BIOVERIS CORP
Form 10-K
August 16, 2004

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, 2004
Commission File Number	000-50583

BioVeris Corporation

(Exact name of Company as specified in its charter)

DELAWARE	80-0076765
(State or other jurisdiction of incorporation or organization)	(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 X No _____

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

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

Yes _____ No X

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Company as of July 30, 2004, computed by reference to the closing sale price of such stock quoted on The Nasdaq National Market, was approximately $154,741,000.

The number of shares outstanding of the Company s Common Stock as of July 30, 2004 was 26,728,070.

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 description of 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, 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:

changes in our strategy and business plan, including our plans for the clinical diagnostics, biodefense, life science and industrial markets and other healthcare opportunities;

our ability to develop and introduce new or enhanced products, including incorporating unit dose cartridges;

our ability to enter into new collaborations on favorable terms, if at all;

our ability to expand the distribution and increase sales of existing products;

the demand for rapid testing products in each of our markets;

our ability to expand our manufacturing capabilities or find a suitable manufacturer on acceptable terms or in a timely manner, including the completion of pending negotiations for contract manufacturing of one of our instruments;

our ability to develop our selling, marketing and distribution capabilities;

our and our licensees ability to obtain FDA and other governmental approvals for our and their clinical testing products;

the ability of our licensees to effectively develop and market products based on the technology we license to them;

domestic and foreign governmental and public policy changes, particularly related to healthcare costs, that may affect new investments and purchases made by our customers;

availability of financing and financial resources in the amounts, at the times and on the terms required to support our future business;

rapid technological developments in each of our markets and our ability to respond to those changes in a timely, cost-effective manner;

any potential future disputes regarding the scope, permitted use and other material terms of our license agreements, including those with Meso Scale Diagnostics, LLC., which we refer to in this Form 10-K as MSD;

the outcome of the litigation and arbitration commenced against Roche Holding Ltd, which we refer to in this Form 10-K as Roche, by Applera Corporation and its affiliate Applied Biosystems, which we refer to in this Form 10-K as Applied Biosystems;

protection and validity of our patent and other intellectual property rights;

statements regarding relationships between us and certain companies with which we are affiliated;

changes in general economic, business and industry conditions; and

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

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

As used herein, BioVeris , we , us and our refer to BioVeris Corporation and its subsidiaries. M-SERIES, TRICORDER and BIOVERIS 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 develop, manufacture and market our M-SERIES® family of products, which can serve as a platform for diagnostic systems to be used for the detection and measurement of biological or chemical substances. We incorporate our technologies into our instrument systems, tests and reagents, which are the biological and chemical components used to perform such tests. Using the M-SERIES platform, we intend to integrate technologies and products to develop small, expandable and modular systems that can perform a wide variety of immunodiagnostic and nucleic acid tests.

Our products are designed to be sold in the worldwide diagnostics markets, including:

Clinical diagnostics. The clinical diagnostics market includes the testing of patient samples to measure the presence of disease and monitor medical conditions. We are developing products to be used in the clinical diagnostics market and believe that our products will be best suited for the immunodiagnostic and nucleic acid testing market segments of the clinical testing market.

Non-clinical diagnostics for the biodefense, life science and industrial markets. The non-clinical diagnostics market includes biodefense products for the detection of bacteria, viruses and toxins that may pose a military or public health threat; life science testing for drug discovery and development that is performed by pharmaceutical and biotechnology companies; and industrial testing for the detection of foodborne and waterborne disease causing pathogens.

We believe that the emergence of simple, more accurate and cost-effective clinical diagnostic products is shifting the site of clinical diagnostic testing from clinical reference laboratories and central hospital laboratories to decentralized patient care centers, such as physicians offices, ambulatory clinics, hospital emergency rooms, surgical and intensive care units, hospital satellite laboratories and nurses stations, which are collectively referred to as clinical point-of-care sites.

Our own product development efforts are focused on M-SERIES instruments and tests for the biodefense market and for the clinical diagnostics market, particularly for point-of-care sites. We are seeking to develop, market and sell products for the clinical point-of-care market segment through a combination of direct efforts and collaborative arrangements. We also are pursuing opportunities in the clinical reference laboratory and central hospital laboratory market segments through collaborative arrangements.

The first clinical diagnostic system being developed by us is an M-SERIES clinical analyzer that builds on the M-SERIES instruments we sell in the biodefense and life science markets. We are developing the assays using, among other things, improvements licensed from an affiliate of Roche. We believe that these improvements will reduce product development timelines. We also believe that the clinical analyzer will provide results to a physician rapidly with the same levels of sensitivity, accuracy or consistency as a large instrument in a clinical reference laboratory or in a central laboratory, thereby permitting the physician to make a more timely decision regarding the patient s course of treatment. We will seek approval from the FDA for the clinical analyzer and other *in vitro* diagnostics products at the appropriate stage of their product development.

Our M-SERIES instruments are already being used in biodefense programs for homeland security, including by the Department of Defense, or DOD. We believe there will be an increasing opportunity to sell our products for biodefense tools by governmental and military organizations around the world, as well as in public health. We are also selling two types of M-SERIES instruments for life science research to pharmaceutical and biotechnology researchers, as well as to scientists at academic and government research institutions.

On February 13, 2004, IGEN and Roche consummated a merger and certain related transactions, which we refer to in this Form 10-K as the merger and related transactions, pursuant to which Roche acquired IGEN and IGEN simultaneously distributed shares of our common stock to its stockholders. The transaction occurred in the following steps:

IGEN restructured its operations so that we, a newly formed, wholly-owned subsidiary of IGEN at the time, assumed IGEN s biodefense, life science and industrial product lines as well as IGEN s opportunities in the clinical diagnostics and healthcare fields and the ownership of IGEN s intellectual property, IGEN s equity interest in MSD, cash and certain other rights and licenses currently held by IGEN; and

a wholly-owned subsidiary of Roche merged with and into IGEN, as a result of which IGEN became a wholly-owned subsidiary of Roche and we became an independent, publicly-traded company. Simultaneously with the completion of the merger, certain ongoing commercial agreements between certain affiliates of Roche and us became effective.

Investor Information

We were organized as IGEN Integrated Healthcare, LLC, a Delaware limited liability company on June 6, 2003, and converted to BioVeris Corporation, a newly formed Delaware corporation on September 22, 2003. Our executive offices are located at 16020 Industrial Drive, Gaithersburg, Maryland 20877. Our Internet website is located at http://www.bioveris.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. Any report, proxy statement or other information we file with the SEC

may be read and copied at the SEC s Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Information on the operation of the Public Reference Room is available by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site (http://www.sec.gov) that makes available reports, proxy statements and other information regarding issuers that file electronically with it.

Our Strategy

Our strategy is based on the direct development and sale of products utilizing our technologies, while at the same time entering into collaborations with third parties that can assist us in product development, manufacturing and marketing efforts. Key elements of our strategy are to:

Pursue collaborative relationships to accelerate new product development and enhance global manufacturing and marketing capabilities.

Establish leadership positions in emerging markets.

Develop and market product line extensions and an expanded menu of assays.

Our Technology

Our M-SERIES family of products will incorporate a number of technologies, including:

ECL technology developed and owned by us;

various improvements to ECL technology developed by Roche Diagnostics GmbH, which we refer to in this Form 10-K as Roche Diagnostics, and licensed to us;

polymerase chain reaction technology developed by Roche Diagnostics and licensed to us for use in several specified markets, including the human and animal *in vitro* diagnostics markets, which we refer to in this Form 10-K as PCR technology; and

unit dose cartridge technology for packaging reagents in a ready-to-use format that remains stable at room temperature.

ECL Technology

ECL technology is a technology based on electrochemiluminescence that is protected by patents in the United States and internationally.

ECL technology permits the detection and measurement of a biological or chemical 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 emitted by the label can be measured with a high degree of accuracy. The level of intensity of the light emitted by the label is determined by the amount of the targeted biological substance present in the sample for the label to attach itself to. Thus, the light emissions permit the accurate detection and measurement of the targeted biological or chemical substance.

ECL technology provides a uniform format that can be used to conduct a multitude of tests, including immunodiagnostic tests and nucleic acid tests. The essential component of an ECL technology-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 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.

We believe that the major features and benefits of ECL technology-based systems are:

Simplicity: uniform testing format reduces time and labor in performing a test or series of tests and permits complete automation of the testing process.

Flexibility: enables a single instrument to perform immunodiagnostic tests on large and small molecules and to perform nucleic acid tests, including in the form of DNA and RNA tests.

Cost: reduces the cost per test by minimizing the amount of expensive reagents needed and the number of steps required to prepare a sample for testing.

Speed: reduces time from test set-up to detection, producing rapid results and enabling high sample throughput.

Sensitivity: allows detection of targeted biological substances at very low concentrations.

Consistency: provides highly-reproducible measurements.

Accuracy: provides results that are identical or close to the standard reference measurement.

Stability: extends the shelf-life of the reagent that contains the label used in testing and improves measurement accuracy.

We believe that ECL technology is well suited for the continued development and sale of the M-SERIES family of instruments that can be used in all of our target diagnostic markets. We believe the technology will permit virtually all immunodiagnostic and nucleic acid tests to be performed on similar instrumentation using the same detection method.

ECL technology is well established in the market, evidenced by the fact that our licensees have developed multiple product lines based on ECL technology and have sold or placed over 10,000 systems with customers worldwide which generate over $500 million in annual sales. Substantially all of these sales and placements have been made by Roche, one of the world s leading providers of clinical diagnostic products, which has a worldwide, non-exclusive, royalty-free license for our ECL technology for use with certain defined systems and immunoassay methods for the clinical diagnostics market. There can be no assurance that we will succeed in profitably developing, marketing and selling products based on ECL technology.

Improvements from Roche

As part of the merger and related transactions, we have acquired from Roche Diagnostics and its affiliates an irrevocable, worldwide, non-exclusive, fully-paid, royalty-free, perpetual license under certain patents covering technologies based on:

Roche Diagnostics ECL instruments and all aspects of ECL assays developed prior to the completion of the merger between Roche and IGEN;

certain PCR technology; and

certain aspects of ECL technology and robotics used or developed prior to the completion of the merger between Roche and IGEN.

The license, which we refer to in this Form 10-K as the improvements license agreement may be used without a field restriction (except as set forth in the next sentence) to develop, make, reproduce, modify, use, sell and otherwise commercially exploit any product or service based on ECL technology. In addition, we are licensed to use certain intellectual property rights of Hitachi High Technology Corporation and its affiliates only outside the field defined in the improvements license agreement to develop, make, reproduce, modify, use, sell and otherwise commercially exploit any product or services based on ECL technology. Subject to an exception, the field in the improvements license agreement is the same as the field in the license agreement. We may sublicense rights under both of these licenses to affiliates and third parties.

The improvements license agreement does not permit us to develop, use, manufacture, sell or otherwise commercialize instruments based on ECL technology that meet certain specifications and use specific intellectual property, in the field. In addition, the license does not permit us to develop, use, manufacture or sell ECL assays that contain labeling that make them useable on ECL instruments manufactured, sold or placed by Roche Diagnostics or its licenses or resellers, in the field.

PCR Technology

PCR technology includes the amplification of specific nucleic acid sequences to a sufficient quantity of the nucleic acid sequence to permit detection and quantification. The process of nucleic acid amplification is commonly used for diagnostic procedures involving infectious agents, such as the AIDS virus, because of the need to detect the smallest amount of virus possible in the blood or other clinical samples.

The PCR license agreements obtained by us from Roche Diagnostics and its affiliates, which we refer to in this Form 10-K as the PCR license agreements, will allow us to develop nucleic acid tests for several specified markets, including the human and animal *in vitro* diagnostics markets. We believe that nucleic acid tests are currently one of the fastest growing segments of the clinical diagnostics market and would complement our immunodiagnostic product line. We do not currently sell, or have under development, any product based on the PCR technology being licensed from Roche. For more information about the license fee and royalty payments in connection with the PCR license agreements, see ITEM 8- Consolidated Financial Statements-Notes to Consolidated Financial Statements-Note 1 .

Roche has advised us that Applied Biosystems has notified Roche that one or more of the PCR licenses granted by certain Roche affiliates to us under the improvements license agreement and the PCR license agreements may infringe exclusive rights to PCR technology held by, or other contract rights of, Applied Biosystems. Applied Biosystems has commenced litigation and arbitration against Roche regarding their respective rights relating to PCR technology. Certain Roche affiliates have made certain representations and provided certain warranties on their right to grant the licenses that have been granted to us, including representations and warranties that: the rights and licenses granted under the improvements license agreement and the performance by Roche Diagnostics of its obligations under the improvements license agreement will not conflict with any agreement, contract or other arrangement to which it is a party or by which it is bound; Roche Diagnostics has title to or license rights sufficient to grant such license rights granted under the improvements license agreement to us and our affiliates; Roche Diagnostics has not licensed or otherwise disposed of such licensed intellectual property rights in any manner that limits our or our affiliates exploitation of the licenses granted by Roche Diagnostics under the improvements license agreement; certain Roche affiliates have the full power and right to grant to us and our affiliates the licenses granted under the PCR license agreements; and the execution by certain Roche affiliates of the PCR license agreements will not constitute a breach or default under any contract, instrument or agreement to which such Roche affiliates or any of their affiliates are a party or by which such Roche affiliates or any of their affiliates are bound.

Roche has advised us that it believes that Applied Biosystems allegations are without merit and intends to contest them vigorously. There are no assurances that we will not be named as a defendant in either of those actions or that Roche will prevail in the litigation and arbitration, or that the terms of any resolution or settlement of these

proceedings will not be unfavorable to us.

The results of these legal proceedings may limit, preclude or interfere with our ability to exploit certain PCR technology licensed under the improvements license agreement and PCR license agreements. See Risk Factors Risks Relating to Our Business Because we intend to develop products that are based on patents and technology that we have licensed from others, the owners of those patents and technology might claim that products developed or sold by us violate those licenses. Additionally, a third party might object to a license that we hold or to the scope of the license granted to us.

Unit Dose Cartridge Technology

We have a unique technology utilizing a disposable unit dose cartridge that we expect will be inexpensive to manufacture and contains all the reagents necessary to perform several different immunoassays on a single sample of blood from a patient. These reagents will be packaged so that they remain stable at room temperature for several months. This method of packaging reagents differs from the typical method of packaging reagents in a container that holds reagents for 100 to 200 tests for a single type of immunoassay and usually must be refrigerated. We have demonstrated that the test results using the unit dose cartridge are accurate and consistent with the results obtained using conventional instruments and kits used in central hospital laboratories. We believe the ease of use, room temperature stability, accuracy and consistency of test results associated with this technology are important features for use in clinical point-of-care sites and biodefense applications.

Products and Markets Using Our Technology

The following table summarizes the range of products that we have developed and are developing using our ECL technology. We expect that our future products will incorporate other technology, which may include the improvements from Roche, PCR technology and unit dose cartridge technology.

BioVeris Products	Customer Application	Market	Status
M-SERIES (Clinical analyzer and clinical diagnostic tests)	Screen, monitor and diagnose medical conditions	Clinical	Development
Picolumi	Screen, monitor and diagnose medical conditions	Clinical	Distribution and manufacturing rights from Eisai (outside Japan)
BioVeris Detection System and Reagents	Detection of bacteria, viruses and toxins	Biodefense	Product sales
	Drug discovery and development	Life science	Product sales
M-SERIES (M384 Analyzer and Reagents)	Drug discovery and development	Life science	Product sales
M-SERIES (M1M and M1R Analyzers)	Drug discovery and development	Life science	Product sales
	Detection of food and beverage contaminants and bacteria, viruses and toxins	Biodefense	Product launch
		Industrial	Product sales

Test Panel for BioVeris Detection System	Detection of food and beverage contaminants		
Cell Culture Reagents	Biological research	Life science	Product sales

The following table summarizes the range of products that our licensees have developed using our ECL technology. In general, we will receive royalties or other payments as a result of product sales by our licensees other than Roche and MSD during the time we are a class A member of MSD. For a description of the commercial arrangements and license agreements that we have with our licensees see Business-Collaborations and License Arrangements .

Licensee Products	Customer Application	Market	Status	Licensee
Elecsys 2010/1010/ECL module of E170	Screen, monitor and diagnose medical conditions	Clinical	Product sales	Roche
NucliSens/NASBA QR	Screen, monitor and diagnose medical conditions	Clinical	Product sales	bioMérieux
	Screen, monitor and diagnose medical conditions	Life science	Product sales	bioMérieux
Picolumi	Screen, monitor and diagnose medical conditions	Clinical	Product sales	Eisai (Japan)
Sector HTS/Sector PR	Drug discovery and development	Life science	Product sales	MSD

Our Products and Markets

Clinical Diagnostics

We plan to manufacture and sell products utilizing our technologies for the clinical *in vitro* diagnostics market. *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 is one type of testing used by the clinical diagnostics market. We believe that ECL technology is best suited for the blood-based immunodiagnostic and nucleic acid testing segments of the clinical diagnostics market. The immunodiagnostic market segment was estimated to have had approximately $6 billion in annual sales in 2002. The nucleic acid testing market segment was estimated to have had approximately $1.5 billion in annual sales in 2001. Clinical diagnostic testing is performed in many locations, including testing by clinical reference laboratories, central hospital laboratories, and blood banks, as well as testing at clinical point-of-care sites. Our products for the clinical *in vitro* diagnostics market will generally require approval or clearance by the FDA prior to the marketing of the products, which we will seek in the appropriate stage of product development. See Business Government Regulation Clinical Diagnostic Products for a more detailed description of the government regulations to which we are subject in connection with products for the clinical *in vitro* diagnostics market.

Point-of-Care Systems. Many diagnostic tests performed today involve a follow-up treatment decision by the physician, but the test and treatment process are usually decoupled. In most situations, samples of blood are drawn from a patient in the physician s office, emergency room or hospital room and sent to a laboratory at another location where the tests are performed. Test results are returned to the physician several hours or even several days later. We believe that there is demand among physicians, patients and third-party payers for clinical diagnostic products that reduce turnaround time by bringing laboratory testing closer to the patient and providing the physician with fast, quality and cost-effective results thereby permitting the physician to deliver prompt feedback to the patient.

Most immunodiagnostic systems for clinical point-of-care sites have had limited market penetration because of the lengthy turnaround time for test results, the need for skilled labor to perform the tests and the high cost of the tests.

We believe that the emergence of simple, more accurate and cost-effective diagnostic products is

shifting the site of *in vitro* diagnostic testing from clinical reference laboratories and central hospital laboratories to alternative sites.

We are developing a new instrument system, a clinical analyzer that would be a part of our M-SERIES family of instruments. We plan to integrate ECL, PCR, and other technologies into a small, expandable and modular system for the performance of immunodiagnostic and nucleic acid tests. The clinical analyzer is being designed for ease of use and the ability to provide fast results and is expected to be marketed to clinical point-of-care sites bringing laboratory testing closer to the patient thereby providing the associated benefits described above. We believe that the clinical analyzer may also be used in clinical reference laboratories, central hospital laboratories, and blood banks, which presently constitute the majority of the clinical diagnostics market.

Currently available immunoassay tests for use at the clinical point-of-care sites are often not as sensitive, accurate, or consistent as similar tests run in a central laboratory. We believe the clinical analyzer can provide rapid turn-around time with the same levels of sensitivity, accuracy and consistency as a large instrument in a clinical reference laboratory or a hospital central laboratory.

We are exploring collaborative business arrangements to accelerate the development, manufacture and marketing of ECL technology-based products for clinical point-of-care applications.

Clinical/Reference and Central Hospital Laboratory Systems. One of the significant applications of ECL technology is in large, highly automated clinical immunodiagnostic systems used in clinical reference laboratories, central hospital laboratories and blood banks. These laboratories currently constitute the vast majority of the clinical diagnostics market. To serve these laboratories, systems must be able to perform a wide variety of immunodiagnostic tests on a large number of samples consistently, cost effectively and quickly. Although we do not currently manufacture or sell products for the clinical diagnostics market, we intend to pursue opportunities for the clinical reference and central hospital laboratory market segment through collaborative arrangements.

Non-Clinical Diagnostics

Biodefense. We are commercializing products in the emerging market segment 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. Our currently available instruments include the BIOVERIS Detection System and the M-SERIES M1R and M1M instruments. We believe there will be an increasing opportunity to use our products as a biodefense tool in governmental and military organizations around the world, as well as in public health, due to the early adoption of our products by key decision makers. We believe there currently are no dominant competitors. We expect that our nonclinical products for biodefense will generally not require the approval of a U.S. government agency prior to marketing of the products. See Business Government Regulation Biodefense and Industrial Testing Products for a more detailed description of the government regulations to which we are subject in connection with our products for biodefense.

U.S. Army scientists at Fort Detrick, Maryland have developed ECL technology-based biological tests designed to measure specific agents and toxins in environmental samples. We have a contract with the DOD pursuant to which the DOD may purchase these tests from us. Under the contract, the DOD may, at its option, make purchases of up to $23.0 million over a period of up to 48 months through June 2007. As of March 31, 2004, the DOD had purchased approximately $3.4 million of products under the contract. The tests are used by various laboratories and field sites of the DOD, as well as other U.S. government agencies. For risks related to our contracts with the government see Risk Factors Risks Relating to Regulation and Government Contracts.

In June 2004, we introduced for sale our new M-SERIES M1M Analyzer which is specifically designed to function in demanding field environments, as well as in the laboratory. The M1M is an automated analyzer designed for use with our BioVerify test kits for the detection of botulinum neurotoxins, anthrax, ricin, and

staphylococcal enterotoxins A and B, among others. The analyzer has also been designed for use with the tests currently being manufactured by us for the DOD.

The system has easy-to-use sample handling and can detect biological agents quickly and with high sensitivity. System software reports positive or negative results automatically in a standard format. The M1M Analyzer was built with specification and configuration inputs from our customers and is designed to meet the needs of field, mobile and centralized laboratories.

We also plan to develop an additional M-SERIES instrument that can be both miniaturized and ruggedized for use primarily by soldiers; first responders, such as fire, police and emergency medical workers; medical workers; hospitals; food processors; field inspectors from the Environmental Protection Agency, or the EPA, the Department of Agriculture, or the Food and Drug Administration, or the FDA; and border patrol inspectors.

We expect to continue to work with the DOD and other U.S. government agencies to expand the use of ECL technology-based products in a variety of homeland security and biodefense initiatives, including the development of reagents for the detection of biological agents, such as anthrax, staphylococcus enterotoxin B and botulinum, or toxins in environmental samples.

The Automated Biological Agent Testing System program at the Edgewood Chemical and Biological Center, Aberdeen Proving Ground, in conjunction with us and Beckman Coulter, has integrated an M-SERIES instrument system with Beckman Coulter s SAGIAN and Biomek® FX lab automation systems to automate sample preparation and plate handling for ECL technology-based immunoassays. This program is designed for high throughput detection of biological agents and incorporates reagents that are being manufactured by us. We are also engaged in early-stage initiatives for product development for this market including:

- the 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;
- a contract with the DOD to develop assays for the detection of select agents in food; and
- integration of ECL technology into the Air Force biological testing program.

Certain of our U.S. government contracts contain provisions that grant to the U.S. government a non-exclusive, non-transferable, irrevocable, paid-up license to use inventions made by us in the course of performing such contracts, or have such inventions used by or on behalf of the U.S. government, for research or other government purposes. See Risk Factors Risks Relating to Regulation and Government Contracts.

Our presence in the biodefense market also provides the opportunity to sell products to other diagnostics markets. In addition to manufacturing specific tests for the detection of biological agents or toxins for the DOD, we have developed our own line of tests that can be sold to the pharmaceutical, biotechnology and food industries. These products include tests for the detection of botulinum toxins A, B, E and F, staphylococcal enterotoxins A and B, ricin and anthrax. We intend to expand this product line to meet the demands of the market. We believe that tests developed for the biodefense field may also have utility in the clinical diagnostic markets by providing tests for patients exposed to biological agents or toxins.

Industrial. We manufacture and sell a panel of tests for the detection of foodborne and waterborne disease-causing pathogens, such as E. coli O157, 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.

We expect that our products for industrial testing will generally not require the approval of a U.S. government agency prior to marketing of the products. See Business Government Regulation Biodefense and Industrial Testing Products for a more detailed description of the government regulations to which we are subject in connection with our products for industrial testing.

Life Science. We provide products and services for the discovery and development of new drugs to the life science market. Our product development and marketing efforts center on two M-SERIES instruments the M384 and the M1R instruments each of which build on the ECL technology-based applications provided by the M-SERIES systems and the BIOVERIS Detection System.

Our products can be used by pharmaceutical and biotechnology companies, universities and other research organizations in most phases of drug discovery, including:

validating targets identified through genomics;

screening of large numbers of compounds generated through combinatorial chemistry;

re-testing and optimization of lead compounds; and

clinical trial testing of drug candidates.

After identifying disease targets and synthesizing chemical compounds, researchers attempt to find compounds that are drug candidates. This drug discovery process involves developing an assay to determine whether a particular compound has the desired effect on a target and then screening compounds using that assay. 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 ECL technology-based systems in the pharmaceutical and biotechnology industry. Our M-SERIES instruments 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. These instruments were designed to enable researchers to test new biological targets against potential drug compounds with higher levels of accuracy and sensitivity. 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 advantages over many competitive detection technologies. They permit the user to:

more quickly adapt the ECL technology to develop and then perform the specific, desired assays, compared to the longer periods required by other existing competing technologies;

reduce the use of rare components, such as proprietary compounds, antibodies or clinical trial samples, that must be used to run assays; and

have more confidence in the 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.

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 instruments we sell or lease, we typically receive commitments from customers for purchases of proprietary reagents. We market the M-SERIES product family directly through our own sales, marketing and applications teams. Instrument systems originally designed for the life science market are now being used in biodefense and may be used in the clinical diagnostics market as well. We believe that our presence in the life science market provides us with the opportunity to identify novel tests that may have utility in the clinical diagnostics market.

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While continuing to support our existing bio-pharmaceutical and academic customers, we may selectively pursue other commercial opportunities in the life science or other markets in support of our overall corporate strategy. Our products that will be sold only for research use in the life science market generally do not require the approval of a U.S. government agency prior to marketing of the products. See Business Government Regulation Life Science Research Products for a more detailed description of the government regulations to which we are subject in connection with our products for the life science market.

Collaborations and License Arrangements

We expect to explore and negotiate collaborative business arrangements to accelerate the development, manufacture and marketing of ECL technology-based products, in particular into the clinical diagnostics market. In addition, we have license arrangements with Roche Diagnostics, bioMérieux, Eisai and MSD.

Roche Diagnostics

In connection with the merger and related transactions, Roche, one of the world s leading providers of clinical diagnostic products, has obtained a worldwide, royalty-free, non-exclusive license, which we refer to in this Form 10-K as the license agreement, to develop, make, reproduce, modify, use, sell and otherwise commercially exploit certain clinical immunoassay instruments and assays using defined ECL technology owned by us in the human *in vitro* diagnostics field, including the continued sale and further development of its Elecsys products. We will not receive royalties or other payments as a result of product sales by Roche in accordance with the license agreement.

Under the improvements license agreement with Roche, we have a worldwide, non-exclusive, fully-paid, royalty-free, perpetual license under certain patents covering and technologies based on:

Roche Diagnostics ECL instruments and all aspects of ECL assays developed prior to the completion of the merger with IGEN;

certain PCR technology; or

all aspects of ECL technology and robotics that, prior to the completion of the merger with IGEN, Roche Diagnostics or any of its affiliates used or developed to be used in performing ECL testing (other than specific antibodies, antigens and reagents).

In addition, we are licensed to use certain intellectual property rights of Hitachi High Technology Corporation and its affiliates only outside the field defined in the improvements license agreement to develop, make, reproduce, modify, use, sell and otherwise commercially exploit any product or service based on ECL technology.

bioMérieux

bioMérieux, Inc., or bioMérieux, has a license from us for the development and worldwide development, use, manufacture and sale of ECL technology-based nucleic acid test systems on a co-exclusive basis for certain segments of the clinical diagnostics market and on a non-exclusive basis for certain segments of the life science market. bioMérieux specializes in products for central hospital laboratories and blood banks and has incorporated its proprietary nucleic acid sequence-based amplification technology and ECL technology into its NucliSens line of diagnostic virology products, which are marketed with test kits for the detection of HIV-1 RNA and CMV (cytomegalovirus). The agreement with bioMérieux extends until the expiration of the patents we license to bioMérieux, and we receive royalty payments from bioMérieux on the relevant product sales by bioMérieux.

Eisai

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Eisai Co., Ltd., or Eisai, a leading Japanese pharmaceutical company, has a license to manufacture and market a class of ECL technology-based diagnostic systems for the clinical diagnostics market in Japan on a non-exclusive basis. Eisai introduced its first ECL-based product under the trade name Picolumi in 1997. We receive royalties on the relevant product sales by Eisai. The agreement with Eisai extends until the later of May 10, 2010, and the expiration of the patents we license to Eisai. Eisai is obligated to make royalty payments to us at a reduced royalty rate for a period of seven years after expiration of the agreement.

MSD

As part of the merger and related transactions, we assumed IGEN s interest in MSD, a joint venture formed in 1995 by IGEN and Meso Scale Technologies, LLC., or MST, which is a company established and wholly-owned by Mr. Jacob Wohlstadter, a son of our chief executive officer. An independent committee of IGEN s board of directors, with the advice of independent advisors and counsel, negotiated and approved the MSD agreements. MSD develops, manufactures, markets and sells products utilizing a combination of MST s multi-array technology and our technology. MSD manufactures, markets and sells instrument systems, including the Sector HTS and the Sector PR, which combine MST s multi-array technology and our ECL 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 its own reagents, assays and plates that are used on these MSD systems. During the year ended December 31, 2003, MSD had revenues of $7.7 million and a net loss of $20.4 million.

The joint venture agreement among MSD, MST and us, which we refer to in the Form 10-K as the MSD joint venture agreement, expired upon completion of the merger and related transactions. As a result, MSD and MST had the right to purchase our interest in MSD. Pursuant to the settlement agreement we entered into with MSD, MST and Jacob Wohlstadter in August 2004, which is referred to in this Form 10-K as the settlement, MSD or MST will purchase and we will sell, our entire interest in MSD. For a more complete description of this purchase right and the MSD agreements, see ITEM 13 Certain Relationships and Related Transactions .

In June and July 2004, we commenced legal actions against MSD, MST and Jacob Wohlstadter in the Court of Chancery in the State of Delaware that were prompted by the discovery of a series of actual and proposed transactions undertaken by MSD without our knowledge. These litigations were settled in August 2004 pursuant to the settlement. See ITEM 3 Legal Proceedings for a more complete description of these litigations and the related settlement.

Patents and Other Proprietary Rights

We pursue a policy of seeking patent protection to preserve our 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 technology. We will also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

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

We own approximately 71 issued U.S. patents, and approximately 28 pending U.S. patent applications in the diagnostics field. Additionally, we own approximately 158 granted foreign patents and approximately 65 pending

foreign patent applications in the diagnostics field. These patents and patent applications are important to our business and cover various aspects of ECL technology and products, as well as the methods for their production and use.

The pending patent applications in the diagnostics field may not be granted and others may challenge our patents. Our ECL patents will begin to expire in 2005; however, patent coverage for ECL technology will continue through 2018. We plan to continue to protect our technology with new patent filings, which could further extend our patent coverage.

Our business could be harmed if we lose our patent protection or if pending patents are not issued to us.

Government Regulation

The research and development, manufacturing, marketing, sale and distribution of both existing and future products based on ECL 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, manufacturing, marketing, sampling, labeling, distribution, record keeping, storage and disposal practices, substantially increases the time, difficulty and costs incurred in obtaining and maintaining the clearance or approval to market newly developed and existing products. In particular, government regulatory actions can result in, among other things, delays in the release of our and our licensees products, injunction, 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, including monetary penalties that could be substantial.

International sales of products by us and our licensees will also be subject to a significant degree of government regulation, including 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 diagnostic 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. In addition, the FDA regulates the export of products from the United States.

Biodefense and Industrial Testing Products

Our biodefense products will be 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 adopted, and is expected to continue to adopt, laws, regulations and rules governing the research, development, procurement and handling 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 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.

Life Science Research Products

Our products that will be sold for life science research use only, including the M-SERIES instruments used in the life science market, must be properly labeled as for research use only not for use in diagnostic procedures , as required by the FDA, but do not generally require FDA approval prior to marketing. Research does not include clinical investigations and is narrowly defined by the FDA to apply to the early development of product concepts. The FDA has begun to impose new distribution requirements and procedures on companies selling research use 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 some of which may adversely affect us.

