IGEN INTERNATIONAL INC /DE
Form 10-K/A
July 17, 2002

SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K/A

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES ACT OF 1934

For Fiscal Year Ended March 31, 2002

Commission File Number 0-23252

IGEN INTERNATIONAL, INC.
(Exact name of Company as specified in its charter)

DELAWARE 94-2852543 (State or other jurisdiction of (IRS Employer Identification No.)
incorporation or organization)

16020 INDUSTRIAL DRIVE, GAITHERSBURG, MD 20877
(Address of principal executive offices) (Zip Code)

301/869-9800
(Company'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 $0.001 par value
(Title of Class)

Indicate by check mark whether the Company (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 Company was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes __X___ 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 Company'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. ___X_____

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Company as of June 17, 2002, computed by reference to the closing sale price of such stock quoted on the Nasdaq National Market, was approximately $628,877,000.

The number of shares outstanding of the Company's Common Stock as of June 17, 2002 was 23,215,738.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K. Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Company's definitive Proxy Statement relating to its Annual Meeting of Shareholders to be held on

August 28, 2002.

IGEN International, Inc., hereby amends Part I, Item 1 (Business) and Part IV, Item 14(c)(Exhibits) of its Annual Report on Form 10-K for the year ended March 31, 2002 to include corrected information and Exhibit 23.2 (Consent of Deloitte & Touche LLP).

PART I

IN ADDITION TO HISTORICAL INFORMATION, THIS FORM 10-K CONTAINS FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF THE "SAFE HARBOR" PROVISION OF THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995. REFERENCE IS MADE IN PARTICULAR TO STATEMENTS REGARDING THE MARKETS AND POTENTIAL MARKETS, AND MARKET GROWTH, FOR DIAGNOSTIC PRODUCTS, POTENTIAL IMPACT OF COMPETITIVE PRODUCTS, THE COMPANY'S EXPECTATIONS REGARDING THE LEVEL OF ANTICIPATED ROYALTY AND REVENUE GROWTH IN THE FUTURE, THE POTENTIAL MARKET FOR PRODUCTS IN DEVELOPMENT, FINANCING PLANS, THE OUTCOME OF LITIGATION, THE DESCRIPTION OF THE COMPANY'S PLANS AND OBJECTIVES FOR FUTURE OPERATIONS, ASSUMPTIONS UNDERLYING SUCH PLANS AND OBJECTIVES, THE NEED FOR AND AVAILABILITY OF ADDITIONAL CAPITAL AND OTHER FORWARD-LOOKING STATEMENTS INCLUDED IN ITEM 7 - "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS" ("MD&A"). THE WORDS "MAY," "SHOULD," "WILL," "EXPECT," "COULD," "ANTICIPATE," "BELIEVE," "ESTIMATE," "PLAN," "INTEND" AND SIMILAR EXPRESSIONS HAVE BEEN USED IN THIS DOCUMENT TO IDENTIFY FORWARD-LOOKING STATEMENTS. WE HAVE BASED THESE FORWARD-LOOKING STATEMENTS ON OUR CURRENT VIEWS WITH RESPECT TO FUTURE EVENTS AND FINANCIAL PERFORMANCE. SUCH STATEMENTS ARE BASED ON MANAGEMENT'S CURRENT EXPECTATIONS AND ARE SUBJECT TO A NUMBER OF RISKS AND UNCERTAINTIES WHICH COULD CAUSE ACTUAL RESULTS TO DIFFER MATERIALLY FROM THOSE DESCRIBED IN THE FORWARD-LOOKING STATEMENTS. IN PARTICULAR, CAREFUL CONSIDERATION SHOULD BE GIVEN TO CAUTIONARY STATEMENTS MADE IN ITEM 7 - "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS" AND IN ITEM 1 - "BUSINESS" UNDER THE HEADING "RISK FACTORS." IGEN DISCLAIMS ANY INTENT OR OBLIGATION TO UPDATE THESE FORWARD-LOOKING STATEMENTS.

ITEM 1. BUSINESS

SUMMARY

We develop and market products that incorporate our proprietary electrochemiluminescence (ORIGEN (R)) technology, which permits the detection and measurement of biological substances. We believe that ORIGEN offers significant advantages over competing detection methods by providing a unique combination of speed, sensitivity, flexibility and throughput in a single technology platform. ORIGEN is incorporated into instrument systems and related consumable reagents, and we also offer assay development and other services used to perform analytical testing. Products based on our ORIGEN technology currently address the following worldwide markets:

- LIFE SCIENCE - drug discovery and development, performed by pharmaceutical and biotechnology companies, universities and other research organizations;
- CLINICAL TESTING - in vitro diagnostic testing of patient samples to measure the presence of disease and monitor medical conditions. This testing is performed at facilities, such as central hospital and clinical reference laboratories, and at other locations, including sites closer to where patient care is delivered. These sites include clinics, emergency rooms, intensive care units and physician offices; and
- INDUSTRIAL TESTING - the testing of food and environmental samples for safety and quality assurance purposes, products for fighting bioterrorism,

as well as agricultural and animal health testing.

We and our corporate collaborators have commercialized multiple product lines to serve these markets. We estimate that approximately over 8,000 ORIGEN-based systems have been sold or placed with customers. These sales and placements have been made predominantly through our license arrangement with Roche Diagnostics GmbH ("Roche"), the world's leading provider of clinical diagnostic products. Roche has adopted ORIGEN as the integral technology for its Elecsys immunodiagnostic product line. Roche has a license to commercialize the ORIGEN technology solely for central hospital and clinical reference laboratories and blood banks. For a discussion of the Roche litigation, see ITEM 3, "Legal Proceedings".

The M-SERIES(TM) System, our product line for use by pharmaceutical and biotechnology companies in drug discovery and development, may be used in all phases of drug discovery, including (1) validating targets identified through genomics, (2) screening of large numbers of compounds generated through combinatorial chemistry, (3) re-testing and optimization of lead compounds, and (4) clinical trial testing of drug candidates. We believe the M-SERIES System provides a number of advantages relative to other drug discovery technologies, including enhanced sensitivity and greater ease and speed of assay formatting. These features are designed to enable our customers to test new biological targets against potential drug compounds with higher levels of accuracy and specificity and may perform highly sensitive tests more quickly and with less cost. This should permit a drug candidate to move more rapidly into the later stages of drug development and ultimately into the market.

The M-SERIES System is the first product that features our electrochemiluminescence module, which we have trademarked as TRICORDER(R). The TRICORDER, which resulted from our extensive research and development efforts, is a self-contained, analytical operating system. By combining all of the features necessary to perform ORIGEN-based testing in a single compact module, the TRICORDER provides a relatively simple-to-use, highly accurate and cost-effective system. The TRICORDER's modular nature is expected to reduce the development time and cost required to incorporate ORIGEN technology into future diagnostic and analytical instruments. We believe that the TRICORDER, through its flexibility as a detection tool and its modular nature, will be the core component for additional products that we plan to develop.

Our M-SERIES customers include many of the major pharmaceutical and biotechnology companies in the United States and Europe. We offer our customers the option of buying M-SERIES Systems or renting them under reagent purchase plans. Under either option, our customers typically make commitments for purchases of proprietary reagents. We also provide custom assay development services based on our existing library of more than 300 assays. We market the M-SERIES System through our sales, marketing and applications team dedicated to the life science market.

We have also applied our ORIGEN technology to the rapidly growing market for the detection of food and water disease causing pathogens, as well as for bio-defense, the detection of microbes, toxins and toxic agents that may pose a military or public health threat. We have begun commercializing our first products for this market, the PATHIGEN panel of tests for Salmonella, Campylobacter, Listeria and E. Coli O157, which are sold primarily as a quality control test method to food producers, food processors and contract laboratories

for the food industry. The E. Coli test, for example, is significantly more sensitive than any other test on the market and we believe it offers unprecedented precision and rapid results in detecting this dangerous strain of the food-borne pathogen. In addition, our Salmonella test was recently approved by the National Poultry Improvement Plan as the first rapid method for the detection of Salmonella in live poultry.

Our executive offices are located at 16020 Industrial Drive, Gaithersburg, Maryland 20877.

ORIGEN TECHNOLOGY

ORIGEN is a proprietary technology based on electrochemiluminescence. ORIGEN permits the detection and measurement of a biological substance within a given sample. It works by labeling the targeted substance within a sample using a compound and binding the newly labeled substance to magnetizable beads. The beads can then be separated from the rest of the sample using a magnet. When this newly labeled substance is stimulated, the label emits light at a particular wavelength. The light emission can be measured with a high degree of accuracy. The level of intensity of the light emitted depends on how much of the label is present, which in turn is determined by how much of the targeted substance is present for the label to attach itself to. Thus, the light emissions permit the accurate detection and measurement of the targeted substance. ORIGEN technology provides a single basic format that can be used to conduct a multitude of tests, including immunodiagnostic tests, nucleic acid probe tests and clinical chemistry tests. The ORIGEN technology is protected by numerous patents in the United States and internationally.

We and our licensees are using the ORIGEN technology to develop and commercialize analytical systems that offer many advantages over current detection technologies. We believe that ORIGEN technology offers a unique combination of improved speed, sensitivity, flexibility and output relative to existing technologies. ORIGEN technology also generally lowers the cost of diagnostic procedures by reducing the number of steps required in preparing a sample for testing. Because the ORIGEN system directly measures electrochemiluminescence, and does not require the use of enzymes in the detection process as is common in competing systems, the ORIGEN system provides a simplified and more stable format that can be used to test a broad range of substances. The ORIGEN-based systems can be automated to provide in a uniform format a large number of immunoassay, nucleic acid probe and clinical chemistry tests. The essential component of an ORIGEN-based system is the flow cell, which contains a magnet to separate the labeled substance from the sample being tested, and a light detector to measure the electrochemiluminescence. The ORIGEN flow cell has been designed so that it can be incorporated into a variety of instruments, ranging from large central laboratory random-access systems to small batch systems.

The major features and benefits of proprietary ORIGEN-based systems are:

- Simple Testing Format: reduces time and labor in performing a test or series of tests. Complete automation of testing process possible.

- Flexibility: enables a single instrument to perform immunodiagnostic tests on large and small molecules and to perform DNA and RNA tests.

- Cost: reduces costs per test by minimizing the amount of expensive reagents needed.
- Speed: reduced time from assay set-up to detection produces rapid results. Enables high sample throughput.
- Sensitivity: allows detection of targeted specimens at very low concentrations.
- Precision: provides highly-reproducible measurements.
- Label Stability: extends the shelf-life of the reagent that contains the label used in testing. Improves measurement accuracy.

