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

FORM 10-K

Mark One

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For The Fiscal Year Ended December 31, 2005

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from to

Commission File Number 0-22677

CLARIENT, INC.

(Exact name of registrant as specified in its charter)

Delaware	**75-2649072**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification Number)
33171 Paseo Cerveza **San Juan Capistrano, CA**	**92675-4824**
(Address of principal executive offices)	(Zip code)

(888) 443-3310
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:
NONE

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $.01
Rights to Purchase Series C Preferred Stock

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

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 ☐ No ☒

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 ☒ No ☐

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 the 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. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.
Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

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

As of June 30, 2005, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $38,447,273 based on the closing price as reported on the National Association of Securities Dealers Automated Quotation System National Market System.

The number of shares outstanding of each of the issuer's classes of common stock as of the latest practicable date,

Class	Outstanding at March 3, 2006
Common Stock, $.01 par value per share	66,813,227 shares

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated into the following parts of this Form 10-K:
(1) proxy statement for 2006 Annual Meeting of Stockholders – Part III Items 10, 11, 12, 13 and 14.

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Cautionary Note concerning Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, the industries in which we operate and other matters, as well as management's beliefs and assumptions and other statements regarding matters that are not historical facts. These statements include, in particular, statements about our plans, strategies and prospects. For example, when we use words such as "projects," "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates," "should," "would," "could," "will," "opportunity," "potential" or "may," variations of such words or other words that convey uncertainty of future events or outcomes, we are making forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Our forward-looking statements are subject to risks and uncertainties. Factors that might cause actual results to differ materially, include, but are not limited to, the Company's ability to obtain additional financing on acceptable terms or at all, the Company's ability to continue to develop and expand its services group business and its technology group business, the Company's ability to successfully move and consolidate the Company's laboratory and other operations into one new facility, the performance and acceptance of the Company's instrument systems in the market place, the Company's ability to expand and maintain a successful sales and marketing organization, continuation of favorable third party payer reimbursement for tests performed using the Company's system and for other diagnostic tests, unanticipated expenses or liabilities or other adverse events affecting cash flow, uncertainty of success in developing any new software applications, the Company's ability to successfully sell instruments under its distribution agreement with Dako A/S , failure to obtain Food and Drug Administration clearance or approval for particular applications, the Company's ability to compete with other technologies and with emerging competitors in cell imaging and dependence on third parties for collaboration in developing new tests and in distributing the Company's systems and tests performed on the system, and those risks which are discussed in "Risk Factors" below. Many of these factors are beyond our ability to predict or control. In addition, as a result of these and other factors, our past financial performance should not be relied on as an indication of future performance. All forward-looking statements attributable to us, or to persons acting on our behalf, are expressly qualified in their entirety by this cautionary statement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report might not occur.

PART I

Item 1. Business

General

Clarient was founded in 1993 and is headquartered in San Juan Capistrano, California. Our business is to combine innovative technologies with world class expertise to improve the ability of physicians to assess and characterize cancer. With the completion of the human genome project in the late 1990s, medical science has entered a new era of diagnostics that will move us closer than ever before to understanding the molecular causes for complex diseases, particularly cancer. As a result, the landscape of cancer management is undergoing significant change. There is now an escalating need for advanced oncology testing to provide physicians with necessary information on the cellular profile of a specific tumor, enabling them to select the most appropriate therapies. Significant business opportunities exist for companies, like Clarient, that execute strategies to extract value from this new environment.

We began performing under our new business plan in 2004 by launching a new business initiative – building a laboratory facility to provide comprehensive services focused on cancer testing for both the clinical and research markets. In 2005, we completed the transformation of our business to capitalize on the growth that is anticipated over the next five to ten years in the cancer diagnostics market. We changed our name from ChromaVision (positioned as a medical device provider with a single application) to Clarient – positioned as a technology and services company offering a full menu of advanced tests to assess and characterize cancer. We built the foundation for the execution of our business plan by gathering an experienced group of professionals from the anatomic pathology laboratory and the in-vitro diagnostics businesses to carefully guide this transition. Armed with our new laboratory license, in 2005 we embarked on a year of rapid growth as we commercialized a set of services to provide the community pathologist with the latest in cancer diagnostic technology. This offering was anchored by our own proprietary image analysis technology and was augmented by other emerging technologies critical to providing a complete assessment of the molecular cause and characteristics of cancer. We believe we are now in a position to capitalize on the growth of the cancer diagnostics market by focusing our business around two aspects of the cancer diagnostics market – services and technology:

Services Group – our services group delivers a wide variety of cancer diagnostics and consultative services, ranging from technical laboratory services to professional interpretation.

Technology Group – our technology group provides leading image analysis tools to hospitals, university medical centers and biopharmaceutical research organizations under the ChromaVision™ label.

Beyond these immediate opportunities, an important strategy is to create future revenue generating opportunities for both business groups by connecting our intellectual property and proprietary software to newly developed cancer therapeutics. This could result in new applications for our instrument technologies in the future as targeted therapeutics are released into the market with an associated test requiring our image analysis platform. By placing systems in key academic research centers and biopharmaceutical organizations, our systems can be established as a powerful standardization tool for the discovery and clinical trial process by aiding in target and patient selection for these emerging therapies. New tests will also drive higher demand for our specialized, high-end diagnostic services as a result of our expertise in related therapeutics.

Industry Overview

The advent of proteomics – the scientific study of DNA expression as specific proteins in cells and their activation pathways – has provided the ability to characterize cells in a number of diseases, such as cancer. This knowledge may be applied to provide early insight into the molecular definition of a disease and to clarify the most probable pathway for that disease process. Many biopharmaceutical and pharmaceutical companies are rapidly developing drugs to inhibit or reduce the adverse effects of certain proteins in cancer progression that will target tumor cells which exhibit certain genetic or behavioral characteristics. The goal is to yield better patient outcomes with fewer drug side effects.

Pharmaceutical companies are investing billions of dollars in the development of these high-potential targeted therapies, one of the fastest growing segment of oncology drug development. Every day of a delay to market has a substantial and quantifiable cost for these pharmaceutical companies. Further, many of these therapies will require a specific test (referred to as a "theranostic" or "companion diagnostic") to assist physicians in selecting the right drug for the right patient. Beginning early in the process, the same theranostic is likely to accelerate the process for drug approval and market introduction by guiding selection of the most appropriate patients for the clinical trials. In fact, the Food and Drug Administration (FDA) Critical Path Initiative specifies this approach.

Currently, we estimate that there are over 1,300 active drug projects focused on 45 cancer indications. Of these, 82 therapies are in Phase III clinical trials and an additional 321 compounds are in Phase II clinical trials. As the compounds that represent targeted therapies are released to the market, the way that cancer is managed will change dramatically. The result will be a clinical need for quantitative or semi-quantitative measurement of the relevant targeted proteins within a cancer cell. An example of a targeted therapy that uses a companion diagnostic test is Genentech's Herceptin, used to target breast tumor cells that have a significant amount of Her2/neu protein on the cell membrane. The National Comprehensive Cancer Network (NCCN) now mandates that all new breast tumors be tested for Her2/neu status levels.

Using traditional methods, it is often difficult to determine the patients that are most likely to benefit from new therapies. Although anatomic pathologists specialize in diagnosing abnormal changes in tissue, most anatomic pathology laboratories are still operating using traditional testing methods with little or no automation, no routine proficiency testing and a lack of standardized systems. We believe that pathologists need to be armed with the best resources to allow them to provide the most reliable and accurate information possible. We expect that new standardized, quantitative methods will be essential as clinicians require answers that are more precise, reliable and consistent.

We estimate that the market for advanced cancer diagnostic testing will increase from an estimated $1.5 billion today to over $2.5 billion by 2010. This increase is attributable to multiple factors including increasing incidences of cancer in an aging population, new therapies and expanded testing panels. Our previous concentration on image analysis systems limited us to participation in only the instrument systems portion of the market, which we estimate represented less than 10% of this market. Recent trends indicate treatment decisions are likely to involve the assessment of a complex panel of protein and gene based testing rather than a single test. Therefore, diagnostic and predictive testing for these therapies will likely become increasingly complex and there will be increased demand for sophisticated services to either interpret test results or assist pathologists in such interpretations. Our goal is to position ourselves to participate in a substantially greater portion of the cancer diagnostics market by serving the needs of the market from drug discovery through clinical practice with the services offered by our two business units.

Business Segments

We operate primarily in two business segments: our Services Group delivers critical oncology testing services to community pathologists, biopharmaceutical companies and other researchers; and our Technology Group is engaged in the development, manufacture and marketing of an automated cellular imaging system which is designed to assist physicians in making critical medical decisions. The segment and geographic area information for the year ended December 31, 2005 is incorporated by reference from Note 9 "Business Segments," of the Notes to the Consolidated Financial Statements.

Services Group

Diagnostic Services – we provide a wide variety of cancer diagnostics and consultative services, ranging from technical laboratory services to professional interpretation. By combining our core competencies in image analysis and data quantification with our knowledge of virtual environments, we believe we have created a unique service offering to community pathologists in the U.S. We believe that the growing need for precise diagnosis combined with the ability to put comprehensive information into a single, coherent computer-accessible platform for clinicians presents development opportunities for new directed diagnostic services using the image analysis platform. We offer a broad menu of specialized technologies such as image analysis, FISH (fluorescent in situ hybridization), flow cytometry, cytogenetics and molecular diagnostics. Our focus in anatomic pathology is on the top four solid tumors (breast, prostate, lung and colon) representing 61% of all new cases. In addition, we also provide hematopathology testing for leukemia and lymphoma. The laboratory expects to expand our service offerings as new assays emerge.

BioAnalytical Services – we provide a complete compliment of commercial services to biopharmaceutical companies and other research organizations to assist their efforts, ranging from drug discovery to the development of directed diagnostics through clinical trials. Through these services, we seek to apply our intellectual property and proprietary software to the ongoing development of custom applications with FDA-cleared reagents using our image analysis platform. We believe that this in turn will allow us to develop a much larger menu of applications for our instrument systems and to drive higher demand for our diagnostic services. In 2005, we signed agreements with Pfizer and Eli Lilly that formally launched our service offering in the biopharmaceutical research segment.

Services Group Billing. Revenues for our services group are derived primarily from billing insurers, pathologists and patients for the diagnositic services that we provide.

Third party billing. The majority of revenue currently generated by our services group is for patients that utilize insurance coverage from Medicare or other third party insurance companies such as Blue Cross. In these situations, we bill an insurer that pays a percentage of the amount billed based on several factors including the type of coverage (for example, HMO or PPO), whether the charges are considered to be in network or out of network, and the amount of any co-pays or deductibles that the patient may have at that time. The rates that are billed are typically a percentage of those amounts allowed by Medicare for the service provided as defined by Common Procedural Terminology (CPT) codes. The amounts that are paid to us are a function of the payers' practice for paying claims of these types and whether we have specific agreements in place with the payers. We also have a Medicare provider number that allows us to bill and collect from Medicare. In 2005, we entered into 15 agreements with health insurance, and other third party payers, and plan to continue these efforts in the future.

Client (pathologist) billing. In some situations, we establish direct billing arrangements with our clients where we bill them for an agreed amount per test for the services provided and the client will then handle all billing directly with the private payers. The amounts that may be charged to our clients is determined in accordance with applicable state and federal laws and regulations.

Patient billing. Less than 10% of our billings are billed directly to patients. These billings can result from co-payment obligations, patient deductibles, circumstances where certain tests are not covered by insurance companies, and patients without any health insurance.

Technology Group

Instrument Systems – we provide hardware, software and web-enabled cellular image analysis systems using FDA-cleared proprietary algorithms. Our technology group provides powerful, innovative analysis platforms for the researcher and clinician – built upon the ChromaVision legacy of the Automated Cellular Imaging System (ACIS®). The ACIS® combines an automated microscope and a digital camera with color imaging software to scan stained slides of tissue or cells. Using proprietary technology, the pathologist is then able to view the stored images for interpretation and quantitative analysis. As the first integrated digital cellular imaging device, the ACIS® has elevated the use of bright field microscopy in anatomic pathology to a new level. Based on the number of system placements, the ACIS® is now a preferred digital imaging solution in cell-based analysis around the world. Studies have shown that the ACIS® provides the reproducible and reliable results that today's targeted cancer therapies and drug discovery efforts require. We have also developed the Access Remote Pathology program, allowing community pathologists to take advantage of this new technology despite having limited in-house staining capability or a low volume of slides that would not justify having a full ACIS® system.

The ACIS® is designed to complement the skills of pathologists by assisting them in generating more accurate, specific and reproducible results – reducing the subjectivity associated with current manual testing methods. The system's ability to overcome the limitations of the human eye (even when aided by a microscope) significantly improves the pathologist's ability to analyze cells and tissue. Our FDA clearance, obtained in 1998, states that "The Automated Cellular Imaging System (ACIS®) device is intended to detect, count, and classify cells of clinical interest based on recognition of cellular objects of particular color, size, and shape." The ACIS® is also FDA-cleared specifically for Her2, Estrogen Receptor (ER) and Progesterone Receptor (PR) applications, which represent the most common applications that are currently used to characterize new breast cancer tumors. Over 200 institutions, including university medical centers and biopharmaceutical companies around the world presently utilize ACIS® technology.

To date, Herceptin therapy for breast cancer has been the only major therapeutic requiring quantitative diagnosis for therapy selection. However, there is increasing evidence that the utility of multiple stains will become more widely accepted and create a significant opportunity to take image analysis to the next level. These stains, commonly referred to as "cocktail" or "multiplex" stains, are likely to require image analysis for quantification because the human eye will be challenged to quantify multiple colors and concentrations of these stains in cells. In addition, the ability to synthesize the complex data from these "biomarker panels" will require more sophisticated analytical tools – yet another emerging opportunity for Clarient.

As more targeted therapeutics become available, our technology strategy is centered on:

- the continued improvement of our hardware and software capabilities;
- positioning our platform as the system of choice for standardization and quantification of new "cocktail" stains;
- leveraging our installed base of ACIS® systems as a foundation for driving market adoption; and
- a growing demand for consistent results requiring high quality reagents that is enhanced and supported by our technology.

In June 2005, we signed a distribution and development agreement with Dako A/S (Dako), a Danish company recognized as a worldwide leader in diagnostic pathology testing services. We believe this arrangement will enable us to significantly expand our reach into this market and to provide a world-class reagent and technology solution. Under the terms of the distribution agreement, Dako pays us a transfer price for each unit sold. Dako offers a number of acquisition options to accommodate the customers and reduce their initial capital burden. In addition, the agreement provides for a recurring per test fee as we jointly develop new FDA cleared applications using Dako's reagents on the ACIS® and future platforms.

Core R&D – in order to compete in the development of biomakers and new assay applications, in November of 2005, we signed a licensing agreement with Health Discovery to gain access to a bio mathematics technology called Support Vector Machines (SVM). This technology is a strong augmentation of our legacy intellectual property. The combination allows the synthesis of large amounts of data to identify key relationships that may lead to a better diagnostic or assessment tool. By combining Clarient's proprietary intellectual property with the newly acquired SVM, our Core R&D group develops new applications and biomarkers to better assess and characterize cancers for both the biopharmaceutical and clinical markets.

While 2005 was a year of transformation, in 2006 we intend to focus primarily on execution. Our guiding strategic agenda is to capitalize on market dynamics to drive short-term and long-term revenue growth through five critical imperatives:

- enhance and expand our market share in the space for oncology services;
- leverage our image analysis leadership and brand equity;
- increase our technology footprint through our alliance with Dako;
- strengthen, leverage and defend our intellectual property position in technology and biomarker development; and
- expand biopharma connectivity related to their efforts ranging from drug discovery to the development of directed diagnostics through clinical trials.

Sales

The process of selling diagnostic services requires a different approach and skill set than the more capital-oriented sales process for the sale and distribution of our ACIS® system. As a result, we established two distinct sales units to cover each of these business units. We have supplemented the sales team in several key markets, such as New York and Florida, to enable us to reach more customers in these areas. We currently have 32 people dedicated to sales and marketing. We are organized into three regions, with a sales manager for each region. Within a region, each sales representative has a dedicated territory selected based on revenue potential. We intend to continue to expand our sales force where appropriate. Our sales approach focuses on expanding organic sales in our current customer base as well as new customer acquisition targets.

The majority of our current sales resources is dedicated to the growing diagnostic services business. Targeting community pathology practices and hospitals, the sales process for this business group is designed to understand the customer's needs and develop appropriate solutions from our range of laboratory service options.

We also have a dedicated instrument systems sales organization. To ensure the success of our joint commercial efforts, this team is now solely focused on assisting the Dako sales team targeting, selling and closing instrument placements in both the clinical and research markets as image analysis specialists.

Marketing & Strategic Initiatives

In 2005, our marketing efforts were focused on establishing a strong and distinctive brand identity for diagnostic services within our targeted segment of community pathologists. We launched a significant advertising campaign in the first six months. In parallel, we also launched the CONTiNUUM regional seminar program as a demonstration of our brand, designed to provide a one-on-one collaborative environment for our advisory board and medical staff to interact directly with potential customers. This program will form the cornerstone of our marketing efforts in 2006 and expand to include national events and "webinar" formats.

We also implemented a web-based sales system to create a focal point for customer and territory management data. We will expand this program in 2006 by implementing the marketing module to allow automated tracking of CONTiNUUM events, tradeshows and other marketing initiatives. Our marketing expenses in 2006 will be used to reinforce our branding around collaboration with the community pathologist, and focused on creating customer advocates for our diagnostic service business.

Market Segmentation

Clinical Market

We approach the clinical market as three distinct groups of potential customers. Our data indicate that there are approximately 4,000 hospitals or networks in the U.S. that require cancer diagnostic or prognostic services. Clarient has a specific offering designed for each target segment.

Regional reference laboratories, regional cancer centers, large hospitals or multi-hospital systems and the associated large pathology practice groups: These customers typically have comprehensive capabilities, including automated staining equipment, and they perform most anatomic pathology tests in-house. Pathologists within these organizations are the primary target for ACIS® placements with Dako staining systems. In addition, they may use a specialized oncology reference laboratory for highly complex testing or difficult cases and represent a secondary target for our services group. Our data indicate approximately 400 institutions are in this category.

Larger community hospitals and pathology groups: While many pathologists have the expertise to perform and evaluate testing, the costs of acquiring the necessary equipment and staff are often prohibitive. These high costs make them the primary targets for our PATHSiTE suite of virtual services. For these customers, we typically perform the technical aspects at our facility, and then allow the pathologist to accesses the information at his convenience via the Internet to perform the professional evaluation. Since community hospitals and pathology groups typically choose to outsource most specialized tests, they are also primary targets for our more comprehensive diagnostic services offerings. Certain of these customers may elect to perform some anatomic pathology testing in-house which represents our secondary targets for ACIS®.

Smaller community hospitals and pathology groups: While these customers typically outsource all testing, their volume is relatively very small. These customers represent secondary targets for our diagnostic services business.

Research Market

We estimate that there are over 1,000 organizations world-wide that could benefit from the ACIS® technology. We focus on two distinct types of organizations that conduct tissue-based research:

Pharmaceutical and biopharmaceutical companies: These companies could benefit by using the ACIS® technology in the drug discovery and development process.

University medical centers and research institution:. These organizations are focused on later stage clinical trials and represent targets for ACIS® placements, depending on grant funding availability. This group also includes the government and entities such as The National Cancer Institute, The National Institutes for Health and The Centers for Disease Control and Prevention as well as cancer cooperative groups such as the Eastern Cooperative Oncology Group, National Surgical Adjuvant Breast and Bowel Project and Southwest Oncology Group.

Patents and Proprietary Technology

We file patent applications to protect technology, innovations and improvements that we consider important to the development of our business. Currently, we have 25 patent applications pending with the U.S. Patent and Trademark Office and eight foreign patent applications pending. We have 21 issued patents in the U.S. and 10 foreign patents, all related to the system and method for cellular specimen grading performed by the ACIS® or related technologies. The patents for which we have received a final issuance have remaining legal lives that vary from 12 to 19 years.

In all our patent applications we have endeavored to file claims which cover the underlying concepts of the unique features of the ACIS®, its associated processes and methodologies as well as our specific implementation of those processes and methodologies. As a further protection against efforts to erode our proprietary position, we have systematically explored other designs, which could achieve results similar to the ACIS® and we have prepared patent applications on those alternate designs.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, through confidentiality agreements with our employees, consultants, customers, business partners, and other third parties. As a condition of employment, we require that all full-time and part-time employees enter into an inventor assignment and non-disclosure agreement.

We intend to continue to broaden the scope of our intellectual property portfolio, which we consider critical to our future product development.

If we are unable to protect our patents and proprietary rights, our reputation and competitiveness in the marketplace could be materially damaged. Litigation may therefore be necessary in order to enforce any patents that we now hold or that are issued to us.

Competition

Competition in the pharmaceutical and biotechnology industries, and the medical devices and diagnostic products segments in particular, is intense and has been accentuated by the rapid pace of technological development. Our competitors in this area include large diagnostics and life sciences companies. In addition, there are a number of small companies in both the U.S. and Europe that are beginning to emerge.

Services Group

The oncology testing marketplace has been consolidating. The esoteric clinical laboratory business, including flow cytometry, molecular diagnostics, analysis of tumors of unknown origin, expanded services for immunohistochemistry and cytogenetics is highly competitive and is dominated by two national laboratories – Laboratory Corporation of America Holdings (LabCorp) and Quest Diagnostics. Both companies offer a wide test and product menu with significant financial, sales and logistical resources. In addition, they have an extensive portfolio of contracts with payer groups. The third major competitor is Genzyme, with a strong presence in oncology diagnostics as a result of its purchase of IMPATH.

Our secondary competitors are laboratories affiliated with large medical centers or universities, such as Mayo Medical Laboratories and Associated Regional University Pathologists (ARUP). An emerging competitor is AmeriPath based on its recent purchase of Specialty Labs.

Technology Group

With the growing acceptance of image analysis in research and clinical markets, the number of competitors has increased. Both large companies with established positions in adjacent markets and small niche companies are targeting this space.

In the clinical market, our primary competition is the continued use of manual microscopy in approximately 70% of breast cancer testing. Our most significant direct competitors are autostainer and reagent companies that are working to expand into image analysis to stabilize their installed base or to enter the image analysis market. Our competitors include Ventana Medical Systems which recently has acquired the rights to market the Tri-Path Imaging system. In addition, BioGenix has just released a new stainer to the market and is believed to be releasing a full image analysis system later this year.

In the research market, Applied Imaging has been our most significant competitor with both a bright field and a dual platform with fluorescence. A large number of research institutions still use systems developed internally.

There are also numerous products that compete in specific areas, such as scanning hardware or image analysis software. The two major microscope companies, Olympus and Zeiss, have released sophisticated image analysis software packages – primarily used by researchers. Aperio has a high-quality scanning platform that has been attractive to certain customers that are not doing quantitative analysis. It recently released a virtual product that is targeted to both the clinical and research market.

Collaborations and Partnerships

In the future, our goal is to become a valued partner for the development and marketing of advanced image analysis products and services. We believe that our relationship with Dako positions us to gain more rapid market acceptance as an "automated solutions" provider. We have entered into and will continue to use scientific collaborations to assist in identifying and validating applications of our technology and enhancing our marketing capabilities. We collaborate with customers as well as researchers at prestigious hospitals and major laboratories to assist with clinical studies and to publish peer reviewed scientific papers.

In order to compete in the development of bio markers and new assay applications, we needed to strengthen our intellectual property base so we may fully capitalize on our legacy patents. In November, we signed a licensing agreement with Health Discovery to gain access to a bio mathematics SVM technology. This technology is a strong augmentation of our legacy intellectual property. The combination allows the synthesis of large amounts of data to identify key relationships that may lead to a better diagnostic or assessment tool.

We intend to utilize the SVM platform to expedite the improvement of our circulating cell capabilities. While the clinical market for circulating tumor/endothelial cells is still emerging, there appears to be strong interest from biopharmaceutical organizations for these assays as new anti-angiogenic drugs enter phase 2 and 3 clinical trials. Such therapeutics could benefit significantly if correlation can be drawn between a therapy regimen and a change in circulating endothelial cells. Recent studies show the promise of circulating tumor cells as a prognostic factor for cancer recurrence. We will also be utilizing the SVMs for other application and test development.

Reimbursement

Laboratory services provided for patients with the assistance of ACIS® technology are eligible for third party reimbursement under well-established medical billing codes. These billing codes are known as Common Procedural Terminology (CPT®) codes and are the means by which Medicare and private insurers identify medical services that are provided to patients in the United States. CPT codes are established by the American Medical Association (AMA). The Medicare reimbursement dollar amounts for the CPT codes are established by the Centers for Medicare and Medicaid Services (CMS), with recommendations from the AMA's Relative Value Update Committee and professional societies representing the various medical specialties.

A new CPT code (88361), specific to computer-assisted image analysis, went into effect on January 1, 2004. Under the new code, in 2004 the total Medicare reimbursement for ACIS®-based procedures performed in physician offices or independent laboratories was approximately $139 per test, reflecting a technical component of approximately $84 and a professional component of approximately $55. The technical component involves preparation of the patient sample and scanning the image on the ACIS®, while the professional component involves the physician's reading and evaluation of the test results.

