite the Company s stated trade terms, several customers are subject to reimbursement delays attributed to government and third party payer compliance and regulation issues. Management determines the allowance for doubtful accounts by identifying troubled accounts and by using historical experience applied to an aging of accounts. Receivables are written off when deemed uncollectible.

Inventories

Inventories are carried at the lower of cost or market on a first in, first out basis. Provision for potentially obsolete or slow-moving inventory is made based on management s analysis of inventory levels and future sales forecasts. Other inventory that is considered excess inventory is fully reserved.

Property and Equipment

Property and equipment are recorded at cost, less accumulated depreciation and amortization. Depreciation is generally computed using the straight-line method over three to seven years, the estimated useful lives of the assets. Leasehold improvements are amortized over the lesser of their useful life or the remaining term of the lease.

Goodwill and Intangible Assets

Goodwill represents the excess of the aggregate purchase price over the fair value of the tangible and identifiable intangible assets acquired by the Company. Goodwill and intangible assets with indefinite lives, which consists of a CLIA license, are not amortized. Goodwill and intangible assets with indefinite lives are subject to impairment tests on an annual basis or more frequently if facts and circumstances warrant such a review. Goodwill and intangible assets with indefinite lives are evaluated in accordance with FASB ASC Topic 350, *Intangibles- Goodwill and Other* (ASC 350), based on various analyses, including a comparison of the carrying value of the reporting unit to its estimated fair value and discounted cash flows. The analysis necessarily involves significant management judgment to evaluate the capacity of an acquired business to perform within projections. If the carrying amount of a reporting unit exceeds its fair value, the goodwill impairment test is performed to measure the amount of the impairment loss, if any. During the years ended December 31, 2010, 2009 and 2008, the Company did not record any impairment charges related to goodwill or intangible assets with indefinite lives.

Intangible assets are initially measured at their fair value, determined either by the fair value of the consideration exchanged for the intangible asset, or the estimated discounted cash flows expected to be generated from the

intangible asset. Intangible assets with a finite life, such as core technology, customer relationships and non-compete agreements are amortized on a straight-line basis over their estimated useful life, ranging from 3 to 20 years. Intangible assets with a finite life are evaluated for impairment using the methodology set forth in FASB ASC Topic 360, *Property, Plant and Equipment*. Recoverability of these assets is assessed only when events have occurred that may give rise to a potential impairment. When a potential impairment has been identified, forecasted undiscounted net cash flows of the operations to which the asset relates are compared to the current carrying value of the long-lived assets present in that operation. If such cash flows are less than such carrying amounts, long-lived

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

assets, including such intangibles, are written down to their respective fair values. During the years ended December 31, 2010, 2009 and 2008, no intangible asset impairment was recorded.

In determining the useful lives of intangible assets, the Company considers the expected use of the assets and the effects of obsolescence, demand, competition, anticipated technological advances, market influences and other economic factors. For technology based intangible assets, the Company considers the expected life cycles of products which incorporate the corresponding technology.

Goodwill and intangible assets as of December 31, 2010 consisted of the following:

	Weighted-Average Amortization Period (in Years)	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, Net
		(Dollars in thousands)		
Intangible assets subject to amortization:				
Core technology	17	$ 8,164	$ (513)	$ 7,651
Customer relationships	5	6	(1)	5
Non-compete agreements	3	100	(15)	85
Subtotal		$ 8,270	$ (529)	7,741
Intangible assets not subject to amortization:				
CLIA License				1,604
Goodwill				3,957
Total intangible assets, net				$ 13,302

Core technology as of December 31, 2010, consists of technology acquired in the acquisition of Leucadia Technologies, Inc. in 2006, technology acquired in the acquisition of AlliedPath, Inc. in July 2010 (see Note 3) and technology acquired from BioMicro Systems, Inc. in November 2010 (see (Note 3).

Goodwill and intangible assets as of December 31, 2009 consisted of the following:

	Weighted-Average Amortization Period (in	Gross Carrying	Accumulated	Intangible

	Years)	Amount	Amortization	Assets, Net
		(In thousands)		
Intangible assets subject to amortization:				
Core technology	20	$ 1,790	$ (336)	$ 1,454
Intangible assets not subject to amortization:				
Goodwill				2,450
Total				$ 3,904

Total expense related to the amortization of intangible assets was $193,000, $89,000 and $90,000 for the years ended December 31, 2010, 2009 and 2008, respectively. In-process research and development will be amortized beginning on the completion date of the acquired product and will be amortized over the estimated useful life determinable at that time.

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Total future amortization expense related to intangible assets subject to amortization at December 31, 2010 is set forth in the table below (in thousands):

2011	$ 330
2012	330
2013	316
2014	297
2015	296
Thereafter	2,888
	$ 4,457

The future amortization expense shown above does not include amortization of core technology acquired from BioMicro Systems, Inc. since a useful life has not yet been determined (see Note 3).

The change in goodwill during the year ended December 31, 2010 is comprised of the following (in thousands):

Balance at December 31, 2009	$ 2,450
Addition recorded in connection with acquisition	1,507
Balance at December 31, 2010	$ 3,957

Of the balance of goodwill and intangibles assets as of December 31, 2010, $10 million relates to the Personalized Medicine segment and $3.3 million relates to the Sample Processing segment. The entire balance of goodwill and intangible assets as of December 31, 2009 relates to the Personalized Medicine segment.

Software Development Costs

The Company capitalizes certain software development costs for new products and product enhancements once all planning, designing, coding and testing activities necessary to establish that the product can be produced to meet our design specifications are completed, and concludes capitalization when the product is ready for general release. Research and development costs relating to software development are expensed as incurred. Amortization of capitalized software development costs is provided on a product-by-product basis at the greater of the amount computed using (i) the ratio of current revenues for a product to the total of current and anticipated future revenues or (ii) the straight-line method over the remaining estimated economic life of the product up to five years.

Total software development costs capitalized totaled $754,000, $835,000 and $1,178,000 for the years ended December 31, 2010, 2009 and 2008, respectively. Amortization expense of software development costs totaled $659,000, $592,000 and $651,000 for the years ended December 31, 2010, 2009 and 2008, respectively.

Impairment of Long-Lived Assets

The Company will identify and record impairment losses for long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. There were no impairments of long-lived assets at December 31, 2010, 2009 and 2008.

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenue recognition

For products, revenue is recognized when risk of loss transfers, when persuasive evidence of an arrangement exists, the price to the buyer is fixed and determinable and collectability is reasonably assured. When a customer enters into an operating-type lease agreement, hardware revenue is recognized on a straight-line basis over the life of the lease, while the cost of the leased equipment is carried in customer leased equipment within property, plant and equipment and amortized over its estimated useful life. Under a sales-type lease agreement, hardware revenue is generally recognized at the time of shipment based on the present value of the minimum lease payments with interest income recognized over the life of the lease using the interest method. Instrument costs under a sales-type lease agreement are recognized at the time of shipment. Service revenues on maintenance contracts are recognized ratably over the life of the service agreement or as service is performed, if not under a contract. For those instrument sales that include multiple deliverables, such as instruments, training, consumables and service, the Company allocated revenue based on the relative fair values of the individual component sold separately, as determined in accordance with FASB ASC Topic 605, *Revenue Recognition.*

The Company s accounting for leases involves specific determinations under FASB ASC Topic 840 *Leases* (ASC 840), which often involve complex provisions and significant judgments. The four criteria of ASC 840 that the Company uses in the determination of a sales-type lease or operating-type lease are: (i) a review of the lease term to determine if it is equal to or greater than 75 percent of the economic life of the equipment; (ii) a review of the minimum lease payments to determine if they are equal to or greater than 90 percent of the fair market value of the equipment; (iii) a determination of whether or not the lease transfers ownership to the lessee at the end of the lease term; and (iv) determination of whether or not the lease contains a bargain purchase option.

Additionally, before classifying a lease as a sales-type lease, the Company assesses whether collectability of the lease payments is reasonably assured and whether there are any significant uncertainties related to costs that the Company has yet to incur with respect to the lease. Generally, the Company s leases that qualify as sales-type lease are non-cancelable leases with a term of 75 percent or more of the economic life of the equipment. Certain of the Company s lease contracts are customized for larger customers and often result in complex terms and conditions that typically require judgment in applying the lease accounting criteria.

The economic life of the Company s leased instruments and their fair value require significant accounting estimates and judgment. These estimates are based on the Company s historical experience. The most objective measure of the economic life of the Company s leased instrument is the original term of a lease, which is typically five years, since a majority of the instruments are returned by the lessee at or near the end of the lease term and there is not a significant after-market for our used instruments without substantial remanufacturing. The Company believes that this is representative of the period during which the instrument is expected to be economically usable, with normal service, for the purpose for which it is intended. The Company regularly evaluates the economic life of existing and new products for purposes of this determination.

The fair value of the Company s leased instruments is determined by a range of cash selling prices which the Company deemed to be verifiable objective evidence. The Company regularly evaluates available objective evidence of instrument fair values using historical data.

The Company has certain government contracts with cancellation clauses or renewal provisions that are generally required by law, such as: (i) those dependant on fiscal funding outside of a governmental unit s control; (ii) those that

can be cancelled if deemed in the tax payers best interest; or (iii) those that must be renewed each fiscal year, given limitations that may exist on multi-year contracts that are imposed by statute. Under these circumstances and in accordance with the relevant accounting literature, as well as considering the Company s historical experience, a thorough evaluation of these contracts is performed to assess whether cancellation is remote or whether exercise of the renewal option is reasonably assured.

