BIOVERIS CORP
Form 10-K
June 14, 2005

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, 2005
Commission File Number	000-50583

BioVeris Corporation

(Exact name of registrant 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
(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:	NONE
Securities registered pursuant to Section 12(g) of the Act:	Common Stock $0.001 par value
	(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes þ No o

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

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

Yes þ No o

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of September 30, 2004, computed by reference to the closing sale price of such stock quoted on The Nasdaq National Market on such date, was approximately $128,125,298.

The number of shares outstanding of the registrant s Common Stock as of June 1, 2005 was 26,726,950.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for our 2005 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K Report.

BIOVERIS CORPORATION

Annual Report On Form 10-K

For The Fiscal Year Ended March 31, 2005

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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 disclosure relating to brand names, trademarks or service marks of other companies, and these brand names, trademarks or service marks are the property of those other holders.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

In addition to historical information, this Annual Report on 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 contained in this report 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 revenue, the potential market for products in development, 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, plan, intend and similar expressions have been used to identify certain of the forward-looking statements. In this Form 10-K we have based these forward-looking statements on management s current expectations, estimates and projections and they are subject to a number of risks, uncertainties and assumptions which could cause actual results to differ materially from those described in the forward-looking statements. The following factors are among those that may cause actual results to differ materially from our forward-looking statements:

changes in our strategy and business plan, including our plans for vaccines, 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 multi/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;

changes in customer demand, the timing of significant orders or 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;

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

our and our licensees ability to obtain approvals from the U.S. Food and Drug Administration which we refer to in this Form 10-K as the FDA, and other governmental approvals for our and their clinical testing products or for vaccine products, including regulatory changes, uncertainties or delays;

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

our ability to win competitively awarded government contracts in the future and retain existing government contracts;

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

competition from companies with greater financial and capital resources than ours;

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

dependence on a limited number of suppliers for materials used in the manufacturing of our products;

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;

our ability to receive payment over time from Meso Scale Technologies, LLC., which we refer to in this Form 10-K as MST, from the sale of our interests in MSD;

protection and validity of our patent and other intellectual property rights and the scope of third party patent rights;

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

changes in general economic, business and industry conditions.

These factors are not necessarily all of the important factors that could cause actual results to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors could also have material adverse effects on future events. We disclaim any intent or obligation to update these forward-looking statements.

PART I

ITEM 1. BUSINESS

Summary

On February 13, 2004, IGEN and Roche Holding Ltd, which we refer to in this Form 10-K as 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.

Diagnostics

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 for the following markets:

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 ideally 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. Among the applications that we plan to develop is a proprietary approach for determining an individual s personal immune status through unique diagnostic panels. 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. There can be no assurance that such approval will be obtained.

Our M-SERIES instruments are 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 commercial, governmental and military organizations around the world, as well as in the public health sector.

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. Immunogenicity testing is performed by pharmaceutical and biotechnology companies in order to characterize the ability of protein-based therapeutics to stimulate an immune response. We have recently introduced proprietary products for immunogenicity testing. Antibodies that result from an immune response to a protein-based drug can reduce its efficacy and cause significant side effects, such as allergic reactions. Because of serious side effects that have been reported over the last year, it has become increasingly necessary to determine if an immune response to protein-based drugs develops in patients by screening for the presence of antibodies, confirming their specificity, characterizing the type of antibodies present and determining whether they interfere with binding events. Immunogenicity testing is done during pre-clinical studies and may continue through the clinical trials required for regulatory approval. In some cases, the FDA requires additional testing after a drug has been approved. Our M-SERIES product line for the life science market is believed by us to be ideally suited to perform immunogenicity testing by measuring low affinity antibodies

with high sensitivity, all in the presence of the highly concentrated drug.

Vaccines

We have expanded our business model to target the field of vaccines. In conjunction with our efforts to determine an individual s personal immune status through unique diagnostic test panels, we have entered into an exclusive option agreement with Children s Hospital & Research Center at Oakland (CHRCO) for exclusive patent rights to a unique vaccine candidate for *Neisseria meningitidis* serogroup B, which causes meningitis. We believe that the availability of an effective vaccine that would prevent meningococcal serogroup B, for use by various population groups, could meet a significant unmet medical need.

We have also entered into an agreement with the National Research Council of Canada (NRC) for a license to patent rights to candidates for a group B streptococcus (GBS) Type II and Type V vaccine and a group B meningococcus (GBM) vaccine. Under the agreement with the NRC, we acquired worldwide, exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of disease caused by GBS, a leading cause of sepsis, pneumonia, and meningitis among newborns. We received similar worldwide rights, with the exclusion of Canada, to NRC s GBM vaccine technologies for the prevention of meningococcal B meningitis and sepsis.

Recently, we entered into an option agreement with the University of Massachusetts at Amherst (UMA) for exclusive patent rights to a unique vaccine candidate for Chlamydia, the most frequently reported infectious disease in the United States. Under the agreement with UMA, we acquired a first option for exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of all chlamydial infections, including the disease, chlamydia, caused by the bacterium, *Chlamydia trachomatis*.

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 which we refer to in this Form 10-K as the SEC. 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; and

maximize high value-added opportunities in vaccines.

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

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

In addition, we have rights to a unique vaccine candidate for *Neisseria meningitidis* serogroup B, which causes meningitis; to candidates for a GBS Type II and Type V vaccine and a GBM vaccine; and to commercialize products for possible use in the prevention, diagnosis and treatment of all chlamydial infections, including the disease, chlamydia, caused by the bacterium, *Chlamydia trachomatis*.

ECL Technology

ECL technology is 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 through 2003 had 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 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 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 any product based on the PCR technology 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 and Supplementary Data Notes to Consolidated Financial Statements Note 1.

Multi/Unit Dose Cartridge Technology

We have a unique technology utilizing a disposable, multiple dose or 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 multi/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.

Vaccines

We have entered into an exclusive option agreement with CHRCO for exclusive patent rights to a unique vaccine candidate for *Neisseria meningitidis* serogroup B, which causes meningitis. We believe that the availability of an effective vaccine that would prevent meningococcal serogroup B, for use by various population groups, could meet a significant unmet medical need.

We have also entered into an agreement with the NRC for a license to patent rights to candidates for a GBS Type II and Type V vaccine and a GBM vaccine. Under the agreement with the NRC, we acquired worldwide, exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of disease caused by GBS, a leading cause of sepsis, pneumonia, and meningitis among newborns. We received similar worldwide rights, with the exclusion of Canada, to NRC s GBM vaccine technologies.

Recently, we entered into an option agreement with the University of Massachusetts at Amherst (UMA) for exclusive patent rights to a unique vaccine candidate for Chlamydia, the most frequently reported infectious disease in the United States. Under the agreement with UMA, the Company acquired a first option for exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of all chlamydial infections, including the disease, chlamydia, caused by the bacterium, *Chlamydia trachomatis*.

Products and Markets Using Our Technology

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

BioVeris Products Diagnostics	Customer Application	Market	Status
M-SERIES (Clinical analyzer and clinical diagnostic tests)	Screen, monitor and diagnose medical conditions	Clinical	Development
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 Analyzers)	Drug discovery and development	Life science	Product sales
	Detection of food and beverage contaminants and bacteria, viruses and toxins	Biodefense	Product sales
Test Panel for BioVeris Detection System	Detection of food and beverage contaminants	Industrial	Product sales
Cell Culture Reagents	Biological research	Life science	Product sales
Vaccines			
Neisseria meningitides serogroup B	Preventative medicine	Vaccine	Pre-clinical research
Group B streptococcus Type II and Type V	Preventative medicine	Vaccine	Pre-clinical research
Group B meningococcus	Preventative medicine	Vaccine	Pre-clinical research
Chlamydia	Preventative medicine	Vaccine	Pre-clinical research

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. 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 product line	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 either ourselves or through additional licensees. *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 ideally suited for the blood-based immunodiagnostic and nucleic acid testing segments of the clinical diagnostics market. 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. There can be no assurance that such approval will be obtained. See ITEM 1 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.

Diagnostic testing of an individual s immune status will provide information about a person s susceptibility to infectious diseases including diseases for which vaccines exist or are being developed. In addition, the establishment of a database on immune status and vaccination history may assist in identifying certain population groups, such as school children, college students, military personnel and the elderly, which are at risk for diseases such as pneumonia and meningitis that can be prevented by vaccination. We expect to be able to offer unique and proprietary diagnostic test panels that would assess an individual s personal immune status and establish a database for individuals in various population groups. Such products and services should support initiatives such as the strategic plan of the Centers for Disease Control, which is developing an immunization registry and the recent Health Information Technology

Initiative of the U.S. Department of Health and Human Services.

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 commercial, 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 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 in the United States. See ITEM 1 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 biodefense products.

U.S. Army scientists at Fort Detrick and the Edgewood Chemical Biological Center (ECBC) 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, 2005, the DOD had purchased approximately $7.8 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 ITEM 1 Risk Factors Risks Relating to Regulation and Government Contracts.

In June 2004, we introduced for sale our new M-SERIES M1M Analyzer which is 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 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 introduced the M-SERIES M1M Analyzer for use by first responders, such as trauma centers, emergency medical workers, firefighters and police.

The Automated Biological Agent Testing System (ABATS) program at the ECBC, 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. In 2004, the ABATS was transferred to Stations of Robotic Monitoring (STORM), a mobile, high-throughput laboratory that can be deployed rapidly to the scene of an accident or terrorist event.

We expect to continue to work with commercial and U.S. governmental 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.

We are also engaged in 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;

the Cooperative Research and Development Agreement with Brooke Army Medical Center for the development of tests for the detection of clinical markers of disease; and

continued 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 ITEM 1 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 government agency prior to marketing of the products in the United States. See ITEM 1 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 M1M 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.

Immunogenicity testing is performed by pharmaceutical and biotechnology companies in order to characterize the ability of protein-based therapeutics to stimulate an immune response. We have recently introduced proprietary products for immunogenicity testing. Antibodies that result from an immune response to a protein-based drug can reduce its efficacy and cause significant side effects, such as allergic reactions. Because of serious side effects that have been reported over the last year, it has become increasingly necessary to determine if an immune response to protein-based drugs develops in patients by screening for the presence of antibodies, confirming their specificity, characterizing the type of antibodies present and determining whether they interfere with binding events. Immunogenicity testing is done during pre-clinical studies and may continue through the clinical trials required for regulatory approval. In some cases the FDA requires additional testing after a drug has been approved. Our M-SERIES product line for the life science market is believed to be ideally suited to perform immunogenicity testing by measuring low affinity antibodies with high sensitivity, all in the presence of the highly concentrated drug.

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.

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 government agency prior to marketing of the products in the United States. See ITEM 1 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.

Vaccines

We have expanded our business model to target the fields of vaccines. In conjunction with our efforts to determine an individual s personal immune status through a unique diagnostic test panel, we have entered into an exclusive option agreement with CHRCO for exclusive patent rights to a unique vaccine candidate for *Neisseria meningitidis* serogroup B, which causes meningitis.

Meningococcal disease is a bacterial infection that strikes approximately 1.2 million people worldwide each year, causing meningitis or sepsis in the majority of cases. Approximately 10 percent of the individuals who contract meningococcal disease will die. Of the survivors, up to 20 percent suffer long-term permanent disabilities such as hearing loss, brain damage and limb amputations. Meningococcal disease often begins with symptoms that can be

mistaken for common viral illnesses, such as the flu. It can progress very rapidly and kill an otherwise healthy young person in 48 hours or less. Communitywide outbreaks of meningococcal disease can persist for several months and controlling them remains a major challenge in public health. Currently, there is no effective vaccine available against disease caused by meningococcal serogroup B, which is responsible for one-third of meningococcal disease in the United States and up to 70 percent in Europe and Canada. The availability of an effective vaccine that would prevent meningococcal serogroup B for use by various population groups is expected to be in high demand for both mass immunization and catch-up vaccination programs.