ORIGEN-BASED PRODUCTS AND MARKETS

We believe that our ORIGEN technology is well suited for the development and commercialization of families of instruments that can be used in all of our target markets. The technology should permit virtually all immunodiagnostic and nucleic acid tests to be performed on similar instrumentation using the same detection method.

The following table summarizes ORIGEN-based products and development programs.

MARKET	PRODUCT	CUSTOMER APPLICATION	STATUS
LIFE SCIENCE MARKET	M-SERIES (M8 & M384 Analyzer and Reagents)	Drug Discovery/ Development	Product Sale
	M-SERIES (M-1 Research Analyzer)	Drug Discovery/ Development	Pre-Launch
	ORIGEN Detection System and Reagents	Drug Discovery/ Development	Product Sale
	C Cell Culture Reagents	Research Biologicals	Product Sale
	NucliSens/NASBA QR	Nucleic Acid Probe Tests	Product Sale
	Sector HTS/ Sector PR	High Throughput Drug Discovery/ Development	Pre-Launch/ Beta
CLINICAL TESTING MARKET			
Central Hospital/Clinical Reference Laboratory Systems	Elecsys 2010	Immunodiagnostic Tests	Product Sale
	Elecsys 1010	Immunodiagnostic Tests	Product Sale

	MODULAR / E170	Immunodiagnostic Tests	Product Sale
	NucliSens/NASBA QR	Nucleic Acid Probe Tests	Product Sale
	Picolumi	Immunodiagnostic Tests (Japan)	Product Sale
Patient Care Systems	Elecsys 2010/1010	Physicians' Office Lab Immunodiagnostic Tests	Product Sale
	M-SERIES (M-1 Clinical Analyzer)	Portable Physicians' Office Lab / Hospital Immunodiagnostic Tests	Development
	Home Self-Testing	Health Screening and Monitoring	Research
INDUSTRIAL MARKETS	PATHIGEN Panel of Tests (ORIGEN Detection System)	Detection of Food and Beverage Contaminants	Product Sale
	M-SERIES (M-1 Analyzer)	Detection of Food and Beverage Contaminants and Biological Toxins	Pre-Launch

(1) IGEN is currently servicing customers pursuant to court judgment issued in the litigation described in ITEM 3 - "Legal Proceedings".

LIFE SCIENCE PRODUCTS AND MARKET

The life science market focuses on providing products and services for the discovery and development of new drugs. Our commercialization efforts in this market center on the M-SERIES System and the ORIGEN Detection System.

Advances in the field of combinatorial chemistry, which is based on the effects of combining different compounds to make potentially new drugs, and in the field of biotechnology have revolutionized drug discovery. Pharmaceutical and biotechnology companies have dramatically expanded their libraries of potential drug candidates. Researchers have completed sequencing of the human genome, which has greatly increased scientists' understanding of how diseases work and the causes of disease, which in turn should provide novel targets for fighting disease.

In order to exploit these advances, pharmaceutical and biotechnology companies are re-engineering their drug development processes. An example of this is the use of automation and the latest advances in technology to accelerate the screening of existing drug compounds against the disease targets of interest. Researchers are challenged to develop new drug screening procedures that are faster and more efficient while reducing costs and processing larger numbers of samples.

After identifying disease targets and synthesizing chemical compounds, researchers attempt to find compounds that are drug candidates. This drug discovery process involves developing the test, or assay, to determine whether a particular compound has the desired effect on a target and then screening compounds using that assay. Compounds of interest from the screening process become drug candidates, which undergo further testing as part of "lead optimization". These drug candidates are then subjected to pre-clinical and

clinical trials before becoming a drug.

M-SERIES SYSTEM. We believe that the need of pharmaceutical and biotechnology companies to rapidly identify therapeutic targets; screen thousands of compounds per day against those targets and then optimize the leads, has created new opportunities for our ORIGEN technology systems in the pharmaceutical and biotechnology industry. The M-SERIES Systems, based on the TRICORDER, build on the applications of the ORIGEN Detection System and provide simultaneous processing of multiple samples using ORIGEN assays. The first M-SERIES System is the M8 Analyzer, which is compatible with multi-well microplates that are commonly used in drug discovery and development laboratories.

The M8 Analyzer has been updated and is named the M-SERIES 384 Analyzer. It is in the process of being introduced to the market with new features. Both systems can be fully integrated with many existing automation and robotic systems and are designed to enable researchers to test new biological targets against potential drug compounds with higher levels of accuracy and specificity. They may also perform highly sensitive tests more quickly and with less cost. This may permit a drug candidate to move more rapidly into the later stages of drug development, clinical trials and ultimately into the market.

We believe that the sensitivity and accuracy of the M-SERIES System create advantages over many competitive detection technologies. The M-SERIES System allows the user (1) to quickly adapt the ORIGEN technology to develop and then perform the specific, desired assays, compared to the longer periods required by other existing competing technologies, (2) to reduce the use of rare components, such as proprietary compounds, antibodies or clinical trial samples, that must be used to run assays and (3) to be more confident in the positive and negative results the tests produce. Our expertise in developing assays allows us to assist customers in determining whether a proposed assay is feasible and to assist with the development and performance of assays that comply fully with the U.S. Food and Drug Administration's (FDA) Good Manufacturing Practices (GMP).

Our M-SERIES customers include many of the major pharmaceutical and biotechnology companies in the United States and Europe. In addition to the M-SERIES Analyzers we sell or place, we typically receive commitments from our customers for purchases of proprietary reagents. We also offer M-SERIES Analyzer users custom assay development services based on our existing library of more than 300 assays. We market the M-SERIES Analyzer directly through our sales, marketing and applications team dedicated to the life science market.

The second product in the M-SERIES family is the M-1, which is in final pre-launch development. The M-1 is being designed as a smaller and lower cost M-SERIES system for use in drug discovery and development, as well as for basic biology research such as the study of general biological processes, proteomics and the understanding of the molecular basis of disease. In addition to pharmaceutical and biotechnology researchers, the M-1 may be used by scientists at academic and government research institutions. Academic customers typically work from small research grants and a lower priced single detector system that works with the standard microplate format is expected to be an alternative to the use of radioisotopic assays or less sensitive ELISA based methods. ORIGEN technology, with its mix and read assay format and high sensitivity should allow researchers to perform multiple experiments more quickly.

ORIGEN DETECTION SYSTEM. Our strategic links with pharmaceutical and biotechnology companies and with customers in government and academic research centers were initially forged with the launch of the ORIGEN Detection System. The ORIGEN Detection System is the precursor to the M-SERIES System and established ORIGEN as a powerful detection technology for applications in life

science research. Some of these customers are performing research in areas that are key to our strategic growth. The ORIGEN Detection System has been important for our developments with the U.S. military and the application of ORIGEN technology to bio-defense.

CLINICAL DIAGNOSTIC PRODUCTS AND MARKET

One of the markets that we have and will continue to target by developing and marketing products and services based on our ORIGEN technology is the clinical diagnostic market. The clinical diagnostic market utilizes in vitro diagnostic testing, which is the process of analyzing blood, urine and other samples to screen for, monitor and diagnose diseases and other medical conditions or to determine the chemical and microbiological constituents of the samples.

This market is composed of various areas of clinical diagnostic testing, including testing by central hospital laboratories and clinical reference laboratories, as well as testing at satellite hospital laboratories and at or near patient care centers.

HOSPITAL/REFERENCE LABORATORY SYSTEMS. One of the significant applications of our ORIGEN technology is in large, highly automated clinical immunodiagnostic systems used in central hospital laboratories, clinical reference laboratories and blood banks. These laboratories constitute the vast majority of the clinical diagnostic market today. To serve these laboratories, systems must be able to perform a wide variety of immunodiagnostic tests on a large number of samples reliably, cost-effectively and quickly. We and our licensees believe that systems based on the ORIGEN technology are well-suited to serve this market and may surpass other systems currently available in central hospital laboratories, clinical reference laboratories and blood banks in terms of speed, cost effectiveness and ease of use.

Roche, one of the companies that licenses our technology, presently sells three ORIGEN-based immunoassay systems for the central hospital and clinical reference laboratory markets: the Elecsys 1010, Elecsys 2010 and the Modular E170. The Elecsys 2010 is designed to perform multiple screenings in a random-access mode, while simultaneously handling tests performed on clinical samples for which immediate results are needed, without interfering with the system workflow. The Elecsys 2010 is designed so that it can be integrated with Roche's clinical chemistry systems. The Elecsys 1010 is a system designed for central hospital and clinical reference laboratory customers that have a lower output requirement. Roche has also developed a third instrument system, the MODULAR/E170, which incorporates ORIGEN technology. The E170 is part of Roche's new MODULAR system that allows laboratories to create customized workstations and has the features of the existing Elecsys line together with expanded throughput capabilities.

Roche presently offers a panel of approximately 50 screening tests or assays, with the Elecsys and E170 systems, including assays for infectious diseases, anemia, cancer, heart attacks, thyroid disease and fertility/pregnancy. Roche continues to develop additional assays that are expected to be introduced to the market in the future. We continue to work with Roche to develop assays, for which Roche reimburses us a portion of our development costs.

See ITEM 3 - "Legal Proceedings" for a description of our litigation with Roche.

PATIENT CARE SYSTEMS. We are independently developing ORIGEN-based products that can be used to perform immunodiagnostic tests and chemistry tests outside of central hospital laboratories and clinical reference laboratories. This market

includes patient care centers such as physicians' offices, ambulatory clinics, hospital emergency rooms, surgical and intensive care units, hospital satellite laboratories, and nurses' stations. Physicians, patients and third-party payers have created a demand for bringing laboratory testing closer to the patient in order to provide the medical practitioner with faster results and, in turn, prompt feed-back to the patient. Most immunodiagnostic systems for individual physicians and group practices have had limited market penetration because of the lengthy turnaround time for test results, the need for skilled labor in performing the tests and the high cost of tests. We believe that the emergence of simple and more accurate and cost-effective diagnostic products is shifting the site of in vitro diagnostic testing from clinical reference and central hospital laboratories to alternative sites.

We believe that significant demand exists for clinical diagnostic products that reduce turnaround time and cost. Our patient care system is being designed to create tests that can provide accurate results to a physician rapidly, thereby permitting the physician to make a more timely decision regarding the patient's course of treatment.