Clinical Diagnostic Products

The FDA, and other Federal, state, local, and foreign authorities, regulate, among other things, the development, clinical testing, manufacture, packaging, labeling, storage, distribution and promotion of medical devices, including products intended for clinical diagnostic purposes. The FDA imposes specific requirements on the conduct of clinical studies and requires approval of the study by an institutional review board and, in some cases, by the FDA, depending upon the product and its use. Before a new device can be introduced into the market, the manufacturer must generally obtain marketing clearance through a section 510(k) pre-market notification or approval through a pre-market approval application. The testing, preparation of necessary applications and processing of those applications by the FDA is expensive and time-consuming.

Our clinical diagnostic products and the clinical diagnostic products of our licensees will be regulated as medical devices. Significant difficulties or costs may be encountered to obtain FDA clearances or approvals and that could delay or preclude us or our licensees from marketing products for clinical diagnostic purposes. Furthermore the FDA may request additional data following the original submission. Delays imposed by the governmental review process may materially reduce the period during which our or our licensees will have the exclusive right to exploit our products or technologies.

The FDA will clear a device under section 510(k) if the submitted information establishes that the proposed device is substantially equivalent to a legally marketed class I or II medical device, or to a class III medical device for which the FDA has not yet called for a pre-market approval application. Commercial distribution can begin only after the FDA issues an order that the device is substantially equivalent to a device that is legally marketed and not subject to a pre-market approval requirement. The FDA may determine that a proposed device is not substantially equivalent to a legally marketed device, in which case a pre-market approval will be required to market the device, unless additional information can be submitted to support a substantial equivalence determination, or the FDA, pursuant to a timely request, makes a risk-based determination that a device that is not a substantially equivalent device can be classified into class I or II.

An FDA request for additional data could require that clinical studies of the device s safety and effectiveness be performed. Clearance, if obtained, may be conditioned on labeling restrictions or conducting a lengthy postmarket surveillance study.

A pre-market approval application must be filed and approved before a device can be marketed if a proposed device is not substantially equivalent to a legally marketed device, as discussed above, or if it is a class III device that was in commercial distribution prior to May 28, 1976, for which the FDA has called for pre-market approval. A pre-market approval application must be supported by valid scientific evidence, which typically includes extensive pre-clinical data and well controlled or partially controlled clinical trials, to demonstrate the safety and effectiveness of the device. Obtaining approval can take several years and approval may be conditioned on, among other things, substantial restrictions on indications for use and the conduct of postmarket surveillance studies. Generally, the pre-market approval process requires much more extensive pre-filing testing than does the section 510(k) pre-market notification procedure and involves a significantly longer FDA review after the date of filing. In responding to a pre-market approval application, 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 the pre-market clearance or approval for the medical device has been received, it may still be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the device reaches the market. The FDA may require post-market surveillance programs to monitor the effect of medical devices that have been sold, and has the power to prevent or limit further marketing of medical devices based on the results of these post-marketing programs. In addition, the FDA s medical device reporting regulation requires reports to the FDA whenever

information reasonably suggests that a marketed device may have caused or contributed to

death or serious injury, or when a device malfunctions and if the malfunction were to recur, the device would be likely to cause or contribute to a death or a serious injury.

In addition to obtaining FDA approval for each medical device, under the pre-market approval application procedures, we or our licensees must seek FDA approval of their manufacturing facilities and procedures. The FDA will also inspect clinical diagnostics companies on a routine basis for regulatory compliance with its Good Manufacturing Practices regardless of whether the product was cleared under section 510(k) or approved under pre-market approval.

We and our licensees clinical diagnostic products will be affected by the Clinical Laboratory Improvement Amendments of 1988, which is intended to insure the quality and reliability of medical testing and may have the effect of discouraging, or increasing the cost of, clinical diagnostic testing. The regulations establish numerous requirements applicable to clinical diagnostics. Under these regulations, the specific requirements that a laboratory must meet depend upon the complexity of the tests performed by the laboratory. Under the clinical laboratory improvement regulations, all laboratories performing moderately complex or highly complex tests will be required to comply with stringent standards and requirements. Because the regulations interpretation is uncertain, it is possible that certain of we or our licensees products may be categorized as highly complex tests, in which case penetration of the point-of-care market would be reduced because not all laboratories would meet the standards required to conduct such tests.

In addition, future changes in regulations or interpretations made by the U.S. Department of Health and Human Services, FDA, Centers for Medicare & Medicaid Services or other regulatory bodies may adversely affect us and our licensees.

In addition to the foregoing, we will be, 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, fire hazard control, and environmental protection, including disposal of hazardous or potentially hazardous substances.

We do not expect compliance with these laws and regulations to have 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 us and our licensees ability to do business.

Sales of our and our licensees products outside the U.S. are also subject to extensive regulatory requirements, which vary widely from country to country. The time required to obtain the necessary approvals may be longer or shorter than that required for FDA clearance or approval.

Government Contracts and Regulation

Our contracts 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 are 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.

During the years ended March 31, 2004, 2003, and 2002, agencies of the U.S. government accounted for 22%, 26% and 11% of total revenue, respectively, and 26% and 43% of total consolidated accounts receivable as of March 31, 2004 and 2003, respectively.

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 will require permits, and these permits will be subject to modification, renewal and revocation by issuing authorities. Although we believe that we are in compliance 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 will be able to charge for 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 contracts that may be terminated at the election of the government.

In the event our biodefense business expands, the portion of our business subject to contracts that may be terminated at the election of the government is likely to expand. For a further description of risks related to our contracts with the government, see Risk Factors Risks Relating to Regulation and Government Contracts.

Competition

We compete in the non-clinical diagnostics markets, including biodefense, industrial and life science markets with our diagnostic instruments, reagents and assays and expect to compete in the clinical diagnostics market. We believe that the principal competitive factors in these markets are:

- the time required to run tests with the product;
- the level of sensitivity, accuracy and consistency of the product;

the relative ease of use of the product;

the quality of support and services for the product;

flexibility and expandability of the product;

product time-to-market;

product safety;

market acceptance of product; and

product price.

Although we believe that we compete favorably with respect to the above factors, competition in the diagnostics market is intense and we do not hold a leading competitive position in any of the markets in which we compete.

We expect to compete with a number of domestic and international companies, including Roche, Johnson & Johnson, Abbott Laboratories, Bayer, Biosite Incorporated and Dade Behring, Inc. Many of our competitors now have and in the future may continue to have access to greater resources than we do and, therefore, may be better equipped to develop, manufacture, market and sell their products. These companies may develop and introduce products and processes competitive with or superior to ours. In addition, we will directly compete against our current and future licensees, including bioMérieux, Roche and MSD.

Manufacturing

Our current commercial manufacturing operations consist of the manufacture of the M-SERIES family of products and reagents, biodefense and industrial testing products, and cell culture research biologicals. We operate a qualified Good Manufacturing Practices 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, to ensure consistent and acceptable performance of the products.

We do not manufacture any clinical diagnostic products. We are presently evaluating plans for future manufacturing of our clinical diagnostic products. These plans may include direct and third-party manufacturing. Negotiations are ongoing with a world leader in mobile electronics and systems technology to manufacture one of our instruments. There can be no assurance that these negotiations will result in an agreement with such manufacturer on terms favorable to us, if at all or that such manufacturer will be successful in manufacturing our instruments.

See Risk Factors Risks Relating to Us and Our Business We have limited manufacturing experience, which puts us at a competitive disadvantage and could have a material adverse effect on our business, financial condition and revenue, Risk Factors Risks Relating to Us and Our Business We have limited manufacturing facilities for our products and we may not find additional facilities suitable for future growth, which could materially adversely affect our business and prospects and Risk Factors Risks Relating to Us and Our Business We depend on a limited number of suppliers for materials used in the manufacturing of our products, and any interruption in the supply of those materials could hamper our ability to manufacture products and meet customer orders.

Sales and Marketing

We maintain a direct sales and marketing group in the United States and Europe that consists of approximately 14 people. Our direct sales group focuses on sales of the M-SERIES family of products and the BIOVERIS Detection System, together with reagents and services, to various government agencies in the biodefense market, food and beverage producers and contract testing laboratories in the industrial market and other potential customers in the life science market.

In addition to our direct and indirect sales and marketing efforts, our licensees and collaborators also conduct sales and marketing of our products. See Business-Collaborations and License Arrangements.

We are evaluating plans for the marketing and sale of our products currently in development. We may seek to market and sell a portion of our products indirectly through distributors who sell products that complement our products.

Human Resources

As of May 31, 2004, we and our subsidiaries employed 223 individuals, of whom 155 were engaged in research, product development, manufacturing and operations support, and 68 in marketing, sales and applications support and general administration. Of our employees, 22 have Ph.D. degrees. None of our employees is covered by a collective bargaining agreement, and management considers relations with its employees to be satisfactory.

Operating Segment

We currently operate in one business segment. We are currently engaged in the development, manufacturing and marketing of diagnostic products for the detection and measurement of biological and chemical substances. Information related to this segment is incorporated herein by reference to ITEM 8- Consolidated Financial Statements-Notes to Consolidated Financial Statements-Note 10 .

Geographic Segments

We do not believe we have material risks relating to our foreign business. Financial information about geographic segments is incorporated herein by reference to ITEM 8- Consolidated Financial Statements-Notes to Consolidated Financial Statements-Note 10 .

Risk Factors

Risks Relating to Us and Our Business

OUR BUSINESS HAS A HISTORY OF LOSSES AND WE WILL HAVE FUTURE LOSSES AND NEGATIVE CASH FLOW.

We incurred net losses of $93.3 million, $50.9 million and $49.2 million for the years ended March 31, 2004, 2003 and 2002, respectively. We expect to continue to incur operating losses and negative cash flow as a result of our expenses for manufacturing, marketing and sales capabilities, research and product development, general and administrative costs and our share of losses in MSD.

While we seek to attain profitability, we cannot be sure that we will ever achieve product or other revenue sufficient for us to attain this objective. Our ability to become profitable in the future will depend on, among other things, our ability to:

expand the distribution and increase sales of certain of our products;

upgrade and enhance the M-SERIES family of products;

introduce new products into the market;

develop our marketing, sales and distribution capabilities cost-effectively; and

continue existing collaborations and establish successful new collaborations with corporate partners to develop and market products that incorporate our technologies and provide necessary funding.

IF WE ARE UNABLE TO ESTABLISH NEW COLLABORATIONS, OR ANY COLLABORATIONS WE ESTABLISH DO NOT RESULT IN THE SUCCESSFUL INTRODUCTION OR MARKETING OF NEW PRODUCTS BASED ON OUR TECHNOLOGY, OUR GROWTH MAY BE SLOWED AND OUR BUSINESS COULD BE MATERIALLY ADVERSELY AFFECTED.

One aspect of our strategy is to enter into collaborative relationships with established healthcare and other companies to assist us in developing our technologies or manufacturing or marketing our products for certain markets. We may not be able to enter into collaborations on terms that are favorable to us, if at all. In addition, we cannot assure you that third parties, including our licensees, suppliers or others will not object to possible new collaborations. See Risk Factors Risks Relating to Us and Our Business We and MSD may have different views of the scope of the exclusive license previously granted to MSD and the scope of MSD s rights under the former joint venture agreement with us, which could affect our ability to expand our business directly or through collaborations.

As a result of this strategy, we may have no, or only limited, control over the amount of resources that our collaborators will devote to the development or marketing of products based on our technology. For instance, our collaborators:

- may decide not to, or may fail to successfully, develop, market or sell products based on our technology;
- may not devote sufficient resources to the development, marketing or sale of these products based on our technology; or
- may terminate their agreements with us.

If any of these events occur with respect to one of the companies we are collaborating with, we would not receive the benefits of the collaboration and our growth could be slowed and our business could be materially adversely affected.

TO ACHIEVE COMMERCIAL SUCCESS, WE MUST COMPLETE THE DEVELOPMENT OF OUR PRODUCTS AND THOSE PRODUCTS MUST GAIN MARKET ACCEPTANCE OR OUR BUSINESS COULD BE MATERIALLY ADVERSELY AFFECTED.

Many of our potential products, including certain M-SERIES products, are at an early stage of development and we have not introduced any clinical diagnostics products. Products under development require additional research and development efforts, including clinical testing and regulatory approval, prior to commercial use. Our potential products are subject to the risks of failure inherent in the development of products based on new technologies. These risks include the possibilities that:

- our design or approach may not be successful;
- our products may not be compatible with existing technology or may rely on technology that has become obsolete;
- our products may be found ineffective or fail to meet the applicable regulatory standards or receive necessary regulatory clearances;
- our estimates of the market size and potential for our products may prove incorrect;
- third parties may market superior or equivalent products;
- our products may not be recognized in the market due to unfamiliar brand names; or

our product development costs may outweigh potential future cash flows associated with those products. Our business, business prospects and financial results would be hurt if our products are not accepted as alternatives to other existing or new products and do not gain market acceptance.

In addition, we have licensed for a license fee of $50 million plus royalties as specified in the PCR license agreements certain PCR technology from Roche, which PCR technology we plan to integrate into certain of our new instrument systems. Although we do not currently sell, or have under development, any product based on the PCR technology being licensed from Roche, any products that we may develop using PCR technology will be also subject to the risks of failure inherent in the development of products based on new technologies as described above.

We have performed a valuation of the PCR technology license and recorded a value of $19.5 million and reflected a $30.5 million adjustment to the consideration paid by Roche with respect to the merger and related transactions. If we are unable to successfully develop any products using PCR technology because such PCR technology has become obsolete or the future undiscounted cash flows attributable to products using PCR technology are insufficient to realize the remaining carrying value of the license, we would be required to write off the remaining net book value or record an impairment of the value of the PCR license. Furthermore, if as a result of the claims made by Applied Biosystems against Roche, we are unable to use the PCR technology being licensed from Roche, we would also be required to write off the remaining net-book value of the PCR license. Such a write-off or the recording of such an impairment could have a material adverse effect on our future results of operations.

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

Our quarterly operating results will depend upon:

- the volume and timing of orders and product deliveries for biodefense products, M-SERIES systems or other products, which orders and deliveries are based on our customers requirements;
- the success of M-SERIES system upgrades and enhancements, which upgrades and enhancements involve increased product costs at the time of the upgrade or enhancement, and customer acceptance of those enhancements and upgrades;
- the amount of revenue recognized from royalties and other contract revenues, which revenues are dependent upon the efforts of our licensees and collaborators;
- whether our instruments are sold or leased to customers, which will affect the timing of the recognition of revenue from the sale or lease;
- the timing of our introduction of new products, which could involve increased expenses associated with product development and marketing;
- the volume and timing of product returns and warranty claims, which, if products are returned or have warranty claims that are unexpected, may involve increased costs in excess of amounts reserved for returns or claims;
- our competitors introduction of new products, which may affect the purchase decision of or timing of orders by our customers and prospective customers while the competitors product is assessed;
- the amount of expenses we incur in connection with the operation of our business, including

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research and development costs, which increases or decreases based on the products in development and

sales and marketing costs, which are based on product launches or promotions and sales incentives that might be in effect from time to time;

the amount that we will record each quarter related to the amortization or impairment of the license to use PCR technology, which may increase based on the outcome of the litigation and arbitration commenced against Roche by Applied Biosystems relating to Roche s and Applied Biosystems respective rights to PCR technology;

unexpected termination of government contracts or orders, which could result in decreased sales and increased costs due to excess capacity, inventory, personnel and other expenses; and

MSD s financial results, which for the years ended December 31, 2003 and 2002 included losses of $20.4 million and $17.1 million, respectively, and which we have commenced consolidating as of March 31, 2004.

These factors may cause our quarterly operating results to fluctuate significantly, which in turn, may cause our stock price to be volatile. In addition, because our revenues and operating results are expected to be volatile and difficult to predict, we believe that period-to-period comparisons of our results of operations will not be a good indication of our future performance.

THE ACCOMPANYING CONSOLIDATED FINANCIAL STATEMENTS MAY NOT NECESSARILY BE INDICATIVE OF OUR FINANCIAL POSITION, RESULTS OF OPERATIONS OR CASH FLOWS HAD WE OPERATED ON A STAND-ALONE BASIS.

Our assets and businesses have historically been owned, operated and fully integrated with IGEN. Our accompanying consolidated financial statements have been prepared and are presented as if we had been operating as a separate entity. In order to fairly present our operating results, these financial statements reflect the application of certain estimates and allocations.

Our consolidated statements of operations include all revenues and costs that are directly attributable to our businesses, as well as certain expenses of IGEN that have been allocated to us using various assumptions.

These expenses include an allocated share of general and administrative salaries as well as certain other shared costs (primarily facility, human resources, legal, accounting and other administrative costs) which were allocated based upon percentage of total revenue or percentage of total headcount, as appropriate. While management believes that the allocation methodologies are reasonable and appropriate, different allocation methodologies would result in changes to our operating results.

Upon completion of the merger and related transactions between Roche and IGEN, we became an independent, publicly-traded company and operate on a stand-alone basis. The financial information in the accompanying consolidated financial statements may not reflect our financial position, results of operations and cash flows in the future or what they would have been had we been operating as a stand-alone entity in the past.

WE MAY CHANGE THE FOCUS OF OUR BUSINESS OR ENTER INTO NEW HEALTHCARE FIELDS, WHICH COULD RESULT IN THE INCURRENCE OF ADDITIONAL COSTS AND EXPOSURE TO ADDITIONAL OR DIFFERENT BUSINESS RISKS.

We have broad discretion in determining the future strategy and focus of our business and may enter new healthcare fields in which we have limited or no experience. A significant change in the focus of our business could result in a loss of our previous investment, the incurrence of additional costs, including research and

development costs, and exposure to additional or different business risks. Incurrence of additional costs and exposure to additional risks could materially adversely affect our business.

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

We will need substantial amounts of money to fund our operations on an ongoing basis. We expect our available cash to be sufficient to fund our operations for at least one year, but cannot predict how long our available cash will be sufficient to fund our operations thereafter.

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

- for research and development to successfully develop our technologies;
- to obtain regulatory approval for our products;
- to file and prosecute patent applications to protect our technology;
- to respond to innovations that our competitors develop;
- to retain qualified employees, particularly in light of competition for qualified scientists and engineers;
- to make new arrangements to market our technology;
- to manufacture products ourselves or through a third party;
- to provide funding for expanded or new facilities; and
- to market different products to different geographic markets, either through expanding our sales and distribution capabilities or relying on a third party.

The failure to raise sufficient additional capital for us to develop our business would adversely affect our business prospects.

OUR ACCESS TO FUNDS COULD BE NEGATIVELY IMPACTED BY MANY FACTORS, INCLUDING VOLATILITY IN THE PRICE OF OUR COMMON STOCK, LOSSES FROM OPERATIONS AND CAPITAL MARKET CONDITIONS.

We may not have access to enough funds on favorable terms, if at all, to successfully operate and 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 that we obtain may contain restrictive terms that limit our operating flexibility. If we raise additional capital by selling additional common or preferred stock, the holdings of existing stockholders would be diluted.

If we are unable to raise additional capital, we may have to consider pursuing arrangements with other companies that may not be available on terms favorable to us. In addition, we may have to scale back, or even eliminate, some of our programs.

WE MAY 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. IN ADDITION, IF THE MARKETS FOR OUR PRODUCTS CHANGE OR EVOLVE IN AN UNEXPECTED MANNER, OUR BUSINESS COULD BE MATERIALLY ADVERSELY AFFECTED.

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 may experience design, development, implementation and other difficulties that could delay or prevent our introduction of new or enhanced products, or products that we may develop, manufacture or market with third parties or affect the performance of existing products, such as those which IGEN experienced with the development of M-SERIES instruments. These difficulties and delays may cause expenses to increase and our product sales to fluctuate. In addition, if we experience design, development or implementation difficulties in developing, manufacturing, distributing or marketing these instruments, we would sell fewer of our products and our business prospects would be adversely affected.

We expect the markets for our products to change and evolve. These changes could facilitate the market demand for our new or enhanced products, including the need for products that could be utilized in clinical point-of-care sites and field-testing of environmental samples in the biodefense market. If market demand does not change or evolve as we anticipate or if 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 success will depend in part upon our ability to profitably enhance existing products and develop and introduce new products. We may not be able to avoid the obsolescence of our products due to technological change and evolving industry standards and government regulations.

If we experience design, development, implementation or other difficulties that delay or prevent our introduction of new or enhanced products or if the markets change or evolve in an unexpected manner, our business could be materially adversely affected.

WE EXPECT TO RELY ON SALES OF THE M-SERIES PRODUCT FAMILY FOR A SIGNIFICANT PORTION OF OUR REVENUES, AND A DECLINE IN SALES OF THESE PRODUCTS COULD CAUSE ADVERSE FINANCIAL RESULTS AND NEGATIVELY AFFECT OUR BUSINESS PROSPECTS.

We expect to derive a significant portion of our revenues from sales of M-SERIES products. Any factor adversely affecting the pricing or demand of M-SERIES products, including market acceptance of competing products, could cause our revenues to decline, resulting in adverse financial results and negatively affecting our business prospects.

Additionally, we intend to market M-SERIES products in markets in which we have little or no experience. We may not be able to successfully market the M-SERIES family of products in those markets, which could cause an adverse affect on our business prospects.

OUR COMPETITORS AND POTENTIAL COMPETITORS MAY HAVE OR DEVELOP DIAGNOSTIC PRODUCTS AND TECHNOLOGIES THAT ARE MORE ATTRACTIVE THAN OUR EXISTING OR FUTURE DIAGNOSTIC PRODUCTS.

Our business will be subject to intensive competition from established companies, development stage 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, among other things:

- more money to invest;

more established diagnostic products;

long-standing relationships with customers;

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

a larger, more experienced workforce; and

more experience in obtaining regulatory approval for clinical testing products.

As a result, our competitors may develop, manufacture market or sell diagnostic products that are more effective or commercially attractive than our current or future diagnostic products. In addition, these competitors may offer broader product lines, discounts and may have greater name recognition than us. Furthermore, we compete against companies that utilize ECL technology licensed to them by us, including Roche and MSD, a company in which we also have an interest.

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

WE HAVE LIMITED MANUFACTURING EXPERIENCE, WHICH PUTS US AT A COMPETITIVE DISADVANTAGE AND COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION AND REVENUE.

We lack experience in large-scale manufacturing and have no experience in the manufacturing of clinical diagnostic products, which could hamper our ability to manufacture existing products or new products that we develop. We have two options to address this competitive disadvantage.

First, we could expand our internal ability to manufacture products, which, to date, has only been done in a limited way. Second, we could contract with a third party to manufacture products for us based on our technology, which, to date, we have not done.

If we are unable to expand our own manufacturing capability or find a suitable manufacturer on acceptable terms in a timely manner, we may be unable to meet demand for existing products and could be delayed in introducing new products to the market. Failure to meet demand for existing products or delays in introducing new products could put us at a competitive disadvantage and could have a material adverse effect on our business, financial condition and revenue.

WE HAVE LIMITED MANUFACTURING FACILITIES FOR OUR PRODUCTS AND WE MAY NOT FIND ADDITIONAL FACILITIES SUITABLE FOR FUTURE GROWTH, WHICH COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS AND PROSPECTS.

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. If our facility were not operational for an extended period of time, including due to an unforeseen plant shutdown, then our business and future prospects could be materially adversely affected.

In addition, we 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 business prospects could be materially adversely affected.

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

WE HAVE NO EXPERIENCE SELLING, MARKETING OR DISTRIBUTING CLINICAL DIAGNOSTIC PRODUCTS. OUR FAILURE TO ESTABLISH A SALES FORCE WITH TECHNICAL EXPERTISE OR TO ESTABLISH AN EFFECTIVE DISTRIBUTION SYSTEM FOR OUR CLINICAL DIAGNOSTIC PRODUCTS COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS PROSPECTS AND REVENUES.

We need to develop selling, marketing and distribution capabilities for our planned clinical diagnostic products. To market clinical diagnostic products directly to customers, and not through a licensee or third party distributor or collaborator, we will need to develop a substantial sales force with technical expertise. We will also need to establish a distribution system to support our sales force. Alternatively, we could license or contract with another company to provide sales and distribution services for our 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, which could materially adversely affect our business prospects and revenues.

FAILURE TO MANAGE OUR GROWTH COULD ADVERSELY AFFECT OUR BUSINESS.

We expect to grow by increasing our presence in existing markets and introducing new products we develop into new potential markets. Our growth strategy will 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 and we will need to hire, train and retain additional personnel. We may also need to improve and expand our financial and management controls, reporting systems and operating systems as well as other aspects of our infrastructure, including research and development or manufacturing facilities. We may encounter difficulties integrating additional personnel, as well as improving, expanding and integrating new systems or facilities, which could adversely affect our business.

THE SUCCESS OF OUR BUSINESS DEPENDS ON PATENTS THAT WILL EXPIRE OVER TIME AND THAT MUST BE ACTIVELY PURSUED, OBTAINED, MAINTAINED AND PROTECTED. OUR BUSINESS COULD BE HARMED IF WE HAVE FUTURE DISAGREEMENTS WITH ROCHE OVER THE SCOPE OF THE LICENSE AGREEMENT.

Our business success or failure will depend, in part, on our ability to pursue, obtain, and maintain adequate patent protection for ECL technology and our other technologies. Our patents may not adequately protect our technology from being used by our competitors.

Our business depends heavily on patents that will expire over time and may be challenged or circumvented by competitors. Patents allow us, for a time, to prevent others from using our inventions to compete against us.

Companies may challenge or seek to invalidate patents or circumvent valid claims in patents, all of which could make it necessary for us to defend our patents in litigation. Litigation over patents poses the following risks to our business:

- litigation costs can be extremely high, which could drain our financial resources; and

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

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 financial condition and business prospects would be adversely affected.

Roche, through its affiliate, has been licensed by us to exploit ECL technology, subject to the limitations of the license agreement. Although the terms of the license agreement were negotiated in an effort to minimize the areas of potential future disputes, there are no assurances that we and Roche will continue to agree on the scope, permitted use and other material terms of the license agreement. Future disputes with Roche over the scope of the license agreement, such as disputes over the field or the types of products that Roche is permitted to develop and sell, might lead to lengthy and costly legal proceedings, which could adversely affect our financial condition and future business prospects.

OUR BUSINESS COULD BE HARMED IF WE INFRINGE, OR ARE ALLEGED TO HAVE INFRINGED, THE INTELLECTUAL PROPERTY OF OTHERS.

If our products or services were to infringe the intellectual property (including patent rights) of others, we or our licensees could:

be required to alter, or abandon products or processes;

be required to obtain a license from the intellectual property holder;

lose customers that are reluctant to continue using our or our licensees products or services;

be forced to abandon development work with respect to these products; and

be required to pay damages that could be substantial.

If we or our licensees infringe the intellectual property (including patent rights) of others, our business could be damaged if we were unable to make necessary alterations or obtain a necessary license on acceptable terms, if at all.

In addition, if our products or services were alleged to have infringed the intellectual property (including patent rights) of others, we would be forced to defend ourselves in litigation and might be enjoined from further sale of our products or required to pay monetary damages or amounts in settlement of the suit, which could adversely affect our prospects, drain our financial resources and discourage other companies from working with us.

BECAUSE WE INTEND TO DEVELOP PRODUCTS THAT ARE BASED ON PATENTS AND TECHNOLOGY THAT WE HAVE LICENSED FROM OTHERS, THE OWNERS OF THOSE PATENTS AND TECHNOLOGY MIGHT CLAIM THAT PRODUCTS DEVELOPED OR SOLD BY US VIOLATE THOSE LICENSES. ADDITIONALLY, A THIRD PARTY MIGHT OBJECT TO A LICENSE THAT WE HOLD OR TO THE SCOPE OF THE LICENSE GRANTED TO US.

Our success or failure will also depend, in part, on the patent rights and technology of others, including patents and technology being licensed to us from affiliates of Roche. We have been licensed by affiliates of Roche to exploit certain improvements from Roche Diagnostics and certain PCR technology, subject to certain limitations. Although the terms of the improvements license agreement and the PCR license agreements were negotiated in an effort to minimize the areas of potential future disputes, there are no assurances that we and Roche will continue to agree on the scope, permitted use and other material terms of the improvements license agreement or the PCR license agreements. Future disputes with Roche over the scope, permitted use and other material terms of the improvements license agreement or the PCR license agreements, such as disputes over the field or types of products that we are permitted to develop and sell, may lead to lengthy and costly legal

proceedings, or could interfere with or preclude us from proceeding with one or more development programs, whether conducted independently or through a collaborative arrangement.

In addition, third parties may object to the scope, permitted use and other material terms of one or more of the licenses granted to us by certain Roche affiliates. For example, Roche has advised us that Applied Biosystems has notified Roche that one or more of the PCR licenses granted by certain Roche affiliates to us under the improvements license agreement and the PCR license agreements may infringe exclusive rights to PCR technology held by, or other contract rights of, Applied Biosystems. Applied Biosystems has commenced litigation and arbitration against Roche regarding their respective rights relating to PCR technology. There are no assurances that we will not be named as a defendant in either of those actions or that Roche will prevail in the litigation and arbitration, or that the terms of any resolution or settlement of these proceedings will not be unfavorable to us.

If we were named as a defendant in either of those proceedings, we would be subject to the risks identified in the immediately preceding risk factor. Further, a final determination, settlement or other resolution in the arbitration or litigation may limit, preclude or interfere with our ability to exploit certain PCR technology licensed under the improvements license agreement or the PCR license agreements. Although we do not sell, or have under development, any product based on the PCR technology being licensed from Roche, if Applied Biosystems prevails in its claims against Roche, we may be required to obtain a license from Applied Biosystems for certain patents covering PCR technology to avoid future potential claims of infringement related to any development program that we might establish for future products based on PCR technology and may face many of the risks described in the immediately preceding risk factor. Business Our Technology PCR Technology .

Further, we license technology from other companies and academic institutions. Because access to this technology is necessary to operate 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 AND MSD MAY HAVE DIFFERENT VIEWS OF THE SCOPE OF THE EXCLUSIVE LICENSE TO OUR TECHNOLOGY PREVIOUSLY GRANTED TO MSD AND THE SCOPE OF MSD S RIGHTS UNDER THE FORMER JOINT VENTURE AGREEMENT WITH US, WHICH COULD AFFECT OUR ABILITY TO EXPAND OUR BUSINESS DIRECTLY OR THROUGH COLLABORATIONS.

We intend to expand our business through internal development programs and through new or expanded collaborative arrangements. MSD may view the scope of its exclusive license and other rights under its license agreement and other agreements with us in a way that interferes with or precludes us from proceeding with one or more development programs. There are no assurances that MSD will not object to our future business plans, whether conducted independently or through a collaborative arrangement. Additionally, MSD may believe that we must obtain MSD s consent prior to entering into proposed collaborative arrangements. The other party to a proposed collaboration with us may also require us to obtain MSD s consent to avoid any future disputes or disagreements. For example, in connection with the merger and related transactions, Roche required IGEN to obtain MSD s consent to the execution and delivery of the license agreement. If we are required to obtain MSD s consent for any reason, there are no assurances that we will be able to obtain that consent at all or on terms that would not have an adverse effect on our business, financial condition or results of operations. In addition, if we choose not to obtain MSD s consent, MSD may sue us to enforce rights it believes it has. Such a lawsuit could materially harm our business and future business prospects.

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WE RELY ON TRADE SECRETS AND OTHER INFORMATION THAT CANNOT BE PROTECTED BY PATENTS, WHICH COULD HARM OUR BUSINESS IF THEY WERE DISCLOSED TO OR INDEPENDENTLY DEVELOPED BY 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 or independently developed by competitors, our business would suffer.

We seek to protect this information, in part, by entering into confidentiality agreements with licensees, employees and consultants that 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 be adequately redressed for 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 THE MANUFACTURING OF 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. In the event of a reduction in, interruption of, or degradation in, the quality of the supply of any of the materials required by us, 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, at a reasonable cost or otherwise on acceptable terms, our ability to manufacture one or more of its products would be delayed or halted.

Any changes in sources of supply may require additional engineering or technical development to ensure consistent and acceptable performance of our products. If any of these events occur, our 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 BE ABLE TO ATTRACT AND RETAIN SUFFICIENT PERSONNEL, WHICH COULD ADVERSELY AFFECT OUR BUSINESS.

We need to hire staff and retain our 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 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.

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MSD AND MST HAVE AGREED TO PURCHASE OUR INTEREST IN MSD BUT THERE IS NO ASSURANCE THAT THE PURCHASE PRICE WILL EQUAL OR EXCEED THE BOOK VALUE OF OUR INTEREST IN MSD AND IF IT DOES NOT, WE MAY INCUR A LOSS. IN ADDITION, THERE IS NO ASSURANCE THAT WE WILL RECEIVE THE FULL PURCHASE PRICE.