We have also entered into an agreement with the NRC for a license to patent rights to candidates for a GBS Type II and Type V vaccine and a GBM vaccine. Under the agreement with the NRC, we acquired worldwide, exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of disease caused by GBS, a leading cause of sepsis, pneumonia, and meningitis among newborns. We received similar worldwide rights, with the exclusion of Canada, to NRC s GBM vaccine technologies for the prevention of meningococcal B meningitis and sepsis.

Approximately 25 percent of pregnant women are carriers for GBS and the newborn infection is predominantly transmitted from mother to baby during labor. Although antibiotic intervention has been used during labor to reduce the rate of disease, the incidence of GBS early-onset disease remains at 0.5 per 1000 live births, and the incidence of late-onset disease remains at 0.3 per 1000, with an overall mortality rate of approximately 4 percent. In addition, GBS accounts for 4 to 7 cases of serious disease per 100,000 non-pregnant adults, with a mortality rate of approximately 20 percent. As a result, the Centers for Disease Control have stated that intrapartum chemoprophylaxis is not a permanent or comprehensive strategy for GBS disease prevention, and that further work on GBS vaccine development is warranted.

The meningococcal B vaccine technology developed by the NRC broadens the technology provided under our option to license exclusive patent rights to a unique vaccine candidate for *Neisseria meningitidis* serogroup B from CHRCO. We now have access to a broad use of the meningococcal B polysaccharide compositions for vaccine development.

Recently, we entered into an option agreement with UMA for exclusive patent rights to a unique vaccine candidate for Chlamydia, the most frequently reported infectious disease in the United States. Under the agreement with UMA, the Company acquired a first option for exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of all chlamydial infections, including the disease, chlamydia, caused by the bacterium, *Chlamydia trachomatis*.

Chlamydia is a sexually transmitted disease caused by *Chlamydia trachomatis*. According to the Centers for Disease Control and Prevention, Chlamydia is the most frequently reported infectious disease in the U.S., with estimates of nearly 3 million cases annually, resulting in a total healthcare cost, estimated by the Institute of Medicine, of more than $2 billion. Although antibiotic therapy is available, chlamydia is a silent disease, showing no symptoms in three quarters of infected women and half of infected men. If left untreated in women, 40% of the infections will cause pelvic inflammatory disease with permanent damage, resulting in chronic pain, infertility and potentially fatal ectopic pregnancy. Infected pregnant women may transmit the infection to the eyes and respiratory tracts of their newborn, resulting in pneumonia and conjunctivitis. It has been estimated that by age 30, half of all sexually active women have been infected. Screening is recommended annually for all sexually active women under 26 years of age, as well as older women with certain risk factors and all pregnant women.

There is no vaccine currently available to protect against Chlamydia. The UMA vaccine technology would be expected to cover all chlamydial infections, including those caused by *Chlamydia psittaci*, which often results in pneumonia and endocarditis in humans, and *Chlamydia pneumoniae*, which is responsible for some pneumonia, bronchitis, pharyngitis, laryngitis, and sinusitis. In addition, *C. pneumoniae* infections have been implicated by some investigators to be associated with atherosclerotic vascular disease, Alzheimer s disease, asthma, and reactive arthritis.

It is our intention to continue to license rights to or acquire certain vaccine candidates.

Collaborations and License Arrangements

We expect to explore and negotiate collaborative business arrangements to accelerate the research, development, manufacture and marketing of ECL technology-based products and vaccines. 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

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 2010, or 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 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 ECL technology. MSD s Sector line of instrumentation is used in drug discovery for high throughput screening, high content screening, multiplexing and target validation. MSD also manufactures and markets a line of its own

reagents, assays and plates that are used on these systems. During the period from January 1, 2004 through December 13, 2004 (the date of the sale of our interests in MSD), MSD had revenues of $12.3 million and a net loss of $17.7 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 interests in MSD and 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, on December 13, 2004 MST

purchased our interests in MSD. For a more complete description of this purchase and the MSD agreements, see ITEM 7 Management s Discussion and Analysis of Financial Condition and Results of Operations and ITEM 8 Consolidated Financial Statements and Supplementary Data Notes to Consolidated Financial Statements Note 3. See ITEM 3 Legal Proceedings for a description of litigation and the related settlement with MSD.

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 83 issued U.S. patents, and own or have exclusively licensed approximately 32 pending U.S. patent applications in the diagnostics field. Additionally, we own or have exclusively licensed approximately 165 granted foreign patents and approximately 88 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. Certain ECL patents will begin to expire in 2006; however, patent coverage for certain key aspects of our ECL technology will continue through 2022. 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 export regulations, 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, the Commerce Department or the State Department regulate the export of products from the United States.

Biodefense and Industrial Testing Products

Our biodefense products are subject to stringent Federal, state, local and foreign laws, regulations and policies governing their manufacture, storage, sale, distribution and export. In addition, the U.S. government has 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, the FDA, the 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 governmental 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 post-market 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 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.

Vaccines

In the U.S., our potential vaccine products are primarily regulated under Federal law and are subject to rigorous FDA approval procedures. No product can be marketed in the U.S. until an appropriate application is approved by the FDA. The FDA applies the approval procedures on a product-by-product basis and typically requires, among other things, an extensive three-phase human clinical testing program. In Phase I, studies are conducted with a relatively small number of subjects to begin to assess the safety of the product. In Phase II, the product is evaluated in a larger group

of subjects to begin to assess efficacy and appropriate dosing. Phase III studies are conducted in the target population with a number of subjects that is large enough to provide sufficient data to establish statistically the safety and efficacy of the product. The FDA approves products to treat specified medical conditions or disorders. Further studies would be required to market the product for other uses. The FDA must inspect and approve all facilities used to manufacture, fill, test and distribute biologic products. If any change in manufacturing facilities or processes occurs after FDA approval, additional regulatory review and possibly additional clinical studies may be required.

Approval procedures in Europe are comparable to those in the U.S. In 1995, the European Union established a centralized procedure for approval of products derived from the use of high technology/biotechnology processes. This procedure leads to the grant of a single license for the entire European Union. The European Union has also adopted a decentralized procedure under which a license granted in one member state is mutually recognized by the other member states recognizing the original license. This procedure is replacing independent national licensing of products in the European Union. In addition, products must receive country pricing approvals in some territories before they can be marketed in that country.

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, 2005, 2004, and 2003, agencies of the U.S. government accounted for 27%, 22% and 26% of total revenue, respectively, and 39% and 26% of total consolidated accounts receivable as of March 31, 2005 and 2004, 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 payors, 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 payors 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 ITEM 1 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 than we are 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 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.

See ITEM 1 Business 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, ITEM 1 Business 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 ITEM 1 Business 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 34 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 ITEM 1 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, 2005, we and our subsidiaries employed 221 individuals, of whom 157 were engaged in research, product development, manufacturing and operations support, and 64 in marketing, sales and applications support and general administration. Of our employees, 23 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 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 and Supplementary Data Notes to Consolidated Financial Statements Note 10.

Geographic Segments

Financial information about geographic segments is incorporated herein by reference to ITEM 8 Consolidated Financial Statements and Supplementary Data Notes to Consolidated Financial Statements-Note 10.

Executive Officers of BioVeris Corporation

The names and ages of all executive officers at May 31, 2005 and their respective positions and offices with us are set forth below.

Name	Age	Position
Samuel J. Wohlstadter	63	Chairman, Chief Executive Officer and Director
Richard J. Massey	58	President, Chief Operating Officer and Director
George V. Migausky	50	Vice President, Chief Financial Officer, Secretary

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.

George V. Migausky has served as our Vice President and Chief Financial Officer 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.

Forward-Looking Information and Risk Factors That May Affect Future Results

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 $77.6 million, $93.3 million and $50.9 million for the years ended March 31, 2005, 2004 and 2003, 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, and general and administrative costs.

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.

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 certain PCR technology from Roche that we plan to integrate into certain of our new instrument systems. Although we do not currently sell any product based on the PCR technology 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 recorded a net book value for the PCR licenses of $17.3 million at March 31, 2005. If we are unable to successfully develop any products using PCR technology because such PCR technology has become obsolete or the future 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. 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 are based on our customers requirements that may vary over time;
- the success of M-SERIES system upgrades and enhancements and customer acceptance of those enhancements and upgrades;
- costs incurred related to expansion into the field of vaccines;
- the amount of revenues 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 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 may record related to the potential impairment of the license to use PCR technology;

amounts received from MSD as payment for the purchase of our interests in MSD and the related accretion of income on the note receivable from MSD;

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

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

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 are not a reliable indication of our future performance.

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 ITEM 1 Business Risk Factors Risks Relating to Us and Our Business 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.

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.

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.

Until February 13, 2004, our assets and businesses had historically been owned, operated and fully integrated with IGEN. Our accompanying consolidated financial statements for fiscal years 2004 and 2003 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 for fiscal 2004 and 2003 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 for fiscal 2004 and 2003 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. During fiscal 2005, we expanded our business model to target the field of

vaccines. A significant change in the focus of our business could result in a loss of our 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 that requires 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.

VACCINE DEVELOPMENT IS A LONG, EXPENSIVE AND UNCERTAIN PROCESS, AND DELAY OR FAILURE CAN OCCUR AT ANY STAGE OF THE PROCESS.

To develop vaccine candidates, we must provide the FDA and foreign regulatory authorities with clinical data that demonstrate adequate safety and immune response. Statistically significant effectiveness of our vaccine product candidates cannot be demonstrated in humans, but instead be demonstrated, in part, by utilizing animal models before they can be approved for commercial sale. Vaccine development to show adequate evidence of effectiveness in animal models and safety and immune response in humans is a long, expensive and uncertain process, and delay or failure can occur at any stage of our animal studies or clinical trials. Any delay or significant adverse clinical events arising during any of our clinical trials could force us to abandon a vaccine candidate altogether or to conduct additional clinical trials in order to obtain approval from the FDA or foreign regulatory bodies. These development efforts and clinical trials are lengthy and expensive, and the outcome is uncertain. If we are unable to successfully develop our vaccine candidates, our business could suffer.

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. Our current and potential life science customers are from the pharmaceutical and biotechnology industries and are subject to risks faced by those industries, including the availability of capital, reduction and delays in research and development expenditures, government regulation and the uncertainty resulting from technological change. In addition, the ongoing consolidation of the pharmaceutical and biotechnology industries could reduce the number of potential customers and they may develop their own competing products or in-house capabilities.

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.

MST HAS PURCHASED OUR INTERESTS IN MSD BUT THERE IS NO ASSURANCE THAT WE WILL RECEIVE THE FULL PURCHASE PRICE.

Pursuant to the settlement, MST purchased our entire interests in MSD and is required to pay us the outstanding purchase price over time, plus simple (cumulated, not compounded) interest at the fixed annual rate of 5.5%. 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 interests 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.

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 interests in MSD.

We have recorded the net present value of the receivable due to us from the sale of our interests in MSD in the amount of $4.7 million at March 31, 2005. If we do not receive the full purchase price over time, from the sale of our interests in MSD, we would be required to write off the remaining net present value or record an impairment of the value of the receivable. Such a write-off or the recording of such an impairment could have a material adverse effect on our future results of operations.

OUR COMPETITORS AND POTENTIAL COMPETITORS MAY HAVE OR DEVELOP DIAGNOSTIC AND VACCINE PRODUCTS AND TECHNOLOGIES THAT ARE MORE ATTRACTIVE THAN OUR EXISTING OR FUTURE DIAGNOSTIC AND VACCINE 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 or vaccine products;
- longer-standing relationships with customers;
- greater expertise and resources in developing, manufacturing, marketing and selling diagnostic or vaccine products;
- a larger, more experienced workforce; and
- more experience in obtaining regulatory approval for clinical testing or vaccine products.

As a result, our competitors may develop, manufacture, market or sell diagnostic or vaccine products that are more effective or commercially attractive than our current or future diagnostic or vaccine 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.