We worked with relevant medical societies and other appropriate constituents to obtain appropriate reimbursement amounts by all payers for providers of image analysis-based services. The objective of these efforts is for the amount paid by Medicare and other payers for image analysis-based services to accurately reflect the technology costs, the benefit that image analysis brings to patients, and its positive impact on healthcare economics. For 2005, these rates were increased to approximately $166 per test, of which $99 was for the technical component of reimbursement and $67 was for professional interpretation. These rates remain in effect for 2006. In California, where our laboratory performs these tests for our diagnostic services operation, 2006 reimbursement is $195 per test, of which $122 is for the technical component and $73 is for professional interpretation.

Beyond image analysis, we perform other tests that are subject to different codes and amounts of reimbursement from Medicare, third party insurance payers, and, in a limited number of cases, from patients. For this reason, our average reimbursement per test will change based on the mix of these tests. Additionally, billing for these services is complicated. We must bill various payers, such as patients, insurance companies, Medicare and other third parties, all of which have different billing requirements. Compliance with applicable laws and regulations as well as internal compliance procedures adds complexity to this process. Other items such as pricing differences and payer disputes also complicate billing.

Research & Development

To ensure our ability to identify and develop new applications for our technology platform, we have re-organized the group around two areas of competencies. Core R&D will focus on the scientific elements of assay design for the use of advanced imaging as applied to the detection and quantification of reagent-stained cellular material by experienced Ph.D.-level staff. Our software engineering group will focus on the advanced programming required to perform these assays on our image analysis platform and in a virtual environment through our services group. Quality and regulatory is also included in this group.

Manufacturing

The ACIS® is currently manufactured at our facility in San Juan Capistrano, California. Our employees assemble the components, optically align the microscope, load the software and quality test the system. Components of the system are manufactured internally, purchased off-the-shelf, or manufactured by subcontractors to our specifications. The system uses an off-the-shelf charged couple device (CCD) camera and personal computer. The system can be adapted for use with most popular microscopes and related optical accessories. The ACIS® has been designed to be fully modular to take advantage of improvements in microscopy and computer hardware.

Governmental Regulatory Status

General

Our business is subject to extensive regulations, including the following.

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. These laws include the federal anti-kickback law which prohibits individuals or entities, including clinical laboratories, from, among other things, making any payments or furnishing other benefits intended to induce or influence the referral of patients for tests billed to Medicare, Medicaid or certain other federally funded programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In addition, some kickback allegations have been claimed to violate the federal False Claims Act (discussed above). In addition, many states have adopted laws similar to the federal anti-kickback law. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs. Many of the federal and state anti-fraud statutes and regulations, including their application to joint ventures and collaborative agreements, are vague or indefinite and have not been interpreted by the courts.

In addition, these laws also include self-referral prohibitions which prevent us from accepting referrals from physicians who have non-exempt ownership or compensation relationships with us as well as anti-markup and direct billing rules that may apply to our relationships with our customers. Specifically, the federal anti-"self-referral" law, commonly known as the "Stark" Law, prohibits, with certain exceptions, Medicare payments for laboratory tests referred by physicians who have, personally or through a family member, an investment interest in, or a compensation arrangement with, the testing laboratory. A person who engages in a scheme to circumvent the Stark Law's prohibitions may be fined up to $100,000 for each such arrangement or scheme. In addition, anyone who presents or causes to be presented a claim to the Medicare program in violation of the Stark Law is subject to monetary penalties of up to $15,000 per claim submitted, an assessment of several times the amount claimed, and possible exclusion from participation in federal healthcare programs. In addition, claims submitted in violation of the Stark Law may be alleged to be subject to liability under the federal False Claims Act and its whistleblower provisions.

Several states in which we operate have enacted legislation that prohibits physician self-referral arrangements and/or requires physicians to disclose any financial interest they may have with a healthcare provider to their patients when referring patients to that provider. Some of these statutes cover all patients and are not limited to Medicare or Medicaid beneficiaries. Possible sanctions for violating state physician self-referral laws vary, but may include loss of license and civil and criminal sanctions. State laws vary from jurisdiction to jurisdiction and, in a few states, are more restrictive than the federal Stark Law. Some states have indicated they will interpret their own self-referral statutes the same way that the U.S. Centers for Medicare and Medicaid Services (CMS) interprets the Stark Law, but it is possible the states will interpret their own laws differently in the future. The laws of many states prohibit physicians from sharing professional fees with non-physicians and prohibit non-physician entities, such as us, from practicing medicine and from employing physicians to practice medicine.

Of particular importance to our operations are federal and state laws prohibiting fraudulent billing and providing for the recovery of non-fraudulent overpayments, as a large number of laboratories have been forced by the federal and state governments, as well as by private payers, to enter into substantial settlements under these laws. In particular, 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 of between $5,500 to $11,000 for each separate false claim. There are many potential bases for liability under the federal False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. Submitting a claim with reckless disregard or deliberate ignorance of its truth or falsity could result in substantial civil liability. A trend affecting the healthcare industry is the increased use of the federal False Claims Act and, in particular, actions under the False Claims Act's "whistleblower" or "qui tam" provisions. Those provisions allow a private individual to bring actions on behalf of the government alleging that the defendant has submitted a fraudulent claim for payment to the federal government. The government must decide whether to intervene in the lawsuit and to become the primary prosecutor. If it declines to do so, the individual may choose to pursue the case alone, although the government must be kept apprised of the progress

of the lawsuit. Whether or not the federal government intervenes in the case, it will receive the majority of any recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, various states have enacted laws modeled after the federal False Claims Act.

The use and disclosure of patient medical information is subject to substantial regulation by federal, state, and foreign governments. For example, the Health Insurance Portability and Accountability Act of 1996, known as HIPAA, was enacted among other things, to establish uniform standards governing the conduct of certain electronic health care transactions and to protect the security and privacy of individually identifiable health information maintained or transmitted by health care providers, health plans and health care clearinghouses. We are currently required to comply with three standards under HIPAA. We must comply with the Standards for Electronic Transactions, which establish standards for common health care transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures; unique identifiers for providers, employers, health plans and individuals; security; privacy; and enforcement. We were required to comply with these Standards by October 16, 2003. We also must comply with the Standards for Privacy of Individually Identifiable Information, which restrict our use and disclosure of certain individually identifiable health information. We were required to comply with the Privacy Standards by April 14, 2003. The Security Standards required us to implement certain security measures to safeguard certain electronic health information by April 20, 2005. In addition, CMS has published a final rule, which will require us to adopt a Unique Health Identifier for use in filing and processing health care claims and other transactions by May 23, 2007. While the government intended this legislation to reduce administrative expenses and burdens for the health care industry, our compliance with this law may entail significant and costly changes for us. If we fail to comply with these standards, we could be subject to criminal penalties and civil sanctions.

Services Group

Because our diagnostic services business operates a clinical laboratory, many aspects of our business are subject to complex federal, state and local regulations applicable to laboratory operations. In 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. CLIA is user fee funded; therefore, all costs of administering the program must be covered by the regulated facilities, including certificate and survey costs.

The final CLIA regulations were published on February 28, 1992 and updated on January 24, 2003. CLIA specifies quality standards for proficiency testing, patient test management, quality control, personnel qualifications and quality assurance for laboratories performing non-waived tests. Non-waived laboratories must enroll in CLIA, pay the applicable fee and follow manufacturers' instructions. Our laboratory service offerings now include tests in the non-waived category.

The Centers for Medicare & Medicaid Services (CMS) is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, approvals of proficiency testing providers, accrediting organizations and exempt states. The Centers for Disease Control and Prevention is responsible for the CLIA studies, convening the Clinical Laboratory Improvement Amendments Committee (CLIAC) and providing scientific and technical support/consultation to the Department of Health and Human Services and CMS. The FDA is responsible for test categorization.

To enroll in the CLIA program, laboratories must first register by completing an application, pay fees, be surveyed, if applicable, and become certified in the state in which they operate. We received our California state licensure with CLIA certification in the fourth quarter of 2004.

The State of California Department of Health Services (DHS) enforces the state's requirement that our facility have a Medical Device Manufacturing License; while the State of California Department of Health and Human Services - Laboratory Field Services enforces the requirements to apply for and maintain licensure, CLIA certification, and proficiency testing. CLIA Accreditation is maintained through regular inspections by the College of American pathologists (CAP). 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 manufacturing of medical devices or provision of laboratory services if we failed to maintain these licenses. We must also satisfy various other state application and provisional requirements.

Laws and regulations pertaining to the products and/or services we provide are subject to change and depend heavily on administrative interpretations by federal and state government agencies, including the FDA.

In anticipation of marketing our products in the European Union (EU) and in accordance with the In-Vitro Diagnostic Directive (IVDD) we applied for and received certification to EN13485:2003. The ACIS® product was CE marked in 1998. The CE Mark was applied after we demonstrated compliance with applicable regulatory requirements, including, but not limited to, compliance with pertinent ISO and EN requirements and certification by a recognized notified body.

Federal law and the laws of many states generally specify who may practice medicine and limit the scope of relationships between medical practitioners and other parties. Under such laws, we are prohibited from practicing medicine or exercising control over the provision of medical services and may only do so through a professional corporation designed for this purpose. In order to comply with such laws, all medical services are provided by or under the supervision of Clarient Pathology Associates, Inc. (the P.C.). We refer to the P.C. and us collectively throughout this report as "we", "us", and "our", except in this paragraph. The P.C. is organized so that all physician services are offered by the physicians who are employed by the P.C. Clarient does not employ practicing physicians as practitioners, exert control over their decisions regarding medical care, or represent to the public that Clarient offers medical services. Clarient has entered into an Administrative Services Agreement with the P.C. pursuant to which Clarient performs all non-medical management of the P.C. and has exclusive authority over all aspects of the business of the P.C. (other than those directly related to the provision of patient medical services or as otherwise prohibited by state law). The non-medical management provided by Clarient includes, among other functions, treasury and capital planning, financial reporting and accounting, pricing decisions, patient acceptance policies, setting office hours, contracting with third party payers, and all administrative services. Clarient provides all of the resources (systems, procedures, and staffing) or contract with third party billing services to bill third party payers or patients. Clarient also provides or outsources all of the resources for cash collection and management of accounts receivables, including custody of the lockbox where cash receipts are deposited. From the cash receipts, Clarient pays all physician salaries and operating costs of the center. Compensation guidelines for the licensed medical professionals at the P.C. are set by Clarient, and Clarient has established guidelines for selecting, hiring, and terminating the licensed medical professionals. Where applicable, Clarient also negotiates and execute substantially all of the provider contracts with third party payers. Clarient will not loan or otherwise advance funds to the P.C. for any purpose.

We believe that the services Clarient provides and will provide in the future to the P.C. does not constitute the practice of medicine under applicable laws. Because of the unique structure of the relationships described above, many aspects of our business operations have not been the subject of state or federal regulatory interpretation. We have no assurance that a review of our business by the courts or regulatory authorities will not result in a determination that could adversely affect our operations or that the health care regulatory environment will not change so as to restrict our existing operations or future expansion.

Technology Group

As a medical device, our ACIS® product is subject to governmental regulation in the U.S. and in other countries. In the U.S., the Federal Food, Drug, and Cosmetic Act (FD&C Act), along with the regulations promulgated by the FDA, as well as various other federal and state statutes and regulations, govern, among other things, the design and development, the testing, manufacture, labeling, storage, record keeping, premarket clearance or approval, distribution, sale, marketing, advertising and promotion and importing and exporting of medical devices.

Before a company can place a medical device into interstate commerce for sale in the United States, the FDA must review and approve or clear the device unless it is exempt under the FDA's regulations. Approvals and clearances are generally for specific intended uses. This regulatory process can be lengthy, expensive and uncertain. Extensive clinical data and other information can be required by the FDA in order for the agency to approve or clear a medical device.

Under the FD&C Act and its regulations, medical devices are placed into one of three classes on the basis of the FDA's view of their risk and the controls necessary for assuring their safety and effectiveness. These three categories are referred to as Class I, Class II and Class III. ACIS® was cleared as a Class II product.

Class I devices are those in the lowest risk category. As such, many Class I medical devices are exempt from certain pre-market and other regulatory requirements. To sell a non-exempt Class I device or a Class II device, a manufacturer must submit a notification and obtain an order from the FDA stating that the product is cleared for marketing in the United States. This FDA clearance is achieved through the filing of a Pre-market Notification (510(k)) based on the device being "substantially equivalent" to a legally marketed product, i.e., a Class I or Class II medical device or a Class III device for which FDA has not yet required a Premarket Approval Application (PMA).

Class III devices are those in the highest risk category. As such, a manufacturer must submit and obtain FDA approval of a PMA before the device can be introduced to the U.S. market. The PMA process is significantly more complex and time-consuming than the 510(k) process. The PMA process almost always requires the submission of well-controlled clinical investigations in order to obtain FDA approval. On average, FDA reviews and clears a 510(k) submission within six months. PMA approval by the agency generally takes at least one year and can even take a number of years. A change or modification of a product cleared through the 510(k) process can result in the need for a new 510(k) submission where the change or modification could significantly adversely affect the safety or effectiveness of the device. A change in a device that is the subject of an approved PMA could require a PMA supplement.

We obtained our first 510(k) clearance in May 1997 from the FDA to market the ACIS® with a test to screen blood for malignancy. In July 1999 we received our second 510(k) clearance from the FDA which granted use of the ACIS® to assist the pathologist to detect, count and classify cells of clinical interest based on recognition of cellular objects of particular color, size and shape. In 2002 we received a 510(k) clearance from the FDA which granted the ability to use ACIS® to conduct an Estrogen Receptor and Progesterone Receptor (ER/PR) test, which aid in the management, prognosis and prediction of therapeutic response for cancer. In December 2003, we received our most recent 510(k) clearance from the FDA which recognizes the ability of ACIS® to detect, count, and classify the presence of the HER2 protein, allowing physicians a more precise and quantitative understanding of the specific traits of individual cancer tumors. Specifically, this FDA clearance allows ACIS® to be used as a complement to Dako's HercepTest™ in the detection and measurement of Her2/*neu* (c-erbB-2).

As a Class II medical device manufacturer, we are also subject to the FDA's Quality System Regulation (QSR) which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process. In addition, we are subject to FDA's regulations regarding labeling, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions, medical device reporting and reports of corrections and removals. The medical device reporting regulations require us to provide certain information to the FDA in the event of a death or serious injury allegedly associated with the use of ACIS® or any product malfunction which would likely cause or contribute to a death or serious injury if the malfunction were to recur. Class II devices may also be required to adhere to certain "special controls" including but not limited to performance standards, post-market surveillance and/or patient registries where applicable. In addition, we must comply with applicable regulatory requirements for the export of our products.

The FDA's QSR requires, among other things, that we have (i) a written quality assurance policy and procedures for controlling and documenting all aspects of our manufacturing processes, (ii) the ability to produce devices which meet the applicable design controls and specifications which have been validated by extensive and detailed review of each of the manufacturing processes, and (iii) the ability to conduct, and written procedures for conducting, corrective and preventative actions. The FDA conducts periodic inspections to determine compliance with all of the regulatory requirements imposed by the FD&C Act and its regulations. If deficiencies are noted during the inspection, the FDA investigator may issue FDA Form 483 that lists the observed deficiencies.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: fines, injunctions, and civil penalties; recall or seizure of our products; operating restrictions; suspension of production; refusing our request for 510(k) clearance or premarket approval of new products; withdrawing 510(k) clearance or premarket approvals that are already granted; and criminal prosecution.

Employees

As of December 31, 2005, we had 139 employees of which 14 persons were in product development, engineering and discovery positions, 15 were in manufacturing, quality assurance, and field services, 65 were in laboratory diagnostics, 13 were in finance, executive and administrative capacities and 32 were in sales and marketing. We are not subject to any collective bargaining agreements, and we believe that our relationship with our employees is good.

In addition to full-time employees, we utilize the services of various independent contractors, primarily for certain product development and foreign sales, marketing and administrative activity.

Available Information

All periodic and current reports, registration statements, and other filings that Clarient, Inc. is required to file with the Securities and Exchange Commission (SEC), including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) of the Exchange Act, are available free of charge from the SEC's website (http://www.sec.gov) or public reference room at 450 Fifth Street N.W., Washington, DC 20549 (1-800-SEC-0330) or through Clarient's Internet website at http://www.clarientinc.com. Such documents are available as soon as reasonably practicable after electronic filing of the material with the SEC. Copies of these reports (excluding exhibits) may also be obtained free of charge, upon written request to: Investor Relations, Clarient, Inc., 33171 Paseo Cerveza, San Juan Capistrano, CA 92675.

The internet website address for Clarient is included in this report for identification purpose. Clarient's internet website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

The following corporate governance documents are available free of charge on the Company's website: the charters of our Audit, Compensation and Corporate Governance Committees, our Statement on Corporate Governance and our Code of Conduct. Copies of these corporate governance documents also may be obtained by any shareholder, free of charge, upon written request to: Corporate Secretary, Clarient, Inc., 33171 Paseo Cerveza, San Juan Capistrano, CA 92675. We also will post on our website any amendments to or waivers of our Code of Conduct that relate to our directors and executive officers.

Item 1A. Risk Factors

Before deciding to invest in us or to maintain or increase your investment, you should carefully consider the risks described below, in addition to the other information contained in this report and other reports we have filed with the Securities and Exchange Commission. The risks and uncertainties described below are not the only ones facing our Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business operations. If any of these risks are realized, our business, financial condition or results of operations could be seriously harmed. In that event, the market price for our common stock could decline and you may lose all or part of your investment.

Risks Related to Our Business

We have limited experience in providing laboratory and other services, which may cause us to experience difficulties that could delay or prevent the development, introduction and marketing of these services.

We began providing the technical component of reference laboratory services in-house beginning in April 2004 and we began to provide additional oncology-focused laboratory services that complement our image analysis and certified Access reference laboratory services in December 2004. The success and viability of these initiatives is dependent on a number of factors including:

- our ability to develop and provide services that we have provided only for a short time;
- adequate reimbursement;
- medical efficacy as demonstrated by clinical studies and governmental clearances;
- governmental clearances, governmental regulations and expansion of the menu of tests performed by ACIS® to bring greater economies of scale to our accounts operations; and
- our ability to obtain timely renewal of state and federal regulatory licenses.

We may not be successful in any of these areas, we may experience difficulties that could delay or prevent the successful development, introduction and marketing of these services, and we may not adequately meet the demands of the marketplace or achieve market acceptance. Our inability to accomplish any of these endeavors may have a material adverse effect on our business, operating results, cash flows and financial condition.

Our instrument business is highly dependent on the efforts of our distribution partners and on increased market penetration of the ACIS®, and it is uncertain whether the ACIS® will achieve that penetration.

Increased market acceptance of the ACIS® depends on a number of variables, including, but not limited to, the following:

- the ability of the ACIS® to perform as expected;
- acceptance by patients, physicians, third party payers and laboratories of the ACIS® to run the tests performed using it;
- our ability to develop a significant number of tests performed with the ACIS®;
- the amount of reimbursement by third party payers for a test performed using the ACIS®;
- our ability to expand our diagnostic laboratory service initiative;
- the effectiveness of our marketing, distribution and pricing strategy;
- availability of alternative and competing diagnostic products; and
- scientific studies and other publicity concerning ACIS® or competitive products.

The future commercial success of our products will depend primarily on convincing research, reference and clinical laboratories to evaluate and offer these products as research tools for scientists and clinical investigators and as diagnostic products to physicians, laboratory professionals and other medical practitioner and convincing physicians, laboratory professionals and other medical practitioners to order tests for their patients involving our technologies. To accomplish this, we will need to convince oncologists, pathologists and other members of the medical and biotechnology communities of the benefits of our products. Additionally, if ongoing or future clinical trials result in unfavorable or inconsistent results, these products may not achieve market acceptance. Even if the efficacy of our future products and services are established, physicians may elect not to use them for a number of reasons. These reasons might include the training required for their use or unfavorable reimbursement from health care payers.

We have entered into and intend to continue to enter into corporate collaborations for the development of new applications, clinical collaborations with respect to tests using the ACIS® and strategic alliances for the distribution of the ACIS® and our other products, including products we may develop in the future. In July 2005, we entered into a distribution and development agreement with Dako, which is exclusive in research and clinical markets and non-exclusive with respect to biotechnology and pharmaceutical companies (and their academic research partners). We therefore depend upon the success of Dako to distribute our ACIS® products and perform their responsibilities under our collaborative arrangements. If Dako is not successful, the marketability of our products and services may be limited and our technology could become underfunded and obsolete relative to new, emerging technologies of companies that have greater financial resources. We cannot assure you that we will be able to enter into additional arrangements that may be necessary in order to develop and commercialize our products, or that we will realize any of the contemplated benefits from existing or new arrangements.

We have a history of operating losses, and our future profitability is uncertain.

We have incurred operating losses in every year since inception, and our accumulated deficit as of December 31, 2005 was $120 million. Those operating losses are principally associated with the research and development of our ACIS® technology, the conducting of clinical trials, preparation of regulatory clearance filings, the development of Dako's sales and marketing organization to commercialize the ACIS® and the capital investments we have made relating to our recently launched diagnostic services business. Although leasing and sales of the ACIS® have been encouraging since we introduced our new business strategy in the third quarter of 2004 and we have recently begun to provide a wide array of laboratory services, we may not be able to achieve profitable operations at any time in the future.

Because our operating expenses are likely to increase in the near term, we will need to generate significant additional revenue to achieve profitability. We expect to continue to incur losses as a result of the expansion of the laboratory services, ongoing research and development expenses, as well as increased sales expenses. We are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and then maintain profitability, the market value of our common stock will decline.

We are in the process of relocating our business and will be required to make significant expenditures in connection therewith.

We recently relocated our diagnostic services laboratory to a new facility in Aliso Viejo, California. We currently lease our corporate headquarters and manufacturing facility on a month-to-month basis, and we intend to move our corporate headquarters and manufacturing facility to the Aliso Viejo facility during the second quarter of 2006. The recent relocation of our diagnostic services laboratory and the move of our corporate headquarters and manufacturing facility to the Aliso Viejo facility could create risk of business interruption and will require substantial capital investment. There is no guarantee that we will be able to successfully complete this move to a new facility.

We may require additional financing for, among other things, planned expansion of our laboratory operations, capital expenditures and other costs related to the move to a new facility, and expenses associated with our anticipated increase in placements of our ACIS® systems and it is uncertain whether such financing will be available on favorable terms, if at all.

We may require additional debt or equity financing if we are unable to access one or more of these financing sources. In addition, we have expended and will continue to expend substantial funds for research and development, clinical trials and marketing of our system and expanding our service offerings. We will also need additional capital if our new business initiatives are not successful or we fail to achieve the level of revenues and gross profit from our services in the time frame contemplated by our business plan.

Our present and future funding requirements will also depend on certain other external factors, including, among other things:

- the level of research and development investment required to maintain and improve our technology position;
- costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our need or decision to acquire or license complementary technologies or acquire complementary businesses;
- competing technological and market developments; and
- changes in regulatory policies or laws that affect our operations.

We do not know whether additional financing will be available on commercially acceptable terms when needed. If adequate funds are not available or are not available on commercially acceptable terms, we might be required to delay, scale back or eliminate some or all of our development activities, new business initiatives, clinical studies or regulatory activities or to license to third parties the right to commercialize products or technologies that we would otherwise seek to commercialize ourselves. If additional funds are raised through an equity or convertible debt financing, our stockholders may experience significant dilution.

Our strategy for the development and commercialization of the ACIS® platform contemplates collaborations with third parties, making us dependent on their success.

We do not have the ability to independently conduct the clinical trials required to obtain regulatory clearances for our applications, but rely on third-party expert clinical investigators and clinical research organizations to perform these functions. If we cannot locate and enter into favorable agreements with acceptable third parties, or if these third parties do not successfully carry out their contractual obligations, meet expected deadlines or follow regulatory requirements, including clinical laboratory, manufacturing and good clinical practice guidelines, then we may be the subject of an enforcement action by the FDA or other regulatory bodies, and may be unable to obtain clearances for our products or to commercialize them on a timely basis, if at all.

Our ability to engage in certain business transactions may be limited by the restrictive covenants of our debt financing agreements.

Our existing financing agreements with Comerica Bank-California contain financial covenants requiring us to meet financial ratios and financial condition tests, as well as covenants restricting our ability to:

- incur additional debt;
- pay dividends or make other distributions or payments on capital stock;
- make investments;
- incur or permit to exist liens;
- enter into transactions with affiliates;
- change business, legal name or state of incorporation;
- guarantee the debt of other entities, including joint ventures;
- merge or consolidate or otherwise combine with another company; and
- transfer or sell our assets.

These covenants could adversely affect our ability to finance our future operations or capital needs and pursue available business opportunities, including acquisitions. A breach of any of these covenants could result in a default in respect of the related indebtedness. If a default occurs, the relevant lenders could elect to declare the indebtedness, together with accrued interest and other fees, to be immediately due and payable and proceed against any collateral securing that indebtedness. We believe that we are currently in compliance with the covenants in our financing agreements.

We have limited commercial manufacturing capacity and may encounter difficulties as we undertake to manufacture our system in increasing quantities.

We may encounter significant delays and incur significant unexpected costs in scaling-up our manufacturing operations. In addition, we may encounter delays and difficulties in hiring and training the workforce necessary to manufacture the ACIS® in the increasing quantities required for us to achieve profitability. The failure to scale-up manufacturing operations successfully, in a timely and cost-effective manner, could have a material adverse effect on our revenues and income. We believe that we have adequate manufacturing capacity to meet anticipated demand for 2006. However, in order to meet demand thereafter, we will have to expand our manufacturing processes and manpower or rely on third-party manufacturers. We might encounter difficulties in expanding our manufacturing processes and hiring qualified personnel or in developing relationships with third-party manufacturers. If we are unable to overcome these difficulties our ability to meet product demand could be impaired or delayed.