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company recognizes revenues from service contracts ratably over the term of the service period, which typically ranges from twelve to sixty months. Payments for service contracts are generally received in advance. Deferred revenue represents the revenues to be recognized over the remaining term of the service contracts.

Shipping and Handling Costs

The Company records shipping and handling costs billed to customers as a component of revenue. Costs to distribute products to customers, including inbound and outbound freight, and other shipping and handling activities are included in cost of goods sold in accordance with FASB ASC Topic 605-45-45-20.

Total shipping and handling costs included as a component of revenue for the years ended December 31, 2010, 2009 and 2008 amounted to approximately $697,000, $707,000 and $964,000, respectively. Total shipping and handling costs included as a component of cost of sales amounted to $2,490,000, $1,871,000 and $2,343,000 for years ended December 31, 2010, 2009 and 2008, respectively.

Warranties

The Company recognizes warranty expense, based on management s estimate of expected cost, as an accrued liability at the time of sale. The Company regularly reevaluates its estimates to assess the adequacy of the recorded warranty liabilities and adjust the amounts as necessary. Warranty expense was approximately $797,000, $1,137,000 and $921,000 during the years ended December 31, 2010, 2009 and 2008, respectively.

Advertising & Literature Expenditures

Advertising and literature costs are charged to expense as incurred. Advertising and literature expense for the years ended December 31, 2010, 2009 and 2008 amounted to $360,000, $244,000 and $234,000, respectively.

Research and Development Expenditures

Except for certain software development costs capitalized as described above, research and development expenditures are charged to operations as incurred. Net research and development expense includes total research and development costs incurred, including costs incurred under research and development grants and contracts, less costs reimbursed under research and development contracts.

From time to time the Company receives grants from agencies of the U.S. Government. The Company does not recognize any revenue from such grants since they are cost reimbursement grants whereby the Company submits requests for reimbursement for certain costs incurred. There are no ongoing obligations or requirements with respect to the grants received, the Company retains ownership of any intellectual property that results from the research and development, and the U.S. Government agency receives a right to use the results of the research for government projects. The Company received cost reimbursements of $41,000, $85,000 and $164,000 during the years ended December 31, 2010, 2009 and 2008, respectively.

Income Taxes

The Company accounts for income taxes in accordance with FASB ASC Topic 740-10, *Income Taxes*, (ASC 740) which requires recognition of deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined based on the differences between the financial statement and the tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense represents the tax payable for the period and the change during the period in deferred tax assets and liabilities.

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company accounts for uncertain tax positions in accordance with ASC 740, which prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return and also provides guidance on various related matters such as derecognition, interest, penalties and disclosures required. The Company recognizes interest and penalties, if any, related to unrecognized tax benefits in income tax expense.

Foreign Currency Exchange Translation

The Company s functional currency is the U.S. dollar. The functional currencies of the Company s foreign subsidiaries are primarily accounted for in their respective local currencies. The statements of operations of foreign operations are translated into U.S. dollars at rates of exchange in effect each month. The balance sheets of these subsidiaries are translated at period-end exchange rates, and the differences from historical exchanges rates are reflected in stockholders equity as other comprehensive income (loss). Foreign currency transaction gains and losses from certain intercompany transactions are recorded in foreign currency transaction gain (loss) and other. Transactions denominated in currencies other than the functional currency are recorded based on rates in effect at the time such transactions arise. Subsequent changes in exchange rates result in transaction gains and losses and are reflected in the accompanying consolidated statements of operations as unrealized (based on the applicable period-end exchange rate) or realized upon settlement of the transactions. All other foreign currency gains and losses are also recorded on foreign currency transaction gain (loss) and other.

Fair Value of Financial Instruments

The carrying amounts of financial instruments including cash and cash equivalents, short term investments in marketable securities, accounts receivable, investment in sales-type leases, accounts payable, accrued expenses and deferred service contract revenues approximate fair value due to their short maturity. The carrying amount of our long-term liabilities also approximates fair value based on interest rates currently available to us for debt of similar terms and remaining maturities.

Earnings Per Share

The Company computes and presents earnings per share in accordance with FASB ASC Topic 260, *Earnings Per Share*. Basic earnings per share are computed by dividing net income or loss by the weighted average number of common shares outstanding, including vested restricted shares and restricted stock units, during each period. Diluted earnings per share is computed by dividing net income by the weighted average number of common shares and common stock equivalents outstanding, calculated on the treasury stock method for options and warrants using the average market prices during the period. The weighted average number of outstanding antidilutive common stock options and warrants excluded from the computation of diluted net income per common share for the years ended December 31, 2010, 2009 and 2008 were 1,777,000, 1,479,000 and 715,000, respectively.

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A reconciliation of the shares used in the calculation of basic and diluted earnings per common share is as follows:

	For the Years Ended December 31,		
	2010	2009	2008
	(In thousands)		
Weighted average common shares outstanding basic	17,903	17,727	18,246
Effect of dilutive securities			
Stock options	94	111	366
Restricted common shares and restricted stock units	22	36	80
Warrants			36
Weighted average common shares outstanding diluted	18,019	17,874	18,728

Stock Based Compensation

The Company accounts for stock based compensation under FASB ASC Topic 718, *Compensation Stock Compensation* (ASC 718) which requires compensation costs related to share-based transactions, including employee stock options, to be recognized in the financial statements based on fair value.

The Company s results for the years ended December 31, 2010, 2009 and 2008 include share-based compensation expense totaling $4,157,000, $3,729,000 and $2,464,000, respectively. In addition, the Company s results include stock based compensation expense of $0, $0 and $3,000 relating to stock issuances under our Employee Stock Purchase Plan for the years ended December 31, 2010, 2009 and 2008, respectively. Accordingly, the Company s stock based compensation expense totaled $4,157,000, $3,729,000 and $2,467,000 for the years ended December 31, 2010, 2009 and 2008, respectively. The total income tax benefit recognized in the income statement for stock based compensation arrangements amounted to $1,369,000, $1,188,000 and $996,000 for the years ended December 31, 2010, 2009, and 2008, respectively.

Foreign Currency Hedge

The Company conducts business in certain foreign markets, primarily in the European Union and Asia. To mitigate the potential impact of adverse fluctuations in the U.S. Dollar exchange rate for these currencies, the Company may periodically purchases foreign currency forward contracts. The Company does not speculate in these hedging instruments in order to profit from foreign currency exchanges; nor does it enter into trades for which there are no underlying exposures.

Under FASB ASC Topic 815, *Accounting for Derivatives Instruments and Hedging Activities,* the Company documents all relationships between hedging instruments and hedged items, as well as its risk management objective for undertaking these hedging transactions. This process includes relating the forward contracts that are designated as fair value or cash flow hedges to specific assets and liabilities on the balance sheet or to specific firm commitments or forecasted transactions. The Company also formally assesses, both at the inception of the hedge and on an ongoing

basis, whether each derivative is highly effective in offsetting changes in fair values or cash flows of the hedged of the hedged items.

At December 31, 2010, the Company did not have any foreign currency forward contracts outstanding. During the year ended December 31, 2008, the Company entered into such contracts for Euros and Japanese Yen totaling $404,000 and $7.6 million, respectively, which expired by December 31, 2008. The contracts were to hedge purchases of product in those countries and the results of these forwards are included in cost of sales.

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Segment Reporting

The Company determines and discloses industry segments in accordance with FASB ASC Topic 280: *Segment Reporting* (ASC 280) which uses a management approach for determining business segments. The management approach designates the internal organization that is used by management for making operating decisions and assessing performance as the source of the Company s reportable segments. ASC 280 also requires disclosures about products and services, geographic areas, and major customers. See Note 19 Segment and Geographic Information .

Reclassifications

In 2009, the Company reclassified employee bonus expenses between cost of goods and operating expense categories in the consolidated statement of income to conform to the presentation used in the current year. The accompanying 2008 consolidated statements of income contain these reclassification adjustments. This resulted in an increase to cost of goods sold and a decrease to operating expenses of $211,000 for the year ended December 31, 2008.

These reclassifications had no impact on the Company s previously reported consolidated operating income, net income or basic or diluted earnings per share.

Certain Risks and Uncertainties

Financial instruments, which potentially expose the Company to concentration of credit risk, consist primarily of cash and cash equivalents, accounts receivable and investment in sales-type leases. Concentration of credit risk with respect to accounts receivable and investment in sales-type leases is mitigated by the Company s performance of on-going credit evaluations of its customers and the Company maintains an allowance for doubtful accounts. Investments in sales-type leases are secured by the underlying instruments.

At December 31, 2010, the amount of the Company s cash deposited in demand deposit accounts which are fully guaranteed by the Federal Deposit Insurance Corporation was $3.7M. The rest of the cash balances on deposit with banks are guaranteed by the Federal Deposit Insurance Corporation up to $250,000. The Company may be exposed to risk for the amount of funds held in one bank in excess of the insurance limit. In assessing the risk, the Company s policy is to maintain cash balances with high quality financial institutions.

The Company derives most of its revenues from the sale of the urinalysis analyzers, and related supplies and services. Declines in unit sales or gross margins could have a material adverse effect on the Company s revenues and profits, respectively.

Certain of the Company s components are obtained from outside vendors, and the loss or breakdown of the Company s relationships with these outside vendors could subject us to substantial delays in the delivery of its products to its customers. Furthermore, certain key components of the Company s instruments and certain consumables are manufactured by only one supplier. The Company s inability to sell products to meet delivery schedules could have a material adverse effect on its reputation in the industry, as well as its financial condition and results of operation.