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 OR VACCINE PRODUCTS. OUR FAILURE TO ESTABLISH A SALES FORCE WITH TECHNICAL EXPERTISE OR TO ESTABLISH AN EFFECTIVE DISTRIBUTION SYSTEM FOR OUR CLINICAL DIAGNOSTIC OR VACCINE PRODUCTS COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS PROSPECTS AND REVENUES.

We need to develop selling, marketing and distribution capabilities for our planned clinical diagnostic and vaccine products. To market clinical diagnostic or vaccine 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 one of its affiliates, 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.

WE INTEND TO DEVELOP PRODUCTS THAT ARE BASED ON PATENTS AND TECHNOLOGY THAT WE HAVE LICENSED FROM OTHERS AND 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.

We also 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.

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 our 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.

ONGOING COMPLIANCE WITH THE REQUIREMENTS OF SECTION 404 OF THE SARBANES-OXLEY ACT OF 2002 AND REVISIONS TO ACCOUNTING STANDARDS, FINANCIAL REPORTING AND CORPORATE GOVERNANCE REQUIREMENTS COULD REQUIRE A SIGNIFICANT EXPENDITURE OF OUR TIME AND RESOURCES.

We must follow accounting standards, financial reporting and corporate governance requirements and tax laws set by the governing bodies and lawmakers in the U.S. and other countries where we do business. From time to time, these governing bodies and lawmakers implement new and revised rules and laws. These new and revised accounting standards, financial reporting and corporate governance requirements and tax laws may require changes to our financial statements, the composition of our board of directors, the composition, the responsibility and manner of operation of various board-level committees, the information filed by us with the governing bodies and enforcement of tax laws against us. Implementing changes required by such new standards, requirements or laws likely will require a significant expenditure of time, attention and resources, especially by our senior management. It is impossible to completely predict the impact, if any, on us of future changes to accounting standards, financial reporting and corporate governance requirements and tax laws.

We have documented and tested our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 which we refer to in this Form 10-K as SOX, and which requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accountants attesting to and reporting on these assessments. If we fail to maintain the adequacy of our internal control over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with SOX. If we cannot favorably assess the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

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 FDA CLEARANCE OR APPROVAL TO MARKET OUR CLINICAL DIAGNOSTIC AND VACCINE 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 clinical diagnostic products and vaccines are subject to governmental regulation by national and local government agencies in the United States and abroad. The 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 or vaccine products. The process of obtaining necessary clearances or approvals is often costly, time consuming and uncertain.

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 clinical diagnostic products 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 diagnostic 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 clinical diagnostic products altogether, we will be unable to market these products at all for clinical use in the U.S.

Our vaccine candidates are in pre-clinical stages of development and have not received regulatory approval from the FDA or foreign regulatory authorities to be marketed and sold. The FDA or foreign regulatory authorities may refuse to approve an application if they believe that applicable regulatory criteria are not satisfied and they may require additional testing for safety or effectiveness.

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 regulations. 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.

Our biodefense products are subject to stringent Federal, state, local and foreign laws, regulations and policies governing their manufacture, storage, sale, distribution and export. In addition, the U.S. government has 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. In addition, 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 vaccines and 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 23% of the outstanding shares of our common stock. Our chairman and chief executive officer owns approximately 18% 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.

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 are from time to time 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; 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 investigated a series of transactions whereby MSD, upon Jacob Wohlstadter s sole approval and without our knowledge, purchased residential real property and luxury automobiles for approximately $7.0 million. On June 15, 2004, we filed an action in the Court of Chancery of the State of Delaware against Jacob Wohlstadter, MSD and MST and sought an order from the court confirming that we remained entitled to designate one of the two members of the MSD Board of Managers and prohibiting MSD from taking any actions outside the ordinary course of MSD s business without giving prior notice to us, pending the final outcome of the litigation. 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.

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 MSD Board of Managers. Jacob Wohlstadter also agreed to assume MSD s obligations with respect to a prospective approximately $4.1 million real property purchase. Also on June 17, 2004, we were informed by the staff of the SEC that it had commenced an informal inquiry as to certain issues relating to 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 19, 2004, all of the members of our Board of Directors met to review the MSD litigation and related issues. As a result of its review, the Board of Directors, with all members participating, unanimously approved a resolution that delegated to the Joint Venture Oversight Committee (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 five independent directors, and provided that action of the JVOC should be by unanimous approval of its members.

Following extensive negotiations and the unanimous approval of the JVOC, on August 12, 2004 the parties entered into an agreement to settle the lawsuits involving MSD, MDT and Jacob Wohlstadter. Pursuant to the terms of the settlement agreement:

- the two lawsuits against MSD, MST and Jacob Wohlstadter were suspended and then dismissed with prejudice.
- subject to certain exceptions, the parties waived all present and future claims against each other and any of their respective affiliates.

MSD or MST agreed to purchase our interests in MSD pursuant to the buyout process set forth in the MSD joint venture agreement in accordance with certain agreed-upon terms and procedures.

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 and a copy of its audited financial statements for the year ended December 31, 2003, enabling us to file our Annual Report on Form 10-K for the fiscal year ended March 31, 2004.

we paid the fees of MSD s independent auditor in connection with the audit of MSD and agreed to indemnify MSD, MST and Jacob Wohlstadter against any losses, costs, fees and expenses arising out of any future audits of MSD, the preparation of MSD financial statements requested by us or with respect to regulatory or legal proceedings and investigations resulting from the fact that we are a public company.

we paid MSD $3.0 million in satisfaction of all amounts that we allegedly owed to MSD pursuant to existing agreements between us and MSD. The $3.0 million payment was 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 interests in MSD.

The foregoing is a summary of certain material terms of the settlement and is qualified in its entirety by reference to the settlement agreement, 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.

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 our license agreement with Roche or if we infringe, or are alleged to have infringed, the intellectual property of others. In addition, we are exposed to product liability risks that, if not adequately covered by insurance, may have a material adverse effect on our financial condition. See ITEM 1 Business Risk Factors Risks Relating to Us and Our Business and ITEM 1 Business Risk Factors Risks Relating to the Industry.

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

During the fourth quarter of the last fiscal year, no matter was submitted to a vote of our security holders.

PART II

ITEM 5. MARKET FOR REGISTRANT 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 May 31, 2005, there were approximately 164 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 for fiscal 2005 and 2004.

Year ended March 31, 2005	**High**	**Low**
First quarter	$ 12.89	$ 7.40
Second quarter	8.90	5.53

Third quarter	7.46	5.80
Fourth quarter	7.58	4.91
Year ended March 31, 2004		
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 as of March 31, 2005 with respect to the equity compensation plans (including individual compensation arrangements) under which our equity securities are authorized for issuance, aggregated by (i) all compensation plans previously approved by our security holders, and (ii) all compensation plans not previously approved by our security holders.

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	123,000	$ 8.89	5,177,000
Equity compensation plans not approved by security holders			
Total	123,000	$ 8.89	5,177,000

For more information about our 2003 stock incentive plan, see ITEM 8 Consolidated Financial Statements and Supplementary Data 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 March 31, 2005, Samuel J. Wohlstadter is the only holder 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 declare dividends for the series B preferred stock in connection with any payments received from MSD related to the sale 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 interests 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 $2.0 million that is allocable to our class C interests.

Through March 31, 2005, we had not declared or paid any dividends for the series B preferred stock. In April 2005, we declared and paid a dividend of $57 in respect of shares of series B preferred stock.

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 years ended March 31, 2005 and 2004 have been derived from our consolidated financial statements that have been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, and are included elsewhere in this Form 10-K. The selected consolidated statements of operations data for the fiscal year ended March 31, 2003 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, 2003 and 2002 and the selected consolidated statements of operations data for the fiscal years ended March 31, 2002 and 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 have been derived from our unaudited consolidated financial statements not included in this Form 10-K.

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 and Supplementary Data.

		Years ended March 31,			
	2005 (1)	2004	2003	2002	2001
		(In thousands, except per share data)			
Consolidated Statements of Operations Data:					
Revenues:					
Product sales	$ **24,662**	$ 18,741	$ 16,487	$ 12,077	$ 8,935
Royalty income	**1,249**	1,060	1,107	1,050	892
Contract fees	**388**	155	180	116	3,987
Total	**26,299**	19,956	17,774	13,243	13,814
Operating costs and expenses:					
Product costs (2)	**12,860**	12,247	8,005	5,361	3,112
Research and development	**21,485**	19,821	22,766	26,829	27,983
Selling, general and administrative	**32,212**	18,656	20,453	19,217	13,200
Merger related costs		75,702			
Total operating costs and expenses	**66,557**	126,426	51,224	51,407	44,295
Loss from operations	**(40,258)**	(106,470)	(33,450)	(38,164)	(30,481)
Interest income	**3,191**	130			
Other, net	**95**	(1,063)	154	(39)	(243)
Loss on joint venture impairments	**(35,077)**				
Equity in loss of joint venture (3)	**(5,524)**	(19,616)	(17,598)	(10,947)	
Net loss before cumulative effect of a change in accounting principle	**(77,573)**	(127,019)	(50,894)	(49,150)	(30,724)

Cumulative effect of a change in accounting principle (1)		33,700			
Net loss	$ **(77,573)**	$ (93,319)	$ (50,894)	$ (49,150)	$ (30,724)
Net loss per common share before cumulative effect of a change in accounting principle (basic and diluted)	$ **(2.90)**	$ (4.75)	$ (1.90)	$ (1.84)	$ (1.15)
Cumulative effect of an accounting change (1)		1.26			
Net loss (basic and diluted)	$ **(2.90)**	$ (3.49)	$ (1.90)	$ (1.84)	$ (1.15)
Shares used in computing net loss per common share	**26,728**	26,728	26,728(4)	26,728(4)	26,728

	2005	2004(1)	2003	2002	2001
			(In thousands)		
Consolidated Balance Sheet Data :					
Cash, cash equivalents and short-term investments (5)	$ **95,629**	$ 182,509	$	$	$
Working capital	**98,639**	169,184	4,733	1,193	(1,301)
Total assets	**134,165**	232,814	29,160	21,518	16,379
Long term obligations	**1,890**	54	60	96	329
Minority interest		54			
Series B preferred stock	**7,500**	7,500			
Stockholders equity	**115,254**	193,826			
Net investment by parent (5)			20,665	14,151	6,775

(1) 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 determined that MSD qualified as a variable interest entity. Accordingly, beginning March 31, 2004 we 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.

On August 12, 2004, BioVeris, MSD and MST entered into a settlement agreement that resolved litigation between the parties and constituted a reconsideration event under FIN 46. We have determined that we no longer met the conditions to be designated as the primary beneficiary of MSD, as certain provisions of the settlement agreement reallocated the obligation to absorb the majority of MSD s future expected losses. Accordingly, for the period April 1, 2004 through August 12, 2004, we have consolidated the financial results of MSD and beginning August 13, 2004, we have deconsolidated the financial results of MSD and have accounted for this investment on the equity method through December 13, 2004, the date of the sale of our interests in MSD.

Historical financial information of MSD is summarized in Note 3 of our consolidated financial statements and the audited MSD financial statements have been filed as Exhibit 99.9 to this Form 10-K.

(2) 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).

(3) See Note 3 of the consolidated financial statements for a description of the recording of losses under the equity method of accounting related to the MSD investment.

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

(5) Prior to the completion of the merger and related transactions, IGEN held all cash in a centralized treasury and provided all 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.

