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IGEN INTERNATIONAL INC /DE  
Form 10-K  
June 30, 2003

SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-K

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

For Fiscal Year Ended March 31, 2003

Commission File Number 0-23252

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

DELAWARE  
(State or other jurisdiction of  
incorporation or organization)

94-2852543  
(IRS Employer Identification No.)

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 ☒ 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. ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined on Rule 12b-2) of the Exchange Act.

Yes ☒ No ☐

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Company as of September 30, 2002, computed by reference to the closing sale price of such stock quoted on the Nasdaq National Market, was approximately \$539,519,000

The number of shares outstanding of the Company's Common Stock as of June 13, 2003 was 23,763,107.

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## 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 Form 10-K is incorporated from the Company's definitive Proxy Statement relating to its 2003 Annual Meeting of Shareholders.

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## 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. All statements that are not statements of historical fact, including statements about markets and potential markets, market growth for diagnostic products, potential impact of competitive products, our expectations regarding future royalties and revenue, the potential market for products in development, prospects for future business arrangements with third parties, financing plans, the outcome of our litigation with Roche Diagnostics GmbH, which we refer to in this Form 10-K as the Roche litigation, the description our 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), are forward-looking statements. The words "may," "should," "will," "expect," "could," "anticipate," "believe," "estimate," "plan," "intend" and similar expressions have been used to identify certain of the forward-looking statements in this Form 10-K. We have based these forward-looking statements on management's current expectations, estimates and projections and they are subject to a number of risks, uncertainties and assumptions which could cause actual results to differ materially from those described in the forward-looking statements. The following factors are among those that may cause actual results to differ materially from our forward-looking statements:

- o the outcome of the Roche litigation and our relationship with Roche Diagnostics GmbH, which we refer to in this Form 10-K as Roche;
- o our ability to develop and introduce new or enhanced products;
- o our ability to enter into new collaborations on favorable terms, if at all;
- o our ability to expand the commercialization of existing products;
- o the demand for rapid testing products in each of our markets;
- o our ability to expand our manufacturing capabilities or find a suitable manufacturer on acceptable terms or in a timely manner;
- o our ability to develop our selling, marketing and distribution capabilities;
- o our and our licensees' ability to obtain FDA and other governmental approvals for our and their clinical testing products;
- o the ability of our licensees to effectively develop and market products based on the technology we license to them;
- o domestic and foreign governmental and public policy changes, particularly related to health care costs, that may affect new investments and purchases

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made by customers;

- o availability of financing and financial resources in the amounts, at the times and on the terms required to support our future business;
- o rapid technological developments in each of our markets and our ability to respond to those changes in a timely, cost-effective manner;
- o protection and validity of patent and other intellectual property rights;
- o changes in general economic, business and industry conditions; and

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- o the other factors discussed below under the heading "Business-Risk Factors" and elsewhere in this Form 10-K.

We disclaim any intent or obligation to update these forward-looking statements.

As used herein, "IGEN", "we", "us" and "our" refer to IGEN International, Inc. and its subsidiaries. ORIGIN(R) refers to our proprietary electrochemiluminescence technology. ORIGIN, IGEN, M-SERIES, TRICORDER and PATHIGEN(R) are our trademarks. This Form 10-K also contains brand names, trademarks or service marks of other companies, and these brand names, trademarks or service marks are the property of those other holders.

### ITEM 1. BUSINESS

#### SUMMARY

We and our licensees develop, manufacture and market products based on our proprietary electrochemiluminescence technology, which we call ORIGIN. We believe that our ORIGIN technology, which permits the detection and measurement of biological substances, offers significant advantages over competing detection and measurement methods by providing a unique combination of speed, sensitivity, flexibility and throughput in a single technology platform. Our ORIGIN technology is incorporated into our and our licensees' instrument systems and related consumable reagents, which are the fluids used in the performance of tests, or assays, on such instrument systems. In addition, we offer assay development and other services used to perform analytical testing.

Our strategy for our ORIGIN technology has been and continues to be based on entering into license arrangements and collaborations with third parties that can assist in our commercialization efforts while at the same time directly developing and commercializing our own products.

**LICENSE ARRANGEMENTS AND COLLABORATIONS.** We have entered into license arrangements and collaborations with established health care companies to commercialize our ORIGIN technology for clinical testing, which is the diagnostic testing of patient samples to measure the presence of disease and monitor medical conditions. Our licensees have developed multiple products lines for this market based on our ORIGIN technology, and have sold or placed approximately 9,000 ORIGIN based systems with customers worldwide. These sales and placements have been made predominantly by Roche, which has an exclusive license for our ORIGIN technology for certain segments of the clinical testing market and is the world's leading provider of clinical testing products. We refer to our license agreement with Roche in this Form 10-K as the Roche license agreement. Roche has adopted our ORIGIN technology for its Elecsys(R) immunodiagnostic product line. We receive royalties and contract fees from Roche and our other licensees, which accounted for 66% of our total revenue in fiscal 2003. For a discussion of our relationship with Roche and the Roche litigation, see "--License Arrangements and Collaborations--Roche", "--Risk Factors--Roche

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Litigation" and ITEM 3 -- "Legal Proceedings."

DIRECT COMMERCIALIZATION EFFORTS. We also directly develop and commercialize our ORIGIN technology. We have developed, and continue to develop, ORIGIN-based products for the following worldwide market. Many of our instruments and assays have been and are being designed to serve customers across multiple markets.

- o BIODEFENSE AND INDUSTRIAL TESTING - We are commercializing our ORIGIN technology for use in the emerging markets for biodefense and industrial testing. The biodefense market includes products for the detection of bacteria, viruses and toxins that may pose a military or public health threat.

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Over the past year, we have worked with numerous departments within the Department of Defense (DOD) and other U.S. government agencies to develop ORIGIN-based products for the detection of biological agents such as anthrax, staphylococcus enterotoxin B and botulinum toxin, among others. We are also commercializing our ORIGIN technology for use in the emerging industrial market for the detection of foodborne and waterborne disease causing pathogens. We have begun to sell our first products for this market, the PATHIGEN panel of tests for E. coli O157, Salmonella, Campylobacter and Listeria, which we sell primarily as a quality control test method to food producers, food processors and contract laboratories for the food industry.

- o LIFE SCIENCE - We are commercializing our ORIGIN technology for use in drug discovery and development that is performed by pharmaceutical and biotechnology companies, universities and other research organizations. Certain of our ORIGIN-based systems are used by pharmaceutical and biotechnology companies in all phases of drug discovery, including:
  - o validating targets identified through genomics;
  - o screening of large numbers of compounds generated through combinatorial chemistry;
  - o re-testing and optimization of lead compounds; and
  - o clinical trial testing of drug candidates.

We believe the ORIGIN-based systems used in this market provide a number of advantages relative to other drug discovery technologies, including enhanced sensitivity and greater ease and speed of assay formatting.

- o CLINICAL TESTING - We are developing our ORIGIN technology to be used in certain fields in the clinical testing market, particularly to perform tests in decentralized sites outside of central hospital laboratories and clinical reference laboratories. Our present strategy is to focus our product development efforts on patient care centers such as physicians' offices, ambulatory clinics, hospital emergency rooms, surgical and intensive care units, hospital satellite laboratories and nurses' stations. We believe our ORIGIN technology permits development of a system 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.

We were incorporated in California in 1982 as IGEN, Inc. and on November 19, 1996, IGEN, Inc. merged into IGEN International, Inc., a newly formed Delaware

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corporation. Our executive offices are located at 16020 Industrial Drive, Gaithersburg, Maryland 20877. Our Internet website is located at <http://www.igen.com>. Information contained on our website is not part of this Form 10-K or any other filing which may incorporate by reference this Form 10-K. We provide to the public on our website, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as amended, as soon as practicable after such material is filed electronically with, or furnished to, the Securities and Exchange Commission.

### 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.

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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 immunoassay tests, nucleic acid probe tests and clinical chemistry tests. The ORIGEN technology is protected by patents in the United States and internationally.

We believe that ORIGEN technology offers a unique combination of speed, sensitivity, flexibility and throughput 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 ORIGEN-based systems are:

- o Simple Testing Format: reduces time and labor in performing a test or series of tests. Complete automation of testing process is possible.
- o Flexibility: enables a single instrument to perform immunodiagnostic tests on large and small molecules and to perform DNA and RNA tests.
- o Cost: reduces the cost per test by minimizing the amount of expensive reagents needed and the number of steps required in preparing a sample for testing.

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- o Speed: reduced time from assay set-up to detection produces rapid results. Enables high sample throughput.
- o Sensitivity: allows detection of targeted specimens at very low concentrations.
- o Precision: provides highly-reproducible measurements.
- o 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 ORIGIN technology is well suited for the development and commercialization of families of instruments that can be used in all of our target markets. We believe the technology will permit virtually all immunoassay and nucleic acid tests to be performed on similar instrumentation using the same detection method.

The following table summarizes our and our licensees ORIGIN-based products and development programs. See "--License Arrangements and Collaborations" for a description of the commercial arrangements and license agreements we have entered into with our licensees and collaborators.

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MARKET -----	PRODUCT -----	CUSTOMER APPLICATION -----	STAT ----
BIODEFENSE AND INDUSTRIAL TESTING MARKETS	ORIGIN Detection System and Detection of Bacteria, Reagents	Viruses and Toxins	Product
	M-SERIES (M-1M Analyzer)	Detection of Food and Beverage Contaminants and Bacteria, Viruses and Toxins	Pre-La
	PATHIGEN Panel of Tests (ORIGIN Detection System)	Detection of Food and Beverage Contaminants	Product S
LIFE SCIENCE MARKET	M-SERIES (M384 Analyzer and Reagents	Drug Discovery / Development	Product
	M-SERIES (M-1R Research Analyzer)	Drug Discovery / Development	Product
	ORIGIN Detection System and Reagents	Drug Discovery / Development	Product

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	Cell Culture Reagents	Research	Product
	NucliSens/NASBA QR	Nucleic Acid Probe Tests	Product
	Sector HTS/Sector PR	High Throughput Drug Discovery/ Development	Product
CLINICAL TESTING MARKET			
Central Hospital/Clinical Reference Laboratory Systems	Elecsys 2010/1010	Immunoassay Tests	Product
	MODULAR ANALYTICS E170	Immunoassay Tests	Product
	NucliSens/NASBA QR	Nucleic Acid Probe Tests	Product
	Picolumi	Immunoassay Tests (Japan)	Product
Patient Care Systems	Elecsys 2010/1010	Physicians' Office Lab Immunoassay Tests	Product
	M-SERIES (M-1M Clinical Analyzer)	Portable Physicians' Office Lab / Hospital	Development

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

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### BIODEFENSE AND INDUSTRIAL TESTING PRODUCTS AND MARKET

Our ORIGEN technology is being commercialized in the emerging market for biodefense which involves the detection of bacteria, viruses and toxins that may pose a military or public health threat, as well as for the detection of foodborne and waterborne disease causing pathogens. Products based on ORIGEN technology are already being used in several biodefense programs for homeland security, including by the DOD. In fiscal 2003, our product sales in the biodefense and industrial testing markets were \$4.6 million. We believe there will be an increasing opportunity to use our ORIGEN technology as a biodefense tool in governmental and military organizations around the world, as well as in public health. There are no dominant competitors and no ideal product solution to the emerging testing requirements.

The biological test reagents being used by the DOD are for the detection of agents or toxins in environmental samples. U.S. Army scientists at Fort Detrick, Maryland have developed ORIGEN-based biological assays designed to measure specific agents and toxins. This technology platform provides the U.S. military with products for the detection of these agents in environmental samples. We have a contract with the DOD for the production of these tests. This contract provides for product sales at the election of the government of up to a total of \$23 million over four years, with approximately \$7 million of product sales through June 2004. For each contract year after June 2004, the DOD, at its option, may elect to purchase additional products from us but has no obligation to do so. These products will be used by various laboratories and field sites of the DOD, as well as other U.S. government agencies. For risks related to our

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contracts with the government, see "--Risk Factors--Regulatory and Government Contract Risks."

Over the past year, we have worked with the DOD and other U.S. government agencies to expand the use of ORIGEN-based products in a variety of Homeland Security and biodefense initiatives for the detection of biological agents such as anthrax, staphylococcus enterotoxin B, and botulinum toxin, among others. These early stage initiatives include:

- o The Automated Biological Agent Testing System program (ABATS) at the Edgewood Chemical and Biological Center (ECBC), Aberdeen Proving Ground. ECBC, in conjunction with IGEN and Beckman Coulter, is integrating an M-SERIES system with Beckman Coulter's SAGIAN(TM) and Biomek(R) FX lab automation systems to automate sample preparation and plate handling for ORIGEN immunoassays;
- o Our cooperative research and development agreement with the U.S. Army Medical Research Institute of Infectious Diseases for the development of tests for the detection of biological toxins;
- o The development of a botulinum toxin test for the Centers for Disease Control and Prevention (CDC);
- o Our contract with the DOD to develop assays for the detection of select agents in food; and
- o Integration of ORIGEN technology into the Air Force biological testing program.

These initiatives have not provided us with significant revenues to date.

The ORIGEN Detection System has been important for our developments with the U.S. military and the initial sales of ORIGEN technology to our biodefense customers. We plan to further develop ORIGEN-based products for the biodefense market, such as the M-SERIES M-1M analyzer.

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These plans include an instrument system that can be both miniaturized and "ruggedized" for use by soldiers in a variety of settings, "first responders" such as fire, police and ambulatory medical workers, hospitals, food processors, field inspectors from the Environmental Protection Agency (EPA), U.S. Department of Agriculture, and Food and Drug Administration (FDA), and border patrol inspectors.

In the industrial testing market, we have commenced sales of our PATHIGEN panel of food pathogen tests to food producers, food processors and contract laboratories for the food industry. This panel includes tests for E. coli 0157, Salmonella, Campylobacter and Listeria. These tests are used as a quality control method for testing food and beverage products, such as meat used in hamburger, for 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 0157 test is significantly more sensitive than conventional tests commonly used to screen food.



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Major food and beverage producers, as well as contract testing laboratories, are the primary targets to become users of the PATHIGEN test panel. We believe 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.

### LIFE SCIENCE PRODUCTS AND MARKET

We provide products and services for the discovery and development of new drugs to the life science market. Our commercialization efforts in this market center on the M-SERIES systems and the ORIGEN Detection System. In fiscal 2003, our life science product sales were \$11.9 million.

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 is expected to 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 attempting 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 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 SYSTEMS. 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. We are selling two M-SERIES instruments - the M384 and the M-1R - each of which build on the applications of the ORIGEN Detection System.

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These systems are compatible with multi-well microplates that are commonly used in drug discovery and development laboratories and can be fully integrated with many existing automation and robotic systems. They were designed to enable researchers to test new biological targets against potential drug compounds with higher levels of accuracy and specificity. We believe they may also perform highly sensitive tests more quickly at a lower cost and 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 these M-SERIES systems create

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advantages over many competitive detection technologies. They allow 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 FDA's Good Manufacturing Practices (GMP).

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

The newest product in the M-SERIES family is the M-1R, which was introduced to the market in September 2002 and has commenced commercial shipments during the spring of 2003. The M-1R was 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-1R 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 enzyme-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 product family and established ORIGEN as a powerful detection technology for applications in life science research.

### CLINICAL TESTING PRODUCTS AND MARKET

One of the markets that we have and will continue to target by developing and marketing products based on our ORIGEN technology is the clinical testing market. The clinical testing 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 testing, including testing by central hospital laboratories, clinical reference laboratories and blood banks, as well as testing at decentralized sites outside of central hospital laboratories and clinical reference laboratories such as hospital satellite laboratories and at physicians' offices, ambulatory clinics, hospital emergency rooms, surgical and intensive care units and nurses' stations. A general characteristic of each of these sites is that they are at or near patient care centers.

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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 currently constitute the vast majority of the clinical diagnostic market. 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, a company that has an exclusive license to our technology covering certain aspects of this market, presently sells three ORIGEN-based immunoassay systems for the central hospital and clinical reference laboratory markets: the Elecsys 1010, Elecsys 2010 and the MODULAR ANALYTICS 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. In addition, Roche has developed a third instrument system, the MODULAR ANALYTICS 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 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 work with Roche to develop a limited number of assays, and Roche reimburses us one-half of our development costs.

See "--Risk Factors - Roche Litigation" and ITEM 3 - "Legal Proceedings" for a description of the Roche litigation.

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.

Our ORIGEN technology permits development of a system that is compact and simple to operate at a low cost per test. The initial clinical ORIGEN-based system we

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are developing is named the M-1M Clinical Analyzer and is part of our M-SERIES family of products 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, future ORIGEN-based systems. We are exploring and negotiating collaborative business arrangements to accelerate the commercialization of ORIGEN-based products for multiple point-of-care applications.

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We distribute clinical assays to physicians' office laboratories (POL's) in the United States that utilize Roche's Elecsys systems. In fiscal 2003, we generated \$2.5 million from product sales to these customers; however, under the final order of judgment issued in the Roche litigation, the U.S. District Court for the District of Maryland enjoined Roche from marketing, selling, or distributing its Elecsys products outside of Roche's licensed field of use, including to POL's but did not require Roche to renew existing POL contracts. 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 Roche litigation. We anticipate that this portion of our business will decrease in size as Roche's existing POL contracts expire. We do not know whether Roche will renew POL contracts as they expire, and accordingly, whether our revenues in this area will decrease in the future. See "--Risk Factors - Roche Litigation" and ITEM 3 - "Legal Proceedings" for a description of our litigation with Roche. See also ITEM 7 - "Management's Discussion and Analysis of Financial Condition and Results of Operations".

### LICENSE ARRANGEMENTS AND COLLABORATIONS

We have entered into license arrangements and collaborations with established diagnostic and pharmaceutical companies. Through these license arrangements and collaboration relationships, we grant licenses to our licensees and collaboration partners (sometimes on an exclusive basis) and in return we receive license fees and product development resources. In addition, we receive ongoing royalties from our licensees' and collaborators' product sales. For the three fiscal years ended March 31, 2003, 2002 and 2001 revenue from licensees and collaborators, which is represented as product-based royalty income and contract revenue, totaled \$37.5 million (66% of total revenue), \$27.5 million (65% of total revenue) and \$20.4 million (65% of total revenue), respectively.

ROCHE DIAGNOSTICS GMBH. In 1992, we entered into the Roche license agreement with Roche, the largest worldwide manufacturer of diagnostic equipment and supplies, to exclusively commercialize ORIGEN-based clinical immunoassay and nucleic acid probe systems in certain defined fields. From fiscal year 1992 through fiscal year 2003, we generated a total of approximately \$154 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 9,000 Elecsys and E170 systems worldwide.

In 1997, we filed a lawsuit in the U.S. District Court for the District of Maryland, which we refer to as the District Court, against Roche and in February 2002, the District Court issued a final order of judgment against Roche. Roche appealed certain aspects of the final order of judgment to the U.S. Court of Appeals for the Fourth Circuit, which we refer to as the Appellate Court. We anticipate that the decision of the Appellate Court will be issued in mid-2003. We have previously advised Roche that the Roche license agreement will

automatically terminate in the event the Appellate Court affirms that portion of the final order of judgment holding that Roche materially breached the Roche license agreement. In the event the Roche license agreement is terminated, Roche will no longer be authorized to utilize ORIGEN technology to manufacture, market, or sell products, including its Elecsys / E170 diagnostics product line. See "- Risk Factors - Roche Litigation" and ITEM 3 - "Legal Proceedings" for a description of our litigation with Roche. We recorded royalty income and contract fees from Roche of \$36.2 million (64% of total revenue), \$26.3 million (63% of total revenue) and \$15.6 million (50% of total revenue) for the three fiscal years ended March 31, 2003, 2002 and 2001, respectively.

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BIOMERIEUX. We have an agreement with BioMerieux Inc., which we refer to as BioMerieux (formerly Organon Teknika B.V.), for development and worldwide commercialization of ORIGEN-based nucleic acid probe systems on a co-exclusive basis for certain segments of the clinical testing market and on a non-exclusive basis for certain segments of the life science market. 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. Our agreement with BioMerieux extends until the expiration of the patents we license to them.

EISAI CO., LTD. We have an agreement with Eisai Co., Ltd., which we refer to as Eisai, a leading Japanese pharmaceutical company, under which Eisai is licensed to manufacture and market a class of ORIGEN-based diagnostic systems for the clinical testing market in Japan on an exclusive basis. 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. We recently executed an extension of our agreement with Eisai which extends the term of the agreement to May 10, 2010, and provides for royalty payments after the expiration date at a reduced royalty rate.

MESO SCALE DIAGNOSTICS, LLC. Meso Scale Diagnostics, LLC., which we refer to as MSD, is a joint venture formed by Meso Scale Technologies, LLC., which we refer to as 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 our technology, which we refer to as the Research Program. MST is a company established and wholly-owned by Jacob Wohlstadter, the son of our Chief Executive Officer. In August 2001, we amended our joint venture agreement and certain license and other agreements with MSD and MST in order to continue the MSD joint venture and entered into various related agreements. We refer to these amendments and agreements entered into in August 2001 as the MSD agreements. An independent committee of our Board of Directors, with the advice of independent advisors and counsel, negotiated and approved the MSD agreements.

MSD manufactures and markets two instrument systems, the Sector HTS and the Sector PR, both of which combine our ORIGEN technology and MST's multi-array technology. The Sector HTS is an ultra high throughput drug discovery system engineered for applications such as high throughput screening and large scale proteomics. The Sector PR is a smaller system designed for benchtop applications such as assay development, research in therapeutic areas, cellular biology and medium throughput screening. MSD also manufactures and markets a line of proprietary reagents, assays and plates that are used on these systems. Product

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sales commenced in October 2002, and during the year ended March 31, 2003, MSD had product sales of \$3.2 million and a net loss of \$18.2 million.

Under the MSD agreements, our funding commitment is based on an annual budget of MSD approved by an independent committee of our Board of Directors. Our funding commitment may be satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. An independent committee of our Board of Directors approved funding for MSD for the period from January 1, 2003 to November 30, 2003 in an amount of \$20.6 million, subject to a permitted variance of fifteen percent. As of March 31, 2003, our remaining funding commitment to MSD was \$17.0 million. In addition, prior to November 30, 2003, we would also pay approximately \$3.7 million to MSD related to the permitted budget variance from prior years. For the years ended March 31, 2003, 2002 and 2001, we made total contributions to MSD of \$20.5 million, \$19.6 million and \$8.3 million, respectively.

The MSD joint venture agreement will expire on November 30, 2003, unless renewed. Following the termination or non-renewal of the joint venture agreement, many of our licenses and other arrangements with MSD and MST will continue indefinitely.

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Under the terms of the MSD agreements, we have granted to MSD a worldwide, perpetual, exclusive license (with certain exceptions) to our technology for use in MSD's Research Program, which is more fully described in the MSD agreements. If we cease to be a member of the joint venture, we will receive royalty payments from MSD on all products developed and sold by MSD using our patents. MST holds a worldwide, perpetual, non-exclusive sublicense from MSD for certain non-diagnostic applications of our technology. We will receive royalty payments from MST on any products developed and sold by MST using our patents. During the term of the MSD joint venture, MSD is our exclusive means of conducting the Research Program and we are obligated to refrain from developing or commercializing any products, processes or services that are related to the Research Program in the diagnostic field or to MSD's research technologies as described in the MSD agreements, subject to certain exceptions. If the MSD joint venture expires or is terminated for any reason, we have agreed not to use the improvements granted to us by MSD to compete with MSD in its field and we have agreed not to directly or indirectly develop or commercialize products, processes or services related to the Research Program in the diagnostic field or to MSD's research technologies.

For more information about the MSD agreements and our relationship with MSD, 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, 2003, we owned 69 issued U.S. patents and had 22 pending U.S. patent applications in the diagnostics field. As of that date, we owned 126 additional issued patents outside of the United States and had 71 pending patent applications outside of the U.S. in the diagnostics field. 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 begin to expire in 2005; however, patent coverage for our ORIGEN technology continues through 2018. We continue to protect our technology with new patent filings, which could further extend our patent coverage.