We may not successfully manage our growth, which may result in delays or unanticipated difficulties in implementing our business plan.

Our success will depend upon the expansion of our operations and the effective management of our growth. We expect to experience growth in the scope of our operations and services and the number of our employees. If we grow significantly, such growth will place a significant strain on management and on administrative, operational and financial resources. To manage any growth, we would need to expand our facilities, augment our operational, financial and management systems, internal controls and infrastructure and hire and train additional qualified personnel. Our future success is heavily dependent upon growth and acceptance of our future products and services. If we are unable to scale our business appropriately or otherwise adapt to anticipated growth and new product introduction, our business, operating results, cash flows and financial condition may be harmed.

The medical imaging technology market is characterized by rapid technological change, frequent new product introductions and evolving industry standards, and we may encounter difficulties keeping pace with changes in this market.

The introduction of diagnostic tests embodying new technologies and the emergence of new industry standards can render existing tests obsolete and unmarketable in short periods of time. We expect competitors to introduce new products and services and enhancements to existing products and services. The life cycles of tests using the ACIS®, and of the ACIS® itself, are difficult to estimate. Our future success will depend upon our ability to enhance our current tests, to develop new tests, and to enhance and continue to develop the hardware and software included in the ACIS®, in a manner that keeps pace with emerging industry standards and achieves market acceptance. Our inability to accomplish any of these endeavors will have a material adverse effect on our business, operating results, cash flows and financial condition.

We face substantial existing competition and potential new competition from others pursuing technologies for imaging systems.

We compete in a highly competitive industry. ACIS® was first released in 1997 for use in research as an imaging system for the detection of rare cellular events. The primary application was for the detection of cells which contained a marker used to distinguish possible cancerous cells in bone marrow. At that time, the most significant competition to the ACIS® for this application was use of manual microscopes and certain other cell-based techniques. These other techniques include polymerase chain reaction (PCR), a technique used in clinical labs to detect DNA sequences, and flow cytometry, a technique used to analyze biological material through the detection of the light-absorbing or fluorescing properties of cells. A natural progression for Clarient and the ACIS® was to penetrate the manually intensive slide-based cancer testing market, with an initial focus on the breast cancer market. Companies such as Dako, Ventana and BioGenex have greater cancer-testing market share and stronger medical laboratory relationships than we do. They also have two of the critical system components needed to drive standardization—reagents and staining automation. In July 2005, we entered into a distribution and development agreement with Dako relating to our ACIS® system, which is exclusive in research and clinical markets and non-exclusive with respect to biotechnology and pharmaceutical companies (and their academic research partners). Other imaging companies such as TriPath and Applied Imaging are currently expanding into this market. Advancements in alternative cancer diagnostic tests and the development of new protein-based therapies will bring increased competition to this market segment, and such competition could adversely affect our operating results, cash flows and financial condition.

The clinical laboratory business is intensely competitive both in terms of price and service. This industry is dominated by several national independent laboratories, but includes many smaller niche and regional independent laboratories as well. Large commercial enterprises, including Quest and LabCorp, have substantially greater financial resources and may have larger research and development programs and more sales and marketing channels than we do, enabling them to potentially develop and market competing products and services. These enterprises may also be able to achieve greater economies of scale or establish contracts with payer groups on more favorable terms. Smaller niche laboratories compete with us based on their reputation for offering a narrow test menu. Academic and regional medical institutions generally lack the advantages of the larger commercial laboratories but still compete with us on a limited basis. Pricing of laboratory testing services is one of the significant factors often used by health care providers in selecting a laboratory. As a result of the clinical laboratory industry undergoing significant consolidation, larger clinical laboratory providers are able to increase cost efficiencies afforded by large-scale automated testing. This consolidation results in greater price competition. We may be unable to increase cost efficiencies sufficiently, if at all, and as a result, our operating results, cash flows and our financial position could be negatively impacted by such price competition.

Competition in the pharmaceutical and biotechnology industries, and the medical devices and diagnostic products segments in particular, is intense and has been accentuated by the rapid pace of technological development. Our competitors in this area include large diagnostics and life sciences companies. Most of these entities have substantially greater research and development capabilities and financial, scientific, manufacturing, marketing, sales and service resources than we do. Some of them also have more experience than we do in research and development, clinical trials, regulatory matters, manufacturing, marketing and sales.

Because of their experience and greater research and development capabilities, our competitors might succeed in developing and commercializing technologies or products earlier and obtaining regulatory approvals and clearances from the FDA more rapidly than we can. Our competitors also might develop more effective technologies or products that are more predictive, more highly automated or more cost-effective, and that may render our technologies or products obsolete or non-competitive.

We rely significantly on third-party manufacturers who may fail to supply us with components necessary to our products and services on a timely basis.

We rely currently and intend to continue to rely significantly in the future on third-party manufacturers to produce all of the components used in our ACIS® device and for future instrument systems that we may develop. We are dependent on these third-party manufacturers to perform their obligations in a timely and effective manner and in compliance with FDA and other regulatory requirements.

To date, we have generally not experienced difficulties in obtaining components from our manufacturers and, in cases where a particular manufacturer was unable to provide us with a necessary component, we have been able to locate suitable secondary sources. However, if the suppliers we rely on in the manufacturing of our products were unable to supply us with necessary components and we were unable to locate acceptable secondary sources, we might be unable to satisfy product demand, which would negatively impact our business. In addition, if any of these components are no longer available in the marketplace, we will be forced to further develop our technologies to incorporate alternate components. If we incorporate new components or raw materials into our products we might need to seek and obtain additional approvals or clearances from the FDA or foreign regulatory agencies, which could delay the commercialization of these products.

Failure in our information technology systems could disrupt our operations.

Our success will depend, in part, on the continued and uninterrupted performance of our information technology systems. Information systems are used extensively in virtually all aspects of our business, including laboratory testing, billing, customer service, logistics and management of medical data. Our success depends, in part, on the continued and uninterrupted performance of our information technology systems.

Our computer systems are vulnerable to damage from a variety of sources, including telecommunications failures, malicious human acts and natural disasters. Moreover, despite reasonable security measures we have implemented, some of our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems, in part because we conduct business on the Internet and because some of these systems are located at third party web hosting providers and we cannot control the maintenance and operation of the data centers. Despite the precautions we have taken, unanticipated problems affecting our systems could cause interruptions in our information technology systems, leading to lost revenue, deterioration of customer confidence, or significant business disruption. Our business, financial condition, results of operations, or cash flows could be materially and adversely affected by any problem that interrupts or delays our operations.

If a catastrophe were to strike our facility, we would be unable to operate our business competitively.

We currently assemble, test and release our ACIS® device at our facility located in San Juan Capistrano, California and we provide diagnostic services from our new laboratory facility in Aliso Viejo, California. We do not have alternative production plans in place or alternative facilities available at this time. If there are unforeseen shutdowns to our facility, we will be unable to satisfy customer orders on a timely basis.

Our facilities may be affected by catastrophes such as fires, earthquakes or sustained interruptions in electrical service. Earthquakes are of particular significance to us because all of our clinical laboratory facilities are located in Southern California, an earthquake-prone area. In the event our existing facilities or equipment are affected by man-made or natural disasters, we may be unable to process our customers' samples in a timely manner and unable to operate our business in a commercially competitive manner.

Our ability to maintain our competitive position depends on our ability to attract and retain highly qualified managerial, technical and sales and marketing personnel.

We believe that our continued success depends to a significant extent upon the efforts and abilities of our executive officers and our scientific and technical personnel, including the following individuals:

- Ronald A. Andrews, our President and Chief Executive Officer;
- Heather Creran, our Executive Vice President and Chief Operating Officer—Diagnostic Services;
- Ken Bloom, M.D., our Chief Medical Director;
- Karen Garza, our Vice President of Marketing and Strategic Initiatives;
- Jose de la Torre-Bueno, Ph.D., our Vice President and Chief Technology Officer;
- David J. Daly, our Vice President of Sales; and
- James Cureton, our Vice President of Instrument Systems.

We do not maintain key-person life insurance on any of our officers, scientific and technical personnel or other employees. The loss of any of our executive officers or senior managers could have a material adverse effect on our business, operating results, cash flows and financial condition.

Our Chief Financial Officer resigned on February 3, 2006. We have engaged a professional search firm to begin recruitment of a new Chief Financial Officer and have hired John A. Roberts to serve as our Acting Chief Financial Officer on an interim basis.

Furthermore, our anticipated growth and expansion will require the addition of highly skilled technical, management, financial, sales and marketing personnel. In particular, we may encounter difficulties in attracting a sufficient number of qualified California licensed laboratory scientists. Competition for personnel is intense, and our failure to hire and retain talented personnel or the loss of one or more key employees could have a material adverse effect on our business. Many members of our current senior management group have been recruited and hired over the past 18 months. These individuals may not be able to fulfill their responsibilities adequately and may not remain with us.

***The reimbursement rate for ACIS*®-based services has changed significantly over the past several years and further changes may result in an adverse effect on our revenues and results of operations.**

The majority of the sales of our products in the U.S. and other markets will depend, in large part, on the availability of adequate reimbursement to users of these products from government insurance plans, including Medicare and Medicaid in the U.S., managed care organizations, private insurance plans and other third-party payers. The continued success of the ACIS® depends upon its ability to replace or augment existing procedures that are covered and otherwise eligible for payments and covered by the medical insurance industry.

We are not able to fully assess or predict the full impact of future changes in reimbursement levels on our business at this time, nor whether Medicare will review the medical necessity and appropriateness of amounts that have been paid in prior years, although it is likely that reductions in reimbursement levels will impact our pricing, profitability and the demand for testing.

Our net revenue will be diminished if payers do not adequately cover or reimburse our services.

There has been and will continue to be significant efforts by both federal and state agencies to reduce costs in government healthcare programs and otherwise implement government control of healthcare costs. In addition, increasing emphasis on managed care in the U.S. may continue to put pressure on the pricing of healthcare services. Uncertainty exists as to the coverage and reimbursement status of new applications or services. Third party payers, including governmental payers such as Medicare and private payers, are scrutinizing new medical products and services and may not cover or may limit coverage and the level of reimbursement for our services. Third party insurance coverage may not be available to patients for any of our existing assays or assays we discover and develop. However, a substantial portion of the testing for which we bill our hospital and laboratory clients is ultimately paid by third party payers. Any pricing pressure exerted by these third party payers on our customers may, in turn, be exerted by our customers on us. If government and other third party payers do not provide adequate coverage and reimbursement for our assays, our operating results, cash flows or financial condition may decline.

Managed care organizations are using capitated payment contracts in an attempt to shift payment risks which may negatively impact our operating margins.

Managed care providers typically contract with a limited number of clinical laboratories and then designate the laboratory or laboratories to be used for tests ordered by participating physicians. The majority of managed care testing is negotiated on a fee-for-service basis at a discount. Such discounts have historically resulted in price erosion and we expect that they could negatively impact our operating margins as we continue to offer laboratory services to managed care organizations.

Third party billing is extremely complicated and will result in significant additional costs to us.

Billing for laboratory services is extremely complicated. The customer refers the tests; the payer is the party that pays for the tests, and the two are not always the same. Depending on the billing arrangement and applicable law, we need to bill various payers, such as patients, insurance companies, Medicare, Medicaid, doctors and employer groups, all of which have different billing requirements. Additionally, our billing relationships require us to undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Insurance companies also impose routine external audits to evaluate payments made. This adds further complexity to the billing process.

Among many other factors complicating billing are:

- pricing differences between our fee schedules and the reimbursement rates of the payers;
- disputes with payers as to which party is responsible for payment; and
- disparity in coverage and information requirements among various carriers.

We incur significant additional costs as a result of our participation in the Medicare and Medicaid programs, as billing and reimbursement for clinical laboratory testing are subject to considerable and complex federal and state regulations. The additional costs we expect to incur include those related to: (1) complexity added to our billing processes; (2) training and education of our employees and customers; (3) implementing compliance procedures and oversight; (4) collections and legal costs; and (5) costs associated with, among other factors, challenging coverage and payment denials and providing patients with information regarding claims processing and services, such as advanced beneficiary notices.

We may acquire other businesses, products or technologies in order to remain competitive in our market and our business could be adversely affected as a result of any of these future acquisitions.

We may make acquisitions of complementary businesses, products or technologies. If we identify any additional appropriate acquisition candidates, we may not be successful in negotiating acceptable terms of the acquisition, financing the acquisition, or integrating the acquired business, products or technologies into our existing business and operations. Further, completing an acquisition and integrating an acquired business will significantly divert management time and resources. The diversion of management attention and any difficulties encountered in the transition and integration process could harm our business. If we consummate any significant acquisitions using stock or other securities as consideration, our shareholders' equity could be significantly diluted. If we make any significant acquisitions using cash consideration, we may be required to use a substantial portion of our available cash. Acquisition financing may not be available on favorable terms, if at all. In addition, we may be required to amortize significant amounts of other intangible assets in connection with future acquisitions, which would harm our operating results, cash flows and financial condition.

Risks Related to Litigation and Intellectual Property

Product liability claims could subject us to significant monetary damage.

The manufacture and sale of the ACIS® and similar products entails an inherent risk of product liability arising from an inaccurate, or allegedly inaccurate, test or diagnosis. We currently maintain numerous insurance policies, including a $2,000,000 general liability policy, a $5,000,000 technology-based errors and omissions policy and a $10,000,000 umbrella liability policy (which excludes technology based errors and omissions). These policies have deductible ranges from $5,000 to $25,000 and contain customary exclusions (including certain exclusions for medical malpractice and asbestos). Although we have not experienced any material losses to date, we cannot assure you that we will be able to maintain or acquire adequate product liability insurance in the future. Any product liability claim against us could have a material adverse effect on our reputation and operating results, cash flows and financial condition.

Clinicians or patients using our products or services may sue us and our insurance may not sufficiently cover all claims brought against us, which will increase our expenses.

The development, marketing, sale and performance of healthcare services expose us to the risk of litigation, including professional negligence. Damages assessed in connection with, and the costs of defending, any legal action could be substantial. We currently maintain numerous insurance policies, including a $3,000,000 professional liability insurance policy ($2,000,000 per incident). This policy has a deductible of $10,000 and contains customary exclusions (including exclusions relating to asbestos and biological contaminants). However, we may be faced with litigation claims which exceed our insurance coverage or are not covered under any of our insurance policies. In addition, litigation could have a material adverse effect on our business if it impacts our existing and potential customer relationships, creates adverse public relations, diverts management resources from the operation of the business or hampers our ability to perform assays or otherwise conduct our business.

If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages.

Our research and development and clinical pathology activities sometimes involve the controlled use of potentially harmful biological materials, hazardous materials, chemicals and various radioactive compounds. We cannot completely eliminate the risk of accidental contamination or injury to third parties from the use, storage, handling or disposal of these materials. We currently maintain numerous insurance policies, including a $2,000,000 general liability policy and a $10,000,000 umbrella liability policy (which excludes technology-based errors and omissions). These policies have deductible ranges from $5,000 to $25,000 and contain customary exclusions (including certain exclusions relating to asbestos and medical malpractice). However, in the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations is significant and could negatively affect our operations, cash flows and financial condition if these costs increase substantially.

Any breakdown in the protection of our proprietary technology, or any determination that our proprietary technology infringes on the rights of others, could materially affect our business.

Our commercial success will depend in part on our ability to protect and maintain our proprietary technology and to obtain and enforce patents on our technology. We rely primarily on a combination of copyright and trademark laws, trade secrets, confidentiality procedures and contractual provisions to protect our proprietary rights. However, obtaining, defending and enforcing our patents and other intellectual property rights involve complex legal and factual questions. We cannot assure you that we will be able to obtain, defend or enforce our patent rights covering our technologies in the U.S. or in foreign countries, or be able to effectively maintain our technologies as unpatented trade secrets or otherwise obtain meaningful protection for our proprietary technology. Moreover, we cannot assure you that third parties will not infringe, design around, or improve upon our proprietary technology or rights.

The healthcare industry has been the subject of extensive litigation regarding patents and other proprietary rights and if we are unable to protect our patents and proprietary rights, through litigation or otherwise, our reputation and competitiveness in the marketplace could be materially damaged.

We may initiate litigation to attempt to stop the infringement of our patent claims or to attempt to force an unauthorized user of our trade secrets to compensate us for the infringement or unauthorized use. Patent and trade secret litigation is complex and often difficult and expensive, and would consume the time of our management and other significant resources. If the outcome of litigation is adverse to us, third parties may be able to use our technologies without payments to us. Moreover, some of our competitors may be better able to sustain the costs of litigation because they have substantially greater resources. Because of these factors relating to litigation, we may be unable to prevent misappropriation of our patent and other proprietary rights effectively.

If the use of our technologies conflicts with the intellectual property rights of third-parties, we may incur substantial liabilities and we may be unable to commercialize products based on these technologies in a profitable manner, if at all.

Our competitors or others may have or acquire patent rights that they could enforce against us. If they do so, we may be required to alter our technologies, pay licensing fees or cease activities. If our technologies conflict with patent rights of others, third parties could bring legal action against us or our licensees, suppliers, customers or collaborators, claiming damages and seeking to enjoin manufacturing and marketing of the affected products. If these legal actions are successful, in addition to any potential liability for damages, we might have to obtain a royalty or licensing arrangement in order to continue to manufacture or market the affected products. A required license or royalty under the related patent or other intellectual property may not be available on acceptable terms, if at all.

We may be unaware of issued patents that our technologies infringe. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, that may later result in issued patents upon which our technologies may infringe. There could also be existing patents of which we are unaware upon which our technologies may infringe. In addition, if third parties file patent applications or obtain patents claiming technology also claimed by us in pending applications, we may have to participate in interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention. If third parties file oppositions in foreign countries, we may also have to participate in opposition proceedings in foreign tribunals to defend the patentability of the filed foreign patent applications. We may have to participate in interference proceedings involving our issued patents or our pending applications.

If a third party claims that we infringe upon its proprietary rights, any of the following may occur:

- we may become involved in time-consuming and expensive litigation, even if the claim is without merit;
- we may become liable for substantial damages for past infringement, including possible treble damages for allegations of willful infringement, if a court decides that our technologies infringe upon a competitor's patent;
- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms, if at all, or which may require us to pay substantial royalties or grant cross licenses to our patents; and
- we may have to redesign our product so that it does not infringe upon others' patent rights, which may not be possible or could require substantial funds or time.

If any of these events occurs, our business, results of operation, cash flows and financial condition will suffer and the market price of our common stock will likely decline.

Risks Related to Regulation of Our Industry

FDA regulations and those of other regulatory agencies can cause significant uncertainty, delay and expense in introducing new applications for the ACIS® and present a continuing risk to our ability to offer applications.

As a medical device, our ACIS® product is subject to extensive and frequently changing federal, state and local governmental regulation in the U.S. and in other countries. The FDA pursuant to its authority under the Food, Drug and Cosmetic Act, regulates virtually all aspects of the development, testing, manufacture, labeling, storage, record keeping, distribution, sale, marketing, advertising and promotion and importing and exporting of medical devices. Failure to comply with applicable governmental requirements can result in 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. In addition, changes in existing laws or regulations, or new laws or regulations, may delay or prevent us from marketing our products or cause us to reduce our pricing.

If we are not able to obtain all of the regulatory approvals and clearances required to commercialize our products, our business would be significantly harmed.

The ACIS® and other medical devices we develop require clearance or approval by the FDA before they can be commercially distributed in the U.S. and may require similar approvals by foreign regulatory authorities before distribution in foreign jurisdictions. Regulatory clearance or approval of applications for the ACIS® or other products we may develop, including the related software, may be denied or may include significant limitations on the indicated uses for which it may be marketed. The FDA actively enforces the prohibition on marketing products that have not been approved or cleared and also imposes and enforces strict regulations regarding the validation and quality of manufacturing, which are enforced through periodic inspection of manufacturing facilities. Foreign countries have comparable regulations.

In most cases, the development and commercialization of additional diagnostic applications in the U.S. will require either pre-market notification, or 510(k) clearance, or pre-market approval (PMA) from the FDA prior to marketing. The 510(k) clearance pathway usually takes from two to twelve months from submission, but can take longer. The pre-market approval pathway is much more costly, lengthy, uncertain and generally takes from one to two years or longer from submission. We do not know whether we will be able to obtain the clearances or approvals required to commercialize these products. In addition, modifications and enhancements to a medical device also require a new FDA clearance or approval if they could significantly affect its safety or effectiveness or would constitute a major change in the device's intended use, design or manufacture. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. If the FDA requires us to seek clearance or approval for modification of a previously cleared product for which we have concluded that new

clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

In the case of a PMA and/or a 510(k), there is no assurance that the agency will agree with the submission and/or clear or approve the product. FDA may reject a 510(k) submission and require that a company file a PMA instead. Determination by FDA that any of our devices or certain applications of ours are subject to the PMA process could have a material adverse effect on our business, results of operations and financial condition. Nonetheless, a business benefit can accrue where FDA approves a PMA because holding a PMA may, in some instances, provide a competitive advantage. A change or modification of a medical device that has already received FDA clearance or approval can result in the need to submit further filings to the agency.

Applications submitted for FDA clearance or approval will be subject to substantial restrictions, including, among other things, restrictions on the indications for which we may market these products, which could result in lower revenues. The marketing claims we will be permitted to make in labeling or advertising regarding our cancer diagnostic products, if cleared or approved by the FDA, will be limited to those specified in any clearance or approval. In addition, we are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. Finally, we are subject to medical device reporting regulations that require us to report to the FDA or similar governmental bodies in other countries if our products cause or contribute to a death or serious injury or malfunction in a way that would be reasonably likely to contribute to death or serious injury if the malfunction were to recur. If the FDA finds that we have failed to comply with these requirements, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions, including:

- fines, injunctions and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- denial of requests for 510(k) clearances or pre-market approvals of product candidates;
- withdrawal of 510(k) clearances or pre-market approvals already granted; and
- criminal prosecution.

Any of these enforcement actions could affect our ability to commercially distribute our products in the U.S. and may also harm our ability to conduct the clinical trials necessary to support the marketing, clearance or approval of additional applications.

We cannot predict the extent of future FDA regulation of our in-house diagnostic laboratory services.

Neither the FDA nor any other governmental agency currently fully regulates the in-house diagnostic laboratory services that we market to physicians, laboratory professionals and other medical practitioners. These tests are commonly referred to as "home brews." FDA maintains that it has the authority to regulate "home brews" under the Federal Food, Drug, and Cosmetic Act as medical devices, however, as a matter of enforcement discretion, but has decided not to exercise its authority. FDA is currently assessing the feasibility of applying additional regulatory controls over in-house diagnostic laboratory testing. We cannot predict the extent of future FDA regulation and there can be no assurance that the FDA will not require in-house diagnostic laboratory testing to receive premarketing clearance, or premarket approval prior to marketing. Additional FDA regulatory controls over our in-house diagnostic laboratory services could add substantial additional costs to our operations, and may delay or prevent our ability to commercially distribute our services in the U.S.

Our medical devices, facilities and products are subject to significant quality control oversight and regulations, and our failure to comply with these could result in penalties or enforcement proceedings.

Manufacturers of medical devices are subject to federal and state regulation regarding validation and the quality of manufacturing facilities, including FDA's Quality System Regulation, or QSR, which covers, among other things, the design, testing production processes, controls, quality assurance, labeling, packaging, storing and shipping of medical devices. The FDA periodically inspects facilities to ascertain compliance with these and other requirements. Our failure to comply with these quality system regulations could result in, among other things, warning letters, fines, injunctions, seizures, civil or criminal penalties or enforcement proceedings, including the recall of a product or a "cease distribution" order requiring us to stop placing our products in service or selling, any one of which could materially adversely affect our business, results of operations and financial condition. Similar results would occur if we were to violate foreign regulations.

Our operations are subject to strict laws prohibiting fraudulent billing and other abuse, and our failure to comply with such laws could result in substantial penalties.

Of particular importance to our operations are federal and state laws prohibiting fraudulent billing and providing for the recovery of non-fraudulent overpayments, as a large number of laboratories have been forced by the federal and state governments, as well as by private payers, to enter into substantial settlements under these laws. In particular, 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 of between $5,500 to $11,000 for each separate false claim. There are many potential bases for liability under the federal False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. Submitting a claim with reckless disregard or deliberate ignorance of its truth or falsity could result in substantial civil liability. A trend affecting the healthcare industry is the increased use of the federal False Claims Act and, in particular, actions under the False Claims Act's "whistleblower" or "qui tam" provisions. Those provisions allow a private individual to bring actions on behalf of the government alleging that the defendant has submitted a fraudulent claim for payment to the federal government. The government must decide whether to intervene in the lawsuit and to become the primary prosecutor. If it declines to do so, the individual may choose to pursue the case alone, although the government must be kept apprised of the progress of the lawsuit. Whether or not the federal government intervenes in the case, it will receive the majority of any recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, various states have enacted laws modeled after the federal False Claims Act.

Government investigations of clinical laboratories have been ongoing for a number of years and are expected to continue in the future. Written "corporate compliance" programs to actively monitor compliance with fraud laws and other regulatory requirements are recommended by the Department of Health and Human Services' Office of the Inspector General and we have a program following the guidelines in place.