Supplemental Consolidated Balance Sheet Data:

	March 31, 2005	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	$ 41,739	$ 147,398	$ 35,111	$	$ 182,509
Short-term investments	53,890				
Accounts receivable, net	4,483	3,417	2,099		5,516
Inventory	5,235	5,013	3,194		8,207
Other current assets	2,813	2,459	2,053	(180)	4,332
Total current assets	108,160	158,287	42,457	(180)	200,564
Equipment and leasehold improvements, net	3,636	5,472	7,362	(269)	12,565
Investment in joint venture		46,208		(46,208)	
Note receivable	4,709				
Technology licenses	17,306	19,256	10		19,266
Other	354	354	65		419
Total assets	$ 134,165	$ 229,577	$ 49,894	$ (46,657)	$ 232,814
Liabilities and Stockholders Equity					
Current Liabilities:					
Accounts payable and accrued expenses	$ 8,170	$ 26,220	$ 3,067	$ (180)	$ 29,107
Other current liabilities	1,351	1,977	296		2,273
Total current liabilities	9,521	28,197	3,363	(180)	31,380
Noncurrent deferred liabilities	1,890	54			54
Total liabilities	11,411	28,251	3,363	(180)	31,434
Minority interest				54	54
Series B preferred stock	7,500	7,500			7,500
Stockholders Equity:					
Common stock	27	27			27
Additional paid-in capital	203,464	203,464	116,707	(116,707)	203,464
Accumulated deficit	(87,238)	(9,665)	(70,176)	70,176	(9,665)
Accumulated other comprehensive income	(999)				

Total stockholders equity	115,254	193,826	46,531	(46,531)	193,826
Total liabilities and stockholders equity	$ 134,165	$ 229,577	$ 49,894	$ (46,657)	$ 232,814

Supplemental Consolidated Statement of Operations Data:

	Year Ended March 31, 2004	Year Ended March 31, 2005			
	BioVeris and Wholly-Owned Subsidiaries	BioVeris and Wholly-Owned Subsidiaries	MSD	Consolidating Eliminations	Consolidated
		(In thousands, except per share data)			
Revenues:					
Product sales	$ 18,741	$ 20,703	$ 3,959	$	$ 24,662
Royalty income	1,060	1,249			1,249
Contract fees	155	32	356		388
Total	19,956	21,984	4,315		26,299
Operating costs and expenses:					
Product costs	12,247	9,167	3,693		12,860
Research and development	19,821	17,877	3,705	(97)	21,485
Selling, general and administrative	18,656	27,710	4,502		32,212
Merger related costs	75,702				
Total operating costs and expenses	126,426	54,754	11,900	(97)	66,557
Loss from operations	(106,470)	(32,770)	(7,585)	97	(40,258)
Interest income	130	3,111	80		3,191
Other, net	(1,063)	95			95
Loss on joint venture impairments		(35,077)			(35,077)
Equity in loss of joint venture	(19,616)	(12,932)		7,408	(5,524)
Net loss before cumulative effect of a change in accounting principle	(127,019)	(77,573)	(7,505)	7,505	(77,573)
Cumulative effect of a change in accounting principle	33,700				
Net loss	$ (93,319)	$ (77,573)	$ (7,505)	$ 7,505	$ (77,573)
Net loss per common share before cumulative effect of a change in accounting principle (basic and diluted)	$ (4.75)	$ (2.90)	$ (0.28)	$ 0.28	$ (2.90)
Cumulative effect of change in accounting principle	1.26				

Net loss per common share (basic and diluted)	$ (3.49)	$ (2.90)	$ (0.28)	$ 0.28	$ (2.90)
Shares used in computing net loss per common share	26,728	26,728	26,728	26,728	26,728

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

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

Overview

We 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 for the following markets:

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 ideally 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. Among the applications that we plan to develop is a proprietary approach for determining an individual s personal immune status through a unique diagnostic panel. 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 used in biodefense programs for homeland security, including by the DOD. We believe there will be an increasing opportunity to sell our products for biodefense tools by commercial, 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. Immunogenicity testing is performed by pharmaceutical and biotechnology companies in order to characterize the ability of protein-based therapeutics to stimulate an immune response. We have recently introduced proprietary products for immunogenicity testing. Antibodies that result from an immune response to a protein-based drug can reduce its efficacy and cause significant side effects, such as allergic reactions. Because of serious side effects that have been reported over the last year, it has become increasingly necessary to determine if an immune response to protein-based drugs develops in patients by screening for the presence of antibodies, confirming their specificity, characterizing the type of antibodies present and determining whether they interfere with binding events. Immunogenicity testing is done during pre-clinical studies and may continue through the clinical trials required for regulatory approval. In some cases, the FDA requires additional testing after a drug has been approved. Our M-SERIES product line for the life science market is believed by us to be ideally suited to perform immunogenicity testing by measuring low affinity antibodies with high sensitivity, all in the presence of the highly concentrated drug.

We have expanded our business model to target the field of vaccines. In conjunction with our efforts to determine an individual s personal immune status through unique diagnostic test panels, we have entered into an exclusive option agreement with CHRCO for exclusive patent rights to a unique vaccine candidate for *Neisseria meningitidis* serogroup B, which causes meningitis. We believe that the availability of an effective vaccine that would prevent meningococcal serogroup B, for use by various population groups, could meet a significant unmet medical need.

We have also entered into an agreement with the NRC for a license to patent rights to candidates for a GBS Type II and Type V vaccine and a GBM vaccine. Under the agreement with the NRC, we acquired worldwide, exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of disease caused by GBS, a leading cause of sepsis, pneumonia, and meningitis among newborns. We received similar worldwide rights, with the exclusion of Canada, to NRC s GBM vaccine technologies for the prevention of meningococcal B meningitis and sepsis.

Recently, we entered into an option agreement with UMA for exclusive patent rights to a unique vaccine candidate for Chlamydia, the most frequently reported infectious disease in the United States. Under the agreement with UMA, we acquired a first option for exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of all chlamydial infections, including the disease, chlamydia, caused by the bacterium, *Chlamydia trachomatis*.

Roche / IGEN Transaction

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.

Investment in MSD

MSD was a joint venture formed by MST and IGEN in 1995. MSD was formed to develop, manufacture, market and sell products utilizing a combination of MST s multi-array technology together with our ECL technology.

Effective March 31, 2004, we consolidated the financial results of MSD in accordance with FIN 46, which 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 it was determined that MSD qualified as a variable interest entity and we were the primary beneficiary. 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.

On August 12, 2004, BioVeris, MSD and MST entered into a settlement agreement that resolved litigation between those parties and constituted a reconsideration event under FIN 46. We have determined that we no longer meet the conditions to be designated as the primary beneficiary of MSD, as through the provisions of the settlement agreement, we have transferred our economic interests to MST and reallocated the obligation to absorb the majority of MSD s future expected losses. Accordingly, beginning August 12, 2004, we have deconsolidated the financial results of MSD.

Except for the period during which we consolidated the financial results of MSD, which was March 31, 2004 through August 12, 2004, we have recorded our proportionate share of MSD losses, representing approximately 100% of MSD s losses. For this consolidation period, we reclassified amounts in the statement of operations formerly recorded on a net basis as equity in loss of joint venture to amounts recorded on a gross basis primarily as revenue, product costs, research and development expenses and selling, general and administrative expenses. As a result, our revenues and expenses for fiscal year ended March 31, 2005 increased significantly.

The MSD joint venture agreement expired upon completion of the merger. As a result, MSD and MST had the option to purchase our interests in MSD and pursuant to the settlement, MSD or MST agreed to purchase, and we agreed to sell, our entire interest in MSD. Fair market value for the purchase of our interests in MSD has been determined in accordance with the valuation process set forth in the MSD joint venture agreement. The fair market value was determined by the independent appraisers to be approximately $9.9 million which equals the average of the two closest determinations, less a 7.5% discount factor. The purchase of our interests was completed on December 13, 2004 and, accordingly, we no longer hold an equity interest in MSD.

MSD or MST is required to pay us the outstanding purchase price 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 interests 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 for the purchase price in the form of a credit against amounts we agreed to pay MSD pursuant to the settlement. 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.

Upon the sale of our interests in MSD, we recorded a note receivable which had a balance at March 31, 2005 of approximately $4.7 million, which represented the net present value of future payments that we expect to realize from the sale of our interests in MSD. Calculating the net present value of future payments that we expect to realize from MSD as payment for the purchase price, requires assumptions about MSD, including the timing and amount of MSD s future financings and revenue, and an appropriate discount rate. If actual results differ from these assumptions, the net present value of future payments received by us could differ from the amount reflected on the balance sheet at March 31, 2005. We expect that MSD will require substantial additional funding for its ongoing operations. If MSD is not able to obtain this funding, or in the event sufficient net sales or third-party financings of MSD do not materialize, we will not receive any additional payments from MST for the purchase of our interests in MSD.

The book value of our interests in MSD, as recorded in the investment in joint venture account on our unconsolidated balance sheet, was greater than the fair market value purchase price of these interests determined by the appraisal

process. Accordingly, we recorded non-cash charges of $35.1 million during fiscal year ended March 31, 2005, representing the estimated amount by which the book value of our interests in MSD exceeded the fair market value.

For a more complete description of the sale of our MSD interests and the MSD agreements, see ITEM 8, Consolidated Financial Statements and Supplementary Data Notes to Consolidated Financial Statements Note 3 and ITEM 3 Legal Proceedings for a description of litigation and the related settlement with MSD.

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 are based on our customers requirements that may vary over time;
- the success of M-SERIES system upgrades and enhancements and customer acceptance of those enhancements and upgrades;
- costs incurred related to expansion into the field of vaccines;
- the amount of revenues 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 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 may record related to the potential impairment of the license to use PCR technology;
- amounts received from MSD as payment for the purchase of our interests in MSD and the related accretion of income on the note receivable from MSD;
- 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
- 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, and general and administrative costs. 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.

Results of Operations

Years Ended March 31, 2005 and 2004

During fiscal year 2005, MSD s results of operations for the period from April 1, 2004 through August 12, 2004 are consolidated with the results of operations of BioVeris and its wholly-owned subsidiaries.

Revenues. Consolidated revenues for the fiscal year ended March 31, 2005 increased by approximately $6.3 million, or 32%, to $26.3 million from $20.0 million in fiscal 2004. Of this $6.3 million increase $4.3 million represents MSD revenues for the period April 1, 2004 through August 12, 2004.

Consolidated product sales were $24.7 million in fiscal 2005, an increase of 32% over the prior year s product sales of $18.7 million. Of this $6.0 million increase, $4.0 million represents MSD product sales. BioVeris s sales of biodefense products for fiscal 2005 were $9.4 million, an increase of $3.3 million, or 53%, over the prior year. Sales of products for the life science market were $11.3 million for fiscal 2005, a decrease of $1.3 million over the prior year. These changes in product sales reflect the change of orders and product deliveries for biodefense and life science products, which are based on our customers requirements.

We anticipate continuing 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 through June 2007. Through March 31, 2005, the DOD had purchased approximately $7.8 million of products. 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.

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. Consolidated product costs were $12.9 million (52% of total product sales) for fiscal 2005 compared to $12.2 million (65% of total product sales) for fiscal 2004. The current year increase of $700,000 consists of $3.7 million due to the consolidation of MSD s product costs, offset by a $3.0 million reduction in Bioveris costs. BioVeris product costs in fiscal 2005, as a percentage of total product sales, were 44% compared to 65% in fiscal 2004.

BioVeris product costs in fiscal 2005, as a percentage of total product sales, decreased due to reduced costs incurred in connection with instrument upgrades and detection module upgrades for existing life science customers. These voluntary upgrades which cost approximately $2.7 million occurred in fiscal 2004 and were provided to enhance overall customer satisfaction. Our future profit margin is subject to change due to a number of uncertainties relating to, among other things, the launch of new instrument systems.

Consolidated research and development expenses were $21.5 million for fiscal 2005, which represents an increase of 8% over the prior year costs of $19.8 million. The $1.7 million increase consists of $3.7 million due to the consolidation of MSD s research and development expenses, offset by a $2.0 million reduction in BioVeris costs.

BioVeris research and development expenditures decreased in the current year due primarily to lower consulting, facilities and personnel costs. 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 vaccines, developing clinical diagnostics and biodefense testing products, and development of a proprietary approach for determining an individual s personal immune status through a unique diagnostic test panel.