#### GOVERNMENT REGULATION

The research and development, manufacturing, marketing, sale and distribution of both existing and future products based on our ORIGEN technology are subject to comprehensive government regulation. Government regulation by various federal, state, and local agencies, which includes detailed inspection of, and controls over, research and laboratory procedures, safety, clinical investigations, and manufacturing, marketing, sampling, labeling, distribution, record keeping, storage, and disposal practices, substantially increases the time, difficulty and costs incurred in obtaining and maintaining the approval to market newly developed and existing products.

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In particular, government regulatory actions can result in delay in the release of our and our licensees' products, seizure or recall of our or our licensees' products, suspension or revocation of the authority necessary for their production and sale, and other civil or criminal sanctions.

Continuing studies of the utilization, safety, and efficacy of our or our licensees' products and their components are being conducted by industry, government agencies and others. Such studies, which employ increasingly sophisticated methods and techniques, can call into question the utilization, safety, and efficacy of products previously marketed by us or our licensees and in some cases have resulted, and may in the future result, in the discontinuance of marketing of such products.

International sales of products by us and our licensees are also subject to a significant degree of government regulation, including, for example, international standards (such as those set by the International Organization for Standards), European Union directives and other country-specific rules and regulations. For example, many countries, directly or indirectly through reimbursement limitations, control the cost of most clinical testing products. Furthermore, many developing countries limit the importation of raw materials and finished products. International regulations may also have an impact on U.S. regulations.

Our regulatory strategy is to pursue development and marketing approval of products worldwide, either independently or through licensees. 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 licensees.

Biodefense and Food Testing Products

Our biodefense products are subject to stringent federal, state, local and foreign laws, regulations and policies governing their manufacture, storage, sale, distribution, and export. In addition, the U.S. government has been, and is expected to continue, to adopt new laws, regulations, and rules governing the research, development, procurement of pathogens that may be used in a bioterrorist attack or other agents that may cause a public health emergency and to permit government inspection and oversight of facilities engaged in the research, development, manufacture or sale of certain select agents. Under several statutes recently enacted, the Department of Homeland Security, FDA, Department of Commerce and various other regulatory authorities have been charged with establishing and implementing programs designed to enhance the security of food and water supplies, as well as the environment, from terrorist attacks. These legislative initiatives include recordkeeping, registration, notification, import, export, manufacturing and various other compliance measures. This is a rapidly evolving regulatory landscape and many of the possible rules and regulations have not yet been proposed or adopted. 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.

#### Research Products

Our products that are being sold for research use only, including the M-SERIES systems used in the life sciences market, 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.

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#### Clinical Testing Systems

The manufacture, distribution and sale in the United States of our or our licensees' products for clinical testing 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 clinical testing products. To obtain FDA approval of a new product for clinical testing purposes, we or our licensees 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 or our licensees from marketing products for clinical testing 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 licensees will have the exclusive right to exploit our products or technologies.

Our and our licensees' clinical testing 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



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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, we or our licensees must seek FDA approval of the manufacturing facilities and procedures. The FDA will also inspect clinical testing companies on a routine basis for regulatory compliance with its GMP.

Our and our licensees' 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. The major difference in requirements between moderate and high complexity testing relates to quality control and personnel standards. Quality control standards for moderate complexity testing are being implemented in stages.

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Personnel standards for high complexity testing are more rigorous than 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 or our licensees' 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

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laboratories, will be evaluating the requirements of CLIA in determining whether to perform certain types of moderate and high complexity clinical tests.

Although we believe that we and our licensees will be able to comply with all applicable regulations regarding the manufacture and sale of clinical testing 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 and our licensees.

In addition to the foregoing, we and our licensees 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 and our licensees 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 and our licensees' ability to do business.

Sales of our and our licensees' 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.

### Government Contracts and Regulation

Our business agreements with U.S. and foreign government agencies and departments require that we comply with numerous regulations, rules and policies, including those governing procedures for soliciting, awarding and funding government contracts. In addition, we are required to comply with numerous ongoing obligations following the award of a government contract, including those relating to record keeping, workplace compliance, third party contracting, and disclosure of information. Failure to comply with these requirements may lead to a denial of a contract award, a challenge to a previously awarded contract, attempts by the U.S. government to terminate a contract, and restrictions on a company's ability to participate in future bids to secure government contracts.

In addition, we may be required to obtain certain security clearance certifications and comply with security clearance standards and requirements, including those affecting personnel and facilities. Sales of certain of our products to international government agencies may be subject to local government regulations and procurement policies and practices, as well as to regulations relating to import-export control, including prior notification of, and pre-clearance for, export of certain goods having military applications.

### Environmental Regulation

Our operations are subject to stringent foreign, federal, state and local laws, rules and regulations relating to the protection of the environment, including those governing the use, handling and disposal of hazardous, radioactive and infectious materials and wastes, the discharge of pollutants into the air and water and the cleanup of contaminated sites. Some of our operations require

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permits, and these permits are subject to modification, renewal and revocation by issuing authorities. Although we believe that we have complied with these laws and regulations in all material respects, we may be required to incur significant costs to maintain or achieve compliance if additional or stricter environmental and health and safety requirements are imposed in the future or in the event of any noncompliance at our facilities.

### 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.

### SEASONAL ASPECTS, BACKLOG AND RENEGOTIATION

There are no significant seasonal aspects to our business. Orders for our products are generally filled on a current basis, and order backlog is not material to our business. A material portion of our business is subject to termination of contracts at the election of the government. In the event our biodefense business expands, the portion of our business subject to termination of contracts at the election of the government is likely to expand. For risks related to our contracts with the government, see "--Risk Factors--Regulatory and Government Contract Risks".

### COMPETITION

We face competition both in the markets in which we sell our own products and in the markets in which our licensees sell their products based on our ORIGEN technology.

We compete in the biodefense and industrial testing markets with our own products. We compete in these markets against a diverse group of technology companies. While existing testing methods are relatively inexpensive, these technologies are time consuming and produce non-specific test results that are often unreliable. We are developing a portfolio of tests that would offer enhanced speed, reliability and specificity in detecting pathogens and other biological contaminants in food, water, air and other samples being tested. We believe this will allow us to position our ORIGEN technology competitively as the detection method of choice for the biodefense and industrial testing markets. We do not hold a leading competitive position in the biodefense and industrial testing markets.

We compete in the life science market with our own and our licensees' products against a diverse group of research products companies. To be competitive in this market, 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 shortening timelines.

These drug discovery companies favor detection systems that combine automation and enhanced sensitivity with integrated equipment and consumables. Because our and our licensees' ORIGIN-based systems encompass all of these elements, we believe they offer 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. Neither we, nor our licensees hold a leading competitive position in the life science market.

We compete in the clinical testing market primarily through our license arrangement with Roche, as well as through our license arrangements with BioMerieux and Eisai. The clinical testing market is dominated by a few large multi-national companies, including Abbott Laboratories, Bayer and Johnson & Johnson. Roche, our licensee, holds a leading competitive position in the clinical testing market.

Our and our licensees' ability to compete in these markets will be determined in part by the potential applications for which our or their products are developed and ultimately approved by regulatory authorities. For certain of our future products, an important factor in competition may be whether we or our competitors are first to introduce competing products. Accordingly, the relative speed with which we or our licensees 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. See "- Risk Factors - Risks Of Our Business - We May Not Be Able To Compete Effectively Against More Established Companies And Institutions, Which Could Adversely Affect Our Business."

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.

#### MANUFACTURING

Our current commercial manufacturing operations consist of the manufacture of the M-SERIES family of products and related reagents, biodefense and 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 testing products that are manufactured by us. Initial clinical testing products, based on our ORIGIN technology, are being manufactured by our licensees. We are presently evaluating plans for future manufacturing of all of our products. These plans may include direct and third party manufacturing.

See "- Risk Factors - Risks Of Our Business - 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

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Products And Meet Customer Orders."

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### SALES AND MARKETING

We market the M-SERIES systems and the ORIGEN Detection System, together with related reagents and services, directly to the life science research market, various government agencies for use in the biodefense market and to food and beverage producers and contract testing laboratories for the industrial testing market. Our sales and marketing effort includes a direct sales force in the United States and Europe, as well as application specialists and in-house technical service personnel. We also utilize distributors in Japan and certain parts of Europe. 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 our licensees and collaborators. See "--License Arrangements and Collaborations."

### HUMAN RESOURCES

As of May 31, 2003, IGEN employed 321 individuals, of whom 243 were engaged in research, product development, manufacturing and operations support, and 78 in marketing, sales and applications support and general administration. Of our employees, 49 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. As of May 31, 2003, none of our employees is covered by a collective bargaining agreement, and management considers relations with its employees to be satisfactory.

Certain of our employees provide services to certain of our affiliated companies. In addition, we satisfy a portion of our funding obligation to MSD through in-kind contributions. For more information about these relationships, see ITEM 13 - "Certain Relationships and Related Transactions."

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.

### OPERATING SEGMENT

The Company operates in one business segment. Information related to this segment is incorporated herein by reference to ITEM 8-"Consolidated Financial Statements-Notes to Consolidated Financial Statements-Note 11".

### GEOGRAPHIC SEGMENTS

We do not view our business as having material risks relating to our foreign business. We attribute royalty income to the United States because that is where we collect payments. We attribute all other revenue to the location of the customer from whom such revenue is derived. 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".

### RISK FACTORS

Roche Litigation

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

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We have an ongoing lawsuit against Roche, which is the largest licensee of our technology in terms of royalty income, accounting for 97% of our royalty income and 63% of our total revenue in fiscal 2003. The Roche litigation was initiated in 1997 and centers on a number of claims we asserted against Roche alleging that they failed to comply with the terms of the Roche license agreement. Roche filed a counterclaim against us in the lawsuit alleging, among other things, that we breached the Roche license agreement by permitting Eisai, another of our licensees, to market some ORIGEN-based products in Japan.

The 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, entitled us to terminate the Roche license agreement, directed Roche to grant to us for use in our retained fields a license to certain improvements developed by Roche under the Roche license agreement, including Roche's Elecsys 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 technology.

We have voluntarily agreed not to terminate the Roche license agreement until the Appellate Court determines that we are entitled to do so; however, we have already notified Roche that the Roche license agreement will terminate immediately in the event the Appellate Court issues an opinion confirming final order of judgment rendered by the District Court that we are entitled to terminate the Roche license agreement.

Roche appealed certain aspects of the final order of judgment to the Appellate Court. During the appeal process, Roche is obligated to continue to comply with the terms of the Roche license agreement. We anticipate that the decision of the Appellate Court will be issued in mid-2003. Our litigation related expenses attributable to Roche were \$5.4 million, \$11.3 million and \$13.8 million in fiscal 2003, 2002 and 2001, respectively.

There are inherent risks in any litigation. In addition to those risks, the Roche litigation involves additional risks including:

- o The Appellate Court may modify or overturn some or all of the final order of judgment including the finding that Roche materially breached the Roche license agreement which is the basis of our right to terminate the Roche license agreement, the scope and extent of the improvements awarded to us, the amount of compensatory and punitive damages.
- o The Appellate Court could overturn some or all of the final order of judgment and order a new trial on those issues. For example, if the Appellate 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, we may not receive any damages or, the amount of damages awarded in a new trial could be lower than the amount already awarded to us.
- o If the Appellate Court orders a new trial on any of the issues, we would be required to continue expending significant amounts of money and management time in pursuing our claims against Roche and we might

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not prevail on any of these issues. This time and money will then be unavailable for use in the development of our business.

- o In the event the Appellate Court upholds the final order of judgment that Roche materially breached the Roche license agreement, and the Roche license agreement is terminated and Roche prevented from continuing to market products based on our technology, virtually all of our royalty revenues would be eliminated.

Roche may at any time 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.

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Roche may increase its efforts 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.

The risks due to our relationship with Roche are general risks of our business. However, the possibility that our right to terminate the Roche license agreement will be upheld by the Appellate Court makes these risks even greater while the appeal in the Roche litigation is pending.

The outcome of the Roche litigation could materially adversely affect our revenues and financial condition.

IF WE ARE UNABLE TO FIND A SUITABLE REPLACEMENT FOR ROCHE OR SUCCESSFULLY INTRODUCE NEW PRODUCTS ON OUR OWN IN THE EVENT THE ROCHE LICENSE IS TERMINATED, OUR BUSINESS WILL BE MATERIALLY ADVERSELY AFFECTED.

We may not be able to find a suitable replacement for Roche or successfully introduce new products on our own in the event the Roche license agreement is terminated. Without the revenues we receive from Roche or a suitable replacement, we may lack sufficient funds to successfully maintain or further develop our business.

Our ability to successfully commercialize new products, including products based on the improvements that may be awarded to us in the Roche litigation, is subject to numerous risks and uncertainties including risks relating to:

- o the need for governmental approvals;
- o our ability to compete effectively;
- o our ability to effectively manufacture and market new products;
- o our need for additional financing; and
- o the other risks applicable to our business as described throughout this Form 10-K.

### Risks of Our Business

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 had a total debt balance at March 31, 2003 of \$49.9 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.

In the event the Roche license agreement is terminated, the holders of the \$18.1 million of our 8.5% senior secured notes outstanding as of March 31, 2003 will be entitled to accelerate those obligations. Accelerated payment would result in approximately \$1.4 million of prepayment costs to be incurred. Accelerated payment of this debt would significantly reduce our cash and cash equivalents.

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The note purchase agreement for the 8.5% senior secured notes also contains covenants that limit our ability to take specified actions, including incurring certain types of secured debt, entering into certain merger or consolidation transactions and amending or terminating our license agreement with Roche, which could affect our ability to resolve issues that are being litigated in the Roche litigation. These restrictions may limit our operating flexibility, as well as our ability to raise additional capital.

At March 31, 2003, \$35 million in aggregate principal amount of 5% subordinated convertible debentures due 2005 was outstanding. 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. In addition, the 5% subordinated convertible debentures due 2005 provide that, in the event our debt in an outstanding principal amount of \$2 million or greater is accelerated and not satisfied within 20 business days, the holders of the debentures may accelerate our obligations under the debentures and cause the debentures to be immediately due and payable. We may not have sufficient funds to pay our debt if any of it is accelerated.

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. Our debt may make it difficult to pursue our business strategy and make us more vulnerable to economic downturns and adverse developments in our business.

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 a combination of lower royalty revenue than we believe we are entitled to under the Roche license agreement, costs incurred in research and development, Roche litigation costs, our share in losses in affiliate, 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, general and administrative costs and our share of losses in MSD.



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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:

- o expand the commercialization of our existing products;
- o upgrade and enhance the M-SERIES family of products;
- o introduce new products into the market;
- o develop our marketing, sales and distribution capabilities cost-effectively; and
- o continue existing collaborations or establish successful new collaborations with corporate partners to develop and commercialize products that incorporate our technologies.

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 the Roche litigation, the volatility of the price of Common Stock, continued losses from operations, our current level of debt and capital market conditions.

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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:

- o for research and development in order to successfully develop our technologies;
- o to obtain regulatory approval for our products;
- o to file and prosecute patent applications in order to protect our technology;
- o to respond to innovations that our competitors develop;
- o to continue to aggressively pursue the Roche litigation;
- o to retain qualified employees, particularly in light of competition for qualified scientists and engineers;
- o to make new arrangements to market our technology;
- o to continue to fund investments in MSD;
- o to manufacture products ourselves or through a third party; and
- o 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

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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.

A SUBSTANTIAL PORTION OF OUR REVENUES DEPENDS ON COMPANIES THAT LICENSE TECHNOLOGY FROM US AND THESE COMPANIES CONTROL THE DEVELOPMENT AND MARKETING OF PRODUCTS BASED ON OUR TECHNOLOGY. IF THESE COMPANIES DO NOT EFFECTIVELY DEVELOP AND MARKET PRODUCTS BASED ON OUR TECHNOLOGY, OUR BUSINESS WOULD BE ADVERSELY AFFECTED.

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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 Roche, BioMerieux and Eisai 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 fields on an exclusive basis. 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 were 65% of our total revenue in fiscal 2003.

We have no control over the resources that companies who license our technology may devote to the development of products based on our technology. These companies may decide not to develop products arising out of our agreements, may not devote sufficient resources to the development, approval, manufacture, marketing or sale of these products or may terminate their agreements. If any of these events occur with respect to one of the companies who licenses our technology, that company may not develop or market new products based on our technology and we would not receive royalties or other payments from that company and our revenue would be adversely affected.

We have brought the Roche litigation against Roche, a licensee which accounted for 63% of our total revenue in fiscal 2003, in part because we believe Roche has not properly calculated and paid royalties to us. See "--Risk Factors - Roche Litigation" and ITEM 3 --"Legal Proceedings" for a more detailed description of the Roche litigation and the risks it poses to us. Business risks faced by Roche may become risks for us, to the extent Roche's sales decline and we have a decline in royalties on those sales. Similar or other problems may arise with other companies to whom we license our technology.

IF WE ARE UNABLE TO IMPLEMENT OUR STRATEGY OF ENTERING INTO COLLABORATIVE RELATIONSHIPS TO COMMERCIALIZE OUR ORIGEN TECHNOLOGY OUR ABILITY TO GROW OUR BUSINESS WILL SUFFER.

One aspect of our strategy is to enter into collaborative relationships with established healthcare companies to assist us in the commercialization of our ORIGEN technology by working with us to develop, manufacture or market products for certain markets. We may not be able to enter into collaborations on terms that are favorable to us, if at all. If we are unable to establish new collaborations or any collaborations we establish are not able to introduce new products based on our ORIGEN technology, our growth may be slowed and our business will suffer.

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

Our quarterly operating results depend upon:

- o the volume and timing of orders for M-SERIES systems or other products;
- o the timing of instrument deliveries and installations;
- o the success of M-SERIES system upgrades and enhancements;
- o the amount of revenue recognized from royalties and other contract revenues;
- o our mix of products sold;
- o whether our instruments are sold to or placed with customers;

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- o the timing of our introduction of new products;
- o the volume and timing of product returns and warranty claims;
- o our competitors' introduction of new products;
- o the amount of expenses we incur in connection with the operation of our business, including costs associated with the transfer of improvements from Roche to us, legal fees, research and development costs, and sales and marketing costs, including costs for upgrading the M-SERIES system or other products;
- o our share of losses in MSD;
- o the timing of and results from the currently pending appeal of our judgment against Roche;
- o the timing of termination of the Roche license agreement, if at all;
- o whether POL customers' contracts are renewed and whether Roche will continue to service POL customers; and
- o our manufacturing capabilities.

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 COMPETE EFFECTIVELY AGAINST BETTER POSITIONED COMPANIES AND INSTITUTIONS, WHICH COULD ADVERSELY AFFECT OUR BUSINESS.

Our business is subject to intensive competition from 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:

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- o more money to invest;
- o greater expertise and resources in developing, manufacturing, marketing and selling products;
- o a larger, more experienced workforce; and
- o more experience in obtaining regulatory approval for clinical testing 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 revenues.

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 WHICH COULD ADVERSELY AFFECT OUR BUSINESS.

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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, such as those which have occurred with our M-SERIES systems. These difficulties and delays have caused, and may continue to cause, our expenses to increase and our product sales to fluctuate. In addition, if we experience design, development or implementation difficulties in developing these instruments, we will sell fewer of our products and our business prospects would be adversely affected.

The markets for our products are expected to evolve and expand. These changes would facilitate the market demand for our new or enhanced products, including the need for products that would be utilized in decentralized sites such as clinical testing in the proximity of the patient and field-testing of environmental samples in the biodefense market. If market demand does not evolve or expand as we anticipate or we are not able to develop products that meet the evolving market demand, our business prospects would be adversely affected.

In addition, the markets for our products are characterized by evolving industry standards and government regulations, the need for updated and effective technology and new product introductions. 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 technological change and evolving industry standards and government regulations.

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 products for us 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

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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, our business and our 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. We may not be able to develop a sufficient sales and distribution force or find a suitable company to fill that role for us.

WE HAVE LIMITED MANUFACTURING FACILITIES FOR OUR PRODUCTS AND WE MAY NOT FIND ADDITIONAL FACILITIES SUITABLE FOR FUTURE GROWTH.

We face risks inherent in operating a single facility for the manufacture of our products. We do not have alternative production facilities available should our Gaithersburg, Maryland manufacturing facility cease to function. This risk includes an unforeseen plant shutdown and if our facility were not operational for an extended period of time, our existing business and future prospects could be materially adversely affected.

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In addition, we also may need to expand and enhance our research, development and production facilities. We may encounter difficulties in locating suitable additional facilities to meet our requirements. We may also be required to make material capital expenditures at a new facility at a time when we have limited capital resources available to us.

We may also experience difficulties or delays in integrating our operations into new facilities. These difficulties might include delays in the availability of a new facility or problems associated with equipment installation. In addition, any facility that we obtain for production of clinical testing or biodefense products will be subject, on an ongoing basis, to a variety of regulatory requirements including quality systems regulations, international quality standards and other regulatory standards. We may encounter difficulties expanding our manufacturing operations in accordance with these regulations and standards, which could result in manufacturing delays and an inability to meet product demand and our future business prospects could be materially adversely affected.

If we are not successful at identifying and obtaining additional facilities to meet future growth needs, or we are unable to pay for facility enhancements and improvements, our business would suffer.

FAILURE TO MANAGE OUR GROWTH COULD ADVERSELY AFFECT OUR BUSINESS.

We 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 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

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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.

We are continuing the implementation of 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 implementation delays or interruptions, our operations, as well as our ability to manage our growth, could be materially adversely affected.

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 ORIGIN technology. Our current patents or future patents may not adequately protect our technology from being used by our competitors.

Companies may 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:

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

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If we lose some patent protection, our competitive advantage could be eroded, third parties may be able to use our technology without paying us and our revenues would be adversely affected.

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

If our ORIGIN technology were to infringe others' patent rights we could be exposed to the following risks:

- o We or our licensees could be required to alter, or abandon products or processes;
- o We or our licensees could be required to obtain a license from the patent holder;
- o We or our licensees could lose customers that are reluctant to continue using products;
- o We or our licensees could be forced to abandon development work with respect to these products; and
- o We or our licensees could be required to pay damages that could be substantial.

If we or our licensees 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, if at all.

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, if at all, or get additional licenses that we may need on acceptable terms, if at all. 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. If we are not able to adequately redress the unauthorized disclosure of our trade secrets, know-how or other proprietary information, our competitive position may be undermined and our business may 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. From time to time, suppliers may extend lead time, limit supplies or increase prices due to capacity constraints or other factors.

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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 in a timely fashion, we could lose sales as well as customers, and our business would be significantly harmed as a result.

WE DEPEND ON HIGHLY TRAINED AND SKILLED EMPLOYEES AND MANAGEMENT, AND WE MAY NOT

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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 a 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 which would adversely affect our business. 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 who have regulatory, manufacturing and marketing capabilities. If we are not able to hire managers with these skills, or develop expertise in these areas, our business could suffer.

### Regulatory and Government Contract Risks

WE MUST OBTAIN FDA APPROVAL TO MARKET OUR CLINICAL TESTING PRODUCTS, WHICH IS OFTEN COSTLY AND TIME CONSUMING. IF WE DO NOT OBTAIN THE NECESSARY APPROVALS 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 testing 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 testing 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 testing systems are substantially equivalent to diagnostic systems that the FDA has already approved.

If an ORIGEN-based 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 initial FDA review process takes approximately 90 days, but the FDA's review and approval could take longer. In addition, we may not be able to demonstrate substantial equivalence for future testing 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 testing 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 products at all for clinical use in the United States.



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WE ARE SUBJECT TO COMPREHENSIVE 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 government regulations. Government agencies, such as the FDA, Department of Homeland Security, Department of Commerce and the EPA, regulate many of the products that we develop, manufacture and commercialize, including products for clinical testing, biodefense and industrial testing.

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 and expand our product offerings, these costs will increase.

Whether we manufacture products ourselves or contract with another company to manufacture products based on our technology, the FDA and other government agencies will continually review and periodically inspect the manufacturing process. If any of these agencies were to discover a problem with our products, the manufacturing process or the manufacturing facility, they 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, management and disposal of hazardous, radioactive and infectious materials and wastes, the discharge of pollutants into the air and water, and the cleanup of contaminated sites. We could incur substantial costs, including cleanup costs, fines and penalties, claims for damages and loss of permits required for our operations if we fail to comply with these laws or regulations, our business and financial condition could be materially adversely affected.