Our laboratory services are subject to extensive federal and state regulation, and our failure to comply with such regulations could result in penalties or suspension of Medicare payments and/or loss of our licenses, certificates or accreditation.

The clinical laboratory testing industry is subject to extensive regulation, and many of these statutes and regulations have not been interpreted by the courts. The CLIA and implementing regulations established quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. Laboratories covered under CLIA are those which perform laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease and other factors. The Centers for Medicare and Medicaid Services is charged with the implementation of CLIA, including registration, surveys, enforcement and approvals of the use of private accreditation agencies. For certification under CLIA, laboratories such as ours must meet various requirements, including requirements relating to quality assurance, quality control and personnel standards. Since we perform patient testing from all states, our laboratory is also subject to strict regulation by California, New York and various other states. State laws require that laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records, and are required to possess state regulatory licenses to offer the professional and technical components of laboratory services. If we are unable to maintain our existing state regulatory licenses in a timely manner or if we are unable to secure new state regulatory licenses for new locations, our ability to provide laboratory services could be compromised. Our failure to comply with CLIA, state or other applicable requirements could result in various penalties, including restrictions on tests which the laboratory may perform, substantial civil monetary penalties, imposition of specific corrective action plans, suspension of Medicare payments and/or loss of licensure, certification or accreditation. Such penalties could result in our being unable to continue performing laboratory testing. Compliance with such standards is verified by periodic inspections and requires participation in proficiency testing programs.

We are subject to significant environmental, health and safety regulation.

We are subject to licensing and regulation under federal, state and local laws and regulations relating to the protection of the environment and human health and safety, including laws and regulations relating to the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials as well as to the safety and health of laboratory employees. In addition, the federal Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including clinical laboratories, whose workers may be exposed to blood-borne pathogens such as HIV and the hepatitis B virus. These regulations, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to, and transmission of, blood-borne pathogens. In addition, the federally-enacted Needlestick Safety and Prevention Act requires, among other things, that we include in our safety programs the evaluation and use of engineering controls such as safety needles if found to be effective at reducing the risk of needlestick injuries in the workplace.

We are subject to federal and state laws governing the financial relationship among healthcare providers, including Medicare and Medicaid laws, and our failure to comply with these laws could result in significant penalties and other adverse consequences.

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. These laws include the federal anti-kickback law which prohibits individuals or entities, including clinical laboratories, from, among other things, making any payments or furnishing other benefits intended to induce or influence the referral of patients for tests billed to Medicare, Medicaid or certain other federally funded programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In addition, some kickback allegations have been claimed to violate the federal False Claims Act (discussed above). In addition, many states have adopted laws similar to the federal anti-kickback law. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs. Many of the federal and state anti-fraud statutes and regulations, including their application to joint ventures and collaborative agreements, are vague or indefinite and have not been interpreted by the courts.

In addition, these laws also include self-referral prohibitions which prevent us from accepting referrals from physicians who have non-exempt ownership or compensation relationships with us as well as anti-markup and direct billing rules that may apply to our relationships with our customers. Specifically, the federal anti-"self-referral" law, commonly known as the "Stark" Law, prohibits, with certain exceptions, Medicare payments for laboratory tests referred by physicians who have, personally or through a family member, an investment interest in, or a compensation arrangement with, the testing laboratory. A person who engages in a scheme to circumvent the Stark Law's prohibitions may be fined up to $100,000 for each such arrangement or scheme. In addition, anyone who presents or causes to be presented a claim to the Medicare program in violation of the Stark Law is subject to monetary penalties of up to $15,000 per claim submitted, an assessment of several times the amount claimed, and possible exclusion from participation in federal healthcare programs. In addition, claims submitted in violation of the Stark Law may be alleged to be subject to liability under the federal False Claims Act and its whistleblower provisions.

Several states in which we operate have enacted legislation that prohibits physician self-referral arrangements and/or requires physicians to disclose any financial interest they may have with a healthcare provider to their patients when referring patients to that provider. Some of these statutes cover all patients and are not limited to Medicare or Medicaid beneficiaries. Possible sanctions for violating state physician self-referral laws vary, but may include loss of license and civil and criminal sanctions. State laws vary from jurisdiction to jurisdiction and, in a few states, are more restrictive than the federal Stark Law. Some states have indicated they will interpret their own self-referral statutes the same way that the U.S. Centers for Medicare and Medicaid Services (CMS) interprets the Stark Law, but it is possible the states will interpret their own laws differently in the future. The laws of many states prohibit physicians from sharing professional fees with non-physicians and prohibit non-physician entities, such as us, from practicing medicine and from employing physicians to practice medicine.

If we do not comply with existing or additional regulations, or if we incur penalties, it could increase our expenses, prevent us from increasing net revenue, or hinder our ability to conduct our business. In addition, changes in existing regulations or new regulations may delay or prevent us from marketing our products or cause us to reduce our pricing.

Our business is subject to stringent laws and regulations governing the privacy, security and transmission of medical information, and our failure to comply could subject us to criminal penalties and civil sanctions.

The use and disclosure of patient medical information is subject to substantial regulation by federal, state, and foreign governments. For example, the Health Insurance Portability and Accountability Act of 1996, known as HIPAA, was enacted among other things, to establish uniform standards governing the conduct of certain electronic health care transactions and to protect the security and privacy of individually identifiable health information maintained or transmitted by health care providers, health plans and health care clearinghouses. We are currently required to comply with three standards under HIPAA. We must comply with the Standards for Electronic Transactions, which establish standards for common health care transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures; unique identifiers for providers, employers, health plans and individuals; security; privacy; and enforcement. We were required to comply with these Standards by October 16, 2003. We also must comply with the Standards for Privacy of Individually Identifiable Information, which restrict our use and disclosure of certain individually identifiable health information. We were required to comply with the Privacy Standards by April 14, 2003. The Security Standards required us to implement certain security measures to safeguard certain electronic health information by April 20, 2005. In addition, CMS has published a final rule, which will require us to adopt a Unique Health Identifier for use in filing and processing health care claims and other transactions by May 23, 2007. While the government intended this legislation to reduce administrative expenses and burdens for the health care industry, our compliance with this law may entail significant and costly changes for us. If we fail to comply with these standards, we could be subject to criminal penalties and civil sanctions.

The Standards for Privacy of Individually Identifiable Information establish a "floor" and do not supersede state laws that are more stringent. Therefore, we are required to comply with both federal privacy regulations and varying state privacy laws. In addition, for health care data transfers from other countries relating to citizens of those countries, we must comply with the laws of those other countries.

Federal law and the laws of many states generally specify who may practice medicine and limit the scope of relationships between medical practitioners and other parties.

Under such laws, we are prohibited from practicing medicine or exercising control over the provision of medical services and may only do so through a professional corporation designed for this purpose. In order to comply with such laws, all medical services are provided by or under the supervision of Clarient Pathology Associates, Inc. (the P.C.). We refer to the P.C. and us collectively throughout this report as "we", "us", and "our", except in this paragraph. The P.C. is organized so that all physician services are offered by the physicians who are employed by the P.C. Clarient does not employ practicing physicians as practitioners, exert control over their decisions regarding medical care, or represent to the public that Clarient offers medical services. Clarient has entered into an Administrative Services Agreement with the P.C. pursuant to which Clarient performs all non-medical management of the P.C. and has exclusive authority over all aspects of the business of the P.C. (other than those directly related to the provision of patient medical services or as otherwise prohibited by state law). The non-medical management provided by Clarient includes, among other functions, treasury and capital planning, financial reporting and accounting, pricing decisions, patient acceptance policies, setting office hours, contracting with third party payers, and all administrative services. Clarient provides all of the resources (systems, procedures, and staffing) or contract with third party billing services to bill third party payers or patients. Clarient also provides or outsources all of the resources for cash collection and management of accounts receivables, including custody of the lockbox where cash receipts are deposited. From the cash receipts, Clarient pays all physician salaries and operating costs of the center and of Clarient. Compensation guidelines for the licensed medical professionals at the P.C. are set by Clarient, and Clarient has established guidelines for selecting, hiring, and terminating the licensed medical professionals. Where applicable, Clarient also negotiates and execute substantially all of the provider contracts with third party payers. Clarient will not loan or otherwise advance funds to the P.C. for any purpose.

Clarient believes that the services Clarient provides and will provide in the future to the P.C. does not constitute the practice of medicine under applicable laws. Because of the unique structure of the relationships described above, many aspects of our business operations have not been the subject of state or federal regulatory interpretation. We have no assurance that a review of our business by the courts or regulatory authorities will not result in a determination that could adversely affect our operations or that the health care regulatory environment will not change so as to restrict our existing operations or future expansion.

Risks Related to Our Common Stock

We have never paid cash dividends on our common stock and do not anticipate paying dividends on our common stock, which may cause you to rely on capital appreciation for a return on your investment.

We currently intend to retain future earnings for use in our business and do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock.

If we raise additional funds you may suffer dilution or subordination and we may grant rights in our technology or products to third parties.

If we raise additional funds by issuing equity securities, further dilution to our stockholders could result, and new investors could have rights superior to those of holders of the shares of our common stock. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may have to delay or may be unable to continue to develop our products.

Our stock price is likely to continue to be volatile, which could result in substantial losses for investors.

The market price of our common stock has in the past been, and in the future is likely to be, highly volatile. These fluctuations could result in substantial losses for investors. Our stock price may fluctuate for a number of reasons including, but not limited to:

- media reports and publications and announcements about cancer or diagnostic products or treatments or new innovations;
- developments in or disputes regarding patent or other proprietary rights;
- announcements regarding clinical trials or other technological or competitive developments by us and our competitors;
- loss of a significant customer or group purchasing organization contract;
- the hiring and retention of key personnel;
- announcements concerning our competitors or the biotechnology industry in general;
- regulatory developments regarding us or our competitors;
- changes in reimbursement policies concerning our products or competitors' products;
- changes in the current structure of the healthcare financing and payment systems;
- stock market price and volume fluctuations, which have particularly affected the market prices for medical products and high technology companies and which have often been unrelated to the operating performance of such companies; and
- general economic, political and market conditions.

In addition, stock markets have from time to time experienced extreme price and volume fluctuations. The market prices for medical device and laboratory service affected by these market fluctuations and such effects have often been unrelated to the operating performance of such companies. These broad market fluctuations may cause a decline in the market price of our common stock.

Securities class action litigation is often brought against a company after a period of volatility in the market price of its stock. This type of litigation could be brought against us in the future, which could result in substantial expense and damage awards and divert management's attention from running our business.

With the advent of the Internet, new avenues have been created for the dissemination of information. We do not have control over the information that is distributed and discussed on electronic bulletin boards and investment chat rooms. The motives of the people or organizations that distribute such information may not be in our best interest or in the interest of our shareholders. This, in addition to other forms of investment information, including newsletters and research publications, could result in a significant decline in the market price of our common stock.

Future sales of shares by existing stockholders could result in a decline in the market price of the stock.

Some of our current stockholders hold a substantial number of shares which they are currently able to sell in the public market, or which they will be able to sell under registration statements that have already been declared effective by the Securities and Exchange Commission, and our employees hold options to purchase a significant number of shares and/or have been issued shares of restricted stock that are covered by registration statements on Form S-8. If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock could fall. Safeguard Scientifics, Inc., which owns a majority of our outstanding common stock, has rights, subject to some conditions, to require us to file registration statements covering shares owned by them that are not already covered by existing registration statements and to include Safeguard's shares in registration statements that we may file for ourselves or other stockholders. Furthermore, if we were to include in a Company-initiated registration statement shares held by Safeguard pursuant to the exercise of its registrations rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

We are controlled by a single existing stockholder, whose interests may differ from other stockholders' interests and may adversely affect the trading price of our common stock.

Safeguard Scientifics, Inc. beneficially owns a majority of the outstanding shares of our common stock. As a result, Safeguard Scientifics, Inc. will have significant influence in determining the outcome of any corporate transaction or other matter submitted to the stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets. In addition, Safeguard Scientifics, Inc. has the ability to elect all of our directors (although Safeguard has contractually agreed with the Company that our board of directors will consist of a majority of directors not specifically designated by Safeguard) and Safeguard could dictate the management of our business and affairs. The interests of Safeguard may differ from other stockholders' interests. In addition, this concentration of ownership may delay, prevent, or deter a change in control and could deprive other stockholders of an opportunity to receive a premium for their common stock as part of a sale of our business. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders.

We have adopted a stockholder rights plan and other arrangements which could inhibit a change in control and prevent a stockholder from receiving a favorable price for his or her shares.

Our board of directors has adopted a stockholders' rights plan providing for discounted purchase rights to its stockholders upon specified acquisitions of our common stock. The exercise of these rights is intended to inhibit specific changes of control of our company.

In addition, Section 203 of the Delaware General Corporation Law limits business combination transactions with 15% stockholders that have not been approved by our board of directors. These provisions and others could make it difficult for a third party to acquire us, or for members of our board of directors to be replaced, even if doing so would be beneficial to our stockholders. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace the current management team. If a change of control or change in management is delayed or prevented, you may lose an opportunity to realize a premium on your shares of common stock or the market price of our common stock could decline.

Our shares of common stock currently trade on the Nasdaq Capital Market which results in a number of legal and other consequences that may negatively affect our business and the liquidity and price of our common stock.

Effective August 15, 2003, a Nasdaq Qualifications Panel terminated our Nasdaq National Market Listing and transferred our securities to the Nasdaq Capital Market. With our securities listed on the Nasdaq Capital Market, we face a variety of legal and other consequences that may negatively affect our business including, without limitation, the following:

- future issuances of our securities may require time-consuming and costly registration statements and qualifications because state securities law exemptions available to us are more limited;

- securities analysts may not initiate coverage of Clarient; and

- we may lose current or potential investors.

In addition, we are required to satisfy various listing maintenance standards for our common stock to be quoted on the Nasdaq Capital Market. If we fail to meet such standards, our common stock would likely be delisted from the Nasdaq Capital Market and trade on the over-the-counter bulletin board, commonly referred to as the "pink sheets." This alternative is generally considered to be a less efficient market and would seriously impair the liquidity of our common stock and limit our potential to raise future capital through the sale of our common stock, which could materially harm our business, results of operations, cash flows and financial position.

Recently enacted and proposed changes in securities laws and regulations will increase our costs.

The Sarbanes-Oxley Act of 2002 along with other recent and proposed rules from the Securities and Exchange Commission and Nasdaq require changes in our corporate governance, public disclosure and compliance practices. Many of these new requirements will increase our legal and financial compliance costs, and make some corporate actions more difficult, such as proposing new or amendments to stock option plans, which now require shareholder approval. These developments could make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These developments also could make it more difficult for us to attract and retain qualified executive officers and qualified members of our board of directors, particularly to serve on our audit committee.

Item 2. Properties

Our headquarters are located in San Juan Capistrano, California, in approximately 21,000 square feet of leased space. This facility accommodates our executive office, development and manufacturing facilities. The term of this lease expired in February 2006 and we currently lease this facility on a month-to-month basis.

We have leased a 78,000 square foot facility in Aliso Viejo, California. The Company's intends to occupy 54,000 square feet and plans to sub-lease the remaining space. The term of the lease commenced on December 1, 2005 with an initial term of 10 years and an option to extend the lease term for up to two additional five-year periods. The initial annual base rent will be approximately $500,000. The annual base rent will be increased to $1.0 million on June 1, 2006 and to $1.4 million on December 1, 2008. The base rent is increased 3% annually effective on December 1 of each year. We are also responsible for payments of common area operating expenses for the premises. This new facility currently houses our diagnostic services laboratory and we expect to relocate our remaining operations located at the San Juan Capistrano facility to the Aliso Viejo facility during the second quarter of 2006.

Item 3. Legal Proceedings

We are not a party to any legal proceedings, the adverse outcome of which, individually or in the aggregate, management believes would have a material adverse effect on our business, financial condition or results of operations.

Item 4. Submission of Matters to a Vote of Security Holders

In connection with a private placement of common stock and warrants in November 2005, the Company obtained the written consent of the holders of a majority of the outstanding shares of the Company's common stock to approve the issuance of shares of common stock and warrants exercisable into common stock in an amount greater than 20% of Clarient's then outstanding shares of common stock. This action was taken solely for the purposes of satisfying requirements of the Nasdaq Capital Market that require an issuer of listed securities to obtain prior stockholder approval to sell or issue a number of shares of common stock (or securities convertible or exercisable into common stock) equal to 20% or more of the common stock or the voting power outstanding before the issuance for less than the greater of book or market value of the common stock. Pursuant to Section 228 of the Delaware General Corporation Law and Section 14C of the Exchange Act, the Company mailed an information statement to the Company's stockholders for the purpose of informing stockholders of this corporate action before the Company issued more that 20% of its outstanding common stock. See note 6 to our financial statements included in Part II of this Form 10-K for further details regarding this private placement.

Item 4A. Executive Officers of the Registrant

The following persons were executive officers of the Company at March 1, 2006:

Name	Age	Position with the Company
Ronald A. Andrews	46	President and Chief Executive Officer
John A. Roberts	47	Acting Chief Financial Officer
Kenneth Bloom, M.D.	47	Chief Medical Director (Clarient Pathology Associates, Inc.)
Heather Creran	38	Executive Vice President and Chief Operating Officer of Diagnostic Services
James D. Cureton	50	Vice President, Instrument Systems Operations
David J. Daly	44	Vice President, Sales
Karen Garza	48	Sr. Vice President Marketing and Strategic Initiatives
Jose de la Torre-Bueno, Ph.D.	57	Vice President and Chief Technology Officer

Ronald A. Andrews, 46, has been President and Chief Executive Officer since July 2004. Mr. Andrews was Senior Vice President of Global Marketing and Commercial Business Development at Pleasanton, California-based Roche Molecular Diagnostics from 2002 to 2004. In that role, he developed and led the strategic execution for all diagnostic commercial operations. This included the oversight of five Business Sector Vice Presidents responsible for all aspects of global marketing and business development in the areas of blood screening, virology, women's health, microbiology and automation/emerging diagnostics. Mr. Andrews was also responsible for executive direction of all marketing functions, directed the development of the 10-year Strategic Plan for the organization and completed the reorganization of commercial operations during that period. From 2000 to 2002, Mr. Andrews held two senior executive positions with Indianapolis-based Roche Diagnostics Corporation. As Vice President, U.S. Commercial Operations, Molecular Diagnostics, he directed sales, marketing, technical field support and product development activities and was responsible for U.S. commercial strategy development for the clinical laboratory market. Prior to that, as Vice President, Marketing, U.S. Commercial Operations, he was responsible for planning and directing all aspects of the Roche U.S. Laboratory Systems Commercial Operations Marketing which included the clinical chemistry, immunochemistry, hematology, near patient testing and

molecular markets. From 1995 to 2000, Mr. Andrews was Vice President of Atlanta-based Immucor, Inc. where he helped lead the transition of that company from a reagent manufacturer to an instrument systems company. Prior to Immucor, he spent almost 10 years in management positions of increasing responsibility at Chicago-based Abbott Diagnostics, culminating in the position of Senior Marketing Manager, Business Unit Operations. Mr. Andrews earned a Bachelor's degree in Biology and Chemistry from Spartanburg, South Carolina-based Wofford College in 1981 and has participated extensively in the executive development programs at both Roche and Abbott Labs.

John A. Roberts, 47, was appointed as Acting Chief Financial Officer in February 2006. He is expected to remain in that position on an interim basis until a permanent replacement is hired to replace Stephen T. D. Dixon, who resigned as the Company's Chief Financial Officer on February 3, 2006. Mr. Roberts, served as Chief Financial Officer and Secretary of Daou Systems, Inc. from December 2003 until February 2006. Prior to joining Daou Systems, Mr. Roberts served from 2001 to 2002 as the Vice President of Business Development for MEDecision, Inc., a software products company providing medical management solutions for managed care organizations. Prior to that, Mr. Roberts held the position of Senior Vice President of Corporate Development and Chief Financial Officer for HealthOnline, Inc. from 1999 to 2001, a provider of web-based community hosting services. Mr. Roberts earned a Bachelor of Science and a Master's degree in Business Administration from the University of Maine.

Kenneth Bloom, M.D., 47, has been Chief Medical Director since August 2004. Prior to joining Clarient, he served as Senior Medical Director of US LABS, Irvine, California from 2001 to 2004. Prior to this position, he served in positions of increasing responsibility with Rush Presbyterian Hospital, most recently as Associate Professor and Director of Laboratory Operations. Dr. Bloom is a board certified Anatomical Pathologist with over two decades of experience serving as senior academic, consultative, and director/clinical roles at leading hospitals and healthcare enterprises principally in the specialty of cancer care. His medical degree is from Rush Medical College in Chicago and he completed his residency in pathology at Rush Presbyterian – St Luke's Medical Center. The academic posts held by Dr. Bloom include Assistant Professor of Pathology, Associate Professor of Pathology at Chicago based Rush Medical College and Clinical Professor of Pathology at the Keck School of Medicine, University of Southern California. Dr. Bloom has also served as a visiting Professor in the Department of Computer Science at DePaul University. Over the past 15 years, Dr. Bloom has held more than 10 appointed positions at Rush Presbyterian – St. Luke's Medical Center, one of the leading cancer research hospitals in the U.S. These positions included Director of Laboratory Operations, Director of Immunohistochemistry, Director of Breast Service in the Department of Pathology, Consultant to the Rush Breast Cancer Center and Director of Information Services for the Rush Cancer Center. Dr. Bloom is active in several national and international societies including the American College of Pathologists where he currently serves as a member of the Diagnostic Immunology Resource Committee. He is a well-known expert in his work with IHC and FISH testing related to Her-2/neu and was instrumental working with College of American Pathologists in constructing guidelines for utilization of image analysis for Her-2. In addition to the roles mentioned above, he has served the industry off and on for the past 20 years in both advisory and operational roles. Those appointments include board of director seats, consulting roles and executive posts including executive level positions at both diagnostics technology and information technology firms including Genentech, Astra-Zeneca, Rubicor, Xoft, Ethicon Endo-surgery and Apple Computer. In addition, he is a well-known author and lecturer with emphasis in breast cancer pathology, immunohistochemistry and data base software.

Heather Creran, 38, has been Executive Vice President and Chief Operating Officer of Diagnostic Services since January 2004**.** Prior to joining Clarient, she worked for IMPATH Inc. for 14 years. IMPATH specialized in cancer pathology, using sophisticated technologies to provide patient-specific cancer diagnostic and prognostic information. Having joined IMPATH at its inception, she served in various positions and for the last five years, held the position of Vice President of Operations with responsibility for the operations at IMPATH's three laboratory locations in New York, Los Angeles and Phoenix. Ms. Creran holds a Bachelor's Degree in Economics and Political Science from Duke University.

James D. Cureton, 50, has been Vice President, Instrument Systems Operations since May 2005. Prior to joining Clarient, Mr. Cureton served as the Marketing Director for Abbott Molecular Diagnostics, where he was responsible for the worldwide marketing of the Vysis FISH and Microarray product lines, including instruments. During his 19 year career at Abbott, Mr. Cureton spent over 13 years in various marketing management roles responsible for instrument and software systems and immunoassays with a focus in the oncology diagnostic marketplace. This included strategic and tactical marketing, product development as well as business development. Prior to his marketing assignments, he also spent time in sales, where he consistently achieved the highest levels of sales performance on a national level. Before joining Abbott, Mr. Cureton spent six years in a hospital clinical laboratory as a Medical Technologist. Mr. Cureton earned a Bachelor's Degree in Biology and Medical Technology from Sterling College in Sterling, Kansas.

David J. Daly, 44, Vice President of Sales, joined Clarient at the end of February 2005. Prior to joining Clarient, Mr. Daly served as Area Marketing Manager for Roche Diagnostics, where he was responsible for the establishment of Molecular Centers of Excellence throughout the western region. Prior to Roche, Mr. Daly spent 10 years in marketing positions of increasing responsibility at Abbott Laboratories, culminating in the position of Director of U.S. Sales, Animal Health division, where he was responsible for a $50 million annual sales plan and managed a 35 member sales organization. Mr. Daly earned a Master's Degree in Economics from the University of California, Santa Barbara and graduated cum laude with a Bachelor's Degree in Economics from the University of California, Irvine.

Karen K. Garza, 48, joined Clarient as Vice President of National Account and Strategic Initiatives in May 2003, and currently is Sr. Vice President of Marketing and Strategic Initiatives. Ms. Garza has more than 20 years of experience in healthcare sales and marketing, most recently with Valley Forge, Pennsylvania-based AmerisourceBergen (formerly Anaheim, California-based Bergen Brunswig Drug Company). In her two years at AmerisourceBergen, she held the titles of Vice President, Corporate Sales and Vice President, Strategic Accounts. In these roles, she was responsible for managing relationships with acute-care based national organizations, representing more than $4 billion in revenues. Prior to AmerisourceBergen, Garza held senior marketing positions at Louisville, Colorado-based RxMarketplace, Inc., where she was Vice President, Sales and Marketing for the internet-based pharmacy solutions company. Prior to that, Garza was with San Francisco-based McKessonHBOC, Inc., where she served for five years as both Vice President, West, Corporate Solutions Group and Corporate Vice President, Integrated Healthcare Systems. Garza also spent nine years in increasingly responsible marketing management roles at Deerfield, Illinois-based Baxter Healthcare Corporation, culminating in the position of Director, Corporate Sales and Marketing where she was responsible for marketing resources and services to the executive suite of major healthcare institutions. Garza graduated with a Bachelor of Science, Medical Technology degree, from the College of Pharmacy & Allied Health Professions at Wayne State University, Detroit, Michigan.