We are expanding our business model to target the field of vaccines which will require substantial research and development expenditures. For example, we have entered into an exclusive option agreement with CHRCO for exclusive patent rights to a unique vaccine candidate for *Neisseria meningitidis* serogroup B, which causes meningitis. The agreement provides that we will sponsor up to $800,000 of research at CHRCO over a two-year period and if the

option is exercised, make additional payments for license and milestone fees for initiating and completing human clinical trials and receiving regulatory approvals. Payments on this agreement began in October 2004 and total $250,000 for fiscal year 2005. We have also recently entered into an agreement with the NRC for a license to patent rights to candidates for a group B streptococcus Type II and Type V vaccine and a group B meningococcus vaccine. Under the license agreement, we are required to pay a royalty on product sales, including a minimum $10,000 annual royalty that commences immediately, and we are responsible for conducting or sponsoring the research and development of these vaccine

candidates. Subsequent to March 31, 2005, we entered into a Sponsored Research Agreement with UMA under which we will sponsor up to $600,000 of research at UMA through calendar 2006 aimed at developing a vaccine candidate for chlamydia. In addition, we have leased facilities at an annual cost of approximately $600,000 for use in the vaccine programs.

Consolidated selling, general and administrative expenses were $32.2 million in fiscal 2005, which represents an increase of 73% over the prior year costs of $18.7 million. Of this $13.5 million increase, $4.5 million represents MSD s selling, general and administrative expenses. BioVeris increase in selling, general and administrative costs of $9.0 million was primarily attributable to higher personnel costs and professional fees in the current year. This includes costs associated with SOX compliance, as well as costs associated with our litigation and settlement with MSD.

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.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the SOX, new SEC regulations and Nasdaq National Market rules are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by on going revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increases in general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

In 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 non-cash 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.

Since 1995 we had 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. We had 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. These two firms merged during 2004 creating the firm of Wilmer, Cutler, Pickering, Hale & Dorr. We recorded approximately $2.2 million and $400,000 in legal fees with the combined law firm for the years ended March 31, 2005 and 2004, respectively.

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 less than 10% stockholder in Proteinix. These companies are therefore considered our affiliates for the purpose of this discussion.

We have shared services arrangements with each of these affiliated companies. These shared services include accounting and finance, human resources and other administrative services, as well as facility related costs and services. Shared services costs allocated to these companies totaled $421,000 and $1 million for the years ended March 31, 2005 and 2004, respectively, which reduced certain Operating Costs and Expenses for the respective years. Amounts allocated to these affiliated companies are calculated and billed monthly based upon costs incurred by us and are determined through allocation methods that include time spent and square footage utilized. The amount due from the affiliated companies was

approximately $8,000 at March 31, 2005 and the affiliated companies had prepaid approximately $12,000 under the shared services arrangements at March 31, 2004. All such balances due were paid subsequent to each respective year end.

Interest Income. Interest income was $3.2 million and $130,000 in fiscal 2005 and 2004, respectively. Interest income for fiscal 2005 includes $171,000 from the accretion of income related to the note receivable from MSD. 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, cash equivalents or short-term investments were held by us and no interest income was generated.

Other Income / Expense. Other income, net of other expenses, was $95,000 in fiscal 2005. Other expense in fiscal 2004 was primarily from a $1.2 million non-cash charge representing the value of MSD s option to purchase our interests in MSD.

Loss on Joint Venture Impairments. The book value of our interests in MSD, as recorded in the investment in joint venture account on our unconsolidated balance sheet, was greater than the fair market value purchase price of these interests determined by the appraisal process. Utilizing the guidance of Accounting Principles Board (APB) Opinion No. 18, during the fiscal year ended March 31, 2005, we recorded non-cash charges of $35.1 million, as loss on joint venture impairment, representing the amount by which the book value of our interests in MSD exceeded the fair market value. These impairment charges are classified as non-operating costs on the Statement of Operations consistent with the guidance of APB 30.

Equity in Loss of Joint Venture. Effective March 31, 2004, we consolidated the financial results of MSD in accordance with FIN 46 which 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 it was determined that MSD qualified as a variable interest entity. The settlement agreement between the parties has been determined to constitute a reconsideration event under FIN 46 and we have determined that we no longer meet the conditions to be designated as the primary beneficiary of MSD, as certain provisions of the settlement agreement reallocated the obligation to absorb the majority of MSD s future expected losses. Accordingly, we have consolidated the financial results of MSD as of March 31, 2004 and for the period from April 1, 2004 through August 12, 2004, and beginning August 13, 2004, we have deconsolidated the financial results of MSD.

For the period from August 13, 2004 through December 13, 2004, the date of the sale of our interests in MSD, we recorded our proportionate share of MSD losses, representing approximately 100% of MSD s losses, as equity in loss of joint venture consistent with accounting for equity method investments. We recorded equity in loss of joint venture of $5.5 million and $19.6 million for the years ended March 31, 2005 and 2004, respectively. MSD s losses decreased in fiscal 2005 primarily due to higher sales which were offset only in part by an increase in operating costs.

Net Loss. The net loss for fiscal year 2005 was $77.6 million ($2.90 per common share), compared to a net loss of $93.3 million ($3.49 per common share) in fiscal year 2004. The net loss during fiscal 2005 includes non-cash charges totaling $35.1 million representing the amount by which the book value of our interests in MSD exceeded the fair market value purchase price. The net loss for fiscal year 2004 includes a one-time, non-cash charge of $33.7 million to reflect a change in accounting principle. The higher net loss in fiscal 2004 is primarily due to the merger related costs incurred in 2004.

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.

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.

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.

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 non-cash 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 (which is more fully described below), 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.

In connection with the merger and related transactions, we made a $37.5 million payment to MSD. The purpose of this payment was specifically to meet the conditions required for the completion of the merger, including the global consent for the transfer of IGEN s interest in MSD to us, and the covenant not to sue whereby MSD and MST agreed not to pursue any claim against Roche that the manufacture, use or sale of a product or the provision of any service

that uses ECL technology in a defined field and is conducted after completion of the merger infringes certain MSD or MST ECL patents that are filed or acquired after the completion of the merger. Prior to signing definitive agreements with Roche, extensive negotiations with MSD were conducted over the terms and payments required by MSD. The $37.5 million payment was completely separate and distinct from any other committed funding provided, or to be provided, under the joint venture arrangements. The $37.5 million payment to MSD did add to the Class C interests by which we were entitled to a preferred return on the funds previously invested (by IGEN or us). Except as described, we did not increase our ownership or voting interests in MSD and did not receive other consideration or enhanced rights. 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.

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.

We have shared services arrangements with each of these affiliated companies. These shared services include accounting and finance, human resources and other administrative services, as well as facility related costs and services. Shared services costs allocated to these companies totaled $1.0 million 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.

Interest Income and Other Income / 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, other income was $137,000 in fiscal 2004 and $154,000 in fiscal 2003.

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, cash equivalents or short-term investments were held by us and no interest income was generated. Subsequent to the completion of the merger and related transactions, we earned approximately $130,000 of interest income.

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.

Liquidity and Capital Resources

March 31:	**2005**	2004	2003
		(In Thousands)	
Cash, cash equivalents and short-term investments	**$ 95,629**	**$** 182,509	$
Working capital	**98,639**	169,184	4,733
Year Ended March 31:			
Cash provided by (used in):			
Operating activities	**(31,059)**	(29,648)	(33,105)
Investing activities	**(59,789)**	(78,080)	(23,861)
Financing activities	**(49,922)**	290,237	56,966
Capital expenditures (included in investing activities above)	**(1,855)**	(1,920)	(3,331)

Beginning March 31, 2004, we 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 and working capital of $169.2 million. Of these respective amounts, $35.1 million represented the cash and cash equivalents of MSD and $39.1 million represented the working capital of MSD. We had no rights or access to these funds or any other capital resources of MSD. The amount of cash and cash equivalents and working capital to which we and our wholly-owned subsidiaries had unrestricted use as of March 31, 2004 was $147.4 million and $130.1 million, respectively. Beginning August 12, 2004, we deconsolidated the financial results of MSD and have accounted for this investment using the equity method through December 13, 2004, the date of the sale of our interests in MSD.

Cash Used in Operating Activities

Net cash used for operations was $31.1 million, $29.6 million and $33.1 million during the years ended March 31, 2005, 2004 and 2003, respectively. The increase in cash used for operations in the current year resulted primarily from a lower net loss offset by changes in non-cash adjustments to the net loss and increased for higher working capital requirements in the current year. The non-cash adjustments in fiscal 2005 were primarily due to losses and impairment charges associated with the MSD joint venture and higher depreciation and amortization charges. Cash used for operations in fiscal 2004 resulted from the net loss, which included an allocated one-time non-cash 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, partially offset by adjustments for our equity in loss of joint venture. Cash used for operations in 2003 resulted from the net loss, offset by an adjustment for our equity in loss of joint venture.

Cash Used in Investing Activities

We used approximately $1.9 million, $1.9 million and $3.3 million of cash for the acquisition of equipment and leasehold improvements during the years ended March 31, 2005, 2004 and 2003, respectively. Our investments in MSD totaled $3.0 million, $56.7 million (including a $37.5 million payment to MSD following the completion of the merger and related transactions) and $20.5 million for the years ended March 31, 2005, 2004 and 2003, respectively. We have no intention to provide additional funding to MSD except that we agreed to pay MSD certain amounts in the August 2004 settlement with respect to certain of its liabilities. See ITEM 8 Consolidated Financial Statements and Supplementary Data Notes to Consolidated Financial Statements Note 9 Litigation.

During fiscal 2005, we purchased $108.7 million of short-term investments and received proceeds of $53.8 million from the sale of short-term investments.

Simultaneously with the execution of the merger agreement in connection with the merger and related transactions in fiscal 2004, 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 performed a valuation of the PCR technology licenses 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.

Cash Used in or Provided by Financing Activities

During fiscal 2005, we used $20.0 million of cash for the distribution gain payment to Roche associated with the merger and related transactions. We also recorded $29.2 million as a reduction of cash which represents the MSD cash balance at the deconsolidation date which is no longer reflected on our balance sheet. In fiscal 2004, we had recorded an increase in cash of $35.1 million from the initial consolidation MSD.

The financing activity during fiscal 2004 was primarily related to the funding provided by IGEN in conjunction with the merger and related transactions ($247.6 million), 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 declare dividends for the series B preferred stock in connection with any payments received from MSD related to the sale 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 Series B preferred stock, of the portion of the $2.0 million that is allocable to our class C interests.

In April 2005, we declared and paid a dividend of $57 in respect of shares of series B preferred stock.

MSD

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 paid MSD the net amount of $3.0 million which represented full and complete satisfaction of amounts due to MSD pursuant to the MSD agreements, including the dispute regarding unsatisfied committed funding obligations.

Our $3.0 million settlement payment was 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 interests in MSD. A total of $5.0 million was treated as a Class C capital contribution during the year ended March 31, 2005. The amount of the pre-payment credit outstanding from time to time bears simple interest (cumulated, not compounded) at the fixed annual rate of 5.0%. 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 buy-out of our interests in MSD. No further cash payments will be payable by MSD to us until the $2.0 million prepayment credit, including accrued interest, is utilized. In the event sufficient net sales or third-party financings do not materialize, we will not receive any additional payments from MST for the purchase of our interests in MSD. As security for the payment obligation, we hold a security interest in the interests in MSD that are being purchased. MST may repay all or any part of the outstanding purchase price plus accrued interest at any time and from time to time without penalty.

Our investment contributions to MSD totaled $5.0 million ($3.0 million in cash and a $2.0 million credit that represents a non-refundable prepayment by MSD to us for future amounts payable by MSD to us pursuant to the buy-out of our interests in MSD), $56.7 million (including a $37.5 million payment to MSD following the completion of the merger and related transactions) and $20.5 million during the years ended December 31, 2005, 2004 and 2003, respectively. Part of the fiscal 2004 and 2003 funding commitment was satisfied 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 the years ended March 31, 2005, 2004 and 2003, operating costs allocated to MSD by us in connection with shared personnel and facilities totaled $743,000, $6.0 million and $11.9 million, respectively. The costs allocated for fiscal 2005 are net of a $476,000 write-off of unpaid costs in connection with the settlement agreement, in which all claims against MSD, MST and Jacob Wohlstadter were dismissed and released. The specific nature and amount of our allocations for fiscal 2005 are being reviewed by MSD.