Recent Accounting Pronouncements

In December 2010, the FASB issued Accounting Standards Update (ASU) ASU 2010-29, *Business Combinations-Disclosure of Supplementary Pro Forma Information*, which specifies that if a public entity presents comparative financial statements, the entity should disclose revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only.

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

ASU 2010-29 is effective on a prospective basis for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010 with early adoption permitted. We are currently evaluating both the timing and the impact of the adoption of the ASU on our consolidated financial statements.

In July 2010, the FASB issued ASU 2010-20, *Disclosures about the Credit Quality of Financing Receivables and the Allowance for Credit Losses* which amends ASC Topic 310, Receivables. ASU 2010-20 requires disclosures about the nature of the credit risk in an entity s financing receivables, how that risk is incorporated into the allowance for credit losses, and the reasons for any changes in the allowance. Disclosure is required to be disaggregated, primarily at the level at which an entity calculates its allowance for credit losses.

ASU 2010-20 is applicable to both private and public companies, and will affect any entity that has financing receivables on its balance sheet, not including short-term trade accounts receivable. Public entities must apply the disclosure requirements applicable to period-end balances beginning with the first interim or annual reporting period ending on or after December 15, 2010 (December 31, 2010 for a calendar year-end entity). The adoption of this guidance resulted in additional disclosures (see Note 7) but did not have an impact on our consolidated financial statements.

In October 2009, the FASB issued Accounting Standards Update (ASU) ASU 2009-14, *Certain Revenue Arrangements That Include Software Elements*, now codified under FASB ASC Topic 985, *Software*. ASU 2009-14, removes tangible products from the scope of software revenue guidance and provides guidance on determining whether software deliverables in an arrangement that includes a tangible product are covered by the scope of the software revenue guidance. ASU 2009-14 is to be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with early adoption permitted. We are currently evaluating both the timing and the impact of the adoption of the ASU on our consolidated financial statements.

In October 2009, the FASB issued Accounting Standards Update (ASU) 2009-13, *Multiple-Deliverable Revenue Arrangements*, which amends ASC Topic 605, *Revenue Recognition*, to require companies to allocate revenue in multiple-element arrangements based on an element s estimated selling price if vendor-specific or other third-party evidence of value is not available. ASU 2009-13 is effective beginning June 15, 2010. Earlier application is permitted. The adoption of ASU 2009-13 did not have a material impact on our consolidated financial statements.

In December 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-28 *When to Perform Step 2 of the Goodwill Impairment Test for Reporting Units with Zero or Negative Carrying Amounts.* This update provides amendments to ASC Topic 350 Intangibles, Goodwill and Other that requires an entity to perform Step 2 impairment test even if a reporting unit has zero or negative carrying amount. Step 1 tests whether the carrying amount of a reporting unit exceeds its fair value. Previously reporting units with zero or negative carrying value passed Step 1 because the fair value was generally greater than zero. Step 2 requires impairment testing and impairment valuation be calculated in between annual tests if an event or circumstances indicate that it is more likely than not that goodwill has been impaired. ASU 2010-28 is effective beginning January 1, 2011. As a result of this standard, goodwill impairments may be reported sooner than under current practice. We do not expect ASU 2010-28 to have a material impact on our financial statements.

3. Acquisitions

On January 1, 2010, the Company purchased certain assets relating to its current distribution of IRIS products in the United Kingdom, Ireland and Germany from one of the Company s European distributors for a cash payment of $660,000. The assets purchased consist primarily of customer leases for installed IRIS instruments and service contracts valued at inventory book value. This purchase increased the Company s direct sales presence within its international sales channels, and will serve as a template for further potential transactions in territories that represent new business opportunities for the Company.

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On July 28, 2010, the Company acquired AlliedPath, Inc. AlliedPath is a high complexity CLIA-certified molecular pathology laboratory offering differentiated, high value molecular diagnostic services in the rapidly growing field of personalized medicine. Pursuant to the terms of the merger agreement dated July 26, 2010, the Company acquired all the issued and outstanding stock of AlliedPath for an amount in cash equal to $4.6 million less certain indebtedness existing at the closing, with an additional earn-out of up to $1.3 million subject to the achievement of specific sales and earnings targets through December 2013. We did not assume any outstanding options or warrants of AlliedPath in connection with the acquisition. AlliedPath is now called Arista Molecular, Inc. (Arista) as of January 2011 and will operate under the Personalized Medicine reporting segment of the consolidated financial statements

Through the acquisition of Arista, the Company seeks to achieve the following goals:

to expand beyond its initial molecular pathology test menu by adding other molecular panels, flow cytometry for the detection and monitoring of leukemia and lymphoma, FISH testing, and proprietary new tests based on the Company s NADiA technology platform;

to have better control of all aspects of the commercial operations of the NADiA platform, starting with NADiA ProsVue;

to enable the acceleration of the development efforts of the NADiA technology product pipeline; and

to enter the attractive personalized medicine market due to its significant growth potential.

The aggregate consideration paid for the acquisition of Arista is as follows:

		(In thousands)
Cash	$	4,630
Fair value of contingent consideration		1,210
Total purchase price	$	5,840

Acquisition related expenses included in marketing and sales and general and administrative total $525,000 for the year ended December 31, 2010.

The following table summarizes the estimated fair values of assets acquired and liabilities assumed as of July 28, 2010.

		(In thousands)
Current assets	$	74
Property and equipment		523
Core technology		3,090

CLIA License		1,604
Customer relationships		6
Non-compete agreements		100
Goodwill		1,507
Other assets		31
Current liabilities		(316)
Lease obligations		(178)
Other liabilities		(61)
Deferred tax liability, net		(540)
Total purchase price	$	5,840

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The purchase price allocations and pro forma adjustments are based on preliminary estimates, available information and certain assumptions, and may be revised as additional information becomes available.

In determining the purchase price allocation, the Company considered, among other factors, historical demand for products, estimates of future demand for those services, customer relationships, the revenue generating potential of core technology, the assets useful lives, and agreements not to compete. The market, income and cost approaches were used to determine fair values of these intangibles. The rate used to discount the net cash flows to their present value was a 16.5% weighted average cost of capital for the business as a whole, and from 16.5% to 17.5% for the individual intangible assets depending on the risk associated with the asset s potential to generate revenues and its projected remaining useful economic life. The weighted average cost of capital was determined after consideration of market rates of return on debt and equity capital of comparable companies, the weighted average return on invested capital and the risk associated with achieving forecasted sales related to technology and assets acquired. The fair value of the contingent consideration was determined considering the probability of payout and using a 3% discount rate. Property and equipment net book value was evaluated at approximately fair value on the acquisition date due to the nature and relative age of the assets acquired.

Acquired property and equipment are being depreciated on a straight-line basis with estimated remaining useful lives ranging from 1 year to 5 years. Intangible assets except the CLIA license are being amortized on a straight-line basis with estimated remaining useful lives ranging from 3 years to 15 years reflecting the expected future value. The CLIA license is considered to have an indefinite useful life. The purchase was structured as a stock purchase therefore the value assigned to the core technology, CLIA license, customers relationships, non-compete agreements and goodwill is not deductible for tax purposes.

Revenue and net loss of Arista included in the Company s consolidated financial statements since the laboratory s acquisition on July 28, 2010 totaled $69,000 and $3,672,000, respectively, for the year ended December 31, 2010

The following table summarizes unaudited pro forma financial information assuming the acquisition of Arista had occurred on January 1, 2009, in the corresponding period of the fiscal year immediately preceding the acquisition. This unaudited pro forma financial information does not necessarily represent what would have occurred if the transaction had taken place on January 1, 2009 and should not be taken as representative of the Company s future consolidated results of operations or financial position.

	For the Years Ended December 31,	
	2010	2009
	(In thousands)	
Revenue	$ 107,697	$ 92,570
Net income	1,720	3,803
Net income per basic and diluted share	$ 0.10	$ 0.21

On November 22, 2010, the Company acquired the assets of a multi-purpose, bench-top instrument platform for automating highly repetitive, manual laboratory protocols for FISH (fluorescence in-situ hybridization) testing and other slide-based cytogenetic applications. The product acquisition is a natural extension to the successful

ThermoBrite® DNA Hybridization System and in line with the Company s entry into personalized medicine with emphasis on cancer diagnostics. The product prototypes and proprietary technology assets were purchased for $3.2 million in cash from BioMicro Systems, Inc. The new product platform will be integrated into the Iris Sample Processing Division and it is expected to position IRIS as a major competitor in the high growth cytogenetic instrumentation market. This acquisition was recorded as an acquisition of assets determined not to be a business, since no workforce nor strategic management, operational or resource management processes were included in the purchase.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The purchase price of $3.2 million plus related asset acquisition costs of $84,000 was allocated to core technology and is recorded in intangible assets on the Company s consolidated balance sheet as of December 31, 2010. The purchase price allocation was based on preliminary estimates and available information, and may be revised as additional information becomes available. Although BioMicro Systems built and tested a working prototype, which proved the technical feasibility of the base technology, several elements of this technology platform requires continued development in order to reach salability for its stated purpose. Once development is completed, a useful life will be determined and the assets will be amortized over the useful life determined at that time.