Jose de la Torre-Bueno, Ph.D., 57, has been Chief Technology Officer since April 2001 and has been Vice President since February 1999. Dr. Torre-Bueno was also Senior Applications Engineer for the Company from July 1998 to February 1999. Prior to joining Clarient, Dr. Torre-Bueno was engaged as a consultant to Tower Technologies in Encinitas, California. In 1982, he founded American Innovision; an image analysis company that configured complete application systems and designed and built software and hardware. He served as President and Vice President of Research and Development for American Innovision, a company in which he had a substantial ownership interest, until its sale to Oncor Instrument Systems in 1992. He remained with Oncor for three years after the sale as Senior Scientist and Research and Development Manager. Dr. Torre-Bueno has been an inventor on four issued patents and eight pending patents, all assigned to Clarient. Dr. Torre-Bueno is currently an Adjunct Professor in the Department of Mathematical Sciences at San Diego State University and a Clinical Professor of Pathology at the Keck School of Medicine, University of Southern California. Dr. Torre-Bueno earned a Bachelor of Science degree in Biology and Psychology from the State University of New York at Stony Brook and a Doctorate of Philosophy in Physiology, Behavior and Genetics from Rockefeller University.

PART II

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

Our common stock trades on the Nasdaq Capital Market under the symbol "CLRT". Prior to March 16, 2005, we were traded under the symbol "CVSN". The table below sets forth the high and low sales prices of the common stock:

	High	Low
2005		
First Quarter	$ 2.18	$ 1.10
Second Quarter	1.95	1.10
Third Quarter	1.83	1.41
Fourth Quarter	1.77	1.00
2004		
First Quarter	$ 3.41	$ 2.15
Second Quarter	2.40	1.26
Third Quarter	1.99	0.88
Fourth Quarter	2.26	0.79

As of March 3, 2006 we had outstanding 66,813,227 shares of common stock held by approximately 422 stockholders including beneficial owners of the common stock whose shares are held in the names of various dealers, clearing agencies, banks, brokers and other fiduciaries. Our shares of common stock are listed on the Nasdaq Capital Market.

We have not paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. The declaration and payment of dividends is restricted in accordance with covenants related to our $8.5 million revolving credit agreement with Comerica Bank which we initially entered into in February 2003 and renewed through February 28, 2007. The restriction on dividends will remain during the term of the revolving credit agreement. We expect to utilize any future earnings to finance our operations. The actual amount of any dividends that may be paid in the future will be subject to the discretion of our board of directors and will depend on our operations, financial and business requirements and other factors.

Item 6. Selected Financial Data

The following table presents selected financial data for the last five years of the operation of our business. The following information should be read in conjunction with the Consolidated Financial Statements and Notes thereto in Item 8 and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7.

	Years Ended December 31,				
	2005	2004	2003	2002	2001
Consolidated Statement of Operations Data:					
Revenue	$ 20,149	$ 9,769	$ 11,928	$ 9,256	$ 4,886
Selling, general and administrative expenses, including diagnostic services administration for 2005 & 2004	19,726	17,209	11,384	11,119	10,951
Research and development expenses	3,805	4,612	4,754	4,782	5,939
Net loss (1)	(14,802)	(19,600)	(7,866)	(9,460)	(13,641)
Accretion of and dividends on redeemable, convertible preferred stock	—	—	—	(4,368)	(1,006)
Net loss attributable to common stock	(14,802)	(19,600)	(7,866)	(13,828)	(14,647)
Basic and diluted net loss per common share (1)	$ (0.27)	$ (0.38)	$ (0.21)	$ (0.54)	$ (0.73)

	As of December 31,				
	2005	2004	2003	2002	2001
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 9,333	$ 10,045	$ 1,699	$ 2,810	$ 7,401
Total assets	25,249	20,157	11,051	10,853	15,065
Current liabilities	8,958	5,883	3,224	2,693	3,941
Long-term obligations and redeemable preferred stock (2)	3,829	2,386	1,808	—	8,567
Accumulated deficit	(120,285)	(105,483)	(85,883)	(78,017)	(64,189)
Total stockholders' equity	12,462	11,888	6,019	8,160	2,557

(1) See Note 2 of the Notes to the Consolidated Financial Statements for information concerning the calculation of net loss per common share.

(2) 2001 includes approximately $8.6 million of convertible, redeemable preferred stock related to the conversion and retirement of all of the outstanding shares of the Series D Preferred Stock in 2002.

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

The following management's discussion and analysis of financial condition and results of operations contains forward-looking statements within the meaning of the private securities litigation reform act of 1995. Such forward-looking statements involve risks and uncertainties, including those set forth in item 1A of this report under the caption "risks relating to our business," and other reports we file with the Securities and Exchange Commission (SEC). Our actual results could differ materially from those anticipated in these forward-looking statements.

Overview

We are an advanced oncology diagnostics technology and services company. Our mission is to combine innovative technologies, meaningful test results and world-class expertise to improve outcomes of patients suffering from cancer. Our Automated Cellular Imaging System (ACIS®) is a versatile automated microscope system that greatly improves the accuracy and reproducibility of digital cell imaging through its unique, patented technology. We also provide comprehensive laboratory services ranging from in-house pathology testing, using the ACIS®, to other cutting-edge diagnostic technologies that assist physicians in cancer assessment. In addition, we develop ACIS®-based tools for academic and biopharmaceutical company researchers, allowing them to perform cellular-level analyses much faster and with improved accuracy. A number of the top clinical laboratories, hospitals, university medical centers and biopharmaceutical companies in the U.S. and Europe have adopted our technology.

We made the decision to provide in-house laboratory services in 2004 to give us an opportunity to capture a significant service-related revenue stream from the much broader and expanding cancer diagnostic testing marketplace while also optimizing the level of service and accuracy provided to remote pathology customers. Our business has historically been focused on the market for breast cancer testing. While this market is not insignificant, based on our market research we believe that the broader advanced cancer diagnostics market is approximately $1.5 billion. Our research indicates that this market will approach $2.5 billion by the end of this decade as a result of the substantial growth that is anticipated for both the incidence of cancer and for the development of new cancer therapies that will require a sophisticated diagnostic test. We believe that we are positioned to participate in this growth because of our proprietary analysis capabilities, the depth of experience of the staff in our diagnostic laboratory, our relationships with pharmaceutical companies and our demonstrated ability to develop unique assays to support these new diagnostic tests.

The initial objective of our service strategy had been to support the expansion of the Access remote pathology program for community pathologists, a large customer segment. The focus of the development of the ACIS® technology platform has been to assist our customers in their diagnosis and assessment of cancer. We continue to explore numerous ways to leverage our relationship with our customers to better serve their needs and expand revenue opportunities. A logical extension of the remote pathology technical services has been the recent introduction of other esoteric tests and related professional diagnosis that support the oncology services marketplace. We provide a broad spectrum of other laboratory services, including flow cytometry, molecular diagnostics including PCR (polymerase chain reaction), analysis of tumors of unknown origin, expanded services for immunohistochemistry.

This year we have placed an increased level of importance, relative to prior years, on the sale of the ACIS® system to clinical accounts and to research accounts, which include biopharmaceutical companies, biotechnology companies and academic medical centers. We believe that there are more than 1,000 such research organizations and an equal number of clinical organizations in the U.S. that are good candidates for the ACIS®. These are customer groups that will be increasingly important to us in the coming years because of the large size of this market and the collaborative development opportunities that research customers particularly provide for the development of new diagnostic tests using ACIS®. Important criteria for research customers include the flexibility and ease of use of the system, the accuracy of the system as a measurement tool in the performance of clinical trials and research studies and the inclusion of certain key features necessary to researchers such as fluorescence or tissue micro array capabilities. By "seeding" the market with ACIS® devices provided to these customers and working with them on their development activities, we believe that we can help to foster the next generation of applications for ACIS®. Similarly, by increasing the count of ACIS® systems with clinical accounts, we provide for a broad distribution network in which to introduce new companion diagnostic tests.

In July 2005, we entered into a distribution and development agreement with Dako A/S (Dako), a Danish company recognized as a worldwide leader in diagnostic pathology testing services. Under the agreement, Dako will become the exclusive distributor of the ACIS® system to the clinical marketplace, which includes local hospitals and pathology practices. Dako will also provide funding for several new development milestones that, when achieved, will enhance and add new features to the ACIS® system. The Company believes that this program will improve the long-term prospects for the placement of systems in the U. S. and overseas.

An important driver of our success in the future will also be our ability to develop new diagnostic tests on the ACIS® and duplicate the success and market penetration that has been achieved within the breast cancer testing markets. Working in collaboration with top-tier pharmaceutical companies, we are developing diagnostic tests and related assays that will target new cancer therapies to those patients most likely to benefit from their use. We believe that the increasing shift towards an aging U.S. population, a group in which cancer incidence is greatest, the large pipeline of targeted cancer therapies in various stages of clinical study and the increasingly high cost of these drugs will result in a demand for proven diagnostic tests. Our future success will rest on our ability to

develop and introduce these tests using our proprietary imaging technology and to expand our installed base of clinical system placements in the marketplace.

An important component of our strategy is to continue to build and, when necessary, defend our intellectual property position. We file patent applications to protect technology, innovations and improvements that we consider important to the development of our business. Currently, we have 25 patent applications pending with the U.S. Patent and Trademark Office and 8 foreign patent applications pending. We have 21 issued patents in the U.S. and 10 foreign patents, all related to the system and method for cellular specimen grading performed by the ACIS® or related technologies. The patents for which we have received a final issuance have remaining legal lives that vary from 12 to 19 years. In all our patent applications we have endeavored to file claims which cover the underlying concepts of the unique features of the ACIS®, its associated processes and methodologies as well as our specific implementation of those processes and methodologies. As a further protection against efforts to erode our proprietary position, we have systematically explored other designs, which could achieve results similar to the ACIS® and we have prepared patent applications on those alternate designs. Our research and development efforts have been further validated in the area of automated immunohistochemistry for which we have obtained five FDA 510(k) clearances over the past several years. These clearances help to validate the efficacy of our technology and to broaden the acceptance of our image analysis. It will be important for us to obtain FDA clearances for our portfolio of new diagnostic tests developed in our Bioanalytical Services development efforts.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and the disclosure of contingent assets and liabilities as of the dates of the balance sheets and revenues and expenses for the periods presented. Therefore, on an ongoing basis, we evaluate our estimates, including those provisions for bad debts and reserves.

Bad Debt

For estimated bad debts, we review on an individual account basis the age of the receivable, all circumstances surrounding the transaction that gave rise to the receivable and whether the customer continues to have the financial resources to pay the receivable as of the balance sheet date and prior to the issuance of the financial statements for the related period. This process is followed for both our instrument and laboratory accounts. However, we have outsourced the direct billing and collection of laboratory related receivables and we work closely with our outsourced billing partner to review the details of each laboratory related account.

Inventory, Long-Lived Assets and Accruals

For ACIS® inventory and work in progress, the respective reserve is based upon the expected future use of the ACIS® components and whether there are any lower of cost or market considerations.

We review our long-lived assets, such as fixed assets and intangibles, for impairment whenever events or changes indicate the carrying value may not be recoverable or that the useful lives are no longer appropriate. If we determine that the carrying value of the long-lived assets may not be recoverable, the asset is then written down to its estimated fair value based on a discounted cash flow basis. Included in long-lived assets are ACIS® units on lease to third parties under operating leases, which are recorded in property and equipment.

For other obligations where judgment is required, we review the circumstances surrounding the obligation and evaluate the facts and circumstances to determine an appropriate level of accrual for each obligation.

Revenue Recognition

Revenue for our diagnostic services is recognized at the time of completion of services at amounts equal to the contractual rates allowed from third parties, including Medicare, insurance companies, and to a small degree, private patients. These expected amounts are based both on Medicare allowable rates and our collection experience with other third party payers. Because of the requirements and nuances of billing for laboratory services, we may invoice amounts that are greater than those allowable for payment. These differences are described as contractual discounts. As noted, however, it is only the expected payment from these parties which is net of these contractual discounts that is recorded as revenue.

Revenue for “fee-per-use” agreements is obtained through the billing information via modem, which accesses the ACIS® database. Revenue is recognized based on the greater of actual usage fees or the minimum monthly rental fee. Under this pricing model, we own most of the ACIS® instruments that are engaged in service and accordingly, all related depreciation and maintenance and service costs are expensed as incurred. For those instruments that are sold, we recognize and defer revenue using the residual method pursuant to the requirements of Statement of Position No. 97-2, “Software Revenue Recognition” (SOP 97-2), as amended by

Statement of Position No. 98-9, "Modification of SOP 97-2, Software Revenue Recognition with Respect to Certain Arrangements." At the outset of the arrangement with the customer, we defer revenue for the fair value of its undelivered elements (e.g., maintenance) and recognize revenue for the remainder of the arrangement fee attributable to the elements initially delivered in the arrangement (e.g., software license) when the basic criteria in SOP 97-2 have been met. Maintenance revenue is recognized ratably over the term of the maintenance contract, which typically is a period of twelve months.

Revenue on system sales is recognized in accordance with Staff Accounting Bulletin No. 101, as amended by Staff Accounting Bulletin No. 104, when all criteria for revenue recognition have been met. Such criteria include, but are not limited to: existence of persuasive evidence of an arrangement; fixed and determinable product pricing; satisfaction of the terms of the arrangement including passing title and risk of loss to our customer upon shipment; and reasonable assurance of collection from our customer in accordance with the terms of the arrangement. For system sales delivered under the Dako distribution and development agreement, we recognize revenue when those ACIS® instruments have been delivered and accepted by an end-user customer.

Systems sold under a leasing arrangement are accounted for as sales-type leases pursuant to SFAS No. 13, "Accounting for Leases," if applicable. We recognize the net effect of these transactions as a sale because of the bargain purchase option granted to the lessee.

Revenues from research and development agreements are recognized over the contract performance period, starting with the contract's commencement. The upfront payment is deferred and recognized on a straight-line basis over the estimated performance period. Milestone payments are recognized as revenue when they are due and payable, but not prior to the removal of any contingencies for each individual milestone.

The following table presents our results of operations as percentages:

	Percentage of Revenues Year ended December 31,		
	2005	2004	2003
Revenue:			
Services group	56.8%	22.9%	0.0%
Technology group	43.2	77.1	100.0
Total revenue	100.0	100.0	100.0
Cost of revenue:			
Services group	76.8	170.4	0.0
Technology group	27.8	48.2	30.2
Cost of revenue	55.6	76.2	30.2
Gross profit	44.4	23.8	69.8
Operating expenses:			
Selling, general and administrative	66.6	140.3	95.4
Diagnostic service administration	31.3	35.8	0.0
Research and development	18.9	47.2	39.9
Total operating expenses	116.8	223.3	135.3
Loss from operations	(72.4)	(199.5)	(65.5)
Other expense	1.1	1.1	0.4
Provision for income taxes	0.0	0.0	0.0
Net loss	(73.5)	(200.6)	(65.9)

Year Ended December 31, 2005 Compared with Year Ended December 31, 2004

Revenue

For the year ended December 31, 2005, revenue of $20.1 million was $10.4 million, or 106% higher than revenue of $9.8 million for the year ended December 31, 2004.

Services Group. Revenue for the year ended December 31, 2005 was $11.4 million compared to $2.2 million for the year ended December 31, 2004. We commenced providing these services in the second quarter of 2004. In generating this revenue, we performed over 29,000 patient cases which resulted in an average revenue per case of $390 for 2005. At the beginning of 2005, the majority of tests performed in our laboratory were related to breast cancer testing and one primary CPT code although the mix of tests increased throughout 2005 to the point where approximately one-half of revenue was derived from breast cancer testing by year end. This shift has changed the average revenue per test and may continue to change in the future depending on the complexity of service

associated with these new tests. We anticipate that diagnostic services revenues will continue to increase in 2006 based on a more comprehensive suite of advanced cancer diagnostic tests available since the prior year and planned expansion to our sales force in 2006.

Technology Group. Revenue for this segment, which includes fee-per-use, system sale and development revenue, was $8.7 million for the year ended December 31, 2005, an increase of approximately $1.2 million or 16% over the year ended December 31, 2004. This was due primarily to an increase in instrument systems sale revenue, which increased $2.6 million from $1.8 million for the year ended December 31, 2004 to $4.4 million for the year ended December 31, 2005 due to the sale of 44 ACIS® systems as compared to 12 ACIS® systems in the comparable period in 2004. This improvement was offset by a decline in fee-per-use revenue caused by a reduction in the aggregate number of ACIS® placements as a result of customers electing to purchase their equipment following the expiration of their lease and certain customers returning their ACIS® equipment in order to utilize the services of our diagnostic services laboratory. We expect revenue to increase in 2006 as a result of the sale of systems through the Dako distribution agreement, development fees earned for the on-going development of a new generation of the ACIS® system and from the recent sale of our ACIS® equipment lease portfolio to Med One.

Cost of Revenue and Gross Margin

For the year ended December 31, 2005, the gross margin as a percentage of revenue was 44% compared to 24% for the year ended December 31, 2004.

Services Group. Cost of revenue for the year ended December 31, 2005 was $8.8 million compared to $3.8 million for the year ended December 31, 2004. These services commenced late in the second quarter of 2004 and included costs incurred to start up our services group operations. Costs were approximately 77% of services group revenue for the current year producing a gross margin of 23%. These costs include the laboratory personnel, depreciation on equipment, laboratory supplies and other direct costs such as shipping that were required to support the launch and service of this operation. We believe that as the diagnostic services operation increases in size, margins for this business will increase to target levels of approximately 40%. However, depending on revenue growth for these services and the incremental costs of the new facility we moved to in the first quarter of 2006, it may take one year or longer for us to fully realize gross margins of this size.

Technology group. Cost of revenue was $2.4 million for the year ended December 31, 2005. This amount is $1.2 million or 33% less than the $3.6 million cost for the year ended December 31, 2004. The cost of revenue primarily consists of cost for manufacturing the ACIS®, which includes the cost for direct material, labor costs, manufacturing overhead and direct customer support costs. For fee-per-use revenue, the cost of the ACIS® is depreciated over a three-year time period and for a system sale or sales-type lease the entire cost of the ACIS® system is expensed at the time of sale. Included in cost of revenue for the year ended December 31, 2004 was a charge of $0.2 million to fully depreciate all of our Access remote viewing stations because they were no longer required to facilitate the remote Access web-based program. Gross margins for our technology group were 72% in 2005 as compared to 51% in 2004. The improvement was due primarily to lower costs for systems sold, which in many cases were refurbished older systems. The increase in gross margins was also due to lower costs of field service. We expect that margins for 2006 will be consistent with those achieved in 2005 from the sale of systems in non-exclusive markets (such as to pharmaceutical companies) where we place the systems directly with our customers. We expect that the margins for systems sold through the Dako distribution agreement will be lower as a result of the pricing terms of our arrangement with Dako. The Dako pricing terms reflect the reduction of certain expenses, including commissions, on sales to Dako which we would normally incur on our direct sales to end users.

Operating and Other Expenses

Selling, general and administrative expenses. These expenses for the year ended December 31, 2005 decreased approximately $0.3 million, or 2%, to $13.4 million compared to $13.7 million in 2004. The decrease was due to higher expenses in the prior year from non-cash compensation charges related to stock options and restricted stock, outside consulting costs for interim CEO management services and a reduction in personnel as a result of a fourth quarter 2004 workforce reduction. These cost reductions from 2004 to 2005 were somewhat offset by higher sales and facility rental charges in 2005. We anticipate that these costs will increase in the future with the addition of sales resources to support our projected increase in service revenues.

Diagnostic services administration. These costs totaled $6.3 million for the year ended December 31, 2005 and included the costs of senior medical staff, senior operations personnel, collection costs, consultants and legal resources to facilitate implementation of this new operation. This amount is $2.8 million, or 80% higher than $3.5 million in the year ended December 31, 2004. In 2006, these costs are expected to continue to increase because of higher collection costs on an anticipated increase in revenue. Collection costs are incurred from a third party billing and collection company that we have engaged to perform these services because of the high degree of technical complexity and knowledge required to effectively perform these operations. These costs are incurred as a percentage of amounts collected and are expected to increase as diagnostic services revenues increase. In the future, we will consider directly providing these services.

Research and development expenses. Expenses of $3.8 million for the year ended December 31, 2005 decreased by approximately $0.8 million, or 17%, from $4.6 million in the comparable period in 2004. This decrease is primarily attributable to the reduction in personnel that resulted from our fourth quarter 2004 workforce reduction. We expect these costs to increase over the next several quarters to support the new development activity contemplated in our distribution and development agreement with Dako. A portion of these expenses will be funded by Dako under the terms of our distribution and development agreement. These new development activities, which are intended to produce features that could expand the volume of clinical tests supported by ACIS® and increase the utility of the ACIS® as a tool for researchers, are important to increasing clinical system test volume, expanding the number of clinical system placements, and increasing research systems sales.

Other expense. Other expense for the year ended December 31, 2005 was $0.2 million, compared to $0.1 million for the year ended December 31, 2004 and consisted of approximately $0.3 million of interest expense offset by approximately $0.1 million of interest income. The interest expense is due primarily to the borrowings under our $3.0 million equipment financing agreement and other equipment financing lines, which commenced in 2003. The $0.1 million of interest income for the year ended December 31, 2005 compares to $0.2 million of interest income for the comparable period of 2004. The decrease in interest income is primarily the result of lower average cash balances in the year ended December 31, 2005 in comparison to the comparable period of 2004.

Year Ended December 31, 2004 Compared with Year Ended December 31, 2003

Revenue

For the year ended December 31, 2004, revenue of $9.8 million was $2.2 million, or 18% lower than revenue of $11.9 million for the year ended December 31, 2003.

Services Group. Revenue for the year ended December 31, 2004 was $2.2 million. There is no comparable figure for the prior year as we commenced providing these services in the second quarter of 2004. In generating this revenue, we performed over 20,000 tests which resulted in an average revenue per test of $111 for 2004. The majority of tests performed in our laboratory were related to breast cancer testing and substantially one primary CPT code.

Technology Group. Revenue for this segment, which includes fee-per-use and system sale revenue, for the year ended December 31, 2004 decreased approximately $4.4 million or 37% compared to 2003. This was due primarily to a decline in fee-per-use revenue of $5.3 million from $10.9 million in 2003 to $5.6 million in 2004. This decline was caused by a reduction in the aggregate number of ACIS® placements and a significant decline in the average monthly revenue for ACIS® placements and remote viewing stations. The overall reduction in instrument systems revenue was offset in part by an increase in revenue from the sale of systems, which increased $0.8 million from $1.0 million in 2003 to $1.8 million in 2004, and revenue generated by our bioanalytical services of $0.1 million.

The number of systems in the field generating fee-per-use charges decreased from 261 at December 31, 2003 to 240 at the end of 2004. The average monthly revenue for ACIS® placements and Access remote viewing stations was approximately $2,850 and $300 in 2004, respectively, as compared to $4,420 and $2,250 for the comparable period in 2003. The decline in the average monthly revenue is primarily due to pricing concessions offered to our customers in response to lower reimbursement levels from 2003 to 2004. These lower reimbursement levels also had an impact on lowering the number of revenue generating systems throughout 2004 due to system returns from customers.

The reduction in Medicare reimbursement and pricing was most significant for those customers that utilized the Access remote viewing stations because their revenues are derived from the professional component of reimbursement which declined from approximately $150 per test in 2003 to $55 per test in 2004. As a result of this significant decline in the professional component of reimbursement and in response to competitive pressures, we decided to lower our fees charged to our Access customers to a $200 annual license fee for use of the Access software. Because all Access customers are also customers of our diagnostic services operation, we are now also able to generate revenue in our diagnostic services business from these customers. We are now transitioning most of these customers to a web-based Access program that does not require the approximate $4,000 investment that has been made historically for the remote viewing stations that these customers require. This has largely eliminated our cost of new Access hardware while providing a differentiating technology for these customers that still utilize the image analysis capabilities contained within our FDA approved technology.

System sale revenue for the year ended December 31, 2004 increased due to an increase in the number of units sold. Twelve systems were sold during 2004 as compared to six for the comparable period in 2003. System sales contributed 19% of total revenue for 2004 as compared to 8% for the comparable period in 2003. Revenue from system sales can fluctuate significantly principally due to the infrequent and limited number of system sales.

Cost of Revenue and Gross Margin

For the year ended December 31, 2004, the gross margin as a percentage of revenue was 24% compared to 70% for the year ended December 31, 2003.

Services Group. Cost of revenue for the year ended December 31, 2004 was $3.8 million. There is no comparable figure for the prior year as these services commenced in the second quarter of 2004. These costs were very high compared to services group revenue because of the substantial costs that were incurred to start up our services group operations. These costs included the laboratory personnel, equipment, laboratory supplies and other direct costs such as shipping that were required to support the launch and service of this operation. Gross margin for our services group in 2004 was negative primarily as a result of the costs incurred to launch our laboratory operation and the relatively fixed nature of the diagnostic services' cost structure.