The MSD joint venture agreement expired upon completion of the merger between Roche and IGEN. As a result, MSD and MST had the right to purchase our interest in MSD. Pursuant to the settlement, MST and MSD agreed to purchase, and we agreed to sell, our entire interest in MSD. MSD and MST s purchase of our interest will be for a purchase price equal to fair market value (determined in accordance with an appraisal process), minus a 7.5% discount factor. The appraisal process will be completed by October 15, 2004, at the latest. Once the fair market value and purchase price are determined, the purchase will occur. MSD or MST will be required to pay us the outstanding purchase price plus simple (cumulated, not compounded) interest at the fixed annual rate of 0.5% over the prime rate in effect on the date that MSD or MST, as the case may be, purchases the interests. The purchase price is payable over time in installments equal to the sum of 5% of MSD net sales, as determined in accordance with the MSD agreements, and 20% of the net proceeds realized by MSD from the sale of its debt or equity securities in any third-party financing after the date of the sale of our interest in MSD. We received a prepayment credit of $2.0 million against our payment obligations to MSD in connection with the settlement, and therefore the initial installment payments will be applied against this credit and not paid to us in cash.

As of March 31, 2004, the book value of our interest in MSD as recorded on our unconsolidated balance sheet was approximately $46.2 million, and we subsequently made an additional capital contribution of $5 million ($3 million of which was in cash) in connection with the settlement. There is no assurance that the purchase price will equal the book value of our interest and if it does not, we would have to record a loss on the sale of our interest.

We expect that MSD will require substantial additional funding for its ongoing operations. We do not intend to provide additional funding and we cannot predict whether MSD will obtain such funding. If MSD is not able to obtain the funding, we could lose our ability to realize the value of most or all of our investment in MSD.

Because the purchase price is payable only out of a percentage of MSD s net sales or future financings, our receipt of the purchase price is dependent on MSD s future performance. In the event sufficient future net sales of MSD or third-party financings do not materialize, we will not receive the full purchase price for our interest in MSD.

OUR ABILITY TO DEVELOP PRODUCTS MAY BE NEGATIVELY AFFECTED BY SOCIAL ISSUES RELATING TO ANIMAL TESTING.

Our research and development activities have occasionally involved, and in the future might involve, limited testing in mice and rats. In addition, testing in the future may involve other animals. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation of such activities and by other means, our ability to develop products may be negatively affected by a ban on animal testing or by action taken by groups or individuals opposed to these tests.

Risks Relating to Regulation and Government Contracts

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

Our ability to secure or retain U.S. government contracts is subject to uncertainties related to the government s future funding commitments. The 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 U.S. 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 U.S. government contracts and orders.

U.S. government contracts may span one or more years and may include multiple renewal options in favor of the U.S. government. 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 the counterparty s 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 non-exclusive, non-transferable, irrevocable, paid-up license to use inventions made by us in the course of performing such contracts, or have such inventions used by or on behalf of the U.S. government, for research or other government purposes. New U.S. government contracts we enter into may also include similar provisions.

WE MUST OBTAIN FOOD AND DRUG ADMINISTRATION CLEARANCE OR APPROVAL TO MARKET OUR CLINICAL DIAGNOSTIC PRODUCTS, WHICH IS OFTEN COSTLY AND TIME CONSUMING. IF WE DO NOT OBTAIN THE NECESSARY CLEARANCES OR APPROVALS, OUR BUSINESS PROSPECTS WOULD SUFFER.

The manufacture, packaging, labeling, advertising, promotion, distribution and sale of medical devices such as clinical diagnostic products are subject to governmental regulation by national and local government agencies in the United States and abroad. The U.S. Food and Drug Administration, or FDA, regulates many of the areas in which we conduct our research and in which we are and expect to be developing, manufacturing and marketing products. In particular, we must obtain FDA clearance or approval before we can market clinical diagnostic products, such as those in development for the clinical point-of-care market segment.

The process of obtaining necessary clearances or approvals is often costly, time consuming and uncertain. In addition, we may begin to distribute reagents specifically for research use under an exemption. If the FDA disagrees with our classification of, or the manner in which we market and sell those reagents, it may impose restrictions on our business operations and subject us to sanctions that could adversely affect our business prospects. We have very limited experience obtaining FDA clearance and approval and may not be successful in obtaining FDA clearance or approval for any of our clinical diagnostic products, which would materially adversely affect our business prospects. Further, clearance or approval may place substantial restrictions on the indications for which the product may be marketed or to whom it may be marketed.

To obtain permission from the FDA to market in the U.S., we, or the companies we work with, will need to either obtain Section 510(k) pre-market notification clearance or approval of a pre-market approval application from the FDA. To obtain clearance for marketing, we, or the companies we work with, must demonstrate substantial equivalence to a similar legally marketed product by submitting a pre-market notification to the FDA. The FDA may require preclinical and clinical data to support a substantial equivalence determination. Clinical trials for gathering

supporting data can take extended periods of time to complete and there can be no assurance that the FDA will find a device substantially equivalent.

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

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

We expect that certain of our future products will be subject to continuing FDA requirements, including compliance with the FDA s Good Manufacturing Practices and the FDA s medical device reporting regulation. 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 Environmental Protection Agency, or EPA, regulate many of our products as well as products that we plan to develop, manufacture, market and sell, including products for the clinical diagnostics, biodefense and industrial markets.

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

Whether we directly manufacture products 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 and impose sanctions. 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 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, such as personal injury or property damages, and loss of permits required for our operations, if we fail to comply with these laws or regulations. Our operations are also subject to various employee health and safety laws and regulations, including those concerning occupational injury and illness and employee exposure to hazardous, radioactive and infectious materials.

While we have procedures in place to protect employees from exposure to such materials, we cannot assure you that potentially harmful exposure will not occur or that we will not be liable to employees as a result. In addition, because of the limited information currently available regarding some of the hazardous, radioactive and infectious materials used in our businesses, there may be unknown risks involved with the use of and exposure to such materials. In some circumstances there may be no body of knowledge or standard protocols for dealing with these risks. Costs associated with such environmental, health and safety matters could have a material adverse effect on our business and financial condition. In addition, in connection with our biodefense business, the DOD or other government agencies may require additional security measures to be implemented at our facility, which could cause us to incur substantial additional costs.

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 CONTRACTS WITH THE U.S. GOVERNMENT COULD SUBJECT US TO LOSSES OR ADVERSELY AFFECT OUR FUTURE BUSINESS.

Our U.S. government contracts are fixed-price contracts and therefore we receive a fixed price irrespective of the actual costs we incur in connection with the performance of the contracts. Consequently, we will be 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 the 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 our performance under the contract and obtain future U.S. government contract awards.

RESTRICTIONS ON HEALTHCARE COSTS AND HEALTHCARE AND INSURANCE FINANCING PRACTICES COULD LIMIT DEMAND FOR OUR PRODUCTS, WHICH WOULD HURT OUR BUSINESS AND BUSINESS PROSPECTS.

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

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

In many foreign markets, governments directly set the prices that clinical diagnostic companies may charge for their products and services. In the U.S., a number of legislative and regulatory proposals aimed at changing the healthcare system have been proposed in recent years and we expect this to continue. Foreign and domestic legislative and regulatory initiatives that limit healthcare coverage may have a material adverse effect on our business and business prospects.

Risks Relating to the Industry

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 diagnostics, biodefense and industrial markets. We may not be able to insure adequately 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 product liability insurance coverage or not covered by our product liability insurance could have a material adverse effect on our financial condition.

Risks Relating to Our Common Stock

OUR EXECUTIVE OFFICERS AND DIRECTORS EXERCISE SIGNIFICANT INFLUENCE OVER US AND MAY HAVE SIGNIFICANT INFLUENCE OVER THE OUTCOME OF PROPOSED CORPORATE ACTIONS SUPPORTED OR OPPOSED BY OTHER STOCKHOLDERS.

Our executive officers and directors, in the aggregate, own approximately 22.8% of the outstanding shares of our common stock. Our chairman and chief executive officer owns approximately 17.8% of the outstanding shares of our common stock. As a result, certain of our executive 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 stockholders. In addition, as a result of their shareholdings, certain of our executive officers and directors could have significant influence over the outcome of potential transactions, including acquisition transactions, that may be supported by other stockholders.

PROVISIONS IN OUR CHARTER DOCUMENTS MAY DISCOURAGE POTENTIAL ACQUISITIONS OF US, EVEN THOSE WHICH THE HOLDERS OF A MAJORITY OF OUR COMMON STOCK MAY FAVOR, WHICH MAY ADVERSELY AFFECT THE MARKET PRICE OF OUR COMMON STOCK, REDUCE THE LIKELIHOOD OF OFFERS TO ACQUIRE US AND PREVENT CHANGES IN OUR MANAGEMENT.

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

- classify our board of directors into three classes, with directors of each class serving for a staggered three-year period;
- provide that our 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 all our shares entitled to vote generally in the election of such directors then outstanding, voting together as a single class;
- prohibit our stockholders from calling special meetings and prohibit action by our stockholders by written consent;
- require at least 66 2/3% of the voting power of all our shares entitled to vote generally in the election of directors then outstanding, voting together as a single class, to alter, amend or repeal certain provisions, including the provisions relating to our classified board, the election, appointment and removal of our directors and action by stockholders by written consent described above;
- permit our board of directors to fill vacancies and newly created directorships on our board of directors; and
- contain advance notice requirements for stockholder proposals.

In addition, under our certificate of incorporation, our board of directors also has the authority to issue up to 15,000,000 shares of preferred stock in one or more series. Our board of directors can fix the powers, preferences and rights of any such series without stockholder approval.

Our 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 our common stock or otherwise make it more difficult for a third party to gain control of us.

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 our board of directors.

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In addition, we have adopted a stockholder rights agreement, pursuant to which one right attached to each share of our common stock outstanding. These rights will in most cases cause substantial dilution to a person that attempts to acquire or merge with us without the approval of the our board of directors by permitting the holders of these rights (other than the person attempting to acquire or merge with us) to, upon the occurrence of specified circumstances, purchase, at a substantial discount, shares of our series A participating cumulative preferred stock or shares of common stock of the person that attempts to acquire or merge with us. Accordingly, the existence of these rights may deter potential acquirers from making a takeover proposal or a tender offer.

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

We have no plans to pay cash dividends on our common stock in the foreseeable future, if at all.

WE MAY NEED TO RAISE ADDITIONAL CAPITAL IN THE FUTURE AND WE MAY GRANT OPTIONS OR OTHER EQUITY-BASED AWARDS TO OUR EXECUTIVE OFFICERS, DIRECTORS, EMPLOYEES AND CONSULTANTS, FROM TIME TO TIME, EITHER OF WHICH WOULD RESULT IN DILUTION TO OUR STOCKHOLDERS.

Your investment in our common stock could be diluted if we issue additional shares of our common stock or securities convertible into, or exercisable for, shares of our 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, or the exercise of securities for, shares of our common stock could cause the market price of our common stock to decrease.

Under the BioVeris 2003 stock incentive plan, our executive officers, directors, employees and consultants may from time to time be granted options or other equity-based awards, such as phantom stock or restricted stock, to purchase up to 5.3 million shares of our common stock. If our executive officers, directors, employees and consultants exercise their options or other equity based awards, if and when granted and exercisable, and purchase shares of our common stock, your investment in our common stock will be diluted.

THE EXON-FLORIO ACT MAY INHIBIT POTENTIAL ACQUISITION BIDS, WHICH MAY ADVERSELY AFFECT THE MARKET PRICE OF OUR COMMON STOCK.

Section 721 of Title VII of the Defense Production Act of 1950, also known as the Exon-Florio Act, authorizes the president of the U.S. or his designees to initiate an investigation into the potential effects on national security of a business combination of a U.S. corporation and a foreign entity that could result in foreign control of the U.S. corporation. Subject to certain exceptions, under the Exon-Florio Act, the president may suspend or prohibit any foreign acquisition, merger or takeover of a U.S. corporation if there is credible evidence that the foreign entity exercising control might take action that threatens national security and there is no provision of law adequate to protect national security.

Due to our current and potential future involvement in the biodefense industry, the Exon-Florio Act could inhibit potential acquisition bids from foreign entities, which could adversely affect the market price of our common stock.

ITEM 2. PROPERTIES

Our principal administrative, marketing, manufacturing and research and development facilities consist of approximately 165,000 square feet located in five 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 2005 through 2010. We believe that current facilities should be adequate for immediate business requirements but additional facilities may be required if we successfully expand our business operations. We are evaluating new facilities for development, manufacturing and other corporate uses and if we secure new space, it would result in additional facilities costs.

See ITEM 1 Business Risk Factors Risks Relating to Us and Our Business and ITEM 7 Management s Discussion and Analysis of Financial Condition and Results of Operations.

ITEM 3. LEGAL PROCEEDINGS

In June 2004, the Audit Committee of our Board of Directors commenced an investigation of MSD that was prompted by the discovery of a series of transactions undertaken by MSD involving the actual or proposed purchase by MSD of residential real property and luxury automobiles having an aggregate cost of approximately $7 million. The transactions were entered into by MSD upon Jacob Wohlstadter s sole approval and without our knowledge.

On June 15, 2004, we filed an action in the Court of Chancery of the State of Delaware, which we refer to in this Form 10-K as the Court, against Jacob Wohlstadter, MSD and MST, seeking Court confirmation that we remained entitled to designate one of the two members of the MSD Board of Managers, and asking the Court to enter an order, pending the outcome of the litigation, prohibiting MSD from taking any actions outside the ordinary course of MSD s business without providing prior notice to us. On June 17, 2004, the Court ordered that, pending the Court s final determination of the lawsuit, our representative on the MSD Board of Managers was to remain on the MSD Board of Managers and that MSD was not to engage in any transaction outside the ordinary course of business which had a value in excess of $10,000 without the approval of both members of the MSD Board of Managers. Also on June 15, 2004, we submitted a formal demand to MSD requesting the right to examine certain books and records of MSD to aid the Audit Committee in its investigation and to permit us to value our interest in MSD. Beginning late June, MSD permitted us to examine the requested books and records.

On June 17, 2004, MSD received $2.9 million from Jacob Wohlstadter as consideration for the proposed sale by MSD to Jacob Wohlstadter of real property and automobiles, pending approval by the Board of Managers. Jacob Wohlstadter also assumed MSD s purchase obligations with respect to a prospective real property purchase in the approximate amount of $4.1 million.

Also on June 17, 2004, we were informed by the staff of the Securities and Exchange Commission that it had commenced an informal inquiry as to certain issues relating to MSD.

On July 6, 2004, we entered into an agreement with MSD, MST and Jacob Wohlstadter pursuant to which it was agreed that the lawsuit filed on June 15, 2004 would be stayed, that the parties would not file new litigation against each other, and that the valuation process in connection with MST s and MSD s right to purchase our interest in MSD would be stayed. This stay agreement was intended to permit the parties to engage in substantive negotiations to resolve the disputed matters and in order to permit us to finalize our Form 10-K for the fiscal year ended March 31, 2004. This stay agreement terminated automatically on July 13, 2004 because MSD s representation letters to the auditors of MSD were not executed.

Because we are required to consolidate the financial information of MSD pursuant to FASB Interpretation No. 46, which we adopted as of March 31, 2004, we require the audited financial statements of MSD to complete our Form 10-K. We were not able to file our Form 10-K on a timely basis because the MSD financial statements were not available and because we were unable to conclude on the appropriate accounting for MSD.

On July 14, 2004, we filed a second action with the Court against MSD, MST and Jacob Wohlstadter. The action alleged, among other things, breach of fiduciary duty and contract, and sought relief including the dissolution of MSD and the appointment of a liquidating trustee.

Also in July 2004, the Audit Committee retained an independent special counsel to investigate whether our management had any prior knowledge of the real property and automobile transactions of MSD described above. This special counsel reported to the Audit Committee that there was no evidence that any member of our management knew of the MSD transactions at issue before they occurred.

On July 16, 2004, we received a letter from the staff of the Nasdaq Listing Qualifications Department notifying us that our common stock was subject to delisting from The Nasdaq Stock Market, Inc. because we had not yet filed our

Form 10-K for the period ending March 31, 2004. In accordance with applicable NASD Marketplace Rules, we requested a hearing to review the Nasdaq staff determination before a Nasdaq Listing Qualifications Panel, which is scheduled for August 19, 2004. As a result of such request, the delisting of our stock was automatically stayed.

On July 19, 2004, all members of the Board of Directors met to review the MSD litigation and related issues. This review included a consideration of the status of the litigation, as well as the effects of the disputes on us generally, including management s ability to conduct our business and to pursue our strategy and the notification from Nasdaq concerning possible delisting of our common stock as a result of our failure to file our Form 10-K on a timely basis. All members of the Board of Directors participated in this review, although some discussions were conducted by the independent directors without the management directors, Samuel Wohlstadter and Richard Massey, or other members of management. As a result of this review, the Board of Directors, with all members participating, unanimously approved a resolution that delegated to the Joint Venture Oversight Committee, or JVOC, the power and authority to (i) initiate, review, evaluate and determine the course of action we should pursue with respect to the pending litigation and any additional litigation against MSD, (ii) communicate and negotiate the terms of any proposed settlement of such litigation and any other matters with respect to MSD and (iii) otherwise deal with MSD in a manner the JVOC deemed to be in the best interests of our company and our stockholders. The resolution also appointed Messrs. Quinn and Crowley as additional members of the JVOC, resulting in the JVOC consisting of all five independent directors, and provided that action of the JVOC should be by unanimous approval of its members. The resolution also directed the JVOC to consult with our management and members of the Board who are not on the JVOC regarding the MSD matters. In addition, by unanimous vote of the five independent directors without the participation of Messrs. Wohlstadter and Massey, the Board of Directors approved a resolution directing the JVOC to pursue negotiations to settle the litigation and other outstanding disputes with MSD, MST and Jacob Wohlstadter and setting forth general terms that would be acceptable for such a settlement.

Between July 19, 2004 and August 3, 2004, there were meetings, telephone conferences and other communications among representatives of the JVOC, MSD, MST and Jacob Wohlstadter to discuss the terms of a settlement. On July 21, 2004, we entered into an agreement with MSD, MST and Jacob Wohlstadter to stay the litigation during these negotiations. During this period, the JVOC also communicated from time to time with our management (other than Samuel Wohlstadter) concerning various aspects of the settlement. Members of management (other than Samuel Wohlstadter) also communicated directly with MSD, MST and Jacob Wohlstadter on particular aspects of the settlement.

On August 3, 2004, the JVOC unanimously approved a draft settlement agreement. Following this approval, a telephonic meeting of the full Board of Directors was held to review the status of the SEC investigation, the status of the Nasdaq notification regarding possible delisting, and the proposed settlement. During this meeting, the management directors, who were previously provided with a copy of the draft settlement agreement, were invited to ask questions or give comments concerning the draft settlement agreement. The management directors informed the independent directors that they had no questions or comments.

On August 12, 2004 the parties entered into the settlement agreement. Under the settlement, the parties agreed to the following:

All proceedings relating to the two lawsuits against MSD, MST and Jacob Wohlstadter will be suspended and the parties will file with the Court stipulations dismissing the lawsuits with prejudice.

Except for claims to enforce the terms of the settlement and certain of the parties indemnity and property rights, all claims we may have against MSD, MST and Jacob Wohlstadter or any of their affiliates are fully, finally and forever, dismissed and released with prejudice by us, and all claims MSD, MST and Jacob Wohlstadter may have against us or any of our affiliates are fully, finally and forever, dismissed and released with prejudice by them.

MSD or MST will purchase, and we will sell, our interests in MSD pursuant to the buyout process set forth in the MSD joint venture agreement, irrespective of the ultimate purchase price. The parties agreed to certain

terms and procedures to determine the purchase price for the buyout, which will be paid over time from a percentage of net sales of MSD or proceeds of certain financings of MSD. MSD is required to provide written reports to us within 60 days after the end of each fiscal quarter stating its aggregate net sales (as defined in the MSD agreement) and the net proceeds, if any, realized by MSD during such quarter from the sale of MSD debt or equity securities in any third party financings (as

defined in the MSD agreement). We also have the right to conduct an audit of such net sales or net proceeds, which will be our sole and exclusive remedy for resolving disputes as to the appropriate amount of payments.

Until the second anniversary of the purchase of our interests, unless certain advance notice and approval requirements are met, MSD will not purchase certain assets defined as real property that is used or contemplated to be used primarily for residential purposes, any automobile with a value, at the time of purchase, equal to or in excess of $75,000, or any airplane. MSD may cure any alleged failure to comply with this restriction if it exchanges, contributes, disposes of or otherwise transfers the asset and receives consideration in return equal to the full net purchase price of such asset, and in no event are we permitted to seek injunctive or declaratory relief.

In consideration for the prior receipt by MSD of approximately $2.9 million from Jacob Wohlstadter, MSD will transfer certain real property and automobiles and MSD s limited liability company interests in MSVE, LLC and MS RE, LLC to Jacob Wohlstadter or an entity or entities wholly owned by Jacob Wohlstadter. Jacob Wohlstadter also assumed MSD s obligation to purchase another residential property for $4.1 million.

Our representative on the MSD Board of Managers will resign and we will execute an amendment to the MSD agreements to change the composition of the MSD Board of Managers to one person designated by MST.

MSD provided the representation letters requested by its and our auditors in connection with MSD s financial statements for the year ended December 31, 2003, concurrently with the execution of the settlement, and subsequently provided to us a copy of its audited financial statements for the year ended December 31, 2003. In addition, until such time as we are no longer required to consolidate or include the unaudited quarterly or audited annual financial results of MSD in our filings with the Securities and Exchange Commission, MSD will deliver to us, per our request, copies of its unaudited and audited financial statements on a timely basis.

We will pay the fees of MSD s independent auditor in connection with the audit of MSD and will indemnify MSD, MST and Jacob Wohlstadter and their respective directors, officers, employees and agents for any losses, costs, fees and expenses arising out of or related in any way to past, current or future audits of MSD, the preparation of MSD financial statements requested by us, and with respect to regulatory or legal proceedings and investigations resulting from or related to the fact that we are a public company. We are not required to indemnify MSD for acts either resulting in a criminal conviction or finally adjudged by a court of competent jurisdiction to constitute fraud or intentional misrepresentations.

We pay MSD the net amount of $3.0 million in full and complete satisfaction of all amount that Jacob Wohlstadter claimed we owed MSD pursuant to the various MSD agreements, including amounts owed by us pursuant to the license agreement between us and MSD and MST, the outstanding dispute regarding unsatisfied committed funding obligations and the outstanding dispute regarding the payment of certain legal fees and expenses incurred by MSD in connection with settlement of litigation involving IGEN and Roche. Our $3.0 million payment is net of a $2.0 million credit, which represents a non-refundable pre-payment by MSD to us for future amounts payable by MSD to us pursuant to the buyout of our interest in MSD. The amount of the pre-payment credit deemed outstanding from time to time shall bear simple interest (cumulated, not compounded) at the fixed annual rate of 0.5% over the prime rate in effect on the date that MSD or MST, as the case may be, purchases our interests in MSD. The amount of the prepayment credit that is deemed outstanding is the total amount, including accrued interest, reduced from time to time by the amount due and payable to us pursuant to the buyout of our interest in MSD. No further cash payments will be payable by MSD to us pursuant to the buyout until the $2.0 million prepayment credit, including accrued

interest, is no longer deemed outstanding. A total of $5.0 million is to be treated as a Class C capital contribution by us to MSD.

MSD s rent for the lease of certain facilities and related equipment from us (including laboratory facilities located in our corporate headquarters) pursuant to the terms of the existing sublease agreements with MSD, for the period from March 1, 2004 through August 31, 2005, will be added to the price payable to us for the purchase of our interest in MSD, in lieu of current payments.

In accordance with the terms of the original MSD agreements, subject to certain exceptions, we consented to the sublicensing by MSD of the licenses granted pursuant to the IGEN/MSD license agreement to any affiliate of MSD. Any such sublicensee is required to, among other things, make royalty payments to us in accordance with the IGEN/MSD license agreement.

The foregoing is a summary of the material terms of the settlement and is qualified in its entirety by reference to the settlement agreement which is included as an exhibit to this report and which is incorporated herein by reference.

We are involved, from time to time, in various 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. However, we may in the future be involved in litigation relating to our business, products or intellectual property, which could adversely affect our prospects or impair our financial resources.

See Item 1- Business-Risk Factors Risks Relating to Us and Our Business The success of our business depends on patents that will expire over time and that must be actively pursued, obtained, maintained and protected. Our business could be harmed if we have future disagreements with Roche over the scope of the license agreement, Item 1- Business-Risk Factors Risks Relating to Us and Our Business Our business could be harmed if we infringe, or are alleged to have infringed, the intellectual property of others and Item 1- Business- Risk Factors Risks Relating to the Industry We are exposed to product liability risks that, if not adequately covered by insurance, may have a material adverse effect on our financial condition.

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

We became a publicly-traded company on February 13, 2004, and no matter was submitted to a vote of our security holders during the fourth quarter of the fiscal year covered by this report. The merger and related transactions, as well as our 2003 stock incentive plan, were approved by IGEN s stockholders at a special meeting of stockholders of IGEN held on February 13, 2004.

PART II

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

Common Stock

Our common stock began trading on February 17, 2004 and is quoted on The Nasdaq National Market under the symbol BIOV . Prior to that time, there was no public market for our common stock. As of June 1, 2004, there were approximately 177 holders of record of our common stock.

The number of record holders is based on the actual number of holders in our books and does not include holders of our common stock in street name or individual participants in security position listings maintained by depositary trust companies.

The following table sets forth the range of high and low bid price per share of our common stock as quoted on The Nasdaq National Market during the fourth quarter of fiscal 2004.

Year ended March 31, 2004	**High**	**Low**
Fourth Quarter (commencing with our first day of trading on February 17, 2004)	$15.85	$11.85

No cash dividends have been paid on our common stock to date, and we currently intend to retain any earnings for development of our business.

2003 Stock Incentive Plan

In September 2003, our Board of Directors adopted the 2003 stock incentive plan pursuant to which 5.3 million shares of our common stock have been reserved for issuance upon the exercise of options granted under the plan. The 2003 stock incentive plan was approved by IGEN stockholders prior to the completion of the merger and related transactions on February 13, 2004. The following table sets forth certain information with respect to our 2003 stock incentive plan as of March 31, 2004.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	20,300	$ 15.80	5,279,700
Equity compensation plans not approved by security holders			
Total	20,300	$ 15.80	5,279,700

For more information about our 2003 stock incentive plan, see ITEM 8 - Consolidated Financial Statements Notes to Consolidated Financial Statements-Note 2 .

Series B Preferred Stock

On February 17, 2004, we sold 1,000 shares of series B preferred stock to Samuel J. Wohlstadter for an aggregate consideration of $7.5 million. The shares of series B preferred stock were not, and will not be, registered under the Securities Act of 1933 and were sold solely to Samuel J. Wohlstadter pursuant to Section 4(2) of the Securities Act of 1933. There is no established public trading market for shares of series B preferred stock. As of June 30, 2004, Samuel J. Wohlstadter is the only holder of series B preferred stock and no dividends have been declared or paid with respect to shares of series B preferred stock. The series B preferred stock, and the proceeds from the sale were applied to fund a portion of the $37.5 million capital contribution that we made to MSD following the completion of the merger and related transactions. Under the terms of the series B preferred stock, we may redeem the series B preferred stock at $0.01 per share at any time that we are no longer entitled to receive distributions with respect to our class C interest in MSD pursuant to the MSD agreements. We will redeem a proportionate part of the series B preferred stock in connection with any redemption by MSD of our class C interests in MSD.

In connection with the settlement, we received a $2.0 million non-refundable pre-payment from MSD for future amounts payable by MSD to us pursuant to the buy-out of our interest in MSD. The holder of our Series B preferred stock will be entitled to a pro-rata share, representing the proportionate amount of our class C interest in MSD that was funded by the sale of the Series B preferred stock, of the portion of the $2 million that is allocable to our class C interests.

ITEM 6. SELECTED FINANCIAL DATA

You should read the following selected financial data in conjunction with our consolidated financial statements and notes and the other information contained in or incorporated by reference into this Form 10-K. The selected consolidated balance sheet data and the selected consolidated statements of operations data as of and for the fiscal year ended March 31, 2004 have been derived from our consolidated financial statements that have been audited by PricewaterhouseCoopers LLP, independent registered public accounting firm, and are included elsewhere in this Form 10-K. The selected consolidated balance sheet data as of March 31, 2003 and the selected consolidated statements of operations data for the fiscal years ended March 31, 2003 and 2002 have

been derived from our consolidated financial statements that have been audited by Deloitte & Touche LLP, independent registered public accounting firm, and are included elsewhere in this Form 10-K. The selected consolidated balance sheet data as of March 31, 2002 and the selected consolidated statements of operations data for the fiscal year ended March 31, 2001 have been derived from audited financial statements not included in this Form 10-K. The selected consolidated balance sheet data as of March 31, 2001 and 2000 and the selected consolidated statements of operations data for the fiscal year ended March 31, 2000 have been derived from our unaudited consolidated financial statements not included in this Form 10-K. Our unaudited consolidated financial statements for the fiscal year ended March 31, 2000 have been prepared on a basis consistent with our audited consolidated financial statements and, in the opinion of our management, include all adjustments, consisting only of normal recurring adjustments considered necessary for a fair presentation of our consolidated financial position and consolidated results of operations for this period.

Our assets and businesses were owned and operated by IGEN until the completion of merger and related transactions between Roche and IGEN on February 13, 2004. The accompanying financial statements have been prepared and are presented as if we had been operating as a separate entity using IGEN s historical cost basis in the assets and liabilities and including the historical operations of the businesses and assets transferred to us from IGEN.

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

	Years ended March 31,				
	2004	**2003**	**2002**	**2001**	**2000**
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenues:					
Product sales	**$ 18,741**	$ 16,487	$ 12,077	$ 8,935	$ 7,743
Royalty income	**1,060**	1,107	1,050	892	1,118
Contract fees	**155**	180	116	3,987	
Total	**19,956**	17,774	13,243	13,814	8,861
Operating costs and expenses:					
Product costs (1)	**12,247**	8,005	5,361	3,112	2,262
Research and development	**19,821**	22,766	26,829	27,983	18,335
Selling, general and administrative	**18,656**	20,453	19,217	13,200	12,242
Merger related costs	**75,702**				
Total operating costs and expenses	**126,426**	51,224	51,407	44,295	32,839
Loss from operations	**(106,470)**	(33,450)	(38,164)	(30,481)	(23,978)
Other, net	**(933)**	154	(39)	(243)	(80)
Equity in loss of joint venture (2)	**(19,616)**	(17,598)	(10,947)		

Net loss before cumulative effect of a change in accounting principle	**(127,019)**	(50,894)	(49,150)	(30,724)	(24,058)
Cumulative effect of a change in accounting principle (5)	**33,700**				
Net loss	**$ (93,319)**	$(50,894)	$(49,150)	$(30,724)	$(24,058)
Net loss per common share before cumulative effect of a change in accounting principle	$ (4.75)	$ (1.90)	$ (1.84)	$ (1.15)	$ (0.90)
Cumulative effect of an accounting change (5)	1.26				
Net loss	$ (3.49)	$ (1.90)	$ (1.84)	$ (1.15)	$ (0.90)
Shares used in computing net loss per common share	**26,728**	26,728(3)	26,728(3)	26,728(3)	26,728(3)

	2004	**2003**	**2002**	**2001**	**2000**
			(In thousands)		
Consolidated Balance Sheet Data (5):					
Cash and cash equivalents (4)	**$182,509**	$	$	$	$
Working capital	**169,184**	4,733	1,193	(1,301)	181
Total assets	**232,814**	29,160	21,518	16,379	13,752
Long term obligations	**54**	60	96	329	978
Minority interest	**54**				
Series B preferred stock	**7,500**				
Stockholders equity	**193,826**				
Net investment by parent (4)		20,665	14,151	6,775	5,955

(1) During the year ended March 31, 2002, product costs included a write-off of $1.1 million of TRICORDER detection modules. The cost of these modules had previously been recorded as a fixed asset and depreciated over their estimated useful life, and should have been recorded as product costs upon shipment and sale. We determined that the adjustment did not have a material impact on fiscal 2002 or prior period financial statements and accordingly, did not revise such financial statements. Of the $1.1 million adjustment, $200,000 is related to fiscal 2002 and the remaining $900,000 is related to prior fiscal years (approximately $400,000 and $500,000 in fiscal 2001 and 2000, respectively).

(2) See Note 4 of the consolidated financial statements for a description of the recording of losses under the equity method of accounting related to the MSD investment.

(3) Based on the number of shares of our common stock outstanding upon completion of the merger and related transactions.