The ORIGEN technology permits development of a system that is compact and simple to operate at a low cost per test and the initial clinical ORIGEN-based system being developed by the Company is utilizing the TRICORDER product platform currently used in the life science market. The broad menu of immunoassays that we, and companies working with us, developed for the first generation of ORIGEN-based products can be performed on, and are expected to be available for use with, TRICORDER-based systems. We are currently exploring collaborative business arrangements to accelerate the commercialization of TRICORDER-based products for multiple point-of-care applications.

We presently distribute clinical assays to approximately 60 physicians' office laboratories in the United States that utilize Roche's Elecsys systems. Under the final order of judgment issued in our litigation with Roche, the Court enjoined Roche from marketing, selling, or distributing its Elecsys products outside of Roche's licensed field of use, including to physicians' office laboratories (POL's). We and Roche signed an agreement under which all of Roche's POL customers in the United States were transferred to us, and Roche provides us with reagent supply for these customers pending final resolution of the litigation.

INDUSTRIAL PRODUCTS

We are seeking to develop further, either independently or with others, ORIGEN-based products for use in food and water quality assurance programs and agricultural and animal health testing. We believe that our ORIGEN-based technology and the reagents employed to run tests, together with an easy to use, low-cost, instrument platform, such as the M-1 System under development, should be well-suited for these market applications.

We have recently commenced sales of our PATHIGEN panel of food pathogen tests. This panel includes tests for E. Coli O157, Salmonella, Listeria and Campylobacter. These tests are used as a quality control method for testing food and beverage products, such as the meat used in hamburger, for the bacteria that have caused numerous outbreaks of gastrointestinal and kidney-related disease worldwide. The PATHIGEN tests are semi-automated and create a permanent record of test results. According to published studies by the USDA and an independent analytical laboratory in the United Kingdom, the PATHIGEN E. Coli O157 test is significantly more sensitive than conventional tests commonly used to screen

food. Major food and beverage producers, as well as contract testing laboratories, could become primary users of the PATHIGEN test panel. The major advantage of the PATHIGEN tests are their ability to perform in complex samples, like hamburger meat, in less time, and with greater sensitivity than other available methods. Our PATHIGEN tests offers food producers the ability to efficiently test many more food samples than with other currently available methods.

We have also expanded our ORIGEN-based product offering to address bio-defense, or the detection of microbes, toxins, and toxic agents that might pose a military or public health threat. ORIGEN-based tests developed by researchers in the U.S. Army are being used as a bio-defense detection method. We believe there will be an increasing opportunity for use of our ORIGEN technology as a bio-defense tool in military organizations around the world, as well as in public health. We plan to further develop ORIGEN-based products for this emerging market.

COLLABORATIONS

We have entered into collaborations with established diagnostic and pharmaceutical companies. These collaborations have provided us with $84 million in license fees over an eight-year period and product development and marketing resources. In addition, we receive ongoing royalties from collaborators' product sales.

For the three fiscal years ended March 31, 2002, 2001 and 2000 revenue from corporate collaborators, which is represented as product-based royalty income and contract revenue, totaled $27.5 million (65%), $20.4 million (65%) and $12.9 million (63%), respectively.

ROCHE DIAGNOSTICS GMBH. In 1992, we entered into a contract with Roche Diagnostics GmbH (then known as Boehringer Mannheim GmbH), the largest worldwide manufacturer of diagnostic equipment and supplies, to commercialize ORIGEN-based clinical immunodiagnostic and nucleic acid probe systems. From fiscal year 1992 through fiscal year 2002, we generated a total of approximately $118 million in license fees, royalties and assay development fees from Roche. Roche currently markets three ORIGEN-based systems together with a test menu of approximately 50 different assays, including tests for infectious diseases, anemia, cancer, heart attacks, thyroid disease and fertility/pregnancy. Roche has placed or sold approximately 8,000 Elecsys and E170 systems worldwide.

In 1997, we filed a lawsuit in Maryland federal court against Roche Diagnostics and in February 2002, the Court issued a final order of judgment against Roche. See ITEM 3 - "Legal Proceedings".

We recorded royalty income from the Roche agreement of $25.7 million (61%), $15.3 million (49%) and $11.1 million (54%) for the three fiscal years ended March 31, 2002, 2001 and 2000 respectively.

BIOMERIEUX. We have an agreement with BioMerieux (formerly Organon Teknika B.V.) for development and worldwide commercialization of ORIGEN-based nucleic acid probe systems to the clinical diagnostic and life science markets. BioMerieux specializes in hospital and blood bank products and has combined its proprietary nucleic acid sequence based amplification technology with ORIGEN technology and markets the NucliSens line of diagnostic virology products together with test kits for the detection of HIV-1 RNA and CMV (cytomegalovirus). We have received $20 million under our agreement with BioMerieux and currently receive royalties on product sales.

EISAI CO., LTD. We have a collaboration with Eisai Co., Ltd., a leading Japanese pharmaceutical company, to market an ORIGEN-based diagnostic system for the clinical diagnostic market in Japan. Eisai introduced its first ORIGEN-based product under the trade name Picolumi during 1997, and we receive royalties on product sales. Eisai is currently marketing the Picolumi product with assays focused primarily in the area of cancer diagnosis.

MESO SCALE DIAGNOSTICS, LLC. During August 2001, we entered into agreements with Meso Scale Technologies, LLC. ("MST") continuing Meso Scale Diagnostics, LLC. ("MSD"), a joint venture formed solely by MST and us in 1995. MSD was formed for the development and commercialization of products utilizing a proprietary combination of MST's multi-array technology together with ORIGEN and other technologies owned by us. MST is a company established and wholly-owned by the son of IGEN's Chief Executive Officer. Under most circumstances, significant MSD governance matters require the approval of both us and MST.

Under the amended agreements that were negotiated by an independent committee of our Board of Directors, we hold a 31% voting equity interest in MSD, and are entitled to a preferred return on $36.4 million of the funds previously invested in MSD through March 31, 2002 and on additional funds we invest thereafter. This preferred return would be payable out of a portion of both future profits and certain third-party financings, before any payments are made to other equity holders. MST owns the remaining 69% of the voting equity interest in MSD. We agreed, subject to certain conditions, to fund the joint venture through November 2003. During the 2002 calendar year, we agreed to fund MSD $21.5 million, subject to a permitted variance of fifteen percent. As of March 31, 2002, the Company has satisfied $5.3 million of this funding commitment. The 2003 calendar year funding commitment would be based on an annual budget to be approved by a committee of our Board of Directors.

The funding commitment may be satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. If the 2003 budget is not approved by our Board of Directors, we would be required to provide transitional funding for an additional six months, estimated at $11.0 million, and under certain conditions, MSD and MST have the right to terminate the joint venture prior to November 2003 under certain circumstances, including a change in control of the Company, as defined. Upon termination, expiration or non-renewal of the joint venture agreement, MSD and MST have the right to purchase our interest in MSD at fair market value less certain discounts.

MSD has developed two instrument systems, the Sector PR and the Sector HTS, along with a variety of consumables which were initially introduced to the life science market in September 2001. The first MSD beta test site was established in March 2002.

For the years ended March 31, 2002, 2001 and 2000, we made total contributions to MSD of $19.6 million, $8.3 million and $4.5 million, respectively. See ITEM 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations", and ITEM 13 "Certain Relationships and Related Transactions."

PATENTS AND OTHER PROPRIETARY RIGHTS

We pursue a policy of seeking patent protection to preserve our proprietary technology and our right to capitalize on the results of our research and development activities and, to the extent it may be necessary or advisable, to exclude others from appropriating our proprietary technology. We also rely on

trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

We prosecute and defend our intellectual property, including our patents, trade secrets and know-how. We regularly search for third-party patents in our fields of endeavor, both to shape our own patent strategy as effectively as possible and to identify licensing opportunities.

As of March 31, 2002, we owned 63 issued U.S. patents and had 23 pending U.S. patent applications in the diagnostics field. As of that date, we owned 130 additional issued patents outside of the United States and had 68 pending patent applications. These patents and patent applications are important to our business and cover various aspects of our ORIGEN technology and products, as well as the methods for their production and use. The pending patent applications may not be granted and others may challenge our existing patents. Our business could be harmed if we lose the patent protection we currently enjoy or if our pending patents are not issued.

Our patents will not begin to expire until 2005; core ORIGEN patents will extend through 2015. We continue to protect our technology with new patent filings, which could further extend our patent coverage.

GOVERNMENT REGULATION

Our research and development, manufacturing and marketing activities of both existing and future products are subject to regulation by numerous governmental authorities in the United States and other countries. In the United States, clinical diagnostic devices are subject to rigorous FDA regulation. The Federal Food, Drug and Cosmetic Act and the Public Health Service Act govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our clinical products.

In addition to FDA regulations, we are subject to other federal and state regulations such as occupational safety and health regulations and environmental regulations. Product development and approval within this regulatory framework may take a number of years and involves the expenditure of substantial resources.

In addition, this regulatory framework may change or additional regulation may arise at any stage of our product development, which may affect approval of or delay an application or require additional expenditures by us.

Our regulatory strategy is to pursue development and marketing approval of products worldwide, either independently or through corporate collaborators. We intend to seek input from the regulatory authorities at each stage of the clinical process to facilitate appropriate and timely clinical development. The clinical development of certain products may be the responsibility of our collaborators.

Clinical Diagnostic Systems

The manufacture, distribution and sale in the United States of our products for clinical diagnostic purposes will require prior authorization by the FDA. The FDA and similar agencies in foreign countries have promulgated substantial regulations that apply to the testing, marketing, export and manufacturing of diagnostic products. To obtain FDA approval of a new product for diagnostic purposes, we or our collaborators will in most cases be required to submit proof of the safety and efficacy of the product, or its "substantial equivalence" to

previously marketed products. Such proof typically entails clinical and laboratory tests. The testing, preparation of necessary applications and processing of those applications by the FDA is expensive and time consuming.

Significant difficulties or costs may be encountered in order to obtain FDA approvals and that could delay or preclude us from marketing products for diagnostic purposes. Furthermore the FDA may request additional data following the original submission. Delays imposed by the governmental approval process may materially reduce the period during which we or our collaborators will have the exclusive right to exploit our products or technologies.

Our clinical diagnostic products are regulated as medical devices. The Roche Elecsys clinical diagnostic products have received FDA approval. Prior to entering commercial distribution, all medical devices must undergo FDA review under one of two basic review procedures depending on the type of assay: a Section 510(k) pre-market notification ("510(k)") or a pre-market approval application ("PMA"). 510(k) notification is generally a relatively simple filing submitted to demonstrate that the device in question is "substantially equivalent" to another legally marketed device. Approval under this procedure may be granted within 90 days if the product qualifies, but generally takes longer, and may require clinical testing.