Contractual Obligations

We have contractual obligations associated with ongoing business activities which will result in cash payments in future periods. In addition, 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 are evaluating additional facilities for manufacturing and other corporate uses and are negotiating to secure new space, which if concluded, would result in additional facilities costs. 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.

As of March 31, 2005, our material future obligations were as follows (in thousands):

Years Ended March 31,	Operating Lease Payments	Sponsored Research	Total
2006	$ 3,003	$ 367	$ 3,370
2007	2,810	233	3,043
2008	2,783		2,783
2009	2,762		2,762
2010	2,179		2,179
2011 and thereafter	547		547
Total	$ 14,084	$ 600	$ 14,684

Included in the operating lease payments above is approximately $600,000 per year of leased facilities for use in our vaccine programs. Subsequent to March 31, 2005, we entered into a Sponsored Research Agreement with UMA under which we will sponsor up to $600,000 of research at UMA through 2006 aimed at developing a vaccine candidate for chlamydia.

Product development for our clinical diagnostic and vaccine products are at an early development stage. 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 and vaccine 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, 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.

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, 2005, we had no off-balance sheet arrangements.

Critical Accounting Policies

A critical accounting policy is one that is both important to the portrayal of our financial position and results of operations and requires the application of difficult, subjective or complex judgments by 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 recognized when persuasive evidence of an arrangement exists, the price to the buyer is fixed or determinable, collectibility is reasonably assured and the product is shipped to the customer thereby transferring title and risk of loss.

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

For instrument sales, the instrument and the related installation are considered to be separate elements under Emerging Issues Task Force (EITF) Issue No. 00-21. Revenue is recognized for the instrument upon shipment or delivery, depending on the terms of each order, 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 and the standard warranty, 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.

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 and for the period from August 13, 2004 through December 13, 2004, we accounted for our ownership in the MSD joint venture on the equity method, as we determined that we do not control MSD s operations.

Factors considered in determining our level of control include the fact that we had less than 50% of the voting equity interest in MSD; that we did 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 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 3 Meso Scale Diagnostics Joint Venture.

In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities, as revised, 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 determined that MSD qualified as a variable interest entity based upon the following rationale:

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

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

Accordingly, as of March 31, 2004, we consolidated the financial results of MSD. Under the transition guidance of FIN 46, because MSD was created before February 1, 2003, we measured the assets, liabilities and noncontrolling interests of MSD as of March 31, 2004 for purposes of the initial consolidation. The amounts of these 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 had historically recorded approximately 100% of MSD s losses. 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 the period of consolidation has reclassified 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.

On August 12, 2004, BioVeris, MSD and MST entered into a settlement agreement that resolved litigation between the parties and constituted a reconsideration event under FIN 46. We have determined that we no longer meet the conditions to be designated as the primary beneficiary of MSD. Factors used in this evaluation include that,

- We do not have a significantly large variable interest in MSD to be the primary beneficiary. We will hold only a secured note whereas the purchaser, MST, will be at risk for all of its equity;

- After December 13, 2004 and for the remaining life of MSD, we will cease to absorb any MSD losses; and

- MST will absorb the majority of the expected losses of MSD.

Accordingly, beginning August 12, 2004, we deconsolidated the financial results of MSD and have accounted for this investment using the equity method through December 13, 2004, the date of the sale of our interests in MSD.

The balance sheet for periods subsequent to August 12, 2004 reclassified amounts formerly consolidated or presented on a gross basis to be reflected on a net basis as investment in joint venture. Effective August 13, 2004, the statement of operations reclassified amounts presented on a gross basis to be reflected on a net basis as equity in loss of joint venture. Accordingly, the statement of operations for the year ended March 31, 2005 includes the consolidated

revenue and expenses of MSD for the period from April 1, 2004 through August 12, 2004 and reflects MSD s net losses for the period from August 13, 2004 through December 13, 2004, the date of the sale of our interests, as equity in loss of joint venture, consistent with accounting for equity method investments.

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. An impairment loss is measured and recorded based on discounted estimated future cash flows.

We recorded a note receivable which has a balance of approximately $4.7 million at March 31, 2005, and which represents the net present value of future payments that we expect to realize from the sale of our interests in MSD. Calculating the net present value of future payments that we expect to realize as payment for the purchase price requires assumptions about MSD, including the timing and amount of MSD s future financings and revenue, and an appropriate discount rate. If actual results differ from these assumptions, the net present value of future payments received by us could differ from the amount reflected on the balance sheet at March 31, 2005.

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

In December 2003, the AICPA issued SOP 03-3, Accounting for Certain Loans or Debt Securities Acquired in a Transfer. The SOP addresses accounting for differences between contractual cash flows expected to be collected from an investor s initial investment in loans or debt securities (loans) acquired in a transfer if those differences are attributable, at least in part, to credit quality. SOP 03-3 limits the yield that may be accreted to the excess of the investor s estimate of undiscounted expected principal, interest, and other cash flows (cash flows expected at acquisition to be collected) over the investor s initial investment in the loan. The SOP requires that the excess of contractual cash flows over cash flows expected to be collected not be recognized as an adjustment of yield, loss accrual or valuation adjustment. Subsequent increases in cash flows expected to be collected generally should be recognized prospectively through adjustment of the loan s yield over its remaining life. Decreases in cash flows expected to be collected should be recognized as impairment. The SOP is effective for loans acquired in fiscal years beginning December 15, 2004. We adopted the provisions of SOP 03-3 as of December 31, 2004.

In November 2004, the EITF reached a consensus on EITF Issue No. 03-13 (EITF 03-13), Applying the Conditions in Paragraph 42 of FAS 144 in Determining Whether to Report Discontinued Operations . EITF 03-13 provides an approach for evaluating whether the criteria in paragraph 42 of Statement of Financial Accounting Standards (SFAS) No. 144 (SFAS 144), Accounting for the Impairment or Disposal of Long-Lived Assets , have been met for classifying as a discontinued operation, a component of an entity that either has been disposed of or is classified as

held for sale. To qualify as a discontinued operation, paragraph 42 of FAS 144 requires that cash flows of the disposed component be eliminated from the operations of the ongoing entity and that the ongoing entity not have any significant continuing involvement in the operations of the disposed component after the disposal transaction. EITF 03-13 defines which cash flows are relevant for assessing whether cash flows have been eliminated and it provides a framework for evaluating what types of ongoing involvement constitute significant continuing involvement. EITF 03-13 should be applied to a component of an entity that is either disposed of or classified as held for sale in fiscal period beginning after December 15, 2004. We do not expect that EITF 03-13 will have a material impact on our financial position or results of operations.

In November 2004, the Financial Accounting Standards Board (FASB) issued SFAS 151, Inventory Costs, an amendment of Accounting Research Bulletin (ARB) No. 43, Chapter 4. SFAS 151 amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing to clarify the accounting for abnormal amounts of idle facility expense, freight handling costs, and wasted material (spoilage). SFAS 151 requires that those items be recognized as current-period charges regardless of whether they meet the criterion of so abnormal. In addition, SFAS 151 requires that allocation of fixed production overhead to the costs of conversion be based on the normal capacity of the production facilities. The provisions of SFAS 151 will be effective for fiscal years beginning after June 15, 2005. We are currently evaluating the provisions of SFAS 151 and do not believe that its adoption will have a material impact on our financial condition, results of operations and liquidity.

In December 2004, the FASB issued SFAS No. 123 (revised 2004) (SFAS 123R), Share-Based Payment. SFAS 123R replaces SFAS No. 123, Accounting for Stock Issued to Employees, and supersedes Accounting Principal Board (APB) Opinion No 25, Accounting for Stock Issued to Employees. SFAS 123R requires that compensation costs relating to share-based payment transactions be recognized in the consolidated financial statements. Compensation costs will be measured based on the fair value of the equity or liability instruments issued. In April 2005, the SEC issued a rule amending the compliance date which allows companies to implement SFAS 123R at the beginning of their next fiscal year, instead of the next reporting period that begins after June 15, 2005. We are currently evaluating the provisions of SFAS 123R and have not yet determined whether to use the modified prospective or the modified retrospective methods allowed by SFAS 123R, nor have we determined its impact on our financial condition, results of operations and liquidity beyond the disclosure on Note 2 of the Notes to Condensed Consolidated Financial Statements.

In December 2004, the FASB issued SFAS 153, Exchange of Nonmonetary Assets , an amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions. SFAS 153 is based on the principle that exchange of nonmonetary assets should be measured based on the fair market value of the assets exchanged. SFAS 153 eliminates the exception of nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. SFAS 153 is effective for nonmonetary asset exchanges in fiscal periods beginning after June 15, 2005. We are currently evaluating the provisions of SFAS 153 and do not believe that its adoption will have a material impact on our financial condition, results of operations and liquidity.

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.

Our balance sheet at March 31, 2005 had cash, cash equivalents and short-term investments of $95.6 million which is approximately 71% of total assets. 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. At March 31, 2005, we had invested $53.9 million in securities of the U.S. government, municipal bonds, and U.S. corporate debt, which were recorded as short-term investments.

Our invested cash is sensitive to changes in the general level of interest rates. Based on our cash, cash equivalents and short-term investments balance at March 31, 2005, a 1% movement in interest rates would have an approximately $1.2 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 AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

We also incorporate herein by reference the Meso Scale Diagnostics, LLC financial statements at December 13, 2004 and December 31, 2003 and for the period ended December 13, 2004 and each of the two years ended December 31, 2003, and Report of the Independent Registered Public Accounting Firm filed as Exhibit 99.9 to this Form 10-K.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of BioVeris Corporation:

We have completed an integrated audit of BioVeris Corporation s 2005 consolidated financial statements and of its internal control over financial reporting as of March 31, 2005 and audit of its 2004 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of BioVeris Corporation and its subsidiaries at March 31, 2005 and 2004, and the results of their operations and their cash flows for each of the years 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 audits. We conducted our audits 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 of financial statements 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 audits provide a reasonable basis for our opinion.

As 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. These consolidated financial statements 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 discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for its investment in Meso Scale Diagnostics, LLC in 2004.

Internal control over financial reporting

Also, in our opinion, management s assessment, included in Management s Annual Report on Internal Control Over Financial Reporting, appearing under ITEM 9A, that the Company maintained effective internal control over financial reporting as of March 31, 2005 based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2005, based on criteria established in *Internal Control Integrated Framework* issued by COSO. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management s assessment and of the effectiveness of the Company s internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control

over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management s assessments, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provide a reasonable basis for our opinions.