OUR ABILITY TO OBTAIN AND RETAIN U.S. GOVERNMENT CONTRACTS IS SUBJECT TO UNCERTAINTIES, AND OUR EXISTING GOVERNMENT CONTRACTS MAY BE TERMINATED, WHICH COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS AND PROSPECTS.

The U.S. government contracts that we have, and our ability to secure additional contracts, are subject to uncertainties related to the government's future funding commitments. The future prospects for our biodefense business are also highly sensitive to changes in national and international government policies and funding priorities. Changes in domestic or foreign government policies or priorities, including funding levels through agency or program budget reductions by the U.S. Congress or executive agencies, could materially adversely affect our ability to retain or obtain government contracts, and our business prospects could suffer.

The U.S. government can terminate, suspend or modify any of its contracts with us either for its convenience or if we default by failing to perform under the terms of the applicable contract. A termination or suspension for convenience could result in our having excess capacity, inventory, personnel, unreimbursable expenses or charges or other adverse effects on our financial condition. A termination arising out of our default could expose us to claims for damages and may have a material adverse effect on our ability to compete for future contracts and orders.

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Our U.S. government contracts may span one or more years and may include multiple option years. U.S. government agencies generally have the right not to exercise these option periods for any reason, including lack of funding, or if the agency is not satisfied with our performance of the contract. If the U.S. government terminates any of our contracts our financial condition and operating results could be materially adversely affected.

In addition to unfavorable termination provisions, certain of our U.S. government contracts contain provisions that grant to the U.S. government a license to use inventions made by us in the course of performing the contract, and to authorize others to use those inventions for or on behalf of the government.

OUR BUSINESS COULD BE ADVERSELY AFFECTED BY A NEGATIVE AUDIT BY THE U.S. GOVERNMENT.

U.S. government agencies routinely audit and investigate government contractors. These agencies review a contractor's performance under its contracts. If an audit results in a finding of improper activities, we may be subject to civil and criminal penalties and administrative sanctions, including termination of contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. In addition, we could suffer serious harm to our business reputation if allegations of impropriety were made against us.

COST OVER-RUNS ON OUR CONTRACTS WITH THE U.S. GOVERNMENT COULD SUBJECT US TO LOSSES OR ADVERSELY AFFECT OUR FUTURE BUSINESS.

Our contracts with the U.S. government have been fixed-price contracts and therefore we receive a fixed price irrespective of the actual costs we incur. Consequently, we are required to absorb any costs in excess of the fixed price that may be set forth in the contract. If we are unable to control costs we incur in performing under these contracts, our financial condition and operating results could be materially adversely affected. Cost over-runs also may adversely affect our ability to sustain existing programs and obtain future contract awards.

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 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 tests and other health care products.

Without adequate coverage and reimbursement, consumer demand for clinical tests may decrease. Decreased demand would likely cause sales of our clinical products, and sales by our licensees, to decrease 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 and we expect this to continue. 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.

## INDUSTRY RISKS

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

Product liability is a major risk in marketing products for the clinical testing, biodefense and industrial markets. We may not be able to adequately insure against risk of product liability. 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.

## RISKS OF OUR COMMON STOCK

MEMBERS OF OUR MANAGEMENT TEAM EXERCISE SIGNIFICANT INFLUENCE OVER US AND MAY HAVE SIGNIFICANT INFLUENCE OVER THE OUTCOME OF PROPOSED CORPORATE ACTIONS SUPPORTED OR OPPOSED BY OTHER OF OUR STOCKHOLDERS.

Our officers and directors in the aggregate, own or have the right to purchase, approximately 24% of the outstanding shares of our Common Stock and our Chief Executive Officer owns approximately 19% of the outstanding shares of our Common Stock at June 13, 2003. As a result, certain of our officers or directors may have significant influence over the election of directors and may be able to significantly influence the outcome of proposed corporate actions supported or opposed by other of our stockholders. In addition, our directors could significantly influence any vote related to transactions that may be in the best interests of our stockholders.

PROVISIONS IN OUR CHARTER DOCUMENTS MAY DISCOURAGE POTENTIAL ACQUISITIONS OF OUR COMPANY, EVEN THOSE WHICH THE HOLDERS OF A MAJORITY OF OUR COMMON STOCK MAY FAVOR.

Our certificate of incorporation and bylaws contain provisions that may have the effect of discouraging a third party from making an acquisition of us by means of a tender offer, proxy contest or otherwise. Our certificate of incorporation and bylaws:

- o classify the Board of Directors into three classes, with directors of each class serving for a staggered three-year period;
- o provide that directors may be removed only for cause and only upon the approval of the holders of at least a majority of the voting power of our shares entitled to vote generally in the election of such directors;
- o prohibit stockholders from calling special meetings and prohibit action by the stockholders by written consent;
- o require at least two-thirds of the voting power of our shares entitled to vote generally in the election of directors to alter, amend or repeal the provisions relating to the classified board, removal of directors and action by stockholders described above;

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- o permit the Board of Directors to fill vacancies and newly created directorships on the Board; and
- o contain advance notice requirements for stockholder proposals.

Such provisions would make the removal of incumbent directors more difficult and time-consuming and may have the effect of discouraging a tender offer or other takeover attempt not previously approved by the Board of Directors.

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In 1996, our Board of Directors adopted a shareholder rights plan and declared a dividend of one preferred share purchase right for each share of Common Stock outstanding. A right will also be attached to each share of Common Stock subsequently issued. The rights will have certain anti-takeover effects. The rights are triggered if a person or group of persons other than Samuel J. Wohlstadter, our Chief Executive Officer, and his affiliates or associates, heirs, trusts or foundations to which he has transferred shares of our Common Stock acquires 15.0% or more of our Common Stock or announces a tender offer that would result in that person or group of persons acquiring 15.0% or more of our Common Stock on terms not approved by our Board of Directors. If triggered, the rights would cause substantial dilution to the person or group of persons that caused them to be triggered. The rights could discourage or make more difficult a merger, tender offer or other similar transaction.

Under our certificate of incorporation, our Board of Directors also has the authority to issue preferred stock in one or more series and to fix the powers, preferences and rights of any such series without stockholder approval. The Board of Directors could, therefore, issue, without stockholder approval, preferred stock with voting and other rights that could adversely affect the voting power of the holders of Common Stock and could make it more difficult for a third party to gain control of us. In addition, under certain circumstances, Section 203 of the Delaware General Corporation Law makes it more difficult for an "interested stockholder", or generally a 15% stockholder, to effect various business combinations with a corporation for a three-year period.

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. For example, from January 1, 2003 until June 27, 2003, the closing price for a share of our Common Stock has ranged from \$30.76 to \$45.02.

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 price of our Common Stock could be affected by:

- o new product introductions;
- o innovations by competitors;
- o our competitors' announcements of their financial results;
- o changes in financial estimates and recommendations by security analysts;

- o disputes over patents or other proprietary rights;
- o new litigation or developments in the Roche litigation;
- o publicity;
- o regulations;
- o economic, business and other market conditions; and

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

In addition, if our revenues or earnings in any period fail to meet the investment community's expectations, there could be an immediate adverse impact on 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, your investment in our Common Stock will be diluted. In addition, we currently have convertible debenture holders who have the right to convert their debentures into Common Stock. Your investment in our Common Stock may be diluted if these convertible debenture holders decide to convert their securities in the future. Moreover, your investment in our Common Stock could be further diluted if we issue additional shares of Common Stock or securities convertible into shares of 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 shares of our Common Stock could cause the market price of our Common Stock to decrease.

## ITEM 2. PROPERTIES

Our principal administrative, marketing, manufacturing and research and development facilities consist of approximately 132,000 square feet located in four buildings in Gaithersburg, Maryland. We have an additional 21,000 square feet of leased research and development, sales and office facilities in McLean, Virginia; San Diego, California; New York, New York, the District of Columbia; and Oxfordshire, England. Our leases expire at various times from fiscal 2004 through 2010.

MSD utilizes approximately 33% of our facilities and is allocated a corresponding portion of the expense associated with these facilities.

We believe our current facilities should be adequate for our immediate business requirements but believe additional facilities may be required as we expand our business operations. We are continuously evaluating our facilities requirements in light of our anticipated growth needs. See ITEM 1 - "Business - Risk Factors -- Risks of our Business" and ITEM 7 - "Management's Discussion and Analysis of Financial Condition and Results of Operations."

## ITEM 3. LEGAL PROCEEDINGS

ROCHE

In 1997, we filed a lawsuit against Roche in the District Court. The lawsuit arose out of the Roche license agreement, under which we licensed to Roche certain rights to develop and commercialize diagnostic products based on our ORIGEN technology. In the Roche litigation, we alleged among other things that Roche failed to perform certain material obligations under the Roche license agreement and engaged in unfair competition against us. The jury trial was completed in January 2002, and the jury rendered a verdict that Roche had materially breached the license agreement, had violated its duty to us of good faith and fair dealing, and had engaged in unfair competition against us.

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In February 2002, the District Court issued a final order of judgment that confirmed the jury's decisions to award \$105 million in compensatory damages and \$400 million in punitive damages, entitled us to terminate the Roche license agreement, and directed Roche to grant to us for use in our retained fields a license to certain improvements. Roche was also ordered, at its sole cost and expense, to deliver such improvements to us and to provide all other information and materials required or necessary to enable us to commercialize these improvements. Improvements, as defined in the final order of judgment, include Roche's Elecsys 1010, 2010 and E170 lines of clinical diagnostic immunoassay analyzers, the tests developed for use on those systems, and certain aspects of Roche's nucleic acid amplification technology called PCR. The final order of judgment also bars 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 technology.

Roche filed counterclaims against us alleging, among other things, that we breached the Roche license agreement by permitting Eisai, another of our licensees, to market certain ORIGEN-based products in Japan. The final order of judgment found in our favor and against Roche on all of Roche's counterclaims, except for one for which we were ordered to pay \$500,000.

In April 2002, the District Court affirmed a final order of judgment that awarded us \$505 million in damages, confirmed our right to terminate the Roche license agreement, and directed Roche to grant us for use in our retained fields a license to improvements developed or acquired by Roche in the course of the Roche license agreement, including Roche's Elecsys and E170 diagnostics product lines. Roche appealed certain aspects of the final order of judgment to the Appellate Court. In connection with that appeal, Roche posted a \$600 million bond to support its financial obligations to us under the final order of judgment. During the appeal process Roche is obligated to continue to comply with the terms of the Roche license agreement, including its obligation to continue to pay us royalties on Roche's sales of royalty bearing products and to share and deliver improvements. Roche's obligations to pay the \$505 million of monetary damages awarded to us is suspended until completion of the appeal process. On February 24, 2003, the Appellate Court heard oral arguments on the appeal by Roche of the final order of judgment. We anticipate that the decision of the Appellate Court will be issued in mid-2003.

We have voluntarily agreed not to terminate the Roche license agreement until the Appellate Court determines that we are entitled to do so; however, we have notified Roche that the Roche license agreement will terminate immediately in the event the Appellate Court issues an opinion confirming judgment rendered by the District Court in the Roche litigation that we are entitled to terminate the Roche license agreement.

We have engaged in settlement discussions with Roche. We cannot assure you that we will be able to settle the Roche litigation in a timely manner, if at all. In addition, although we are vigorously opposing Roche's appeal, Roche may ultimately prevail in its attempt to modify or overturn the judgment issued in this litigation.

See "- Risk Factors - Roche Litigation".

#### Other Proceedings

In 2001, Brown Simpson Strategic Growth Fund L.P., Brown Simpson Strategic Growth Fund, Ltd. and Brown Simpson Partners I (collectively Brown Simpson) and Laurence Paskowitz initiated separate shareholder derivative lawsuits for and on behalf our shareholders in the Circuit Court for Montgomery County, Maryland (Circuit Court) against four of our current directors, two former directors, three executive officers and us as a nominal defendant. The complaints alleged breach of fiduciary duties by the named individual defendants in connection with transactions between us and other entities in which certain directors and officers were alleged to have an interest, including MSD.

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Both lawsuits sought principally the following: that the defendants hold in trust and be required to account for and restore to us damages that we have allegedly sustained by reason of the allegations and relief relating to board and management composition. The Paskowitz complaint also sought damages for a class of our shareholders for direct claims against the individual defendants. The complaints did not include any claims against us.

In May 2002, the Circuit Court issued an opinion and order dismissing all claims asserted against all of the defendants in both cases. No appeal was filed by the Brown Simpson plaintiff and the decision in that case is now final. The Paskowitz plaintiff filed an appeal to the Court of Special Appeals in Maryland seeking review only for one direct claim.

A final decision of the Court of Special Appeals was issued in March 2003 affirming the dismissal of the complaint by the Circuit Court. No appeal was filed and the decisions dismissing all claims in all of these cases are now final.

We are involved, from time to time, in various other routine legal proceedings arising out of the normal and ordinary operation of our business which we do not anticipate will have a material adverse impact on our business, financial condition, results of operations or cash flows.

#### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted to a vote of our security holders during the fourth quarter of the fiscal year covered by this report.

#### PART II

#### ITEM 5. MARKET FOR COMPANY'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Our Common Stock is quoted on The Nasdaq National Market under the symbol "IGEN". As of May 28, 2003, there were approximately 11,400 holders of record of our Common Stock. No cash dividends have been paid on the Common Stock to date, and we currently intend to retain any earnings for development of our business.

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The following table sets forth, for periods indicated, the range of high and low closing sales prices of the Common Stock as quoted on The Nasdaq National Market.

FISCAL 2003 -----	HIGH -----	LOW -----
First Quarter	\$ 42.20	\$ 30.99
Second Quarter	\$ 34.70	\$ 27.35
Third Quarter	\$ 44.42	\$ 26.78
Fourth Quarter	\$ 45.02	\$ 30.76
 FISCAL 2002 -----		
First Quarter	\$ 26.00	\$ 16.75
Second Quarter	\$ 32.72	\$ 23.55
Third Quarter	\$ 40.52	\$ 26.98
Fourth Quarter	\$ 44.23	\$ 35.84

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### ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below with respect to the Company's consolidated statements of operations for each of the years in the three-year period ended March 31, 2003 and with respect to the consolidated balance sheets at March 31, 2003 and 2002 are derived from, and are qualified by reference to, the consolidated financial statements that have been audited by Deloitte & Touche LLP, independent auditors, and are included elsewhere in this Form 10-K. The statement of operations data for each of the years in the two-year period ended March 31, 2000, and the balance sheet data at March 31, 2001, 2000 and 1999 are derived from audited financial statements not included in this Form 10-K.

The following selected financial data should be read in conjunction ITEM 1 - Business - Risk Factors and ITEM 8 - Consolidated Financial Statements.

	Years ended Mar -----		
	2003 -----	2002 -----	2001 -----
	(In thousands, except per		
Statements of Operations Data:			
Revenues:			
Product sales	\$ 18,986	\$ 14,583	\$ 10,913
Royalty income	36,650	26,768	16,157
Contract fees	830	696	4,292
	-----	-----	-----
Total	56,466	42,047	31,362
	-----	-----	-----



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## Operating Costs and Expenses:

Product costs (1)	9,059	6,070	3,625
Research and development	23,714	27,203	28,497
Selling, general and administrative	24,741	24,031	16,849
Litigation related costs (2)	5,401	11,299	13,782
	-----	-----	-----
Total operating expenses	62,915	68,603	62,753
	-----	-----	-----
Loss from operations	(6,449)	(26,556)	(31,391)
Other (expense) income, net	(3,941)	(5,023)	(4,867)
Equity in loss of affiliate (3)	(17,598)	(10,947)	-
	-----	-----	-----
Loss before cumulative effect of accounting change	(27,988)	(42,526)	(36,258)
Cumulative effect of accounting change (4)	-	-	(6,995)
	-----	-----	-----
Net loss	(27,988)	(42,526)	(43,253)
Preferred dividends	(201)	(1,402)	(2,052)
	-----	-----	-----
Net loss attributed to common stockholders	\$ (28,189)	\$ (43,928)	\$ (45,305)
	=====	=====	=====
Basic and diluted net loss per common share	\$ (1.19)	\$ (2.20)	\$ (2.84)
	=====	=====	=====
Shares used in computing net loss per common share	23,590	19,947	15,929
	=====	=====	=====

	March 31,			
	-----	-----	-----	-----
	2003	2002	2001	
	-----	-----	-----	-----
Balance Sheet Data:	(In thousands)			
Cash, cash equivalents and short term investments	\$ 34,245	\$ 74,819	\$15,089	\$38
Working capital	38,955	71,371	9,096	38
Investment in affiliate (3)	9,164	6,243	-	
Total assets	75,266	106,198	39,133	57
Long term obligations	44,436	48,192	56,821	59
Accumulated deficit	(228,011)	(200,023)	(157,497)	(114)
Stockholders' equity (deficit)	12,741	38,519	(36,373)	(11)

(1) During the year ended March 31, 2002, product costs included a write-off of \$1.1 million attributable to costs associated with the TRICORDER detection modules, which had previously been recorded as fixed assets.

(2) During the year ended March 31, 2002, litigation related costs have been reduced by \$5.7 million due to a reimbursement payment received from F. Hoffman LaRoche, Ltd. (Hoffman LaRoche), the parent company of Roche, in connection with the settlement of certain patent infringement litigation with them.

(3) Since inception of our MSD joint venture, we have utilized the equity method to account for the investment in MSD. In conjunction with entering into the MSD agreements and taking into account the progress made by MSD in the development of its products, we determined that, after July 1, 2001, contributions to MSD would be made based on the future investment benefit expected to be obtained by us. Therefore, our share of MSD losses, since July 1, 2001, has been recorded as Equity in Loss of Affiliate. Prior to this date, we accounted for our equity investments in MSD as research and development funding and accordingly, recorded all MSD investments as research and development expenses as incurred. These research and development expenses totaled \$2.4 million, \$8.3 million, \$4.5 million and \$3.6 million for the years ended March 31, 2002, 2001, 2000 and 1999, respectively. During the years ended March 31, 2003, 2002, 2001, 2000 and 1999, operating costs allocated to MSD by us in connection with shared personnel and facilities totaled \$11.9 million, \$11.4 million, \$5.6 million, \$3.7 million and \$3.2 million, respectively. Since July 1, 2001, these allocated operating costs reduced certain Operating Costs and Expenses and increased Equity in Loss of Affiliate.

(4) For a description of this accounting change, see ITEM 8 - Consolidated Financial Statements - Notes to Consolidated Financial Statements - Note 1-Organization and Summary of Significant Accounting Policies - Cumulative Effect of Accounting Change.

#### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The numbers in this Management's Discussion and Analysis of Financial Condition and Results of Operations may not tie directly to the numbers in our Consolidated Financial Statements due to rounding.

##### OVERVIEW

We and our licensees develop, manufacture and market products based on our ORIGIN technology. We believe that our ORIGIN technology, which permits the detection and measurement of biological substances, offers significant advantages over competing detection and measurement methods by providing a unique combination of speed, sensitivity, flexibility and throughput in a single technology platform. Our ORIGIN technology is incorporated into our and our licensees' instrument systems and related consumable reagents, which are the fluids used in the performance of tests, or assays, on such instrument systems. In addition, we offer assay development and other services used to perform analytical testing.

Our strategy for our ORIGIN technology has been and continues to be based on entering into license arrangements and collaborations with third parties that can assist in our commercialization efforts while at the same time directly developing and commercializing our own products.

**LICENSE ARRANGEMENTS AND COLLABORATIONS.** We have entered into license arrangements and collaborations with established health care companies to commercialize our ORIGIN technology for clinical testing, which is the diagnostic testing of patient samples to measure the presence of disease and monitor medical conditions. Our licensees have developed multiple products lines for this market based on our ORIGIN technology, and have sold or placed approximately 9,000 ORIGIN based systems with customers worldwide.

These sales and placements have been made predominantly by Roche, which has an exclusive license for our ORIGIN technology for certain segments of the clinical testing market and is the world's leading provider of clinical testing products. Roche has adopted our ORIGIN technology for its Elecsys immunodiagnostic product line. We receive royalties and contract fees from Roche and our other licensees, which accounted for 66% of our revenue in fiscal 2003. For a discussion of our relationship with Roche and the Roche litigation, see "--License Arrangements and Collaborations--Roche", "--Risk Factors-Roche Litigation" and ITEM 3 -- "Legal Proceedings".

DIRECT COMMERCIALIZATION EFFORTS. We also directly develop and commercialize our ORIGIN technology. We have developed, and continue to develop, ORIGIN-based products for the following worldwide markets. Many of our instruments and assays have been and are being designed to serve customers across multiple markets.

- o BIODEFENSE AND INDUSTRIAL TESTING - We are commercializing our ORIGIN technology for use in the emerging markets for biodefense and industrial testing. The biodefense market includes products for the detection of bacteria, viruses and toxins that may pose a military or public health threat. Over the past year, we have worked with numerous departments within the Department of Defense (DOD) and other U.S. government agencies to develop ORIGIN-based products for the detection of biological agents such as anthrax, staphylococcus enterotoxin B and botulinum toxin, among others. We are also commercializing our ORIGIN technology for use in the emerging industrial market for the detection of foodborne and waterborne disease causing pathogens. We have begun to sell our first products for this market, the PATHIGEN panel of tests for E. coli O157, Salmonella, Campylobacter and Listeria, which we sell primarily as a quality control test method to food producers, food processors and contract laboratories for the food industry.
- o LIFE SCIENCE - We are commercializing our ORIGIN technology for use in drug discovery and development that is performed by pharmaceutical and biotechnology companies, universities and other research organizations. Certain of our ORIGIN-based systems are used by pharmaceutical and biotechnology companies in all phases of drug discovery, including:
  - o validating targets identified through genomics;
  - o screening of large numbers of compounds generated through combinatorial chemistry;
  - o re-testing and optimization of lead compounds; and
  - o clinical trial testing of drug candidates.

We believe the ORIGIN-based systems used in this market provide a number of advantages relative to other drug discovery technologies, including enhanced sensitivity and greater ease and speed of assay formatting.

- o CLINICAL TESTING - We are developing our ORIGIN technology to be used in certain fields in the clinical testing market, particularly to perform tests in decentralized sites outside of central hospital laboratories and clinical reference laboratories. Our present strategy is to focus our product development efforts on patient care centers such as physicians' offices, ambulatory clinics, hospital emergency rooms, surgical and intensive care units, hospital satellite laboratories and nurses' stations. We believe our ORIGIN technology permits development of a system that can

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provide accurate results to a physician rapidly, thereby permitting the physician to make a more timely decision regarding the patient's course of treatment.

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Results of operations in the future are likely to fluctuate substantially from quarter to quarter as a result of various factors, which include the volume and timing of orders for M-SERIES systems or other products; the timing of instrument deliveries and installations; the success of M-SERIES systems upgrades and enhancements; the amount of revenue recognized from royalties and other contract revenues; the mix of products sold; whether instruments are sold to or placed with customers; the timing of the introduction of new products; the volume and timing of product returns and warranty claims; our competitors' introduction of new products; the amount of expenses incurred in connection with the operation of the business, including costs associated with the transfer of improvements from Roche to us, legal fees, research and development costs and sales and marketing costs, including costs for upgrading the M-SERIES system; the timing of and results from the currently pending appeal of our judgment against Roche; the timing of termination of the Roche license agreement, if at all; whether POL customers' contracts are renewed and whether Roche will continue to supply service and assays to POL customers; our share of losses in affiliate; the continued supply of the materials that we use in our products; our manufacturing capabilities and the volume and timing of product returns and warranty claims.

We have experienced significant operating losses each year since inception and expect those losses to continue. Losses have resulted from a combination of lower royalty revenue than we believe we are entitled to under the Roche license agreement, costs incurred in research and development, Roche litigation costs, our share of losses in affiliate, 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, research and product development, general and administrative costs and equity in loss of affiliate, offset in part by lower Roche litigation costs. Our ability to become profitable in the future will be affected by, among other things, our ability to expand the commercialization of existing products; upgrade and enhance the M-SERIES family of products; introduce new products into the market; generate higher revenue; develop marketing, sales and distribution capabilities cost-effectively; and continue existing collaborations or establish successful new collaborations with corporate partners to develop and commercialize products that incorporate our technologies.

### RESULTS OF OPERATIONS

YEARS ENDED MARCH 31, 2003 AND 2002.

**REVENUES.** Total revenues for the fiscal year ended March 31, 2003 increased by approximately \$14.5 million or 34% to \$56.5 million from \$42.0 million in fiscal 2002. The revenue growth for fiscal 2003 was due to increases in all revenue categories - product sales, royalty income and contract fees.