Technology Group. Cost of revenue was $3.6 million in 2004. This amount is less than a 1% increase over cost of revenue in 2003. The cost of revenue primarily consists of cost for manufacturing the ACIS® and remote Access viewing stations, which includes the cost for direct material, labor costs, manufacturing overhead, and direct customer support costs. For fee-per-use revenue, the cost of the ACIS® is depreciated over a three-year time period and for a system sale the entire cost of the ACIS® system is recognized at the time of sale. As noted above, we transitioned Access customers to a web-based Access program. As a result, during the fourth quarter of 2004, we made the decision to fully depreciate all of our Access remote viewing stations because these are no longer required to facilitate the web-based program. The charge related to this decision was $200,000. Gross margins for the technology group were 51% in 2004 as compared to 70% in 2003. The reduction was due primarily to lower average revenue per ACIS® system from fee-per-use systems.

Operating and Other Expenses

Selling, general and administrative expenses. These expenses for the year ended December 31, 2004 increased approximately $2.3 million or 20% over the comparable period in 2003. The increase included cost increases for new staffing, particularly in the sales force, non-cash compensation costs related to our 2003 restricted stock grant retention program, relocation for new personnel, legal costs primarily related to litigation and compliance with Sarbanes Oxley Section 404 requirements.

Diagnostic services administration. These costs totaled $3.5 million in 2004 and included the costs of senior medical staff, senior operations personnel, consultants and legal resources to facilitate implementation of this new operation. There were no comparable costs in 2003. Collection costs are incurred from a third party billing and collection company that we have engaged to perform these services because of the high degree of technical complexity and knowledge required to effectively perform these operations. These costs are incurred as a percentage of amounts collected.

Research and development expenses. These expenses for the year ended December 31, 2004 decreased by approximately $0.1 million, or 3%, from the comparable period in 2003. The decrease is due to a reduction in personnel cost that resulted from a workforce reduction to streamline costs that occurred in the third quarter of 2003. This decline was somewhat offset by an increase in patent amortization costs due to a decision to lower the average amortization life of our patent portfolio.

Other income (expense). Other expense for the year ended December 31, 2004 of $0.1 million was slightly higher than the comparable figure in 2003 and consisted primarily of interest expense from borrowings under our equipment financing facility and our laboratory equipment leasing facility. This interest cost was partially offset by interest income from our average cash balance throughout 2004. The average cash balance was higher than 2003 due to our February 2004 and March 2004 private sales of common stock which raised an aggregate of approximately $24.5 million of net proceeds.

Liquidity and Capital Resources

At December 31, 2005, we had approximately $9.3 million of cash and cash equivalents, and $5.5 million available under our revolving line of credit. Cash used in operating activities was $11.1 million for the year ended December 31, 2005 due primarily to our net loss of $14.8 million and increases in working capital requirements. Cash used in investing activities of $4.3 million consisted of capital expenditures related primarily to purchases of new equipment for the diagnostic services laboratory and leasehold improvements at the new facility. Net cash provided from financing activities during the year ended December 31, 2005 was $14.7 million which was primarily attributable to our private placement of common stock and warrants in the fourth quarter.

On November 8, 2005, we entered into a securities purchase agreement with a limited number of accredited investors pursuant to which we agreed to issue and the investors agreed to purchase 15,000,000 shares of common stock, together with warrants to purchase an additional 2,250,000 shares of common stock at an exercise price of $1.35 per share, for an aggregate purchase price of $15 million. The warrants issued in this transaction are exercisable for a period of four years after the date they were issued. We structured this transaction so that a portion of the common stock and warrants issued (8,900,000 shares of common stock and warrants

to purchase 1,350,000 shares of common stock for aggregate gross proceeds of $8.9 million) were issued at an initial closing that occurred on November 9, 2005. The remaining shares and warrants were issued at a subsequent closing on December 14, 2005. Safeguard Scientifics, Inc. (Safeguard) was one of the purchasers in this financing and acquired 9,000,000 shares of common stock and warrants to purchase 1,350,000 shares of common stock for an aggregate investment of $9 million. Following consummation of the financing, Safeguard will continue to own a majority of our common stock. The aggregate net proceeds to us from the financing (after payment of placement fees and expenses) were approximately $14.7 million. The securities issued in the financing were issued to a limited number of accredited investors in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act) and may not be resold unless there is either an effective registration statement under the Securities Act or a valid exemption from the registration requirements of the Securities Act. There is a currently effective registration statement covering resales of the shares of common stock issued in the private placement and the shares of common stock underlying the warrants issued in the private placement.

We currently lease our corporate headquarters and manufacturing facility and our diagnostic laboratory services facility under separate operating lease arrangements. The lease for the corporate headquarters and manufacturing facility expired in February 2006 and will continue on a month-to-month term. In July 2005, we signed a lease for a new, single facility. The new facility lease has a term of 10 years beginning December 1, 2005 with two five-year renewal options. We relocated our laboratory operations to the new facility in January 2006. We expect to relocate our corporate headquarters and manufacturing operation to the new facility in the second quarter of 2006. The landlord of the new facility has agreed to fund approximately $3.5 million of tenant improvements, subject to the terms of the lease agreement. Our total projected spending for the build-out of this facility, including the $3.5 million of tenant improvements funded by the landlord, is approximately $8 million to $9 million. As of December 31, 2005, we have spent approximately $5 million in total tenant improvements and equipment purchases to build out the facility. We expect to spend approximately $3 million to $4 million to complete the facility project. Of the $5 million spent through December 31, 2005, the landlord has funded approximately $1 million and we expect the landlord to fund the balance of approximately $2.5 million in 2006.

Our instrument systems business generates revenues from leases of the ACIS® system to certain customers (pursuant to which those customers pay us on a "fee-per-use" basis for each time the instrument is used to perform a test) and from sales of our ACIS® systems. Revenues from system leases are recognized over the lease term and revenues from system sales are recognized upon customer acceptance of the system. We do not anticipate leasing a significant number of new ACIS® systems on a going forward basis. Instead, we expect that sales of our ACIS® system to new customers will comprise the substantial majority of new system placements. These sales will include sales of systems pursuant to our distribution arrangement with Dako and direct sales by us in markets where our distribution arrangement with Dako is not exclusive. The rate of inventory purchases as it relates to ACIS® equipment purchases has been lower than prior periods due to the slower pace of system placements. However, as a result of our new distribution arrangement with Dako, we expect sales of systems to increase during 2006 and that the rate of related inventory purchases will also increase. We also expect our research and development expenditures to increase with respect to development of a future ACIS® system. Future ACIS® system development expenses will be funded in part by Dako under the terms of our distribution and development arrangement.

We believe that we have substantially all of the laboratory equipment that is required to support our current operating activities. A substantial increase in diagnostic service activity in excess of our annual revenue plan may result in significant additions to this equipment. We expect to fund any purchases of additional laboratory equipment from our $3.0 million 2006 equipment financing lease line.

We currently have an $8.5 million revolving credit agreement with Comerica, which expires on February 28, 2007. The line of credit was increased from $5.5 million to $8.5 million in August 2005. The borrowings under the line of credit are being used for working capital purposes and a $3.0 million stand-by letter of credit that was provided to the landlord of our new leased facility and bears interest at the bank's prime rate minus 0.5% percent. The agreement also includes an annual facility fee of $27,500 and various restrictive covenants and requirements to maintain certain financial ratios. Borrowings under the line of credit are guaranteed by Safeguard in exchange for an annual fee of 0.5% of the amount guaranteed and an amount equal to 4.5% per annum of the daily-weighted average principal balance outstanding under the line of credit. The Company also issued a warrant to Safeguard to purchase 50,000 shares of common stock for an exercise price of $2.00 per share as additional consideration for Safeguard's guarantee. The agreement has only one financial covenant related to tangible net worth, which is required to be not less that $0. Exclusive of the $3.0 million stand-by letter of credit, no amounts were outstanding under the line of credit at December 31, 2005.

In August 2003, we entered into a $3.0 million equipment financing agreement with General Electric Capital Corporation (GE Capital). The original loan principal amortized ratably over a 33-month term. The borrowings under the equipment financing agreement were used for working capital purposes and bear interest at an annual rate of interest of 8.16%. The agreement was subject to various restrictive covenants, required maintenance of certain financial ratios and included a collateral monitoring fee of $5,000 per year. In September 2003, the entire $3.0 million available under the financing agreement was borrowed. As of December 31, 2005, $700,000 of debt remained outstanding under this agreement, all of which is classified as current. On March 3, 2006, the total outstanding amount under this agreement was paid in full and the agreement has terminated..

In June 2004, we entered into a master lease agreement with GE Capital for capital equipment financings of laboratory services related equipment. During 2004, we financed $2.6 million of capital equipment under this arrangement, which was recorded as a capital lease obligation. Each lease financing has a term of 36 months and provides for an early purchase option after 30 months at 26.6% of the cost of the equipment.

In January 2005, GE Capital approved additional equipment lease financings of up to $2.3 million under this master lease agreement for equipment leases during 2005, subject to execution of definitive documentation for each separate equipment lease and GE Capital's review of our financial condition at the time of each funding request. These additional equipment lease financings have a term of 36 months for each equipment purchase and provide for an early purchase option by the Company after 24 months for a purchase price equal to 40.5% of the cost of the equipment. As of December 31, 2005, the Company had financed $2.0 million of capital equipment under this line, which was recorded as a capital lease obligation.

In February 2006, GE Capital provided a conditional acceptance to finance additional equipment up to $3.0 million during 2006 under the master lease agreement, subject to execution of definitive documentation for each separate equipment lease and GE Capital's review of our financial condition at the time of each funding request. These additional equipment lease financings have a term of 36 months for each equipment purchase and provides for an early purchase option after 24 months for a purchase price equal to 43.1% of the cost of the equipment.

On March 1, 2006, we entered into a Master Purchase Agreement with Med One Capital, Inc. (Med One) pursuant to which Med One has agreed to purchase ACIS® cost per test units that we currently lease to customers for a gross amount of $2.3 million (the leased equipment would have produced approximately $1 million of customer lease revenue during 2006). Med One also has the option to purchase additional units worth up to $1 million. Under the agreement, 10 percent of the purchase price will be held in escrow and may be recoverable by Med One to the extent that any units returned to Med One prior to the expiration of the applicable equipment lease are not successfully remarketed.

We believe that our existing cash resources together with access to the financing sources described above (including the remaining $5.5 million available under our revolving line of credit with Comerica Bank, the $3.0 million of availability under our new equipment lease line with GE Capital (which remains subject to GE Capital's ongoing review of our financial condition at the time of each funding request),and proceeds from the Master Purchase Agreement with Med One) will be sufficient to satisfy the cash needs of our existing operations through the end of 2006. However, we may require additional debt or equity financing if we are unable to access one or more of these financing sources or if we encounter difficulties in executing our business plan. There can be no assurance that we will be able to obtain additional debt or equity financing when needed or on terms that are favorable to us and our stockholders. Furthermore, if additional funds are raised through an equity or convertible debt financing, our stockholders may experience significant dilution.

The following table summarizes our contractual obligations and commercial commitments at December 31, 2005, including our new facility lease. These commitments exclude any remaining amounts necessary to complete the build-out of our new facility and a $3.0 million standby letter of credit provided to the landlord under the lease agreement for our new facility.

	Payment due by period (in thousands)				
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Long-Term Debt Obligations	$ 700	$ 700	$ —	$ —	$ —
Capital Lease Obligations	3,526	1,453	2,073	—	—
Operating Leases	14,071	971	3,785	3,001	6,314
Total	$ 18,297	$ 3,124	$ 5,858	$ 3,001	$ 6,314

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that provide financing, liquidity, market or credit risk support or involve leasing, hedging or research and development services for our business or other similar arrangements that may expose us to liability that is not expressly reflected in the financial statements, except for facilities operating leases.

As of December 31, 2005, we did not have any relationships with unconsolidated entities or financial partnerships, often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such we are not subject to any material financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

Recent Accounting Pronouncements

Several new accounting standards have been issued and adopted recently. None of these standards had a material impact on our financial position, results of operations or liquidity. See also Note 2 of Notes to the Consolidated Financial Statements.

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004), "Share-Based Payment" (SFAS No. 123(R)). SFAS No. 123(R) will require companies to measure all employee stock-based compensation awards using a fair value method and record such expense in their consolidated financial statements. The adoption of SFAS No. 123(R) requires additional accounting and disclosure related to the income tax and cash flow effects resulting from share-based payment arrangements. SFAS No. 123(R) would have been effective beginning as of the first interim or annual reporting period beginning after June 15, 2005. On April 14, 2005, the Securities and Exchange Commission changed the effective date for most public companies with annual periods that begin after June 15, 2005. Based on stock options granted through and outstanding as of December 31, 2005, we estimate that the expense recorded in the year ended December 31, 2006 related to the adoption of SFAS No. 123(R) will be approximately $1.0 million. Actual amounts recorded in 2006 may differ from this estimate due to assumptions used in calculating the expense amount and any option grants, cancellations or modifications during the year.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs," (SFAS No. 151), an amendment of Accounting Research Bulletin No. 43, "Inventory Pricing." SFAS No. 151 requires all companies to recognize a current-period charge for abnormal amounts of idle facility expense, freight, handling costs and wasted materials. The statement also requires that the allocation of fixed production overhead to the costs of conversion be based on the normal capacity of the production facilities. This new standard will be effective for fiscal years beginning after June 15, 2005. We do not believe its adoption will have a material impact on our financial position, results of operation or cash flows.

In June 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections-a replacement of APB No. 20 and FAS No. 3" (SFAS No. 154). SFAS No. 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes, unless impracticable, retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. SFAS No. 154 also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The correction of an error in previously issued financial statements is not an accounting change. However, the reporting of an error correction involves adjustments to previously issued financial statements similar to those generally applicable to reporting an accounting change retrospectively. Therefore, the reporting of a correction of an error by restating previously issued financial statements is also addressed by SFAS No. 154. SFAS No. 154 is required to be adopted in fiscal years beginning after December 15, 2005. We do not believe its adoption will have a material impact on our financial position, results of operation or cash flows.

In June 2005, the FASB's Emerging Issues Task Force reached a consensus on Issue No. 05-6, "Determining the Amortization Period for Leasehold Improvements Purchased after Lease Inception or Acquired in a Business Combination" (EITF 05-6). This guidance requires that leasehold improvements acquired in a business combination or purchased subsequent to the inception of a lease be amortized over the shorter of the useful life of the assets or a term that includes required lease periods and renewals that are reasonably assured at the date of the business combination or purchase. This guidance is applicable only to leasehold improvements that are purchased or acquired in reporting periods beginning after June 29, 2005. The adoption of EITF 05-6 is not expected to have an impact on our consolidated financial position, results of operations or cash flows.

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

Historically, we have invested excess cash in short-term debt securities that are intended to be held to maturity. These short-term investments typically have various maturity dates which do not exceed one year. We had no short-term investments as of December 31, 2005.

Two of the main risks associated with these investments are interest rate risk and credit risk. Typically, when interest rates rise, there is a corresponding decline in the market value of debt securities. Fluctuations in interest rates would not have a material effect on our financial statements because of the short-term nature of the securities in which we invest and our intention to hold the securities to maturity. Credit risk refers to the possibility that the issuer of the debt securities will not be able to make principal and interest payments. We have limited the investments to investment grade or comparable securities and have not experienced any losses on our investments to date due to credit risk.

Changes in foreign exchange rates, and in particular a strengthening of the U.S. dollar, may negatively affect our consolidated sales and gross margins as expressed in U.S. dollars. To date, we have not entered into any foreign exchange contracts to hedge our exposure to foreign exchange rate fluctuations. However, as our international operations grow, we may enter into such arrangements in the future. Effective January 1, 2002, our foreign sales were denominated in U.S.dollars or Euros. Foreign currency-denominated sales have not been significant.

Item 8. Financial Statements and Supplementary Data

CLARIENT, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Clarient, Inc.:

We have audited the accompanying consolidated balance sheets of Clarient, Inc. and subsidiaries as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2005. Our audits include the financial statement schedule listed in the Index at Item 15. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule 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. An audit also includes 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 presents fairly, in all material respects, the financial position of Clarient, Inc., and subsidiaries as of December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2005 in conformity with U.S. generally accepted accounting principles. Also in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

/s/ KPMG LLP

Costa Mesa, California
March 6, 2006

CLARIENT, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

ASSETS

	December 31, 2005	December 31, 2004
Current assets:		
Cash and cash equivalents	$ 9,333	$ 10,045
Accounts receivable, net of allowance for doubtful accounts of $740 and $140 in 2005 and in 2004, respectively (services group)	3,928	1,273
Accounts receivable, net of allowance for doubtful accounts of $207 and $135 in 2005 and in 2004, respectively (technology group)	858	1,387
Net investment in sales type leases	81	—
Inventories	1,088	740
Prepaid expenses and other current assets	754	528
Total current assets	16,042	13,973
Property and equipment, net of accumulated depreciation	8,007	5,344
Patents, net of accumulated amortization of $572 and $434 in 2005 and in 2004, respectively	742	743
Net investment in sales type leases	188	—
Other	270	97
Total assets	$ 25,249	$ 20,157

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 3,122	$ 1,566
Accrued payroll	1,109	1,148
Accrued expenses	1,341	1,040
Deferred revenue	1,233	98
Current maturities of long-term debt, including capital lease obligation	2,153	2,031
Total current liabilities	8,958	5,883
Long-term debt, including capital lease obligation	2,073	2,386
Deferred rent	1,756	—
Commitments and contingencies		
Stockholders' equity:		
Common stock $0.01 par value, authorized 100,000,000 shares, issued and outstanding 66,912,762 and 51,590,448 in 2005 and in 2004, respectively	669	516
Additional paid-in capital	132,388	117,481
Accumulated deficit	(120,285)	(105,483)
Deferred compensation	(268)	(576)
Accumulated other comprehensive loss	(42)	(50)
Total stockholders' equity	12,462	11,888
Total liabilities and stockholders' equity	$ 25,249	$ 20,157

See accompanying notes to consolidated financial statements.

CLARIENT, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	For the Year Ended December 31,		
	2005	2004	2003
Revenue:			
Services group	$ 11,439	$ 2,238	$ —
Technology group	8,710	7,531	11,928
Total revenue	20,149	9,769	11,928
Cost of revenue:			
Services group	8,789	3,813	—
Technology group	2,419	3,627	3,597
Cost of revenue	11,208	7,440	3,597
Gross profit	8,941	2,329	8,331
Operating expenses:			
Selling, general and administrative	13,414	13,710	11,384
Diagnostic services administration	6,312	3,499	—
Research and development	3,805	4,612	4,754
Total operating expenses	23,531	21,821	16,138
Loss from operations	(14,590)	(19,492)	(7,807)
Other expense	212	106	58
Loss before income taxes	(14,802)	(19,598)	(7,865)
Income taxes	—	2	1
Net loss attributable to common stock	$ (14,802)	$ (19,600)	$ (7,866)
Basic and diluted net loss per common share	$ (0.27)	$ (0.38)	$ (0.21)
Weighted average number of common shares outstanding	53,971,275	51,590,448	37,095,175

See accompanying notes to consolidated financial statements.

CLARIENT, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Deferred		Comprehensive
	Shares	Amount	Capital	Deficit	Loss	Compensation	Total	Loss
Balances at December 31, 2002	32,846	$ 328	$ 85,915	$ (78,017)	$ (66)	$ —	$ 8,160	
Exercise of stock options	205	2	449	—	—	—	451	
Sale of common stock, net of offering costs	4,646	47	4,922	—	—	—	4,969	
Issuance of options to consultants	—	—	75	—	—	—	75	
Issuance of restricted stock	885	9	1,084	—	—	(1,021)	72	
Restricted stock amortization	—	—	—	—	—	165	165	
Comprehensive Loss:								
Net loss	—	—	—	(7,866)	—	—	(7,866)	(7,866)
Foreign currency translation adjustment	—	—	—	—	(7)	—	(7)	(7)
Comprehensive loss								$ (7,873)
Balances at December 31, 2003	38,582	386	92,445	(85,883)	(73)	(856)	6,019	
Exercise of stock options	213	2	268	—	—	—	270	
Sale of common stock, net of offering costs	12,795	128	24,292	—	—	—	24,420	
Issuance of options to consultants	—	—	142	—	—	—	142	
Issuance of options to employees	—	—	334	—	—	(273)	61	
Restricted stock amortization	—	—	—	—	—	482	482	
Employee stock option amortization	—	—	—	—	—	71	71	
Comprehensive loss:								
Net loss	—	—	—	(19,600)	—	—	(19,600)	(19,600)
Foreign currency translation adjustment	—	—	—	—	23	—	23	23
Comprehensive loss								$ (19,577)
Balances at December 31, 2004	51,590	516	117,481	(105,483)	(50)	(576)	11,888	
Exercise of stock options	154	1	194	—	—	—	195	
Sale of common stock, net of offering costs	15,000	150	14,508	—	—	—	14,658	
Issuance of restricted stock to consultants	153	2	184	—	—	(186)	—	
Issuance of restricted stock to employees	15	—	21	—	—	(21)	—	
Restricted stock amortization	—	—	—	—	—	498	498	
Employee stock option amortization	—	—	—	—	—	17	17	
Comprehensive loss:								
Net loss	—	—	—	(14,802)	—	—	(14,802)	(14,802)
Foreign currency translation adjustment	—	—	—	—	8	—	8	8
Comprehensive loss								$ (14,794)
Balances at December 31, 2005	66,912	$ 669	$ 132,388	$ (120,285)	$ (42)	$ (268)	$ 12,462	

See accompanying notes to consolidated financial statements.

CLARIENT, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the Year Ended December 31,		
	2005	2004	2003
Cash flows from operating activities:			
Net loss	$ (14,802)	$ (19,600)	$ (7,866)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,904	3,434	2,747
Non-cash compensation charges	515	756	312
Gain on sale of assets	(1,254)	—	—
Provision for bad debt	1,217	221	617
Reserve for excess and obsolete inventory	—	191	(80)
Changes in operating assets and liabilities:			
Accounts receivable, net (services group)	(3,599)	(1,413)	—
Accounts receivable, net (technology group)	256	1,028	(758)
Net investment in sales type leases	(269)	—	—
Inventories	(348)	(191)	31
Prepaid expenses and other assets	(399)	315	(517)
Accounts payable	1,556	1,172	(357)
Accrued severance	—	(254)	(272)
Accrued payroll	(39)	464	(179)
Accrued expenses	301	283	326
Deferred rent	1,756	—	—
Deferred revenue	1,135	(9)	(15)
Net cash used in operating activities	(11,070)	(13,603)	(6,011)
Cash flows from investing activities:			
Additions to patents	(137)	(248)	(380)
Additions to property and equipment	(5,656)	(4,097)	(2,969)
Proceeds from sale of assets	1,481	—	—
Net cash used in investing activities	(4,312)	(4,345)	(3,349)
Cash flows from financing activities:			
Proceeds from exercise of stock options	195	270	451
Borrowings on long-term debt, including equipment lease financing	1,975	2,796	3,000
Repayments on long-term debt, including capital lease obligation	(2,166)	(1,215)	(164)
Issuance of common stock	15,000	26,000	5,000
Offering costs	(342)	(1,580)	(31)
Net cash provided by financing activities	14,662	26,271	8,256
Effect of exchange rate changes on cash and cash equivalents	8	23	(7)
Net increase (decrease) in cash and cash equivalents	(712)	8,346	(1,111)
Cash and cash equivalents at beginning of year	10,045	1,699	2,810
Cash and cash equivalents at end of year	$ 9,333	$ 10,045	$ 1,699
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 295	$ 269	$ —
Cash paid for income taxes	$ —	$ 2	$ 1
Non-cash investing and financing activities:			
Issuance of restricted common stock	$ 207	$ —	$ 1,093

See accompanying notes to consolidated financial statements.

(1) Description of Business

Clarient, Inc. (the Company) combines innovative technologies, meaningful test results and world class expertise to improve patient outcomes. Clariant is a comprehensive cancer diagnostic company providing cellular assessment and cancer characterization to three major customer groups:

- community pathologists;
- academic researchers and university hospitals; and
- bio pharmaceutical companies.

Clarient approaches these customers' needs by leveraging its proprietary bright field microscopy technology. Its highly reliable Automated Cellular Imaging System (ACIS®) is a premiere digital cellular imaging solution selected by clinicians and researchers conducting cell-based analysis around the world. ACIS® provides the precise, reproducible results that targeted cancer therapies and drug discovery efforts require. The FDA-cleared ACIS® device is currently being used by pathologists and researchers to analyze specimens placed on slides and stained with color-producing, commercially available reagents. Building upon its core image analysis capabilities, the Company began to offer diagnostic laboratory services in May 2004. Initially the Company offered scan and stain technical services that were expanded in November 2004 to a broad range of diagnostic services after receiving its California Department of Health license including specified diagnostic services provided by physicians. Because of the corporate practice of medicine laws in the states in which the Company operates, the Company does not own medical practices but instead has entered into exclusive long-term management services agreements with the professional corporations which operate the medical practices. Consolidation of the financial statements for the medical practice component is required under Financial Accounting Standards Board (FASB) Interpretation No. 46, as revised, (FIN 46) "Consolidation of Variable Interest Entities."

The financial statements have been prepared on a going concern basis which assumes that the Company will have sufficient resources to pay its obligations as they become due during 2006. The Company has $5.5 million availability under a revolving line of credit, which will be used for working capital purposes (described in Note 8). Management believes that its current cash resources and committed borrowings will enable the Company to maintain operations through December 31, 2006.