4. Investments in Marketable Securities

In 2008, the Company adopted FASB ASC Topic 820, *Fair Value Measurement* (ASC 820), for assets and liabilities measured at fair value on a recurring basis. ASC 820, defines fair values as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a fair value hierarchy, which prioritizes the inputs used in measuring fair value into three broad levels as follows:

Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 inputs include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability and inputs that are derived principally from or corroborated by observable market data by correlation or other means.

Level 3 inputs are unobservable inputs for the asset or liability

At December 31, 2010 and 2009, the Company did not hold any investments in marketable securities.

5. Inventories

Inventories consist of the following:

	At December 31,	
	2010	2009
	(In thousands)	
Finished goods	$ 3,423	$ 2,595
Work-in-process	181	214
Raw materials, parts and sub-assemblies	6,706	8,057
Inventories	$ 10,310	$ 10,866

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Property and Equipment

Property and equipment consist of the following:

	At December 31, 2010	2009
	(In thousands)	
Machinery and equipment	$ 13,894	$ 11,145
Leasehold improvements	8,021	6,385
Tooling, dies and molds	1,224	2,158
Furniture and fixtures	2,088	1,152
Rental units	1,299	540
	26,526	21,380
Less: accumulated depreciation	(14,491)	(11,713)
	$ 12,035	$ 9,667

Depreciation expense for Property and Equipment, for the years ended December 31, 2010, 2009 and 2008 was $3.3 million, $2.8 million, and $2.4 million, respectively.

7. Sales-type Leases

The components of net investment in sales-type leases consist of the following:

	At December 31, 2010	2009
	(In thousands)	
Total minimum lease payments	$ 16,044	$ 12,735
Less: unearned income	(2,464)	(1,897)
Net investment in sales-type leases	13,580	10,838
Less: current portion	(3,578)	(3,397)
Net investment in sales-type leases, non-current portion	$ 10,002	$ 7,441

Future minimum lease payments due from customers under sales-type leases for each of the five succeeding years:

	(In thousands)
Year Ending December 31,	
2011	$ 3,578
2012	3,151
2013	2,736
2014	2,366
2015	1,509
Thereafter	240
	$ 13,580

Our leases are primarily to customers in the health care industry or to governments. We assess credit risk for all of our customers including those who lease equipment. Credit risk is assessed using an internally developed model which incorporates credit scores from third party providers and our own custom risk ratings and is updated on a quarterly basis. The external credit scores are developed based on the customer s historical payment patterns and an

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

overall assessment of the likelihood of delinquent payments. Our internal ratings are weighted based on company size, years in business, and other credit related factors (i.e. profitability, cash flow, liquidity, tangible net worth, etc.). Any one of the following factors may result in a customer being classified as high risk: i) the customer has a history of late payments; ii) the customer has open lawsuits, liens or judgments; and iii) the customer has been in business less than three years. Our lease receivables are collateralized by the equipment s fair value, which mitigates our credit risk. The following table presents the risk profile by creditworthiness category of our sales-type lease receivables at December 31, 2010:

	(In thousands)
Low risk	$ 12,128
Moderate risk	785
High Risk	667
	$ 13,580

The balance of the allowance for uncollectible accounts for our sales-type leases was zero as of December 31, 2010. We determine the adequacy of our allowance for uncollectible accounts for sales-type leases based on an analysis of historical write-offs. There have been no write-offs of sales-type lease receivables for the years ended December 31, 2010, 2009 or 2008. As of December 31, 2010, the amount of sales-type leases which were past due was not significant and there were no impaired sales-type leases. Accordingly, there was no material risk of default with respect to sales-type leases as of December 31, 2010.

8. Bank Credit Facility

The Company has a credit facility with a commercial bank. The credit facility consists of a $6.5 million revolving line of credit for working capital and a $10.0 million line of credit for acquisitions and product opportunities. The credit facility has variable interest rates, which will change from time to time based on changes to either the LIBOR rate or the lender s prime rate. Borrowings under the credit facility are secured by all of the Company s assets and mature in June 2012 and June 2015, respectively.

As of December 31, 2010 and 2009, there were no borrowings under the credit facility. However, the Company is subject to certain financial and non financial covenants under the credit facility with the bank and as of December 31, 2010, the Company was in compliance with these covenants.

9. Accrued Expenses

Accrued expenses consist of the following:

	At December 31,	
	2010	2009
	(In thousands)	

Accrued bonuses	$ 1,762	$ 197
Accrued commissions	824	607
Accrued payroll	1,059	1,334
Accrued vacation	1,624	1,234
Accrued professional fees	499	416
Accrued warranty	705	946
Accrued laboratory information system implementations	487	335
Accrued other	553	692
	$ 7,513	$ 5,761

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Changes in accrued warranty were as follows:

	At December 31,	
	2010	2009
	(In thousands)	
Balance beginning of year	$ 946	$ 808
Additions for provisions during year	797	1,137
Reductions during year	(1,038)	(999)
Balance end of year	$ 705	$ 946

10. Income Taxes

The provision for income taxes from operations consists of the following:

	For the Years Ended December 31,		
	2010	2009	2008
	(In thousands)		
Current:			
Federal	$ 514	$ 1,879	$ 2,323
Foreign	63		
State	665	757	644
	1,242	2,636	2,967
Deferred:			
Federal	243	364	1,182
Foreign	170	(32)	(55)
State	(567)	(514)	269
	(154)	(182)	1,396
	$ 1,088	$ 2,454	$ 4,363

Income taxes have been based on the following components of pre-tax income (loss):

	For the Years Ended December 31,		
	2010	2009	2008
	(In thousands)		
Domestic	$ 3,541	$ 8,821	$ 13,557
Foreign	589	(116)	(181)
	$ 4,130	$ 8,705	$ 13,376

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The provision for income taxes differs from the amount obtained by applying the federal statutory income tax rate to income before provision for income taxes as follows:

	For the Years Ended December 31,		
	2010	2009	2008
	(In thousands)		
Tax provision computed at Federal statutory rate	$ 1,404	$ 2,960	$ 4,549
State taxes, net of federal benefit	252	544	499
R&D tax credits	(790)	(258)	(507)
Incentive stock options	293	303	(10)
Nondeductible expenses	72	(83)	(120)
Change in valuation allowance	(45)	(269)	(260)
Rate differential on Foreign Income	(9)	(32)	(55)
Prior year return to provision adjustment	(61)	(772)	
Other	(28)	61	267
	$ 1,088	$ 2,454	$ 4,363

The primary components of temporary differences, which give rise to the Company s net deferred tax asset at December 31, 2010 and 2009, are as follows:

	At December 31,	
	2010	2009
	(In thousands)	
Depreciation and amortization	$ (2,738)	$ (998)
Allowance for doubtful accounts	187	166
Accrued liabilities	1,382	1,562
Inventory	145	196
Stock compensation	2,132	1,449
Net operating loss carryforwards	2,740	1,264
Tax credits	3,603	3,585
Valuation allowance	(598)	(335)
State deferred taxes	(1,103)	(753)
	$ 5,750	$ 6,136

As of December 31, 2010, withholding and U.S. taxes have not been provided on approximately $200,000 of cumulative undistributed earnings of the Company s non-U.S. subsidiaries because the Company intends to

indefinitely reinvest these earnings in its non-U.S. subsidiaries.

At December 31, 2010, the Company has Federal, state and foreign net operating loss carryforwards of approximately $5.2 million, $3.9 million, and $1.9 million, respectively expiring beginning in 2011 through 2030. The federal and state net operating loss carryforwards are subject to limitations on their utilization. The Company also has federal and state tax credit carryforwards of $666,000 and $2.9 million, respectively, net of valuation allowances.

Realization of deferred tax assets associated with foreign net operating losses (NOL) and tax credit carryforwards is dependent upon the Company s ability to generate sufficient taxable income prior to their expiration. Management believes it is more likely than not that the deferred tax assets will be realized through future taxable income or alternative tax strategies. However, the net deferred tax assets could be reduced in the near term if

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

management s estimates of taxable income during the carryforward period are not realized or are significantly reduced or alternative tax strategies are not available. The company has recorded a valuation allowance of $308,000 related to net operating loss carryforwards of Arista which will likely expire due to a section 382 limitation on their utilization. The Company has reversed a $45,000 valuation allowance related to foreign net operating losses based on its estimate of future utilization. The Company will continue to review estimates of taxable income and will adjust the valuation allowance, when necessary.

In connection with the acquisition of Arista, the company recorded deferred tax liabilities of $540,000 net of the aforementioned valuation allowance.

The Company adopted the provisions of FASB ASC Topic 740-10, *Income Taxes*, which requires that the Company recognize the impact of a tax position in its financial statements if that position is more likely than not of being sustained upon audit, based on the technical merits of the position.

The Company files income tax returns in the U.S. federal jurisdiction and various state and foreign jurisdictions. In general, the U.S. federal statute for the assessment of taxes for the Company is no longer open for tax years prior to 2007 and for state income tax purposes for tax years prior to 2006. The Company is not under examination by any taxing authorities other than in Germany, which is examining the Company s 2006 through 2009 income tax returns. The Company does not believe any additional taxes will be due in connection with the examination.

As of December 31, 2010, the total amount of unrecognized tax benefits was $1,908,000. The unrecognized tax benefits primarily relate to uncertainties with respect to tax credit carryovers and all future reductions to the unrecognized tax benefits would result in a reduction to the future effective tax rate.