When the product does not qualify for approval under the 510(k) procedure, the manufacturer must file a PMA to show that the product is safe and efficacious, based on extensive clinical testing among several diverse testing sites and population groups, and shows acceptable sensitivity and specificity. This procedure requires much more extensive pre-filing testing than does the 510(k) procedure and involves a significantly longer FDA review after the date of filing. In responding to a PMA, the FDA may grant marketing approval, may request additional information, may set restrictive limits on claims for use or may deny the application altogether.

After product approvals have been received, they may still be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. The FDA may require surveillance programs to monitor the effect of products that have been commercialized, and has the power to prevent or limit further marketing of the products based on the results of these post-marketing programs.

In addition to obtaining FDA approval for each product, under the PMA guidelines, the Company must seek FDA approval of the manufacturing facilities and procedures. The FDA will also inspect diagnostic companies on a routine basis for regulatory compliance with its GMP.

Our products for the physician's office market will be affected by the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), which is intended to insure the quality and reliability of medical testing and may have the effect of discouraging, or increasing the cost of, testing in physicians' offices.

The regulations establish requirements for laboratories in the area of administration, participation in proficiency testing, patient test management, quality control, personnel, quality assurance and inspection. Under these regulations, the specific requirements that a laboratory must meet depend upon the complexity of the tests performed by the laboratory.

Laboratory tests are categorized as either waived tests, tests of moderate complexity or tests of high complexity. Laboratories that perform either moderate or high complexity tests must meet standards in all areas, with the

major difference in requirements between moderate and high complexity testing concerning quality control and personnel standards. Quality control standards for moderate complexity testing are being implemented in stages. Personnel standards for high complexity testing are more rigorous then those for moderate complexity testing. In general, personnel conducting high complexity testing will need more education and experience than those doing moderate complexity testing. Under the CLIA regulations, all laboratories performing moderately complex or highly complex tests will be required to obtain either a registration certificate or certificate of accreditation from the Healthcare Financing Administration ("HCFA").

Because the regulations' interpretation is uncertain, it is possible that certain of our products may be categorized as tests of high complexity, in which case penetration of the point-of-care market would be reduced since not all laboratories would meet the standards required to conduct such tests. We understand that laboratories, including physician office laboratories, will be evaluating the requirements of CLIA in determining whether to perform certain types of moderate and high complexity diagnostic tests.

Although we believe that we will be able to comply with all applicable regulations regarding the manufacture and sale of diagnostic devices, such regulations are always subject to change and depend heavily on administrative interpretations. Future changes in regulations or interpretations made by the U.S. Department of Health and Human Services, FDA, HCFA or other regulatory bodies, with possible retroactive effect, may adversely affect us.

In addition to the foregoing, we are subject to numerous federal, state and local laws and regulations relating to such matters as safe working conditions, laboratory and manufacturing practices, environmental, fire hazard control, and disposal of hazardous or potentially hazardous substances. To date, compliance with these laws and regulations has not had a material effect on our financial results, capital requirements or competitive position, and we have no plans for material capital expenditures relating to such matters. However, we may be required to incur significant costs to comply with such laws and regulations in the future, and such laws or regulations may have a material adverse effect upon our ability to do business.

Sales of the Company's products outside the United States are also subject to extensive regulatory requirements, which vary widely from country to country. The time required to obtain such approval may be longer or shorter than that required for FDA approval.

Research Products

Our products that are being sold for research use only, including the M-SERIES System, must be properly labeled as such, as required by the FDA, but do not generally require FDA approval prior to marketing. The FDA has begun to impose new distribution requirements and procedures on companies selling research-only products, such as the requirement that the seller receive specified certifications from its customers as to the customers' intended use of the product. We expect that the FDA will develop additional restrictions of this nature that may adversely affect us.

Environmental Regulation

Due to the nature of our current and proposed research, development and manufacturing processes, we are subject to stringent federal, state and local laws, rules, regulations and policies governing the use, generation,

manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials and wastes. Although we believe that we have complied with these laws and regulations in all material respects and have not been required to take any action to correct any noncompliance,we may be required to incur significant costs to comply with environmental and health and safety regulations in the future.

Reimbursement

Third-party payers, such as governmental programs and private insurance plans, can indirectly affect the pricing or the relative attractiveness of our products by regulating the maximum amount of reimbursement they will provide for diagnostic testing services. In recent years, healthcare costs have risen substantially, and third-party payers have come under increasing pressure to reduce such costs.

In this regard, the Federal government, in an effort to reduce healthcare costs, may take actions that may involve reductions in reimbursement rates. If the reimbursement amounts for diagnostic testing services are decreased in the future, it may decrease the amount which physicians, clinical laboratories and hospitals are able to charge patients for such services and consequently the price we and our collaborators can charge for our products.

COMPETITION

Competition varies in the three markets in which we operate. In the life science market, competition is fragmented. To be competitive, a company must be able to address the needs of pharmaceutical and biotechnology companies, which are facing pressure to increase productivity while decreasing drug discovery costs and timelines. These drug discovery companies favor detection systems that combine automation and enhanced sensitivity with integrated equipment and consumables.

Because our ORIGEN system encompasses all of these elements, we believe it offers significant advantages over competing systems. In addition, we, unlike some of our competitors, offer our customers assay development services, which we believe enhance the speed and robustness of their screening operations.

The clinical testing market is dominated by a few large multi-national companies, including Abbott Laboratories, Roche, Bayer and Johnson & Johnson. We participate in this market through our license arrangements with Roche, the world's largest provider of diagnostics products, BioMerieux and Eisai.

The industrial testing market is highly fragmented. While existing testing methods are relatively inexpensive, these technologies are time consuming and produce non-specific test results that are often unreliable.

As in the life science market, we are developing a portfolio of tests that would offer enhanced speed, reliability and specificity in detecting pathogens and other microbial contaminants in food, water and other industrial samples being tested. We believe this will allow us to position ORIGEN competitively as the detection method of choice for the industrial testing market.

Our competition will be determined in part by the potential applications for which our products are developed and ultimately approved by regulatory authorities. For certain of our future products, an important factor in competition may be the timing of market introduction of our own or competing

products. Accordingly, the relative speed with which we or our corporate collaborators can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market are expected to be important competitive factors.

We expect that competition with products approved for sale will be based, among other things, on product efficacy, safety, reliability, availability, price and patent protection.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and may be better equipped to develop, manufacture and market products. These companies may develop and introduce products and processes competitive with or superior to ours.

Our competitive position also depends upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often substantial period between technological conception and commercial sales.

We do not hold a leading competitive position in the three principal markets in which we compete.

MANUFACTURING

Our current commercial manufacturing operations consist of the manufacture of the M-SERIES System and related reagents, PATHIGEN products and cell culture research biologicals. We operate a qualified GMP and ISO 9001 facility. We use a variety of suppliers and believe that we do not depend on any supplier that cannot be replaced in the ordinary course of business.

Any changes in source of supply may require additional engineering or technical development, with costs and delays that could be significant, in order to ensure consistent and acceptable performance of the products.

We have not yet introduced clinical diagnostic products that are manufactured by us. Initial clinical diagnostic products, based on our ORIGEN technology, are being manufactured by corporate collaborators. We are presently evaluating plans for future manufacturing of clinical diagnostic products that include direct or third party manufacturing.

SALES AND MARKETING

We market the M-SERIES System and the ORIGEN Detection System, together with related reagents and services, directly to the life science research market. In conjunction with the U.S. and European launch of the M-SERIES System, we have expanded our direct sales force, including the addition of application specialists and in-house technical service personnel. We also utilize distributors in Japan and Scandanavia. The ORIGEN cell culture products are sold directly and through distributors. Substantial sales and marketing of products based on our ORIGEN technology is conducted by corporate collaborators. See "Collaborations."

HUMAN RESOURCES

As of May 31, 2002, IGEN employed 370 individuals full-time, of whom 277 were engaged in research, product development, manufacturing and operations support, 55 in marketing, sales and applications support and 38 in general administration. Of our employees, 64 have Ph.D. degrees. A significant number of

our management and professional employees have had prior experience with pharmaceutical, biotechnology, diagnostic or medical products, computer software or electronics companies. None of our employees are covered by collective bargaining agreements, and management considers relations with its employees to be good.

The ability to maintain our competitive position will depend, in part, upon our continued ability to attract and retain qualified scientific, technical and managerial personnel. Competition for such personnel is intense.

GEOGRAPHIC SEGMENTS

Information on domestic and foreign product sales is incorporated herein by reference to ITEM 8 - Consolidated Financial Statements - Notes to Consolidated Financial Statements - Note 11.

EXECUTIVE OFFICERS OF THE COMPANY

The names and ages of all executive officers at May 31, 2002 and their respective positions and offices with us are set forth below. Each officer serves without a set term.

NAME	AGE	POSITION
Samuel J. Wohlstadter	60	Chairman, Chief Executive Officer and Director
Richard J. Massey, Ph.D.	55	President, Chief Operating Officer and Director
George V. Migausky	47	Vice President, Chief Financial Officer and Secretary

SAMUEL J. WOHLSTADTER is a founder of IGEN and has been our Chairman of the Board and Chief Executive Officer since 1982. Mr. Wohlstadter has been a venture capitalist for more than 25 years and has experience in founding, supporting and managing high technology companies, including Amgen Inc., a biotechnology company, and Applied Biosystems, Inc., a medical and biological research products company. Mr. Wohlstadter is also Chief Executive Officer of Hyperion Catalysis International, an advanced materials company, which he founded in 1981; of Pro-Neuron, Inc., a drug discovery company, which he founded in 1985; of Proteinix Corporation, a development stage company organized to conduct research in intracellular metabolic processes, which he founded in 1988; and of Pro-Virus, Inc., a drug discovery company, which commenced operations in 1984.

RICHARD J. MASSEY, Ph.D. is one of our founders and has been President and Chief Operating Officer since February 1992 and a director since 1990. He served as Senior Vice President from 1985 to 1992. From 1981 until he joined us in 1983, Dr. Massey was a faculty member in the Microbiology and Immunology Department at Rush Medical Center in Chicago. Prior to that, he was Senior Research Scientist at the Fredrick Cancer Center/National Cancer Institute.

GEORGE V. MIGAUSKY has been our Chief Financial Officer since 1985, assuming that position on a full-time basis in 1992. Between 1985 and 1992, in addition to serving as our Chief Financial Officer on a part-time basis, Mr. Migausky also served as financial advisor to several other privately held companies. Prior to joining us in 1985, he spent nine years in financial management and public accounting positions, most recently as a Manager with the High Technology Group of Deloitte & Touche.