(4) Prior to the completion of the merger and related transactions, IGEN held all cash in a centralized treasury and provided all of the necessary funding for the operations of BioVeris. Accordingly, prior to February 13, 2004, no cash is reflected on the accompanying condensed consolidated balance sheets and IGEN s (Parent s) net investment in us is shown in lieu of stockholders equity.

(5) In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities, or FIN 46. FIN 46 provides guidance on variable interest entities such as the MSD joint venture and the framework through which an enterprise assesses consolidation of a variable interest entity. We have adopted FIN 46 as of March 31, 2004 and have determined that MSD qualifies as a variable interest entity. Accordingly, beginning March 31, 2004 we have consolidated the financial results of MSD. Under the transition guidance of FIN 46, because MSD was created before February 1, 2003, we have measured the assets, liabilities and noncontrolling interests of MSD as of March 31, 2004 for purposes of the initial consolidation. The amounts of the assets, liabilities and noncontrolling interests are reflective of their respective carrying amounts had FIN 46 been effective when we first met the conditions to be the primary beneficiary of MSD upon MSD s inception in 1995. We have historically recorded approximately 100% of MSD s losses. In connection with the merger and related transactions we made a $37.5 million payment to MSD. We determined that at the time of the payment, recording the entire payment to the investment in joint venture account would result in the book value of our investment in MSD being greater than its fair market value. Accordingly, we expensed $33.7 million, which represents the amount of the payment that gave rise to the net recorded investment exceeding the fair market value of our interests. Upon implementation of FIN 46, we recorded a one-time, non-cash $33.7 million adjustment to reflect this change in accounting principle, thereby adjusting the book value of our investment in the joint venture to equal the consolidated net assets of MSD. The balance sheet reclassified amounts formerly recorded on a net basis as investment in joint venture to be reflected on a gross basis primarily as cash, accounts receivable, inventory, fixed assets, accounts payable and accrued expenses.

Historical financial information of MSD is summarized in Note 4 of our consolidated financial statements and the audited MSD financial statements have been filed as Exhibit 99.9 to this Form 10-K.

Supplemental Consolidated Balance Sheet Data:

	March 31,2003	March 31, 2004			
	BioVeris and Wholly-Owned Subsidiaries	BioVeris and Wholly-Owned Subsidiaries	MSD	Consolidating Eliminations	Consolidated BioVeris
Assets					
Current Assets:					
Cash and cash equivalents	$	$147,398	$ 35,111	$	$182,509
Accounts receivable, net	5,434	3,417	2,099		5,516
Inventory	5,448	5,013	3,194		8,207
Other current assets	2,286	2,459	2,053	(180)	4,332
Total current assets	13,168	158,287	42,457	(180)	200,564
Equipment and leasehold improvements, net	6,456	5,472	7,362	(269)	12,565
Investment in joint venture	9,164	46,208		(46,208)	
Technology licenses		19,256	10		19,266
Other	372	354	65		419
Total assets	$29,160	$229,577	$ 49,894	$ (46,657)	$232,814
Liabilities and Stockholders Equity					
Current Liabilities:					
Accounts payable and accrued expenses	$ 7,928	$ 26,220	$ 3,067	$ (180)	$ 29,107
Other current liabilities	507	1,977	296		2,273
Total current liabilities	8,435	28,197	3,363	(180)	31,380
Noncurrent liabilities	60	54			54
Total liabilities	8,495	28,251	3,363	(180)	31,434
Minority interest				54	54
Series B preferred stock		7,500			7,500
Stockholders Equity:					

Common stock		27			27
Additional paid-in capital		203,464	116,707	(116,707)	203,464
Net investment by parent	20,665				
Accumulated deficit		(9,665)	(70,176)	70,176	(9,665)
Total stockholders equity	20,665	193,826	46,531	46,531	193,826
Total liabilities and stockholders equity	$29,160	$229,577	$ 49,894	$ 46,657	$232,814

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

On February 13, 2004, IGEN and Roche completed the merger and related transactions pursuant to which Roche acquired IGEN and IGEN simultaneously distributed shares of our common stock to its stockholders. The transaction occurred in the following steps:

IGEN restructured its operations so that we, a wholly-owned subsidiary of IGEN at the time, assumed IGEN s biodefense, life science and industrial product lines as well as IGEN s opportunities in the clinical diagnostics and healthcare fields and the ownership of IGEN s intellectual property, IGEN s equity interest in MSD, cash and certain other rights and licenses currently held by IGEN; and

A wholly-owned subsidiary of Roche merged with and into IGEN, as a result of which IGEN became a wholly-owned subsidiary of Roche and we became an independent, publicly-traded company. Simultaneously with the completion of the merger, certain ongoing commercial agreements between certain affiliates of Roche and us became effective.

Prior to February 13, 2004, our assets and businesses were owned and operated by IGEN. Our financial statements have been prepared and are presented as if we had been operating as a separate entity in periods prior to February 13, 2004 using the historical cost basis in the assets and liabilities of IGEN and including the historical operations of businesses and assets transferred to us from IGEN as part of the merger and related transactions.

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 and product deliveries for biodefense products, M-SERIES systems or other products, which orders and deliveries are based on our customers requirements that may vary over time;

the success of M-SERIES system upgrades and enhancements, which upgrades and enhancements involve increased product costs at the time of the upgrade or enhancement, and customer acceptance of those enhancements and upgrades;

the amount of revenue recognized from royalties and other contract revenues, which revenues are dependent upon the efforts of our licensees and collaborators;

whether our instruments are sold or leased to customers, which will affect the timing of the recognition of revenue from the sale or lease;

the timing of our introduction of new products, which could involve increased expenses associated with product development and marketing;

the volume and timing of product returns and warranty claims, which, if products are returned or have warranty claims that are unexpected, may involve increased costs in excess of amounts reserved for returns or claims;

our competitors introduction of new products, which may affect the purchase decision of or timing of orders by our customers and prospective customers while the competitors product is assessed;

the amount of expenses we incur in connection with the operation of our business, including:

research and development costs, which increases or decreases based on the product in development and

sales and marketing costs, which are based on product launches or promotions and sales incentives that might be in effect from time to time;

the amount that we will record each quarter related to the amortization or impairment of the license to use PCR technology, which may increase based on the outcome of the litigation and arbitration

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commenced against Roche by Applied Biosystems relating to Roche s and Applied Biosystems respective rights to PCR technology;

unexpected termination of government contracts or orders, which could result in decreased sales and increased costs due to excess capacity, inventory personnel and other expenses;

MSD s financial results, which for the years ended December 31, 2003 and 2002 included losses of $20.4 million and $17.1 million, respectively, and which we have commenced consolidating as of March 31, 2004; and

additional costs which we may incur as we explore new health care opportunities, including costs for acquisitions of technologies, facilities and personnel.

We expect to incur additional operating losses as a result of our expenses for manufacturing, marketing and sales capabilities, research and product development, general and administrative costs, and the net loss of MSD, whose financial results have been consolidated with ours beginning as of March 31, 2004. Our ability to become profitable in the future will be affected by, among other things, our ability to expand the distribution and increase sales 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 collaborations established by IGEN or establish successful new collaborations with corporate partners to develop, manufacture, market and sell products that incorporate our technologies.

Investment in MSD

MSD is a joint venture formed by MST and IGEN in 1995. MSD was formed for the development, manufacture, marketing and sale of products utilizing a proprietary combination of MST s multi-array technology together with our ECL technology. We have recorded our proportionate share of MSD losses, representing approximately 100% of MSD s losses.

In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities, or FIN 46. FIN 46 provides guidance on variable interest entities such as the MSD joint venture and the framework through which an enterprise assesses consolidation of a variable interest entity. We adopted FIN 46 as of March 31, 2004 and have determined that MSD qualifies as a variable interest entity. Accordingly, beginning as of March 31, 2004 we have consolidated the financial results of MSD. Under the transition guidance of FIN 46, because MSD was created before February 1, 2003, we have measured the assets, liabilities and noncontrolling interests of MSD as of March 31, 2004 for purposes of the initial consolidation. The amounts of the assets, liabilities and noncontrolling interests are reflective of their respective carrying amounts had FIN 46 been effective when we first met the conditions to be the primary beneficiary of MSD upon MSD s inception in 1995. We have historically recorded approximately 100% of MSD s losses. In connection with the merger and related transactions, we made a $37.5 million payment to MSD. We determined that at the time of the payment, recording the entire payment to the investment in joint venture account would result in the book value of the Company s investment in MSD being greater than its fair market value. Accordingly, we expensed $33.7 million, which represented the amount of the payment that gave rise to its net recorded investment exceeding the fair market value of its interests. Upon implementation of FIN 46, we recorded a one-time, non-cash $33.7 million adjustment to reflect this change in accounting principle, thereby adjusting the book value of our investment in the MSD joint venture to equal the consolidated net assets of MSD. In fiscal 2005, the statement of operations will reclassify amounts formerly recorded on a net basis as equity in loss of joint venture to be reflected on a gross basis primarily as revenue, product costs, research and development expenses and selling, general and administrative expenses.

The MSD joint venture agreement expired upon completion of the merger and related transactions. As a result, MSD and MST had the option to purchase our interest in MSD. As of March 31, 2004, the value of such option to purchase our interest was $1.2 million, which has been recorded as a liability and as other expense on the accompanying consolidated statements of operations. Pursuant to the settlement, MSD or MST will purchase, and we will sell, our entire interest in MSD. We are in the process of evaluating the impact of this purchase on our future of accounting treatment for

MSD under the provisions of FIN 46. For a more complete description of this purchase right and the MSD agreement, see ITEM 13 Certain Relationships and Related Transactions .

The purchase price is payable in installments from a percentage of MSD s future net sales or financings. There is no assurance the purchase price will be paid in full. In particular, we expect that MSD will require substantial additional funding for its ongoing operations. If MSD is not able to obtain this funding, it may not be able to pay the purchase price in full and we could lose our ability to realize the value of most or all of our investment in MSD.

In June and July 2004, we commenced legal actions against MSD, MST and Jacob Wohlstadter in the Court of Chancery in the State of Delaware that were prompted by the discovery of a series of actual and proposed transactions undertaken by MSD without our knowledge. These lawsuits were settled in August 2004. See ITEM 3 Legal Proceedings for a more complete description of the lawsuits and the related settlement.

Results of Operations

Years Ended March 31, 2004 and 2003

Revenues. Total revenues for the fiscal year ended March 31, 2004 increased by approximately $2.2 million, or 12%, to $20.0 million from $17.8 million in fiscal 2003.

Product sales were $18.7 million in fiscal 2004, an increase of 14% over the prior year s product sales of $16.5 million. This growth in product sales was from biodefense products, an increase of $1.5 million to $6.1 million, and products for the life science market, an increase of $700,000 to $12.6 million. These increases in product sales during fiscal 2004 reflect the growth of orders and product deliveries for biodefense products and M-SERIES systems, which orders and deliveries are based on our customers requirements.

We anticipate increases in biodefense-related sales as a result of our ongoing biodefense initiatives. As part of the merger and related transactions, we assumed a contract between IGEN and the DOD pursuant to which the DOD may purchase tests for the detection of specific toxins in environmental samples from IGEN. Under the contract, the DOD may, at its option, make purchases of up to $23.0 million over a period of up to 48 months. As of March 31, 2004, the DOD had purchased approximately $3.4 million of products.

Sales of our products for the life science market are subject to a number of uncertainties, including the fact that we are not a party to significant long-term contracts for the sale of our products for the life science market that would provide predictable sales. Therefore, the volume and timing of product orders from our life science customers are based on their requirements, which may vary over time. As a result, we believe that we do not have sufficient information to reasonably project our future sales in the life science market.

Operating Costs and Expenses. Product costs were $12.2 million (65% of total product sales) for fiscal 2004 compared to $8.0 million (49% of total product sales) for fiscal 2003. Product costs, as a percentage of total product sales, increased in fiscal 2004 due to costs incurred in connection with instrument upgrades (4% of total product sales) and detection module upgrades (17% of total product sales) for existing life science customers. These voluntary upgrades were provided to enhance overall customer satisfaction. The instrument and detection module upgrade programs were substantially completed as of December 31, 2003. Our future profit margin is subject to chance due to a number of uncertainties relating to, among other things, the launch of new instrument systems.

Research and development expenses decreased $3.0 million, or 13%, in fiscal year 2004 to $19.8 million from $22.8 million in fiscal year 2003. This decrease was due primarily to lower personnel and facilities costs for development projects. 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 and research and development of new systems and technologies, including point-of-care products. We expect research and development costs to increase as product development and core research expand, including costs associated with our efforts in developing clinical diagnostics and biodefense testing products, and as we explore other opportunities in the healthcare field.

Selling, general and administrative expenses were $18.7 million in fiscal 2004, a decrease of $1.8 million (9%) from the prior year s total of $20.5 million. This decrease was primarily attributable to lower personnel costs in the current year. Until the completion of the merger and related transactions on February 13, 2004, we were fully integrated with IGEN and the accompanying consolidated financial statements reflect the application of certain estimates and allocations. For periods prior to February 13, 2004, our consolidated statements of operations include all revenues and costs that were directly attributable to our businesses. In addition, certain expenses of IGEN were allocated to us using various assumptions that, in the opinion of management, are reasonable. These expenses include an allocated share of general and administrative salaries as well as certain other shared costs (primarily facility, human resources, legal, accounting and other administrative costs) which were allocated based upon percentage of total revenue, or percentage of total headcount, or estimates of actual time spent on businesses, as appropriate. These allocated expenses comprise a significant portion of our selling, general and administrative expenses for fiscal 2004.

We incurred certain nonrecurring costs of $75.7 million in connection with the merger and related transactions, which consisted of, an allocated one-time noncash compensation charge of $38.8 million associated with the cancellation of IGEN stock options and the payment of merger consideration for each share of IGEN common stock covered by such stock options, a $33.7 million charge related to the $37.5 million MSD payment made in connection with the merger and related transactions, as well as accounting, legal, printing and registration fees. With respect to employee stock options, the compensation charge is calculated based on the difference between the last trading price of IGEN common stock, which was $64.09 per share, and the exercise price of each employee stock option, including both vested and unvested employee stock options. With respect to nonemployee stock options, the compensation charge is calculated based on the incremental fair value of the nonemployee stock options resulting from the merger and related transactions. With respect to the MSD payment, it was determined that at the time of the payment in February 2004, recording the payment to the Investment in Joint Venture account would result in the value of our investment in MSD being greater than its fair market value. Accordingly, we expensed the amount of the payment that would exceed fair market value. No additional expenses related to the merger and related transactions are expected to be recorded in periods after March 31, 2004.

Since 1995 we have engaged the law firm of Wilmer, Cutler & Pickering to provide legal services. Jennifer M. Drogula, who became the daughter-in-law of our Chief Executive Officer in March 2002, has been a partner of that firm since January 2001. In addition, Mr. Richard Cass, one of IGEN s directors, was formerly a partner of the firm. We recorded approximately $300,000 and $100,000 in legal fees with the law firm for the years ended March 31, 2004 and 2003, respectively.

We have also engaged the law firm of Hale & Dorr LLP to provide legal services. We 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 $100,000 in legal fees with that law firm for each of the years ended March 31, 2004 and 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 Therapeutics Corporation Hyperion Catalysis International Proteinix Corporation and Integrated Chemical Synthesizers, Inc. 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.

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 for each of the years ended March 31, 2004 and 2003, 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 us and are determined

through allocation methods that include time spent and square footage utilized. The affiliated companies had prepaid approximately $12,000 under the shared services arrangements at March 31, 2004, and the amount due from affiliated companies under the shared services arrangements was approximately

$200,000 at March 31, 2003. All such balances were paid subsequent to each respective year end. See ITEM 13- Certain Relationships and Related Transactions .

Interest Income and Other Expense. In fiscal 2004, we recorded a $1.2 million non-cash charge representing the value of MSD s option to purchase our interests in MSD. In addition, interest income, net of interest and other expense, was $267,000 in fiscal 2004 and $154,000 in fiscal 2003. This increase in net interest income resulted from a growth in interest earned in the current year due to a higher balance of invested funds.

Equity in Loss of Joint Venture. Equity in loss of joint venture was $19.6 million and $17.6 million for the years ended March 31, 2004 and 2003, respectively. MSD s losses increased in fiscal 2004 primarily due to higher costs associated with its transition from a development stage entity to a commercial operating company. The increase in MSD s losses during the year ended March 31, 2004 results primarily from increases in sales and marketing expenses which were offset only in part by the growth in revenues which commenced in October 2002.

Change in Accounting Principle Upon implementation of FIN 46, we recorded a one-time, non-cash $33.7 million adjustment to reflect a change in accounting principle, thereby adjusting the book value of our investment in the MSD joint venture to equal the consolidated net assets of MSD. This adjustment is reflected on our consolidated statements of operations as the cumulative effect of a change in accounting principle.

Net Loss. The net loss for fiscal year 2004 was $93.3 million ($3.49 per common share), compared to a net loss of $50.9 million ($1.90 per common share) in fiscal year 2003. The net loss is primarily caused by operating expenses and equity in loss of joint venture exceeding our revenues. The increase in net loss is primarily due to the merger related costs incurred in 2004.

Years Ended March 31, 2003 and 2002

Revenues. Total revenues were $17.8 million for the fiscal year ended March 31, 2003, an increase of approximately $4.6 million or 34% from $13.2 million in fiscal 2002. Product sales were $16.5 million in fiscal 2003, an increase of $4.4 million or 37% from $12.1 million in fiscal 2002. This increase in product sales resulted from sales of products for the life science market of $11.9 million in fiscal 2003, an increase of $1.0 million from $10.9 million in fiscal 2002, and sales of biodefense products of $4.6 million in fiscal 2003, an increase of $3.4 million from $1.2 million in fiscal 2002. Sales of products for the life science market increased due to increased sales of the M-SERIES family of products.

Operating Costs and Expenses. Product costs were $8.0 million (49% of product sales) in fiscal 2003 compared to $5.4 million (44% of product sales) in fiscal 2002. Product costs in fiscal 2002 included a write-off of approximately $1.1 million representing the remaining net book value of the TRICORDER detection modules incorporated into customers M-SERIES systems. The cost of these modules had previously been recorded as a fixed asset and depreciated over their estimated useful life, and should have been recorded as product costs upon shipment and sale. We determined that the adjustment did not have a material impact on fiscal 2002 or prior period financial statements and, accordingly, did not revise such financial statements. Of the $1.1 million adjustment, approximately $200,000 is related to fiscal 2002 and the remaining $900,000 is related to prior fiscal years (approximately $400,000 and $500,000 related to fiscal 2001 and 2000, respectively). Excluding the $900,000 write-off, product costs were 37% of product sales in fiscal 2002. Product costs in fiscal 2003, as a percentage of product sales, increased from 37%, as adjusted, to 49% primarily due to costs incurred in connection with instrument upgrades for existing life science customers ($1.1 million or 7% of product sales) and warranty costs in excess of the warranty reserve ($600,000 or 4% of product sales). The voluntary instrument upgrades were provided to enhance overall customer satisfaction.

Research and development expenses were $22.8 million in fiscal 2003, a decrease of $4.0 million or 15% from $26.8 million in fiscal 2002. Of the $26.8 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 Joint Venture below for a discussion of activities relating to MSD 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 the life science market and research and development of new systems and technologies, including point-of-care products.

Selling, general and administrative expenses were $20.5 million in fiscal 2003, an increase of $1.3 million or 6% from $19.2 million in fiscal 2002. This increase was primarily attributable to additional personnel and support costs required to support the increase in sales and customers. For each of the periods, we were fully integrated with IGEN and the accompanying consolidated financial statements reflect the application of certain estimates and allocations. Our consolidated statements of operations include all revenues and costs that are directly attributable to our businesses. In addition, certain expenses of IGEN have been allocated to us using various assumptions that, in the opinion of management, are reasonable. These expenses include an allocated share of general and administrative salaries as well as certain other shared costs (primarily facility, human resources, legal, accounting and other administrative costs) which were allocated based upon percentage of total revenue or percentage of total headcount, as appropriate. There are no other selling, general and administrative expenses for fiscal 2003 and fiscal 2002 other than these allocated expenses.

Since 1995, we have retained Wilmer, Cutler & Pickering to perform legal services. Jennifer M. Drogula, who became the daughter-in-law of our chief executive officer in March 2002, has been a partner of the firm since January 2001. In addition, Mr. Richard Cass, one of IGEN s directors, was formerly a partner of the firm. We recorded approximately $100,000 and $400,000 in legal fees to the law firm for the years ended March 31, 2003 and 2002, respectively.

We have shared services arrangements with each of the 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 in fiscal 2003 and 2002, respectively, which reduced certain operating costs and expenses for the respective years. Amounts allocated to the 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. Amounts due from affiliated companies under these shared services agreements were approximately $200,000 and $100,000 at March 31, 2003 and 2002, respectively, and were paid subsequent to each respective year end. See ITEM 13- Certain Relationships and Related Transactions .

Interest Income and Other Expense. Interest income, net of other expense, was approximately $200,000 in fiscal 2003. Interest expense, net of other income, was approximately $39,000 in fiscal 2002. This increase in income was due to foreign currency transaction gains in the fiscal 2003 period.

Equity in Loss of Joint Venture. As discussed above, MSD is a joint venture formed by MST and us in 1995. Beginning on July 1, 2001, MSD was transitioning from a development stage entity to a commercial enterprise and milestones establishing the continued viability of MSD were first achieved in the quarter ended September 30, 2001. For example, prototypes had been assembled demonstrating product feasibility, and MSD was anticipating initial product launch in approximately one year. As a result of this transition, MSD s expenses were no longer primarily research and development. Accordingly, since July 1, 2001, we have recorded only our proportionate share of MSD losses, representing approximately 100% of MSD s losses, for each respective period as equity in loss of joint venture consistent with accounting for equity method investments. Equity in loss of joint venture was $17.6 million in fiscal 2003, and $10.9 million in fiscal 2002. In addition, approximately $2.4 million of the fiscal 2002 MSD contributions, all occurring prior to July 1, 2001, were recorded by us as research and development expenses based upon the significance and character of the MSD losses. In connection with entering into the MSD agreements in August 2001, IGEN transferred certain equipment and leasehold improvements to MSD in an amount of approximately $800,000, which amount is included in the in-kind contributions to MSD in such year.

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MSD s losses increased in fiscal 2003, primarily due to higher costs associated with its transition from a development stage entity to a commercial operating company. MSD commenced product sales in October 2002, and during the year ended March 31, 2003, its product sales totaled $3.2 million. MSD increased its staffing during fiscal 2003 primarily for development personnel and new sales and marketing personnel to support the launch of its products. These personnel increases resulted in higher costs for both research and development and sales and marketing.

Net Loss. The net loss was $50.9 million in fiscal 2003, an increase of $1.7 million or 4% from the net loss of $49.2 million in fiscal year 2002. This increase was primarily due to higher losses by MSD in fiscal 2003, reflected as an increase in equity in loss of joint venture, offset by the growth in our fiscal 2003 product sales.

Liquidity and Capital Resources

Beginning as of March 31, 2004, we have consolidated the financial results of MSD in accordance with the requirements of FIN 46. Our consolidated balance sheet at March 31, 2004 had cash and cash equivalents of $182.5 million. Of this amount, $35.1 million represented the cash and cash equivalents of MSD. We have no rights or access to these funds or any other capital resources of MSD. The amount of cash and cash equivalents to which we and our wholly-owned subsidiaries have unrestricted use is $147.4 million. In addition, our consolidated balance sheet includes the accounts receivable, inventory and other assets and liabilities of MSD. We have no rights or access to MSD s assets and we do not have obligations with respect to MSD s liabilities.

In connection with the merger and related transactions, Roche loaned IGEN approximately $210 million. These funds, less transaction costs of approximately $25 million, were contributed by IGEN as equity to us as part of the merger and related transactions. The related promissory note remained the obligation of IGEN and we have no obligations associated with that debt. Simultaneously with the execution of the merger agreement in connection with the merger and related transactions, we entered into worldwide, non-exclusive PCR license agreements with certain affiliates of Roche. We paid Roche a license fee of $50 million and will also pay royalties on sales of licensed products, royalties for every PCR plasma test we perform or have a laboratory perform and royalties on net service revenue that we receive for diagnostic testing procedures that we perform using PCR technology. We have performed a valuation of the PCR technology licenses and have recorded a value of $19.5 million and reflected a $30.5 million adjustment to the consideration paid by Roche with respect to the merger and related transactions.

Net cash used in operations was $29.6 million, $33.1 million and $34.2 million during the years ended March 31, 2004, 2003 and 2002, respectively. Cash used for operations in 2004 resulted from the net loss, partially offset by adjustments for the equity in loss of joint venture, and a non cash compensation charge related to stock options. Cash used for operations in 2003 resulted from the net loss, offset by an adjustment for the equity in loss of joint venture.

We used approximately $1.9 million, $3.3 million and $5.6 million of cash for the acquisition of equipment and leasehold improvements during the years ended March 31, 2004, 2003 and 2002, respectively. Our investments in MSD totaled $56.7 million (including a $37.5 million payment to MSD following the completion of the merger and related transactions), $20.5 million and $19.6 million for the years ended March 31, 2004, 2003 and 2002, respectively. We also used $50 million during the year ended March 31, 2004 for acquisition of the PCR license, as discussed above.

We believe that 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.

Under the tax allocation agreement associated with the merger and related transactions, Roche and IGEN will be solely liable for, will jointly and severally indemnify us against, and will be entitled to receive and retain all refunds of, taxes (other than transfer taxes) directly or indirectly resulting from, arising in connection with or

otherwise related to the merger and related transactions, any transaction undertaken to prepare for the merger and related transactions and any of the actions taken pursuant to the ongoing litigation agreement. This agreement also provides that we were required to pay IGEN a $20 million distribution gain payment. This amount was calculated based on the average of the high and low trading prices of our common stock on the first day of trading of our common stock after the completion of the merger, exceeding a specified threshold. The $20 million distribution gain amount was recorded as a liability on our balance sheet at March 31, 2004 and payment was made by us subsequent to March 31, 2004.

Net cash provided by financing activities, excluding the consolidation of MSD s cash and cash equivalents in 2004, was $255.1 million, $57.0 million and $56.3 million for the years ended March 31, 2004, 2003 and 2002, respectively. The financing activity for the year ended March 31, 2004 was primarily related to the funding provided by IGEN in conjunction with the merger and related transactions, as well as the sale of $7.5 million of Series B preferred stock to Samuel J. Wohlstadter, our Chairman and Chief Executive Officer. Under the terms of the Series B preferred stock, we may redeem the Series B preferred stock at $0.01 per share at any time we are no longer entitled to receive distributions with respect to our class C interests in MSD. We will redeem a proportionate part of the Series B preferred stock in connection with any redemption by MSD of the class C interests held by us described in the previous sentence. No distributions on the Series B preferred stock will be paid unless and until distributions are paid on such class C interests in accordance with the MSD limited liability company agreement, in which event distributions on the Series B preferred stock will be paid in the same manner and amount as such distributions on the class C interests. In connection with the settlement, we received a $2.0 million non-refundable pre-payment from MSD for future amounts payable by MSD to us pursuant to the buy-out of our interest in MSD. The holder of our Series B preferred stock will be entitled to a pro-rata share, representing the proportionate amount of our class C interest in MSD that was funded by the sale of Series B preferred stock, of the portion of the $2.0 million that is allocable to our class C interests.

As of March 31, 2004, our material future obligations were as follows:

		Years Ended March 31,					
Contractual Obligations (in thousands)	Total	2005	2006	2007	2008	2009	2010 and Thereafter
BioVeris and Wholly-Owned Subsidiaries:							
Operating leases	$18,652	$3,181	$3,164	$3,241	$3,338	$3,333	$2,395
MSD Payment	3,046	3,046					
Meso Scale Diagnostics: (1)							
Real estate commitments (2)	1,625	1,625					
Total contractual obligations	$23,323	$7,852	$3,164	$3,241	$3,338	$3,333	$2,395

1. Included in the table are contractual obligations of MSD whose balance sheet is consolidated with ours. We have no direct or contingent commitment for these contractual obligations.

2. In June, 2004, MSD received $2.9 million from Jacob Wohstadter as consideration for the proposed sale by MSD of real property and automobiles, pending approval by the Board of Managers. Jacob Wohlstadter also assumed MSD s purchase obligations with respect to a prospective real property purchase in the approximate amount of $4.1 million. In August 2004, MSD transferred the real property and automobiles and MSD s limited liability company interests to Jacob Wohlstadter.

Under the MSD agreements, IGEN s funding commitment was based on an annual budget of MSD approved by the JVOC. The JVOC 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 15%, of which approximately $19.1 million was spent by MSD and funded by us. MSD asserted that we were obligated to pay MSD up to an additional $4.6 million, which is the difference between the amount spent by MSD and the budgeted amount plus the permitted variance. As part of the settlement, we agreed to pay MSD the net amount of $3.0 million which represents full and complete satisfaction of amounts due to MSD pursuant to the MSD agreements, including this dispute regarding unsatisfied committed funding obligations, certain intellectual property matters, and the

previously outstanding dispute regarding the payment of certain legal fees and expenses incurred by MSD in connection with its participation and involvement in the merger and related transactions. Our $3.0 million payment is net of a $2.0 million non-refundable pre-payment by MSD to us for future amounts payable by MSD to us pursuant to the buy-out of our interest in MSD. The amount of the pre-payment credit outstanding from time to time shall bear simple interest (cumulated, not compounded) at the fixed annual rate of 0.5% over the prime rate in effect on the date that MSD or MST, as the case may be, purchases our interests in MSD. The amount of the outstanding credit balance of the prepayment credit, including accrued interest, shall be reduced for amounts due and payable to us pursuant to the buy-out of our interest in MSD and no further cash payments will be payable by MSD to us until the $2.0 million prepayment credit, including accrued interest, is utilized. A total of $5.0 million is to be treated as a Class C capital contribution. There is no assurance that we will be able to realize any value from this additional contribution.

For the years ended March 31, 2004, 2003 and 2002 total contributions to MSD were $56.7 million, $20.5 million and $19.6 million, respectively, including $3.7 million in the year ended March 31, 2004, which constituted discretionary funding related to the permitted budget variances from prior years. The funding commitment was satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. In accordance with the MSD joint venture agreement, the value of these in-kind contributions is based upon costs incurred by us as determined through allocation methods that include time-spent and square footage utilized. During years ended March 31, 2004, 2003 and 2002, operating costs allocated to MSD in connection with shared personnel and facilities totaled $6.0 million, $11.9 million and $11.4 million, respectively. In fiscal 2005, we made payments to MSD in connection with the settlement as described in the preceding paragraph. We have no intention to provide additional funding to MSD.

As noted above, MSD or MST will purchase our interest in MSD for a purchase price equal to fair market value less a discount of 7.5%, with fair market value to be determined by an appraisal process. The current book value of our investment is $46.2 million. There is no assurance that the purchase price will enable us to recover the book value of our investment. In addition, because the purchase price is payable in installments from a percentage of future MSD net sales or financings, there is no assurance that we will receive all or any portion of the purchase price, other than the $2.0 million prepayment credit we received in connection with the settlement.

Product development for our clinical diagnostic products is at an early development stage and products based on the PCR technology being licensed from Roche are not yet under development. Product development is subject to a number of technical and commercial uncertainties and in part depends upon our ability to enter into new collaborative arrangements. Accordingly, we have not yet completed a business plan for our clinical diagnostic products, including immunodiagnostic and PCR technology-based products, do not have definitive product introduction timelines or budgets and have not determined the additional funding, personnel, facilities, equipment or technology that may be required to implement our plans.

Our ability to become profitable in the future will depend on, among other things, the introduction of new products to the market. If we are unable to develop new products, including products based on PCR technology, our business prospects and financial results would be adversely affected.

Furthermore, we will need substantial amounts of money to fund our operations on an ongoing basis. We expect our available cash to be sufficient to fund our operations for at least one year, but we cannot predict how long our available cash will be sufficient to fund our operations thereafter. In this regard, we expect that we will from time to time 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.

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 volatility of the price of our common stock, continuing losses from our operations, establishment of new business arrangements, the status of new product launches, general market conditions and other factors. If we are unable to raise additional capital, 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, 2004, we had no special purpose entities.

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 management. As a result, critical accounting policies are subject to an inherent degree of uncertainty.

In applying those policies, management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. These estimates are based on our management s experience, terms of existing contracts, observance of trends in the industry, information provided by customers, and information available from other outside sources, as appropriate. Our critical accounting polices include:

Expense Allocations Prior to February 13, 2004, our assets and businesses were owned, operated and fully integrated with IGEN. Our financial statements have been prepared and are presented as if we had been operating as a separate entity during the periods shown. In order to fairly present our operating results, these financial statements reflect the application of certain estimates and allocations for periods prior to February 13, 2004. For such periods, our consolidated statements of operations include all costs that were directly attributable to our businesses, as well as certain expenses of IGEN that were allocated to us using various assumptions. These expenses include an allocated share of general and administrative salaries as well as certain other shared costs (primarily facility, human resources, legal, accounting and other administrative costs) which were allocated based upon percentage of total revenue or percentage of total headcount, as appropriate. While management believes that the allocation methodologies are reasonable and appropriate, different allocation methodologies could result in changes to our operating results.