The following changes occurred in the amount of unrecognized tax benefits (including related interest and penalties) during the years ended December 31, 2010, 2009 and 2008 as follows:

	For the Years Ended December 31,		
	2010	2009	2008
	(In thousands)		
Balance at January 31	$ 1,282	$ 998	$ 616
Additions for current year tax positions	626	284	382
Balance at December 31	$ 1,908	$ 1,282	$ 998

The Company does not expect any reduction to the unrecognized tax benefits in the next twelve months. Currently, there are no amounts of interest or penalties recorded in the financial statements as the unrecognized tax benefits relate to deferred tax assets. The Company will recognize potential interest and penalties related to income tax positions as a component of the provision for income taxes on the consolidated statements of income in any future periods in which the Company must record a liability.

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11. Stock-Based Compensation

The Company accounts for stock-based compensation pursuant to FASB ASC Topic 718, *Stock Compensation,* which requires compensation costs related to share-based transactions, including employee stock options, to be recognized in the financial statements based on fair value. Share-based compensation expense for the years ended December 31, 2010, 2009 and 2008 is as follows:

	For the Years Ended December 31,		
	2009	2009	2008
		(In thousands)	
Cost of sales	$ 357	$ 417	$ 341
Marketing and selling	688	631	398
General and administrative	2,233	2,026	1,210
Research and development	879	655	518
Stock-based compensation	$ 4,157	$ 3,729	$ 2,467

Stock Options

As of December 31, 2010, the Company had a stock option plan under which the Company may grant future non-qualified stock options, incentive stock options and stock appreciation rights. No stock appreciation rights have been granted under any of the Company s stock option plans. On July 13, 2007, the Company s stockholders approved the adoption of the IRIS International, Inc. 2007 Stock Incentive Plan, which authorizes the issuance of up to 1,750,000 shares of common stock pursuant to equity awards granted under the plan. On May 22, 2009, the Company s stockholders approved an increase of 1,550,000 shares to the 2007 Stock Incentive Plan for a total of 3,300,000 authorized shares.

The following schedule sets forth options authorized, exercised, outstanding and available for grant under the Company s existing stock option plans as of December 31, 2010:

		Number of Option Shares		
Plan	Authorized	Exercised	Outstanding	Available for Grant
		(In thousands)		
1994 Plan	700	680	20	
1998 Plan	4,100	2,717	899	
2007 Plan	3,300		1,849	794
	8,100	3,397	2,768	794

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The following table sets forth certain information relative to stock options during the three years ended December 31, 2010.

	Shares	Weighted Average Exercise Price	Average Intrinsic Value
	(In thousands, except for per share)		
Outstanding at January 1, 2008	1,861	$ 11.62	
Granted	502	$ 13.03	
Exercised	(369)	$ 4.90	
Canceled or expired	(20)	$ 11.47	
Outstanding at December 31, 2008	1,974	$ 13.24	
Granted	571	$ 9.02	
Exercised	(197)	$ 7.34	
Canceled or expired	(143)	$ 13.10	
Outstanding at December 31, 2009	2,205	$ 12.97	
Granted	827	$ 10.74	
Exercised	(22)	$ 1.44	
Canceled or expired	(241)	$ 14.52	
Outstanding at December 31, 2010 average remaining life 4.8 years	2,769	$ 12.26	$ 1,564
Exercisable at December 31, 2010, average remaining life 3.2 years	1,642	$ 13.30	$ 1,217

The weighted average grant-date fair value of options granted during the years ended December 31, 2010, 2009 and 2008 was $5.14, $4.91, and $4.48, respectively. The intrinsic value of options exercised during the years ended December 31, 2010, 2009 and 2008 was $201,000, $729,000, and $4,073,000, respectively. Of the total outstanding stock options shown above, 1,068,000, 790,000 and 663,000 were incentive stock options as of December 31, 2010, 2009 and 2008, respectively.

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between the Company s closing stock price on December 31, 2010 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders, had all option holders exercised their options on December 31, 2010. As of December 31, 2010, total unrecognized stock-based compensation expense related to non-vested stock options was $4,547,000, which is expected to be recognized over the remaining weighted average period of approximately 2.8 years.

The Compensation Committee of the board of directors determines the total value of the stock based compensation grants. The exercise price of options is the closing price on the date the options are granted. Payment of the exercise

price may be made either in cash or with shares of common stock that have been held at least six months. The options generally vest over four years and expire between five or ten years from the date of grant. The

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IRIS INTERNATIONAL, INC.

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fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	For the Years Ended December 31,		
	2010	2009	2008
	(In thousands)		
Risk free interest rate	1.75%	2.0%	2.4%
Expected lives (years)	4.35	4.0	3.0
Expected volatility	56.57%	60.5%	48%
Expected dividend yield			

The expected volatilities are based on the historical volatility of the Company s stock. The observation is made on a weekly basis. The expected terms of the stock options are based on the average vesting period on a basis consistent with the historical experience for similar option grants. The risk-free interest rate is consistent with the expected terms of the stock options and based on the U.S. Treasury yield curve in effect at the time of grant. The Company estimates forfeiture rates based on historical data.

A summary of the Company s non-vested stock options during the year ended December 31, 2010 is presented below:

	Shares	Weighted Average Grant Date Fair Value
	(In thousands)	
Non-vested options at January 1, 2010	933	$ 11.26
Granted	827	$ 11.91
Vested	(524)	$ 11.40
Forfeited or expired	(109)	$ 5.88
Non-vested options at December 31, 2010	1,127	$ 10.74

As of December 31, 2010, there was approximately $4,547,000 of accumulated unrecognized stock compensation based on fair value on the grant date related to non-vested options granted under the stock option plans. That cost is expected to be recognized during the weighted average service period of 2.8 years. The share-based compensation will be amortized based on the straight line method over the vesting period and the expense includes an estimate of the awards that will be forfeited. The total fair value of shares vested during the year ended December 31, 2010 was $266,000.

Restricted Shares

The Company began awarding restricted shares of its common stock in 2006. In March 2009, the Company began to grant restricted stock units to its non-employee directors and to certain employees. Such awards generally require that certain performance conditions and service conditions be met before the awards vest. Restricted shares currently vest 25% after one year and 61/4% quarterly thereafter. Restricted stock units currently vest 25% after thirteen months and 61/4% quarterly thereafter. However, awards to non-employee directors are immediately vested on the grant date. Unvested restricted shares are forfeited if the recipient s employment terminates for any reason other than death, disability, or special circumstances as determined by the Compensation Committee of the

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Company s board of directors. Restricted share and restricted stock unit activity during the year ended December 31, 2010 is as follows:

	Shares and Units	Weighted Average Grant Date Fair Value per Share
	(In thousands, except for per share)	
Unvested at January 1, 2010	248	$ 11.40
Granted	193	$ 10.80
Vested during period	(134)	$ 11.56
Cancelled during period	(21)	$ 11.73
Unvested at December 31, 2010	286	$ 10.89

Fair value of the Company s restricted shares and restricted stock units is based on the Company s closing stock price on the date of grant. As of December 31, 2010, total unrecognized stock-based compensation expense related to nonvested restricted share grants was $2,863,000 which is expected to be recognized over the remaining weighted average period of approximately 2.8 years.

From time to time, the company retains shares of common stock from employees upon vesting of restricted shares and restricted stock units to cover income tax withholding. The impact of such withholding totaled $315,000, $179,000 and $22,000 for the years ended December 31, 2010, 2009 and 2008, respectively, and was recorded as settlement on restricted stock tax withholding in the accompanying consolidated statements of stockholders equity.

12. Capital Stock

At December 31, 2010, there were no warrants outstanding. During the year ended December 31, 2009, 24,016 warrants were exercised prior to their expiration. At December 31, 2008, there were warrants outstanding to purchase 74,300 shares of common stock at $7.80 per share, which expired on April 23, 2009. During the year ended December 31, 2008, no warrants were issued, exercised, cancelled or expired.

The Company has 1,000,000 shares of Callable Series C preferred stock authorized, none of which has been issued.

13. Common Stock Repurchase Plan

In August 2010, the Company s board of directors authorized a share repurchase and retirement plan of up to $10 million of the Company s common stock over a 12-month period. During the year ended December 31, 2010, the Company repurchased 330,454 shares of common stock at an average price per share of approximately $9.10, for an aggregate amount of approximately $3.0 million.

In 2008, the Company s board of directors authorized two stock repurchase plans. On March 3, 2008, the Company s board of directors authorized the first share repurchase and retirement plan of up to $15 million of the Company s common stock over a 12-month period. Under this first plan the Company repurchased 492,068 shares of common stock for approximately $5.7 million. On July 25, 2008, the Company s board of directors terminated the first share repurchase and retirement plan.

On November 21, 2008, the Company s board of directors authorized a second share repurchase and retirement plan of up to $10 million of the Company s common stock over a 12-month period. During the year ended December 31, 2008, the Company repurchased 491,511 shares of common stock for approximately $6.2 million against this second authorization. During the year ended December 31, 2009, the Company repurchased an additional 250,800 shares of common stock for approximately $2.5 million. As of December 31, 2009, under this

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

second repurchase plan, the Company had repurchased a cumulative total of 742,311 shares of common stock for approximately $8.7 million.

Cumulatively between the three plans mentioned above, the Company purchased a total of 1,564,833 shares of common stock for approximately $17.4 million in 2010, 2009 and 2008.