Product sales were \$19.0 million in fiscal 2003, an increase of 30% over the prior year's product sales of \$14.6 million. This growth in product sales was from the M-SERIES family of products (\$900,000), and new sales of biodefense products for detection of biological agents or toxins (\$3.5 million). We anticipate continued increases in biodefense related sales as a result of our ongoing biodefense initiatives. We have a contract with the DOD for the production of tests for the detection of specific toxins in environmental samples. This contract provides for product sales at the election of the government of up to a total of \$23.0 million over four years, with approximately \$7.0 million of product sales through June 2004. For each contract year after

June 2004, the DOD, at its option, may elect to purchase products from us but has no obligation to do so. Sales to POL customers totaling \$2.5 million were unchanged from the prior year. We began serving these POL customers in June 2000 when Roche transferred the customers in order to comply with a court ordered preliminary injunction. In February 2002, the District Court issued a final order of judgment against Roche, which does not require Roche to renew existing POL contracts, some of which are scheduled to expire during fiscal 2004. In the event POL customer contracts are not renewed, future POL product sales from these contracts would experience a decline.

Royalty income was \$36.7 million in fiscal 2003, an increase of 37% over the prior year's royalty income of \$26.8 million. Royalties from Roche represent approximately \$35.5 million (97%) of the total royalty income for fiscal 2003 as compared to approximately \$25.7 million (96%) for fiscal 2002.

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These increases are attributable to higher Roche sales of its Elecsys and E170 product lines, which are based on our ORIGEN technology that was licensed to Roche under the Roche license agreement, as well as certain modifications made by Roche to their methodology for computing and paying royalties as a result of the Roche litigation. While we are not satisfied that Roche is properly calculating and paying the required royalties, the recent changes in the way in which Roche calculates and pays its royalties to us is expected to have a continued positive impact on our royalty income in future periods. We have voluntarily agreed not to terminate the Roche license agreement until the Appellate Court determines that we are entitled to do so; however, we have notified Roche that the Roche license agreement will terminate immediately in the event the Appellate Court issues an opinion confirming judgment rendered by the District Court in the Roche litigation that we are entitled to terminate the Roche license agreement. In the event the Roche license agreement is terminated, our royalty income from Roche would cease. See ITEM 3 - "Legal Proceedings".

Contract fees in the current fiscal year increased to \$830,000 from \$696,000 last year. These fees related primarily to work completed in conjunction with the development of clinical assays for Roche. In the event the Roche license agreement is terminated, revenue from these fees would cease.

OPERATING COSTS AND EXPENSES. Product costs were \$9.1 million (48% of product sales) for fiscal 2003 compared to \$6.1 million (42% of product sales) for fiscal 2002. Product costs for fiscal 2003, as a percentage of product sales, increased due to costs incurred in connection with the recent launch of our new M-SERIES 384 instrument for life science customers and related warranty costs (8% of product sales in the current year), third party leasing costs incurred by us related to instruments being used by POL customers, which were previously paid by Roche (3% of product sales in the current year), as well as a change in the product mix (instrumentation vs. consumable reagents) from the prior year.

Included in product costs for fiscal 2002 is a write-off of \$1.1 million of TRICORDER detection modules costs, previously recorded as fixed assets. The TRICORDER modules are incorporated into customers' M-SERIES systems and continue to be utilized by customers to generate ongoing reagent product sales.

Research and development expenses decreased \$3.5 million (13%) in fiscal year 2003 to \$23.7 million from \$27.2 million in fiscal year 2002. Of the \$27.2 million in fiscal 2002, \$2.4 million was spent funding MSD joint venture activities prior to the amendment and extension of the MSD joint venture agreements in August 2001. See "--Equity in Loss of Affiliate" below for a discussion of MSD activity in fiscal 2003 and 2002. Research and development expenses primarily relate to ongoing development costs and product enhancements associated with the M-SERIES family of products, development of new assays for

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the life science and clinical markets, and research and development of new systems and technologies, including hospital point-of-care products. We expect research and development costs to increase as product development and core research continue to expand, including costs associated with our efforts in developing biodefense testing products.

Selling, general and administrative expenses were \$24.7 million in fiscal 2003, an increase of \$700,000 (3%) over the prior year's total of \$24.0 million. This increase was primarily attributable to our hiring additional personnel and support costs required to support the growth in sales and customers.

Costs related to the Roche litigation, which include financial and legal advisory fees associated with settlement discussions, were \$5.4 million and \$11.3 million for fiscal 2003 and 2002, respectively. The fiscal 2002 amount is net of a \$5.7 million settlement payment for a patent infringement action made by Hoffman LaRoche to us. The decline in litigation costs in the current year reflects the lower costs associated with moving from the trial phase to the appellate phase of the Roche litigation.

Since 1995, we have engaged the law firm of Wilmer, Cutler & Pickering to provide legal services in connection with the Roche litigation and various other matters. A partner of the law firm, Richard W. Cass, is one of our directors. In addition, Jennifer M. Drogula, who became the daughter-in-law of our Chief Executive Officer in March 2002, is a partner of the firm.

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We recorded approximately \$1.8 million and \$11.2 million in legal fees with the law firm for the years ended March 31, 2003 and 2002, respectively.

We have also engaged the law firm of Hale and Dorr LLP to provide legal services in connection with the Roche litigation and otherwise. We first engaged this law firm in 1994. Deborah Wohlstadter, the wife of Jacob Wohlstadter and the daughter-in-law of our Chief Executive Officer since December, 2001, is a junior partner of that law firm. We recorded approximately \$396,000 in legal fees with that law firm for the year ended March 31, 2003.

Our Chief Executive Officer, Samuel J. Wohlstadter, is the principal and controlling stockholder, a director and the Chief Executive Officer of each of Wellstat Biologics Corporation (Wellstat Biologics), Wellstat Therapeutics Corporation (Wellstat Therapeutics), Hyperion Catalysis International (Hyperion) and Proteinix Corporation (Proteinix). Our President and Chief Operating Officer, Richard J. Massey, is also a director of Hyperion and a less than 10% stockholder in Proteinix. These companies are therefore considered our affiliates for the purpose of this discussion. We have shared services arrangements with each of these affiliated companies. These shared services include accounting and finance, human resources and other administrative services, as well as facility related costs and services. Shared services costs allocated to these companies totaled \$1.0 million and \$1.3 million for the years ended March 31, 2003 and 2002, respectively, which reduced certain Operating Costs and Expenses for the respective years. Amounts allocated to these affiliated companies are calculated and billed monthly based upon costs incurred by the Company and are determined through allocation methods that include time spent and square footage utilized. Amounts due from affiliated companies under the shared services arrangements were approximately \$200,000 and \$100,000 at March 31, 2003 and 2002, respectively which were paid subsequent to each respective year-end. See ITEM 13 -- "Certain Relationships and Related Party Transactions".

INTEREST AND OTHER EXPENSE. Interest and other expense, net of interest income, were \$3.9 million in fiscal 2003 and \$5.0 million in fiscal 2002. This decrease

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in net interest expense resulted from a growth in interest income in the current year due to a higher average cash and investment balance, as well as a reduction of interest expense on current year debt service.

EQUITY IN LOSS OF AFFILIATE. MSD is a joint venture formed by MST and us in 1995. MSD was formed for the development and commercialization of products utilizing a propriety combination of MST's multi-array technology together with our technology. In conjunction with entering into the MSD agreements and taking into account the progress made by MSD in the development of its products, we determined that future contributions to MSD would be made based on the future investment benefit we expect to obtain. Accordingly, our contributions to MSD since July 1, 2001 have been recorded as Investment in Affiliate and we have recorded approximately 100% of MSD's losses since that date as Equity in Loss of Affiliate. For the year ended March 31, 2003, our Equity in Loss of Affiliate totaled \$17.6 million compared to \$10.9 million in the prior year. This increase is due to higher losses incurred by MSD in fiscal 2003 (\$4.3 million), as well as \$2.4 million of fiscal 2002 MSD costs incurred prior to July 1, 2001 that were recorded as research and development expenses. See ITEM 1 -- "Business-License Arrangements and Collaborations - Meso Scale Diagnostics, LLC", and ITEM 13 -- "Certain Relationships and Related Transactions".

NET LOSS. The net loss for fiscal year 2003 was \$28.0 million (\$1.19 per common share, after consideration of the effect of preferred dividends) compared to a net loss of \$42.5 million (\$2.20 per common share, after consideration of the effect of preferred dividends) in fiscal year 2002. As of March 31, 2003, we had net operating loss and general business credit tax carryforwards of approximately \$213.6 million, which expire at various times through 2023, including \$6.8 million during 2004. Our ability to utilize net operating loss and general business credit tax carryforwards may be subject to an annual limitation in future periods pursuant to the "change in ownership rules" under Section 382 of the Internal Revenue Code of 1986, as amended.

YEARS ENDED MARCH 31, 2002 AND 2001.

REVENUES. Total revenues for the fiscal year ended March 31, 2002 increased by approximately \$10.6 million or 34% to \$42.0 million from \$31.4 million in fiscal 2001. The revenue growth for fiscal 2002 was due to increases in product sales and royalty income.

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Product sales were \$14.6 million in fiscal 2002, an increase of 34% over the prior year's product sales of \$10.9 million. This growth in product sales was led by the M-SERIES family of products (\$3.2 million), as well as, the revenue generated from the sale of clinical diagnostic assays to POL customers in the United States, which increased by \$500,000. We began serving these POL customers in June 2000 when Roche transferred the customers in order to comply with a court ordered preliminary injunction. In February 2002, the District Court issued a final order of judgment against Roche which does not require Roche to renew existing POL contracts, some of which are scheduled to expire during fiscal year 2004.

Royalty income was \$26.8 million in fiscal 2002, an increase of 66% over the prior year's royalty income of \$16.2 million. Royalties from Roche represent approximately \$25.7 million (96%) of the total royalty income for fiscal 2002 as compared to approximately \$15.3 million (94%) for fiscal 2001. These increases are attributable to higher Roche sales of its Elecsys and E170 product lines, which are based on our ORIGEN technology that was licensed to Roche under the Roche license agreement, as well as certain modifications made by Roche to their methodology for computing royalties as a result of the Roche litigation.

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Contract revenue in fiscal 2002 decreased to \$696,000 from \$4.3 million in fiscal 2001. The 2002 fees related primarily to work completed in conjunction with the development of assays for Roche. The prior year's contract fees were primarily from non-recurring amounts received in connection with our alliance with Bayer Diagnostics.

OPERATING COSTS AND EXPENSES. Product costs were \$6.1 million (42% of product sales) for fiscal 2002 compared to \$3.6 million (33% of product sales) for fiscal 2001. Included in product costs for fiscal 2002 is a write-off of \$1.1 million of TRICORDER detection modules costs, previously recorded as fixed assets. The TRICORDER modules are incorporated into customers M-SERIES systems and continue to be utilized by customers to generate ongoing reagent product sales. The impact on prior individual annual periods was not significant.

Research and development expenses decreased \$1.3 million (5%) in fiscal year 2002 to \$27.2 million from \$28.5 million in fiscal year 2001. Funding of the MSD joint venture activities prior to the amendment and extension of the MSD joint venture agreements in August 2001 was \$2.4 million in 2002 and \$8.3 million in 2001. See "--Equity in Loss of Affiliate" below for a discussion of MSD activity in fiscal 2002. The 2002 increase in other research and development expense of \$4.6 million (23%) is primarily due to ongoing development costs and product enhancements associated with the M-SERIES family of products, development of new assays for the life sciences market and research and development of new systems and technologies, including hospital point-of-care products.

Selling, general and administrative expenses were \$24.0 million in fiscal 2002, an increase of \$7.1 million (43%) over the prior year's total of \$16.9 million. This increase was primarily attributable to additional personnel costs of \$4.6 million required to support the growth in sales and customers, as well as legal and other expenses of \$1.6 million largely associated with the amendment and extension of the MSD agreements.

Costs related to the Roche litigation were offset by a settlement payment we received from Hoffman LaRoche related to patent litigation during fiscal 2002 regarding a claim by Hoffman LaRoche that we and one of our licensees infringed on a patent held by Hoffman LaRoche. Under the terms of the settlement, Hoffman LaRoche dismissed, with prejudice, all claims against us, reimbursed us for our legal fees incurred in defending this litigation which totaled approximately \$5.7 million and granted us a fully paid-up, perpetual, worldwide, non-exclusive license (with the right to sublicense) under the patent in suit. Absent this settlement, costs related to our litigation increased \$3.2 million (23%) to \$17.0 million in fiscal 2002 from \$13.8 million in fiscal 2001. The increases are attributable to expanded activities in several areas, including pre-trial motions and the preparation and conduct of the trial that ran from October 2001 through January 10, 2002. The increased litigation costs also included financial and legal advisory fees associated with settlement discussions with Roche.

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Since 1995, we have engaged the law firm of Wilmer, Cutler & Pickering to provide legal services in connection with the Roche litigation and various other matters. A partner of the law firm, Richard W. Cass, is one of our directors. In addition, Jennifer M. Drogula, who became the daughter-in-law of our Chief Executive Officer in March 2002, is a partner of the firm. We recorded approximately \$11.2 million and \$5.8 million in legal fees with the law firm for the years ended March 31, 2002 and 2001, respectively.

Our Chief Executive Officer, Samuel J. Wohlstadter, is the principal and controlling stockholder, a director and the Chief Executive Officer of each of



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Wellstat Biologics, Wellstat Therapeutics, Hyperion and Proteinix. Our President and Chief Operating Officer, Richard J. Massey, is also a director of Hyperion and a less than 10% stockholder in Proteinix. These companies are therefore considered our affiliates for the purpose of this discussion. We have shared services arrangements with each of these affiliated companies. These shared services include accounting and finance, human resources and other administrative services, as well as facility related costs and services. Shared services costs allocated to these companies totaled \$1.3 million and \$1.4 million for the years ended March 31, 2002 and 2001, respectively, which reduced certain Operating Costs and Expenses for the respective years. Amounts allocated to affiliated companies are calculated and billed monthly based upon costs incurred by us and are determined through allocation methods that include time spent and square footage utilized. The amounts due from affiliated companies under the shared services arrangements was approximately \$100,000 at March 31, 2002, which was paid subsequent to year-end. See ITEM 13 -- "Certain Relationships and Related Party Transactions".

INTEREST AND OTHER EXPENSE. Interest and other expense, net of interest income, were \$5.0 million in fiscal 2002 and \$4.9 million in fiscal 2001.

EQUITY IN LOSS OF AFFILIATE. In conjunction with entering into the MSD agreements and taking into account the progress made by MSD in the development of its products, we determined that future contributions to MSD would be made based on the future investment benefit we expect to obtain. Accordingly, our contributions to MSD since July 1, 2001 have been recorded as Investment in Affiliate and we have recorded approximately 100% of MSD's losses since this date as Equity in Loss of Affiliate. MSD incurred a net loss of \$13.5 million for the year ended March 31, 2002 of which \$10.9 million was recorded as Equity in Loss of Affiliate. In addition, in connection with entering into the MSD agreements in August 2001, we transferred certain equipment and leasehold improvements to MSD in an amount of \$839,000, which amount is included in the contributions to MSD in such year. See ITEM 1-"Business-License Arrangements and Collaborations - Meso Scale Diagnostics, LLC", and ITEM 13- "Certain Relationships and Related Transactions".

NET LOSS. The net loss for fiscal year 2002 was \$42.5 million (\$2.20 per common share, after consideration of the effect of preferred dividends) compared to a net loss of \$43.3 million (\$2.84 per common share, after consideration of the effect of preferred dividends) in fiscal year 2001. The loss in the prior year comparable period included a one-time, non-cash charge of \$7.0 million (\$0.44 per share) to record the cumulative effect of an accounting change resulting from the adoption of Emerging Issue Task Force Release No. 00-27.

### LIQUIDITY AND CAPITAL RESOURCES

We have financed operations through the sale of preferred and common stock, debt financings and the placement of convertible debentures. In addition, we have received funds from research and licensing agreements, sales of our ORIGEN line of products and royalties from product sales by licensees. As of March 31, 2003, we had \$34.2 million in cash, cash equivalents and short-term investments, with working capital of \$39.0 million.

Net cash used in operations was \$10.0 million, \$27.0 million and \$27.4 million during the years ended March 31, 2003, 2002 and 2001, respectively. The decrease in cash used in 2003 was due primarily to a reduction in the current year's net loss, as compared to prior years.

We used approximately \$3.3 million, \$5.6 million, and \$4.9 million of cash for

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the acquisition of equipment and leasehold improvements during the years ended March 31, 2003, 2002 and 2001, respectively. Our investments in MSD totaled \$20.5 million, \$19.6 million and \$8.3 million for the years ended March 31, 2003, 2002 and 2001, respectively.

We believe material commitments for capital expenditures and additional or expanded facilities may be required in a variety of areas, such as product development programs. We have not, at this time, made material commitments for any such capital expenditures or facilities and have not secured additional sources, if necessary, to fund such commitments. If we are unable to fund such commitments, we may have to scale back or even eliminate some programs or plans.

Net cash used for financing activities was \$6.3 million during the year ended March 31, 2003, while net cash provided by financing activities was \$108.8 million and \$9.0 million during the years ended March 31, 2002 and 2001, respectively. The net use of funds in 2003 was primarily due to debt service of \$5.1 million and Series B Convertible Preferred dividend payments of \$3.4 million, offset by a loan repayment of \$1.6 million. The net provision of funds in 2002 and 2001 was primarily due to cash received from the issuance of common stock of \$116.8 million and \$12.9 million, respectively, offset by debt service, Series B Convertible Preferred dividend payments and, in 2001, an increase in restricted cash totalling \$8.0 million and \$3.9 million, respectively. During fiscal 2003, all Series B Convertible Preferred shares were converted into common stock and there are no remaining Series B shares outstanding.

As of March 31, 2003, our material future obligations were as follows:

	Years Ended March				
Contractual Obligations (in thousands)	Total	2004	2005	2006	
Note payable	\$18,065	\$ 5,523	\$ 6,008	\$ 6,534	\$
Subordinated convertible debentures	35,000	-	35,000	-	
MSD funding commitment	20,659	20,659	-	-	
Operating and capital leases	6,188	2,185	2,334	653	
Total contractual obligations	\$79,912	\$28,367	\$43,342	\$ 7,187	\$

MSD is a joint venture formed by MST and us in 1995. Under the MSD agreements, our funding commitment is based on an annual budget of MSD approved by an independent committee of our Board of Directors. Our funding commitment may be satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. An independent committee of our Board of Directors approved funding for MSD for the period from January 1, 2003 to November 30, 2003 in an amount of \$20.6 million, subject to a permitted variance of fifteen percent. As of March 31, 2003, our remaining funding commitment to MSD was \$17.0 million. In addition, prior to November 30, 2003, we would also pay approximately \$3.7 million to MSD related to the permitted budget variance from prior years, which is included in the MSD funding commitment in the table above. For the years ended March 31, 2003, 2002 and 2001, we made total contributions to MSD of \$20.5 million, \$19.6 million and \$8.3 million, respectively. Operating leases in the table above excludes amounts expected to be allocated to MSD to meet a portion of our funding commitment.

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The MSD joint venture agreement will expire on November 30, 2003, unless renewed. In addition, MST and MSD have the right to terminate the joint venture under certain circumstances, including a change in control of the Company, as defined. Upon the expiration of the MSD joint venture as a result of non-renewal or the termination by MSD and MST of the joint venture, MSD and MST have the right to purchase our interest in MSD for a purchase price equal to fair market value (to be determined in accordance with the provisions and procedures set forth in the MSD agreements) minus a discount factor varying from 7.5%, in the case of non-renewal and certain other events, to 15.0%, in the case of termination because of a breach by us and certain other events.

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If MSD or MST exercises this right, it will be entitled to pay us the purchase price, plus interest, over time in installments equal to the sum of five percent of MSD Net Sales, as determined in accordance with the MSD agreements, and twenty percent of the net proceeds realized by MSD from the sale of debt or equity securities in any third party financing after the date of the sale of our interest in MSD.

MSD has an employment agreement with Jacob Wohlstadter, its President and Chief Executive Officer, the current term of which runs through November 30, 2004, and provides for a salary of \$250,000 for the year ending December 31, 2003. In addition, Jacob Wohlstadter is also eligible to receive, at the discretion of an independent committee of the Company's Board of Directors, an annual cash bonus in an amount not to exceed 20% of his annual salary. If MSD terminates the employment agreement without cause, or Jacob Wohlstadter terminates the employment agreement for good reason (which includes a "change in control" of the Company, as defined), Jacob Wohlstadter shall be entitled to receive, in addition to salary and pro rata bonus and adjustments earned through the 60th day following the notice of termination, an amount equal to from 3 to 12 times (depending on the reason for the termination) the monthly pro rata salary, bonus and adjustments in effect at the time of the termination. We are responsible for all amounts payable, costs incurred and other obligations under the employment agreement, which generally are expected to be paid out of our funding commitment to MSD.

For more information about the MSD agreements and our relationship with MSD, see ITEM 13--"Certain Relationships and Related Transactions."

Roche has the right to continue to market its Elecsys products within its licensed field, however, in the event the Roche license agreement is terminated, Roche will no longer have this right. We have voluntarily agreed not to terminate the Roche license agreement until the Appellate Court determines that we are entitled to do so; however, we have notified Roche that the Roche license agreement will terminate immediately in the event the Appellate Court issues an opinion confirming our right to do so. Termination of the Roche license agreement would have a material adverse effect on our royalty income unless, and until, we enter into one or more strategic partnerships with other companies that are able to develop and commercialize diagnostic instruments in a manner that provides comparable revenues to us. We cannot assure you that we will be able to enter into one or more strategic partnerships on favorable terms, if at all.

We have a substantial amount of indebtedness, and 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 with respect to indebtedness

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when due, or in the event any of it is accelerated. In the event the Roche license agreement is terminated, the holders of the \$18.1 million of our 8.5% senior secured notes outstanding as of March 31, 2003 would be entitled to accelerate those obligations. If the 8.5% senior secured notes had been accelerated at March 31, 2003, we would have incurred approximately \$1.4 million in prepayment costs. In addition, as of March 31, 2003, \$35 million in aggregate principal amount of our 5% subordinated convertible debentures due 2005 were outstanding. Our debentures provide that, in the event debt of the Company in an outstanding principal amount of \$2 million or greater is accelerated and not satisfied within 20 business days, the holders of the debentures may accelerate our obligations under the debentures and cause the debentures to be immediately due and payable. We may not have sufficient funds to pay our debt if any of it is accelerated. In addition, our indebtedness may require that we dedicate a substantial portion of our expected cash flow from operations to service indebtedness, which would reduce the amount of expected cash flow available for other purposes, including working capital and capital expenditures.

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We need substantial amounts of money to fund operations. In this regard, from time to time we have discussions with third parties, including multinational corporations, regarding various business arrangements including distribution, marketing, research and development, joint venture and other business agreements, which could provide for substantial up-front fees or payments. Further, we are considering and evaluating the advisability and feasibility of a variety of financing alternatives, which could be completed in the near term, including issuance of additional debt or equity securities. We cannot assure you that we will successfully complete any of the foregoing arrangements and access to funds could be adversely impacted by many factors, including the results of the Roche litigation, the volatility of the price of our common stock, continuing losses from operations, establishment of new business arrangements, the status of new product launches, general market conditions and other factors described under ITEM 1 "Business--Risk Factors" and elsewhere in this Form 10-K.

We believe that existing capital resources, together with revenue from royalties, product sales and contract fees will be adequate to fund operations through the middle of calendar year 2004. If we are unable to raise additional capital or in the event the Roche license agreement is terminated, we may have to scale back, or even eliminate, some programs. Alternatively, we may consider pursuing arrangements with other companies, such as granting licenses or entering into joint ventures or collaborations, on terms that may not be favorable to us.

As of March 31, 2003, we had no off-balance sheet arrangements.