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

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

/s/ PricewaterhouseCoopers LLP
Baltimore, Maryland
June 13, 2005

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors of BioVeris Corporation:

We have audited the accompanying consolidated statements of income, stockholders equity, and cash flows for the year ended March 31, 2003 of BioVeris Corporation and subsidiaries (the Company), a component of IGEN International, Inc. (Parent). 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 audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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 results of operations and cash flows of the Company for the year ended March 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

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 year ended March 31, 2003 in the consolidated statements of operations and as to the basic and diluted loss per common share-as reported and pro forma for the year ended March 31, 2003 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,		
	2005	2004	2003
REVENUES:			
Product sales	$ **24,662**	$ 18,741	$ 16,487
Royalty income	**1,249**	1,060	1,107
Contract fees	**388**	155	180
Total	**26,299**	19,956	17,774
OPERATING COSTS AND EXPENSES:			
Product costs	**12,860**	12,247	8,005
Research and development	**21,485**	19,821	22,766
Selling, general, and administrative	**32,212**	18,656	20,453
Merger related costs		75,702	
Total	**66,557**	126,426	51,224
LOSS FROM OPERATIONS	**(40,258)**	(106,470)	(33,450)
INTEREST INCOME	**3,191**	130	
OTHER, NET	**95**	(1,063)	154
LOSS ON JOINT VENTURE IMPAIRMENTS	**(35,077)**		
EQUITY IN LOSS OF JOINT VENTURE	**(5,524)**	(19,616)	(17,598)
NET LOSS BEFORE CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE	**(77,573)**	(127,019)	(50,894)
CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE		33,700	
NET LOSS	$ **(77,573)**	$ (93,319)	$ (50,894)
Net loss per common share before cumulative effect of change in accounting principle (basic and diluted)	$ **(2.90)**	$ (4.75)	$ (1.90)
Cumulative effect of change in accounting principle		1.26	
Net loss per common share (basic and diluted)	$ **(2.90)**	$ (3.49)	$ (1.90)

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, 2005	2004
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ **41,739**	$ 182,509
Short-term investments	**53,890**	
Accounts receivable, net	**4,483**	5,516
Inventory	**5,235**	8,207
Other current assets	**2,813**	4,332
Total current assets	**108,160**	200,564
Equipment and leasehold improvements, net	**3,636**	12,565
OTHER NONCURRENT ASSETS:		
Note receivable	**4,709**	
Technology licenses	**17,306**	19,266
Other	**354**	419
TOTAL ASSETS	$ **134,165**	$ 232,814
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ **6,457**	$ 7,187
Accrued wages and benefits	**1,713**	1,876
Distribution gain accrual		20,000
Other current liabilities	**1,351**	2,273
Note payable		44
Total current liabilities	**9,521**	31,380
NONCURRENT DEFERRED LIABILITIES	**1,890**	54
Total liabilities	**11,411**	31,434
COMMITMENTS (see Note 6) and CONTINGENCIES (see Note 9)		
MINORITY INTEREST		54
SERIES B PREFERRED STOCK, 1,000 shares designated, issued and outstanding	**7,500**	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**	27
Additional paid-in capital	**203,464**	203,464
Accumulated deficit	**(87,238)**	(9,665)
Accumulated other comprehensive loss	**(999)**	
Total stockholders equity	**115,254**	193,826
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ **134,165**	$ 232,814

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,		
	2005	2004	2003
OPERATING ACTIVITIES**:**			
Net loss	$ **(77,573)**	$ (93,319)	$ (50,894)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	**6,229**	3,385	3,677
Loss on disposal of equipment	**138**	58	90
Equity in loss of joint venture	**5,524**	19,616	17,598
Joint venture impairments	**35,077**	33,700	
Accretion of interest on note receivable	**(171)**		
Impairment of receivable from joint venture	**476**		
Change in accounting principle		(33,700)	
Expense related to stock options		38,800	386
Minority interest		54	
Changes in assets and liabilities:			
(Increase) decrease in accounts receivable	**(988)**	2,017	(2,666)
(Increase) decrease in inventory	**(1,516)**	158	(1,428)
Decrease (increase) in other current assets	**663**	(173)	(1,052)
Increase (decrease) in accounts payable and accrued expenses	**1,306**	(1,708)	1,131
(Decrease) increase in deferred revenue	**(224)**	1,464	53
Net cash used in operating activities	**(31,059)**	(29,648)	(33,105)
INVESTING ACTIVITIES:			
Expenditures for equipment and leasehold improvements	**(1,855)**	(1,920)	(3,331)
Purchases of short term-investments	**(108,706)**		
Sales of short-term investments	**53,817**		
Investments in joint venture	**(3,045)**	(56,660)	(20,519)
Purchase of technology licenses		(19,500)	
Increase in other assets			(11)
Net cash used in investing activities	**(59,789)**	(78,080)	(23,861)
FINANCING ACTIVITIES:			
Payment of distribution gain	**(20,000)**		
(Deconsolidation) consolidation of joint venture cash and cash equivalents	**(29,922)**	35,111	
Sale of preferred stock		7,500	
Cash contributed by Parent, net		247,626	57,022
Payments on note payable and capital lease obligations			(56)
Net cash (used in) provided by financing activities	**(49,922)**	290,237	56,966
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	**(140,770)**	182,509	

CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR		**182,509**						
CASH AND CASH EQUIVALENTS, END OF YEAR	$	**41,739**	$	182,509	$			
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:								
Cash payments of interest	$		$	1	$	29		
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:								
Transfer of inventory into fixed assets	$	**217**	$	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	Common Stock Amount	Additional Paid - in Capital	Net Investment by Parent	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
BALANCE at April 1, 2002		$	$	$ 14,151	$	$	$ 14,151
Net loss				(50,894)			(50,894)
Capital contributed by parent				57,408			57,408
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
Net loss						(77,573)	(77,573)
Unrealized losses from short-term investments					(999)		(999)
Comprehensive loss							(78,572)
BALANCE at March 31, 2005	26,728	$ 27	$ 203,464	$	$ (999)	$ (87,238)	$ 115,254

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

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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.

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, whose net investment in the Company was shown in lieu of stockholders equity, 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 for fiscal years 2004 and 2003 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.

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. They have been prepared and are presented as if the Company had been operating as a separate entity using IGEN s historical costs 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. 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 and $20.5 million are included in selling, general and administrative expenses in the accompanying consolidated statements of operations for the years ended March 31, 2004 and 2003, respectively. These allocated expenses were derived from total IGEN selling, general and administrative expenses of $22.3 million and $24.7 million for the years ended March 31, 2004 and 2003, respectively.

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 what results of operations and cash

flows of the Company 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. All significant intercompany transactions and balances have been eliminated.

The Company adopted FASB Interpretation No. 46, Consolidation of Variable Interest Entities, an Interpretation of Accounting Research Bulletin No. 51 , as revised or FIN 46, as of March 31, 2004. FIN 46 requires certain variable

interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties.

The Company determined that MSD (a joint venture formed in 1995 by IGEN and Meso Scale Technologies, LLC. (MST), which is a company established and wholly-owned by Mr. Jacob Wohlstadter, a son of the Company s chief executive officer) qualified as a variable interest entity with the Company as the primary beneficiary. Accordingly, beginning March 31, 2004, the Company began to consolidate the financial results of MSD.

Under the transition guidance of FIN 46, because MSD was created before February 1, 2003, the Company measured the assets, liabilities and noncontrolling interests of MSD as of March 31, 2004 for purposes of the initial consolidation. The amounts of these assets, liabilities and noncontrolling interests were 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. The Company s 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. The statement of operations reclassified 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.

On August 12, 2004, the Company, MSD and MST entered into a settlement agreement (settlement) that resolved litigation between the parties and constituted a reconsideration event under FIN 46. The Company has determined that it no longer meets the conditions to be designated as the primary beneficiary of MSD. Factors used in this evaluation include the following,

The Company does not have a significantly large variable interest in MSD to be the primary beneficiary. The Company will hold only a secured note whereas the purchaser, MST, will be at risk for all of its equity;

After December 13, 2004 and for the remaining life of MSD, the Company will cease to absorb any MSD losses; and

MST will absorb the majority of the expected losses of MSD.

Accordingly, beginning August 12, 2004, the Company deconsolidated the financial results of MSD and resumed accounting for this investment using the equity method through December 13, 2004, the date of the sale of the Company s interests in MSD.

The balance sheets for periods subsequent to August 12, 2004 reclassified amounts formerly consolidated or presented on a gross basis to be reflected on a net basis as investment in joint venture and effective August 13, 2004, the statement of operations reclassified amounts presented on a gross basis to be reflected on a net basis as equity in loss of joint venture. Accordingly, the statement of operations for fiscal year 2005 include the consolidated revenues and expenses of MSD for the period from April 1, 2004 through August 12, 2004, and reflects MSD s net losses for the period from August 13, 2004 through December 13, 2004, the date of the sale of the Company s interests in MSD, as equity in loss of joint venture.

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

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

Short-Term Investments Short-term investments consist primarily of corporate, federal and municipal debt-securities that are classified as available for sale. 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. These available for sale securities, which are all due within one year, are accounted for at their fair market value and unrealized gains and losses on these securities, if any, are included in accumulated other comprehensive gain or loss in stockholders equity. As of March 31, 2005, the Company had net unrealized losses on available for sale securities of approximately $999,000. The Company uses the specific identification method in computing realized gains and losses on the sale of investments, which are included in results of operation as generated. For the years ended March 31, 2005 and 2004, the Company did not have any realized gains or losses.

The following is a summary of the Company s available-for-sale marketable securities as of March 31, 2005 :

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government agencies	$ 20,328	$	$ (263)	$ 20,065
Municipal bonds	8,000			8,000
U.S. corporate debt	26,561		(736)	25,825
	$ 54,889	$	$ (999)	$ 53,890

Concentration of Credit Risk During the years ended March 31, 2005, 2004 and 2003 agencies of the U.S. government accounted for 27%, 22% and 26% of total revenue, respectively, and 39% and 26% of total consolidated accounts receivable as of March 31, 2005 and 2004, respectively. For the year ended March 31, 2004, one commercial customer accounted for 18% of total accounts receivable.

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. Amounts later determined and specifically identified to be uncollectible are charged or written-off against the reserve. Historically, the Company has not experienced significant credit losses related to an individual customer or group of customers and estimated losses have been within the Company s expectation. Allowance for doubtful accounts was $227,000 and $208,000 at March 31, 2005 and 2004, respectively.

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

	Years Ended March 31,	
	2005	2004
	(in thousands)	
BioVeris and Wholly-Owned Subsidiaries:		
Finished Goods	**$ 1,561**	$ 1,740
Work in process	**749**	619
Raw materials	**2,925**	2,654
Total	**$ 5,235**	5,013

MSD:	
Finished Goods	757
Work in process	366
Raw materials	2,071
Total	3,194
Total	$ 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 the straight-line method of depreciation. Leasehold improvements are amortized on a straight-line basis over the shorter of the estimated useful life or the term of the lease. Equipment and leasehold improvements consist of the following:

	Years Ended March 31,	
	2005	2004
	(in thousands)	
BioVeris and Wholly-Owned Subsidiaries:		
Lab instruments and equipment	**$ 6,575**	$ 6,413
Office furniture and equipment	**4,936**	5,511
Leasehold improvements	**4,005**	3,980
	15,516	15,904
Accumulated depreciation and amortization	**(11,880)**	(10,432)
Total	**$ 3,636**	5,472
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 polymerase chain reaction (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 in fiscal 2004 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. The Company 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. During fiscal 2004, the Company performed a valuation of the PCR technology licenses and 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.

These PCR 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 was $2.0 million and $244,000 for the years ended March 31, 2005 and 2004, respectively. Accumulated amortization was $2.2 million and $244,000 at March 31, 2005 and 2004, respectively. Amortization expense is expected to

approximate $2.0 million for each year through March 31, 2014.

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. An impairment loss is measured and recorded based on discounted estimated future cash flows. Management believes that no impairment of these assets exists as of March 31, 2005.

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.

The following is a reconciliation of the Company s general product warranty reserve:

	Year Ended March 31,	
	2005	2004
BioVeris and Wholly-Owned Subsidiaries:		
Balance, beginning of period	$ 450	$ 250
Provisions recorded	296	734
Actual costs incurred	(380)	(534)
Balance, end of period	$ 366	$ 450

The following is a reconciliation of the Company s deferred revenue related to extended warranty arrangements and includes a summary of the revenue and cost components associated with extended warranties:

	Year Ended March 31,	
	2005	2004
BioVeris and Wholly-Owned Subsidiaries:		
Deferred revenue, beginning of period	$ 678	$ 566
Extended warranties issued	1,105	1,066
Amortization of extended warranties	(1,162)	(954)
Costs incurred during the period	768	1,083
Settlement during the period of costs incurred	(768)	(1,083)
Balance, end of period	$ 621	$ 678

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.

Distribution Gain Accrual- 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 was recorded on the Company s balance sheet at March 31, 2004 and was paid during fiscal 2005.

Comprehensive Loss- Comprehensive loss is comprised of net loss and other items of comprehensive loss. The Company s comprehensive loss for the year ended March 31, 2005 was $78.6 million. Other comprehensive loss of $999,000 for the year ended March 31, 2005, includes unrealized gains and losses on available for sale securities that are excluded from net loss. There were no significant elements of comprehensive loss for the fiscal years ended March 31, 2004 and 2003.