OTHER KEY MANAGEMENT

In addition to our executive officers and directors, we have the following managers directing key functions:

NAME	AGE	POSITION
Daniel Abdun-Nabi.....	47	General Counsel
Gerald Andros.....	40	Director of Sales
David Boudreau.....	45	Director of Operations
R. Don Elsey.....	48	Director of Finance and Administration
Stephen Kondor.....	47	General Manager - Clinical Diagnostics
Robert Proulx.....	45	General Manager - Life Science Business

DANIEL ABDUN-NABI joined us in September 1999 as General Counsel. He is responsible for all areas of corporate law, including advising us about our domestic and international legal matters, and he provides guidance in developing legal and business strategies and negotiating financial transactions. From 1990 to September 1999, Mr. Abdun-Nabi was Senior Vice President - Legal Affairs & General Counsel for North American Vaccine, Inc., where he oversaw domestic and international legal issues for that pharmaceutical company and its operating subsidiaries. Prior to that, Mr. Abdun-Nabi spent several years in private practice in Washington, D.C. and served for three years as an attorney with the Division of Corporation Finance at the SEC.

GERALD ANDROS has been our Director of Sales for Life Science since 1994. He is responsible for sales of ORIGEN products both in the United States and internationally. Prior to joining us, Mr. Andros spent six years working in sales management, marketing and sales training for Abbott Laboratories, where he focused on sales of immunoassay, chemistry and hematology product lines.

DAVID BOUDREAU joined us in August 1999 as Director of Operations. He is responsible for manufacturing, logistics and inventory management. From 1995 to August 1999, Mr. Boudreau served as Director of Manufacturing Operations at i-Stat, a medical diagnostics company, where he handled operational planning and supply chain management for the United States and Canada. Prior to that he held the position of Manufacturing Manager at Analog Devices Inc. and worked as a process engineer at Chevron USA.

R. DON ELSEY joined us in May 2000 as Director of Finance and Administration. He is responsible for the accounting, treasury, risk management, and human resources functions for us. From April 1998 to February 2000, Mr. Elsey served as Director of Finance at PE Biosystems. From 1980 to April 1998, Mr. Elsey held a variety of financial management positions with International Business Machines, Inc.

STEPHEN KONDOR joined us in September 2001 as General Manager, Clinical Diagnostics. He has 22 years experience in the medical device, clinical diagnostic, and life science markets, including 14 years for Abbott Labs Diagnostic Products Division where during his tenure, he held various sales, marketing, and business general management positions most recently as Worldwide Commercial Director for the Hematology Business Unit. Mr. Kondor was Senior Vice President at Avocet Medical from January 2000 until joining us in September 2001, where he was responsible for marketing products to the point of care clinical diagnostic community. From 1996 to 2000, he was Executive Vice President World Wide Marketing & Sales at Biometric Imaging, Inc.

ROBERT PROULX joined us in March 2000 as General Manager of the Life Sciences Business. Mr. Proulx has primary responsibility for managing sales, marketing and product development efforts for our life science research business. From 1989 to February 2000 Mr. Proulx held various positions at Packard Instrument Company, Inc., which specializes in instrumentation and reagents for the life science research market. Immediately prior to leaving Packard, Mr. Proulx served as Vice President, Marketing.

RISK FACTORS

IF THE COMPANIES THAT LICENSE TECHNOLOGY FROM US DO NOT EFFECTIVELY DEVELOP AND MARKET PRODUCTS BASED ON THAT TECHNOLOGY, OUR REVENUE WOULD BE ADVERSELY AFFECTED.

The success of our business depends, in large part, on how effectively the companies to which we have licensed our technology develop and market that technology. If these companies do not effectively develop and market products based on this technology, our revenues would decrease.

We have licensed our technology to BioMerieux, Eisai Co., Ltd., and Roche Diagnostics GmbH for selected markets and uses. Our license agreements with each of these companies allow each company to develop products using our technology and to manufacture and sell those products in selected markets. In return for the right to use our technology, each of these companies must pay royalties to us based on revenues they receive from sales of products based on our technology. These royalties are a significant part of our overall revenue.

For example, they accounted for 64% of our revenue in fiscal year 2002. We have brought a lawsuit against Roche, one of our licensees, in part because we believe Roche has not properly calculated and paid royalties to us. See the risk factor immediately below for a more detailed description of this litigation and the risks it poses to us. Similar or other problems may arise with other companies to whom we license our technology.

WE ARE SUING THE LARGEST LICENSEE OF OUR TECHNOLOGY, AND THE OUTCOME OF THAT LITIGATION COULD MATERIALLY ADVERSELY AFFECT OUR REVENUES AND FINANCIAL CONDITION.

We have an ongoing lawsuit against Roche, which is the largest licensee of our technology in terms of royalty income accounting for over 90% of our royalty income in fiscal 2002. The lawsuit centers on a number of claims we assert against Roche in which we allege that they failed to comply with the terms of our license agreement with them. Roche filed a counterclaim against us in the lawsuit alleging, among other things, that we breached the Roche license agreement by permitting Eisai Co. Ltd., another of our licensees, to market some ORIGEN-based products in Japan.

The United States District Court issued a final order of judgment in our case against Roche that awarded us $105 million in compensatory damages and $400 million in punitive damages, confirmed our right to terminate the Roche license agreement, directed and commanded Roche to grant to us for use in our retained fields a license to all improvements developed by Roche under the agreement, including Roche's Elecsys(R) diagnostics product line, and barred Roche from marketing, selling, placing or distributing outside of its licensed field any products, including its Elecsys diagnostics product line, that are based on our ORIGEN(R) technology. We have voluntarily agreed not to terminate the license agreement until an appellate court determines that we are entitled to do so; however, we have already notified Roche that the license agreement will terminate automatically once the judgment is affirmed by the Court of Appeals.

The final judgment issued in this case also found in our favor and against Roche on all of Roche's counterclaims, except for one in which we were ordered to pay $500,000. Roche has filed a notice of appeal. During the appeal process, Roche is obligated to continue to comply with the terms of the license agreement.

The risks involved in the litigation include:

- The appellate court may modify or overturn some or all of the judgment favorable to us including the finding that Roche materially breached the license agreement, the scope and extent of the improvements awarded to us, the amount of compensatory and punitive damages, or the favorable findings relating to Roche's counterclaims against us.

- The appellate court could overturn some or all of the judgment and order a new trial on those issues. For example, if the court orders a new trial on whether or not Roche miscalculated and underpaid royalties, breached its duty of good faith and fair dealing, or engaged in unfair competition against us, the amount of damages awarded in a new trial could be lower than the amount already awarded to us.

- If the court orders a new trial on any of the issues, we might need to continue expending significant amounts of money and management time in pursuing our claims against Roche. This time and money will then be unavailable for use in the development of our business.

- If the appellate court upholds the judgment that Roche materially breached the license agreement, and the license agreement is terminated, our royalty revenues would suffer unless and until we were able to introduce new products and generate revenues on our own or find one or more comparable replacements for Roche.

- We may not be able to find a suitable replacement for Roche or successfully introduce new products on our own following termination of the license. Our ability to successfully commercialize new products, including products based on the improvements awarded to us in this litigation, is subject to numerous risks and uncertainties including risks relating to:

    - the need for governmental approvals;

    - our ability to compete effectively;

    - our ability to effectively manufacture and market new products;

    - our ability to attract and retain employees;

    - our need for additional financing;

    - our dependence on suppliers; and

    - the other risks applicable to our business as more completely described herein and in other filings with the SEC.

While an appeal is pending, Roche may divert its attention from selling the licensed products that generate royalties to us and focus its energies instead to find alternative products to develop and market.

While an appeal is pending, Roche may continue to market and sell other Roche products that compete with its ORIGEN-based products, thereby lowering the royalty revenues that we would have otherwise received if Roche had sold more ORIGEN-based products instead of its other competing products.

We also sued Hitachi Ltd. which manufactures diagnostic equipment based on ORIGEN technology for Roche. On June 13, 2002, we and Hitachi reached agreement that settled this lawsuit. In the past, Roche has attempted to sue us for interfering with its contract with Hitachi because we filed this lawsuit. That claim was twice dismissed by the court. Roche may, following this settlement agreement, try to bring this claim against us again.

FAILURE TO MEET OUR DEBT OBLIGATIONS COULD ADVERSELY AFFECT OUR RESULTS OF OPERATIONS AND FINANCIAL CONDITION; IN ADDITION, OUR DEBT SERVICE OBLIGATIONS COULD IMPAIR OUR OPERATING FLEXIBILITY.

We have a total debt balance at March 31, 2002 of $53.2 million. There is a possibility that we may be unable to generate cash or arrange financing sufficient to pay the principal of, interest on and other amounts due in respect of our indebtedness when due, or in the event any of our indebtedness is accelerated.

Termination of the license agreement with Roche would cause approximately $23.1 million of our debt payment obligations as of March 31, 2002, under our 8.5% senior secured notes to accelerate. The note purchase agreement for the 8.5% senior secured notes also contains covenants that limit our ability to take specified actions, including incurring additional secured debt and amending our license agreement with Roche, which could affect our ability to resolve issues that are being litigated through an amendment to the existing license agreement with Roche. These restrictions may limit our operating flexibility, as well as our ability to raise additional capital.

In addition, our substantial leverage may require that we dedicate a substantial portion of our expected cash flow from operations to service our indebtedness, which would reduce the amount of our expected cash flow available for other purposes, including working capital and capital expenditures.

In January 2000, we sold $35 million in aggregate principal amount of 5% subordinated convertible debentures due 2005. Unless and until holders of the debentures convert their debentures into Common Stock, we are required to make semi-annual interest payments of $875,000 through 2005. If we are unable to meet our obligations under the subordinated convertible debentures, the debenture holders could require us to repay the principal amount of, and accrued interest on, the subordinated convertible debentures, and we may not have sufficient financial resources or be able to arrange sufficient financing to make those payments when required.

WE HAVE A HISTORY OF OPERATING LOSSES AND EXPECT TO INCUR FUTURE LOSSES.

We have experienced significant operating losses each year since our inception, and we expect those losses to continue. We also have an accumulated deficit. Our losses have resulted principally from costs incurred in research and development, litigation costs, selling costs and other general and administrative costs. We expect to incur additional operating losses as a result of increases in expenses for manufacturing, marketing and sales capabilities, litigation costs and expenses, research and product development, the transfer and commercialization of improvements from Roche, general and administrative costs and our share of losses in MSD.