(2) Summary of Significant Accounting Policies

(a) Basis of Consolidation

The consolidated financial statements include the results of operations, account balances and cash flows of Clarient, Inc. and its wholly owned subsidiaries. All significant inter-company accounts and transactions have been eliminated in consolidation.

(b) Revenue Recognition

Revenue for the Company's diagnostic services is recognized at the time of completion of services at amounts equal to the contractual rates allowed from third parties, including Medicare, insurance companies, and to a small degree, private patients. These expected amounts are based both on Medicare allowable rates and the Company's collection experience with other third party payers. Because of the requirements and nuances of billing for laboratory services, the Company may invoice amounts that are greater than those allowable for payment. These differences are described as contractual discounts. As noted, however, it is only the expected payment from these parties which is net of these contractual discounts that is recorded as revenue.

Revenue for "fee-per-use" agreements is obtained through the billing information via modem, which accesses the ACIS® database. Revenue is recognized based on the greater of actual usage fees or the minimum monthly rental fee. Under this pricing model, the Company owns most of the ACIS® instruments that are engaged in service and accordingly, all related depreciation and maintenance and service costs are expensed as incurred. For those instruments that are sold, the Company recognizes and defers revenue using the residual method pursuant to the requirements of Statement of Position No. 97-2, "Software Revenue Recognition" (SOP 97-2), as amended by Statement of Position No. 98-9, "Modification of SOP 97-2, Software Revenue Recognition with Respect to Certain Arrangements." At the outset of the arrangement with the customer, the Company defers revenue for the fair value of its undelivered elements (e.g., maintenance) and recognizes revenue for the remainder of the arrangement fee attributable to the elements initially delivered in the arrangement (e.g., software license) when the basic criteria in SOP 97-2 have been met. Maintenance revenue is recognized ratably over the term of the maintenance contract, which typically is a period of twelve months.

Revenue on system sales is recognized in accordance with Staff Accounting Bulletin No. 101, as amended by Staff Accounting Bulletin No. 104, when all criteria for revenue recognition have been met. Such criteria include, but are not limited to: existence of persuasive evidence of an arrangement; fixed and determinable product pricing; satisfaction of the terms of the arrangement including passing title and risk of loss to the customer upon shipment; and reasonable assurance of collection from the customer in accordance with the terms of the arrangement. For system sales delivered under the Dako distribution and development agreement, the Company recognizes revenue when those ACIS® instruments have been delivered and accepted by an end-user customer.

Systems sold under a leasing arrangement are accounted for as sales-type leases pursuant to SFAS No. 13, "Accounting for Leases," if applicable. The Company recognizes the net effect of these transactions as a sale because of the bargain purchase option granted to the lessee.

Revenues from research and development agreements are recognized over the contract performance period, starting with the contract's commencement. The upfront payment is deferred and recognized on a straight-line basis over the estimated performance period. Milestone payments are recognized as revenue when they are due and payable, but not prior to the removal of any contingencies for each individual milestone.

(c) Stock-Based Compensation

The Company applies Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25), for stock options and other stock-based awards to employees while disclosing pro forma net loss and net loss per share as if the fair value method had been applied in accordance with Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation" as amended by SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure", see Note 3. The fair value of options granted to non-employees is expensed over the performance period and is measured based on the fair value of options when performance is complete.

The Company applies APB 25 and related interpretations in accounting for stock option plans. Had compensation cost been recognized consistent with SFAS No. 123, the Company's consolidated net loss and loss per share would have been increased to the pro forma amounts indicated below:

(in thousands except for per share information)

	December 31,		
	2005	2004	2003
Consolidated net loss attributable to common stock:			
As reported	$ (14,802)	$ (19,600)	$ (7,866)
Add: Stock-based employee compensation expense included in net-loss	515	614	237
Deduct: Total stock-based employee compensation expense determined under fair value based methods for all awards	(1,895)	(1,865)	(1,484)
Pro forma	$ (16,182)	$ (20,851)	$ (9,113)
Loss per share — Basic and Diluted:			
As reported	$ (0.27)	$ (0.38)	$ (0.21)
Pro forma	$ (0.30)	$ (0.40)	$ (0.25)
Per share weighted-average fair value of stock options granted	$ .98	$ 2.48	$ 3.20

The following assumptions were used by the Company to determine the fair value of stock options granted using the Black-Scholes option-pricing model:

	2005	2004	2003
Dividend yield	0.0%	0.0%	0.0%
Volatility	101%	103%	99%
Average expected option life	4 years	4 years	4 years
Risk-free interest rate	3.9-4.5%	2.7-3.6%	2.1-2.8%

(d) Use of Estimates

The preparation of the Company's financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses. Actual results could differ from those estimates. Significant estimates include the depreciation and valuation of ACIS® systems and ACIS® in progress, receivables valuations and valuation of deferred income tax assets.

(e) Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred taxes are reduced by a valuation allowance to an amount whose realization is more likely than not to be realized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

(f) Net Loss Per Share

Basic and diluted loss per common share is calculated by dividing net loss by the weighted average common shares outstanding during the year. These outstanding options and warrants are not included in the computation of diluted earnings per share because the Company incurred a net loss in all periods presented and therefore, the impact would be anti-dilutive. The following table shows options and warrants outstanding:

December 31,	Outstanding options and warrants to purchase aggregate shares of common stock	Weighted average option price
2005	12,540,478	$ 2.56
2004	9,249,225	2.48
2003	6,103,450	3.20

(g) Cash and Cash Equivalents

Cash and cash equivalents consist of amounts held as bank deposits and money market funds with a maturity of three months or less. The Company has not experienced any significant losses on cash equivalents and does not believe it is exposed to any significant credit risk on such cash equivalents.

(h) Financial Instruments

The Company estimates the fair value of its monetary assets and liabilities based upon the existing interest rates related to such assets and liabilities compared to current market rates of interest for instruments with a similar nature and degree of risk. The Company estimates that the fair value of all of its monetary assets and liabilities approximates the recorded value as of December 31, 2005 and 2004.

(i) Inventories

Inventories are stated at the lower of first-in, first-out average cost or market. Amounts related to raw materials, work in process and ACIS® systems not yet shipped to a customer have been reclassified from property and equipment to inventory for all periods presented.

(j) Depreciation and Amortization

Property and equipment are depreciated and amortized on the straight-line basis over the following estimated useful lives:

Office, Computer and Laboratory Equipment	3 to 5 years
ACIS® units	3 years
Furniture and Fixtures	5 years
Leasehold Improvements	Shorter of useful life or remaining life of lease

The following is a summary of property and equipment (in thousands):

	December 31,	
	2005	2004
Office furniture, computer and laboratory equipment.....	$ 8,854	$ 6,384
Automated Cellular Imaging Systems (ACIS®)	10,982	11,962
Leasehold improvements	4,218	1,139
Total	$ 24,054	$ 19,485
Less: accumulated depreciation.....	16,047	14,141
Property and equipment, net.....	$ 8,007	$ 5,344

The ACIS® units included in the above summary of property and equipment are offered under cancelable lease arrangements in which the customer is charged based on the number of tests performed subject to a minimum monthly payment.

Expenditures for maintenance, repairs and minor improvements are charged to expense as incurred. Major improvements and additions are capitalized. Depreciation on ACIS® instruments begins upon placement into service. Depreciation related to ACIS® instruments for research and development or placed for commercial use are expensed in research and development or cost of sales, respectively.

(k) Impairment of Long-Lived Assets and Patents

The Company assesses the impairment of patents and long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors the Company considers to be important which could trigger an impairment review include the following:

- significant underperformance relative to expected historical or projected future operating results;
- timing of the Company's revenue, significant changes in the manner of use of the acquired assets or the strategy for the Company's overall business;
- significant negative industry or economic trends;
- significant decline in the Company's stock price for a sustained period; and
- the Company's market capitalization relative to net book value.

When the Company determines that the carrying value of patents and other long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment and the carrying value of the asset cannot be recovered from projected undiscounted cash flows, the Company measures any impairment based on a projected discounted cash flow method using a discount rate determined by its management to be commensurate with the risk inherent in the current business model. Significant management judgment is required in determining whether an indicator of impairment exists and projecting cash flows.

(l) Patent Costs

Development costs and filing fees for patents which protect the Company's intellectual property for ACIS® machines are stated at amortized cost. Amortization of the patent-related costs is provided using the straight-line method over the term of the remaining estimated useful life of 10 years. The amortization period coincides with the estimated useful life of the asset.

The following table summarizes the future estimated annual pretax amortization expense for these assets (in thousands):

Fiscal Year		
2006	$	126
2007		126
2008		125
2009		110
2010 & thereafter		255
Total	$	742

(m) Net Investment in Sales-Type Leases

The Company derives a portion of its revenues under leasing arrangements. Such arrangements provide for monthly payments covering the system sales, maintenance and interest. These arrangements meet the criteria to be accounted for as sales-type leases pursuant to SFAS No. 13, "Accounting for Leases." Accordingly, the system sale is recognized upon delivery of the system and acceptance by the customer. Upon the recognition of revenue, an asset is established for the "investment in sales-type leases." Maintenance revenue and interest income are recognized monthly over the lease term.

The components of the net investment in sales-type leases as of December 31, 2005 (in thousands) are listed below:

Total minimum lease payments to be received	$	367
Less: Amount representing estimated maintenance costs including profit thereon, included in total minimum lease payments		62
Net minimum lease payments receivable		305
Less: Unearned income & interest		36
Net investment in sales-type leases	$	269

(n) Research and Development

Research and development costs, including costs incurred for software development prior to establishment of technological feasibility, are expensed as incurred. The Company does not currently have any software development costs capitalized because management believes software is available for general release concurrently with the establishment of technological feasibility.

(o) Restructuring Charges

Restructuring charges incurred for exit or disposal activities are recognized when incurred in accordance with the provisions of SFAS No. 146 "Accounting for Costs Associated with Exit or Disposal Activities" which was adopted by the Company on January 1, 2003.

In August of 2003, the Company recorded a charge of $550,000 related to a third quarter workforce reduction involving 16 positions, including the resignation of the Company's Chief Executive Officer and Vice President of Sales and Marketing which is included in selling, general and administrative expenses. As of December 31, 2004, these charges had been fully paid.

In November 2004, the Company recorded a charge of approximately $100,000 related to a fourth quarter workforce reduction involving 10 employees, which is included in selling, general, and administrative expense. As of December 31, 2004, these charges had been fully paid.

(p) Concentrations of Credit Risk

The Company's customer base is comprised of two principal market segments, 1) the clinical market which consists of hospitals, pathology practice groups and reference laboratories and 2) the research and biotechnology market which consists of pharmaceutical companies, universities and research institutions. The Company's customer base is geographically diverse, and historically the Company has not experienced significant losses related to receivables for its fee-per-use revenue. The credit profile of the Company's pathology practice and hospital customer group does not often lend itself to formal credit evaluations. Where applicable, the Company will perform periodic credit evaluations, although these are infrequent. The Company does not require collateral. ACIS® fee-per-use customers are billed monthly based on their volume of activity. Diagnostic services revenue is largely derived from third-party payers, such as Medicare, to whom the Company submits bills for services based upon established rates of reimbursement. The Company estimates an allowance for doubtful accounts based upon the actual payment history of each customer in addition to reserving for a portion of receivables that are delinquent.

(q) Foreign Currency Translation

The financial position and results of operations of the Company's foreign subsidiaries are determined using the applicable local currency as the functional currency. Assets and liabilities of these subsidiaries are translated at the exchange rate in effect at each year-end. Revenues and expenses are translated at the average rate of exchange prevailing during the year. Translation adjustments arising from the use of differing exchange rates from period to period are included in accumulated other comprehensive loss in stockholders' equity.

(r) Recent Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004), "Share-Based Payment" (SFAS No. 123(R)). SFAS No. 123(R) will require companies to measure all employee stock-based compensation awards using a fair value method and record such expense in their consolidated financial statements. The adoption of SFAS No. 123(R) requires additional accounting and disclosures related to the income tax and cash flow effects resulting from share-based payment arrangements. SFAS No. 123(R) would have been effective beginning as of the first interim or annual reporting period beginning after June 15, 2005. On April 14, 2005, the Securities and Exchange Commission changed the effective date for most public companies with annual periods that begin after June 15, 2005. The Company's effective date for adoption is January 1, 2006 and will be reflected in the Company's financial statements beginning in the first quarter of 2006. Based on stock options granted through and outstanding as of December 31, 2005, the Company estimates that the expense to be recorded in the year ended December 31, 2006 related to the adoption of SFAS No. 123(R) will be approximately $1.0 million. Actual amounts recorded in 2006 may differ from this estimate due to assumptions used in calculating the expense amount and any option grants, cancellations or modifications during the year.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs," an amendment of Accounting Research Bulletin No. 43, "Inventory Pricing." SFAS No. 151 requires all companies to recognize a current-period charge for abnormal amounts of idle facility expense, freight, handling costs and wasted materials. The statement also requires that the allocation of fixed production overhead to the costs of conversion be based on the normal capacity of the production facilities. This new standard will be effective for fiscal years beginning after June 15, 2005. The Company does not believe its adoption will have a material impact on its financial position, results of operations or cash flows.

In June 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections-a replacement of APB No. 20 and FAS No. 3". SFAS No. 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes, unless impracticable, retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. SFAS No. 154 also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The correction of an error in previously issued financial statements is not an accounting change. However, the reporting of an error correction involves adjustments to previously issued financial statements similar to those generally applicable to reporting an accounting change retrospectively. Therefore, the reporting of a correction of an error by restating previously issued financial statements is also addressed by SFAS No. 154. SFAS No. 154 is required to be adopted in fiscal years beginning after December 15, 2005. The Company does not believe its adoption will have a material impact on its financial position, results of operations or cash flows.

In June 2005, the FASB's Emerging Issues Task Force reached a consensus on Issue No. 05-6, "Determining the Amortization Period for Leasehold Improvements Purchased after Lease Inception or Acquired in a Business Combination" (EITF 05-6). This guidance requires that leasehold improvements acquired in a business combination or purchased subsequent to the inception of a lease be amortized over the shorter of the useful life of the assets or a term that includes required lease periods and renewals that are reasonably assured at the date of the business combination or purchase. This guidance is applicable only to leasehold improvements

that are purchased or acquired in reporting periods beginning after June 29, 2005. The adoption of EITF 05-6 is not expected to have an impact on the Company's consolidated financial position, results of operations or cash flows.

(s) Reclassifications

Prior year amounts in the consolidated financial statements have been reclassified to conform with current year presentation. Reclassified amounts had no impact on the Company's net losses.

(3) Stock Options

The Company has a stock option plan (the Plan) pursuant to which its board of directors or a committee of the board may grant stock options to employees, directors and consultants. The Plan authorizes grants of options to purchase up to 9,200,000 shares of authorized but unissued common stock, including increases of 2,500,000 shares and 2,000,000 shares approved by the stockholders in 2004 and 2003, respectively. All options granted by the Company under the Plan have an exercise price equal to the stock's fair value at the date of grant except for options to purchase 150,000 and 540,250 shares granted to employees in 2004 and 2002, respectively. The Company recorded compensation expense of approximately $132,000 and $4,000 to recognize the excess of the fair market value on the date of the grant over the exercise price of the employee options issued in 2004 and 2002, respectively. Stock options granted have terms of up to 10 years and become exercisable in increments over periods of up to four years. All options terminate three months after termination of the option holder's employment or relationship with the Company as a director or consultant except in the case of death and disability, in which the period is extended to one year. The vesting and exercise periods have been extended by agreement for some present and former officers and employees as part of their severance arrangements for periods from 12 to 48 months. None of these new measurement dates for the extension of the vesting period resulted in a charge to compensation expense as the stock price was below the option price at the time the extension was granted.

The Company granted non-qualified stock options in 2005, 2004 and 2003 to purchase 25,000, 135,000 and 100,000 shares, respectively, to consultants of Clarient at exercise prices equal to the fair market value of the stock at date of grant. The Company recorded compensation expense based on the fair value of the options as determined using the Black-Scholes model. Compensation expense of approximately $78,000, $142,000 and $75,000 was recorded for the years ended December 31, 2005, 2004 and 2003, respectively, related to consultant options.

Option activity is summarized as follows:

	2005		2004		2003	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	7,583,666	$ 2.48	5,500,765	$ 3.17	4,604,950	$ 4.26
Options granted	507,000	1.39	3,161,500	1.39	1,798,000	1.19
Options exercised	(154,376)	1.26	(212,614)	1.28	(205,161)	2.20
Options cancelled	(1,061,371)	3.38	(865,985)	3.13	(697,024)	5.37
Outstanding at year-end	6,874,919	$ 2.29	7,583,666	$ 2.48	5,500,765	$ 3.20
Options exercisable at year-end	4,140,655		3,107,308		2,536,564	
Shares available for future grant	2,164,854		1,778,241		273,756	

The following summarizes information about the Company's stock options outstanding at December 31, 2005:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at 12/31/05	Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable at 12/31/05	Weighted Average Exercise Price
$0.82 — $0.98	710,250	5.48	$ 0.92	372,268	$ 0.92
$1.04 — $1.12	571,500	8.41	$ 1.06	200,000	$ 1.07
$1.15 — $1.15	741,125	5.88	$ 1.15	200,792	$ 1.15
$1.19 — $1.19	750	3.79	$ 1.19	625	$ 1.19
$1.20 — $1.20	737,518	4.81	$ 1.20	554,727	$ 1.20
$1.24 — $1.45	709,875	4.79	$ 1.34	330,438	$ 1.37
$1.48 — $1.57	206,500	5.09	$ 1.53	111,500	$ 1.55
$1.58 — $1.58	750,000	8.55	$ 1.58	265,625	$ 1.58
$1.64 — $2.38	469,125	6.46	$ 1.75	272,007	$ 1.73
$2.40 — $23.19	1,978,276	2.32	$ 4.79	1,832,673	$ 4.94
$0.82 — $23.19	6,874,919	5.10	$ 2.29	4,140,655	$ 3.02

(4) Income Taxes

The following table summarizes the tax effects of temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carry forwards which give rise to significant portions of the deferred tax assets and liability at December 31 (in thousands):

	2005	2004	2003
Deferred tax assets:			
Current assets:			
Accrued liabilities and other	$ 764	$ 600	$ 492
Non-current assets:			
Net operating loss carryforward	40,219	35,550	28,321
Intangible asset, net of amortization	389	510	601
Depreciation	1,297	1,098	1,003
Accrued liabilities and other	792	214	158
R&D and other tax credits	3,118	2,973	3,004
Non-current deferred tax assets	45,815	40,345	33,087
Total	46,579	40,945	33,579
Less valuation allowance for net deferred tax assets	(46,579)	(40,945)	(33,579)
Deferred tax assets (liability), net	$ -0-	$ -0-	$ -0-

Substantially all of the Company's pre-tax losses are derived from the domestic entity. The valuation allowance increased by $5,634,000 for the year ended December 31, 2005. In the event the valuation allowance is reversed in the future, tax benefits as of December 31, 2005 shall be allocated as follows:

Income tax benefit resulting from operations	$ 45,360
Additional paid-in capital	1,219
Total valuation allowance	$ 46,579

Actual income tax expense differs from amounts computed by applying the U.S. federal income tax rate of 34% to pretax loss as a result of the following for the year ending December 31 (in thousands):

	2005	2004	2003
Computed expected tax benefit	$ (5,033)	$ (6,664)	$ (2,642)
State income taxes net of federal benefit	(584)	(637)	(417)
Nondeductible expenses	25	(1)	180
Change in valuation allowance	5,634	7,333	2,577
Tax credit benefit	—	(70)	287
Other	(42)	41	16
Actual tax expense	$ -0-	$ 2	$ 1

As of December 31, 2005, the Company had net operating loss carry forwards for federal and state income tax purposes of approximately $105,509,000 and $66,308,000, respectively, which will commence expiration in 2011 and 2006, respectively. As of December 31, 2005, the Company had tax credit carry forwards for federal and state income tax purposes of $2,067,000 and $1,575,000, respectively, which will begin to expire in 2011.

Due to both historical and recent changes in the capitalization structure of the Company, the utilization of net operating losses may be limited pursuant to section 382 of the Internal Revenue Code.

(5) Commitments and Contingencies

Voluntary Employee Retirement 401(k) Plan. The Company has a voluntary employee retirement 401(k) plan available to all full time employees 21 years or older. The plan provides for a matching of the employee's contribution to the plan for 33.3% of the first 6% of the employee's annual compensation. The Company's matching contributions were approximately $158,000, $122,000 and $126,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

Operating Lease Commitment. The Company utilizes various operating leases for office space and equipment. The Company entered into a lease agreement dated as of July 20, 2005 for a mixed-use building with approximately 78,000 square feet in Aliso Viejo, California. The term of the lease commenced on December 1, 2005 with an initial term of 10 years and an option to extend the lease term for up to two additional five-year periods. The initial annual base rent is approximately $500,000. As the Company occupies additional square footage, the annual base rent will be increased to approximately $1.0 million on June 1, 2006 and to approximately $1.4 million on December 1, 2008. The base rent is increased 3% annually effective on December 1 of each year. The Company is also responsible for payments of common area operating expenses for the premises. The landlord has agreed to fund

approximately $3.5 million of tenant improvements toward design and construction costs associated with the build-out of the Aliso Viejo facility. Such costs will be capitalized as leasehold improvements and amortized over their estimated useful life, while the reimbursement will be recorded to deferred rent and recovered ratably over the term of the lease.

At December 31, 2005, future minimum lease payments for all operating leases are as follows (in thousands):

Fiscal year:	
2006	$ 971
2007	1,128
2008	1,178
2009	1,479
2010	1,503
Thereafter	7,812
	$ 14,071

Rent expense was approximately $1.2 million, $431,000 and $188,000 for the years ended December 31, 2005, 2004 and 2003.

Construction Agreement. On October 26, 2005, the Company entered into a construction agreement with LCS Constructors, Inc. (LCS), a team of general contractors and construction managers dedicated to the planning, design, construction and facility support of laboratories and technical facilities, to build-out its newly-leased facility in Aliso Viejo, California. Under the terms of the agreement, LCS will provide or arrange for construction services, materials, equipment, permits and liability insurance for the construction of the Aliso Viejo facility. The project is expected to be completed in three phases, with a first phase target substantial completion date of December 31, 2005 after which time the Company moved its laboratory facilities in January 2006 to the new location. The total amount to be paid for the first phase of the build-out pursuant to the contract is $3.7 million with an additional $200,000 contingency to cover change orders, in each case subject to adjustment. Fees for the remaining two phases of the build-out will be included in amendments to this contract and are estimated to be approximately $1.5 million for Phase II and $350,000 for Phase III. The anticipated substantial completion date for Phase II is March 31, 2006 and phase III as soon as practicable thereafter. Payments for all phases will be made in installments based on the percentage of completion. The final payment on each phase will be made after LCS has completed the applicable phase in its entirety, all corrective items have been completed and the architect prepares a final completion notice.

Distribution and Development Agreement with Dako. On July 18, 2005, the Company entered into a distribution agreement with Dako A/S (Dako), a Danish company that provides system solutions for cancer diagnostics and cell analysis worldwide. Under the terms of the agreement, Dako will distribute and market the Company's ACIS® II system and related software. The distribution arrangement is exclusive on a worldwide basis in research and clinical markets, and non-exclusive with respect to biotechnology and pharmaceutical companies (and their academic research partners). The agreement has a five-year initial term.

Dako has agreed to order a minimum of 40 ACIS® II systems per contract year (15 in the first year), subject to certain adjustments. Revenue from systems sold under this agreement will be recognized when these ACIS® systems have been delivered and accepted by an end-user.

Dako has also agreed to invest research and development funds toward future ACIS® devices and related software, and such products would also be subject to the terms of the agreement. The Company will own all intellectual property created under the agreement that is related to image analysis and execution thereof, and Dako will own all intellectual property created under the agreement that is related to Dako's specific implementation of the products or integration of the products with a product supplied by Dako. Such intellectual property will be cross-licensed from one party to the other. In the event the Company fails to supply ACIS® systems as set forth in the agreement, Dako will have the right and license to manufacture the ACIS® systems for that purpose for a reduced fee. Revenues received from research and development agreements are recognized over the contract performance period, starting with the contract's commencement. The upfront payment is deferred and recognized on a straight-line basis over the estimated performance period. Milestone payments are recognized as revenue when they are due and payable, but not prior to the removal of any contingencies for each individual milestone.

(6) Stock Transactions

On February 26, 2003, the Company issued 4,646,408 shares of common stock for an aggregate cash purchase price of $5,000,000 ($1.0761 per share) in a private placement to Safeguard Scientifics, Inc. (Safeguard). As a result of the transaction, Safeguard's percentage of beneficial ownership increased from 56% to 62%. The Company and Safeguard also entered into an agreement giving Safeguard certain rights to have the purchased shares registered under the Securities Act of 1933.

On September 1, 2003, the Company issued 816,950 shares of restricted stock to employees with a value on the date of grant of $1,021,188 ($1.25 per share), which was recorded as deferred compensation. This restricted stock vested over a two-year period. Compensation expense was recognized on a straight-line basis over the vesting period and was reduced to the extent that a participant forfeited shares of restricted stock received prior to vesting. The deferred compensation charge is unaffected by future changes in the price of the common stock. Safeguard did not exercise its anti-dilution rights in conjunction with the restricted stock grant. As a result, Safeguard's beneficial ownership decreased from 62% to 60%.