On September 11, 2008, the Company s Chief Executive Officer exercised a stock option to purchase an aggregate of 130,000 shares of common stock with an exercise price of $4.34 per share, on a net issue basis, in a transaction approved by the compensation committee of the board of directors. The Company issued 62,081 shares of common stock to the Chief Executive Officer, and retained 67,919 shares of common stock with an aggregate market value of $1,219,000 based on the last closing price of the Company s common stock immediately prior to exercise of $17.95 per share. Of this amount, $564,000 was applied in payment of the aggregate exercise price of the stock options and $655,000 was applied in payment of payroll taxes arising from the option exercise.

14. Employee Benefits

All employees are also eligible to participate in a 401(k) Plan at the beginning of the first quarter following their employment start date. The Company s contributions are discretionary. Effective January 1, 2006 the Company commenced matching $0.50 per $1.00 contributed by the employees up to 4% of the employee s annual salary; prior to 2006, the Company s practice was to match $0.25 per $1.00 contributed by the employees up to 4% of the employee s annual salary. Employees vest in amounts contributed by the Company immediately. The Company contributed $408,000, $362,000 and $312,000 to the 401(k) Plan for the years ended December 31, 2010, 2009, and 2008, respectively.

15. Manufacturing Transition Rights

On December 30, 2008, the Company entered into a manufacturing, supply and transition agreement (manufacturing transition rights) with IDEXX Operations, Inc. Under this agreement, the Company sold its exclusive rights to manufacture and distribute rotors compatible with the drives of IDEXX machines to IDEXX. The Company received a nonrecurring $1.5 million payment, which was offset by $268,000 related to costs associated with the manufacturing transition rights. The $1.5 million payment was classified as other income and did not impact revenue from operations, as this payment was not contingent upon any significant action by the Company.

During the transition period, the Company will provide IDEXX with its know-how related to the manufacturing of the rotors and will manufacture any rotors needed by IDEXX. Prices for these transition services and rotors are exclusive of the aforementioned nonrecurring payment. As of December 31, 2010, the Company has continued to manufacture and sell the rotors to IDEXX at a set price.

In addition, IDEXX owns the rights to manufacture the rotors without any further involvement or commitment from the Company. Commencing January 2014 and continuing through December 2020, if IDEXX uses this manufacturing technology, a royalty fee for each rotor unit sold will be assessed and paid to the Company.

16. Shelf Registration

In November 2010, the Company filed a Form S-3 shelf registration statement ($125 million shelf) to provide for financial flexibility. The $125 million shelf allows the Company to issue common stock, preferred stock and debt securities of the Company. Under the $125 million shelf, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. In December 2010 the Form S-3 registration statement was declared effective. As of December 31, 2010, no securities had been issued under the $125 million shelf which will expire in December 2013.

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. Commitments and Contingencies

Leases

The Company leases real property, automobiles and equipment under operating lease agreements, which expire at various times through 2018. Certain leases contain renewal options and generally require us to pay utilities, insurance, taxes and other operating expenses.

Future minimum rental payments required under operating lease agreements that have an initial term in excess of one year as of December 31, 2010, are as follows:

	Operating Leases (In thousands)
Year Ended December 31,	
2011	$ 2,358
2012	2,148
2013	2,052
2014	1,528
2015	1,190
Thereafter	114
	$ 9,390

Consolidated rental expense under all operating leases during the years ended December 31, 2010, 2009 and 2008 was $2,424,000 $1,997,000 and $1,787,000, respectively.

Litigation

From time to time, the Company is party to certain litigation arising in the normal course of business. Management believes that the resolution of such matters will not have a material adverse effect on the Company s financial position, results of operations or cash flows.

Guarantees

The Company enters into indemnification provisions under (i) agreements with other companies in its ordinary course of business, typically with business partners, contractors, and customers, landlords and (ii) agreements with investors. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of its activities or, in some cases, as a result of the indemnified party s activities under the agreement. These indemnification provisions often include indemnifications relating to representations made by the Company with regard to intellectual property rights. These indemnification provisions generally survive termination of the underlying agreement. In addition, in some cases, the Company has

agreed to reimburse employees for certain expenses and to provide salary continuation during short-term disability. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. The Company reviews its exposure under these agreements no less than annually, or more frequently when events indicate. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of its obligations under these agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of December 31, 2010 and 2009.

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

18. Supplier Concentration

One supplier comprised greater than 10% of the Company s consolidated purchases. Consolidated purchases from this supplier amounted to 17%, 12% and 15% for the years end December 31, 2010, 2009, and 2008, respectively.

19. Segments and Geographic Information

The Company s operations are organized on the basis of products and related services, and under FASB ASC Topic 280, *Segment Reporting*, the Company operates in three segments: (1) Iris Diagnostics Division (IDD), (2) Sample Processing and (3) Personalized Medicine.

The IDD segment designs, develops, manufactures, markets and distributes in-vitro diagnostic systems based on patented and proprietary technology for automating microscopic and clinical chemistry procedures for urinalysis. The segment also provides ongoing sales of consumables and services necessary for the operation of installed urinalysis workstations. In the United States, these products are mostly sold through a direct sales and service force. Internationally, these products are sold and serviced through distributors, with the exception of France, Germany, United Kingdom and Puerto Rico.

The Sample Processing segment designs, develops, manufactures and markets a variety of benchtop centrifuges, small instruments and supplies. These products are used primarily for manual specimen preparation and dedicated applications in coagulation, cytology, hematology, urinalysis and DNA processing. These products are sold worldwide through distributors.

The Personalized Medicine segment operates a CLIA-certified laboratory focused on oncology and molecular diagnostics services in personalized medicine. This segment also includes the research and development operations of Iris Molecular Diagnostics, or IMD.

The accounting policies of the segments are the same as those described in the Summary of Significant Accounting Policies . The Company evaluates the performance of its segments and allocates resources to them based on earnings before income taxes, excluding corporate charges.

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The tables below present information about reported segments for the three years ended December 31, 2010:

	IDD	Sample Processing	Personalized Medicine	Unallocated Corporate Expenses	Total
			(In thousands)		
For the Year Ended December 31, 2010					
Revenues	$ 93,195	$ 14,408	$ 69	$	$ 107,672
Gross profit (loss)	47,469	7,789	(372)		54,886
Marketing and selling	17,375	1,189	1,265		19,829
General and administrative	6,386	1,360	1,872	7,769	17,387
Research and development, net	8,840	619	5,103		14,562
Total operating expenses	32,601	3,168	8,240	7,769	51,778
Operating income (loss)	14,868	4,621	(8,612)	(7,769)	3,108
Interest income	141	26		956	1,123
Interest expense				(10)	(10)
Depreciation and amortization	3,612	181	357	14	4,164
Segment pre-tax income (loss)	15,744	4,545	(8,620)	(7,539)	4,130
Segment assets	76,981	12,683	11,195	5,750	106,609
Investment in long-lived assets	24,281	3,720	11,045		39,046
For the Year Ended December 31, 2009					
Revenues	$ 78,231	$ 14,335	$	$	$ 92,566
Gross profit	41,295	7,370			48,665
Marketing and selling	14,999	1,123			16,122
General and administrative	5,077	1,345		6,899	13,321
Research and development, net	6,275	824	4,312		11,411
Total operating expenses	26,351	3,292	4,312	6,899	40,854
Operating income (loss)	14,944	4,078	(4,312)	(6,899)	7,811
Interest income	663	25		169	857
Interest expense				(21)	(21)
Depreciation and amortization	3,051	230	226	16	3,523
Segment pre-tax income (loss)	16,787	4,014	(4,262)	(7,834)	8,705
Segment assets	78,453	8,784	4,417	6,136	97,790
Investment in long-lived assets	19,681	399	4,298		24,378

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	IDD	Sample Processing	Personalized Medicine	Unallocated Corporate Expenses	Total
			(In thousands)		
For the Year Ended December 31, 2008					
Revenues	$ 81,771	$ 13,731	$	$	$ 95,502
Gross profit	42,171	6,868			49,039
Marketing and selling	14,687	1,019			15,706
General and administrative	5,459	1,183		5,367	12,009
Research and development, net	5,443	658	4,256		10,357
Total operating expenses	25,589	2,860	4,256	5,367	38,072
Operating income (loss)	16,582	4,008	(4,256)	(5,367)	10,967
Interest income	28			1,152	1,180
Interest expense				(11)	(11)
Depreciation and amortization	2,784	218	109	16	3,127
Segment pre-tax income (loss)	16,479	5,113	(4,256)	(3,960)	13,376
Segment assets	75,100	6,050	3,950	5,538	90,638
Investment in long-lived assets	18,229	419	3,916		22,564

The Company ships products from two locations in the United States and one location in Germany. Substantially all long-lived assets are located in the United States. Sales to international customers amounted to approximately $36.0 million in 2010, $30.2 million in 2009 and $31.6 million in 2008. For the year ended December 31, 2010, one customer represented 13% of international sales. For the year ended December 31, 2009, three customers represented 19%, 12% and 12% of international sales, respectively. For the year ended December 31, 2008, two customers represented 21% and 10% of international sales, respectively.

Segment assets attributed to corporate unallocated expenses are deferred taxes. Long-lived assets include property and equipment, intangible assets, long-term portion of inventory and other long-term assets. Deferred income taxes are excluded from long-lived assets.