We may not achieve profitability in the future. Our ability to become profitable in the future will depend on, among other things, our ability to:

- expand the commercialization of our existing products;
- upgrade and enhance the M SERIES product capabilities;
- introduce new products into the market, including products for the markets currently served by Roche following termination of Roche's license with us;
- develop our marketing capabilities cost-effectively;
- develop sales and distribution capabilities cost-effectively; and
- establish successful collaborations with corporate partners to develop and commercialize products that incorporate our technologies.

OUR QUARTERLY OPERATING RESULTS MAY FLUCTUATE SIGNIFICANTLY, AND THESE FLUCTUATIONS MAY CAUSE OUR STOCK PRICE TO FALL.

Our quarterly operating results depend upon:

- the volume and timing of orders for M-SERIES or other products;
- the timing of instrument deliveries and installations;
- the success of M-SERIES upgrades and enhancements;
- variations in revenue recognized from royalties and other contract revenues;
- our mix of products sold;
- whether our instruments are sold to or placed with customers;
- the timing of our introduction of new products;
- our competitors' introduction of new products;
- variations in expenses we incur in connection with the operation of our business, including costs associated with the transfer of improvements from Roche to us, research and development costs including costs associated with developing and commercializing new products for the markets currently served by Roche, and sales and marketing costs, including costs for upgrading the M-SERIES products;
- our share of losses in MSD;
- our manufacturing capabilities; and
- the volume and timing of product returns and warranty claims.

These factors may cause our quarterly operating results to fluctuate significantly, which in turn, may cause our stock price to fall. In addition,

because our revenues and operating results are volatile and difficult to predict, we believe that period-to-period comparisons of our results of operations are not a good indication of our future performance.

WE MAY NOT BE ABLE TO RAISE SUFFICIENT ADDITIONAL CAPITAL TO SUCCESSFULLY DEVELOP OUR BUSINESS.

We need substantial amounts of money to fund our operations. Our access to funds could be negatively impacted by many factors, including the results of pending litigation, the volatility of the price of Common Stock, continued losses from operations, acceleration of debt payment obligations resulting from termination of the license agreement with Roche and other factors.

We may need to raise substantial amounts of money to fund a variety of future activities integral to the development of our business, including the following:

- for research and development in order to successfully develop our technologies, including to develop new products for the clinical diagnostic markets that are currently being served by Roche;

- to obtain regulatory approval for some of our products;

- to file and prosecute patent applications in order to protect our technology;

- to respond to innovations that our competitors develop;

- to continue to aggressively pursue our ongoing litigation against Roche;

- to retain qualified employees, particularly in light of intense competition for qualified scientists and engineers;

- to make new arrangements to market our technology, including the markets currently being served by Roche following the termination of our license agreement with Roche;

- to continue to fund investments in MSD;

- to manufacture products ourselves or through a third party; and

- to market different products to different markets, either through building our own sales and distribution capabilities or relying on a third party.

We may not have access to enough funds to successfully develop our business. We may try to raise necessary additional capital by issuing additional debt or equity securities. Holders of debt securities would have priority over our equity holders with respect to the proceeds from the sale of our assets in the event of liquidation of our business, and any debt financings we obtain may contain restrictive terms that limit our operating flexibility. If, on the other hand, we raise additional capital by selling more common or preferred stock, the holdings of existing stockholders would be diluted.

If we are unable to raise additional capital, we may have to scale back, or even eliminate, some programs. Alternatively, we may have to consider pursuing arrangements with other companies, which may not be on terms favorable to us.

WE MAY NOT BE ABLE TO COMPETE EFFECTIVELY AGAINST MORE ESTABLISHED COMPANIES AND INSTITUTIONS, WHICH COULD ADVERSELY AFFECT OUR BUSINESS.

We are a relatively young company in a highly competitive industry. We compete against established companies and research and academic institutions, and we expect this competition to intensify. Many of these companies and institutions have one or more competitive advantages over us, including:

- more money to invest;

- greater expertise and resources in developing, manufacturing, marketing and selling products;

- a larger, more experienced workforce; and

- more experience in obtaining regulatory approval for clinical diagnostic products.

As a result, we may not be able to compete successfully against our current or future competitors. This could have a material adverse effect on our business, financial condition and revenue.

OUR PRODUCTS MAY BECOME OBSOLETE IF WE EXPERIENCE DIFFICULTIES OR DELAYS IN PRODUCT DEVELOPMENT.

The market for our products is characterized by rapidly changing technology, evolving industry standards, the need for updated and effective technology and new product introduction. Our future success will depend in part upon our ability to enhance existing products and to develop and introduce new or enhanced products. We may not be able to avoid the obsolescence of our products due to rapid technological change and evolving industry standards. The development of new or enhanced products is a complex and uncertain process requiring the accurate anticipation of technological and market trends as well as precise technological execution. We have and may continue to experience design, development, implementation and other difficulties that could delay or prevent our introduction of new or enhanced products or affect the performance of existing products. These difficulties and delays have caused, and may continue to cause, our expenses to increase and our product sales to fluctuate.

WE DEPEND ON HIGHLY TRAINED AND SKILLED EMPLOYEES AND MANAGEMENT, AND WE MAY NOT BE ABLE TO ATTRACT AND RETAIN SUFFICIENT PERSONNEL.

We need to hire additional staff and to retain existing staff, both of which are difficult in today's competitive marketplace. Because we are a technology company, we depend heavily on scientists and engineers to develop products and to build a successful business. Research and development efforts could suffer if we are not able to hire and retain enough qualified scientists and engineers. We compete with other technology companies and research and academic institutions for experienced scientists. Many of these companies and institutions have greater resources than we do and thus may be in a better position to attract desirable candidates.

In addition to scientists, we will also need to hire managers as the business grows. We will need managers who are able to address the need for regulatory, manufacturing and marketing capabilities. If we are not able to hire managers with these skills, or develop expertise in these areas, our business prospects could suffer.

WE DEPEND ON A LIMITED NUMBER OF SUPPLIERS FOR MATERIALS USED IN MANUFACTURING

OUR PRODUCTS, AND ANY INTERRUPTION IN THE SUPPLY OF THOSE MATERIALS COULD HAMPER OUR ABILITY TO MANUFACTURE PRODUCTS AND MEET CUSTOMER ORDERS.

We depend on vendors to supply key materials that we use in our products. Some of these materials are available only from limited sources. In the event of a reduction in, interruption of, or degradation in the quality of the supply of any of our required materials, or an increase in the cost of obtaining those materials, we would be forced to locate an alternative source of supply. If no alternative source were available or if an alternative source were not available on a timely basis or at a reasonable cost or otherwise on acceptable terms, our ability to manufacture one or more of our products would be delayed or halted. Any changes in sources of supply may require additional engineering or technical development in order to ensure consistent and acceptable performance of the products. If any of these events occur, product costs may increase, we might be unable to deliver products timely, we could lose sales as well as customers, and our business would be significantly harmed as a result.

WE MUST OBTAIN FDA APPROVAL TO MARKET OUR CLINICAL DIAGNOSTIC PRODUCTS, WHICH IS OFTEN COSTLY AND TIME CONSUMING, AND IF WE DO NOT OBTAIN THE NECESSARY APPROVAL OUR BUSINESS PROSPECTS WOULD SUFFER.

The FDA regulates many areas in which we conduct research and in which we develop, produce and market products. In particular, we must obtain FDA approval before we can market clinical diagnostic products such as those we are currently developing for the patient care market. The approval process is often costly and time consuming. We may not be successful in obtaining FDA approval for any of our clinical diagnostic products, which would materially adversely affect our future prospects.

In order to obtain FDA approval in the United States, we, or the companies with whom we work, will need to either obtain pre-market application approval or pre-market notification clearance from the FDA. In order to obtain pre-market notification clearance, we must submit data from clinical trials demonstrating that new clinical diagnostic systems are substantially equivalent to diagnostic systems that the FDA has already approved. If a product is subject to the substantial equivalence requirement, neither we, nor any of our licensees can sell that system for clinical use in the United States until the FDA determines that a new ORIGEN-based system is substantially equivalent to a previously approved system. Typically, the FDA review process takes 90 days, but the FDA's review could take longer. In addition, we may not be able to demonstrate substantial equivalence for future diagnostic systems.

If we do not successfully demonstrate substantial equivalence, or if we are required to obtain pre-market application approval as an initial matter, we will have to conduct extensive clinical testing of these products, which could take years to complete. Extensive testing could involve substantial additional costs and might delay bringing clinical diagnostic products to market, weakening our competitive position. If we fail to obtain FDA approval for new products altogether, we will be unable to market our ORIGEN-based systems at all for clinical use in the United States.

WE ARE SUBJECT TO EXTENSIVE, ONGOING GOVERNMENT REGULATION, WHICH MAY INVOLVE SIGNIFICANT COSTS AND MAY RESTRICT OUR ABILITY TO CONDUCT BUSINESS.

We expect that we may need to spend a substantial amount of money to comply on an ongoing basis with the regulations of the FDA and other government agencies. Government agencies, such as the FDA and the Environmental Protection Agency, regulate manufacturers of diagnostic products and the manufacturing process itself.

The costs of complying with governmental regulations and any restrictions that government agencies might impose could have a significant impact on our business. As we increase our manufacturing, these costs will increase.

Whether we manufacture products ourselves or contract with another company to manufacture products based on our technology, the FDA will continually review and periodically inspect the manufacturing process. If the FDA were to discover a problem with our products, the manufacturing process or the manufacturing facility, the FDA could place restrictions on these products and on the manufacturer. For example, the FDA could require us to recall, or even totally withdraw, a product from the market or close a manufacturing facility. In addition to FDA regulations, the process of manufacturing products is subject to a variety of environmental and safety laws and regulations, including laws and regulations governing the use and disposal of hazardous materials. If we fail to comply with these laws or regulations, our business and financial condition could be materially adversely affected.

WE HAVE LIMITED MANUFACTURING AND MARKETING EXPERIENCE, WHICH PUTS US AT A COMPETITIVE DISADVANTAGE.

We lack experience in large-scale manufacturing, which could hamper our ability to manufacture existing products or new products that we develop. We have two options to address this issue. First, we could expand our internal ability to manufacture products. Second, we could contract with a third party to manufacture for us products based on our technology. If, however, we are unable to expand our own manufacturing capability or find a suitable manufacturer on acceptable terms in a timely manner, we may be unable to meet demand for existing products and could be delayed in introducing new products to the market. Failure to meet demand for existing products or delays in introducing new products could put us at a competitive disadvantage and could harm our financial condition or our business prospects.