### CRITICAL ACCOUNTING POLICIES

A critical accounting policy is one that is both important to the portrayal of our financial position and results of operations and requires the application of difficult, subjective or complex judgments by our management. As a result, they are subject to an inherent degree of uncertainty. In applying those policies, our management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. These estimates are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our customers, and information available from other outside sources, as appropriate. Our significant accounting policies include:

Revenue Recognition - We derive revenue principally from three sources: product

sales, royalty income and contract fees. Product sales revenue is generally recognized when persuasive evidence of an arrangement exists, title and risk of loss has been transferred, the price to the buyer is fixed and determinable, and collectibility is reasonably assured. Rental revenue associated with instruments that are leased is recognized ratably over the life of the lease agreements. We also offer extended warranty arrangements to customers with the resulting revenue recognized over the term of the contract. Royalty income is recorded when earned based on information provided by licensees. See ITEM 8 -- Consolidated Financial Statement -- Notes to Consolidated Financial Statement -- Note 12 -- Litigation. Revenue from services performed under contracts is recognized over the term of underlying customer contract or at the end of the contract, when obligations have been satisfied. For services performed on a time and material basis, revenue is recognized upon performance. Amounts received in advance of performance under contracts or commercialization agreements are recorded as deferred revenue until earned.

The majority of our product sales and contract fees contain standard terms and conditions. Certain transactions may contain negotiated terms that require contract interpretation in order to determine the appropriate amount of revenue to be recognized. In addition, we must assess whether collectibility is reasonably assured. While management believes its interpretations and judgments are reasonable, different assumptions could result in changes in the timing of revenue recognition.

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Equity Accounting - We account for our ownership in the MSD joint venture on the equity method as we have determined that we do not control MSD's operations. Factors considered in determining our level of control include the fact that we own less than 50% of the voting equity interest in MSD; that we do not have exclusive authority over MSD decision making and have no ability to unilaterally modify the joint venture agreements; and that we have the right to appoint only one out of two seats on MSD's board of managers. A different assessment of these factors could provide for the use of consolidation accounting rather than the equity method, in which case a consolidation of our financial statements with those of MSD would be appropriate. Consolidation accounting would require certain reclassifications within our consolidated financial statements but would not materially effect our financial position or net loss. See ITEM 8 - Consolidated Financial Statements - Notes to Consolidated Financial Statements - Note 6 - Meso Scale Diagnostics Joint Venture.

Available-For-Sale Securities -Our short-term investments consist of marketable securities with original maturities of greater than three months. Due to the fact that market or business conditions may lead us to sell a short-term investment prior to maturity, we classify our short-term investments as "available-for-sale". Investments in securities that are classified as available-for-sale and have readily determinable fair values are measured at fair market value in the balance sheets, and unrealized holding gains and losses for these investments are reported as a separate component of stockholders' equity until realized. All of our "available for sale" securities are included in current assets as management considers the securities readily available to fund current operations.

If we held investments that were classified as "held-to maturity" securities, these would be carried at amortized cost rather than at fair market value. If we held investments that were classified as "trading" securities, these would be carried at fair market value, with a corresponding adjustment to earnings for any change in fair market value.

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**Allowance for Doubtful Accounts** - We maintain reserves on customer accounts where estimated losses may result from the inability of our customers to make required payments. These reserves are determined based on a number of factors, including the current financial condition of specific customers, the age of accounts receivable balances and historical loss rates. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, an additional allowance may be required.

**Inventory** - We carry our inventory at the lower of cost or market using the first-in, first-out method. We regularly review inventory quantities on hand and record a reserve for excess and obsolete inventory based primarily on an estimated forecast of product demand and production requirements for the next twelve months. Reserves are recorded for the difference between the cost and the market value. Those reserves are based on significant estimates. Our estimates of future product demand may prove to be inaccurate, in which case we may have understated or overstated the provision required for excess and obsolete inventory. In addition, our industry is characterized by technological change; frequent new product development and product obsolescence that could result in an increase in the amount of obsolete inventory quantities on hand. Although we make every effort to ensure the accuracy of our forecasts of future product demand, any significant unanticipated changes in demand or technological developments could have a significant impact on the values of our inventory and our reported operating results.

**Value of Long-lived Assets** - We have different long-lived assets recorded on our balance sheet that include equipment and leasehold improvements, investments and other assets. We evaluate the potential impairment of long-lived assets based upon current estimated market values and projections of undiscounted cash flows whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. While management believes that estimates are reasonable and that no impairment of these assets exists, different assumptions could affect these evaluations and result in impairment charges against the carrying value of these assets.

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**Warranty Reserve** - We warrant our products against defects in material and workmanship for one year after sale and record estimated future warranty costs at the time revenue is recognized. A reserve for future warranty claims is recorded based upon management's review of historical results and expectations of future costs. Unanticipated changes in actual warranty costs could impact our operating results.

**Capitalized Software Costs** - We record software development costs in accordance with SFAS No. 86 "Accounting for the Costs of Computer Software to be Sold, Leased, or Otherwise Marketed." We apply our judgment in determining when software being developed has reached technological feasibility, and at that point we would capitalize software development costs. Through March 31, 2003, software development has been substantially completed concurrently with the establishment of technological feasibility, and accordingly, no costs have been capitalized to date.

### RECENT ACCOUNTING PRONOUNCEMENTS

In April 2002, the FASB issued SFAS 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections" (SFAS 145). SFAS 145 requires the classification of gains and losses from extinguishments of debt as extraordinary items only if they meet certain criteria for such classification in APB No. 30, "Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and

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Extraordinary, Unusual, and Infrequently Occurring Events and Transactions". Any gain or loss on extinguishments of debt classified as an extraordinary item in prior periods that does not meet the criteria must be reclassified as other income or expense. These provisions are effective for fiscal years beginning after May 15, 2002. Additionally, SFAS 145 requires sale-leaseback accounting for certain lease modifications that have economic effects similar to sale-leaseback transactions. These lease provisions are effective for transactions occurring after May 15, 2002. SFAS 145 is not expected to have a material effect on our financial position or results of operations.

In July 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" (SFAS 146). SFAS 146 replaces Emerging Issues Task Force Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)". SFAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. SFAS 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. SFAS 146 is not expected to have a material effect on our financial position or results of operations.

In November 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others," (FIN 45). FIN 45 establishes new disclosure and liability recognition requirements for direct and indirect debt guarantees with specified characteristics. The initial recognition and measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements in this Interpretation are effective for financial statements of interim or annual periods ending after December 15, 2002. We adopted FIN 45 as of March 31, 2003 and the implementation did not have a material effect on our results of operations or financial position.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation- Transition and Disclosure- an amendment of SFAS 123" (SFAS 148). SFAS 148 amends SFAS 123 "Accounting for Stock-Based Compensation" (SFAS 123) to provide alternative methods of voluntarily transitioning to the fair value based method of accounting for stock-based employee compensation. SFAS 148 also amends the disclosure requirements of SFAS 123 to require disclosure of the method used to account for stock-based employee compensation and the effect of the method on reported results in both annual and interim financial statements. This pronouncement is effective for both annual and interim periods beginning after December 15, 2002.

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We have elected to continue to follow the recognition and measurement principles of Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees," in our accounting for employee stock options. In accordance with SFAS 148, we have adopted the annual period disclosure requirements in this Form 10-K and will adopt the disclosure provisions effective for interim periods in our fiscal quarter ending June 30, 2003.

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities" (FIN 46). FIN 46 provides guidance on the consolidation of certain entities in which equity investors do not have the characteristics of a controlling financial interest. Such entities are referred to as variable interest entities. FIN 46 was effective immediately for variable interest entities created or acquired after January 31, 2003 and is effective

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July 1, 2003 for variable interest entities created or acquired on or before January 31, 2003. We are in the process of evaluating the impact of adopting FIN 46. It is possible that the adoption of FIN 46 might require that our investment in MSD and the results of MSD's operations be consolidated in our financial statements.

In April 2003, the FASB issued SFAS No. 149, "Amendment of SFAS No. 133 on Derivative Instruments and Hedging Activities" (SFAS 149). SFAS 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities". The amendments set forth in SFAS 149 improve financial reporting by requiring that contracts with comparable characteristics be accounted similarly. SFAS 149 is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. We do not expect the adoption of this pronouncement to have a material effect on our financial position or results of operations or cash flows.

### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Changes in interest rates do not affect interest expense incurred on our long-term borrowings because they bear interest at a fixed rate. The principal terms of this debt are as follows:

- Note payable with John Hancock Life Insurance Company: \$30 million principal (\$18.1 million principal at March 31, 2003), seven year, 8.5% Senior Secured Notes secured by future royalty revenue from Roche, maturing in 2006 with quarterly principal and interest payments through March 2006.
- Subordinated convertible debentures: \$35 million principal, 5% interest maturing January 2005 with semi-annual interest payments in cash or equivalent value of Common Stock.

However, we run a risk that market rates will decline and that the interest rate will exceed those based on the then-current market rate. We are currently not using interest rate derivative instruments to manage our exposure to interest rate changes.

Interest income earned on our investment portfolio is affected by changes in the general level of interest rates. We have invested excess cash generally in securities of the U.S. Treasury, money market funds, certificates of deposit and corporate bonds.

We invest excess cash in accordance with a policy approved by our Board of Directors. This policy is designed to provide both liquidity and safety of principal. The policy limits investments to certain types of instruments issued by institutions with strong investment grade credit ratings and places restrictions on our investments by terms and concentrations by type and issuer.

Given the amount invested as of March 31, 2003, a 1% change in the LIBOR rate would not have a material effect on our interest income.

We are exposed to changes in exchange rates where we sell direct in local currencies, primarily in the United Kingdom and Germany. Certain other foreign sales are denominated in U.S. dollars and have no exchange rate risk. Gains and losses resulting from foreign currency transactions have historically not been material.



ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Independent Auditors' Report

Consolidated Statements of Operations for the Years  
Ended March 31, 2003, 2002 and 2001

Consolidated Balance Sheets at March 31, 2003 and 2002

Consolidated Statements of Cash Flows for the Years  
Ended March 31, 2003, 2002 and 2001

Consolidated Statements of Stockholders' Equity (Deficit) for the Years  
Ended March 31, 2003, 2002 and 2001

Notes to Consolidated Financial Statements

We also incorporate herein by this reference Meso Scale Diagnostics, LLC., Financial Statements at December 31, 2002 and 2001, and for each of the three years ended in the period ended December 31, 2002, and Independent Auditors' Report filed as Exhibit 99.2 to this report.

INDEPENDENT AUDITORS' REPORT

TO THE STOCKHOLDERS AND BOARD OF DIRECTORS  
OF IGEN INTERNATIONAL, INC.:

We have audited the accompanying consolidated balance sheets of IGEN International, Inc. (the "Company") as of March 31, 2003 and 2002, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended March 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of March 31, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

DELOITTE & TOUCHE LLP

McLean, Virginia  
May 14, 2003

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### IGEN INTERNATIONAL, INC. CONSOLIDATED STATEMENTS OF OPERATIONS (IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

	Years Ended March 31,		
	2003	2002	
REVENUES:	-----	-----	-----
Product sales	\$ 18,986	\$ 14,583	\$
Royalty income	36,650	26,768	
Contract fees	830	696	
	-----	-----	-----
Total	56,466	42,047	
	-----	-----	-----
OPERATING COSTS AND EXPENSES:			
Product costs	9,059	6,070	
Research and development	23,714	27,203	
Selling, general, and administrative	24,741	24,031	
Litigation related costs	5,401	11,299	
	-----	-----	-----
Total	62,915	68,603	
	-----	-----	-----
LOSS FROM OPERATIONS	(6,449)	(26,556)	(
	-----	-----	-----
OTHER (EXPENSE) INCOME:			
Interest expense	(5,621)	(6,059)	

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Other income, net	1,680	1,036	
	-----	-----	---
Total	(3,941)	(5,023)	
	-----	-----	---
EQUITY IN LOSS OF AFFILIATE	(17,598)	(10,947)	
	-----	-----	---
LOSS BEFORE CUMULATIVE EFFECT OF ACCOUNTING CHANGE	(27,988)	(42,526)	(
CUMULATIVE EFFECT OF ACCOUNTING CHANGE	-	-	
	-----	-----	---
NET LOSS	(27,988)	(42,526)	(
PREFERRED DIVIDENDS	(201)	(1,402)	
	-----	-----	---
NET LOSS ATTRIBUTED TO COMMON STOCKHOLDERS	\$ (28,189)	\$ (43,928)	\$ (
	=====	=====	==
BASIC AND DILUTED NET LOSS PER COMMON SHARE:			
Loss before cumulative effect of accounting change	\$ (1.19)	\$ (2.20)	\$
Cumulative effect of accounting change	-	-	
	-----	-----	---
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$ (1.19)	\$ (2.20)	\$
	=====	=====	==
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING- BASIC AND DILUTED	23,590	19,947	
	=====	=====	==

See notes to consolidated financial statements.

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## IGEN INTERNATIONAL, INC. CONSOLIDATED BALANCE SHEETS (IN THOUSANDS, EXCEPT SHARE DATA)

ASSETS	2003
CURRENT ASSETS:	-----
Cash and cash equivalents	\$ 19,447
Short-term investments	14,798
Accounts receivable, net	14,536
Inventory	5,469
Other current assets	2,794
	-----
Total current assets	57,044
EQUIPMENT AND LEASEHOLD IMPROVEMENTS, NET	6,456

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## OTHER NONCURRENT ASSETS:

Investment in affiliate	9,164
Restricted cash	1,721
Other	881

TOTAL	\$ 75,266
	=====

## LIABILITIES AND STOCKHOLDERS' EQUITY

### CURRENT LIABILITIES:

Accounts payable	7,175
Accrued expenses	1,714
Accrued wages and benefits	3,170
Current portion of note payable	5,523
Convertible preferred stock dividend payable	-
Deferred revenue	507

Total current liabilities	18,089
	-----

### NONCURRENT LIABILITIES:

Note payable	12,542
Subordinated convertible debentures	31,834
Deferred revenue	60

Total noncurrent liabilities	44,436
	-----

## COMMITMENTS AND CONTINGENCIES

### STOCKHOLDERS' EQUITY:

Convertible preferred stock , \$ 0.001 par value, 10,000,000 shares authorized, issuable in Series: Series A, 600,000 shares designated, none issued; Series B, 25,000 shares designated, none and 8,500 shares issued and outstanding - liquidation value of \$0 and \$8,500 plus accrued and unpaid dividends	-
Common stock: \$0.001 par value, 50,000,000 shares authorized: 23,750,461 and 23,064,392 shares issued and outstanding	24
Additional paid-in capital	243,046
Stock notes receivable	(2,061)
Accumulated other comprehensive income	(257)
Accumulated deficit	(228,011)

Total stockholders' equity	12,741
	-----

TOTAL	\$ 75,266
	=====

See notes to consolidated financial statements.

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## OPERATING ACTIVITIES:

Net loss	\$ (27,9
Adjustments to reconcile net loss to net cash used for operating activities:	
Depreciation and amortization	4,2
Loss on disposal of equipment	
Equity in loss of affiliate	17,5
Beneficial conversion feature of convertible debenture	
Common stock issued in payment of interest	
Amortization of detachable warrant value	1,4
Expense related to stock options	3
Changes in assets and liabilities:	
Increase in accounts receivable	(4,6
(Increase) decrease in inventory	(1,4
(Increase) decrease in other current assets	(1,1
Decrease (increase) restricted cash	
Increase (decrease) in accounts payable and accrued expenses	1,3
Increase (decrease) in deferred revenue	

Net cash used for operating activities	(10,0
--	-------

## INVESTING ACTIVITIES:

Expenditures for equipment and leasehold improvements	(3,3
Investments in affiliate	(20,5
Sales of short-term investments	5,1
Maturities of short-term investments	8,6
Purchases of short-term investments	(23,5
Increase in other assets	(1

Net cash (used for) provided by investing activities	(33,8
--	-------

## FINANCING ACTIVITIES:

Issuance of common stock, net	6
Payments on note payable and capital lease obligations	(5,1
Preferred stock dividends paid	(3,4
Increase in restricted cash	
Repayment of stock notes receivable	1,6

Net cash (used for) provided by financing activities	(6,2
--	------

NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(50,0
--	-------

CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	69,5
--	------

CASH AND CASH EQUIVALENTS, END OF YEAR	\$ 19,4
--	---------

## SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:

Cash payments of interest	\$ 3,5
---------------------------	--------

## SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

Common stock issued in exchange for notes receivable	\$
--	----

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Accrued preferred dividends

\$ 2

Equipment and leasehold improvements contributed to affiliate

\$

See notes to consolidated financial statements.

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## IGEN INTERNATIONAL, INC. CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (IN THOUSANDS)

	Convertible Preferred Stock		Common	Stock	Additional	Stock	Accumulated
	Shares	Amount	Shares	Amount	Paid - in Capital	Notes Receivable	Other Comprehensive Loss
BALANCE at April 1, 2000	23	\$ 1	15,578	\$ 15	\$ 102,420	\$ -	\$ -
Net loss	-	-	-	-	-	-	-
Issuance of shares of common stock	-	-	1,307	2	17,453	(3,710)	-
Preferred stock converted	(5)	-	376	-	-	-	-
Preferred stock, dividends payable	-	-	-	-	(2,052)	-	-
Beneficial conversion feature of convertible debentures	-	-	-	-	6,995	-	-
BALANCE at March 31, 2001	18	1	17,261	17	124,816	(3,710)	-
Net loss	-	-	-	-	-	-	-
Issuance of shares of common stock	-	-	5,107	5	118,596	-	-
Preferred stock converted	(9)	-	696	1	(1)	-	-
Preferred stock, dividends payable	-	-	-	-	(1,402)	-	-
Expense related to stock options	-	-	-	-	219	-	-
BALANCE at March 31, 2002	9	1	23,064	23	242,228	(3,710)	-
Comprehensive loss:							
Unrealized loss on investments	-	-	-	-	-	-	(257)
Net loss	-	-	-	-	-	-	-
Comprehensive loss	-	-	-	-	-	-	-
Issuance of shares of common stock	-	-	77	-	633	-	-
Preferred stock converted	(9)	(1)	609	1	-	-	-
Preferred stock, dividends payable	-	-	-	-	(201)	-	-
Expense related to stock options	-	-	-	-	386	-	-
Repayment of stock note receivable	-	-	-	-	-	1,649	-

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BALANCE at March 31, 2003 - \$ - 23,750 \$ 24 \$ 243,046 \$ (2,061) \$ (257)

See notes to consolidated financial statements.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Business Activity - IGEN International, Inc. (the Company) develops, manufactures, and markets products that permit the detection and measurements of biological substances utilizing its patented ORIGEN(R) technology, which is based on electrochemiluminescence. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, IGEN Europe, Inc. and IGEN International, K.K. All significant inter-company transactions and balances have been eliminated.

Estimates and Reclassifications- The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Certain amounts from the prior years have been reclassified to conform to the current year presentation.

Cash and Cash Equivalents- Cash and cash equivalents include cash in banks, money market funds, securities of the U.S. Treasury, and certificates of deposit with original maturities of three months or less.

Short-Term Investments - Short-term investments consist primarily of corporate debt-securities that are classified as "available for sale". These "available for sale" securities, which are all due within one year, are accounted for at their fair value and unrealized gains and losses on these securities, if any, are included in accumulated other comprehensive loss in stockholders' equity. As of March 31, 2003, the Company had unrealized losses on "available-for-sale" securities of approximately \$257,000. The Company uses the specific identification method in computing realized gains and losses on the sale of investments, which are included in results of operations as generated. Any realized gains or losses were not material as of and for the years ended March 31, 2003, 2002 and 2001.

Concentration of Credit Risk - The Company has invested its excess cash generally in securities of the U.S. Treasury, money market funds, certificates of deposit and corporate bonds. The Company invests its excess cash in accordance with a policy approved by the Company's Board of Directors. This policy is designed to provide both liquidity and safety of principal. The policy limits investments to certain types of instruments issued by institutions with strong investment grade credit ratings and places restrictions on the Company's investment by terms and concentrations by type and issuer. The Company has not experienced any losses on its investments due to credit risk. Due to the Company's dependence on its business arrangements with Roche Diagnostics GmbH (Roche), however, the Company has a high concentration of exposure to Roche's credit risks. See "-- Note 2 -- License and Research Agreements".

Restricted Cash -The Company has a debt service reserve of approximately \$1.7

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million at March 31, 2003 and 2002 that is restricted in use and held in trust as collateral (see Note 4). In conjunction with the Roche litigation, the Company escrowed approximately \$1.4 million related to Physician's Office Laboratory (POL) sales. This escrow was released to the Company without restriction upon conclusion of the Roche trial in January 2002 (see Note 12).

Allowance for Doubtful Accounts - The Company maintains reserves on customer accounts where estimated losses may result from the inability of its customers to make required payments. These reserves are determined based on a number of factors, including the current financial condition of specific customers, the age of accounts receivable balances and historical loss rates.

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### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Inventory - Inventory is recorded at the lower of cost or market using the first-in, first-out method and consists of the following:

(in thousands)	2003	2002
-----	-----	-----
Finished Goods	\$ 2,255	\$ 2,070
Work in process	869	1,149
Raw materials	2,345	1,272
	-----	-----
Total	\$ 5,469	\$ 4,491
	=====	=====

Equipment and Leasehold Improvements - Equipment and leasehold improvements are carried at cost. Depreciation on equipment and furniture is computed over the estimated useful lives of the assets, generally three to five years, using straight-line or accelerated methods. Leasehold improvements are amortized on a straight-line basis over the life of the lease.

Equipment and leasehold improvements consist of the following:

(in thousands)	2003	2002
-----	-----	-----
Lab instruments and equipment	\$ 6,274	\$ 7,761
Office furniture and equipment	5,847	7,492
Leasehold improvements	3,618	2,864
	-----	-----
	15,739	18,117
Accumulated depreciation and amortization	(9,283)	(11,688)
	-----	-----
	\$ 6,456	\$ 6,429
	=====	=====

Other Noncurrent Assets - Other noncurrent assets includes Deferred Debt Issuance Costs of approximately \$1.4 million which are amortized using the effective interest method over the terms of the debt agreements. Accumulated amortization was \$1,031,000 and \$806,000 at March 31, 2003 and 2002, respectively.

Capitalized Software Costs - Software development costs incurred subsequent to the establishment of technological feasibility are capitalized in accordance with SFAS No. 86 "Accounting for the Costs of Computer Software to Be Sold, Leased, or Otherwise Marketed." Through March 31, 2003, software development has



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been substantially completed concurrently with the establishment of technological feasibility, and accordingly, no costs have been capitalized to date.

**Evaluation of Long-lived Assets** - The Company evaluates the potential impairment of long-lived assets based upon projections of undiscounted cash flows whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. Management believes no impairment of these assets exists as of March 31, 2003 and 2002.

**Warranty Reserve** - The Company warrants its products against defects in material and workmanship for one year after sale and records estimated future warranty costs at the time revenue is recognized. A reserve for future warranty claims is recorded based upon historical results, supplemented by expectations of future costs. The Company also offers extended warranty arrangements to customers with related costs recorded as incurred.

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Warranty reserve activity for the year ended March 31, 2003 is as follows (in thousands):

Balance at March 31, 2002	\$	170
Provisions recorded		1,278
Actual costs incurred		(1,198)
		-----
Balance at March 31, 2003	\$	250
		=====

**Fair Value of Financial Instruments** - The following disclosures of estimated fair value were determined by management using available market information and appropriate valuation methodologies. The fair value of the Company's financial instruments, including cash equivalents, accounts receivable, accounts payable, accrued expenses, notes payable, and long-term debt approximate their carrying values. Disclosure about fair values of financial instruments is based on pertinent information available to management as of March 31, 2003. Although management is not aware of any factors that would significantly affect the reasonableness of the fair value amounts, current estimates of fair value may differ significantly from the amounts presented to them.

**Comprehensive Loss**- Comprehensive loss is comprised of net loss and other items of comprehensive loss. For the year ended March 31, 2003, other comprehensive loss includes unrealized losses on "available for sale" securities that are excluded from net loss. There were no significant elements of comprehensive loss for the years ended March 31, 2002 and 2001.

**Revenue Recognition** - The Company derives revenue principally from three sources: product sales, royalty income and contract fees. Product sales revenue is generally recognized when persuasive evidence of an arrangement exists, title and risk of loss has been transferred, the price to the buyer is fixed and determinable, and collectibility is reasonably assured. Rental revenue associated with instruments that are leased is recognized ratably over the life of the lease agreements. The Company also offers extended warranty arrangements to customers with the resulting revenue recognized over the term of the contract.