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

20. Valuation and Qualifying Accounts

	Beginning Balance	Charged to Costs and Expenses	Additions Charged to Other Accounts	Deductions	Ending Balance
			(In thousands)		
Year Ended December 31, 2010					
Allowance for doubtful accounts	$ 369	$	$ 43	$ (7)[1]	$ 405
Allowance for sales returns	48			(1)	48
Reserve for inventory obsolescence	983	131		(969)[1]	145
Valuation of deferred tax assets	335		308	(45)[2]	598
Year Ended December 31, 2009					
Allowance for doubtful accounts	$ 410	$	$ (20)	$ (21)[1]	$ 369
Allowance for sales returns	35		13		48
Reserve for inventory obsolescence	846	255		(118)[1]	983
Valuation of deferred tax assets	596			(261)[2]	335
Year Ended December 31, 2008					
Allowance for doubtful accounts	$ 401	$ 26	$	$ (17)[1]	$ 410
Allowance for sales returns	35			(1)	35
Reserve for inventory obsolescence	623	462		(239)[1]	846
Valuation of deferred tax assets	856			(260)[2]	596

(1) Relates to the write-off of accounts receivable, return of merchandise, disposal of obsolete inventory or specific portion of the accounts receivable reserve or reserve for sales returns no longer needed.

(2) Valuation adjustment relating to realization of deferred tax assets.

21. Selected Quarterly Data (Unaudited)

The following table summarizes certain financial information by quarter:

	2010 Quarter Ended			
	March 31	June 30	September 30	December 31
	(In thousands, except per share)			
Net revenues	$ 25,980	$ 26,688	$ 25,726	$ 29,278
Gross profit	13,254	14,495	13,159	13,978
Net income	1,042	624	924	452
Net income per share basic	0.06	0.03	0.05	0.03

Net income per share	diluted	0.06	0.03	0.05	0.03

		2009 Quarter Ended			
		March 31	**June 30**	**September 30**	**December 31**
		(In thousands, except per share)			
Net revenues		$ 21,575	$ 22,342	$ 22,186	$ 26,463
Gross profit		11,695	11,332	12,182	13,456
Net income		1,392	1,012	1,916	1,931
Net income per share	basic	0.08	0.06	0.11	0.11
Net income per share	diluted	0.08	0.06	0.11	0.11

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IRIS INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(1) 2010 results include the operating losses, including acquisition related costs, of approximately $3.7 million related to our acquisition in July 2010 of Arista Molecular, Inc. In addition, we incurred $923,000 in CFO and related transition costs, $1.1 million for foreign currency translation loss and $800,000 related to higher instrument cost of goods due to a price premium on the last purchase of automated chemistry analyzers from Arkray.

(2) 2009 results include the following expenses totaling $1.1 million; an accrual of $475,000 for payroll taxes attributable to the exercise of stock options, $350,000 in start-up expenses for the initiation of direct sales operations in the UK and Germany and $250,000 for product retrofit costs related to the voluntary recall of approximately 1,565 StatSpin Express 4 Centrifuges.

21. Shareholders Rights Plan

On September 24, 2010, the Company s board of directors adopted a shareholders rights plan under which each holder of a share of common stock also has one right to purchase one one-thousandth of a newly created Series A preferred share at $100 per one one-thousandth of a share.

The rights are not presently exercisable. Upon the occurrence of certain flip-in events, each right becomes exercisable which then entitles its holder to receive the number of Series A preferred shares having an aggregate per share market value price equal to two times the purchase price. Upon certain flip-over events, each right when exercised entitles its holder to receive equity securities of the acquiring company having a value equal to two times the purchase price. A flip-in event includes the acquisition by a person or group (an acquiring person) of 20 percent or more of the Company s common stock. Rights held by an acquiring person are void. The Company may redeem the rights for $0.001 per right and may amend the rights under the plan at any time prior to a triggering event. The rights expire on September 24, 2020.

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Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.***

None.

Item 9A. ***Controls and Procedures.***

Disclosure Controls and Procedures.

Based on their evaluation as of December 31, 2010, our Chief Executive Officer and Chief Financial Officer, with the participation of management, have concluded that our disclosure controls and procedures (as defined in Rules 13a 15(e) and 15d 15(e) of the Securities Exchange Act of 1934) were effective.

Management s Annual Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2010 using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework*. Based on this evaluation, our management concluded that as of December 31, 2010, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm.

BDO USA LLP, our independent registered public accounting firm that has audited our financial statements included herein, has issued an attestation report on our internal control over financial reporting, which report is included under Item 8 of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls.

Our disclosure controls and procedures provide our Chief Executive Officer and Chief Financial Officer reasonable assurances that our disclosure controls and procedures will achieve their objectives. However, company management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting can or will prevent all human error. A control system, no matter how well designed and implemented, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Furthermore, the design of a control system must reflect the fact that there are internal resource constraints, and the benefit of controls must be weighed relative to their corresponding costs. Because of the limitations in all control systems, no evaluation of controls can provide complete assurance that all control issues and instances of error, if any, within our company are detected. These inherent limitations include the realities that

judgments in decision-making can be faulty, and that breakdowns can occur due to human error or mistake. Additionally, controls, no matter how well designed, could be circumvented by the individual acts of specific persons within the organization. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated objectives under all potential future conditions.

Item 9B. ***Other Information.***

None.

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PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because the registrant will file with the U.S. Securities and Exchange Commission a definitive proxy statement pursuant to Regulation 14A in connection with the solicitation of proxies for our Annual Meeting of Stockholders expected to be held in May 2011 (the Proxy Statement) not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information included therein is incorporated herein by reference.

Item 10. ***Directors, Executive Officers and Corporate Governance.***

The information required by this item with respect to directors and executive officers may be found in the section Election of Directors appearing in the Proxy Statement. Such information is incorporated herein by reference.

The information required by this Item with respect to our audit committee and audit committee financial expert may be found in the section entitled Election of Directors Audit Committee appearing in the Proxy Statement. Such information is incorporated herein by reference.

The information required by this Item with respect to compliance with Section 16(a) of the Securities Exchange Act of 1934 and our code of ethics may be found in the sections entitled Section 16(a) Beneficial Ownership Reporting Compliance and Election of Directors Code of Business Conduct and Ethics, respectively, appearing in the Proxy Statement. Such information is incorporated herein by reference.

Item 11. ***Executive Compensation.***

The information required by this Item with respect to director and executive officer compensation is incorporated herein by reference to the information from the Proxy Statement under the section entitled Executive Compensation.

The information required by this Item with respect to Compensation Committee interlocks and insider participation is incorporated herein by reference to the information from the Proxy Statement under the section entitled Election of Directors Compensation Committee Interlocks and Insider Participation.

The information required by this Item with respect to our Compensation Committee s review and discussion of the Compensation Discussion and Analysis included in the Proxy Statement is incorporate herein by reference to the information from the Proxy Statement under the section entitled Election of Directors Compensation Committee Report.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.***

The information required by this Item with respect to security ownership of certain beneficial owners and management is incorporated herein by reference to the information from the Proxy Statement under the section entitled Security Ownership of Certain Beneficial Owners and Management.

The information required by this Item with respect to securities authorized for issuance under our equity compensation plans is incorporated herein by reference to the information from the Proxy Statement under the section entitled Equity Compensation Plan Information.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence.***

The information required by this Item with respect to related party transactions is incorporated herein by reference to the information from the Proxy Statement under the section entitled Certain Relationships and Related Transactions.

The information required by this Item with respect to director independence is incorporated herein by reference to the information from the Proxy Statement under the section entitled Election of Directors Independence of the Board of Directors.

Item 14. ***Principal Accounting Fees and Services.***

The information required by this Item is incorporated herein by reference to the information from the Proxy Statement under the section entitled Ratification of Selection of Independent Registered Public Accounting Firm.

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PART IV

Item 15. ***Exhibits, Financial Statement Schedules.***

(a) Documents filed as part of this report

1. *Financial Statements*

See Index to Financial Statements in Item 8 of this Annual Report on Form 10-K, which is incorporated herein by reference.

2. *Financial Statement Schedules*

All financial statement schedules are omitted because the information is inapplicable or presented in the Notes to Financial Statements.

The following exhibits are included herein or incorporated herein by reference:

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Exhibit	Filing Date	
2.1	Merger Agreement, dated July 26, 2010, by and among Iris International, Inc., AlliedPath Inc., and API Acquisition Corp.	8-K	001-11181	2.1	July 30, 2010	
3.1(a)	Certificate of Incorporation, filed June 9, 1987	8-K	001-11181	3.1(a)	September 29, 2010	
3.1(b)	Certificate of Amendment of Certificate of Incorporation, filed July 9, 1993	8-K	001-11181	3.1(b)	September 29, 2010	
3.1(c)	Certificate of Amendment of Certificate of Incorporation, filed June 6, 2001	8-K	001-11181	3.1(c)	September 29, 2010	
3.1(d)	Certificate of Ownership and Merger, filed November 26, 2003	8-K	001-11181	3.1(d)	September 29, 2010	
3.1(e)	Certificate of Correction of Certificate of Ownership and Merger, filed December 11, 2003	8-K	001-11181	3.1(e)	September 29, 2010	
3.1(f)	Certificate of Designation of Rights, Preferences and Privileges of Series A Preferred Stock, filed September 27, 2010	8-K	001-11181	3.1(f)	September 29, 2010	
3.2(a)	Restated Bylaws	10-KSB	001-11181	3.2	March 26, 2004	
3.2(b)	Amendment to Amended and Restated Bylaws	8-K	001-11181	3.2	July 18, 2007	
3.2(c)		8-K	001-11181	3.3	January 20, 2010	