We will also need to develop greater selling, marketing and distribution capabilities. To market clinical diagnostic products directly to customers, and not through a licensee, we need to develop a substantial sales force with technical expertise. We also need to establish a distribution system to support the sales force. Alternatively, we could license or contract with another company to provide sales and distribution services for products, in much the same way as we have done with Roche, Eisai and BioMerieux. We may not be able to develop a sufficient sales and distribution force or find a suitable company to fill that role for us.

THE SUCCESS OF OUR BUSINESS DEPENDS ON PATENTS THAT WILL EXPIRE AND THAT MUST BE ACTIVELY PURSUED AND PROTECTED.

Our business depends heavily on patents that will expire over time and may be challenged or circumvented by competitors. Patents allow us to prevent others, for a time, from using our inventions to compete against us. Our business success or failure will depend, in part, on our ability to obtain and maintain adequate patent protection for the ORIGEN technology. Our current patents or future patents may not adequately protect our technology from being used by our competitors.

Because there is no consistent policy governing the scope of claims in medical patents, patent protection is uncertain. Companies may, for example, challenge and invalidate patents or circumvent valid claims in patents, all of which could make it necessary for us to defend our patents in litigation. Litigation over patents poses the following risks to our business:

- Litigation costs can be extremely high, which could drain our financial resources.

- Litigation over our patents could discourage other companies from working with us to develop and market new products based on technology covered by these disputed patents.

- If we lose some patent protection as a result of litigation, our competitive advantage could be eroded.

OUR BUSINESS WOULD BE HARMED IF WE VIOLATE THE PATENT RIGHTS OF OTHERS.

Our business success or failure will also depend, in part, on the patent rights of others. We license technology from other companies and academic institutions. Because access to this technology is necessary to our business, we must be certain that we comply with these license agreements. Our business could be harmed if we breached any of these license agreements and lost the rights to use this patented technology or if we were unable to renew existing licenses on acceptable terms or get additional licenses that we may need on acceptable terms.

We must also make sure that we do not infringe the patent rights of others. If we were to infringe others' patent rights we could be exposed to the following risks:

- We could be required to alter, or abandon, our products or processes.

- We could be required to obtain a license from the patent holder.

- We could lose customers that are reluctant to continue using our products or doing business with us.

- We could be forced to abandon development work that we had begun with respect to these products.

- We could be required to pay damages that could be substantial.

If we infringe others' patent rights, our business could be damaged if we were unable to make necessary alterations or obtain a necessary license on acceptable terms.

In addition, we may need to litigate the scope and validity of patents held by others and such litigation could be a substantial cost for us.

WE RELY ON TRADE SECRETS AND OTHER INFORMATION THAT CANNOT BE PROTECTED BY PATENTS, AND WE FACE RISKS THAT THIS INFORMATION WILL BE DISCLOSED TO OTHERS.

In addition to patents, we also rely in our business on trade secrets, know-how and other proprietary information. If this information were disclosed to competitors, our business would suffer. We seek to protect this information, in part, by entering into confidentiality agreements with licensees, employees and consultants, which prohibit these parties from disclosing our confidential information. These agreements may not provide adequate protection for our trade secrets, know-how and other proprietary information or ensure that the information we share with others during the course of our business will remain confidential. We may not have sufficient legal remedies under the agreements or otherwise to correct or compensate for unauthorized disclosures or sufficient

resources to seek redress.

RESTRICTIONS ON HEALTH CARE COSTS AND HEALTH CARE AND INSURANCE FINANCING PRACTICES COULD LIMIT DEMAND FOR OUR PRODUCTS.

In the United States and elsewhere, demand for clinical diagnostic testing is dependent, in part, on consumers' ability to be reimbursed for the cost of the tests by third-party payers, such as government agencies, health maintenance organizations and private insurers. Medicaid and other third-party payers are increasingly challenging the prices charged for medical services, including clinical diagnostic tests. They are also attempting to contain costs by limiting their coverage of, and the amount they will reimburse for, clinical diagnostic tests and other health care products.

Without adequate coverage and reimbursement, consumer demand for clinical diagnostic tests may decrease. Decreased demand would likely cause sales of our clinical diagnostic products, and sales by our licensees, to fall since fewer tests would be performed or prices would be lowered, or both. Reduced sales or royalty income would hurt our business and our business prospects.

In many foreign markets, governments directly set the prices that clinical diagnostic companies may charge for their products and services. In the United States, a number of legislative and regulatory proposals aimed at changing the health care system have been proposed in recent years. Foreign and domestic legislative and regulatory initiatives that limit health care coverage may have a materially adverse effect on our business and our business prospects.

WE ARE EXPOSED TO PRODUCT LIABILITY RISKS THAT, IF NOT ADEQUATELY COVERED BY INSURANCE, MAY HAVE A MATERIAL ADVERSE EFFECT ON OUR FINANCIAL CONDITION.

We may not be able to adequately insure against risk of product liability. As we begin marketing products, we may face product liability for claims and lawsuits brought by customers. Damages awarded in product liability cases can be very large. While we have product liability insurance, this coverage is limited. We may not have adequate product liability insurance to cover us against our potential liabilities or be able to maintain current levels of product liability insurance on acceptable terms, if at all. Claims or losses in excess of our current or future product liability insurance coverage could have a material adverse effect on our financial condition.

MEMBERS OF OUR MANAGEMENT TEAM EXERCISE SIGNIFICANT CONTROL OVER IGEN AND MAY BE ABLE TO CONTROL THE OUTCOME OF PROPOSED CORPORATE ACTIONS SUPPORTED OR OPPOSED BY OTHER IGEN STOCKHOLDERS.

Our officers and directors in aggregate, own or have the right to purchase, approximately 28% of Common Stock and our Chief Executive Officer owns approximately 21% of the Common Stock at January 17, 2002. As a result, certain of our officers and directors have significant influence over the election of directors and may be able to control the outcome of proposed corporate actions supported or opposed by other IGEN stockholders.

FAILURE TO MANAGE OUR GROWTH COULD ADVERSELY AFFECT OUR BUSINESS.

We have grown rapidly and expect to continue to grow by hiring new employees in all areas of our operations, increasing our presence in existing markets and

introducing new products we develop into new potential high-growth markets. Our growth has placed, and continues to place, a strain on our management and our operating and financial systems.

As we grow, our personnel, systems, manufacturing capabilities and resources, procedures and controls may be inadequate to support future operations. In order to accommodate the increased operations for sales and marketing, research and development, facilities and administration, we will need to hire, train and retain the appropriate personnel. We may also need to improve our financial and management controls, reporting systems and operating systems. We may encounter difficulties in developing and implementing other new systems.

In response to our growth, we have recently implemented a new enterprise resource planning system in order to automate all of our accounting, manufacturing, sales and purchasing. If the enterprise resource planning system fails to operate as we expect or experiences delays or interruptions, our operations, as well as our ability to manage our increased growth, could be materially adversely affected.

PROVISIONS OF OUR GOVERNING DOCUMENTS MAY DETER OTHERS FROM ATTEMPTING TO ACQUIRE US.

Our governing documents contain provisions designed to prevent hostile takeovers, which may limit the ability of stockholders to sell their stock at a premium in a takeover. According to our governing documents, stockholders can only act at annual meetings or at special meetings of stockholders. Stockholders are not allowed to act by written consent. In addition, stockholders are not allowed to call for a special meeting. Only our board of directors, the chairman of the board or the president may call a special meeting. These provisions may make it difficult for stockholders to force us to hold special meetings. These provisions may also limit the ability of stockholders to consider transactions that they may want to approve, such as a hostile takeover of us.

Our governing documents also contain other provisions that could make it more difficult for a change in control to be effected. Our board of directors can issue preferred stock and can determine the rights of those preferred stockholders without the approval of holders of Common Stock. For example, our board of directors could give preferred stockholders one or more votes on issues on which holders of Common Stock vote. This could have the effect of diluting the voting rights of holders of Common Stock, which might further discourage other companies from trying to acquire us.

In addition, our certificate of incorporation contains provisions dividing our board of directors into three classes. Each class serves until the third succeeding annual meeting, and one class is elected at each annual meeting of stockholders.

As a result, even if our stockholders might prefer to effect a change sooner, it could take at least two annual meetings of stockholders to change a majority of the members of the board of directors.

Furthermore, our certificate of incorporation authorizes, and we have adopted, a preferred share purchase rights plan, commonly referred to as a "poison pill." Under the rights plan, we made a dividend distribution to the stockholders of record on November 6, 1996 of one right to purchase from us one one-hundredth of a share of our preferred stock for each outstanding share of our Common Stock.

The terms of the rights and the circumstances under which they may be exercised are contained in a rights agreement, which has been filed with the SEC.

These terms have been designed to deter hostile takeovers of us, even though our stockholders might favor a takeover, especially if it were to afford them an opportunity to sell their stock at a price above the prevailing market rate.

OUR STOCK PRICE IS VOLATILE AND COULD DROP PRECIPITOUSLY AND UNEXPECTEDLY.

Our Common Stock currently trades on The Nasdaq National Market. The prices of publicly traded stock often fluctuate. The price of our stock may rise or fall dramatically, even though our business performance has not changed. In the past, the stock price of technology companies has been especially volatile. We expect that this will continue to be the case.

In addition to these fluctuations, an investment in our stock could be affected by a wide variety of factors that relate to our business and industry, many of which are outside of our control. For example, the value of our Common Stock could be affected by:

- new product introductions;

- innovations by competitors;

- our competitors' announcements of their financial results;

- the failure of our operating results to meet or exceed the expectations of investors and analysts;

- changes in financial estimates and recommendations by security analysts;

- general economic conditions;

- disputes over patents or other proprietary rights;

- new or existing litigation, including our litigation with Roche;

- publicity;

- regulations;

- market conditions; and

- fluctuations in our performance and the performances of our licensees.

On May 22, 2002, we notified holders of the outstanding Series B shares that we plan to redeem those shares on July 9, 2002 for their liquidation value. We expect that holders will elect to convert their Series B shares into our common stock prior to that date, which could lead to volatility in our stock price.

WE DO NOT PLAN TO PAY ANY CASH DIVIDENDS ON OUR COMMON STOCK.

We have never paid cash dividends on our Common Stock and we have no plans to pay cash dividends in the foreseeable future.

THE VALUE OF THE COMMON STOCK MAY BE DILUTED IN THE FUTURE.