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, the price to the buyer is fixed and determinable, collectibility is reasonably assured and the product is shipped to the customers thereby transferring title and risk of loss. For instrument sales, the instrument and the related installation are considered to be separate elements under EITF 00-21. Revenue is recognized for the instrument upon shipment and is recognized for the installation when complete based upon the residual value method. For instrument and reagent sales, there is no option of return and refund, only the option to repair or replace. Other than the installation required for the instruments, there are no contingencies, allowances or other post-sale obligations. For instrument leases, the instrument rental and related minimum reagent purchases are considered to be separate elements under EITF 00-21 and, accordingly, the sales price is allocated to the two elements based upon their relative fair values. Instrument rental revenue is recognized ratably over the life of the lease agreements and the related reagent revenue is recognized upon shipment. Revenue associated with extended warranty arrangements is recognized over the term of the extended warranty contract. Royalty income is recorded when earned, based on information provided by licensees.

Revenue from services performed under contracts is recognized when obligations under the contract have been satisfied. The satisfaction of obligations may occur over the term of the underlying customer contract, if the contract is based on the achievement of certain milestones, or may occur at the end of the underlying customer contract, if based only upon delivery of the final work product.

The majority of our product sales and contract fees contain standard terms and conditions. Certain transactions may contain negotiated terms that require contract interpretation 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.

Joint Venture Accounting For periods prior to March 31, 2004, we accounted 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 have 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 had the right, prior to the Settlement, to appoint only one out of two seats on MSD s board of managers. A different assessment of these factors could have provided 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 have been appropriate. Consolidation accounting would have required certain reclassifications within our consolidated financial statements but would not have materially affected our financial position or net loss. See ITEM 8- Consolidated Financial Statements-Notes to Consolidated Financial Statements Note 4 Meso Scale Diagnostics Joint Venture.

In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities, or FIN 46. FIN 46 provides guidance on variable interest entities such as the MSD joint venture and the framework through which an enterprise assesses consolidation of a variable interest entity. We have adopted FIN 46 as of March 31, 2004 and have determined that MSD qualifies as a variable interest entity based upon the following rationale:

- We have provided substantially all of MSD s funding since inception through capital contributions consisting of class B and C non-voting equity interests. Such funding is not considered at risk as the investments do not participate significantly in the profits of MSD given their stated return rates. As such, the at risk equity of MSD is insufficient to absorb MSD s expected future losses.

- We hold 31% of the voting rights in MSD while providing 100% of MSD s funding, and are thereby considered to be involved in all of MSD s activities as defined under FIN 46.

Accordingly, beginning as of March 31, 2004 we have consolidated the financial results of MSD. Under the transition guidance of FIN 46, because MSD was created before February 1, 2003, we have measured the assets, liabilities and noncontrolling interests of MSD as of March 31, 2004 for purposes of the initial consolidation. The amounts of the assets, liabilities and noncontrolling interests are reflective of their respective carrying amounts had FIN 46 been effective when we first met the conditions to be the primary beneficiary of MSD upon MSD s inception in 1995. We have historically recorded approximately 100% of MSD s losses. In connection with the merger and related transactions, we made a $37.5 million payment to MSD. We determined that at the time of the payment, recording the entire payment to the investment in joint venture account would result in the book value of the Company s investment in MSD being greater than its fair value. Accordingly, we expensed $33.7 million, which represents the amount of the payment that gave rise to its net recorded investment exceeding the fair market value of its interests. Upon implementation of FIN 46, we recorded a one-time, non-cash $33.7 million adjustment to reflect this change in accounting principle. The balance sheet as of March 31, 2004 reclassified amounts formerly recorded on a net basis as investment in joint venture to be reflected on a gross basis primarily as cash, accounts receivable, inventory, fixed assets, accounts payable and accrued expenses. The statement of operations for periods subsequent to March 31, 2004 will reclassify amounts formerly recorded on a net basis as equity in loss of joint venture to be reflected on a gross basis primarily as revenue, product costs, research and development expenses and selling, general and administrative expenses. Historical financial information of MSD is summarized in Note 4 of our consolidated financial statements and the audited MSD financial statements are included elsewhere in this Form 10-K.

Inventory We record 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.

Evaluation of Long-lived Assets We have different long-lived assets recorded on our balance sheet that include equipment and leasehold improvements, investments, licenses and other assets. We evaluate the potential impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. In evaluating the recoverability of an asset,

management s policy is to compare the carrying amount of an asset with the projected undiscounted cash flow. While management believes that its projections 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.

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, supplemented by expectations of future costs. Unanticipated changes in actual warranty costs could impact our operating results.

Recent Accounting Pronouncements

See discussion of FASB Interpretation No. 46, Consolidation of Variable Interest Entities, under -Critical Accounting Policies above.

In April 2003, the FASB issued SFAS No. 149, Amendment of SFAS No. 133 on Derivative Instruments and Hedging Activities, or SFAS 149. SFAS 149 amends and clarifies financial accounting and reporting 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 require that contracts with comparable characteristics be accounted for similarly. SFAS 149 is generally effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The implementation of SFAS 149 did not have a material effect on our financial position, results of operations or cash flows.

In May 2003, the FASB issued SFAS No. 150 Accounting for Certain Financial Instruments with Characteristics of Both Liability and Equity, or SFAS 150. SFAS 150 establishes standards regarding the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The implementation of SFAS 150 did not have a material effect on our financial position, results of operations or cash flows. On February 17, 2004, we issued $7.5 million Series B preferred stock, and we concluded that such financial instrument did not meet the definition of a liability under SFAS 150.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Prior to the completion of the merger and related transactions on February 13, 2004, our assets and businesses were owned and operated by IGEN. IGEN held all cash in a centralized treasury and provided all of the necessary funding for our operations. Accordingly, no cash is reflected on our consolidated balance sheets prior to February 13, 2004.

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.

Beginning as of March 31, 2004, we have consolidated the financial results of MSD in accordance with the requirements of FIN 46. Our consolidated balance sheet at March 31, 2004 had cash and cash equivalents of $182.5 million. Of this amount, $35.1 million represented cash and cash equivalents of MSD. We have no rights or access to these funds. The amount of cash and cash equivalents to which we and our wholly-owned subsidiaries have unrestricted use is $147.4 million, which is 63.3% of total consolidated assets at March 31, 2004.

We invest excess cash in accordance with a policy approved by our Board of Directors. The 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. We invest our excess cash in money market funds, securities of the U.S. Treasury, and certificates of deposit with original maturities of three months or less.

Our invested cash is sensitive to changes in the general level of interest rates. Based on our cash and cash equivalents balance at March 31, 2004, a 100 basis point movement in interest rates would have an approximately $1.5 million impact on our annual interest income and annual net loss. Actual changes in rates may differ from the hypothetical assumption used in computing this exposure.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS

We also incorporate herein by reference the Meso Scale Diagnostics, LLC, Financial Statements at December 31, 2003 and 2002, and for each of the three years ended in the period ended December 31, 2003, and Independent Auditors Report filed as Exhibit 99.2 to this report.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
of BioVeris Corporation:

In our opinion, the accompanying consolidated balance sheet and the related consolidated statement of operations, of cash flows and of stockholders equity and net investment by parent present fairly, in all material respects, the financial position of BioVeris Corporation and its subsidiaries (the Company) at March 31, 2004, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America. 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 audit. We conducted our audit of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

As more fully discussed in Note 1, the accompanying consolidated statement of operations, of cash flows and of stockholders equity include the results of the Company s operations and cash flows for the period from April 1, 2003 through February 13, 2004 while the Company was affiliated with IGEN International, Inc., have been prepared from the separate records maintained by the Company and may not necessarily be indicative of the condition that would have existed or the results of operations if the Company had been operated as an unaffiliated company. Portions of certain expenses represent allocations made from parent company items applicable to the Company as a whole.

As more fully discussed in Note 1, as of March 31, 2004 the Company changed its method for accounting for its investment in Meso Scale Diagnostics, LLC.

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland
August 12, 2004

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors of
Bio Veris Corporation:

We have audited the accompanying consolidated balance sheet of Bio Veris Corporation and subsidiaries (the Company), a component of IGEN International, Inc. (Parent), as of March 31, 2003, and the related consolidated statements of operations, cash flows, and net investment by Parent for each of the two 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 standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying consolidated financial statements have been prepared from the separate records maintained by the Company and may not necessarily be indicative of the conditions that would have existed or the results of operations if the Company had been operated as an unaffiliated company. Portions of certain expenses represent allocations made from Parent Company items applicable to the Company as a whole.

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

/s/ Deloitte & Touche LLP

McLean, Virginia
September 25, 2003, except as to net loss per common share before cumulative effect of change in accounting principle, net loss per common share, and common shares outstanding for the years ended March 31, 2003 and 2002 in the consolidated statements of operations and as to the basic and diluted loss per common share-as reported and pro forma for the years ended March 31, 2003 and 2002 in Note 1- ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES- *Stock-based Compensation*, for which the date is August 13, 2004

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

	Years Ended March 31,		
	2004	2003	2002
REVENUES:			
Product sales	**$ 18,741**	$ 16,487	$ 12,077
Royalty income	**1,060**	1,107	1,050
Contract fees	**155**	180	116
Total	**19,956**	17,774	13,243
OPERATING COSTS AND EXPENSES:			
Product costs	**12,247**	8,005	5,361
Research and development	**19,821**	22,766	26,829
Selling, general, and administrative	**18,656**	20,453	19,217
Merger related costs	**75,702**		
Total	**126,426**	51,224	51,407
LOSS FROM OPERATIONS	**(106,470)**	(33,450)	(38,164)
INTEREST EXPENSE		(29)	(27)
OTHER, NET	**(933)**	183	(12)
EQUITY IN LOSS OF JOINT VENTURE	**(19,616)**	(17,598)	(10,947)
NET LOSS BEFORE CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE	**(127,019)**	(50,894)	(49,150)
CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE	**33,700**		
NET LOSS	**$ (93,319)**	$(50,894)	$(49,150)
Net loss per common share before cumulative effect of change in accounting principle	**$ (4.75)**	$ (1.90)	$ (1.84)
Cumulative effect of change in accounting principle	**1.26**		

Net loss per common share	**$ (3.49)**	$ (1.90)	$ (1.84)
COMMON SHARES OUTSTANDING (Basic and Diluted)	**26,728**	26,728	26,728

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

BIOVERIS CORPORATION
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	March 31,	
	2004	2003
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	**$182,509**	$
Accounts receivable, net	**5,516**	5,434
Inventory	**8,207**	5,448
Other current assets	**4,332**	2,286
Total current assets	**200,564**	13,168
Equipment and leasehold improvements, net	**12,565**	6,456
OTHER NONCURRENT ASSETS:		
Investment in joint venture		9,164
Technology licenses	**19,266**	
Other	**419**	372
TOTAL ASSETS	**$232,814**	$29,160
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	**$ 7,187**	$ 4,758
Accrued wages and benefits	**1,876**	3,170
Distribution gain accrual	**20,000**	
Other current liabilities	**2,273**	507
Note payable	**44**	
Total current liabilities	**31,380**	8,435
NONCURRENT DEFERRED REVENUE	**54**	60
Total liabilities	**31,434**	8,495

COMMITMENTS (see Note 8)		
MINORITY INTEREST	**54**	
SERIES B PREFERRED STOCK, 1,000 shares designated, issued and outstanding	**7,500**	
STOCKHOLDERS EQUITY:		
Preferred stock, par value $0.01 per share, 15,000,000 shares authorized, issuable in series:		
Series A, 600,000 shares designated, none issued		
Common stock, par value $0.001 per share, 100,000,000 shares authorized, 26,728,000 shares issued and outstanding	**27**	
Additional paid-in capital	**203,464**	
Net investment by parent		20,665
Accumulated deficit	**(9,665)**	
Total stockholders equity	**193,826**	20,665
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	**$232,814**	$29,160

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

BIOVERIS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended March 31,		
	2004	2003	2002
OPERATING ACTIVITIES:			
Net loss	**$ (93,319)**	$(50,894)	$(49,150)
Adjustments to reconcile net loss to net cash used provided by (used in) operating activities:			
Depreciation	**3,123**	3,677	5,322
Amortization	**262**		
Minority interest	**54**		
Loss on disposal of equipment	**58**	90	
Equity in loss of joint venture	**19,616**	17,598	10,947
Joint venture impairment	**33,700**		
Change in accounting principle	**(33,700)**		
Expense related to stock options	**38,800**	386	219
Changes in assets and liabilities:			
Decrease (increase) in accounts receivable	**2,017**	(2,666)	(1,326)
Decrease (increase) in inventory	**158**	(1,428)	1,666
(Increase) decrease in other current assets	**(173)**	(1,052)	330
Increase (decrease) in accounts payable and accrued expenses	**(1,708)**	1,131	(1,631)
Increase (decrease) in deferred revenue	**1,464**	53	(553)
Net cash used in operating activities	**(29,648)**	(33,105)	(34,176)
INVESTING ACTIVITIES:			
Expenditures for equipment and leasehold improvements	**(1,920)**	(3,331)	(5,642)
Investments in joint venture	**(56,660)**	(20,519)	(16,351)
Purchase of technology licenses	**(19,500)**		
Increase in other assets		(11)	(85)
Net cash used for investing activities	**(78,080)**	(23,861)	(22,078)
FINANCING ACTIVITIES:			
Cash contributed by Parent, net	**247,626**	57,022	56,307
Consolidation of joint venture cash and cash equivalents	**35,111**		
Payments on note payable and capital lease obligations		(56)	(53)
Sale of preferred stock	**7,500**		

Net cash provided by financing activities	**290,237**	56,966	56,254
NET INCREASE IN CASH AND CASH EQUIVALENTS	**182,509**		
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR			
CASH AND CASH EQUIVALENTS, END OF YEAR	**$182,509**	$	$
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash payments of interest	**$ 1**	$ 29	$ 27
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Equipment and leasehold improvements contributed to joint venture	**$**	$	$ 839
Transfer of inventory into fixed assets	**$ 277**	$	$

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

BIOVERIS CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
AND NET INVESTMENT BY PARENT
(in thousands)

	Common Stock Shares	Amount	Additional Paid - in Capital	Net Investment by Parent	Accumulated Deficit	Total
BALANCE at April 1, 2001		$	$	$ 6,775	$	$ 6,755
Capital contributed by parent				56,526		56,526
Net loss				(49,150)		(49,150)
BALANCE at March 31, 2002				14,151		14,151
Capital contributed by parent				57,408		57,408
Net loss				(50,894)		(50,894)
BALANCE at March 31, 2003				20,665		20,665
Net loss					(93,319)	(93,319)
Non-cash compensation charge			38,800			38,800
Capital contributed by parent			164,664	(20,665)	83,654	227,653
Restructuring and issuance of common stock	26,728	27				27
BALANCE at March 31, 2004	26,728	$ 27	$203,464	$	$ (9,665)	$193,826

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

On February 13, 2004, IGEN International, Inc. (IGEN or Parent) and Roche Holding Ltd (Roche) consummated a transaction pursuant to which Roche acquired IGEN and IGEN simultaneously distributed the common stock of BioVeris Corporation (the Company), to its stockholders (the merger). The transaction occurred in the following steps:

IGEN restructured its operations so that the Company, a newly formed, wholly-owned subsidiary of IGEN at the time, assumed IGEN s biodefense, life science and industrial product lines as well as IGEN s opportunities in the clinical diagnostics and healthcare fields and the ownership of IGEN s intellectual property, IGEN s equity interest in Meso Scale Diagnostics, LLC. (MSD), cash and certain other rights and licenses currently held by IGEN; and

A wholly-owned subsidiary of Roche merged with and into IGEN, as a result of which IGEN became a wholly-owned subsidiary of Roche and the Company became an independent, publicly-traded company. Simultaneously with the completion of the merger, certain ongoing commercial agreements between the Company and certain affiliates of Roche became effective.

The Company was organized as IGEN Integrated Healthcare, LLC, a Delaware limited liability company, on June 6, 2003, and converted into BioVeris Corporation, a newly formed Delaware corporation on September 22, 2003.

Simultaneous with the execution of the merger, the Company entered into worldwide, non-exclusive PCR license agreements with certain affiliates of Roche. One agreement grants the Company rights to make, import, use and sell certain PCR products within specified fields, while the other agreement grants the Company rights to perform certain PCR services within specified fields. The Company paid Roche a license fee of $50 million and will also pay royalties on sales of licensed products, royalties for every PCR plasma test it performs or has a laboratory perform and royalties on net service revenue that the Company receives for diagnostic testing procedures that it performs using PCR technology. The Company has performed a valuation of the PCR technology licenses and has recorded a value of $19.5 million and reflected a $30.5 million adjustment reducing the amount recorded for consideration paid by Roche with respect to the merger and related transactions.

The tax allocation agreement executed in conjunction with the merger and related transactions provides that Roche and IGEN will be solely liable for, will jointly and severally indemnify the Company against, and will be entitled to receive and retain all refunds of, taxes (other than transfer taxes) directly or indirectly resulting from, arising in connection with or otherwise related to the merger and related transactions, any transaction undertaken to prepare for the merger and related transactions and any of the actions taken pursuant to the ongoing litigation agreement. This agreement also provides that the Company was required to pay IGEN a $20 million distribution gain payment. This amount was calculated based on the average of the high and low trading prices of the Company s common stock on the first day of trading of the Company s common stock after the completion of the merger, exceeding a specified threshold. The distribution gain accrual is recorded on the Company s balance sheet at March 31, 2004 and an adjustment was made to the consideration paid by Roche with respect to the merger and related transactions. The distribution gain payment was made by the Company subsequent to March 31, 2004.

Prior to the completion of the merger and related transactions, the assets and businesses of the Company had historically been owned and operated by IGEN and IGEN held all cash in a centralized treasury, providing all of the necessary funding for the operations of the Company. The accompanying financial statements have been prepared and are presented as if the Company had been operating as a separate entity using IGEN s historical cost basis in the assets and liabilities and including the historical operations of the businesses and assets transferred to the Company from

IGEN as part of the restructuring. Results of operations and cash flows for the year ended March 31, 2004 include its business through February 13, 2004 while it was owned and operated by

IGEN, and the period from February 14, 2004 through March 31, 2004 when it operated as an independent entity.

In connection with the merger and related transactions, Roche loaned IGEN approximately $210 million. These funds, less transaction costs of approximately $25 million, were contributed by IGEN as equity to us as part of the merger and related transactions. The related promissory note remained the obligation of IGEN and we have no obligations associated with that debt. Accordingly, prior to the completion of the merger and related transactions, IGEN s net investment in the Company is shown in lieu of stockholders equity in the accompanying consolidated balance sheets and no cash is reflected on the accompanying consolidated balance sheets.

For each of the periods presented in the consolidated financial statements prior to the completion of the merger and related transactions, the Company was fully integrated with IGEN and these financial statements reflect the application of certain estimates and allocations. The Company s consolidated statements of operations include all revenues and costs that are directly attributable to the Company s businesses. In addition, certain expenses of IGEN have been allocated to the Company using various assumptions. These expenses include an allocated share of general and administrative salaries as well as certain other shared costs (primarily facility, human resources, legal, accounting and other administrative costs). General and administrative salaries have been allocated primarily based upon an estimate of actual time spent on the businesses of the Company. Facilities costs and centralized administrative services have been allocated based upon a percentage of total product sales as well as a percentage of total headcount. Allocated expenses of $15.7 million, $20.5 million and $19.2 million are included in selling, general and administrative expenses in the accompanying consolidated statements of operations for the years ended March 31, 2004, 2003 and 2002, respectively. These allocated expenses were derived from total IGEN selling, general and administrative expenses of $22.3 million, $24.7 million and $24.0 million for the years ended March 31, 2004, 2003 and 2002, respectively. In addition, certain merger related costs have been allocated to the Company based upon an estimate of actual time spent by professional service providers (see Note 2 to consolidated financial statements for discussion of other allocated merger costs). Management believes these allocation methodologies and estimations are reasonable based upon the nature of the related expenses and management s knowledge of the level of effort and space required to support the businesses of the Company. The financial information included herein may not be indicative of the financial position, results of operations and cash flows of the Company in the future or what they would have been had the Company been operating as a stand-alone entity in the past.

Consolidation Accounting The consolidated financial statements include the accounts of the Company and its subsidiaries. In addition, the Company adopted FIN 46 as of March 31, 2004 and has determined that MSD qualifies as a variable interest entity and the Company is the primary beneficiary. Accordingly, beginning March 31, 2004, the Company has consolidated the financial results of MSD. All significant intercompany transactions and balances have been eliminated.

Change in Accounting Principle Under the transition guidance of FIN 46, because MSD was created before February 1, 2003, the Company has measured the assets, liabilities and noncontrolling interests of MSD as of March 31, 2004 for purposes of the initial consolidation. The amounts of the assets, liabilities and noncontrolling interests are reflective of their respective carrying amounts had FIN 46 been effective when the Company first met the conditions to be the primary beneficiary of MSD upon MSD s inception in 1995. The Company has historically recorded approximately 100% of MSD s losses. In connection with the merger and related transactions, the Company made a $37.5 million payment to MSD. The Company determined that at the time of the payment, recording the entire payment to the investment in joint venture account would result in the book value of the Company s investment in MSD being greater than its fair market value. Accordingly, the Company expensed $33.7 million, which represents the amount of the payment that gave rise to its net recorded investment exceeding the fair market value of its interests. Upon implementation of FIN 46, the Company recorded a one-time, non-cash $33.7 million adjustment to reflect this change in accounting principle, thereby adjusting the book value of the Company s investment in the MSD joint venture to equal the consolidated net assets of MSD.

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The balance sheet reclassified amounts formerly recorded on a net basis as investment in joint venture to be reflected on a gross basis primarily as cash, accounts receivable, inventory, fixed assets, accounts payable and accrued expenses. In fiscal 2005, the statement of operations will reclassify amounts formerly recorded on a net basis as equity in loss of joint venture to be reflected on a gross basis primarily as revenue, product costs, research and development expenses and selling, general and administrative expenses. The historical financial information of MSD is summarized in Note 4 of our consolidated financial statements.

Estimates In addition to the estimates noted above, 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.

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. 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.

Concentration of Credit Risk The Company has not experienced any losses on its investments due to credit risk. During the years ended March 31, 2004, 2003 and 2002, agencies of the U.S. government accounted for 22%, 26% and 11% of total revenue, respectively, and 26% and 43% of total consolidated accounts receivable as of March 31, 2004 and 2003, respectively. Additionally, one commercial customer accounted for 18% of total consolidated accounts receivable as of March 31, 2004.

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.

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

	Year Ended March 31,	
	2004	2003
	(in thousands)	
BioVeris and Wholly-Owned Subsidiaries:		
Finished Goods	$1,740	$2,234
Work in process	619	869
Raw materials	2,654	2,345
Total	5,013	$5,448

MSD:	
Finished Goods	757
Work in process	366
Raw materials	2,071
Total	3,194
	$8,207

Equipment and Leasehold Improvements Equipment and leasehold improvements are carried at cost, less accumulated depreciation and amortization. Depreciation on equipment, which includes lab instruments and furniture, is computed over the estimated useful lives of the assets, generally three to five years, using straight-line.

Leasehold improvements are amortized on a straight-line basis over the life of the lease. Equipment and leasehold improvements consist of the following:

	Year Ended March 31, 2004	2003
	(in thousands)	
BioVeris and Wholly-Owned Subsidiaries:		
Lab instruments and equipment	$ 6,413	$ 6,274
Office furniture and equipment	5,511	5,847
Leasehold improvements	3,980	3,618
	15,904	15,739
Accumulated depreciation and amortization	(10,432)	(9,283)
Total	5,472	$ 6,456
MSD:		
Lab instruments and equipment	7,555	
Office furniture and equipment	3,166	
Leasehold improvements	1,327	
	12,048	
Accumulated depreciation and amortization	(4,686)	
Total	7,362	
Consolidating eliminations	(269)	
Total	$ 12,565	

Technology Licenses Simultaneous with the execution of the merger, the Company entered into worldwide, non-exclusive PCR license agreements with certain affiliates of Roche. One agreement grants the Company rights to make, import, use and sell certain PCR products within specified fields, while the other agreement grants the Company rights to perform certain PCR services within specified fields. The Company paid Roche a license fee of $50 million and will also pay royalties on sales of the licensed products in the licensed fields and on any instrument, accessory, device or system sold for use with the licensed products in the licensed fields at royalty rates ranging from 3% to 20% of net sales, depending on the field, the year, the country of sale and the patents covering such products. It will also pay royalties of $16 or $25 for every PCR plasma test it performs or has a laboratory perform and royalties

ranging from 5% to 20% of net service revenue that the Company receives for diagnostic testing procedures that it performs using PCR technology. The Company has performed a valuation of the PCR technology licenses and has recorded their value of $19.5 million and reflected a $30.5 million adjustment reducing the amount recorded for consideration paid by Roche with respect to the merger and related transactions. These licenses are being amortized over an estimated useful life of ten years which is based upon a consideration of the range of patent lives and the weighted average remaining life of the most important underlying patents, as well as a consideration of technological obsolescence and product life cycles. Amortization expense and accumulated amortization was $244,000 for the year ended and at March 31, 2004. Amortization expense is expected to approximate $2.0 million for each year through March 31, 2009.

Evaluation of Long-lived Assets The Company evaluates the potential impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. In evaluating the recoverability of an asset, management s policy is to compare the carrying amount of an asset with the projected undiscounted future cash flow. Management believes no impairment of these assets exists as of March 31, 2004.

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 management s review of historical claims, supplemented by

expectations of future costs. The Company also offers extended warranty arrangements to customers, for which related costs are recorded as incurred.

Warranty reserve activity is as follows:

	Years Ended March 31,		
	2004	**2003**	**2002**
BioVeris and Wholly-Owned Subsidiaries:			
Balance, Beginning of Period	$ 250	$ 170	$ 225
Provisions recorded	1,817	1,278	401
Actual costs incurred	(1,617)	(1,198)	(456)
Balance, End of Period	$ 450	$ 250	$ 170

MSD had no warranty reserve at March 31, 2004.

Other Current Assets- Other current assets includes certain assets of MSD aggregating $1.5 million that represent automobiles and deposits on real property. On June 17, 2004, MSD received $2.9 million from Jacob Wohstadter as consideration for the proposed sale by MSD of real property and automobiles, pending approval by the Board of Managers. Jacob Wohlstadter also assumed MSD s purchase obligations with respect to a prospective real property purchase in the approximate amount of $4.1 million. In August 2004, MSD transferred the real property and automobiles and MSD s limited liability company interests to Jacob Wohlstadter.

Fair Value of Financial Instruments The carrying amounts of the Company s financial instruments, which include cash equivalents, accounts receivable, accounts payable and accrued expenses, approximate their fair value due to their short maturities.

Comprehensive Loss- Comprehensive loss is comprised of net loss and other items of comprehensive loss. 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, 2004, 2003 and 2002.

Revenue Recognition The Company derives revenue principally from three sources: product sales, royalty income and contract fees.

Product sales revenue is recognized when persuasive evidence of an arrangement exists, the price to the buyer is fixed and determinable, collectibility is reasonably assured and the product is shipped to the customer thereby transferring title and risk of loss. For instrument sales, the instrument and the related installation are considered to be separate elements under EITF 00-21 Accounting for revenue arrangements with multiple deliverables . Revenue is recognized for the instrument upon shipment and is recognized for the installation when complete based upon the residual value method. For instrument and reagent sales, there is no option of return and refund, only the option to repair or replace the product. Other than the installation required for the instruments, there are no contingencies, allowances or other post-sale obligations. For instrument leases, the instrument rental and related minimum reagent purchases are

considered to be separate elements under EITF 00-21 and, accordingly, the sales price is allocated to the two elements based upon their relative fair values. Instrument rental revenue is recognized ratably over the life of the lease agreements and the related reagent revenue is recognized upon shipment. Revenue associated with extended warranty arrangements is recognized over the term of the extended warranty contract.

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

Revenue from services performed under contracts is recognized when obligations under the contract have been satisfied. The satisfaction of obligations may occur over the term of the underlying customer contract, if the contract is based on the achievement of certain milestones, or may occur at the end of the underlying customer contract, if based only upon delivery of the final work product.

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

Merger Related Costs Merger related costs for the year ended March 31, 2004 included the following (in thousands):

Stock option compensation charge	$38,800
MSD payment	33,700
Other	3,202
	$75,702

With respect to the MSD payment, it was determined that at the time of the payment in February 2004, recording the payment to the Investment in Joint Venture account would result in the value of the Company s investment in MSD being greater than its fair market value. Accordingly, the Company expensed the amount of the payment that would exceed fair market value. See Note 1- Change In Accounting Principle for the accounting treatment under FIN 46.

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, 2004, 2003 and 2002.

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 follow the recognition and measurement principles of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations in accounting for employee stock options and, accordingly, will not recognize compensation cost for options granted under its 2003 Stock Incentive Plan whose exercise price equaled the market value of a share of the underlying common stock on the date of grant.

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 31,	
2004	2003	2002

Net loss, as reported		$(93,319)	$(50,894)	$(49,150)
Deduct: Total stock-based employee compensation expense determined under fair value method		(121)	(2,455)	(1,974)
Pro forma net loss		$(93,440)	$(53,349)	$(51,124)
Loss per share:				
Basic and diluted loss per common share	as reported	$ (3.49)	$ (1.90)	$ (1.84)
Basic and diluted loss per common share	pro forma	$ (3.50)	$ (2.00)	$ (1.91)

All per share information for the Company is based on the number of shares of common stock of the Company outstanding upon completion of the merger and related transactions. The net loss, pro forma, and net loss per share, pro forma, disclosed above are not representative of the effects on net loss and net loss per share on a pro forma basis in future years, as future years may include grants by the Company of options for the Company common stock. In addition, information for the years ended March 31, 2003 and 2002 represent options for IGEN common stock which were canceled upon completion of the merger.

The fair value BioVeris options for the year ended March 31, 2004 was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions:

Expected dividend yield	0.00%
Expected stock price volatility	52.62%
Risk-free interest rate	2.71%
Expected option term (in years)	3

Based on this calculation, the weighted average fair value of BioVeris options granted during the year ended March 31, 2004 was $5.97. The Company did not have a stock option plan prior to September 2003.

The fair value of IGEN options of each of the years ended March 31, 2003 and 2002 was estimated at the date of grant using Black-Scholes option pricing model with the following assumptions:

	Years Ended March 31,	
	2003	2002
Expected dividend yield	0%	0%
Expected stock price volatility	68%	71%
Risk-free interest rate	3.4%	4.3%
Expected option term (in years)	5	5

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

Loss Per Share - The Company uses SFAS No. 128 Earnings per Share for the calculation of basic and diluted earnings (loss) per share. For each of the three years ended March 31, 2004, 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. For the years ended March 31, 2003 and 2002, the pro forma net loss per share is based on the number of common shares outstanding upon completion of the merger and related transactions. The Company incurred a loss for the year ended March 31, 2004 and, accordingly, did not assume exercise of 20,300 options because to do so would have been anti-dilutive.

New Accounting Standards In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities, or FIN 46. FIN 46 provides guidance on variable interest entities such as the MSD joint venture and the framework through which an enterprise assesses consolidation of a variable interest entity. The Company adopted FIN 46 as of March 31, 2004 and has determined that MSD qualifies as a variable interest entity based upon the following rationale:

The Company has provided substantially all of MSD s funding since inception through capital contributions consisting of class B and C non-voting equity interests. Such funding is not considered at risk as the investments do not participate significantly in the profits of MSD given their stated return rates. As such the at risk equity of MSD is insufficient to absorb MSD s expected future losses.

The Company holds 31% of the voting rights in MSD while providing 100% of MSD s funding, and the Company is thereby considered to be involved in all of MSD s activities as defined under FIN 46. Accordingly, beginning March 31, 2004, the Company has consolidated the financial results of MSD. See Note 1 Consolidation Accounting and Change in Accounting Principle for a further discussion of the consolidation of MSD s financial results.

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 financial accounting and reporting 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 require that contracts with comparable characteristics be accounted for similarly. SFAS 149 is generally effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The implementation of SFAS 149 did not have a material effect on the Company s financial position, results of operations or cash flows.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity (SFAS 150). SFAS 150 establishes standards regarding the classification and measurement of certain financial instruments with characteristics of both liabilities and equity.

SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. In February 17, 2004, we issued $7.5 million Series B preferred stock, and we concluded that such financial instrument did not meet the definition of a liability under SFAS 150.

Liquidity The Company s consolidated balance sheet at March 31, 2004 had cash and cash equivalents of $182.5 million. Of this amount, $35.1 million represented the cash and cash equivalents of MSD. The Company has no rights or access to these funds or any other capital resources of MSD. The amount of cash and cash equivalents to which the Company and its wholly-owned subsidiaries had unrestricted use is $147.4 million. In addition, the Company s consolidated balance sheet includes the accounts receivable, inventory and other assets and liabilities of MSD. The Company has no rights or access to MSD s assets and the Company does not have obligations with respect to MSD s liabilities.

Product development for the Company s clinical diagnostic products is at an early development stage and products based on the PCR technology being licensed from Roche are not yet under development. Product development is subject to a number of technical and commercial uncertainties and in part depends upon the Company s ability to enter into new collaborative arrangements. Accordingly, the Company has not yet completed a business plan for its clinical diagnostic products, and it does not have definitive product introduction timelines or budgets and has not determined the additional funding, personnel, facilities, equipment or technology that may be required to implement its plans.

The Company s ability to become profitable in the future will depend on, among other things, the introduction of new products to the market. If the Company is unable to develop new products, its business prospects and financial results would be adversely affected.

2. STOCKHOLDERS EQUITY

Series B Preferred Stock In February 2004, the Company issued 1,000 shares of its Series B preferred stock to its chairman and chief executive officer for $7.5 million. The Series B preferred stock economically mirrors the class C interest in MSD (see Note 4) that is held by the Company. Under the terms of the Series B preferred stock, the Company may redeem the Series B preferred stock for $0.01 per share at any time it is no longer

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entitled to receive distributions with respect to the class C interests in MSD, pursuant to the MSD limited liability company agreement. The Company will redeem a proportionate part of the Series B preferred stock in connection with any redemption by MSD of the class C interests held by the Company in MSD described in the previous sentence. No distributions on the Series B preferred stock will be paid unless and until distributions are paid on such class C interests in accordance with the MSD limited liability company agreement, in which event distributions on the Series B preferred stock will be paid in the same manner and amount as such distributions on the class C interests. The shares of the Company s Series B preferred stock are entitled in the aggregate to 1,000 votes on all matters on which holders of the Company s common stock may vote. In addition, the Company may not consent to any adverse change to the terms of the class C interests in MSD described in this paragraph without the consent of the holders of the Series B preferred stock.

In connection with an August 2004 agreement between the Company and MSD, the Company received a $2.0 million non-refundable pre-payment from MSD for future amounts payable by MSD to it pursuant to the buy-out of its interest in MSD. The holder of the Company s Series B preferred stock will be entitled to a pro-rata share, representing a proportionate amount of the Company s class C interest in MSD that was funded by the sale of the Series B preferred stock, of the portion of the $2.0 million that is allocable to our class C interests.

Stock Option Plan In September 2003, the Board of Directors of the Company adopted the 2003 Stock Incentive Plan (Stock Plan) under which 5.3 million shares of common stock have been reserved for issuance upon exercise of options granted to employees, non-employee directors or consultants of the Company and its subsidiaries. The Stock Plan was approved by an affirmative vote of the IGEN stockholders prior to the completion of the merger.

The Stock Plan provides for the grant of incentive stock options intended to qualify under Section 422 of the Internal Revenue Code of 1986, as amended, non-statutory stock options, restricted stock awards and other stock-based awards, including the grant of shares based upon certain conditions, the grant of securities convertible into common stock of the Company and the grant of stock appreciation rights. Incentive stock options may only be granted to employees of the Company and its subsidiaries. The Stock Plan also provides that on the day following each annual meeting of the Company s stockholders each non-employee director will receive an automatic grant of options to purchase 4,000 shares of the Company s common stock. In addition, any person who is appointed or elected as a non-employee director at any other time will receive an automatic grant of options to purchase 4,000 shares of the Company s common stock on the date of such appointment or election. Each grant will have an exercise price equal to fair market value on the date of grant and will vest in full on the first anniversary of the grant date.

In February 2004, 22,200 options were granted to employees.

Activity related to options under the option plans for the fiscal year ended March 31, 2004 was:

	Shares	Exercise Price
Outstanding at February 13, 2004		
Granted	22,200	$
Exercised		
Cancelled/forfeited	(1,900)	$15.80
Outstanding at year-end	20,300	$15.80

Options exercisable at year-end		$15.80
Options available for future grant	5,267,700	

For all options outstanding at March, 31, 2004, the remaining contractual life was 9.9 years, the exercise price was $15.80 per share, and there were no shares exercisable. The Company did not have any stock option activity prior to February 13, 2004.

Certain detailed stock option disclosures related to options granted under IGEN s stock option plans have been omitted from these notes to consolidated financial statements as all such options relate only to IGEN and all IGEN options were cancelled in connection with the merger and related transactions.

In connection with the cancellation of IGEN stock options and the payment of the merger consideration for each share covered by IGEN stock options, the Company has recorded an allocated noncash compensation charge of $38.8 million during the year ended March 31, 2004. This compensation charge is a component of merger related costs in the consolidated statement of operations and the amount is an allocation from IGEN to the Company based upon an estimate of actual time spent on BioVeris matters by each option holder. In calculating this compensation charge associated with the completion of the merger and related transactions and the cancellation of the IGEN stock options, the Company has applied the guidance of FIN 44 Accounting for Certain Transactions Involving Stock Compensation for employee stock options and SFAS 123 for nonemployee stock options. With respect to employee stock options, FIN 44 guidance provides that the compensation charge is calculated based upon the difference between the last trading price of IGEN common stock and the exercise price of each employee stock option, including both vested and unvested employee stock options. With respect to nonemployee stock options, SFAS 123 guidance, provides that the compensation charge is calculated based upon the incremental fair value of the nonemployee stock options resulting from the merger.

In August 2000, IGEN granted 75,000 non-qualified stock options under its 1994 Stock Option Plan in connection with a consulting arrangement for services to be provided to it. The consultant is also the sole owner of Meso Scale Technologies (MST) and is a son of IGEN s and the Company s chairman and chief executive officer (see Note 4). 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, IGEN 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. The options vested ratably over a five-year period through August 2005. As the consulting services were provided to the Company s businesses, compensation expense of $219,000, $386,000 and $2.2 million has been reflected in the accompanying financial statements for the years ended March 31, 2002, 2003 and 2004, respectively. Of the amount in 2004, $1.8 million was incurred in connection with the cancellation of IGEN stock options and the payment of merger consideration.

Shareholder Rights Plan - In December 2003, the Company s Board of Directors adopted a shareholder rights plan and declared a dividend of one preferred stock purchase right (Right) for each outstanding share of the Company s common stock. The Rights were issued to the holders of record of the Company s common stock outstanding as of February 13, 2004, and with respect to shares of the Company s common stock issued thereafter. Prior to becoming exercisable, the Rights are evidenced by certificates representing shares of the Company s common stock and are transferable only in connection with the transfer of Company s common stock. Each Right, when exercisable, will detach from the Company s common stock and will entitle the registered holder to purchase from the Company one one-thousandth of a share of Series A participating cumulative preferred stock, par value $0.001 per share, at a price of $50.00, subject to adjustment. Subject to certain exceptions, the Rights are triggered upon the earlier of (1) such time as the Company learns that a person (other than Samuel Wohlstadter and Nadine Wohlstadter and their affiliates, associates and heirs and any trust or foundation to which they have transferred or may transfer shares of the Company s common stock) has become the beneficial owner of more that 10% of the Company s common stock then outstanding and (2) such date as may be designated by the Company s Board of Directors following the commencement of, or the first public disclosure of an intent to commence, a tender offer or exchange offer that would result in a person becoming the beneficial owner of more that 10% of the Company s common stock then outstanding. If triggered, the Rights would cause substantial dilution to the person that caused them to be triggered. Subject to certain conditions, the Rights are redeemable in whole, but not in part, for $0.001 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 2014 unless redeemed by the Company prior to that date.

3. LICENSE AGREEMENTS

Effective with the completion of the merger, the Company granted to an affiliate of Roche a worldwide, non-exclusive, fully-paid, royalty-free license under patents and technology that relate to detection methods and systems which employ ECL technology, but specifically excluding technology related to gene amplification or compounds composed of or capable of binding with nucleotides, which collectively are referred to as the licensed ECL technology. The license may be used only in a specific field, generally described as the human *in vitro* diagnostics field, to develop, make, reproduce, modify, use, sell and otherwise commercially exploit specified products.

The Company granted a license to bioMérieux for the development and worldwide-development, use, manufacture and sale of ECL-based nucleic acid test systems on a co-exclusive basis for certain segments of the clinical diagnostics market and on a non-exclusive basis for certain segments of the life science market. Among

other things, the agreement provides for royalty payments to the Company on product sales and for product supply arrangements between the parties. Royalty income from bioMérieux of $231,000, $236,000 and $252,000 has been recognized in the accompanying consolidated financial statements for the years ended March 31, 2004, 2003, and 2002, respectively.

The Company granted a license to Eisai for the manufacture and market of a class of ECL-based diagnostic systems for the clinical diagnostics market in Japan. The agreement provides for royalty payments to the Company on product sales. In 2002, The Company and Eisai executed an extension of the license under which the license became non-exclusive in July 2003. Royalty income from Eisai of $828,000, $871,000 and $798,000 has been recognized in the accompanying consolidated financial statements for the years ended March 31, 2004, 2003 and 2002, respectively.

4. MESO SCALE DIAGNOSTICS JOINT VENTURE

MSD is a joint venture formed by MST and IGEN in 1995. As part of the merger and related restructuring, IGEN transferred its equity interest in MSD to the Company and assigned the MSD agreements to the Company. MSD was formed for the development, manufacture, marketing and sale of products utilizing a combination of MST s multi-array technology together with IGEN s technology.

MST is a company established and wholly-owned by Mr. Jacob Wohlstadter, a son of the Company s chairman and chief executive officer. In August 2001, there were amendments to the MSD joint venture agreement, the MSD limited liability company agreement and certain license and other agreements with MSD and MST to continue the MSD joint venture and various related agreements (the MSD agreements). As part of the merger agreement and related transaction agreements, the Company, IGEN and MSD agreed that the MSD joint venture agreement would expire upon completion of the merger and related transactions.

MSD manufactures, markets and sells instrument systems, including the Sector HTS and the Sector PR, which combine MST s multi-array technology and the Company s ECL 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 its own reagents, assays and plates that are used on these systems. MSD commenced product sales in October 2002.

Under the MSD agreements, IGEN s funding commitment was based on an annual budget of MSD approved by the Joint Venture Oversight Committee (JVOC), a committee of the IGEN board of directors consisting of independent directors. The JVOC 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 15%, of which approximately $19.1 million was spent by MSD and funded by the Company. The funding commitment was satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. MSD asserted that the Company was obligated to pay MSD up to an additional $4.6 million, which is the difference between the amount spent by MSD and the budgeted amount plus the permitted variance.

For the years ended March 31, 2004, 2003 and 2002, there were total contributions made to MSD of $56.7 million, $20.5 million and $19.6 million respectively, including $3.7 million in the year ended March 31, 2004, which constituted discretionary funding relating to the permitted budget variances from prior years. During the year ended March 31, 2002, IGEN 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.

Separate from and in addition to IGEN s funding commitment under the MSD agreements for the period from January 1, 2003 to November 30, 2003, the Company made a capital contribution of $37.5 million to MSD following the completion of the merger. We determined that at the time of the payment, recording the entire payment to the investment in joint venture account would result in the book value of the Company s investment in MSD being greater than its fair value. Accordingly, we expensed $33.7 million, which represents the amount of the payment that gave rise to its net recorded investment exceeding the fair market value of its interests. Of the $37.5 million, Mr. Samuel Wohlstadter, the Company s chairman and chief executive officer, funded $7.5 million through the purchase of the Company s series B preferred stock that economically mirrors the class C interests in MSD held by the Company.

After the restructuring, and subject to MSD s and MST s right to buy the Company s interests in MSD, the Company replaced IGEN as a member of MSD and holds a 31% voting equity interest in MSD and is entitled to a preferred return on approximately $114 million of the funds previously invested by IGEN in MSD through the date of the merger and on the additional funds invested by the Company 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.

The Company and MST are the sole members of MSD, and each held one seat on MSD s two-member board of managers. Dr. Richard Massey, the Company s president and chief operating officer, was the Company s representative on the MSD board of managers and also served as the treasurer and secretary of MSD. The other member of the MSD board of managers is Mr. Jacob Wohlstadter, who is the sole owner of MST and serves as president and chief executive officer of MSD. As part of an August 2004 settlement agreement between the parties, the Company s representative on the MSD board of managers has resigned and the Company has executed an amendment to the MSD agreements for the purpose of changing the composition of the MSD board of managers to one person designated by MST.

Under the terms of one of the MSD agreements, IGEN granted to MSD a worldwide, perpetual, exclusive license (with certain exceptions) to IGEN s technology, including ECL technology, for use in MSD s research program, defined in the MSD agreements. If the Company ceases to be a member of MSD, it will become entitled to receive royalty payments from MSD on all products developed and sold by MSD using the Company s patents.

MST holds a worldwide, perpetual, non-exclusive sublicense from MSD for certain non-diagnostic applications of the Company s technology. The Company is entitled to receive royalty payments from MST on any products developed and sold by MST using the patents the Company received as part of the restructuring.

Upon completion of the merger and related transactions, the MSD joint venture agreement expired. As a result, MSD and MST had the option to purchase the Company s interest in MSD and as part of an August 2004 settlement agreement between the parties, they agreed to do so. As of March 31, 2004, the value of this option was approximately $1.2 million, which has been recorded as a liability and as other expense on the accompanying consolidated statements of operations. The purchase price will be equal to fair market value (determined in accordance with the MSD agreements), which includes third-party appraisal if the parties are unable to agree on fair market value) minus a 7.5% discount factor.

The parties have commenced the valuation process and the initial appraisers reports are due on August 30, 2004. If those reports do not reflect fair market value calculations within 10% of each other, then a third appraiser will be appointed to provide a report on or about October 15, 2004. The average of the two closest appraisals will be the purchase price. MSD or MST will be required to pay the Company the outstanding purchase price plus simple (cumulated, not compounded) interest at the fixed annual rate of 0.5% over the prime rate in effect on the purchase date. The purchase price is payable over time in installments equal to the sum of 5% of MSD net sales, as determined in accordance with the MSD agreements, and 20% of the net proceeds realized by MSD from the sale of its debt or equity securities in any third-party financing after the date of the sale of the Company s interest in MSD. In fiscal 2004, the Company recorded a $1.2 million non-cash charge representing the value of MSD s option to purchase the Company s interests in MSD.

As part of an August 2004 settlement agreement between the parties, the Company received a $2.0 million non-refundable pre-payment from MSD for future amounts payable by MSD to the Company pursuant to the buy-out of its interest in MSD. The amount of the pre-payment credit outstanding from time to time shall bear simple interest (cumulated, not compounded) at the fixed annual rate of 0.5% over the prime rate in effect on the date that MSD or MST, as the case may be, purchases the Company s interests in MSD. The amount of the outstanding credit balance of the prepayment credit, including accrued interest, shall be reduced for amounts due and payable to the Company pursuant to the buy-out of its interest in MSD and no further cash payments will be payable by MSD to the Company until the $2.0 million prepayment credit, including accrued interest, is utilized. In the event future net sales or third-party financings in excess of the prepayment credit and accrued interest do not materialize, the Company will not receive any additional payments from MSD or MST, as the case may be, for the purchase of the Company s interest in MSD. As security for the payment obligation, the Company will hold a security interest in the interests in MSD that are being purchased. MST or MSD, as the case may be, may repay all or any part of the outstanding purchase price plus accrued interest at any time and from time to time without penalty. The holder of the Company s Series B preferred stock will be entitled to a pro-rata share, representing the amount of the Company class C interest in MSD that was funded by the sale of the Series B stock, of the portion of the $2.0 million that is allocable to our class C interests.

Upon expiration of the MSD joint venture agreement, many of the licenses and other arrangements with MSD and MST assigned to the Company continue indefinitely in accordance with their terms and the Company may not use the improvements granted to it by MSD if doing so would compete with MSD in the diagnostic field or use research technologies defined in the MSD agreements.

Following the expiration of the MSD joint venture agreement, MSD is entitled to continue to lease certain facilities and related equipment from the Company (including laboratory facilities located in the Company s corporate headquarters) pursuant to the terms of the existing sublease agreements with MSD. The term of each sublease will expire one day prior to the expiration of the prime lease for that facility. Each sublease agreement provides that, subject to certain exceptions, the Company must exercise all available extension rights under the prime lease. Each of MSD and the Company may unilaterally terminate any or all of the subleases by providing at least 18 months prior written notice of termination and on February 29, 2004, the Company elected to terminate all of the subleases effective the earlier of September 1, 2005, or the date on which the applicable prime lease terminates. As part of an August 2004 settlement agreement between the parties, MSD s rental and expense payment obligations under the sublease agreements, for the period from March 1, 2004 through August 31, 2005, for approximately $2.2 million will be added into the price payable to the Company for the purchase of its interest in MSD, in lieu of current payments. MSD may elect, notwithstanding any termination of the sublease, to remain in the subleased facility after the 18 month period expires for any period of time selected by MSD, but not longer than one day prior to the expiration of the prime lease (including any extensions of the prime lease). In that event, MSD will be required to pay rent in cash for any additional rental period MSD may elect.

MSD has an employment agreement with Mr. Jacob Wohlstadter, its president and chief executive officer, the current term of which runs through November 30, 2005. The term of the employment agreement will automatically renew for a 12-month period on November 30 of each year unless either MSD or Mr. Jacob

Wohlstadter gives notice of termination no later than 180 days prior to that renewal date. That employment agreement provides for a salary at the annual rate of $250,000 through November 30, 2004, and 2005. Thereafter, the salary is to be increased as agreed to by MSD and Mr. Jacob Wohlstadter. In addition, Mr. Jacob Wohlstadter is also eligible to receive an annual cash bonus in an amount not to exceed 20% of his annual salary upon the achievement of agreed-upon performance factors. During the year ended December 31, 2003, Mr. Jacob Wohlstadter received $250,000 from his employment at MSD. Mr. Jacob Wohlstadter is also entitled to receive pension, welfare and fringe benefits comparable to those received by senior executives of the Company and other insurance benefits. If MSD terminates the employment agreement without cause, or Mr. Jacob Wohlstadter terminates the employment agreement for good reason (which includes a change in control of the Company, as defined), Mr. Jacob Wohlstadter will 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. Under the employment agreement Mr. Jacob Wohlstadter is also entitled to receive a gross-up for any parachute excise tax that may be imposed on payments made or benefits provided pursuant to the agreement. The Company is obligated to maintain in effect directors and officer s liability insurance coverage for Mr. Jacob Wohlstadter and to pay Mr. Jacob Wohlstadter the applicable salary, pro rata bonus and adjustments in effect at the time of termination as described above and a gross-up for any parachute excise tax that may be imposed.

MSD and Mr. Jacob Wohlstadter have each agreed that the merger and related transactions did not constitute a change in control for purposes of the MSD agreements and the employment agreement. The Company will also indemnify Mr. Jacob Wohlstadter against certain liabilities, including certain liability from the MSD joint venture relating to the period of IGEN s or the Company s involvement with MSD. In addition, the Company will be obligated to the extent provided in the MSD agreements to indemnify each board member or officer of MSD with respect to any action taken by such person prior to the termination of the MSD joint venture agreement by reason of the fact that such person is or was a board member or an officer of MSD. In connection with the audit of MSD, the Company will indemnify MSD, MST and Jacob Wohlstadter and their respective directors, officers, employees and agents for any losses, costs, fees and expenses arising out of or related in any way to past, current or future audits of MSD, the preparation of MSD financial statements requested by the Company, and with respect to regulatory or legal proceedings and investigations resulting from or related to the fact that the Company is a public company. With respect to such indemnification obligations, there are no pending or known matters covered by these indemnification provisions that would have a material effect on the Company s financial position or results of operations.

Since inception of the MSD joint venture, the equity method has been utilized to account for this investment. Prior to July 1, 2001, given MSD s status as a development stage enterprise without having established technological feasibility of its intended product offering, the Company considered its investments in MSD to be other than temporarily impaired. As such, any residual investment book value, after recognizing the Company s share of MSD losses in accordance with the equity method, was written off upon contribution. All expenses related to the MSD investment prior to July 1, 2001 were recorded as research and development expenses based upon the significance and character of the MSD losses as substantially all contributions supported research and development initiatives.

Beginning on July 1, 2001, taking into account the progress made by MSD in the development of its products, the Company determined that no additional impairments were required to its prospective contributions and thus ceased writing-off the amount of its contributions to MSD that were in excess of MSD s losses. At that time, MSD was transitioning from a development stage entity to a commercial enterprise and milestones establishing the continued viability of MSD were first achieved in the quarter ended September 30, 2001. For example, prototypes had been assembled demonstrating product feasibility, and MSD was anticipating initial product launch in approximately one year. As a result of this transition, MSD s expenses were no longer primarily research and development. Accordingly, since July 1, 2001, the Company has recorded only its proportionate share of MSD losses, representing approximately 100% of MSD s losses, for each respective period as equity in loss of joint venture consistent with accounting for

equity method investments.

MSD-related research and development expenses totaled $8.3 million ($5.9 million of equity method losses and $2.4 million of impairment losses) and $2.4 million ($2.2 million of equity method losses and $200,000 of impairment losses) for the years ended March 31, 2001 and 2002, respectively. MSD-related losses included in equity in loss of joint venture were $19.6 million, $17.6 million and $10.9 million for the years ended March 31, 2004, 2003 and 2002, respectively.

During the years ended March 31, 2004, 2003 and 2002, operating costs allocated to MSD by the Company in connection with shared personnel and facilities totaled $6.0 million, $11.9 million and $11.4 million, respectively. Since July 1, 2001, these allocated operating costs reduced certain operating costs and expenses and increased Equity in Loss of Joint Venture in the accompanying consolidated statements of operations. The Company s investment in joint venture totaled $9.2 million at March 31, 2003. At March 31, 2004, the Company s investment in joint venture has been eliminated as part of the consolidation of MSD s balance sheet. See Note 1 for discussion of consolidation accounting of the MSD investment as of March 31, 2004.

Summarized financial information for MSD is as follows:

	Years Ended March 31,		
	2004	**2003**	**2002**
Revenue	$ 8,383	$ 3,247	$
Operating expenses	28,258	21,357	13,560
Net loss	19,851	18,215	13,541

	March 31,	
	2004	**2003**
Current assets	$42,457	$ 5,685
Total assets	49,894	11,904
Current liabilities	3,363	2,226
Total liabilities	3,363	2,226
Total members equity	46,531	9,678

See Note 9 for a discussion of the litigations and settlement agreement between the Company and MSD.

5. INCOME TAXES

The Company s operating results historically have been included in IGEN s consolidated Federal and state income tax returns. For purposes of the pro-forma, however, income taxes have been calculated as if the Company was a stand-alone entity filing a separate tax return.

For the years ended March 31, 2004, 2003 and 2002, the Company recorded no Federal or state income tax expense nor would it have owed any Federal or state income taxes.

In connection with the merger and related transactions, Roche will be acquiring all of the historical net operating loss and tax credit carryforwards of IGEN. The Company, however, has assumed IGEN s historical cost basis in the assets and liabilities transferred to the Company from IGEN. Deferred income tax assets and liabilities have been computed

for differences between financial reporting and tax bases of the assets and liabilities assumed that will result in taxable or deductible amounts in the future. The computation of deferred income taxes is based on enacted tax laws and rates applicable to periods in which the differences are expected to affect the taxable income of the Company. The approximate tax effects of temporary differences that will give rise to the Company s deferred tax assets are as follows:

	March 31,		
	2004	2003	2002
	(In thousands)		
Deferred tax assets:			
Accruals and reserves	$ 895	$ 551	$ 468
Deferred revenue	321	219	198
Equipment and leasehold improvements	1,612	1,304	976
Investment in affiliate	1,466	1,954	1,791
Net operating loss carry forwards	3,246		
Other	(306)	(238)	45
Total deferred tax asset	7,234	3,790	3,478
Less: valuation allowance	(7,234)	(3,790)	(3,478)
Net deferred tax asset	$	$	$

A valuation allowance equal to the total net deferred tax assets has been provided as of March 31, 2004, 2003 and 2002 as management has determined that it is more likely than not that deferred tax assets will not be realized. The increase in the valuation allowance on the deferred tax asset was $3.4 million and $300,000 for the years ended March 31, 2004 and 2003, respectively. Net operating loss carry forwards as of March 31, 2004 approximate $8.4 million which expire during the year ended March 31, 2025. The provision for income taxes recorded in the accompanying consolidated statements of operations differs from the amount that would have resulted by applying the U.S. Federal income tax statutory rate as a result of the following:

	March 31,		
	2004	2003	2002
Income tax provision at federal statutory tax rate	34.0%	34.0%	34.0%
State and local taxes net of federal benefit	4.6%	4.6%	4.6%
Non-deductible items	(0.1)%	(0.2)%	(0.3)%
Change in valuation allowance	(3.8)%	(40.0)%	(39.9)%
Loss in tax attributes due to change in control	(35.5)%	0.0%	0.0%
Other	0.8%	1.6%	1.6%
Income tax provisions	0.0%	0.0%	0.0%

6. 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 $508,000, $544,000 and $459,000 for the years ended March 31, 2004, 2003 and 2002, respectively.

The Company is not obligated under any postretirement benefit plan.

7. RELATED PARTIES

The Company s chairman and chief executive officer, Mr. Samuel 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, Proteinix Corporation and Integrated Chemical Synthesizers, Inc. The Company s president and chief operating officer, Dr. Richard 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, $1.0 million and $1.3 million for the years ended March 31, 2004, 2003 and 2002, respectively, which reduced certain operating costs and expenses for the respective periods. 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. The affiliated companies had prepaid approximately $12,000 under the shared services arrangements at March 31, 2004, and the amount due from affiliated companies under the shared services arrangements was approximately $200,000 at March 31, 2003. All such balances were settled subsequent to each respective year-end.

Since 1995, the Company has engaged the law firm of Wilmer, Cutler & Pickering to provide legal services. Jennifer M. Drogula, who became the daughter-in-law of the Company s Chief Executive Officer in March 2002, is a partner of that law firm. In addition, Mr. Richard Cass, one of IGEN s directors, was formerly a partner of the firm. The Company recorded approximately $300,000, $100,000 and $400,000 in legal fees with the law firm for the years ended March 31, 2004, 2003 and 2002, respectively.

In addition, the Company has engaged the law firm of Hale & Dorr LLP to provide legal services. 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 $100,000 in legal fees with that firm during each of the fiscal years ended March 31, 2004 and 2003.

8. COMMITMENTS

The Company leased office, laboratory and manufacturing facilities pursuant to operating leases expiring at various times from fiscal 2005 through fiscal 2010. Rent expense for these operating leases totaled approximately $2.9 million, $2.9 million and $2.6 million for the years ended March 31, 2004, 2003 and 2002, respectively.

At March 31, 2004, the future minimum operating lease payments are as follows (in thousands):

	BioVeris and Wholly-Owned Subsidiaries
2005	$ 3,181
2006	3,164
2007	3,241
2008	3,338
2009 and thereafter	5,728
Total	$18,652

MSD had no future operating lease payments at March 31, 2004.

9. LITIGATION

In June 2004, the Audit Committee of the Company s Board of Directors commenced an investigation of MSD that was prompted by the discovery of a series of transactions undertaken by MSD involving the actual or proposed purchase by MSD of residential real property and luxury automobiles having an aggregate cost of approximately $7 million. The transactions were entered into by MSD upon Jacob Wohlstadter s sole approval and without the Company s knowledge.

On June 15, 2004, the Company filed an action in the Court of Chancery of the State of Delaware (Court) against Jacob Wohlstadter, MSD and MST, seeking Court confirmation that the Company remain entitled to designate one of the two members of the MSD Board of Managers, and asking the Court to enter an order, pending the outcome of the litigation, prohibiting MSD from taking any actions outside the ordinary course of MSD s business without providing prior notice to the Company. On June 17, 2004, the Court ordered that, pending the Court s final determination of the lawsuit, the Company s representative on the MSD Board of Managers was to remain on the MSD Board of Managers and that MSD was not to engage in any transaction outside the ordinary course of business which had a value in excess of $10,000 without the approval of both members of the MSD Board of Managers. Also on June 15, 2004, the Company submitted a formal demand to MSD requesting the right to examine certain books and records of MSD to aid the Audit Committee in its investigation and to permit the Company to value its interest in MSD. Beginning late

June, MSD permitted the Company to examine the requested books and records.

On June 17, 2004, MSD received $2.9 million from Jacob Wohlstadter as consideration for the proposed sale by MSD to Jacob Wohlstadter of real property and automobiles, pending approval by the Board of Managers. Jacob Wohlstadter also assumed MSD s purchase obligations with respect to a prospective real property purchase in the approximate amount of $4.1 million.

Also on June 17, 2004, the Company was informed by the staff of the Securities and Exchange Commission that it had commenced an informal inquiry as to certain issues relating to MSD.

On July 6, 2004, the Company entered into an agreement with MSD, MST and Jacob Wohlstadter pursuant to which it was agreed that the lawsuit filed on June 15, 2004 would be stayed, that the parties would not file new litigation against each other, and that the valuation process in connection with MST s and MSD s right to purchase the Company s interest in MSD would be stayed. This stay agreement was intended to permit the parties to engage in substantive negotiations to resolve the disputed matters and in order to permit the Company to finalize its Form 10-K for the fiscal year ended March 31, 2004. This stay agreement terminated automatically on July 13, 2004 because MSD s representation letters to the auditors of MSD were not executed.

Because the Company is required to consolidate the financial information of MSD pursuant to FASB Interpretation No. 46, which it adopted as of March 31, 2004, the Company requires the audited financial statements of MSD to complete its Form 10-K. The Company was not able to file its Form 10-K on a timely basis because the MSD financial statements were not available and because it was unable to conclude on the appropriate accounting for MSD.

On July 14, 2004, the Company filed a second action with the Court against MSD, MST and Jacob Wohlstadter. The action alleged, among other things, breach of fiduciary duty and contract, and sought relief including the dissolution of MSD and the appointment of a liquidating trustee.

Also in July 2004, the Audit Committee retained an independent special counsel to investigate whether the Company s management had any prior knowledge of the real property and automobile transactions of MSD described above. This special counsel reported to the Audit Committee that there was no evidence that any member of the Company s management knew of the MSD transactions at issue before they occurred.

On July 16, 2004, the Company received a letter from the staff of the Nasdaq Listing Qualifications Department notifying it that its common stock was subject to delisting from The Nasdaq Stock Market, Inc. because it had not yet filed its Form 10-K for the period ending March 31, 2004. In accordance with applicable NASD Marketplace Rules, the Company requested a hearing to review the Nasdaq staff determination before a Nasdaq Listing Qualifications Panel. As a result of such request, the delisting of the Company s stock was automatically stayed.

On July 19, 2004, all members of the Board of Directors met to review the MSD litigation and related issues. As a result of this review, the Board of Directors, with all members participating, unanimously approved a resolution that delegated to the Joint Venture Oversight Committee, or JVOC, the power and authority to (i) initiate, review, evaluate and determine the course of action the Company should pursue with respect to the pending litigation and any additional litigation against MSD, (ii) communicate and negotiate the terms of any proposed settlement of such litigation and any other matters with respect to MSD, and (iii) otherwise deal with MSD in a manner the JVOC deemed to be in the best interests of the Company and its stockholders. The resolution also appointed Messrs. Quinn and Crowley as additional members of the JVOC, resulting in the JVOC consisting of all five independent directors, and provided that action of the JVOC should be by unanimous approval of its members. The resolution also directed the JVOC to consult with the Company s management and members of the Board who are not on the JVOC regarding the MSD matters. In addition, by unanimous vote of the five independent directors without the participation of Messrs. Wohlstadter and Massey, the Board of Directors approved a resolution directing the JVOC to pursue negotiations to settle the litigation and other outstanding disputes with MSD, MST and Jacob Wohlstadter and setting forth general terms that would be acceptable for such a settlement.

Between July 19, 2004 and August 3, 2004, there were meetings, telephone conferences and other communications among representatives of the JVOC, MSD, MST and Jacob Wohlstadter to discuss the terms of a settlement. On July 21, 2004, the Company entered into an agreement with MSD, MST and Jacob Wohlstadter to stay the litigation

during these negotiations.