Royalty income is recorded when earned, based on information provided by licensees.

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Revenue from services performed under contracts is recognized over the term of the underlying customer contract or at the end of the contract, when obligations have been satisfied. For services performed on a time and material basis, revenue is recognized upon performance. Amounts received in advance of performance under contracts or commercialization agreements are recorded as deferred revenue until earned.

Research and Development - Research and development costs are expensed as incurred.

Foreign Currency - Gains and losses from foreign currency transactions such as those resulting from the settlement of foreign receivables or payables, are included in the results of operations as incurred. These amounts were not material during the years ended March 31, 2003, 2002 and 2001.

Deferred Income Taxes - Deferred income tax assets and liabilities are computed annually for differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

Stock-based Compensation - The Company has elected to continue to follow the recognition and measurement principals of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees", and related Interpretations for its stock option plans. No stock-based employee compensation cost is reflected in net loss for the years ended March 31, 2003, 2002 and 2001, as all options granted under those plans had an exercise price equal to the market value of a share of the underlying Common Stock on the date of grant.

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The following table illustrates the effect on net loss and net loss per share as if the Company had applied the fair value recognition provisions of SFAS No. 123, "Accounting for Stock-Based Compensation" as amended by SFAS 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - An Amendment of SFAS 123" to stock-based employee compensation (in thousands, except per share amounts):

	Years Ended March 2003	2002
	-----	-----
Net loss, as reported	\$ (27,988)	\$ (42,526)
Deduct: Total stock-based employee compensation expense determined under fair value method	(4,492)	(3,448)
	-----	-----
Pro-forma net loss	\$ (32,480)	\$ (45,974)
	=====	=====
Loss per share:		
Basic loss per common share - as reported	\$ (1.19)	\$ (2.20)
Basic loss per common share - pro-forma	\$ (1.38)	\$ (2.38)

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The pro-forma information above may not be representative of the effects on potential pro-forma effects on results for future years.

The fair value of options was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions:

	2003	2002	2001
Expected dividend yield	0%	0%	0%
Expected stock price volatility	68%	71%	71%
Risk-free interest rate	3.4%	4.3%	5.5%
Expected option term (in years)	5	5	5

Based on this calculation, the weighted average fair value of options granted during the years ended March 31, 2003, 2002 and 2001 was \$20.56, \$15.68 and \$9.66, respectively.

Loss Per Share - The Company uses SFAS No. 128 "Earnings per Share" for the calculation of basic and diluted earnings per share. The Company's loss has been adjusted by dividends accumulated on the Company's Series B Convertible Preferred Stock for all years presented. For each of the three years ended March 31, 2003, the Company incurred a net loss; therefore, net loss per common share does not reflect the potential dilution that could occur to common shares related to outstanding stock options, warrants, convertible preferred stock and convertible debentures. The weighted average number of common shares outstanding together with potentially dilutive shares was 25,530,000, 21,876,000 and 18,282,000 for the years ended March 31, 2003, 2002 and 2001, respectively.

Cumulative Effect of Accounting Change - During the year ended March 31, 2001, the Company adopted the provisions of Emerging Issues Task Force (EITF) Release No. 00-27, "Application of EITF Issue No. 98-5, Accounting for Convertible Securities and Beneficial Conversion Features". This standard established new guidelines for convertible securities with beneficial conversion features. The EITF requires conversion options to be calculated using the effective conversion price based on the proceeds allocated to the convertible instruments. Previously, the Company had calculated the beneficial conversion feature of Subordinated Convertible Debentures, issued in January 2000, using the stated conversion price (see Note 5). The change in methods resulted in a one-time, non-cash charge that was recorded during the year ended March 31, 2001 as a cumulative effect of accounting change.

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Prior year financial statements have not been restated to reflect the change in accounting. The effect of the change on the Company's Consolidated Statement of Operations for the year ended March 31, 2001 was to increase the net loss by approximately \$7 million (\$0.44 per share). There was no effect on loss before the cumulative effect of the accounting change for the year ended March 31, 2001.

New Accounting Standards -- In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections" (SFAS 145). SFAS 145 requires the

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classification of gains and losses from extinguishments of debt as extraordinary items only if they meet certain criteria for such classification in APB No. 30, "Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual, and Infrequently Occurring Events and Transactions." Any gain or loss on extinguishments of debt classified as an extraordinary item in prior periods that does not meet the criteria must be reclassified as other income or expense. These provisions are effective for fiscal years beginning after May 15, 2002. Additionally, SFAS 145 requires sale-leaseback accounting for certain lease modifications that have economic effects similar to sale-leaseback transactions. These lease provisions are effective for transactions occurring after May 15, 2002. SFAS 145 is not expected to have a material effect on the Company's financial position or results of operations.

In July 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" (SFAS 146). SFAS 146 replaces Emerging Issues Task Force Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs incurred in a Restructuring)." SFAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. SFAS 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. The Company does not expect the adoption of SFAS 146 to have a material effect on its financial position or results of operations.

In November 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Guarantees of Indebtedness of Others," (FIN 45). FIN 45 establishes new disclosure and liability recognition requirements for direct and indirect guarantee with specified characteristics. The initial recognition and measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements in FIN 45 are effective for financial statements of interim or annual periods ending after December 15, 2002. The Company adopted FIN 45 as of March 31, 2003 and the implementation did not have a material effect on the Company's results of operations or financial position.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation- Transition and Disclosure- an amendment of SFAS 123" (SFAS 148). This statement amends SFAS 123 "Accounting for Stock-Based Compensation" (SFAS 123) to provide alternative methods of voluntarily transitioning to the fair value based method of accounting for stock-based employee compensation. SFAS 148 also amends the disclosure requirements of SFAS 123 to require disclosure of the method used to account for stock-based employee compensation and the effect of the method on reported results in both annual and interim financial statements. This pronouncement is effective for both annual and interim periods beginning after December 15, 2002. The Company has elected to continue to follow the recognition and measurement principles of Accounting Principles Board Opinion No. 25, "Accounting For Stock Issued to Employees," in its accounting for employee stock options. In accordance with SFAS 148, the Company has adopted the annual period disclosure requirements and will adopt the disclosure provisions effective for interim periods in its fiscal quarter ending June 30, 2003.

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities" (FIN 46). FIN 46 provides guidance on the consolidation of certain entities in which equity investors do not have the characteristics of a controlling financial interest.

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Such entities are referred to as variable interest entities. FIN 46 was effective immediately for variable interest entities created or acquired after January 31, 2003 and is effective July 1, 2003 for variable interest entities created or acquired on or before January 31, 2003. The Company is in the process of evaluating the impact of adopting FIN 46. It is possible that the adoption of FIN 46 might require that the Company's investment in MSD and the results of MSD's operations be consolidated in the Company's financial statements.

In April 2003, the FASB issued SFAS No. 149, "Amendment of SFAS No. 133 on Derivative Instruments and Hedging Activities" (SFAS 149). SFAS 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities". The amendments set forth in SFAS 149 improve financial reporting by requiring that contracts with comparable characteristics be accounted similarly. SFAS 149 is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The Company does not expect the adoption of this pronouncement to have a material effect on its financial position or results of operations or cash flows.

### 2. LICENSE AND RESEARCH AGREEMENTS

In 1992, the Company entered into a license agreement with Roche (Roche license agreement), under which Roche was granted rights to exclusively commercialize ORIGEN-based clinical immunoassay and nucleic acid probe systems. Under the terms of the agreement, the Company has received license fees and payments for certain product development work, as well as royalties on product sales. The Company recorded royalty and contract fee revenue from Roche of \$36.2 million (64% of total revenue), \$26.3 million (63% of total revenue) and \$15.6 million (50% of total revenue) for the three fiscal years ended March 31, 2002 and 2001 respectively. The Company is currently in litigation with Roche (see Note 12).

In 1993, the Company entered into a license and stock purchase agreement with BioMerieux, Inc. (formerly Organon Teknika, B.V.). Under this agreement, the Company sold 346,135 shares of Common Stock, granted a license for the development and worldwide-commercialization of ORIGEN - based nucleic acid probe systems on a co-exclusive basis for certain segments of the clinical testing market and on a non-exclusive basis for certain segments of the life science market. In addition, the Company and BioMerieux agreed to invest in research and development under a joint development program. Among other things, the agreement provides for royalty payments to the Company on product sales and for product supply arrangements between the parties. The Company recorded royalty income from BioMerieux of \$236,000, \$252,000 and \$276,000 for the fiscal years ended March 31, 2003, 2002, and 2001, respectively.

In 1990, the Company granted a license to Eisai Co., Ltd., under which Eisai is licensed to manufacture and market a class of ORIGEN-based diagnostic systems for the clinical testing market in Japan on an exclusive basis. The agreement provided for license fees tied to the achievement of product development milestones and for royalty payments to the Company on product sales. In 2002, the Company executed an extension of the license with Eisai. The Company recorded royalty income of \$871,000, \$798,000, and \$607,000 for the fiscal years ended March 31, 2003, 2002 and 2001, respectively.

### 3. STOCKHOLDERS' EQUITY

Stock Option Plans - The Company has three stock-based plans under which employees and non-employee directors may be granted options to purchase Common Stock: the 1994 Stock Option Plan under which 2,500,000 shares of Common Stock have been reserved for issuance upon exercise of options granted to employees or consultants; the 1994 Non-Employee Directors Stock Option Plan under which

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150,000 shares of Common Stock have been reserved for issuance upon exercise of options granted to Non-Employee Directors; and the 2001 Broad Based Option Plan under which 250,000 shares of Common Stock have been reserved for issuance under the plan. The 1994 Stock Option Plan replaced the 1985 Stock Option Plan which expired in February 1995 and continues to have unexercised options outstanding.

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The 1985 Stock Option Plan and the 1994 Stock Option Plan provide for the grant of both incentive stock options intended to qualify as such under Section 422 of the Internal Revenue Code of 1986, as amended, and other stock options that do not so qualify.

The Non-Employee Directors Stock Option Plan and the 2001 Broad Based Option Plan only provide for the grant of options that are not intended to so qualify.

Activity related to options under the option plans for the fiscal years ended March 31, 2003, 2002 and 2001 was (shares in thousands):

	2003		2002	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	1,336	\$ 13.31	2,244	\$ 9.40
Granted	378	34.21	79	25.38
Exercised	(77)	9.29	(957)	5.27
Cancelled/forfeited	(51)	25.00	(30)	11.64
Outstanding at year-end	1,586	\$ 18.16	1,336	\$ 13.31
Options exercisable at year-end	865	\$ 11.97	735	\$ 10.30
Options available for future grant	732		1,073	

The following table summarizes information about stock options outstanding at March 31, 2003 (shares in thousands):

	Options Outstanding		Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Number Exercisable	Weighted Average Exercise Price
Range of Exercise Prices	-----	-----	-----	-----

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\$ 4.57	-	\$ 7.50	333	3.70	\$ 5.66	333	\$ 5.66
8.75	-	11.56	333	6.35	10.95	213	10.64
12.75	-	18.00	42	5.82	14.74	32	14.43
18.75	-	24.69	499	7.10	19.43	270	19.49
26.78	-	37.91	379	9.22	34.21	17	27.63
			-----	----	-----	---	-----
\$ 4.57	-	\$ 37.91	1,586	6.70	\$ 18.16	865	\$ 11.97
			=====	=====	=====	===	=====

In August 2000, the Company granted 75,000 non-qualified stock options in connection with a consulting arrangement for services to be provided to the Company. The consultant is also the sole owner of MST and is the son of the Chief Executive Officer of the Company (see Note 6). As a result of certain events in fiscal 2002 and pursuant to Financial Accounting Standards Board Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation - an Interpretation of APB Opinion No. 25" and EITF 96-18, "Accounting for Equity Instruments That Are Issued To Other Than Employees For Acquiring, or in Conjunction with Selling, Goods or Services," the Company began recognizing expense on a monthly basis as the options are earned and vest, based upon fair value calculated in accordance with the Black-Scholes option pricing model. Changes in the fair value of the unvested options will result in changes in future expense recognition. The options vest ratably over a five-year period through August 2005 and the Company recorded \$386,000 and \$219,000 of non-cash expense during the years ended March 31, 2003 and 2002, respectively.

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Stock Notes Receivable - In connection with the exercise of stock options by officers in July 2000, the Company granted one loan to the Company's Chief Executive Officer and one loan to the Company's President and Chief Operating Officer in a combined aggregate principal amount of \$3.7 million, maturing in July 2007. The loans are 6.62% simple interest (paid annually), full recourse loans against all assets of the borrowers, collateralized by the pledge of 180,000 shares of the Company's Common Stock owned by the borrowers. In September 2002, the loan to the Company's President and Chief Operating Officer totaling \$1.6 million was fully repaid with interest and the corresponding collateral was released.

Convertible Preferred Stock - In 1997, the Company issued 25,000 shares of Series B Convertible Preferred Stock (Series B) with a stated value of \$1,000 per share that have converted into 1,790,830 shares of Common Stock of the Company. Upon conversion, the Company paid dividends of \$3.4 million, \$3.3 million and \$1.3 million during the years ended March 31, 2003, 2002 and 2001, respectively. There are no remaining Series B shares outstanding and all Series B dividend obligations have been satisfied. Dividends payable on the Series B shares at March 31, 2002 have been reclassified to current liabilities in the accompanying consolidated balance sheets.

Shareholder Rights Plan - In 1996, the Board of Directors adopted a shareholder rights plan and declared a dividend of one preferred share purchase right (Right) for each outstanding share of the Company's Common Stock (par value \$.001 per share). A Right has also been attached to each share of Common Stock subsequently issued. Prior to becoming exercisable, the Rights are evidenced by certificates representing shares of Common Stock and are transferable only in connection with the transfer of Common Stock. Each Right, when exercisable, will detach from the Common Stock and will entitle the registered holder to purchase from the Company one one-hundredth of a share of Series A Junior Participating Preferred Stock, par value \$.001 per share, at a price of \$65.00 per one one-hundredth of a Preferred Share, subject to adjustment. The Rights are

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triggered if a person or group of persons other than Samuel J. Wohlstadter, the Company's Chief Executive Officer, and his affiliates or associates, heirs, trusts or foundations to which he has transferred shares of the Common Stock acquires 15.0% or more of the Common Stock or announces a tender offer that would result in that person or group of persons acquiring 15.0% or more of the Common Stock on terms not approved by the Company's Board of Directors. If triggered, the Rights would cause substantial dilution to the person or group of persons that caused them to be triggered. The Rights are redeemable in whole, but not in part, for \$.01 per Right (subject to adjustment) at the option of the Board of Directors. Until a Right is exercised, the holder of the Right has no rights as a stockholder of the Company. The Rights will expire in 2006 unless redeemed by the Company prior to that date.

#### 4. NOTE PAYABLE

In March 1999, the Company entered into a debt financing under a Note Purchase Agreement (Note) from which the Company received \$30 million. The seven year, 8.5% Senior Secured Notes mature in 2006 with principal and interest installments of \$1.7 million due quarterly through March 2006. Collateral for the debt is represented by royalty payments and rights of the Company to receive monies due, pursuant to the Roche license agreement. Additional collateral is represented by restricted cash (see Note 1), which had a balance of approximately \$1.7 million at March 31, 2003 and 2002. Covenants within the Note include compliance with annual and quarterly Royalty Payment Coverage Ratios, which are tied to royalty payments and debt service.

In the event the Roche license agreement is terminated, the holders of our 8.5% senior secured notes outstanding would be entitled to accelerate those obligations and collect a prepayment penalty.

#### 5. SUBORDINATED CONVERTIBLE DEBENTURES

In January 2000, the Company completed a placement of \$35 million principal amount of Subordinated Convertible Debentures. The 5% debentures, if not converted, mature January 2005 with semi-annual interest payments to be made in cash or an equivalent value of Common Stock.

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The debentures are immediately convertible into 1,129,032 shares of the Company's Common Stock, which represents a \$31 per share conversion price.

The debentures had a one-time beneficial conversion feature totaling \$9.6 million measured as the difference between the conversion price of \$31 per share and the fair value of the Common Stock at the time of the issuance of the debentures. This beneficial conversion feature was recorded as a one-time, non-cash charge to interest expense in fiscal 2000. See Note 1, "Cumulative Effect of Accounting Change" for a description of the effect of a change in accounting in fiscal 2001 related to the convertible debentures.

The Company's debentures provide that, in the event debt of the Company in an outstanding principal amount of \$2 million or greater is accelerated and not satisfied within 20 business days, the holders of the debentures may accelerate the Company's obligations under the debentures and cause the debentures to be immediately due and payable.

As part of this financing, the Company also issued detachable warrants to purchase 282,258 shares of Common Stock with an exercise price of \$31 per share. Using the Black-Scholes option pricing model and the relative fair value of the



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warrants and the debentures at the time of issuance, these warrants were valued at approximately \$7.0 million. The detachable warrant value has been recorded as a reduction of the face value of the convertible debentures. Costs associated with placing the debentures totaling approximately \$1.9 million, were deferred and have been netted against the recorded convertible debenture balance. The convertible debenture discount consisting of the warrant value and debt issuance costs is being amortized over the five-year life of the debentures. All warrants remain outstanding as of March 31, 2003.

### 6. MESO SCALE DIAGNOSTICS JOINT VENTURE

Meso Scale Diagnostics, LLC. ("MSD") is a joint venture formed by Meso Scale Technologies, LLC. ("MST") and the Company in 1995. MSD was formed for the development and commercialization of products utilizing a proprietary combination of MST's multi-array technology together with our technology, which we refer to as the Research Program. MST is a company established and wholly-owned by Jacob Wohlstadter, the son of the Company's Chief Executive Officer. In August 2001, we amended our joint venture agreement and certain license and other agreements with MSD and MST in order to continue the MSD joint venture and entered into various related agreements. The Company refers to these amendments and agreements entered into in August 2001 as the MSD agreements. An independent committee of our Board of Directors, with the advice of independent advisors and counsel, negotiated and approved the MSD agreements.

Under the MSD agreements, the Company's funding commitment is based on an annual budget of MSD approved by an independent committee of its Board of Directors. The Company's funding commitment may be satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. An independent committee of the Company's Board of Directors approved funding for MSD for the period from January 1, 2003 to November 30, 2003 in an amount of \$20.6 million, subject to a permitted variance of fifteen percent. As of March 31, 2003, our remaining funding commitment to MSD was \$17 million. In addition, prior to November 30, 2003, the Company would also pay approximately \$3.7 million to MSD related to the permitted budget variance from prior years. For the years ended March 31, 2003, 2002 and 2001, the Company made total contributions to MSD of \$20.5 million, \$19.6 million and \$8.3 million, respectively. During the year ended March 31, 2002, the Company transferred certain equipment and leasehold interests to MSD in the amount of \$839,000, which amount is included in our contributions to MSD in such year.

The Company holds a 31% voting equity interest in MSD. The Company also owns 100% of the non-voting equity interest in MSD and is entitled to a preferred return on \$56.9 million of the funds previously invested in MSD through March 31, 2003, and on additional funds the company invests thereafter. This preferred return would be payable out of a portion of both future profits and certain third-party financings of MSD, generally before any payments are made to other equity holders.

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Although MST owns the remaining 69% of the voting interest in MSD, the Company generally has the right to approve significant MSD governance matters. In exercising this right, a committee of our Board of Directors must consider the interests of the Company and our stockholders while also taking into consideration the interests of MSD.

Under the terms of the MSD agreements, the Company has granted to MSD a worldwide, perpetual, exclusive license (with certain exceptions) to its technology for use in MSD's Research Program, which is more fully described in

the MSD agreements. If the Company ceases to be a member of the joint venture, it will receive royalty payments from MSD on all products developed and sold by MSD using its patents. MST holds a worldwide, perpetual, non-exclusive sublicense from MSD for certain non-diagnostic applications of the Company's technology. The Company will receive royalty payments from MST on any products developed and sold by MST using our patents. During the term of the MSD joint venture, MSD is the Company's exclusive means of conducting the Research Program and the Company is obligated to refrain from developing or commercializing any products, processes or services that are related to the Research Program in the diagnostic field or to MSD's research technologies as described in the MSD agreements, subject to certain exceptions. If the MSD joint venture expires or is terminated for any reason, the Company has agreed not to use the improvements granted to them by MSD to compete with MSD in its field the Company has agreed not to directly or indirectly develop or commercialize products, processes or services related to the Research Program in the diagnostic field or to MSD's research technologies.

The MSD joint venture agreement will expire on November 30, 2003, unless renewed. In addition, MST and MSD have the right to terminate the joint venture under certain circumstances, including a change in control of the Company, as defined. Upon the expiration of the MSD joint venture as a result of non-renewal or the termination by MSD or MST of the joint venture, MSD and MST have the right to purchase the Company's interest in MSD for a purchase price equal to fair market value (to be determined in accordance with the provisions and procedures set forth in the MSD agreements) minus a discount factor varying from 7.5%, in the case of non-renewal and certain other events, to 15.0%, in the case of termination because of a breach by the Company and certain other events. If MSD or MST exercises this right, it will be entitled to pay us the purchase price, plus interest, over time in installments equal to the sum of five percent of MSD Net Sales, as determined in accordance with the MSD agreements, and twenty percent of the net proceeds realized by MSD from the sale of debt or equity securities in any third party financing after the date of the sale of our interest in MSD.

MSD has an employment agreement with Jacob Wohlstadter, its President and Chief Executive Officer, the current term of which runs through November 30, 2004, and provides for a salary of \$250,000 for the year ending December 31, 2003. In addition, Jacob Wohlstadter is also eligible to receive, at the discretion of an independent committee of the Company's Board of Directors, an annual cash bonus in an amount not to exceed 20% of his annual salary. During the fiscal year ended March 31, 2003, Jacob Wohlstadter received \$250,000 from his employment at MSD. If MSD terminates the employment agreement without cause, or Jacob Wohlstadter terminates the employment agreement for good reason (which includes a "change in control" of the Company, as defined), Jacob Wohlstadter shall be entitled to receive, in addition to salary and pro rata bonus and adjustments earned through the 60th day following the notice of termination, an amount equal to from 3 to 12 times (depending on the reason for the termination) the monthly pro rata salary, bonus and adjustments in effect at the time of the termination. The Company is responsible for all amounts payable, costs incurred and other obligations under the employment agreement, which generally are expected to be paid out of the Company's funding commitment to MSD. The Company has also agreed to indemnify Jacob Wohlstadter against certain liabilities, including liability from the joint venture. In addition, the Company is obligated under the MSD agreements to indemnify each board member or officer of MSD with respect to any action taken by such person by reason of the fact that such person is or was a board member or an officer of MSD.

Since inception of the joint venture, the Company has utilized the equity method

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to account for the investment. In conjunction with entering into the MSD agreements and taking into account the progress made by MSD in the development of its products, the Company determined that future contributions to MSD would be made based on the future investment benefit to be obtained by the Company. Therefore, the Company's share of MSD losses since July 1, 2001, has been recorded as Equity in Loss of Affiliate. Prior to this date, the Company accounted for its equity investments in MSD as research and development funding and accordingly, recorded all MSD investments as research and development expenses as incurred. These research and development expenses totaled \$2.4 million and \$8.3 million for the years ended March 31, 2002 and 2001, respectively. During the years ended March 31, 2003, 2002 and 2001, operating costs allocated to MSD by the Company in connection with shared personnel and facilities totaled \$11.9 million, \$11.4 million and \$5.6 million, respectively. Since July 1, 2001, these allocated operating costs reduced certain Operating Costs and Expenses and increased Equity in Loss of Affiliate in the accompanying Consolidated Statements of Operations. The Company's Investment in Affiliate totaled \$9.2 million and \$6.2 million at March 31, 2003 and 2002, respectively.

Summarized financial information for MSD (unaudited) is as follows (in thousands):

	Years Ended March 31,		
	2003	2002	2001
Revenue	\$ 3,247	\$ -	\$ -
Operating expenses	21,537	13,560	6,185
Net loss	18,215	13,541	6,185

  

	March 31,	
	2003	2002
Current assets	\$ 5,685	\$ 4,571
Total assets	11,904	8,305
Current liabilities	2,226	885
Total liabilities	2,226	931
Total members' equity	9,678	7,374

### 7. INCOME TAXES

For the years ended March 31, 2003, 2002 and 2001, the Company recorded no federal or state income tax expense and did not owe or pay federal or state tax, as calculated by applying statutory rates to pretax income.