	Amendment to Amended and Restated Bylaws				
4.1	Rights Agreement, dated as of September 24, 2010, between the Registrant and Continental Stock Transfer & Trust Company, as Rights Agent, including the Certificate of Designation of Rights, Preferences and Privileges of Series A Preferred Stock, the Form of Rights Certificate, and the Summary of Rights to Purchase Preferred Stock, attached thereto as Exhibits A, B and C, respectively.	8-K	001-11181	4.1	September 29, 2010

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Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Exhibit	Filing Date	
10.1(a)	Key Employee Agreement, dated February 13, 2004, between the Registrant and Cesar M Garcia.	10-K	001-11181	10.8(i)	March 26, 2004	
10.1(b)	First Amendment to Key Employee Agreement, dated December 21, 2006, between the Registrant and Cesar M Garcia.	10-K	001-11181	10.9(b)	March 23, 2007	
10.1(c)	Second Amendment to Key Employee Agreement, dated November 14, 2007, between the Registrant and Cesar M. Garcia.	8-K	001-11181	10.1	November 14, 2007	
10.1(d)	Third Amendment to Key Employee Agreement for Cesar M. Garcia effective May 14, 2010 between IRIS International, Inc. and Cesar M. Garcia.	8-K	001-11181	10.1	September 7, 2010	
10.2(a)	Key Employee Agreement, dated March 1, 2007, between the Registrant and Thomas E. Warekois.	10-K	001-1181	10.12	March 14, 2008	
10.2(b)	Amendment to Key Employee Agreement for Thomas Warekois, effective May 14, 2010 between IRIS International, Inc. and Thomas Warekois.	8-K	001-11181	10.3	September 7, 2010	
10.3(a)	Key Employee Agreement, dated November 7, 2007, between the Registrant and Robert Mello.	8-K	001-11181	10.2	November 14, 2007	
10.3(b)	Amendment to Key Employee Agreement for Robert Mello, effective May 14, 2010 between IRIS International, Inc. and Robert Mello.	8-K	001-11181	10.2	September 7, 2010	
10.4	Key Employee Agreement for Thomas H. Adams, PhD, dated September 2, 2010 between IRIS International, Inc. and Thomas H. Adams, Ph.D.	8-K	001-11181	10.5	September 7, 2010	
10.5	Key Employee Agreement for Amin Khalifa dated October 11, 2010 between IRIS International, Inc. and Amin Khalifa.	8-K	001-11181	10.1	October 13, 2010	
10.6		8-K	001-11181	10.1		

	Key Employee Agreement for Richard A. O Leary, dated February 14, 2011, between IRIS International, Inc. and Richard A. O Leary				February 17, 2011
10.7(a)	Key Employee Agreement, dated November 7, 2007, between the Registrant and John Yi.	8-K	001-11181	10.3	November 14, 2007

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Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Exhibit	Filing Date	
10.7(b)	Amendment to Key Employee Agreement for John Yi, effective May 14, 2010 between IRIS International, Inc. and John Yi.	8-K	001-11181	10.4	September 7, 2010	
10.8	Key Employee Agreement for Philip Ginsburg, dated July 28, 2010, by and between Iris International, Inc. and Philip Ginsburg.	8-K	001-11181	10.1	July 30, 2010	
10.9	Key Employee Agreement for Vance Randal White, dated July 28, 2010, by and between Iris International, Inc. and Vance Randal White.	8-K	001-11181	10.2	July 30, 2010	
10.10	1994 Stock Option Plan and forms of Stock Option Agreements.	S-8	33-82560	n/a		
10.11	1997 Stock Option Plan and form of Stock Option Agreement.	S-8	333-31393	4.2(a), 4.2(b)	July 16, 1997	
10.12	Amended and Restated 1998 Stock Option Plan.	10-K	001-11181	10.6	March 23, 2007	
10.13(a)	2007 Stock Incentive Plan.	S-8	333-145635	4.3	August 22, 2007	
10.13(b)	Amendment No. 1 to 2007 Stock Incentive Plan	8-K	001-11181	10.1	May 29, 2009	
10.14	Form of Restricted Stock Unit Agreement.	10-K	001-11181	10.18	March 16, 2010	
10.15	Form of Non-Qualified Stock Option Agreement.	10-K	001-11181	10.19	March 16, 2010	
10.16	Form of Incentive Stock Option Agreement.	10-K	001-11181	10.20	March 16, 2010	
10.17	Form of Restricted Stock Unit Deferral Election.	10-K	001-11181	10.21	March 16, 2010	
10.18	Letter Agreement, May 11, 2010, between IRIS International, Inc. and Avant Advisory Group.	10-Q	001-11181	10.1	August 6, 2010	
10.19(a)	Lease for Property Located at 9172 Eton Avenue, Chatsworth, California, dated November 29, 2001.	10-K	001-11181	10.1(a)	April 1, 2002	
10.19(b)	Amendment No. 1, dated October 17, 2005, to the Lease for Property Located at 9172 Eton Avenue, Chatsworth, California, dated November 28, 2001.	8-K	001-11181	10.2	November 18, 2005	
10.20		8-K	001-11181	10.1		

	Lease for Property Located at 9158-9162 Eton Avenue, Chatsworth, California, dated October 17, 2005.				November 18, 2005
10.21	Lease for Property Located at 9232 Eton Avenue, Chatsworth, California, dated February 8, 2010.	10-K	001-11181	10.17	March 16, 2010
10.22(a)	Business Loan Agreement dated May 25, 2004 by and between the Registrant and California Bank & Trust.	10-K	001-11181	10.3(b)	March 16, 2005

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Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Exhibit	Filing Date	
10.22(b)	Change in Terms Agreement dated March 24, 2006 by and between the Registrant and California Bank & Trust.	10-K	001-11181	10.6(b)	March 16, 2010	
10.22(c)	Change in Terms Agreement dated May 1, 2008 by and between the Registrant and California Bank & Trust.	8-K/A	001-11181	10.2	July 14, 2008	
10.22(d)	Letter Agreement, dated June 9, 2010, between IRIS International, Inc. and California Bank & Trust.	10-Q	001-11181	10.2	August 6, 2010	
10.23	Commercial Guaranty Agreement dated May 25, 2004 by and between the Registrant, StatSpin, Inc (the Registrant s affiliate) and California Bank & Trust.	10-K	001-11181	10.3(f)	March 16, 2005	
10.24	Commercial Security Agreements dated May 25, 2004 by and between the Registrant and California Bank & Trust.	10-K	001-11181	10.3(d)	March 16, 2005	
10.25(a)	Business Loan Agreement dated March 24, 2006 by and between the Registrant and California Bank & Trust.	10-K	001-11181	10.8(b)	March 16, 2010	
10.25(b)	Change in Terms Agreement dated March 24, 2006 by and between the Registrant and California Bank & Trust.	10-K	001-11181	10.8(c)	March 16, 2010	
10.25(c)	Change in Terms Agreement dated May 1, 2008 by and between the Registrant and California Bank & Trust.	8-K/A	001-11181	10.1	July 14, 2008	
10.25(d)	Change in Terms Agreement, dated August 31, 2010, by and between IRIS International, Inc. and California Bank & Trust.	8-K	001-11181	10.1	September 2, 2010	
10.26	Commercial Guaranty, dated August 31, 2010, by IRIS Molecular Diagnostics, Inc.	8-K	001-11181	10.2	September 2, 2010	
10.27	Commercial Security Agreement, dated August 31, 2010, by and among IRIS Molecular Diagnostics, Inc., IRIS International, Inc. and California	8-K	001-11181	10.3	September 2, 2010	

	Bank & Trust.	
21	List of Subsidiaries.	*
23.1	Consent of BDO USA, LLP.	*
24.1	Power of Attorney (included on signature page)	*
31.1	Certification of Principal Executive officer pursuant to Securities Exchange Act Rules 13a-14 and 15d-14 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	*

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Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Exhibit	Filing Date	
31.2	Certification of Principal Financial officer pursuant to Securities Exchange Act Rules 13a-14 and 15d-14 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
32.1	Certification of Principal Executive officer pursuant to Securities Exchange Act Rules 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					*
32.2	Certification of Principal Financial officer pursuant to Securities Exchange Act Rules 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					*

Each a management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report on Form 10-K.

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SIGNATURES

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in Chatsworth, California, on March 16, 2011.

IRIS INTERNATIONAL, INC.

By: /s/ CESAR M. GARCIA

Cesar M. García,
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Cesar M. Garcia and Amin I. Khalifa, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution for him, and in his name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the Registrant in the capacities indicated and on the date indicated:

Signature	Title	Date
/s/ CESAR M. GARCIA Cesar M. Garcia	President, Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	March 16, 2011
/s/ AMIN I. KHALIFA Amin I. Khalifa	Corporate Vice President of Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2011
/s/ THOMAS H. ADAMS Thomas H. Adams	Director	March 16, 2011
/s/ STEVEN M. BESBECK Steven M. Besbeck	Director	March 16, 2011

/s/ DAVID T. DELLA PENTA	Director	March 16, 2011
David T. Della Penta		
/s/ BETH Y. KARLAN	Director	March 16, 2011
Beth Y. Karlan		

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Signature	Title	Date
/s/ MICHAEL D. MATTE Michael D. Matte	Director	March 16, 2011
/s/ RICHARD G. NADEAU Richard G. Nadeau	Director	March 16, 2011
/s/ RICK TIMMINS Rick Timmins	Director	March 16, 2011
/s/ EDWARD F. VOBORIL Edward F. Voboril	Director	March 16, 2011
/s/ STEPHEN E. WASSERMAN Stephen E. Wasserman	Director	March 16, 2011