On August 3, 2004, the JVOC unanimously approved a draft settlement agreement and on August 12, 2004 the parties entered into the settlement agreement. Under the settlement, the parties agreed to the following:

All proceedings relating to the two lawsuits against MSD, MST and Jacob Wohlstadter will be suspended and the parties will file with the Court stipulations dismissing the lawsuits with prejudice.

Except for claims to enforce the terms of the settlement and certain of the parties indemnity and property rights, all claims the Company may have against MSD, MST and Jacob Wohlstadter or any of their affiliates are fully, finally and forever, dismissed and released with prejudice by the Company, and all claims MSD, MST and Jacob Wohlstadter may have against the Company or any of its affiliates are fully, finally and forever, dismissed and released with prejudice by them.

MSD or MST will purchase, and the Company will sell, the company s interests in MSD pursuant to the buyout process set forth in the MSD joint venture agreement, irrespective of the ultimate purchase price. The parties agreed to certain terms and procedures to determine the purchase price for the buyout, which will be paid over time from a percentage of net sales of MSD or proceeds of certain financings of MSD. MSD is required to provide written reports to us within 60 days after the end of each fiscal quarter stating its aggregate net sales (as defined in the MSD agreement) and the net proceeds, if any, realized by MSD during such quarter from the sale of MSD debt or equity securities in any third party financings (as defined in the MSD agreement). The Company also has the right to conduct an audit of such net sales or net proceeds, which will be the Company s sole and exclusive remedy for resolving disputes as to the appropriate amount of payments.

Until the second anniversary of the purchase of the Company s interests, unless certain advance notice and approval requirements are met, MSD will not purchase certain assets defined as real property that is used or contemplated to be used primarily for residential purposes, any automobile with a value, at the time of purchase, equal to or in excess of $75,000, or any airplane. MSD may cure any alleged failure to comply with this restriction if it exchanges, contributes, disposes of or otherwise transfers the asset and receives consideration in return equal to the full net purchase price of such asset, and in no event is the Company permitted to seek injunctive or declaratory relief.

In consideration for the prior receipt by MSD of approximately $2.9 million from Jacob Wohlstadter, MSD will transfer certain real property and automobiles and MSD s limited liability company interests in MSVE, LLC and MS RE, LLC to Jacob Wohlstadter or an entity or entities wholly owned by Jacob Wohlstadter. Jacob Wohlstadter also assumed MSD s obligation to purchase another residential property for $4.1 million.

The Company s representative on the MSD Board of Managers will resign and the Company will execute an amendment to the MSD agreements to change the composition of the MSD Board of Managers to one person designated by MST.

MSD provided the representation letters requested by its and the Company s auditors in connection with MSD s financial statements for the year ended December 31, 2003, concurrently with the execution of the settlement, and subsequently provided to the Company a copy of its audited financial statements for the year ended December 31, 2003. In addition, until such time as the Company is no longer required to consolidate or include the unaudited quarterly or audited annual financial results of MSD in its filings with the Securities and Exchange Commission, MSD will deliver to the Company copies of its unaudited and audited financial statements on a timely basis.

The Company will pay the fees of MSD s independent auditor in connection with the audit of MSD and will indemnify MSD, MST and Jacob Wohlstadter and their respective directors, officers, employees and agents for any losses, costs, fees and expenses arising out of or related in any way to past, current or future audits of MSD, the preparation of MSD financial statements requested by the Company, and with respect to regulatory or legal proceedings and investigations resulting from or related to the fact that the Company is a public company. The Company is not required to indemnify MSD for acts either resulting in a criminal conviction or finally adjudged by a court of competent jurisdiction to constitute fraud or intentional misrepresentations.

The Company pay MSD the net amount of $3.0 million in full and complete satisfaction of all amounts that Jacob Wohlstadter claimed the Company owed MSD pursuant to the various MSD agreements, including amounts owed by the Company pursuant to the license agreement between it and MSD and MST, the outstanding dispute regarding unsatisfied committed funding obligations and the outstanding dispute regarding the payment of certain legal fees and expenses incurred by MSD in connection with the settlement of litigation involving IGEN and Roche. The Company s $3.0 million payment is net of a $2.0 million credit, which represents a non-refundable pre-payment by MSD to the Company for future amounts payable by MSD to it pursuant to the buyout of the Company s interest in MSD. The amount of the pre-payment credit deemed outstanding from time to time shall bear simple interest (cumulated, not compounded) at the fixed annual rate of 0.5% over the prime rate in effect on the date that MSD or MST, as the case may be, purchases the Company s interests in MSD. The amount of the prepayment credit that is deemed outstanding is the total amount, including accrued interest, reduced from time to time by the amount due and payable to us pursuant to the buyout of the Company s interest in MSD. No further cash payments will be payable by MSD to the Company pursuant to the buyout until the $2.0 million prepayment credit, including accrued interest, is no longer deemed outstanding. A total of $5.0 million is to be treated as a Class C capital contribution by the Company to MSD. There is no assurance that the Company will be able to realize the value of this additional contribution.

MSD s rent for the lease of certain facilities and related equipment from the Company (including laboratory facilities located in its corporate headquarters) pursuant to the terms of the existing sublease agreements with MSD, for the period from March 1, 2004 through August 31, 2005, will be added to the price payable to the Company for the purchase of its interest in MSD, in lieu of current payments.

In accordance with the terms of the existing MSD agreements, subject to certain exceptions, the Company consented to the sublicensing by MSD of the licenses granted pursuant to the IGEN/MSD license agreement to any affiliate of MSD. Any such sublicensee is required to, among other things, make royalty payments to the Company in accordance with the IGEN/MSD license agreement.

The Company is involved, from time to time, in various routine legal proceedings arising out of the normal and ordinary operation of its business, which the Company does not anticipate will have a material adverse impact on its business, financial condition, results of operations or cash flows. However, the Company may in the future be involved in litigation relating to its business, products or intellectual property, which could adversely affect its prospects or impair its financial resources.

10. SEGMENT INFORMATION

The Company operates in one business segment. It is engaged in the development, manufacturing and marketing of diagnostic products for the detection and measurement of biological and chemical substances. Product sales by region are as follows:

	Years Ended March 31,		
	2004	2003	2002
	(In thousands)		
United States	$13,585	$11,993	$ 8,004
United Kingdom	1,607	1,823	1,789
All other foreign	3,549	2,671	2,284

Total foreign	5,156	4,494	4,073
Total	$18,741	$16,487	$12,077

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

Product sales by market are as follows:

	Year Ended March 31,		
	2004	2003	2002
		(in thousands)	
Life Science	$12,635	$11,895	$10,940
Biodefense	6,106	4,592	1,137
Total	$18,741	$16,487	$12,077

11. VALUATION AND QUALIFYING ACCOUNTS

The following tables set forth activity in the Company s valuation and qualifying accounts (in thousands):

For the years Ended March 31,	Balance at Beginning of Period	Provisions Recorded	Write-offs	Balance at End of Period
Allowance for doubtful accounts				
2002	$ 30	$ 60	$ (1)	$ 89
2003	89	135	(76)	148
2004	148	60		208
Inventory reserve				
2002	$	$1,528	$(1,205)	$ 323
2003	323	102	(112)	313
2004	313	402		715
Income tax valuation				
2002	1,036	2,442		3,478
2003	3,478	312		3,790
2004	3,790	3,444		7,234

MSD did not have an allowance for doubtful accounts or an income tax valuation account at March 31, 2004.

12. QUARTERLY OPERATING RESULTS (Unaudited)

For the years ended March 31,	First	Second	Third	Fourth

	(In thousands, except per share data)			
2004				
Revenue	$ 5,073	$ 5,951	$ 3,784	$ 5,148
Loss from operations(1)	(7,368)	(6,817)	(12,367)	(64,118)
Net loss (2)	(12,518)	(11,299)	(15,984)	(53,352)
Net loss per common share (3)	(0.47)	(0.42)	(0.60)	(2.00)
2003				
Revenue	$ 3,130	$ 4,403	$ 5,529	$ 4,712
Loss from operations	(8,630)	(8,924)	(8,008)	(7,888)
Net loss (2)	(12,924)	(13,926)	(11,313)	(12,731)
Net loss per common share (3)	(0.48)	(0.52)	(0.42)	(0.48)
2002				
Revenue	$ 2,429	$ 3,366	$ 4,144	$ 3,304
Loss from operations (4)	(10,705)	(8,639)	(7,902)	(10,918)
Net loss (2)	(10,712)	(11,877)	(11,669)	(14,892)
Net loss per common share (3)	(0.40)	(0.44)	(0.44)	(0.56)

(1) Operating costs and expenses for the fourth quarter includes certain nonrecurring costs of $75.7 million in connection with the merger and related transactions, which consisted of an allocated one-time noncash compensation charge of $38.8 million associated with the cancellation of IGEN stock options and the payment of merger consideration of each share of IGEN common stock covered by such stock options, a $33.7 million charge related to an MSD payment, as well as accounting, legal, printing and registration fees.

(2) See Note 4 of the consolidated financial statements for a description of the recording of losses under the equity method of accounting related to the MSD investment.

(3) Based on the number of shares of the Company common stock outstanding upon completion of the merger and related transactions.

(4) 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 cost of these modules had previously been recorded as a fixed asset and depreciated over their estimated useful life, and should have been recorded as product costs upon shipment and sale. The Company determined that the adjustment did not have a material impact on fiscal 2002 or prior period financial statements and accordingly, did not revise such financial statements. Of the $1.1 million adjustment, $200,000 is related to fiscal 2002 and the remaining $900,000 is related to prior fiscal years (approximately $400,000 and $500,000 in fiscal 2001 and 2000, respectively).

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 the effects of rounding for each period.

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

As reported on our Form 8-K filed on March 11, 2004, we changed our principal accountant from Deloitte & Touche LLP to PricewaterhouseCoopers LLP on March 11, 2004.

ITEM 9A. CONTROLS AND PROCEDURES.

We, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this Form 10-K. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely making known to them material information relating to our company required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE COMPANY.

The following table sets forth the names and certain other information regarding our directors and executive officers at July 30, 2004. Each officer serves without a set term.

Name	Age	Position	Director Since	Expiration of Term
Samuel J. Wohlstadter[3]	62	Chairman, Chief Executive Officer and Director	2003	2006
Richard J. Massey[3]	57	President, Chief Operating Officer and Director	2003	2004
William J. Crowley Jr.[1,4,5]	58	Director	2004	2006
John Quinn[2,4,5]	57	Director	2004	2004
Anthony Rees[1,2,4,5]	60	Director	2003	2005
Robert Salsmans[1,4,5]	59	Director	2003	2004
Joop Sistermans[1,4,5]	61	Director	2003	2005
George V. Migausky	49	Vice President, Chief Financial Officer, Secretary		

1 Member of Audit Committee

2 Member of Executive Compensation Committee

3 Member of Non-Officer Stock Option Committee

4. Member of Joint Venture Oversight Committee

5. Member of Governance and Nominating Committee

Our Board of Directors has determined that each of William J. Crowley Jr., Robert Salsmans and Joop Sistermans qualifies as an audit committee financial expert as defined in Item 401 of Regulation S-K and is independent as defined in Item 7(d)(3)(iv) of Schedule 14A and the listing requirements of The NASDAQ National Market.

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

Samuel J. Wohlstadter is our Chairman of the Board and Chief Executive Officer. He was one of the founders of IGEN and, from IGEN s formation in 1982 until its merger with Roche, he was IGEN s Chairman of the Board and Chief Executive Officer. 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, 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, a drug discovery company, which commenced operations in 1994.

Richard J. Massey, Ph.D. is our President and Chief Operating Officer. He was one of the founders of IGEN and, from February 1992 until IGEN s merger with Roche, he was IGEN s President and Chief Operating Officer. He served as Senior Vice President of IGEN from 1985 to 1992. From 1981 until he joined IGEN 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 Frederick Cancer Research Center/National Cancer Institute.

William J. Crowley Jr. has served as director since May 2004. He is a certified public accountant and is an independent business advisor to companies. Prior to his retirement in 2002, Mr. Crowley had a thirty-two year career with Arthur Andersen LLP, most recently serving for 7 years as Managing Partner of the Baltimore, Maryland office. Mr. Crowley also is a director for Provident Bankshares Corporation, a financial institution based in Baltimore, Maryland, a position he has held since June 2003.

John Quinn has served as a director since May 2004. He is Group Vice President of the elastomers and performance additives business of PolyOne Corporation, an international polymer services company headquartered in Cleveland, Ohio, a position he has held since 2000. Previously, Mr. Quinn was President of M.A. Hanna Company from 1988 until its merger with the Geon Company in 2000, which resulted in the formation of PolyOne Corporation. Mr. Quinn was with the General Electric Company, Plastics Group, from 1993 to 1998, most recently as General Manager of the Noryl Resins Business.

Anthony Rees, D. Phil. has served as a director since September 2003. Prior to the completion of the merger between IGEN and Roche, he served as a director of IGEN since 2000. He serves as Chief Executive Officer of MIP Technologies in Lund, Sweden, a private biotechnology company founded in 2000. Previously, Professor Rees was Director of Science at Syntem, a biopharmaceutical company, a position he held from January 2000 until August 2003. He continues as a member of the Syntem Scientific Advisory Board. From 1997 to the end of 1999, he served as a non-executive director of Syntem. Professor Rees has held faculty positions at the University of Oxford from 1980 to 1990 and the University of Bath where, from 1990 to 1993, he was Head of the Biochemistry Department and from 1993 to 1997 he was Head of the School of Biology and Biochemistry. He now holds an Emeritus Professorship. In 1989, he co-founded and in 1994, he took public Oxford Molecular PLC, a British software company. Professor Rees received his doctoral degree from Oxford University.

Robert R. Salsmans has served as a director since September 2003. Prior to the completion of the merger between IGEN and Roche, he served as a director of IGEN since 1995. From November 2001 to August 2003, he was President and Chief Executive Officer of Diosynth RTP, Inc., the United States subsidiary of Diosynth, which is 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 had 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 has served as a director since September 2003. Prior to the completion of the merger between IGEN and Roche, he served as a director of IGEN since 1999. He is also 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 is also 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 has served on the Boards of Directors of United Biomedical Inc., Hauppauge, NY since 1999, of the Bio Primate Research Centre, Rijswijk, the Netherlands from 1997 to 2004, and of Keygene N.V. in Wageningen, the Netherlands since 2002. 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.

George V. Migausky has served as our Vice President , Chief Financial Officer and Secretary since September 2003. From 1985 until the completion of IGEN s merger with Roche, he was IGEN s Vice President and Chief Financial Officer. Between 1985 and 1992, in addition to serving as IGEN s Chief Financial Officer on a part-time basis, Mr. Migausky also served as financial advisor to several other privately held companies. Prior to joining IGEN 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.

Section 16(a) Beneficial Ownership Reporting Compliance

Under Section 16(a) of the Securities Exchange Act of 1934, our directors, our officers and beneficial holders of more than 10% of our common stock are required to file reports of ownership and changes in ownership with the Securities and Exchange Commission. Based upon a review of Section 16(a) filings furnished to us in the fiscal year ended March 31, 2004, we believe all applicable Section 16(a) filing requirements were met except that Joop Sistermans failed to timely file one Form 4 and each of William J. Crowley Jr. and John Quinn failed to timely file a Form 3. The late Form 4 was filed by Joop Sistermans on February 23, 2004, disclosing that on February 13, 2004, he acquired 20,000 shares of our common stock as a result of the cancellation of his IGEN stock options in connection with the merger and related transactions. Each of William J. Crowley Jr. and John Quinn filed a late Form 3 on August 12, 2004 disclosing that William J. Crowley Jr. and John Quinn, respectively, were appointed to our Board of Directors on May 24, 2004.

Corporate Code of Conduct and Business Ethics

We have adopted a Corporate Code of Conduct and Business Ethics that meets the requirements of a code of ethics as defined by Item 406 of Regulation S-K under the Securities Act of 1933, as amended, and a code of conduct as defined by the qualitative listing requirements of The Nasdaq National Market. The Corporate Code of Conduct and Business Ethics applies to all of our directors, officers and employees, including our Chief Executive Officer, Chief Financial Officer, Principal Accounting Officer and Controller, and persons performing similar functions. A current copy of our Corporate Code of Conduct and Business Ethics is attached as an exhibit to this Form 10-K and may also be obtained by any person, without charge, upon request directed to: BioVeris Corporation, Attention: Investor Relations, 16020 Industrial Drive, Gaithersburg, Maryland 20877.

ITEM 11. EXECUTIVE COMPENSATION.

Compensation of Directors

The following information relates to our compensation and reimbursement practices during fiscal 2004 for directors who were not our officers or employees. In fiscal 2004, the aggregate compensation paid to non-employee directors (consisting of all directors other than Mr. Wohlstadter and Dr. Massey) was $59,000. In fiscal 2004, each non-employee director:

- received an annual retainer of $10,000 and an attendance fee of $1,000 for each meeting of the board of directors that he attended;

- that served on the JVOC or the audit committee received an additional annual retainer of $10,000 plus an attendance fee of $1,000 for each meeting of such committee he attended; and

that served on the executive compensation committee received an additional annual retainer of $5,000 plus an attendance fee of $1,000 for each meeting of the executive compensation committee he attended.

We maintain a policy for reimbursing all expenses incurred by members of the Board of Directors in connection with attendance at Board of Directors meetings.

Under our 2003 stock incentive plan, on the day following each annual meeting of stockholders, each non-employee director shall be entitled to receive a grant of options to purchase 4,000 shares of our common stock and any person who is appointed or elected as a non-employee director at any other time shall be entitled to receive an option to purchase 4,000 shares of our common stock on the date of such appointment or election. In addition, as of February 13, 2004, the date the merger between IGEN and Roche was completed, each non-employee director who was serving at the time became entitled to receive an option to purchase 4,000 shares of our common stock. Accordingly, in August 2004, we granted an option to purchase 4,000 shares of our common stock to each of Joop Sistermans, Robert Salsmans, Anthony Rees, William J. Crowley Jr. and John Quinn pursuant to our 2003 stock incentive plan. Each grant has an exercise price equal to fair market value on the date the non-employee director became entitled to receive such grant and will vest in full on the first anniversary of the grant date. We did not grant any options to our non-employee directors under our 2003 stock incentive plan in fiscal 2004.

Compensation of Executive Officers

We became an independent, publicly traded company on February 13, 2004 upon completion of the merger and related transactions. Prior to such date, the assets and business of our company were owned by IGEN. Our consolidated statements of operations include all costs attributable to our business during the period we were owned by IGEN, including an allocated share of general and administrative salaries. The following table sets forth certain information regarding the compensation we and IGEN paid to its executive officers in fiscal 2004, including amounts paid by IGEN and allocated to us. The current annual salary we pay to Samuel Wohlstadter, Richard Massey and George Migausky is $426,000, $344,000 and $241,000, respectively.

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Underlying Options (# shares)	All Other Compensation
Samuel J. Wohlstadter Chairman and Chief Executive Officer[4]	2004	$422,500	$1,278,000[5]		$1,584[1]
Richard J. Massey, Ph.D. President and Chief Operating Officer	2004	$341,083	$ 450,000[5]		$1,892[2]
George V. Migausky Vice President and Chief Financial Officer	2004	$238,958	$ 450,000[5]		$ 963[3]

(1) Consists of life insurance premiums paid in the amount of $1584

(2) Consists of 401(k) match amount of $860 and annual life insurance premiums paid in the amount of $1032.

(3) Consists of 401(k) match amount of $603 and annual life insurance premiums paid in the amount of $360.

(4) Excludes annual salary of $21,000 paid to Nadine Wohlstadter, the wife of Samuel J. Wohlstadter, who is employed full-time by us as an Executive Coordinator.

(5) Such amount represents the transaction bonus payment received by the officer from IGEN on February 13, 2004 in his capacity as an officer of IGEN in connection with the merger and related transactions.

We have not granted options to our executive officers under our 2003 stock incentive plan.

Employment Agreements, Termination of Employment and Change in Control Arrangements

We do not have an employment agreement with any of our named executive officers. We have a termination protection program, the purpose of which is to encourage the named executive officers and other key employees who participate in the program to continue as employees in the event of a change of control of our company, as defined in the termination protection program. The termination protection program provides that in the event a covered employee s employment is terminated without cause or the employee resigns for good reason within 30 months following a change of control of our company, or a covered employee s employment is terminated prior to a change of control at the request of a party involved in such change of control or otherwise in connection with or in anticipation of a change of control , then the employee shall be entitled to receive a cash payment equal to 1.5 to 3 times the sum of the employee s annual salary plus bonus (3 times in the case of the named executive officers). Subject to certain exceptions, good reason means, for purposes of the termination protection program:

a decrease (or failure to increase in accordance with the terms of any employment contract) the covered employee s base salary or bonus opportunity;

a diminution in the aggregate employee benefits and perquisites provided to the covered employee;

a diminution in the covered employee s title, reporting relationship, duties or responsibilities;

relocation of the covered employee s, primary office more than 35 miles from its current location; or

the failure of our successor to explicitly assume the termination protection program and our obligations thereunder.

The termination protection program also provides that covered employees are entitled to continued welfare and pension benefits for up to 18 months (or in the case of the named executive officers, for up to 36 months (or life, with respect to medical and dental benefits and an annual comprehensive physical)). In addition, the termination protection program provides reimbursement for outplacement services and will provide a gross-up for any parachute excise tax imposed on payments made under the termination protection program, and for the advancement of costs and expenses incurred by the employee related to the termination protection program.

Compensation Committee Interlocks and Insider Participation

From September 2003 to May 2004, Joop Sistermans and Robert Salsmans served as members of our Executive Compensation Committee. Since May 2004, John Quinn and Anthony Rees have been serving as members of our Executive Compensation Committee. All members of the Executive Compensation Committee have been and are outside directors and none of our directors or executive officers serves on the compensation committee or the board of directors of any company for which Messrs. Salsmans, Sistermans, Quinn or Rees serves as an executive officer or director.

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

The following table sets forth, as of July 28, 2004 (except as otherwise indicated in the footnote below), certain information regarding the ownership of our common stock of: (i) each current director; (ii) each of the named executive officers; (iii) each person known by us to be the beneficial owner of more than 5% of our outstanding common stock; and (iv) all of our executive officers and directors as a group.

Name[1]	Number of Shares	Percent of Total
Samuel J. and Nadine Wohlstadter[2]	4,765,437	17.80%
Richard J. Massey, Ph.D.[3]	1,122,375	4.20%
George V. Migausky[4]	145,065	*
Robert R. Salsmans	20,000	*
Joop Sistermans	20,000	*
Anthony Rees	23,100	*
William J. Crowley, Jr.		
John Quinn		
Columbia Wanger Asset Management, L.P.[5]	1,519,900	5.69%
All directors and executive officers as a group (7 persons)	7,615,877	27.69%

* Less than 1%

(1) This table is based upon information supplied by officers, directors and principal stockholders. Unless otherwise indicated in the notes to this table and subject to the community property laws where applicable, each of the stockholders named in this table has sole voting and investment power with respect to the shares shown as beneficially owned by him.

(2) Samuel J. and Nadine Wohlstadter s address is: c/o BioVeris Corporation, 16020 Industrial Drive, Gaithersburg, MD 20877. Does not include shares held by Mr. Wohlstadter s adult children.

(3) Richard J. Massey s address is: c/o BioVeris Corporation, 16020 Industrial Drive, Gaithersburg, MD 20877.

(4) Includes 4,620 shares held by Mr. Migausky s children.

(5) Information as to the holding of Columbia Wanger Asset Management, L.P. is as of June 30, 2004 and is based on information

provided by a third party market data provider. According to the SEC filings of Columbia Wanger Asset Management, L.P., its business address is 227 W. Monroe Street, Suite 3000, Chicago, IL 60606.

For certain information with respect to our 2003 stock incentive plan, see ITEM 5 Market for Company s Common Stock and Related Stockholder Matters 2003 Stock Incentive Plan and ITEM 8 Consolidated Financial Statements Notes to Consolidated Financial Statements Note 2 and ITEM 11 Executive Compensation Compensation of Directors.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

MSD and the MSD Agreements

General

MSD is a joint venture formed by IGEN and MST in 1995. MST is a company established and wholly-owned by Mr. Jacob Wohlstadter, a son of our chief executive officer. Mr. Jacob Wohlstadter is the president and chief executive officer of MSD.

MSD was formed to develop, manufacture, market and sell products utilizing a combination of MST s multi-array technology together with our ECL technology. MSD s instrument systems include the Sector HTS and the Sector PR. 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 its own reagents, assays and plates that are used on these systems. During fiscal 2004, MSD had product sales of $8.4 million and a net loss of $19.9 million.

In August 2001, IGEN amended the MSD joint venture agreement, the MSD limited liability company agreement and certain license and other agreements with MSD and MST to continue the MSD joint venture and entered into various related agreements, including employment and consulting agreements with Mr. Jacob Wohlstadter. These agreements are collectively referred to in this Form 10-K as the MSD agreements. An independent committee of the IGEN board of directors, with the advice of independent advisors and counsel, negotiated and approved the MSD agreements.

As part of the merger and related transactions, IGEN transferred its equity interest in MSD to us and assigned the MSD agreements to us. On February 13, 2004, we replaced IGEN as a member of MSD. Pursuant to the agreements executed in connection with the merger and related transactions, the MSD joint venture agreement expired upon the completion of the merger on February 13, 2004. However, the MSD limited liability company agreement continued (and we remain as a member of MSD) and many provisions the MSD joint venture agreement survived its expiration. In addition, certain of the other MSD agreements, including certain licenses and other arrangements with MSD, MST and Mr. Jacob Wohlstadter assigned to us by IGEN continue indefinitely in accordance with their terms.

In August 2004, an independent committee of our board of directors, with the advice of independent counsel, negotiated and approved an agreement with MSD, MST and Jacob Wohlstadter to settle pending litigation and other disputes, pursuant to which MSD or MST agreed to purchase our interest in MSD. We also agreed to further amendments to the MSD limited liability company agreement and certain of the other MSD agreements that continue to be in effect. For a more detailed discussion of the settlement, see ITEM 3 Legal Proceedings .

Equity interest and capital contributions

We hold a 31% voting equity interest in MSD. MST is the only other member of MSD and owns the remaining 69% voting equity interest. We also hold non-voting interests that entitle us to receive a preferred return on substantially all of our capital contributions. As of the completion date of the buyout by MSD or MST of our interest in MSD as described below, we will no longer hold these interests and will be entitled to receive only the purchase price in the buyout.

Prior to the settlement, we had a right to appoint one of two members of MSD s board of managers. Dr. Richard Massey, our president and chief operating officer, served as our representative on the MSD board of managers and also served as the treasurer and secretary of MSD. Dr. Massey received no compensation from MSD or us for serving as the treasurer and secretary of MSD. Pursuant to the settlement, Dr. Richard Massey has resigned and we executed an amendment to the MSD agreements to change the composition of the MSD board of managers to one person designated by MSD. The member of the MSD board of managers designated by MSD is Mr. Jacob Wohlstadter. Neither Dr. Massey nor our other executive officers or directors have any ownership interest in MST or MSD, other than through ownership of interests in us and other than the series B preferred stock purchased by Mr. Samuel Wohlstadter. Mr. Samuel Wohlstadter and Mrs. Nadine Wohlstadter disclaim any ownership interest in MST or MSD as a result of Mr. Jacob Wohlstadter s ownership interest in those entities.

During the years ended March 31, 2004, 2003 and 2002, the contributions we and IGEN made to MSD were $56.7 million, $20.5 million, $19.6 million, respectively. The contribution to MSD in fiscal 2004 included a capital contribution of $37.5 million we made to MSD on February 17, 2004 in connection with the merger and related transactions. Of the $37.5 million, Mr. Samuel Wohlstadter funded $7.5 million through the purchase of shares of our series B preferred stock that economically mirror our class C interests in MSD. In August 2004, we made a capital contribution of $5 million as part of the settlement, of which $3 million was in cash and $2 million was in the form of a credit against payment of the purchase price for the buyout by MSD or MST of our interest in MSD. There were no other contributions in fiscal 2005 through the date hereof and we do not expect to make any further capital contributions to MSD.

During the years ended March 31, 2004, 2003, and 2002, we recorded $19.2 million, $17.6 million and $13.3 million ($10.9 million as equity in loss of joint venture and $2.4 as research and development expense),

respectively, as equity in loss of joint venture. Our investment in affiliate totaled $9.2 million at March 31, 2003. Effective March 31, 2004, we consolidated the financial results of MSD in accordance with FIN 46. FIN 46 provides guidance on variable interest entities such as the MSD joint venture and the framework through which an enterprise assesses consolidation of a variable interest entity. We adopted FIN 46 as of March 31, 2004 and have determined that MSD qualifies as a variable interest entity. See ITEM 8 Consolidated Financial Statements Notes to Consolidated Financial Statements Note 4 Meso Scale Diagnostics Joint Venture for a discussion of consolidation accounting of the MSD investment.

Buyout of our interest in MSD

Pursuant to the MSD joint venture agreement, MSD and MST had a joint right to purchase our entire interest in MSD upon termination or expiration of the MSD joint venture agreement at a price equal to fair market value less a discount that depended on the circumstances giving rise to termination or expiration of the agreement. The MSD joint venture agreement sets forth a valuation process for determination of the purchase price, which was to be determined before MSD or MST was required to commit to purchasing the interest. On April 29, 2004, following the expiration of the MSD joint venture agreement, MSD and MST gave notice to commence the valuation process. The valuation process was temporarily stayed in connection with the litigation we brought against MSD, MST and Jacob Wohlstadter. See ITEM 3 Legal Proceedings for a more detailed description of the stay.

Pursuant to the settlement, MST or MSD will purchase, and we will sell, our entire interest in MSD, regardless of the purchase price. As contemplated by the MSD joint venture agreement, the purchase price will be equal to fair market value of our interests less a discount factor of 7.5%. Fair market value will be determined in accordance with the valuation process set forth in the MSD joint venture agreement. In the settlement, we agreed to certain matters in connection with the valuation process, including the timetable for the appraisals. We and MSD have each appointed an appraiser and their appraisal reports are due on August 30, 2004. If the value determined by the two appraisers differs by more than 10%, a third appraiser will be appointed. The third appraiser s report will be due on or about October 15, 2004. The fair market value will equal the average of the determinations of both appraisers, if there are only two appraisers, or the average of the two closest determinations, if there are three appraisers. Once the fair market value and purchase price are determined, the purchase will occur, which date we refer to as the completion date, and we will no longer be a member of MSD.

As provided in the MSD joint venture agreement, MSD or MST will be required to pay us the outstanding purchase price plus simple (cumulated, not compounded) interest at the fixed annual rate of 0.5% over the prime rate in effect on the purchase date. The purchase price is payable over time in installments equal to the sum of 5% of MSD net sales, as determined in accordance with the MSD agreements, and 20% of the net proceeds realized by MSD from the sale of its debt or equity securities in any third-party financing after the date of the sale of our interest in MSD. As part of the settlement, we received a $2.0 million non-refundable prepayment from MSD for future amounts payable by MSD to us in respect of the purchase price in the form of a credit against amounts we agreed to pay MSD pursuant to the settlement. The amount of the prepayment credit outstanding from time to time will bear simple interest (cumulated, not compounded) at the fixed annual rate of 0.5% over the prime rate in effect on the date that MSD or MST, as the case may be, purchases our interests in MSD. The amount of the prepayment credit that is outstanding is the total amount, including accrued interest, reduced from time to time by the amount due and payable to us pursuant to the buyout of our interest in MSD. No further cash payments will be payable by MSD to us pursuant to the buyout until the $2.0 million prepayment credit, including accrued interest, is no longer deemed outstanding. In the event sufficient net sales or third-party financings do not materialize, we will not receive any additional payments from MSD or MST, as the case may be, for the purchase of our interest in MSD. As security for the payment obligation, we will hold a security interest in the interests in MSD that are being purchased. MST or MSD, as the case may be, may repay all or any part of the outstanding purchase price plus accrued interest at any time and from time to time without penalty.

Under the MSD joint venture agreement, the parties are responsible for all fees and costs of the appraiser designated by it and one-half of all fees and costs of the third appraiser, if any. Pursuant to the settlement, we

agreed to pay MSD s or MST s, as applicable, share of such fees and costs, and to add such fees and costs to the purchase price payable by MSD or MST for our interest in MSD.

MSD joint venture agreement and MSD limited liability company agreement

During the term of the MSD joint venture agreement, MSD was IGEN s and MST s exclusive means of conducting the MSD research program, as defined in the MSD agreements and which is referred to in this Form 10-K as the MSD research program. The MSD research program involves the use in diagnostic procedures, including diagnostic procedures utilizing ECL technology, of:

selection and screening methods, including high throughput screening and methods involving large numbers of determinations, in each case relating only to claimed or inventive subject matter of the patents or know-how licensed by MST to MSD;

disposable electrodes; and

multi-array diagnostic.