As of March 31, 2003, the Company has available for income tax reporting purposes net operating loss and general business credit carryforwards approximating \$206.3 million and \$7.3 million, respectively. Approximately \$20.5 million of the net operating loss carryforward results from the exercise of nonqualified stock options. Utilization of net operating loss carryforwards related to stock-based compensation will result in the benefit being credited to stockholders' equity.

The use of the Company's net operating loss carryforward may be significantly reduced if substantial changes in stock ownership take place. The carryforwards expire as follows (in thousands):

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2004	\$	6,556
2005		3,029
2006		-
2007		-
2008		142
2009 through 2022		196,609
		-----
Total	\$	206,336
		=====

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The approximate tax effects of temporary differences that gave rise to the Company's deferred tax assets are as follows:

	(in thousands)	
	2003	2002
	-----	-----
Deferred tax assets		
Accruals and reserves	\$ 551	\$ 661
Deferred revenue	219	198
Equipment and leasehold improvements	1,304	976
Investment in affiliate	1,954	1,791
Net operating loss and tax credit carryforwards	86,918	77,018
Other	(294)	6
	-----	-----
Total deferred tax asset	90,652	80,650
Less: valuation allowance	(90,652)	(80,650)
	-----	-----
Net deferred tax asset	\$ -	\$ -
	=====	=====

Due to uncertainties surrounding realizability, a valuation allowance equal to the total net deferred tax assets has been provided as of March 31, 2003 and 2002. The increase in the valuation allowance on the deferred tax asset was \$10.0 million and \$24.8 million for the years ended March 31, 2003 and 2002, respectively.

A reconciliation of the statutory federal income tax rate with the Company's effective income tax rate is as follows:

	2003	2002	2001
	-----	-----	-----
Statutory federal rate	(34.0%)	(34.0%)	(34.0%)
State income taxes, net of valuation allowance	-	-	-
Beneficial conversion	-	-	5.5
Valuation allowance	33.7	33.7	28.4
Other	0.3	0.3	0.1
	-----	-----	-----

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Effective tax rates	-%	-%	-%	-%
	=====	=====	=====	=====

### 8. EMPLOYEE SAVINGS PLAN

The Company has an Employee Savings Plan intended to qualify under Sections 401(a) and 401(k) of the Internal Revenue Code of 1986, as amended, and subject to the Employee Retirement Income Security Act of 1974, as amended. The Company made discretionary contributions of \$575,000, \$486,000 and \$299,000 for the years ended March 31, 2003, 2002 and 2001, respectively.

The Company is not obligated under any postretirement benefit plan.

### 9. RELATED PARTIES

The Company's Chief Executive Officer, Samuel J. Wohlstadter, is the principal and controlling stockholder, a director and the Chief Executive Officer of each of Wellstat Biologics Corporation, Wellstat Therapeutics Corporation, Hyperion Catalysis International ("Hyperion") and Proteinix Corporation ("Proteinix"). The Company's President and Chief Operating Officer, Richard J. Massey, is also a director of Hyperion and a less than 10% stockholder in Proteinix. These companies are therefore considered the Company's affiliates for the purpose of this discussion. The Company has shared services arrangements with each of these affiliated companies. These shared services include accounting and finance, human resources and other administrative services, as well as facility related costs and services. Shared services costs allocated to these companies totaled \$1.0 million, \$1.3 million and \$1.4 million for the years ended March 31, 2003, 2002 and 2001, respectively, which reduced certain Operating Costs and Expenses for the respective years.

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Amounts allocated to these affiliated companies are calculated and billed monthly based upon costs incurred by the Company and are determined through allocation methods that include time spent and square footage utilized. Amounts due from affiliated companies under the shared services arrangements were \$228,000 and \$94,000 at March 31, 2003 and 2002, respectively, which were paid subsequent to each respective year end.

Since 1995, the Company has engaged the law firm of Wilmer, Cutler & Pickering to provide legal services in connection with the Roche litigation and various other matters. A partner of the law firm, Richard W. Cass, is a director of the Company. In addition, Jennifer M. Drogula, who became the daughter-in-law of the Company's Chief Executive Officer in March 2002, is a partner of the law firm. The Company recorded approximately \$1.8 million, \$11.2 million and \$5.8 million in legal fees with the law firm for the years ended March 31, 2003, 2002 and 2001, respectively. Amounts due to the law firm totaled \$432,000 and \$1.7 million as of March 31, 2003 and 2002, respectively.

In addition, the Company has engaged the law firm of Hale and Dorr LLP to provide legal services in connection with the Roche litigation and otherwise. The Company first engaged this law firm in 1994. Deborah Wohlstadter, the wife of Jacob Wohlstadter and daughter-in-law of our Chief Executive Officer, since December 2001, is a junior partner in that law firm. The Company recorded approximately \$396,000 in legal fees paid to that firm during the fiscal year ended March 31, 2003.

The Company has licensed certain diagnostic technologies from affiliated companies and has licensed certain pharmaceutical technologies to affiliated

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companies. No royalties have ever been earned or accrued under these license agreements.

### 10. COMMITMENTS

**Capital Leases** - The Company is obligated under capital lease agreements for certain equipment. These agreements expire during the year ending March 31, 2004. The aggregate discounted lease payments are recorded as a liability, and the fair market value of the related leased assets are capitalized and amortized over the assets estimated useful lives. Total assets capitalized pursuant to such agreements were approximately \$224,000 and \$350,000 at March 31, 2003 and 2002, respectively with accumulated amortization totaling approximately \$220,000 and \$307,000 at March 31, 2003 and 2002, respectively.

**Operating Leases** - The Company leased office, laboratory and manufacturing facilities pursuant to operating leases expiring at various times from fiscal 2004 through fiscal 2010. Rent expense for facility and equipment operating leases totaled approximately \$2.9 million, \$2.6 million and \$2.4 million for the years ended March 31, 2003, 2002 and 2001, respectively.

At March 31, 2003, the future minimum operating lease payments are as follows (in thousands):

2004	\$ 2,635
2005	2,334
2006	653
2007	357
2008	258
2009 and thereafter	401
	-----
Total	\$ 6,638
	=====

### 11. SEGMENT INFORMATION

The Company operates in one business segment. It is engaged in the development and commercialization of ORIGEN-based products for the detection and measurement of biological substances.

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Product sales by region are as follows (in thousands):

	2003	2002	2001
	-----	-----	-----
United States	\$ 14,492	\$ 10,510	\$ 6,349
United Kingdom	1,823	1,789	612
All other foreign	2,671	2,284	3,952
	-----	-----	-----
Total	\$ 18,986	\$ 14,583	\$ 10,913
	=====	=====	=====

Substantially all of the Company's assets are held in the United States.

Except for royalty and contract fee revenue from Roche, a German entity, no single customer accounted for more than 10% of total revenue. Roche is the only customer with an account receivable balance that exceeds 10% of total outstanding receivables. The amount receivable from Roche totaled 61% and 65% of total accounts receivable at March 31, 2003 and 2002, respectively. (see Note 2)

## 12. LITIGATION

### Roche

In 1997, the Company filed a lawsuit, which is referred to as the Roche litigation, against Roche in the U.S. District Court for the District of Maryland (District Court). The lawsuit arose out of the Roche license agreement, under which the Company licensed to Roche certain rights to develop and commercialize diagnostic products based on the Company's ORIGEN technology. In the Roche litigation, the Company alleged, among other things, that Roche failed to perform certain material obligations under the Roche license agreement and engaged in unfair competition against the Company. The jury trial in this litigation was completed in January 2002, and the jury rendered a verdict that Roche had materially breached the license agreement, had violated its duty to the Company of good faith and fair dealing, and had engaged in unfair competition against the Company.

In February 2002, the District Court issued a final order of judgment that confirmed the jury's decisions to award \$105 million in compensatory damages and \$400 million in punitive damages, entitled the Company to terminate the Roche license agreement, and directed Roche to grant to the Company for use in its retained fields a license to certain improvements. Roche was also ordered, at its sole cost and expense, to deliver such improvements to the Company and to provide all other information and materials required or necessary to enable the Company to commercialize these improvements. Improvements, as defined in the final order of judgment, include Roche's Elecsys 1010, 2010 and E170 lines of clinical diagnostic immunoassay analyzers, the tests developed for use on those systems, and certain aspects of Roche's nucleic acid amplification technology called PCR. The final order of judgment also bars Roche from marketing, selling, placing or distributing outside of its licensed field any products, including its Elecsys diagnostics product line, that are based on the Company's ORIGEN technology.

Roche filed counterclaims against the Company alleging, among other things, that the Company breached the Roche license agreement by permitting Eisai, another of the Company's licensees, to market certain ORIGEN-based products in Japan. The final order of judgment found in the Company's favor and against Roche on all of Roche's counterclaims, except for one for which the Company was ordered to pay \$500,000.

In April 2002, the District Court affirmed a final order of judgment that awarded the Company \$505 million in damages, confirmed the Company's right to terminate the Roche license agreement, and directed Roche to grant to the Company for use in its retained fields a license to improvements developed or acquired by Roche in the course of the Roche license agreement, including Roche's Elecsys and E170 diagnostics product lines.

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Roche appealed certain aspects of the final order of judgment to the U.S. Court of Appeals for the Fourth Circuit (Appellate Court). In connection with that appeal, Roche posted a \$600 million bond to support its financial obligations to the Company under the final order of judgment. During the appeal process Roche is obligated to continue to comply with the terms of the Roche license agreement, including its obligation to continue to pay the Company royalties on Roche's sales of royalty bearing products and to share and deliver improvements. Roche's obligation to pay the \$505 million of monetary damages awarded to the Company is suspended until completion of the appeal process. On February 24,

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2003, the Appellate Court heard oral arguments on the appeal by Roche of the final order of judgment.

The Company has voluntarily agreed not to terminate the Roche license agreement until the Appellate Court determines that it is entitled to do so; however, the Company has notified Roche that the Roche license agreement will terminate immediately in the event the Appellate Court issues an opinion confirming the final order of judgment rendered by the District Court that the Company is entitled to terminate the Roche license agreement.

### Other Proceedings

In 2001, Brown Simpson Strategic Growth Fund L.P., Brown Simpson Strategic Growth Fund, Ltd. and Brown Simpson Partners I (collectively Brown Simpson) and Laurance Paskowitz initiated separate shareholder derivative lawsuits for and on behalf of the shareholders of the Company in the Circuit Court for Montgomery County, Maryland (Circuit Court) against four of the Company's current directors, two former directors, three executive officers and the Company as a nominal defendant.

The complaints alleged breach of fiduciary duties by the named individual defendants in connection with transactions between the Company and other entities in which certain directors and officers are alleged to have an interest, including MSD.

Both lawsuits sought principally the following: that the defendants hold in trust and be required to account for and restore to the Company damages that the Company has allegedly sustained by reason of the allegations and relief relating to board and management composition. The Paskowitz complaint also sought damages for a class of the Company shareholders for direct claims against the individual defendants. The complaints did not include any claims against the Company.

In May 2002, the Circuit Court issued an opinion and order dismissing all claims asserted against all of the defendants in both cases. No appeal was filed by the Brown Simpson plaintiff and the decision in that case is now final. The Paskowitz plaintiff filed an appeal to the Court of Special Appeals in Maryland seeking review only for one direct claim. A final decision of the Court of Special Appeals was issued in March 2003 affirming the dismissal of the complaint by the Circuit Court. No appeal was filed and the decisions dismissing all claims in all of these cases are now final.

The Company is involved, from time to time, in various other routine legal proceedings arising out of the normal and ordinary operation of its business which it does not anticipate will have a material adverse impact on its business, financial condition, results of operations or cash flows.

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### 13. VALUATION AND QUALIFYING ACCOUNTS

The following table sets forth activity in the Company's allowance for doubtful accounts (in thousands):

For the Years Ended March 31,	Balance at Beginning of Period	Provisions Recorded	Write-Offs	Balance at End of Period
----------------------------------	--------------------------------------	------------------------	------------	--------------------------------



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2001	\$	64	\$	135	\$	(169)	\$	30
2002		30		60		(1)		89
2003		89		135		(76)		148

## 14. QUARTERLY OPERATING RESULTS (Unaudited)

For the years ended March 31,	First	Second	Third	Fourth
	(In thousands, except per share data)			
2003				
Revenue	\$ 11,999	\$ 13,425	\$ 16,251	\$ 14,791
Income (loss) from operations	(2,176)	(2,331)	70	(2,012)
Net loss	(7,362)	(8,342)	(4,306)	(7,978)
Basic and diluted loss per share	(0.33)	(0.35)	(0.18)	(0.34)
2002				
Revenue (1)	\$ 8,258	\$ 9,396	\$ 10,424	\$ 13,969
Loss from operations (2,3,4)	(10,619)	(7,636)	(4,184)	(4,117)
Net loss (4)	(11,917)	(12,103)	(9,227)	(9,279)
Basic and diluted loss per share	(0.69)	(0.64)	(0.48)	(0.43)

- (1) Revenues for the first and fourth quarters includes \$550,000 and \$3.2 million, respectively of Roche royalties relating to modifications made by Roche to their methodology for computing royalties.
- (2) Operating costs and expenses for the third quarter have been reduced by a reimbursement of \$5.7 million resulting from the settlement of certain patent infringement litigation with Hoffman LaRoche.
- (3) Operating costs and expenses for the fourth quarter includes a write-off of \$1.1 million of TRICORDER detection modules previously recorded as fixed assets. The impact on individual prior interim and annual periods was not significant.
- (4) See Note 6 of Notes to Consolidated Financial Statements for a description of the recording of losses under the equity method of accounting related to the MSD investment.

The sum of quarterly per share amounts may not be equal to per share amounts reported for year-to date periods. This is due to changes in the number of weighted average shares outstanding and the effects of rounding for each period.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not Applicable.

## PART III

Certain information required by Part III is omitted from this Report in that the Company will file a definitive proxy statement pursuant to Regulation 14A (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Report, and certain information included therein is incorporated herein by reference. Only those sections of the Proxy Statement which specifically address the items set forth herein are incorporated by reference.

## ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE COMPANY.

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The following table sets forth, the names and certain other information regarding our directors and executive officers at June 30, 2003. Each officer serves without a set term.

NAME	AGE	POSITION	DIRECTOR SINCE
Samuel J. Wohlstadter (3)	61	Chairman, Chief Executive Officer and Director	1982
Richard J. Massey (3)	56	President, Chief Operating Officer and Director	1990
Richard W. Cass	57	Director	2000
Anthony Rees (1,4)	59	Director	2000
Robert Salsmans (1,2,4)	58	Director	1995
Joop Sistermans (1,2,4)	60	Director	1999
George V. Migauskys	48	Vice President, Chief Financial Officer; Secretary	--

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- 1 Member of Audit Committee
- 2 Member of Executive Compensation Committee
- 3 Member of Non-Officer Stock Option Committee
- 4 Member of Joint Venture Operating Committee

Set forth below is certain biographical information regarding our directors and executive officers.

Samuel J. Wohlstadter is one of our founders 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 Wellstat Therapeutics Corporation (formerly 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 Wellstat Biologics Corporation (formerly 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.

Richard W. Cass has been a partner with the law firm of Wilmer, Cutler & Pickering since 1979 and is a former member of his firm's Management Committee and co-chairman of its Corporate Business Transactions Practice Group. He specializes in corporate and securities law and represents companies and entrepreneurs in acquisitions, dispositions, joint ventures and public securities offerings. Mr. Cass received his bachelor's degree from Princeton University and his law degree from Yale University.

Anthony Rees, D. Phil. is Director of Science at Synt:em, a private biopharmaceutical company that is focused on the discovery and development of novel Central Nervous System (CNS) medicines, a position he has held since January 2000. During 1997-1999, he served as a non-executive employee of Synt:em. Professor Rees has held faculty positions at the University of Oxford (1980-1990) and the University of Bath (Great Britain) where, from 1990-1993, he was Head of the Biochemistry Department and from 1993-1997 Head of the School of Biology and Biochemistry. He is currently Professorial Research Fellow. Professor Rees has been Executive Editor of the journal Protein Engineering since 1997. In 1989 he co-founded Oxford Molecular PLC, a British software company. While on sabbatical from Oxford University from 1989 to 1990, Professor Rees was employed by us as Vice President of Research. Professor Rees received his doctoral degree from Oxford University

Robert R. Salsmans serves as President and Chief Executive Officer of Diosynth RTP, Inc. the U.S. subsidiary of Diosynth, a business unit that is part of the Pharma group of Akzo Nobel N.V., a holding company with high technology operating units in the biotechnology, medical, and pharmaceutical industries, a position he has held since November 2001. From September 1994 to August 2001, Mr. Salsmans was President and Chief Executive Officer of Organon Teknika B.V. in The Netherlands. From October 1993 through August 1994, Mr. Salsmans served as Managing Director of Organon Teknika B.V., a business unit of Akzo Nobel, and from 1990 through September 1993, he served as Managing Director of Organon International B.V.

Joop Sistermans serves as Chairman, Advisory Council for Science and Technology Policy to the Dutch Government and Parliament, a position he has held since January 1, 2003. In addition Mr. Sistermans has been Chairman Supervisory Board of Thuiszorg Kempenstreek (Netherlands), a public organization for homecare, a position he has held since 2000. He also serves on the Advisory Committee Economy, Ecology and Technology for the Dutch Ministry of Economic Affairs, a position he has held since 1999. Mr. Sistermans is a Supervisory Board member for the University of Twente, the Netherlands, a position he has held since 1997 and of the Maastricht School of Management, the Netherlands, a position he has held since 2001. Mr. Sistermans serves on the Boards of Directors of United Biomedical Inc., Hauppauge, NY since 1999, of the Bio Primate Research Centre, Rijswijk, the Netherlands since 1997, of Keygene N.V. in Wageningen, the Netherlands since 2002 and of Aglaia Biomedical N.V. since 2003. He was Vice Chairman of the Framework Programme Expert Advisory Group of the European Commission for Innovative Products, Processes and Organisations in Brussels, Belgium from 1998 until 2003. From 1999 to 2000, Mr. Sistermans served as Executive Vice President of Origin International B.V., a member company of the Philips Electronics Group of Companies based in the Netherlands. Mr. Sistermans was employed by Akzo Nobel from 1974 to 1999, and was a member of the Executive Council and Executive Vice President responsible for Strategy and Technology from 1994 until 1999. Mr. Sistermans previously served on the Board of Directors of the Company from 1993 to 1995 while in the position of President and Chief Executive Officer of Akzo Nobel's Organon Teknika business unit.

George V. Migauskys 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. Migauskys 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

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

NAME	AGE	POSITION
Daniel Abdun-Nabi.....	48	General Counsel
Gerald Andros.....	41	Director of Sales
David Boudreau.....	46	Director of Operations
R. Don Elsey.....	49	Director of Finance and Administration

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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 Securities and Exchange Commission.

Gerald Andros has been our Director of Sales 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.

### SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of Common Stock and other of our equity securities. Officers, directors and greater than 10% stockholders are required by Securities and Exchange Commission regulation to furnish us with copies of all Section 16(a) forms they file. Based on our records and other information, we believe that all of our current directors and executive officers, reported all transactions in our Common Stock and options on a timely basis during the fiscal year ended March 31, 2003, except for one Form 5 prepared by the Company 27 days late and immediately filed by Samuel J. Wohlstadter reporting the June 2002 grant of a stock option.

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## ITEM 11. EXECUTIVE COMPENSATION.

The information required under this item is incorporated herein by reference to the sections entitled "Election of Directors -- Compensation for Directors", and -- Compensation Committee Interlocks and Insider Participation", and "Executive Compensation", in the Company's Proxy Statement with respect to the Annual Meeting of Shareholders to be held on September 10, 2003.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth, as of March 31, 2003 certain information with respect to compensation plans under which the Company's common stock is authorized for issuance.

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### EQUITY COMPENSATION PLAN INFORMATION

PLAN CATEGORY	NUMBER OF SECURITIES TO BE ISSUED UPON EXERCISE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS	WEIGHTED AVERAGE EXERCISE PRICE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS	NUMBER OF SEC REMAINING AVAIL FUTURE ISSUANC EQUITY COMPENSAT (EXCLUDING SEC REFLECTED IN CO
	(A) (B) (C)		
EQUITY COMPENSATION PLANS APPROVED BY SECURITY HOLDERS	1,585,821	\$18.16	481,841
EQUITY COMPENSATION PLANS NOT APPROVED BY SECURITY HOLDERS	—	N/A	250,000
TOTAL	1,585,821	\$18.16	731,841

### DESCRIPTION OF 2001 BROAD BASED OPTION PLAN

Our 2001 Broad Based Option Plan provides for the grant of options to acquire up to 250,000 shares of Common Stock. As of March 31, 2003, no options have been granted under this plan. The purpose of the plan is to attract and retain the services of selected employees. The plan is administered by a committee of our Board of Directors, which has the authority to interpret, and grant options under, the plan. Options may only be granted to employees who are not our officers or directors. The exercise price for options granted under the plan may not be less than fair market value of a share of Common Stock on the date of grant. Options will vest in accordance with a schedule determined by the Committee and may have a term of up to ten years. The plan will terminate on July 24, 2010, although the Board may suspend or terminate the plan at any time. The number of shares related to outstanding options, the exercise price per share of Common Stock subject to such outstanding options and the number of shares of Common Stock pursuant to the plan will be appropriately adjusted in the event of a stock dividend, stock split or other similar event. If any

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outstanding option expires, or is terminated or canceled without being exercised, then the shares underlying the option will again be available for grant under the plan. In the event of dissolution, liquidation, merger or other corporate reorganization, any surviving corporation will be required to assume the outstanding options, substitute similar options, or allow the outstanding options to continue. If the surviving corporation in such a transaction fails to do so, then the outstanding options will become immediately exercisable and will expire if not exercised before the stated event.

Other information required under this item is incorporated herein by reference to the section entitled "Security Ownership of Certain Beneficial Owners and Management" in the Company's Proxy Statement with respect to the Annual Meeting of Shareholders to be held on September 10, 2003.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

MSD is a joint venture formed 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 our technology, which we refer to as the Research Program. MST is a company established and wholly-owned by Jacob Wohlstadter, the son of our Chief Executive Officer. In August 2001, we amended our joint venture agreement and certain license and other agreements with MSD and MST in order to continue the MSD joint venture and entered into various related agreements. We refer to these amendments and agreements entered into in August 2001 as the MSD agreements. An independent committee of our Board of Directors, with the advice of independent advisors and counsel, negotiated and approved the MSD agreements.

MSD manufactures and markets two instrument systems, the Sector HTS and the Sector PR, both of which combine our ORIGIN technology and MST's multi-array technology. The Sector HTS is an ultra high throughput drug discovery system engineered for applications such as high throughput screening and large scale proteomics. The Sector PR is a smaller system designed for benchtop applications such as assay development, research in therapeutic areas, cellular biology and medium throughput screening.

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MSD also manufactures and markets a line of proprietary reagents, assays and plates that are used on these systems. Product sales commenced in October 2002, and during the year ended March 31, 2003, MSD had product sales of \$3.2 million and a net loss of \$18.2 million.

Under the MSD agreements, our funding commitment is based on an annual budget of MSD approved by an independent committee of our Board of Directors. Our funding commitment may be satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. An independent committee of our Board of Directors approved funding for MSD for the period from January 1, 2003 to November 30, 2003 in an amount of \$20.6 million, subject to a permitted variance of fifteen percent. As of March 31, 2003, our remaining funding commitment to MSD was \$17.0 million. In addition, prior to November 30, 2003, the Company would also pay approximately \$3.7 million to MSD related to the permitted budget variance from prior years. For the years ended March 31, 2003, 2002 and 2001, we made total contributions to MSD of \$20.5 million, \$19.6 million and \$8.3 million, respectively. During the year ended March 31, 2002, the Company transferred certain equipment and leasehold interests to MSD in the amount of \$839,000, which amount is included in the in-kind contributions to MSD in such year.

We hold a 31% voting equity interest in MSD, and are entitled to a preferred return on \$56.9 million of the funds previously invested in MSD through March 31, 2003, 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 of MSD, generally before any payments are made to other equity holders. Although MST owns the remaining 69% of the voting interest in MSD, the Company generally has the right to approve significant MSD governance matters. In exercising this right, a committee of our Board of Directors must consider the interests of the Company and our stockholders while also taking into consideration the interests of MSD.