Our officers, directors, employees and consultants have options to purchase a

significant aggregate amount of our Common Stock. If they exercise their options and purchase Common Stock, our Common Stock will be diluted. In addition, we currently have preferred stockholders and convertible debenture holders who have the right to convert their preferred shares and debentures, as the case may be, to Common Stock. Our Common Stock would be diluted if these preferred stockholders or convertible debenture holders decide to convert their securities in the future. Moreover, our Common Stock could be further diluted if we issue additional Common Stock or securities convertible into Common Stock in the future, which we may need to do to raise funds for our business.

Sales of additional shares of our Common Stock or the conversion of securities into our Common Stock could cause the market price of our Common Stock to decrease.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(c) Exhibits. The Exhibits filed as part of this Form 10-K are listed on and incorporated by reference to the Exhibit Index immediatly following the Signature page on this Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

IGEN International, Inc.

July 17, 2002

By:/s/ Samuel J. Wohlstadter

Samuel J. Wohlstadter
Chief Executive Officer

INDEX TO EXHIBITS

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
2.1(4)	Agreement and Plan of Merger effective November 19, 1996 (by virtue of a reincorporation), by and between IGEN, Inc., a California corporation and IGEN International, Inc. a Delaware corporation.
3.1(4)	Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on August 30, 1996.
3.2(4)	Certificate of Designation of Series A Junior Participating Preferred Stock, as filed with the Secretary of State of the State of Delaware on November 18, 1996.
3.3(8)	Certificate of Designation of Series B Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware on December 18, 1997.
3.4(4)	Bylaws, as currently in effect.
4.1(7)	Form of Specimen Right Certificate.

4.2(7)	Rights Agreement, dated November 6, 1996, between the Company and The First National Bank of Boston.
4.3(9)	Note Purchase Agreement between the Company and the purchasers named therein dated as of March 22, 1999.
4.4(10)	Securities Purchase Agreement, dated as of January 11, 2000, among Company and the Purchasers listed on Schedule I thereto.
4.5(8)	Purchase Agreement for the Series B Convertible Preferred Stock between the Company and the purchasers named therein dated as of December 16, 1997.
10.1(11)	Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington North American Equities Fund, Ltd. dated as of February 9, 2001.
10.2(11)	Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington North American Equities Fund, Ltd. dated February 9, 2001.
10.3(3*)	Agreement between the Company and Eisai Co., Ltd. dated May 25, 1990.
10.4(1)	Supplemental Agreement between Eisai Co., Ltd. and the Company.
10.5(3*)	License and Development Technology Agreement between the Company and Boehringer Mannheim GmbH dated September 23, 1992.
10.6(2)	Advanced Royalty Agreement between the Company and Boehringer Mannheim GmbH dated January 9, 1997.
10.7(3)	License Agreement between the Company and Hyperion Catalysis International ("Hyperion") dated October 10, 1993 as amended March 15, 1990.
10.8(3)	Common Stock Purchase Agreement between the Company and Organon Teknika B.V. ("Organon") dated May 19, 1993.
10.9(3*)	License and Technology Development agreement between the Company and Organon dated May 19, 1993.
10.10(3*)	Term Sheet for Consolidation of Research Projects between the Company and Proteinix Corporation dated December 14, 1993.

INDEX TO EXHIBITS (CONTINUED)

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
10.11(3*)	Term Sheet for consolidation of Cancer Research Projects between the Company and Pro-Neuron, Inc. dated December 14, 1993.
10.12(3)	Form of Indemnity Agreement entered into between the Company and its directors and officers.

10.13(3+) 1985 Stock Option Plan, as amended, and related Form of Incentive Stock Option Grant and Form of Nonqualified Stock Option Grant.

10.14(5+) 1994 Stock Option Plan as amended in 1998.

10.15(5+) 1994 Non-Employee Directors Stock Option Plan, and related Form of Incentive Stock Option Grant.

10.16(5) Lease Agreement between the Company and W-M 16020 Limited Partnership dated October 5, 1994.

10.17(5) Agreement for Purchase and Sale of Joint Venture Interest between the Company and Hyperion, dated December 28, 1994.

10.18(6*) Joint Venture Agreement, dated as of November 30, 1995, between Meso Scale Diagnostics, LLC. ("MSD"), Meso Scale Technologies, LLC. ("MST") and the Company.

10.19(6) Limited Liability Company Agreement, dated as of November 30, 1995, between MSD, MST and the Company.

10.20(6*) IGEN/MSD License Agreement, dated as of November 30, 1995, between MSD and the Company.

10.21(6+) Indemnification Agreement, dated as of November 30, 1995, between the Company and Jacob Wohlstadter.

10.22(12) Letter Agreement dated November 29, 2000 between Meso Scale Technologies, LLC., Meso Scale Diagnostics, LLC. and IGEN International, Inc.

10.23(15*) Amendment No.1 to Joint Venture Agreement between Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC., and IGEN International, Inc. dated August 15, 2001.

10.24(15) First Amendment of Limited Liability Company Agreement of Meso Scale Diagnostics, LLC. dated August 15, 2001 between IGEN International, Inc. and Meso Scale Technologies, LLC.

10.25(15*) Amendment No.1 to IGEN/MSD License Agreement dated August 15, 2001 between Meso Scale Diagnostics, LLC. and IGEN International, Inc.

10.26(15) MSD/MST Sublicense Agreement dated November 31, 1995 between Meso Scale Diagnostics, LLC. and Meso Scale Technologies, LLC.

10.27(15*) Amendment No. 1 to MSD/MST Sublicense Agreement dated August 15, 2001 between Meso Scale Technologies, LLC. and IGEN International, Inc.

10.28(15+) Consulting Agreement between IGEN International, Inc. and Jacob N. Wohlstadter dated November 31, 1996.

10.29(15+) Indemnification Agreement between IGEN International, Inc., Jacob N. Wohlstadter and JW Consulting Services, LLC. dated November 30, 1996.

10.30(15+*) Employment Agreement between Meso Scale Diagnostics, LLC., IGEN International, Inc., Meso Scale Technologies, LLC. and Jacob N. Wohlstadter dated August 15, 2001.

10.31(19+) Indemnification Agreement between IGEN International, Inc. and Jacob N. Wohlstadter dated October 6, 2001.

10.32(13+) Amended Restated Promissory Note effective as of July 22, 2000 between Samuel J. Wohlstadter and the Company.

10.33(13+) Stock Pledge Agreement effective as of July 22, 2000 between Samuel J. Wohlstadter and the Company.

10.34(13+) Amended Restated Promissory Note effective as of July 22, 2000 between Richard J. Massey and the Company.

10.35(13+) Stock Pledge Agreement effective as of July 22, 2000 between Richard J. Massey and the Company.

10.36(18+) IGEN International, Inc. 2001 Broad Based Stock Option Plan .

10.37(17) Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington Private Placement Fund, Ltd. dated December 17, 2001.

10.38(17) Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington Opportunity I Limited dated December 17, 2001.

10.39(17) Registration Rights Agreement between IGEN International, Inc. and Acqua Wellington Private Placement Fund, Ltd. dated December 17, 2001.

10.40(17) Registration Rights Agreement between IGEN International, Inc. and Acqua Wellington Opportunity I Limited dated December 17, 2001.

10.41(22) Common Stock Purchase Agreement between IGEN International, Inc. and Brown Simpson Partners I, Ltd. dated December 26, 2001.

10.42(22) Registration Rights Agreement between IGEN International, Inc. and Brown Simpson Partners I, Ltd. dated December 26, 2001.

10.43(21) Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington Private Placement Fund, Ltd. dated March 8, 2002.

10.44(21) Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington Opportunity I Limited dated March 8, 2002.

10.45(21) Registration Rights Agreement between IGEN International Inc. and Acqua Wellington Private Placement Fund, Ltd. dated March 8, 2002.

10.46(21) Registration Rights Agreement between IGEN International, Inc. and Acqua Wellington Opportunity I Limited dated March 8, 2002.

10.47(14+) Amended 1994 Non-Employee Directors' Stock Option Plan dated June 6, 2001.

10.48(19+) Termination Protection Program.

10.49(20) Final Order of Judgment issued in IGEN International, Inc. v. Roche Diagnostics GmbH dated February 15, 2002.

99.1(23) Meso Scale Diagnostics LLC.(A Development Stage Company), Financial Statements at December 31, 2001 and 2000, and for the Three Years Ended December 31, 2001, and for the period November 30, 1995 (Inception) Through December 31, 2001, and Independent Auditors' Report.

23.1(23) Consent of Deloitte & Touche LLP.

23.2 Consent of Deloitte & Touche LLP. Filed herewith.

+ Denotes management contract or compensatory plan or arrangement.
* Denotes confidential treatment applied.

(1) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended September 30, 1997.

(2) Previously filed as an exhibit to the Company's Annual Report on Form 10-K, as amended, for the fiscal year ended March 31, 1997.

(3) Previously filed as an exhibit to the Registration Statement on Form S-1, as amended (Registration No. 33-72992).

(4) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended November 14, 2000.

(5) Previously filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 1995.

(6) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended December 31, 1995.

(7) Previously filed as an exhibit to the Company's Form 8-A filed December 10, 1996.

(8) Previously filed as an exhibit to the Company's Registration Statement on Form S-3, as amended (Registration No. 333-45355).

(9) Previously filed as an exhibit to the Company's Form 10-K for the fiscal year ended March 31, 1999.

(10) Previously filed as an exhibit to the Company's Form 8-K on January 12, 2000.

(11) Previously filed as an exhibit to the Company's Form 8-K on February 12, 2001.

(12) Previously filed as an exhibit to the Company's Form 8-K on December 12, 2000.

(13) Previously filed as an exhibit to the Company's Form 10-K for the fiscal year ended March 31, 2001.

(14) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended June 30, 2001.

(15) Previously filed as an exhibit to the Company's Form 8-K as amended on September 5, 2001.

(16) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended September 30, 2001.

(17) Previously filed as an exhibit to the Company's Form 8-K on December 19, 2001.

(18) Previously filed as an exhibit to the Company's Registration Statement on Form S-8 (Registration No. 333-76624).

(19) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended December 31, 2001.

(20) Previously filed as an exhibit to the Company's Form 8-K on February 20, 2002.

(21) Previously filed as an exhibit to the Company's Form 8-K on March 15, 2002.

(22) Previously filed as an exhibit to the Company's Registration Statement on Form S-3 (Registration No. 333-76760).

(23) Previously filed an an exhibit to the Company's Form 10-K for the fiscal year ended March 31, 2002.