On February 10, 2004, the Company completed a private placement of 2,295,230 shares of common stock and a warrant to purchase shares of common stock to Safeguard for a purchase price of $5,000,000 . The warrant issued to Safeguard is exercisable until March 1, 2008 and is currently exercisable to purchase 344,285 shares of common stock for an exercise price of $2.95 per share. As a result of this transaction, Safeguard's percentage of beneficial ownership of the Company's common stock increased from approximately 60% immediately preceding the transaction to approximately 63%. The Company also entered into a registration rights agreement giving Safeguard certain rights to have the purchased shares registered under the Securities Act of 1933, as amended.

On March 25, 2004, the Company entered into a securities purchase agreement with a limited number of accredited investors pursuant to which the Company agreed to issue and the investors agreed to purchase 10,500,000 shares of common stock, together with warrants to purchase an additional 1,575,000 shares of common stock at an exercise price of $2.75 per share for an aggregate purchase price of $21,000,000 (this financing is referred to as the "March 2004 financing"). The warrants issued in this transaction are exercisable for a period of four years after the date they were issued. This transaction was structured so that a portion of the common stock and warrants issued (4,200,000 shares of common stock and warrants to purchase 630,000 shares of common stock for aggregate gross proceeds of $8,400,000) were issued at an initial closing that occurred on March 31, 2004. The remaining shares and warrants were issued at a subsequent closing which occurred on April 27, 2004. Safeguard was one of the purchasers in the March 2004 financing and acquired 3,750,000 shares (of which 1,500,000 shares were acquired at the initial closing) of common stock and warrants to purchase 562,500 shares of common stock (of which 225,000 were acquired at the initial closing) for an aggregate investment of $7,500,000. In connection with the March 2004 financing, the Company entered into a registration rights agreement with the purchasers in that financing and the Company has registered the resale of shares issued in the March 2004 financing with the Securities and Exchange Commission. Following consummation of the financing, Safeguard beneficially owned approximately 56.5% of the Company's outstanding common stock.

As described below in Note 8, on August 1, 2005, the Company amended its Loan Agreement with Comerica Bank to increase the revolving line of credit from $5,500,000 to $8,500,000. In conjunction with this increase, the Company issued to Safeguard a warrant to purchase 50,000 shares of common stock for an exercise price of $2.00 per share as additional consideration for Safeguard's guarantee of the increased amount.

On November 8, 2005, the Company entered into a securities purchase agreement with a limited number of accredited investors pursuant to which the Company agreed to issue and the investors agreed to purchase 15,000,000 shares of common stock, together with warrants to purchase an additional 2,250,000 shares of common stock at an exercise price of $1.35 per share, for an aggregate purchase price of $15,000,000 (this financing is referred to as the "2005 financing"). The warrants issued in this transaction are exercisable for a period of four years after the date they were issued. This transaction was structured so that a portion of the common stock and warrants issued (8,900,000 shares of common stock and warrants to purchase 1,335,000 shares of common stock for aggregate gross proceeds of $8,900,000) were issued at an initial closing that occurred on November 9, 2005. The remaining shares and warrants were issued at a subsequent closing on December 14, 2005. Safeguard was one of the purchasers in the 2005 financing and acquired 9,000,000 shares (of which 5,340,000 shares were acquired at the initial closing) of common stock and warrants to purchase 1,350,000 shares of common stock (of which 801,000 were acquired at the initial closing) for an aggregate investment of $9,000,000. Following consummation of the financing, Safeguard beneficially owned approximately 57.0% of the Company's outstanding common stock. In connection with the 2005 financing, the Company entered into a registration rights agreement with the purchasers in that financing and the Company has registered the resale of shares issued in the 2005 financing with the Securities and Exchange Commission.

Due to its beneficial ownership of approximately 57.0% of the Company's outstanding common stock, Safeguard has the power to elect all of the directors of the Company, although Safeguard has contractually agreed with the Company that a majority of the board of directors will consist of individuals not specifically designated by Safeguard. The Company has given Safeguard contractual rights enabling it to exercise significant control over the Company.

The Company recorded $498,000, $482,000 and $165,000 of compensation expense related to restricted stock in 2005, 2004 and 2003, respectively.

The Company has a stockholders' rights plan providing for discounted purchase rights to its stockholders upon specified acquisitions of its common stock. The exercise of these rights is intended to inhibit specific changes in control of the Company.

(7) Equipment Financing

In August 2003, the Company entered into an agreement for an equipment financing line from General Electric Capital Corporation (GE Capital). That equipment financing line provided for $3.0 million in immediate financing resources and an additional $2.0 million as the Company achieves certain system placement objectives. The loan principal amortizes ratably over the 33 month term. In September 2003, the Company borrowed $3.0 million at an interest rate of 8.16% under the equipment financing agreement. These borrowings were used for working capital purposes and were secured by substantially all of the assets of the Company. The agreement also provided for various restrictive covenants, maintenance of certain financial ratios and a collateral monitoring fee of $5,000 per year.

The agreement also included a provision whereby a material adverse change to the Company's financial condition may be considered an event of default. Based on current operations, committed borrowings and the Company's $9.3 million cash balance as of December 31, 2005, the Company believes that it will remain in compliance with its debt covenants over the next 12 months and that it is not probable that GE Capital will exercise the material adverse change clause as an event of default. The covenants in the equipment financing agreement incorporate the restrictive covenants and certain other requirements of the Comerica revolving credit agreement described in Note 8, including any subsequent waivers or amendments granted by Comerica. As of December 31, 2005, the debt balance outstanding on the equipment financing line was $700,000 all of which is classified as current.

In June 2004, the Company entered into a master lease agreement with GE Capital for capital equipment financings of diagnostic services (laboratory) related equipment. During 2004, the Company financed $2.6 million of capital equipment under this arrangement, which was recorded as a capital lease obligation. Each lease financing has a term of 36 months and provides for an early purchase option by the Company after 30 months at 26.6% of the cost of the equipment.

In January 2005, GE Capital approved additional equipment lease financings of up to $2.3 million under this master lease agreement for equipment leases during 2005, subject to execution of definitive documentation for each separate equipment lease and subject to GE Capital's review of the Company's financial condition at the time of each funding request. These additional equipment lease financings have a term of 36 months for each equipment purchase and provide for an early purchase option by the Company after 24 months for a purchase price equal to 40.5% of the cost of the equipment. During 2005, the Company financed $2.0 million of capital equipment under this line, which was recorded as a capital lease obligation.

The debt and capital lease obligations as of December 31, 2005 are as follows (in thousands):

Fiscal Year:	
2006	$ 2,153
2007	1,464
2008	536
2009	
	73
Total	4,226
Less: current portion	(2,153)
Debt and capital lease obligation, excluding current portion	$ 2,073

(8) Line of Credit

The Company currently has an $8.5 million revolving credit agreement, which expires on February 28, 2007 (the line of credit was increased from $5.5 million to $8.5 million in August 2005) and bears interest at the bank's prime rate minus one-half percent. The borrowings under the line of credit are being used for working capital purposes and to provide a $3.0 million stand-by letter of credit to the landlord of our new facility. The agreement also includes an annual facility fee of $27,500 and various restrictive covenants and requirements to maintain certain financial ratios. The Company paid Safeguard a commitment fee of $15,000 and issued to Safeguard a warrant to purchase 50,000 shares of common stock for an exercise price of $2.00 per share as additional consideration for Safeguard's $3.0 million increase in the guarantee in August 2005. The Company is also obligated to pay Safeguard an amount equal to 0.5% of the amount guaranteed and 4.5% per annum of the daily-weighted average principal balance outstanding under the line of credit. The revolving credit agreement has only one financial covenant related to tangible net worth, which is required to be not less than $0.

(9) Business Segments

The Company operates primarily in two business segments: 1) our services group delivers critical oncology testing services to community pathologists, biopharmaceutical companies and other researchers, and 2) our technology group is engaged in the development, manufacture and marketing of an automated cellular imaging system which is designed to assist physicians in making critical medical decisions. The segments are determined based on product and/or services delivered to customer groups. The Company's chief operating decision maker is the Chief Executive Officer and President. The chief operating decision maker allocates resources and assesses performance and other activities at the operating segment level.

Revenue and gross profit for our operating segments are as follows (in thousands):

	Year Ended December 31, 2005			Year Ended December 31, 2004			Year Ended December 31, 2003
	Services Group	Technology Group	Total	Services Group	Technology Group	Total	Technology Group
Total revenues	$ 11,439	$ 8,710	$ 20,149	$ 2,238	$ 7,531	$ 9,769	$ 11,928
Cost of revenue	8,789	2,419	11,208	3,813	3,627	7,440	3,597
Gross profit (loss)	$ 2,650	$ 6,291	8,941	$ (1,575)	$ 3,904	2,329	8,331
Selling, general and administrative (including diagnostic services administration)			19,726			17,209	11,384
Research & development			3,805			4,612	4,754
Loss from operations			(14,590)			(19,492)	(7,807)
Other expense			212			108	59
Net loss			$ (14,802)			$ (19,600)	$ (7,866)
Identifiable assets	$ 21,806	$ 3,443	$ 25,249	$ 14,292	$ 5,865	$ 20,157	$ 11,051

The following table represents business segment information by geographic area (in thousands):

	Year Ended December 31,		
	2005	2004	2003
Net Sales:			
United States	$ 19,789	$ 8,820	$ 11,883
International (a)	360	949	45
Total net sales	$ 20,149	$ 9,769	$ 11,928
Operating income (loss):			
United States	$ (14,377)	$ (19,854)	$ (7,286)
International (a)	(213)	362	(521)
Loss from operations	$ (14,590)	$ (19,492)	$ (7,807)

(a) International operations represent business activities conducted primarily in Canada, Germany, Great Britain and France.

(10) Subsequent Events

In February 2006, GE Capital provided a conditional acceptance to finance additional equipment up to $3.0 million during 2006 under the master lease agreement, subject to execution of definitive documentation for each separate equipment lease and GE Capital's review of the Company's financial condition at the time of each funding request. These additional equipment lease financings have a term of 36 months for each equipment purchase and provide for an early purchase option after 24 months for a purchase price equal to 43.1% of the cost of the equipment.

On March 1, 2006, the Company entered into a Master Purchase Agreement with Med One Capital, Inc. (Med One) pursuant to which Med One has agreed to purchase ACIS® cost per test units that the Company currently leases to customers for a gross amount of $2.3 million (the leased equipment would have produced approximately $1 million of customer lease revenue during 2006). Med One also has the option to purchase additional units worth up to $1 million. Under the agreement, 10 percent of the purchase price

will be held in escrow and may be recoverable by Med One to the extent that any units returned to Med One prior to the expiration of the applicable equipment lease are not successfully remarketed.

On March 1, 2006, the balance outstanding on the 2003 equipment financing line with General Electric Capital Corporation was paid in its entirety.

Supplemental Financial Information:

Quarterly Results of Operations (unaudited)
(in thousands except for per share information)

Quarter Ended:	Total Revenue	Gross Profit	Net Loss Attributable to Common Stock	Net Loss Per Share
December 31, 2005.....	$ 6,027	$ 2,873	$ (3,700)	$ (0.06)
September 30, 2005.....	4,906	2,013	(4,297)	(0.08)
June 30, 2005	5,209	2,522	(2,931)	(0.06)
March 31, 2005	4,007	1,533	(3,874)	(0.08)
December 31, 2004.....	$ 2,883	$ (333)	$ (5,765)	$ (0.11)
September 30, 2004.....	2,564	397	(5,352)	(0.10)
June 30, 2004	2,391	1,260	(5,137)	(0.10)
March 31, 2004	1,931	1,005	(3,346)	(0.08)

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

None

Item 9A. Controls and Procedures

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in the Company's reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), the Company carried out an evaluation under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective to provide reasonable assurance that the Company would meet its disclosure obligations.

During 2005, the Company's services group business became an increasingly significant component of the Company's operations. As a result, in the ordinary course, the Company has reviewed and continues to review its system of internal control over financial reporting for the laboratory operations, and the Company has implemented changes based on its ongoing review that are designed to improve and increase the efficiency of the Company's internal controls while maintaining an effective control environment. For example, during the fourth quarter of 2005, the Company continued evaluating the automation of various processes relating to our laboratory services to replace certain processes that are currently conducted manually. Except for the foregoing, there has been no change in the Company's internal control over financial reporting during the most recent fiscal quarter that has materially affected, or is reasonably likely to affect, the Company's internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors and Executive Officers of the Registrant

Directors

We incorporate by reference the information contained under the caption "ELECTION OF DIRECTORS" in our definitive Proxy Statement for our 2006 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Form 10-K pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended.

Executive Officers

The information with respect to executive officers required by this Item is set forth in Part I, Item 4A of this report.

Compliance with Section 16(a) of the Exchange Act

We incorporate by reference the information contained under the caption "SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE" in our definitive Proxy Statement for our 2006 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Form 10-K pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended.

Code of Ethics

We incorporate by reference the information contained under the caption "CODE OF ETHICS" in our definitive Proxy Statement for our 2006 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Form 10-K pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended.

Item 11. Executive Compensation

We incorporate by reference the information contained under the caption "EXECUTIVE COMPENSATION & OTHER ARRANGEMENTS" in our definitive Proxy Statement for our 2006 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Form 10-K pursuant to Regulation 14A under the Securities Exchange Act of l934, as amended.

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

We incorporate by reference the information contained under the caption "SECURITY OWNERSHIP OF DIRECTORS AND OFFICERS AND BENEFICIAL OWNERS OF MORE THAN 5%" in our definitive Proxy Statement for our 2006 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Form 10-K pursuant to Regulation 14A under the Securities Exchange Act of l934, as amended.

The following table shows aggregated information as of December 31, 2005 with respect to all of our compensation plans, agreements and arrangements under which our equity securities were authorized for issuance. More detailed information with respect to our compensation plans is included in Note 3 of Notes to Consolidated Financial Statements.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a)) (c)
Equity compensation plans approved by security holders:	6,874,919	$ 2.29	2,164,854
Equity compensation not approved by security holders(1):	1,700,000	1.39	—
Total:	8,574,919	$ 2.11	2,164,854

(1) Represents inducement stock option grants to certain officers that were made upon commencement of employment by such officers with the Company that were outstanding as of December 31, 2005.

Item 13. Certain Relationships and Related Transactions

We incorporate by reference the information contained under the caption "RELATIONSHIPS AND RELATED TRANSACTIONS WITH MANAGEMENT AND OTHERS" in our definitive Proxy Statement for our 2006 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Form 10-K pursuant to Regulation 14A under the Securities Exchange Act of l934, as amended.

Item 14. Principal Accountant Fees and Services

We incorporate by reference the information contained under the caption "INDEPENDENT PUBLIC ACCOUNTANT – AUDIT AND NON-AUDIT FEES" in our definitive Proxy Statement for our 2006 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Form 10-K pursuant to Regulation 14A under the Securities Exchange Act of l934, as amended.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Financial Statements and Schedules

The following financial statements and schedules listed below are included in this Form 10-K.

Financial Statements (See Item 8)
Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets as of December 31, 2005 and 2004
Consolidated Statements of Operations for the Years Ended December 31, 2005, 2004 and 2003
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2005, 2004, and 2003
Consolidated Statements of Cash Flows for the Years Ended December 31, 2005, 2004, and 2003
Notes to Consolidated Financial Statements

Financial Statement Schedules

Schedule II-Valuation and Qualifying Accounts

(b) Exhibits

The following is a list of exhibits filed as part of this Form 10-K. Where so indicated by footnotes, exhibits which were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated in parentheses.

EXHIBIT INDEX

Exhibit Number	Description
3.1	Certificate of Incorporation of the Company (as amended) (a)
3.2	Certificate of Designations of Series C Preferred Stock (b)
3.3	Certificate of Designations of the Powers and Preferences and Relative, Participating, Optional and Other Special Rights of Preferred Stock and Qualifications, Limitations and Restrictions Thereof of Series D 5% Cumulative Convertible Preferred Stock (d)
3.4	By-laws of the Company, as amended (a)
3.5	Amendment to Certificate of Incorporation (n)
3.6	Amended and Restated Rights Agreement between the Company and Mellon Investor Services LLC (q)
3.7	Certificate of Ownership and Merger dated March 15, 2005 (r)
10.1	Master Security Agreement dated July 15, 2003 between the Company and GE Capital Corp. (h)
10.2	Amendment to Master Security Agreement dated July 31, 2003 between the Company and GE Capital Corp. (h)
10.3	Assignment Agreement with Recourse and Promissory Note dated September 26, 2003 between the Company and GE Capital Corp. (h)
10.4	Loan agreement dated February 13, 2003 between the Company and Comerica Bank-California, Inc. (g)
10.5	First Amendment to Loan and Security Agreement dated October 21, 2003 between the Company and Comerica Bank (h)
10.6	Second Amendment dated January 22, 2004 to Loan and Security Agreement between the Company and Comerica Bank (q)
10.7	Third Amendment dated January 31, 2005 to Loan and Security Agreement between the Company and Comerica Bank (p)
10.8	Fourth Amendment dated March 11, 2005 to Loan and Security Agreement between the Company and Comerica Bank (q)
10.9	Amended and Restated Unconditional Guaranty dated March 11, 2005 to Comerica provided by Safeguard Delaware, Inc. and Safeguard Scientifics, Inc. (Delaware) (q)
10.10	Waiver and Fifth Amendment to Loan Agreement dated August 1, 2005 by and between Comerica Bank and Clarient, Inc. (t)
10.11	Sixth Amendment dated February 28, 2006 to Loan and Security Agreement between the Company and Comerica Bank (*)
10.12	Second Amended and Restated Unconditional Guaranty dated August 1, 2005, to Comerica Bank provided by Safeguard Delaware, Inc. and Safeguard Scientifics (Delaware), Inc. (t)
10.13	Reimbursement and Indemnity Agreement dated March 11, 2005 between the Company and Safeguard Delaware, Inc. and Safeguard Scientifics, Inc. (Delaware) (q)
10.14	Reimbursement and Indemnity Agreement dated August 1, 2005, by Clarient, Inc. in favor of Safeguard Delaware, Inc. and Safeguard Scientifics (Delaware), Inc. (t)
10.15	Securities Purchase Agreement between the Company, Safeguard Delaware, Inc. and Safeguard Scientifics, Inc. dated June 13, 2002 (e)
10.16	Registration Rights Agreement between the Company and Safeguard Delaware, Inc. dated June 13, 2002 (e)
10.17	Warrant to Purchase Shares of Common Stock dated June 2002 (e)
10.18	Form of Amended and Restated Stock Purchase Warrant dated June 13, 2002 (e)
10.19	Securities Purchase Agreement dated February 26, 2003 between the Company and Safeguard Delaware, Inc. (f)
10.20	Registration Rights Agreement between the Company and Safeguard Delaware, Inc. dated February 21, 2003 (f)
10.21	Securities Purchase Agreement dated February 10, 2004 between the Company and Safeguard Delaware, Inc. (i)
10.22	Registration Rights Agreement between the Company and Safeguard Delaware, Inc. dated February 10, 2004 (i)
10.23	Amended and Restated Common Stock Purchase Warrant issued to Safeguard Delaware, Inc. on March 25, 2004 (l)
10.24	Securities Purchase Agreement dated March 25, 2004 among the Company and the purchasers' signatories thereto (k)
10.25	Registration Rights Agreement dated March 25, 2004 among the Company and the investors' signatories thereto (k)
10.26	Form of Warrant issued March 31, 2004 by the Company. (k)
10.27	Warrant to Purchase 50,000 Shares of Common Stock dated August 1, 2005 issued to Safeguard Scientifics (Delaware), Inc. (t)
10.28	Securities Purchase Agreement dated November 8, 2005, by and among the Company and the investors named therein. (w)
10.29	Registration Rights Agreement dated November 8, 2005, by and among the Company and the investors named therein. (w)
10.30	Form of Common Stock Purchase Warrant issued pursuant to Securities Purchase Agreement dated November 8, 2005 (w)
10.31	1996 Equity Compensation Plan as amended (n) +
10.32	Employment Agreement dated as of January 10, 2001 between the Company and Jose de la Torre-Bueno (c)+
10.33	Employment Agreement dated as of March 19, 2003 between the Company and Karen K. Garza (q)+
10.34	Employment Agreement dated as of December 5, 2003 between the Company and Heather Creran (j)+
10.35	Employment Agreement dated as of June 18, 2004 between the Company and Ronald A. Andrews (m)+
10.36	Employment Agreement dated as of August 2, 2004 between the Company and Dr. Kenneth J. Bloom (n)+
10.37	Employment Letter dated as of February 28, 2005 between the Company and David J. Daly (q)+

10.38	Separation Agreement dated August 23, 2005 between the Company and Kenneth D. Bauer, Ph.D. (v)
10.39	Capital financing lease between the Company and General Electric Capital Corporation dated June 23, 2004 (m)
10.40	Form of Option Award Certificate (o)
10.41	Form of Stock Option Grant Certificate to be used in connection with 2006 option grants to certain management level employees (y)
10.42	Consulting Agreement dated as of April 8, 2005 between the Company and Dr. Richard J. Cote (s)
10.43	Distribution and Development Agreement dated July 18, 2005 between the Company and Dako A/S (x)
10.44	Facility Lease between the Company and 31 Columbia, Inc. dated July 20, 2005 (u)
10.45	Assignment Agreement and Bill of Sale between the Company and Med One Capital, inc. dated March 1, 2006 (*)
21	Subsidiaries of the Registrant (*)
23	Consent of KPMG LLP (*)
31.1	Certifications pursuant to Exchange Act Rule 13a-14(a) or Rule 15d-14(a) for Ronald A. Andrews. (*)
31.2	Certifications pursuant to Exchange Act Rule 13a-14(a) or Rule 15d-14(a) for John A. Roberts (*)
32.1	Certifications Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for Ronald A. Andrews. (*)
32.2	Certifications Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for John A. Roberts (*)

(*) Filed herewith.

(a) Filed on April 30, 1997 as an exhibit to the Company's Registration Statement on Form S-1 (No. 333-26129) and incorporated by reference.

(b) Filed on March 12, 1999 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(c) Filed on April 2, 2001 as an exhibit to the Company's Annual Report on Form 10-K and incorporated by reference.

(d) Filed on July 12, 2001 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(e) Filed on June 17, 2002 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(f) Filed on February 28, 2003 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(g) Filed on March 31, 2003 as an exhibit to the Company's Annual Report on Form 10-K and incorporated by reference.

(h) Filed on November 14, 2003 as an exhibit to the Company's Quarterly Report on Form 10-Q and incorporated by reference.

(i) Filed on February 12, 2004 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(j) Filed on March 9, 2004 as an exhibit to the Company's Annual Report on Form 10-K and incorporated by reference.

(k) Filed on April 1, 2004 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(l) Filed on May 10, 2004 as an exhibit to the Company's Quarterly Report on Form 10-Q and incorporated by reference.

(m) Filed on August 9, 2004 as an exhibit to the Company's Quarterly Report on Form 10-Q and incorporated by reference.

(n) Filed on November 9, 2004 as an exhibit to the Company's Quarterly Report on Form 10-Q and incorporated by reference.

(o) Filed on December 1, 2004 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(p) Filed on February 3, 2005 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(q) Filed on March 15, 2005 as an exhibit to the Company's Annual Report of Form 10-K and incorporated by reference.

(r) Filed on March 17, 2005 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(s) Filed on April 15, 2005 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(t) Filed on August 4, 2005 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(u) Filed on August 8, 2005 as an exhibit to the Company's Quarterly Report on Form 10-Q and incorporated by reference.

(v) Filed on August 29, 2005 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(w) Filed on November 9, 2005 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

(x) Filed on January 31, 2006 as an exhibit to the Company's Quarterly Report on Form 10-Q/A and incorporated by reference.

(y) Filed on February 27, 2006 as an exhibit to the Company's Current Report on Form 8-K and incorporated by reference.

+ Management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned; thereunto duly authorized, in San Juan Capistrano, California on March 13, 2006.

CLARIENT, INC.

By: /s/ Ronald A. Andrews
Ronald A. Andrews
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities indicated on March 13, 2006.

Signatures	Title(s)
/s/ Michael F. Cola Michael F. Cola	Chairman of the Board of Directors
/s/ Ronald A. Andrews Ronald A. Andrews	Chief Executive Officer and President (Principal Executive Officer)
/s/ John A. Roberts John A. Roberts	Acting Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ Peter J. Boni Peter J. Boni	Director
/s/ James A. Datin James Datin	Director
/s/ Steven J. Feder Steven J. Feder	Director
/s/ Steve Hamm Steve Hamm	Director
/s/ Irwin Scher, M.D. Irwin Scher, M.D.	Director
/s/ Frank P. Slattery, Jr. Frank P. Slattery, Jr.	Director
/s/ Jon R. Wampler Jon R. Wampler	Director

CLARIENT, INC. AND SUBSIDIARIES

SCHEDULE II-VALUATION AND QUALIFYING ACCOUNTS

	Allowance for Doubtful Receivables and Sales Returns	Reserve for Excess and Obsolete Inventory
Balance at December 31, 2002	$ 218,014	$ 325,973
Charges to operations	617,179	(80,000)
Deductions	(583,848)	(37,922)
Balance at December 31, 2003	251,345	208,051
Charges to operations	221,376	191,236
Deductions	(197,721)	—
Balance at December 31, 2004	275,000	399,287
Charges to operations	1,217,000	—
Deductions	(545,000)	(66,369)
Balance at December 31, 2005	$ 947,000	$ 332,918

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