The Company and MST are the sole members of MSD and each holds one seat on MSD's two-member board of managers. Our representative on the MSD Board of Managers is Richard J. Massey, the Company's President and Chief Operating Officer, who also serves as the Treasurer and Secretary for MSD. Dr. Massey receives no compensation from MSD or the Company for serving as the Treasurer and Secretary of MSD. The other member of the MSD Board of Managers is Jacob Wohlstadter, who is the sole owner of MST and serves as President and Chief Executive Officer of MSD. Neither Dr. Massey nor any other executive officer or director of the Company has any ownership interest in MST or MSD, other than through ownership of interests in the Company. Samuel J. Wohlstadter disclaims any ownership interest in MST or MSD as a result of Jacob Wohlstadter's ownership interest in those entities.

Under the terms of the MSD agreements, we have granted to MSD a worldwide, perpetual, exclusive license (with certain exceptions) to our technology, for use in MSD's Research Program, which is more fully described in the MSD agreements. If we cease to be a member of the joint venture, we will receive royalty payments from MSD on all products developed and sold by MSD using our patents. MST holds a worldwide, perpetual, non-exclusive sublicense from MSD for certain non-diagnostic applications of the Company's technology. The Company will receive royalty payments from MST on any products developed and sold by MST using our patents. During the term of the MSD joint venture, MSD is our exclusive means of conducting the Research Program and we are obligated to refrain from developing or commercializing any products, processes or services that are related to the Research Program in the diagnostic field or to MSD's research technologies as described in the MSD agreements, subject to certain exceptions. If the MSD joint venture expires or is terminated for any reason, we have agreed not to use the improvements granted to us by MSD to compete with MSD in its field and we have agreed not to directly or indirectly develop or commercialize products, processes or services related to the Research Program in the diagnostic field or to MSD's research technologies.

The MSD joint venture agreement will expire on November 30, 2003, unless renewed. In addition, MST and MSD have the right to terminate the joint venture under certain circumstances, including (1) breach of our obligations, including our funding obligations to MSD, (2) MSD's termination of Jacob Wohlstadter's employment (other than for cause or disability),

(3) if Jacob Wohlstadter is entitled to terminate his employment agreement for good reason (as defined in his employment agreement) or (4) upon a change in control of the Company, as defined. For purposes of the MSD agreements, a change in control includes, among other things, the acquisition by any person or group (other than Samuel Wohlstadter and his affiliates) of 30% or more of the beneficial ownership of any class of voting securities of the Company.

Upon the expiration of the MSD joint venture as a result of non-renewal or the termination by MSD or MST of the joint venture, MSD and MST have the right to purchase the Company's interest in MSD for a purchase price equal to fair market value (to be determined in accordance with the provisions and procedures set forth in the MSD agreements, which shall include a determination by appraisers if the parties are unable to agree on fair market value) minus a discount factor varying from 7.5%, in the case of non-renewal and certain other events, to 15.0%, in the case of termination because of a breach by us and certain other events. If MSD or MST exercises this right, it will be entitled to pay us the purchase price, plus interest, over time in installments equal to the sum of five percent of MSD Net Sales, as determined in accordance with the MSD agreements, and twenty percent of the net proceeds realized by MSD from the sale of debt or equity securities in any third party financing after the date of the sale of our interest in MSD.

Following the termination or non-renewal of the joint venture agreement, many of our licenses and other arrangements with MSD and MST will continue indefinitely.

MSD has an employment agreement with Jacob Wohlstadter, its President and Chief Executive Officer, the current term of which runs through November 30, 2004, and provides for a salary of \$250,000 for the year ending December 31, 2003. In addition, Jacob Wohlstadter is also eligible to receive, at the discretion of an independent committee of the Company's Board of Directors, an annual cash bonus in an amount not to exceed 20% of his annual salary. During the fiscal year ended March 31, 2003, Jacob Wohlstadter received \$250,000 from his employment at MSD. If MSD terminates the employment agreement without cause, or Jacob Wohlstadter terminates the employment agreement for good reason (which includes a "change in control" of the Company, as described above), Jacob Wohlstadter shall be entitled to receive, in addition to salary and pro rata bonus and adjustments earned through the 60th day following the notice of termination, an amount equal to from 3 to 12 times (depending on the reason for the termination) the monthly pro rata salary, bonus and adjustments in effect at the time of the termination. In addition, upon such a termination, MSD and MST shall have a joint right to purchase our interest in MSD on terms described above. We are responsible for all amounts payable, costs incurred and other obligations under the employment agreement, which generally are expected to be paid out of the Company's funding commitment to MSD. We have agreed to indemnify Jacob Wohlstadter against certain liabilities, including liability from the joint venture. In addition, we are obligated under the MSD agreements to indemnify each board member or officer of MSD with respect to any action taken by such person by reason of the fact that such person is or was a board member or an officer of MSD.

Since inception of the joint venture, the Company has utilized the equity method to account for the investment. In conjunction with entering into the MSD agreements and taking into account the progress made by MSD in the development of its products, the Company determined that future contributions to MSD would be made based on the future investment benefit to be obtained by the Company. Therefore, the Company's share of MSD losses since July 1, 2001, has been recorded as Equity in Loss of Affiliate. Prior to this date, the Company accounted for its equity investments in MSD as research and development funding and accordingly, recorded all MSD investments as research and development expenses as incurred. These research and development expenses totaled \$2.4 million and \$8.3 million for the years ended March 31, 2002 and 2001, respectively. During the years ended March 31, 2003, 2002 and 2001, operating costs allocated to MSD by the Company in connection with shared personnel and facilities totaled \$11.9 million, \$11.4 million and \$5.6 million, respectively.



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Since July 1, 2001, these allocated operating costs reduced certain Operating Costs and Expenses and increased Equity in Loss of Affiliate in the accompanying Consolidated Statements of Operations. The Company's Investment in Affiliate totaled \$9.2 million and \$6.2 million at March 31, 2003 and 2002, respectively.

Jacob Wohlstadter has a consulting agreement with us that terminates on August 15, 2004. Pursuant to the consulting agreement, Jacob Wohlstadter will be entitled to receive such fees as the Company and Jacob Wohlstadter agree to when particular services are requested by the Company. During fiscal 2002, Jacob Wohlstadter received \$275,000 for consulting services performed for the Company for the period 1995 through 2001. In his role as a consultant, Jacob Wohlstadter has received stock option grants. In May 1997, he was granted options to purchase 180,000 shares of Common Stock, with an exercise price of \$6.00 per share, which was the fair market value on the date of grant. The options will expire on May 8, 2007, and are fully vested. In August 2000, Jacob Wohlstadter was granted options to purchase 75,000 shares of Common Stock, with an exercise price of \$18.75 per share, which was the fair market value on the date of grant. These options will expire on August 1, 2010, and 45,000 shares are exercisable within 60 days of June 15, 2003.

Our Bylaws provide that we will indemnify our directors and its officers to the fullest extent permitted by Delaware law. We are also empowered under our Bylaws to enter into indemnification contracts with its directors and officers and to purchase insurance on behalf of any person whom it is required or permitted to indemnify. Pursuant to these provisions, we have entered into indemnity agreements with each of our directors and executive officers and certain of our key employees. We have also obtained director and officer liability insurance for claims up to \$30 million.

In addition, our Certificate of Incorporation provides that our directors shall not be liable for monetary damages for breach of the directors' fiduciary duty of care as a director, except liability for

- o any breach of the director's duty of loyalty to the Company or its stockholders,
- o acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law,
- o under Section 174 of the Delaware General Corporation Law or
- o any transaction from which a director derived an improper personal benefit.

If the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting personal liability of directors, then the liability of a director shall be eliminated or limited to the fullest extent permitted by the Delaware law.

During fiscal year 1995 the Company entered into agreements to develop and commercialize biomedical products utilizing advanced materials and a supply agreement with Hyperion. Messrs. Massey and Wohlstadter are directors of Hyperion. In addition, Mr. Wohlstadter is the principal and controlling stockholder of Hyperion, beneficially owning more than 50% of the outstanding common stock of Hyperion. Mr. Wohlstadter is also the Chief Executive Officer of Hyperion. During the fiscal year ended March 31, 2003, the Company did not pay to, or receive from, Hyperion any amounts under these agreements. In addition, Hyperion has a service arrangement with the Company under which the Company provides certain administrative and other services at cost to Hyperion. The total amount billed by and paid to the Company under this arrangement for the year-ended March 31, 2003 was \$338,000. Mr. Wohlstadter is the principal and

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controlling stockholder, a director and the Chief Executive Officer of Wellstat Biologics, Wellstat Therapeutics and Proteinix. Dr. Massey is a less than 10% stockholder in Proteinix.

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In 1993, the Company licensed certain diagnostic technologies from, and certain pharmaceutical technologies to, Proteinix and Wellstat Therapeutics. No royalties have ever been earned or accrued under these agreements. Wellstat Biologics, Proteinix and Wellstat Therapeutics each has had a services arrangement with the Company since 1994, 1992 and 1986, respectively, under which the Company provides certain services. These services include accounting and finance, human resources and other administrative services, as well as facility related costs and services. For the year ended March 31, 2003, the total amounts billed to, and paid by, Wellstat Biologics, Wellstat Therapeutics and Proteinix, under this arrangement were \$313,000, \$352,000, and \$6,000, respectively.

In connection with the exercise of employee stock options in July 2000, Samuel J. Wohlstadter, our Chief Executive Officer, received a loan from us. The loan is a 6.62% simple interest only, full recourse loan against all assets of Mr. Wohlstadter in the principal amount of \$2,060,500 maturing in July 2007. Interest charged to and paid by Mr. Wohlstadter under this loan arrangement during fiscal 2003 was \$136,405. The loan is collateralized by the pledge of 100,000 shares of Common Stock.

In connection with the exercise of an employee stock option in July 2000, Richard Massey, President and Chief Operating Officer, received a loan from the Company. The loan is a 6.62% simple interest only, full recourse loan against all assets of Dr. Massey in the principal amount of \$1,649,000, maturing in July 2007. Interest charged to and paid by Dr. Massey under this loan arrangement during fiscal 2003 was \$109,164. The loan was collateralized by the pledge of 80,000 shares of Common Stock owned by Dr. Massey. This loan has been repaid in full and the pledged collateral has been released.

Since 1995 the Company has retained Wilmer Cutler & Pickering to perform legal services in connection with the Roche litigation and other matters. Richard Cass, one of our directors, is a partner of the law firm of Wilmer, Cutler & Pickering and is a member of that firm's Management Committee and co-chairman of its Corporate Practices Group. In addition, Jennifer M. Drogula, who became the daughter-in-law of our Chief Executive Officer in March 2002, is a partner of the firm since January 1, 2001. We recorded approximately \$2.1 million, \$11.2 million and \$5.8 million in legal fees with the law firm for the years ended March 31, 2003, 2002 and 2001, respectively. Amounts due to the law firm totaled \$432,000 and \$1.7 million as of March 31, 2003 and 2002, respectively.

In addition, we engaged the law firm of Hale and Dorr LLP to provide legal services in connection with the Roche litigation and otherwise. The Company first engaged this law firm in 1994. Deborah Wohlstadter, the wife of Jacob Wohlstadter and daughter-in-law of our Chief Executive Officer since December, 2001, is a junior partner in that law firm. We recorded approximately \$396,000 in legal fees paid to that firm during the fiscal year ended March 31, 2003.

In 2001, Brown Simpson and Laurance Paskowitz initiated separate shareholder derivative lawsuits for and on behalf of the shareholders of the Company in the Circuit Court against four of the Company's current directors, two former directors, three executive officers and the Company as a nominal defendant.

The complaints alleged breach of fiduciary duties by the named individual defendants in connection with transactions between the Company and other

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entities in which certain directors and officers are alleged to have an interest, including MSD.

Both lawsuits sought principally the following: that the defendants hold in trust and be required to account for and restore to the Company damages that the Company has allegedly sustained by reason of the allegations and relief relating to board and management composition. The Paskowitz complaint also sought damages for a class of the Company shareholders for direct claims against the individual defendants. The complaints did not include any claims against the Company.

In May 2002, the Circuit Court issued an opinion and order dismissing all claims asserted against all of the defendants in both cases.

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No appeal was filed by the Brown Simpson plaintiff and the decision in that case is now final. The Paskowitz plaintiff filed an appeal to the Court of Special Appeals in Maryland seeking review only for one direct claim. A final decision of the Court of Special Appeals was issued in March 2003 affirming the dismissal of the complaint by the Circuit Court. No appeal was filed and the decisions dismissing all claims in all of these cases are now final.

### ITEM 14. CONTROLS AND PROCEDURES

Our management, including our Chairman of the Board and Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer), evaluated within 90 days prior to the filing of this Form 10-K the effectiveness of the design and operation of our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities and Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

As a result of this evaluation, these executive officers have concluded that, as of such date, the design and operation of our disclosure controls and procedures were effective. There have been no significant changes in our internal controls, subsequent to the date of our Chairman of the Board and Chief Executive Officer and our Chief Financial Officer completed their evaluation.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

### ITEM 15. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required under this item is incorporated herein by reference to the section entitled "Principal Accountant Fees and Services" in the Company's Proxy Statement with respect to the Annual Meeting of Shareholders to be held on September 10, 2003.

### PART IV

### ITEM 16. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(a) Documents filed as a part of this report.

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### (1) Index to Financial Statements.

The financial statements listed in the Index to Financial Statements are filed as part of this Annual Report on Form 10-K. See ITEM 8 - Consolidated Financial Statements and Supplementary Data.

### (2) Index to Financial Statement Schedules.

All financial statement schedules are omitted because they are not applicable, or not required, or because the required information is included in the financial statements or notes thereto.

### (3) Index to Exhibits.

The Exhibits filed as part of this Form 10-K are listed on and incorporated by reference to the Exhibit Index immediately following the Certifications to this Form 10-K.

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### (b) Reports on Form 8-K:

The Company did not furnish any reports on Form 8-K during the quarter ended March 31, 2003.

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

### (d) Financial Statement Schedules. All financial Statement schedules are omitted because they are not applicable, or not required, or because the required information is included in the financial statements or notes thereto.

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## 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.

June 30, 2003

By: /s/ Samuel J. Wohlstadter

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Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company and in

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the capacities and on the dates indicated.

Signature	Title	
/s/ Samuel J. Wohlstadter ----- Samuel J. Wohlstadter	Chief Executive Officer  (Principal Executive Officer); Director	Ju
/s/ George V. Migausky ----- George V. Migausky	Vice President  and Chief Financial Officer (Principal Financial and Accounting Officer)	Ju
/s/ Richard J. Massey ----- Richard J. Massey	President, Chief Operating Officer;  Director	Ju
/s/ Richard Cass ----- Richard Cass	Director	Ju
/s/ Anthony Rees ----- Anthony Rees	Director	Ju
/s/ Robert Salsmans ----- Robert Salsmans	Director	Ju
/s/ Joop Sistermans ----- Joop Sistermans	Director	Ju

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### CERTIFICATIONS PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

#### CERTIFICATION

I, Samuel J. Wohlstadter, certify that:

1. I have reviewed this annual report on Form 10-K of IGEN International, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial

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information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: June 30, 2003

/s/Sameul J. Wohlstadter

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Samuel J. Wohlstadter

Chairman of the Board and Chief Executive Officer

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IGEN INTERNATIONAL, INC.  
CERTIFICATIONS PURSUANT TO  
SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002

CERTIFICATION

I, George V. Migausky, certify that:

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1. I have reviewed this annual report on Form 10-K of IGEN International, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: June 30, 2003

/s/George V. Miagusky

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George V. Migausky  
Vice President and Chief Financial Officer

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## INDEX TO EXHIBITS

EXHIBIT	NUMBER DESCRIPTION OF DOCUMENT
3.1 (3)	Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on August 30, 1996.
3.2 (3)	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 (7)	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 (10)	Bylaws, as currently in effect.
4.1 (6)	Form of Right Certificate.
4.2 (6)	Rights Agreement, dated November 6, 1996, between the Company and The First National Bank of Boston.
4.3 (8)	Note Purchase Agreement between the Company and the purchasers named therein dated as of March 22, 1999, including the form of 8.5% Senior Secured Notes due 2006.
4.4 (9)	Securities Purchase Agreement, dated as of January 11, 2000, among Company and the Purchasers listed on Schedule I thereto, including the form of 5% Subordinated Convertible Debentures and the form of Common Stock Purchase Warrant.
10.1 (2*)	Agreement between the Company and Eisai Co., Ltd. dated May 25, 1990.
10.2 (1)	Supplemental Agreement between Eisai Co., Ltd. and the Company.
10.3 (20)	Extension Agreement between the Company and Eisai Co. Ltd., dated July 11, 2002.
10.4 (2*)	License and Technology Development Agreement between the Company and Boehringer Mannheim GmbH dated September 23, 1992.
10.5 (2*)	License and Technology Development Agreement between the Company and Organon Teknika B.V. dated May 19, 1993.
10.6 (2*)	Term Sheet for Consolidation of Research Projects between the Company and Proteinix Corporation dated December 14, 1993.
10.7 (2*)	Term Sheet for consolidation of Cancer Research Projects between the Company and Pro-Neuron, Inc. dated December 14, 1993.
10.8 (2)	Form of Indemnity Agreement entered into between the Company and its directors and officers. Filed herewith.
10.9 (2+)	1985 Stock Option Plan, as amended, and related Form of Incentive Stock Option Grant and Form of Nonqualified Stock Option Grant.
10.10 (4+)	1994 Stock Option Plan.
10.11 (4)	Lease Agreement between the Company and W-M 16020 Limited Partnership dated October 5, 1994.
10.12 (5*)	Joint Venture Agreement, dated as of November 30, 1995, between Meso Scale Diagnostics, LLC. ("MSD"), Meso Scale Technologies, LLC. ("MST") and the Company.
10.13 (5)	Limited Liability Company Agreement, dated as of November 30, 1995, between MSD, MST and the Company.
10.14 (5*)	IGEN/MSD License Agreement, dated as of November 30, 1995, between MSD and the Company.



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## INDEX TO EXHIBITS (CONTINUED)

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
10.15 (5+)	Indemnification Agreement, dated as of November 30, 1995, between the Company and Jacob Wohlstadter.
10.16 (13*)	Amendment No.1 to Joint Venture Agreement between Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC., and IGEN International, Inc. dated August 15, 2001.
10.17 (13)	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.
10.18 (13*)	Amendment No.1 to IGEN/MSD License Agreement dated August 15, 2001 between Meso Scale Diagnostics, LLC. and IGEN International, Inc.
10.19 (13)	MSD/MST Sublicense Agreement dated November 30, 1995 between Meso Scale Diagnostics, LLC. and Meso Scale Technologies, LLC.
10.20 (13*)	Amendment No. 1 to MSD/MST Sublicense Agreement dated August 15, 2001 between Meso Scale Technologies, LLC. and IGEN International, Inc.
10.21 (13+)	Consulting Agreement between IGEN International, Inc. and Jacob N. Wohlstadter effective as of November 30, 1996.
10.22 (13+)	Indemnification Agreement between IGEN International, Inc., Jacob N. Wohlstadter and JW Consulting Services, LLC. dated as of November 30, 1996.
10.23 (13+*)	Employment Agreement between Meso Scale Diagnostics, LLC., IGEN International, Inc., Meso Scale Technologies, LLC. and Jacob N. Wohlstadter dated August 15, 2001.
10.24 (16+)	Indemnification Agreement between IGEN International, Inc. and Jacob N. Wohlstadter dated October 26, 2001.
10.25 (11+)	Amended and Restated Promissory Note effective as of July 22, 2000 between Samuel J. Wohlstadter and the Company.
10.26 (11+)	Stock Pledge Agreement effective as of July 22, 2000 between Samuel J. Wohlstadter and the Company.
10.27 (15+)	IGEN International, Inc. 2001 Broad Based Stock Option Plan.
10.28 (14)	Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington Private Placement Fund, Ltd. dated December 7, 2001.
10.29 (14)	Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington Opportunity I Limited dated December 7, 2001.
10.30 (14)	Registration Rights Agreement between IGEN International, Inc. and Acqua Wellington Private Placement Fund, Ltd. dated December 7, 2001.
10.31 (14)	Registration Rights Agreement between IGEN International, Inc. and Acqua Wellington Opportunity I Limited dated December 7, 2001.
10.32 (19)	Common Stock Purchase Agreement between IGEN International, Inc. and Brown Simpson Partners I, Ltd. dated December 26, 2001.
10.33 (19)	Registration Rights Agreement between IGEN International, Inc. and Brown Simpson Partners I, Ltd. dated December 26, 2001.
10.34 (18)	Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington Private Placement Fund, Ltd. dated March 8, 2002.
10.35 (18)	Common Stock Purchase Agreement between IGEN International, Inc. and Acqua Wellington Opportunity I Limited dated March 8, 2002.
10.36 (18)	Registration Rights Agreement between IGEN International Inc. and Acqua Wellington Private Placement Fund, Ltd. dated March 8, 2002.

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## INDEX TO EXHIBITS (CONTINUED)

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
10.37 (18)	Registration Rights Agreement between IGEN International, Inc. and Acqua Wellington Opportunity I Limited dated March 8, 2002.
10.38 (12+)	1994 Non-Employee Directors' Stock Option Plan, as amended.
10.39 (16+)	Termination Protection Program.
10.40	Letter Agreement between the Company and Meso Scale Diagnostics, LLC dated March 12, 2003. Filed herewith.
10.41	Registration Rights Agreement between the Company and Citadel Equity Fund Ltd. dated March 26, 2002. Filed herewith.
10.42	Collateral Account and Security Agreement between the Company and Bankers Trust Company dated as of March 22, 1999. Filed herewith
21.1	List of subsidiaries of the Company. Filed herewith.
23.1	Consent of Deloitte & Touche LLP. Filed herewith.
23.2	Consent of Deloitte & Touche LLP. Filed herewith.
99.1 (17)	Final Order of Judgment issued in IGEN International, Inc. v. Roche Diagnostics GmbH dated February 15, 2002.
99.2	Meso Scale Diagnostics LLC., Financial Statements at December 31, 2002 and 2001, and for the Three Years Ended December 31, 2002, 2001 and 2000, and Independent Auditors' Report. Filed herewith
99.3	Certification of Chief Executive Officer pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley act of 2002. Filed herewith.
99.4	Certification of Chief Financial Officer pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley act of 2002. 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 filed November 14, 1997.
(2)	Previously filed as an exhibit to the Registration Statement on Form S-1, as amended (Registration No. 33-72992).
(3)	Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended December 31, 1996 filed February 14, 1997.
(4)	Previously filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 1995 filed May 22, 1995.
(5)	Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended December 31, 1995 filed February 14, 1996.
(6)	Previously filed as an exhibit to the Company's Form 8-A filed December 10, 1996.
(7)	Previously filed as an exhibit to the Company's Registration Statement on Form S-3 (Registration No. 333-45355) filed January 30, 1998.
(8)	Previously filed as an exhibit to the Company's Form 10-K for the fiscal year ended March 31, 1999 filed June 29, 1999.

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- (9) Previously filed as an exhibit to the Company's Form 8-K filed January 12, 2000.
- (10) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended September 30, 2000 filed November 14, 2000.
- (11) Previously filed as an exhibit to the Company's Form 10-K for the fiscal year ended March 31, 2001 filed June 29, 2001.
- (12) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended June 30, 2001 filed August 9, 2001.
- (13) Previously filed as an exhibit to the Company's Amendment to Form 8-K filed September 5, 2001.
- (14) Previously filed as an exhibit to the Company's Form 8-K on December 19, 2001.
- (15) Previously filed as an exhibit to the Company's Registration Statement on Form S-8 (Registration No.333-76624).
- (16) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended December 31, 2001 filed February 13, 2001.
- (17) Previously filed as an exhibit to the Company's Form 8-K filed February 20, 2002.
- (18) Previously filed as an exhibit to the Company's Form 8-K filed March 15, 2002.
- (19) Previously filed as an exhibit to the Company's Registration Statement on Form S-3 (Registration No.333-76760). Filed January 29, 2002.
- (20) Previously filed as an exhibit to the Company's Form 10-Q for the quarter ended June 30, 2002 filed August 14, 2002.