IGEN was obligated to refrain from developing or commercializing any products, processes or services that are related to the MSD research program in the diagnostic field, as defined for the purposes of the MSD agreements, or to MSD s research technologies as described in the MSD agreements, subject to certain exceptions. For purposes of the MSD agreements, the diagnostic field is defined to mean all diagnostic devices and procedures for the measurement or detection of identifiable substances for human clinical research, environmental, agricultural, veterinary, food testing, industrial or similar purposes. As part of the MSD joint venture agreement, MSD granted to us an exclusive, worldwide, royalty-free license to use in the diagnostic field certain defined improvements developed by MSD in the MSD research program. However, we may not make, use or sell products, processes or services that use certain defined ECL improvements granted to us by MSD if doing so would compete with MSD in the diagnostic field or use research technologies defined in the MSD agreements. Although the MSD joint venture agreement has expired, the license granted to us to use in the diagnostic field certain defined ECL improvements developed by MSD remains in effect. In addition, after we cease to be a member of MSD, MSD may require us to distribute MSD s products pursuant to a mutually agreeable distribution agreement, and we will be required to pay to MST a royalty of 3% of net sales of MSD products sold by us.

During its term, the MSD joint venture agreement limited the business of MSD to performing the MSD research program and developing, manufacturing, marketing and selling products in the diagnostic field. Because the MSD joint venture agreement has expired, this limitation on MSD s business activity no longer applies. In the settlement, the parties acknowledged that it is the current intent of MSD that it will operate and do business in technology related fields, including the healthcare field, the software field, and detection and measurement technologies. Furthermore, although the MSD joint venture agreement has expired, we remain subject to limitations on our ability to manufacture, market and sell in the diagnostic field, as defined in the MSD agreements, instruments that use an electrode to start the ECL process where the electrode is disposable, consumable or not permanently installed and MST retains sole ownership of all inventions, concepts, know-how and technology developed by MSD as well as all patent applications, patents and copyrights.

In addition, because the MSD joint venture agreement has expired, the restrictions on MSD offering employment to our employees have ceased.

Certain of our other obligations under the MSD joint venture agreement survive its termination, including the following:

to cooperate and work in good faith and use reasonable best efforts to assist MSD in securing third-party financing,

confidentiality obligations,

to make available to MSD the benefits of certain agreements with third-party licensors, suppliers, vendors, distributors and other providers,

to assign to MSD all proprietary information and intellectual property within the MSD research program or research technologies, as described in the MSD agreements, and to ensure that its employees protect such proprietary information, and

to defend and indemnify MSD against all claims arising out of the conduct of the MSD research program and to maintain liability insurance to cover the risk of liability resulting from the conduct of that program.

In addition, we are obligated under the MSD limited liability company agreement to indemnify each officer and member of the board of managers of MSD with respect to any action taken by such person during the time IGEN or we, as the case may be, was or were a member of MSD by reason of the fact that such person is or was an officer or a member of the board of managers of MSD. Under the settlement, the parties agreed that this indemnification obligation applies only to acts, events or inactions, actual or alleged, occurring on or before the completion date without regard to whether the legal proceeding or other event triggering the indemnification obligation is initiated prior to or after this date.

Prior to the exercise by MSD and MST of their right to purchase our interest in MSD, we were required to pay the expenses associated with prosecuting and maintaining the patents licensed by MST to MSD under the MSD, MST license agreement. A portion of the $3.0 million payment we made to MSD in connection with the settlement was made in full and complete satisfaction of any obligation we had in connection with such expenses.

In addition, because MSD and MST have exercised their right to purchase our interest in MSD, we are obligated under the MSD joint venture agreement to vote our interest in MSD in the manner requested by MST (subject to certain limitations), provide reasonable cooperation and provide such consents to permit MSD to raise additional capital and terminate our status as a party to the MSD/MST license agreement entered into in connection with the original formation of the joint venture.

IGEN/MSD license agreement

Under the terms of the IGEN/MSD license agreement, which is one of the MSD agreements, we granted to MSD a worldwide, perpetual, exclusive license (with certain exceptions) to our technology, including ECL technology, for use in MSD s research program. In connection with the merger and related transactions, IGEN assigned the IGEN/MSD license agreement to us. The IGEN/MSD license agreement survived the expiration of the MSD joint venture agreement and will survive the termination of our status as a member of MSD. In addition, when we cease to be a member of MSD, we will become entitled to receive quarterly royalty payments from MSD of 3% of the net sales price on all products developed and sold by MSD using the patents we received as part of the merger and related transactions. The royalty obligation will expire as the relevant patents expire.

In accordance with the terms of the MSD agreements and subject to certain exceptions, we consented to the sublicensing by MSD of the licenses granted pursuant to the IGEN/MSD license agreement to any affiliate of MSD. Any such sublicensee is required to, among other things, make royalty payments to us in accordance with the IGEN/MSD license agreement.

MSD/MST sublicense agreement

MST holds a worldwide, perpetual, non-exclusive sublicense from MSD, which is referred to in this Form 10-K as the MSD/MST sublicense agreement, to use our technology to make, use or sell products or processes applying or related to the technologies used in the MSD research program outside the diagnostic field. Whether or not we are a member of MSD, we are entitled to receive quarterly royalty payments from MST of 6% of the

net sales price on any products developed and sold by MST using the patents we received as part of the merger and related transactions. We assumed IGEN s obligation under the MSD agreements to make our technology available for sublicense by MSD to MST, and these obligations survived the expiration of the MSD joint venture agreement and will survive the termination of our or MST s status as a member of MSD. We are not, however, obligated to make available for sublicense by MSD to MST any technology or improvements to our technology developed after the expiration of the MSD joint venture agreement or the termination of our or MST s status as a member of MSD. In addition, we may terminate our participation in the MSD/MST sublicense agreement upon MSD s or MST s material breach, after notice and an opportunity to cure the breach.

Transitional services and subleases

When the MSD joint venture agreement expired, we were no longer required to provide research personnel and corporate services to MSD. We have continued, and expect that we will continue, to provide limited corporate services, consisting primarily of information technology and purchasing services support, to MSD on a transitional basis at MSD s expense. We bill MSD for these services on a periodic basis.

MSD leases certain facilities and related equipment from us (including laboratory facilities located in our corporate headquarters) pursuant to sublease agreements which remained in effect following the expiration of the joint venture agreement. The term of each sublease will expire one day prior to the expiration of the prime lease for that facility. Each sublease agreement provides that, subject to certain exceptions, we must exercise all available extension rights under the prime lease. Each of MSD and us may unilaterally terminate any or all of the subleases by providing at least 18 months prior written notice of termination. Notwithstanding the termination of any sublease, MSD may elect to remain in the subleased facility after the 18-month period expires for any period of time selected by MSD, but not longer than one day prior to the expiration of the prime lease (including any extensions to the prime lease). After a notice of termination of a sublease has been sent, MSD will be required to pay its pro rata share of all rental and other expenses we incur under the prime lease. On February 29, 2004, we elected to terminate all of the subleases effective the earlier of September 1, 2005, or the date on which the applicable prime lease terminates. As part of the settlement, MSD s rental and expense payment obligations for the period from March 1, 2004 through August 31, 2005, will be added to the purchase price of our interest in MSD in lieu of MSD making current payments. In addition, pursuant to the settlement, MSD will sublease certain warehouse space to Mr. Jacob Wohlstadter for the period from August 1, 2004 through August 31, 2005 for an upfront payment by Jacob Wohlstadter to MSD of $23,994.75.

Employment agreement

We assumed an employment agreement pursuant to which Mr. Jacob Wohlstadter is serving as the president and chief executive officer of MSD. The current term of the employment runs through November 30, 2005. The term of the employment agreement will automatically renew for a 12-month period on November 30 of each year unless either MSD or Mr. Jacob Wohlstadter gives notice of termination no later than 180 days prior to that renewal date. Most of our obligations under the employment agreement have ended, except that we remain obligated to maintain in effect directors and officers liability insurance coverage for Mr. Jacob Wohlstadter, to pay or cause MSD to pay a gross-up for any parachute excise tax that may be imposed and to indemnify Mr. Jacob Wohlstadter against certain liabilities, including liability from the MSD joint venture relating to the period of IGEN s or our involvement with MSD.

Consulting agreement

Mr. Jacob Wohlstadter has a consulting agreement with IGEN that we assumed. This consulting agreement will terminate on August 15, 2004. Pursuant to the consulting agreement, Mr. Jacob Wohlstadter is entitled to receive such fees as we and Mr. Jacob Wohlstadter agree to when consulting services are requested by us. We have no obligation to request any consulting services from Mr. Jacob Wohlstadter. We did not ask Mr. Jacob Wohlstadter to perform, nor

did he perform, any compensable consulting services during the years ended March 31, 2004 and 2003. During fiscal 2002, Mr. Jacob Wohlstadter received from IGEN $275,000 and options to purchase IGEN common stock for consulting services performed for IGEN for the period from 1995 through 2001.

Certain indemnification agreements and obligations

Mr. Jacob Wohlstadter and JW Consulting Services, L.L.C., a company established and wholly-owned by Mr. Jacob Wohlstadter, have an indemnification agreement with IGEN that we assumed. Pursuant to the indemnification agreement, we will indemnify Mr. Jacob Wohlstadter and JW Consulting Services, L.L.C. against any claims arising out of the performance or non-performance of services to or for the benefit of us.

In addition, we assumed a letter agreement dated August 15, 2001 among Jacob Wohlstadter, MSD, MST and IGEN. Pursuant to the letter agreement, IGEN agreed to fund reasonable ongoing legal fees and related charges and costs incurred by Jacob Wohlstadter, MSD and MST arising out of or related to IGEN s litigation with Roche. MSD had submitted to IGEN invoices for legal fees and expenses for the period from March 1, 2003 through September 30, 2003 of approximately $1.3 million. IGEN paid approximately $423,000 of the submitted expenses, which an independent committee of IGEN s board of directors believed was the maximum amount IGEN was obligated to pay under the letter agreement. A portion of the $3.0 million payment we made to MSD in connection with the settlement was made in full and complete satisfaction of the dispute.

We agreed under the settlement to indemnify MSD, MST and Jacob Wohlstadter and their respective directors, officers, employees and agents for any losses, costs, fees and expenses arising out of or related in any way to past, current or future audits of MSD, the preparation of MSD audited or unaudited financial statements requested by us. In addition, we agreed to indemnify MSD, MST and Jacob Wohlstadter and their respective directors, officers, employees and agents for any losses, costs, fees and expenses with respect to regulatory (Securities and Exchange Commission or otherwise) or legal proceedings and investigations resulting from or related to the fact that we are (or our predecessor, IGEN, was) an issuer of publicly traded securities. We are not required to indemnify MSD, MST or Jacob Wohlstadter for acts either resulting in a criminal conviction or finally adjudged by a court of competent jurisdiction to constitute fraud or intentional misrepresentations.

Related Companies

Our chief executive officer, Samuel 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, Proteinix Corporation and Integrated Chemical Synthesizers, Inc. Our president and chief operating officer, Richard Massey, is also a director of Hyperion and he is a less than 10% stockholder in Proteinix.

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 Hyperion, Wellstat Biologics, Wellstat Therapeutics, Proteinix and Integrated Chemical Synthesizers totaled $1.0 million, $1.0 million and $1.3 million for the years ended March 31, 2004, 2003 and 2002, respectively, which reduced certain operating costs and expenses for the respective periods. Amounts allocated to these affiliated companies are calculated and billed monthly based upon costs incurred by the us and are determined through allocation methods that include time-spent and square footage utilized. The affiliated companies had prepaid approximately $12,000 under the shared services arrangements at March 31, 2004, and the amount due from affiliated companies under the shared services arrangements was approximately $200,000 at March 31, 2003. All such balances were settled subsequent to each respective year-end.

Equity right purchase and license amendment agreement

In 1993, IGEN enacted a reorganization that included the discontinuation of its pharmaceutical development operations. As part of that reorganization, IGEN entered into an agreement with Pro-Neuron, Inc., which was renamed Wellstat Therapeutics. Under the agreement, Wellstat Therapeutics assumed contractual and financial responsibility

for IGEN s commitments, agreements and contract research programs related to the IGEN prodrug cancer program. In connection with this assumption, IGEN granted to Wellstat Therapeutics an

exclusive, worldwide and perpetual license to its patents, patent applications, know-how and trade secrets relating to the IGEN prodrug cancer program, subject to certain limitations. IGEN was entitled to receive a royalty from Wellstat Therapeutics based on net sales of products made pursuant to the license. To date, there have been no products developed under this license. At the same time, Wellstat Therapeutics granted to IGEN an exclusive, worldwide and perpetual license to its patents, patent applications, know-how and trade secrets relating to Wellstat Therapeutics s proprietary diagnostics product opportunities, subject to certain limitations, in a field that includes research, industrial and clinical diagnostic markets. Wellstat Therapeutics was entitled to receive a royalty from us based on net sales made pursuant to the license. To date, there have been no products developed under this license. In connection with the assumption of contractual and financial responsibility for IGEN s commitments, agreements and contract research programs and the grants of the licenses, Wellstat Therapeutics was paid $5 million by IGEN, which was scheduled to convert into 4.5% of the fully diluted equity of Wellstat Therapeutics on December 31, 2003. This equity right has no historic cost basis in the consolidated financial statements of IGEN.

In lieu of the conversion, on December 30, 2003, IGEN and Wellstat Therapeutics entered into an equity right purchase and license amendment agreement pursuant to which effective as of February 10, 2004:

Wellstat Therapeutics repurchased IGEN s right to receive a 4.5% equity interest in Wellstat Therapeutics;

the intellectual property licenses from IGEN to Wellstat Therapeutics and from Wellstat Therapeutics to IGEN was terminated; and

IGEN confirmed the 1993 transfer to Wellstat Therapeutics of its interest in the ProGen joint venture through which IGEN had conducted its prodrug research prior to the execution of the 1993 agreement.

In return, Wellstat Therapeutics paid IGEN $1.7 million in cash. Although these transactions were completed on February 10, 2004, certain representations, warranties and covenants under the equity right purchase and license amendment agreement survived and we have assumed the agreement in connection with the merger and related transactions. IGEN s audit committee, with the assistance of independent financial and legal advisors, negotiated and approved the agreement on behalf of IGEN.

Also in 1993, as part of the discontinuation of its pharmaceutical development operations, IGEN entered into an agreement with Proteinix. Under the agreement, Proteinix assumed contractual and financial responsibility for IGEN s commitments, agreements and contract research programs related to the IGEN Abzymes program development operations. In connection with this assumption, IGEN granted to Proteinix an exclusive, worldwide and perpetual license to its patents, patent applications, know-how and trade secrets relating to the IGEN Abzymes program, subject to certain limitations. IGEN was entitled to receive a royalty from Proteinix based on net sales of products made pursuant to the license. To date, there have been no products developed under this license. At the same time, Proteinix granted to IGEN an exclusive, worldwide and perpetual license to its patents, patent applications, know-how and trade secrets relating to Proteinix s ubiquitin fusion technology for the production of diagnostic reagents together with product opportunities, subject to certain limitations, in a field that includes research, industrial and clinical diagnostic markets. Proteinix was entitled to receive a royalty from us based on net sales made pursuant to the license. To date, there have been no products developed under this license. In connection with the assumption of contractual and financial responsibility for IGEN s commitments, agreements and contract research programs and the grants of the licenses, Proteinix was paid $3.2 million by IGEN, which was scheduled to convert into 4.5% of the fully diluted equity of Proteinix on December 31, 2003. This equity right has no historic cost basis in the consolidated financial statements of IGEN.

In lieu of the conversion, on December 30, 2003, IGEN and Proteinix entered into an equity right purchase and license amendment agreement pursuant to which effective as of February 10, 2004:

Proteinix repurchased IGEN s right to receive a 4.5% equity right in Proteinix,

the intellectual property licenses from IGEN to Proteinix and from Proteinix to IGEN were terminated, and

Proteinix purchased the intellectual property assets, including the Abzyme trademark, underlying the licenses between IGEN and Proteinix and between IGEN and Wellstat Therapeutics.

In return, Proteinix paid IGEN $50,000 in cash and granted to IGEN a fully-paid, worldwide, perpetual, royalty-free, non-exclusive license to practice all diagnostic rights in the abzyme technology embodied in the sold intellectual property. We have assumed this license in connection with the merger and related transactions. Under this license, we have limited rights to sublicense the intellectual property to strategic partners, customers, distributors and in the context of bona fide research collaborations. Although these transactions were completed on February 10, 2004, certain representations, warranties and covenants under the equity right purchase and license amendment agreement survived and we have assumed the agreement in connection with the merger and related transactions. IGEN s audit committee, with the assistance of independent financial and legal advisors, negotiated and approved the agreement on behalf of IGEN.

Transactions with Directors and Executive Officers

In connection with the exercise of employee stock options in July 2000, Mr. Samuel Wohlstadter, IGEN s chairman and chief executive officer at the time, received a loan from IGEN. The loan was 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. This loan was to be transferred to us as part of the merger and related transactions, but Mr. Wohlstadter repaid the loan in full in January 2004.

We have retained Wilmer, Cutler & Pickering to perform legal services. This law firm has been engaged by IGEN since 1995. Ms. Jennifer M. Drogula, who became the daughter-in-law of our chairman and chief executive officer in March 2002, has been a partner of the firm since January 1, 2001. In addition, Mr. Richard Cass, one of IGEN s directors, was formerly a partner of the firm. We recorded approximately $300,000, $100,000 and $400,000 in legal fees to the law firm for fiscal 2004, 2003 and 2002, respectively. Amounts due to the law firm totaled $128,000 as of March 31, 2004. There were no amounts due at March 31, 2003.

In addition, we have engaged the law firm of Hale and Dorr LLP to provide legal services. IGEN first engaged this law firm in 1994. Ms. Deborah Wohlstadter, the wife of Mr. Jacob Wohlstadter and daughter-in-law of our chairman and chief executive officer since December 2001, is a junior partner in that law firm. We recorded approximately $100,000 in legal fees paid to that firm during fiscal years ended 2004 and 2003.

Wilmer Cutler & Pickering merged with Hale and Dorr during 2004 and we expect that we will continue to retain the law firm in the future.

Limitation on the Liability of Directors and Executive Officers

Our certificate of incorporation provides that it will indemnify our directors and officers to the fullest extent permitted by Delaware law. Our certificate of incorporation also provides that we may maintain insurance, at our expense, to protect ourselves and any of our directors, officers or employees against any expense, liability or loss whether or not we would have the power to indemnify that person against such expense, liability or loss under Delaware law. 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:

any breach of the director s duty of loyalty to us or our stockholders;

acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

under section 174 of the Delaware General Corporation Law; or

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 or directors, then the liability of a director shall be eliminated or limited to the fullest extent permitted by the Delaware law.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

In addition to performing the audit of our consolidated financial statements, PricewaterhouseCoopers LLP provided various other services during fiscal 2004. The aggregate fees billed by PricewaterhouseCoopers LLP and Deloitte & Touche LLP for fiscal 2004 were as follows:

Audit Fees - The aggregate fees billed in fiscal year 2004 for professional services rendered by PricewaterhouseCoopers LLP for the audit of our annual financial statements were $107,000. The aggregate fees billed in fiscal year 2004 for professional services rendered by Deloitte & Touche LLP were $789,000, of which $627,000 related to the merger and related transactions, including review of the Company s Registration Statement on Form S-4. .

Audit-Related Fees - The aggregate fees billed in fiscal year 2004 for assurance and related services rendered by PricewaterhouseCoopers LLP and Deloitte & Touche LLP that are reasonably related to the performance of the audit or review of the financial statements and are not reported under Audit Fees above were $11,000 and $26,000, respectively. These fees relate primarily to consultative services provided regarding our application of generally accepted accounting principles.

Tax Fees - The aggregate fees billed in fiscal year 2004 by PricewaterhouseCoopers LLP and Deloitte & Touche LLP for tax compliance, tax advice and tax planning services were $0 and $75,000, respectively.

All Other Fees - The aggregate fees billed in fiscal year 2004 by PricewaterhouseCoopers LLP and Deloitte & Touche LLP for all other services were $1,000 and $0, respectively.

In addition, we reimbursed MSD for audit fees of $31,000 for fiscal 2004.

PricewaterhouseCoopers LLP did not provide any services related to financial information systems design and implementation during fiscal year 2004. The Audit Committee s policy is to pre-approve all services and fees for the independent accountants, and it has considered whether, and determined that, the provision of services described in All Other Fees, above, is consistent with maintaining PricewaterhouseCoopers LLP independence.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(a) Documents filed as part of this report

(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 the Exhibit Index immediately following the signature page of this Form 10-K.

(b) Reports on Form 8-K:

During the quarter ended March 31, 2004, we filed reports on Form 8-K with the Securities and Exchange Commission on the dates indicated below:

February 17, 2004, reporting on Item 5 Other Events and Regulation FD Disclosure and Item 7 Financial Statements and Exhibits (financial statements for the quarter ended December 31, 2003, were filed as exhibit 99.1 thereto); and

March 11, 2004, reporting on Item 4 Changes in Registrant s Certifying Accountant.

(c) Exhibits. The exhibits filed as part of this Form 10-K are listed on the Exhibit Index immediately following the signature page of 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.

SIGNATURES

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

BioVeris Corporation

August 16, 2004

By: /s/ Samuel J. Wohlstadter

Samuel J. Wohlstadter
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 the capacities and on the dates indicated.

Signature	Title	Date
/s/ Samuel J. Wohlstadter Samuel J. Wohlstadter	Chief Executive Officer (Principal Executive Officer); Director	August 16, 2004
/s/ George V. Migausky George V. Migausky	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	August 16, 2004
/s/ Richard J. Massey Richard J. Massey	President, Chief Operating Officer; Director	August 16, 2004
/s/ William J. Crowley Jr. William J. Crowley Jr.	Director	August 16, 2004
/s/ John Quinn John Quinn	Director	August 16, 2004
/s/ Anthony Rees Anthony Rees	Director	August 16, 2004
/s/ Robert Salsmans Robert Salsmans	Director	August 16, 2004
/s/ Joop Sistermans Joop Sistermans	Director	August 16, 2004

Index to Exhibits

Index to Exhibits

2.1[13]	Agreement and Plan of Merger dated July 24, 2003 among Roche Holding Ltd, 66 Acquisition Corporation II, IGEN International, Inc. and IGEN Integrated Healthcare, LLC.
3.1[9]	Certificate of Incorporation of BioVeris Corporation.
3.2[14]	Certificate of Voting Powers, Designations, Preferences and Relative, Participating, Optional and other Special Rights and Qualifications, Limitations or Restrictions of Series A Participating Cumulative Preferred Stock of BioVeris Corporation.
3.3[11]	Form of Certificate of Designation of Series B Preferred Stock of BioVeris Corporation.
3.4[9]	Bylaws of BioVeris Corporation.
4.1[14]	Rights Agreement dated January 9, 2004 between BioVeris Corporation and EquiServe Trust Company, N.A.
4.2	Form of Right Certificate for BioVeris Series A Preferred Stock. Filed as Exhibit B to the Rights Agreement filed as Exhibit 4.1 to this Form 10-K
4.3[11]	Specimen Common Stock Certificate.
4.4[11]	Specimen Series B Preferred Stock Certificate.
10.1[13]	License Agreement dated July 24, 2003 by and between IGEN International, Inc. and IGEN LS LLC.
10.2[13]	Improvements License Agreement dated July 24, 2003 by and between Roche Diagnostics GmbH and IGEN International, Inc.
10.3[13]	Covenants Not to Sue dated July 24, 2003 among IGEN Integrated Healthcare, LLC, Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC., Roche Diagnostics GmbH, Roche Holding Ltd and IGEN LS LLC.
10.4[13]	License Agreement (Human IVD, Veterinary IVD, HLA Typing, Paternity, DNA Manufacturing and Plasma Testing) dated as of July 24, 2004 among IGEN Integrated Healthcare, LLC, F. Hoffman-La Roche Ltd, Roche Diagnostics GmbH and Roche Molecular Systems, Inc.
10.5[13]	License agreement (Human IVD Services and Animal Diagnostics Services) dated July 24, 2003 among IGEN Integrated Healthcare, LLC, F. Hoffman-La Roche Ltd, Roche Diagnostics GmbH and Roche Molecular Systems, Inc.
10.6[1*]	Agreement dated May 25, 1990 between IGEN, Inc. and Eisai Co., Ltd.
10.7[4]	Supplemental Agreement dated July 23, 1997 between IGEN, Inc. and Eisai Co., Ltd.
10.8[6]	Extension Agreement dated July 11, 2002 between IGEN International, Inc. and Eisai Co., Ltd.
10.9[1*]	License and Technology Developmental Agreement dated May 19, 1993 between IGEN, Inc. and Organon Teknika B.V.
10.10[1*]	Term Sheet for Consolidation of Research Projects between IGEN, Inc. and Proteinix Corporation dated December 14, 1993.
10.11[1*]	Term Sheet for Consolidation of Cancer Research Projects between IGEN, Inc. and Pro-Neuron, Inc. dated December 14, 1993.
10.12[10]	Form of Indemnity Agreement entered into between BioVeris Corporation and its directors and officers.
10.13[13+]	BioVeris Corporation 2003 Stock Incentive Plan.
10.14[2]	Lease Agreement between IGEN International, Inc. and W-M 16020 Limited Partnership dated September 27, 1994.

10.15[3*]	Joint Venture Agreement, dated as of November 30, 1995, between Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC. and IGEN, Inc.

10.16[3]	Limited Liability Company Agreement, dated as of November 30, 1995, between Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC., and IGEN, Inc.
10.17[3*]	IGEN/MSD License Agreement, dated as of November 30, 1995, between Meso Scale Diagnostics, LLC., and IGEN, Inc.
10.18[3+]	Indemnification Agreement, dated as of November 30, 1995, between IGEN, Inc. and Jacob Wohlstadter.
10.19[5*]	Amendment No.1 to Joint Venture Agreement between Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC., and IGEN International, Inc. dated August 15, 2001.
10.20[5]	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.
10.21[5*]	Amendment No.1 to IGEN/MSD License Agreement dated August 15, 2001 between Meso Scale Diagnostics, LLC. and IGEN International, Inc.
10.22[5]	MSD/MST Sublicense Agreement dated November 31, 1995 between Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC. and IGEN, Inc.
10.23[5*]	Amendment No. 1 to MSD/MST Sublicense Agreement dated August 15, 2001 between Meso Scale Technologies, LLC. and IGEN International, Inc.
10.24[5+]	Consulting Agreement between IGEN International, Inc. and Jacob N. Wohlstadter dated November 31, 1996.
10.25[5+]	Indemnification Agreement between IGEN International, Inc., Jacob N. Wohlstadter and JW Consulting Services, L.L.C. dated November 30, 1996.
10.26[5+*]	Employment Agreement between Meso Scale Diagnostics, LLC., IGEN International, Inc., Meso Scale Technologies, LLC. and Jacob N. Wohlstadter dated August 15, 2001.
10.27[8+]	Indemnification Agreement between IGEN International, Inc. and Jacob N. Wohlstadter dated October 6, 2001.
10.28[10+]	BioVeris Corporation Termination Protection Program.
10.29[7]	Letter Agreement dated March 21, 2003 between IGEN International, Inc., Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC. and JW Consulting Services, L.L.C.
10.30[12*]	Solicitation, Offer and Award dated June 20, 2003 between IGEN International, Inc. and U.S. Army Space & Missile Defense Command, as amended September 2, 2003.
10.31[12]	Letter Agreement dated August 15, 2001 between IGEN International, Inc., Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC. and Jacob N. Wohlstadter.
10.32[12]	Letter Agreement dated December 1, 2003 between IGEN International, Inc., BioVeris Corporation, Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC. and JW Consulting Services, L.L.C. and Jacob N. Wohlstadter.
10.33[12]	Equity Right Purchase and License Amendment Agreement dated December 30, 2003 between IGEN International, Inc. and Proteinix Corporation.
10.34[12]	Equity Right Purchase and License Amendment Agreement dated December 30, 2003 between IGEN International, Inc. and Wellstat Therapeutics Corporation.
10.35	Services Agreement dated February 10, 2004, among Wellstat Therapeutics Corporation, Wellstat Biologics Corporation, Hyperion Catalysis International Corporation, Proteinix, Inc., Integrated Chemical Synthesizers, Inc. and BioVeris Corporation. Filed herewith.
10.36	Agreement dated August 12, 2004, among BioVeris Corporation, Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC., Jacob N. Wohlstadter and Richard J. Massey. Filed herewith.

14.1	Corporate Code of Conduct and Business Ethics. Filed herewith.
21.1	List of Subsidiaries of BioVeris Corporation. Filed herewith.
23.1	Consent of PricewaterhouseCoopers LLP. Filed herewith.
23.2	Consent of Deloitte & Touche LLP. Filed herewith.
23.3	Consent of Deloitte & Touche LLP. Filed herewith.
99.1[13]	Restructuring Agreement dated July 24, 2003 between IGEN International, Inc. and IGEN Integrated Healthcare, LLC.
99.2[13]	Post-Closing Covenants Agreement dated July 24, 2003 among Roche Holding Ltd, IGEN International, Inc. and IGEN Integrated Healthcare, LLC.
99.3[13]	Tax Allocation Agreement dated as of July 24, 2003 among Roche Holding Ltd, 66 Acquisition Corporation II, IGEN International, Inc. and IGEN Integrated Healthcare, LLC.
99.4[13]	Ongoing Litigation Agreement dated July 24, 2003 between IGEN International, Inc., Roche Diagnostics GmbH and Roche Diagnostics Corporation.
99.5[13]	Global Consent and Agreement dated July 24, 2003 among Roche Holding Ltd, IGEN International, Inc., IGEN Integrated Healthcare, LLC, Meso Scale Diagnostics LLC., Meso Scale Technologies, LLC., Jacob Wohlstadter and JW Consulting Services, L.L.C.
99.6[13]	Release and Agreement dated July 24, 2003 among IGEN International, Inc., IGEN Integrated Healthcare, LLC, Hyperion Catalysis International, Inc., Wellstat Biologics Corporation, Wellstat Therapeutics Corporation, Proteinix Corporation and Integrated Chemical Synthesizers, Inc.
99.7[13]	Letter Agreement dated July 24, 2003 among Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC., JW Consulting Services, L.L.C., Jacob N. Wohlstadter and IGEN International, Inc.
99.8[13]	Letter Agreement dated July 24, 2003 between Samuel J. Wohlstadter and IGEN Integrated Healthcare, LLC.
99.9	Meso Scale Diagnostics, LLC. Financial Statements at December 31, 2003 and 2002 and for the three years ended December 31, 2003, 2002 and 2001, and Independent Auditor s Report. Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002. Filed herewith.
32.1	Certificate 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.
32.2	Certificate 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 IGEN, Inc. s Registration Statement on Form S-1, as amended (Registration No. 33-72992), filed December 16, 1993.

(2) Previously filed as an exhibit to IGEN, Inc. s Annual Report on Form 10-K for the fiscal year ended March 31, 1995, filed July 14, 1995.

(3) Previously filed as an exhibit to IGEN, Inc. s Form 10-Q for the quarter ended December 31, 1995, filed February 14, 1996.

(4) Previously filed as an exhibit to IGEN International, Inc. s Form 10-Q for the quarter ended September 30, 1997, filed November 14, 1997.

(5) Previously filed as an exhibit to IGEN International, Inc. s Amendment to Form 8-K, filed September 5, 2001.

(6) Previously filed as an exhibit to IGEN International, Inc. s Form 10-Q for the quarter ended June 30, 2002, filed August 14, 2002.

(7) Previously filed as an exhibit to IGEN International, Inc. s Form 10-K for the fiscal year ended March 31, 2003, filed June 30, 2003.

(8) Previously filed as an exhibit to IGEN International, Inc. s Form 10-Q for the quarter ended December 31, 2001, filed February 14, 2002.

(9) Previously filed as an exhibit to BioVeris Corporation s Registration Statement on Form S-4 (Registration No. 333-109196), filed September 26, 2003.

(10) Previously filed as an exhibit to BioVeris Corporation s Registration Statement on Form S-4 (Registration No. 333-109196), filed November 12, 2003.

(11) Previously filed as an exhibit to BioVeris Corporation s Registration Statement on Form S-4 (Registration No. 333-109196), filed December 11, 2003.

(12) Previously filed as an exhibit to BioVeris Corporation s Registration Statement on Form S-4 (Registration No. 333-109196), filed December 30, 2003.

(13) Previously filed as an annex to BioVeris Corporation s Registration Statement on Form S-4 (Registration No. 333-101916), filed January 13, 2004.

(14) Previously filed as an exhibit to BioVeris Corporation s Form 8-A filed February 10, 2004.