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 or 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 Emerging Issues Task Force (EITF) Issue No. 00-21 (EITF 00-21) Accounting for Revenue Arrangements with Multiple Deliverables. Revenue is recognized for the instrument upon shipment or delivery, depending on the terms of each order, and is recognized for the installation when complete using the residual value method. For instrument and reagent sales, there is no option of return and refund and instead there is only the option to repair or replace the product.

Other than the installation required for the instruments and the standard warranty, 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 and are comprised of costs incurred in performing research and development activities including salaries, benefits, facilities costs, overhead costs, contract services and other outside costs.

Merger Related Costs There were no merger related costs for the year ended March 31, 2005. 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, 2005, 2004 and 2003.

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 No. 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,		
	2005	2004	2003
Net loss, as reported	**$ (77,573)**	$ (93,319)	$ (50,894)
Deduct: Total stock-based employee compensation expense determined under fair value method	**(224)**	(121)	(2,455)
Pro-forma net loss	**$ (77,797)**	$ (93,440)	$ (53,349)
Loss per share:			
Basic and diluted loss per common share as reported	**$ (2.90)**	$ (3.49)	$ (1.90)
Basic and diluted loss per common share pro forma	**$ (2.91)**	$ (3.50)	$ (2.00)

Per share information for the Company for fiscal years 2004 and 2003 is based on the number of shares of common stock of the Company outstanding upon completion of the merger and related transactions. The pro forma net loss and pro forma net loss per share disclosed above is not representative of the effects on net loss and net loss per share on a pro forma basis in future periods, as future periods may include grants by the Company of options for the Company s common stock. In addition, information for the years ended March 31, 2003 represents options for IGEN common stock which were canceled upon completion of the merger.

The fair value of BioVeris options for the year ended March 31, 2005 and 2004 was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions:

	Years Ended March 31,	
	2005	2004
Expected dividend yield	0.00%	0.00%
Expected stock price volatility	74.00%	52.62%
Risk-free interest rate	3.48%	2.71%
Expected option term (in years)	3-5	3

Based on this calculation, the weighted average fair value of BioVeris options granted during the year ended March 31, 2005 and 2004 was $4.35 and $5.97, respectively. The Company did not have a stock option plan prior to fiscal 2004.

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

Expected dividend yield	0.00%
Expected stock price volatility	68.00%
Risk-free interest rate	3.40%
Expected option term (in years)	5

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

Loss Per Share - The Company uses SFAS No. 128 Earnings per Share for the calculation of basic and diluted loss per share. For each of the three years ended March 31, 2005, 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 year ended March 31, 2003, the unaudited pro-forma net loss per share is based on the number of common shares outstanding upon completion of the merger and related transactions. As the Company incurred a loss for the years ended March 31, 2005 and 2004, it did not assume exercise of 123,000 and 20,300 outstanding options, respectively, because to do so would have been anti-dilutive.

New Accounting Standards -In December 2003, the AICPA issued SOP 03-3, Accounting for Certain Loans or Debt Securities Acquired in a Transfer . The SOP addresses accounting for differences between contractual cash flows expected to be collected from an investor s initial investment in loans or debt securities (loans) acquired in a transfer if those differences are attributable, at least in part, to credit quality. SOP 03-3 limits the yield that may be accreted to the excess of the investor s estimate of undiscounted expected principal, interest, and other cash flows (cash flows

expected at acquisition to be collected) over the investor s initial investment in the loan. The SOP requires that the excess of contractual cash flows over cash flows expected to be collected not be recognized as an adjustment of yield, loss accrual or valuation adjustment. Subsequent increases in cash flows expected to be collected generally should be recognized prospectively through adjustment of the loan s yield over its remaining life. Decreases in cash flows expected to be collected should be recognized as impairment. The SOP is effective for loans acquired in fiscal years beginning December 15, 2004. The Company adopted the provisions of SOP 03-3 as of December 31, 2004.

In November 2004, the EITF reached a consensus on EITF Issue No. 03-13 (EITF 03-13), Applying the Conditions in Paragraph 42 of FAS 144 in Determining Whether to Report Discontinued Operations . EITF 03-13 provides an approach for evaluating whether the criteria in paragraph 42 of Statement of Financial Accounting Standards (SFAS) No. 144 (SFAS 144), Accounting for the Impairment or Disposal of Long-Lived Assets , have been met for classifying as a discontinued operation, a component of an entity that either has been disposed of or is classified as held for sale. To qualify as a discontinued operation, paragraph 42 of FAS 144 requires that cash flows of the disposed component be eliminated from the operations of the ongoing entity and that the ongoing entity not have any significant continuing involvement in the operations of the disposed component after the disposal transaction. EITF 03-13 defines which cash flows are relevant for assessing whether cash flows have been eliminated, and it provides a framework for evaluating what types of ongoing involvement constitute significant continuing involvement. EITF 03-13 should be applied to a component of an entity that is either disposed of or classified as held for sale in fiscal periods beginning after December 15, 2004. The Company does not expect that EITF 03-13 will have a material impact on its financial position or results of operations.

In November 2004, the Financial Accounting Standards Board (FASB) issued SFAS 151, Inventory Costs, an Amendment of Accounting Research Bulletin (ARB) No. 43, Chapter 4. SFAS 151 amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing to clarify the accounting for abnormal amounts of idle facility expense, freight handling costs, and wasted material (spoilage). SFAS 151 requires that those items be recognized as current-period charges regardless of whether they meet the criterion of so abnormal. In addition, SFAS 151 requires that allocation of fixed production overhead to the costs of conversion be based on the normal capacity of the production facilities. The provisions of SFAS 151 will be effective for fiscal years beginning after June 15, 2005. The Company is currently evaluating the provisions of SFAS 151 and does not believe that its adoption will have a material impact on its financial condition, results of operations and liquidity.

In December 2004, the FASB issued SFAS No. 123 (revised 2004) (SFAS 123(R)), Share-Based Payment. SFAS 123(R) replaces SFAS No. 123, Accounting for Stock Issued to Employees, and supersedes Accounting Principal Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees. SFAS 123(R) requires that compensation costs relating to share-based payment transactions be recognized in the consolidated financial statements. Compensation costs will be measured based on the fair value of the equity or liability instruments issued. In April 2005, the SEC issued a rule amending the compliance date which allows companies to implement SFAS 123(R) at the beginning of their next fiscal year, instead of the next reporting period that begins after June 15, 2005. As a result, the Company will implement SFAS 123(R) in the reporting period starting April 1, 2006. The Company is currently evaluating the provisions of SFAS 123(R) and has not yet determined whether to use the modified prospective or the modified retrospective methods allowed by SFAS 123(R), nor has it determined the impact on its financial condition, results of operations and liquidity beyond the disclosure on Note 2 of the Notes to Condensed Consolidated Financial Statements.

In December 2004, the FASB issued SFAS 153, Exchange of Nonmonetary Assets, an amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions. SFAS 153 is based on the principle that exchange of nonmonetary assets should be measured based on the fair market value of the assets exchanged. SFAS 153 eliminates the exception of nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. SFAS 153 is effective for nonmonetary asset exchanges in fiscal periods beginning after June 15, 2005. The Company is currently evaluating the provisions of SFAS 153 and does not believe that its adoption will have a material impact on its financial condition, results of operations and liquidity.

Liquidity -The Company s consolidated balance sheet at March 31, 2005 had cash, cash equivalents and short-term investments of $95.6 million. Product development for the Company s clinical diagnostic and vaccine products are at an early development stage. 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 and vaccine products, including immunodiagnostic and PCR technology-based products, 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 mirrored the class C interest in MSD (see Note 3) that was 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 entitled to receive distributions with respect to its class C interests in MSD, pursuant to the MSD limited liability company agreement. 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. The Company will declare dividends for the Series B preferred stock in connection with any payments received from MSD related to the sale of the Company s class C interests in MSD.

In connection with the settlement 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 interests 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 the Company s class C interests.

In April 2005, the Company declared and paid a dividend of $57 in respect of shares of Series B preferred stock.

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.

Activity related to options under the option plans was as follows:

	Shares	Weighted Average Exercise Price
Outstanding at February 13, 2004		
Granted	22,200	$ 15.80
Exercised		
Cancelled/forfeited	(1,900)	$ 15.80
Outstanding at March 31, 2004	20,300	$ 15.80

Granted	123,900	$	7.53
Exercised			
Cancelled/forfeited	(21,200)	$	8.03
Outstanding at March 31, 2005	123,000	$	8.89
Options exercisable at March 31, 2005	29,000	$	15.80
Options available for future grant	5,177,000		

Summary information about the Company s stock options outstanding at March 31, 2005 is as follows:

Range of Exercise Prices	Options Outstanding	Weighted Average Remaining Years of Contractual Life	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price
$6.21 $6.62	86,000	9.67	$ 6.29		$
$11.85	8,000	9.38	$ 11.85		$
$15.80	29,000	9.02	$ 15.80	29,000	$ 15.80
Total	123,000	9.50	$ 8.89	29,000	$ 15.80

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 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 was also the sole owner of Meso Scale Technologies (MST) and a son of IGEN s and the Company s chairman and chief executive officer (see Note 3). 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 were earned and vested, 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 $2.2 million and $386,000 has been reflected in the accompanying financial statements for the years ended March 31, 2004 and 2003, respectively. This amount included $1.8 million incurred in connection with the cancellation of IGEN stock options and the payment of merger consideration recorded in 2004.

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 the 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 than 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

than 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. MESO SCALE DIAGNOSTICS JOINT VENTURE

MSD is a joint venture formed by IGEN and MST in 1995. MST was established and is wholly-owned by Mr. Jacob Wohlstadter, a son of the Company s chief executive officer, and Jacob Wohlstadter is the president and chief executive officer of MSD. MSD develops, manufactures, markets and sells products utilizing a combination of MST s multi-array technology together with the Company s electrochemiluminescence (ECL) technology. MSD s Sector line of instrumentation is used in drug discovery for high throughput screening, high content screening, multiplexing and target validation. MSD also manufactures and markets a line of its own reagents, assays and plates that are used on these systems.

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 Jacob Wohlstadter. These agreements are collectively referred to 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 the Company and assigned the MSD agreements to the Company. On February 13, 2004, the Company 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 the Company remained a member of MSD) and many provisions of the MSD joint venture agreement survived its expiration. In addition, certain other MSD agreements, including certain licenses and other arrangements with MSD, MST and Jacob Wohlstadter assigned to the Company by IGEN continue indefinitely in accordance with their terms.

In August 2004, an independent committee of the Company s 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 the Company s interest in MSD, as provided for in the MSD Agreements. The Company 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. On December 13, 2004, the Company completed the sale to MST of its interests in MSD. For a more detailed discussion of the settlement, see Note 9 Litigation.

Equity interest and capital contributions

Until the time of the sale of its interests in MSD on December 13, 2004, the Company held a 31% voting equity interest in MSD. MST was the only other member of MSD and owned the remaining 69% voting equity interest. The Company also held non-voting interests that entitled it to receive a preferred return on substantially all of its capital contributions. Following the completion of the buyout of the Company s interests in MSD on December 13, 2004, the Company no longer holds these interests and is entitled to receive only the buyout purchase price.

Neither Dr. Massey nor the Company s other executive officers or directors had any ownership interest in MST or MSD, other than through ownership of interests in the Company and other than the Series B preferred stock of the

Company purchased by Samuel Wohlstadter. Mr. Samuel Wohlstadter disclaims any ownership interest in MST or MSD as a result of Mr. Jacob Wohlstadter s ownership interest in those entities.

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. As part of the settlement between the parties, the Company paid 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.

During the years ended March 31, 2005, 2004 and 2003, the contributions the Company and IGEN made to MSD were $5.0 million, $56.7 million and $20.5 million, respectively. In August 2004, the Company s capital contribution of $5.0 million was part of the settlement, of which $3.0 million was in cash and $2.0 million was in the form of a credit against payment of the purchase price for the buyout by MST of the Company s interest in MSD.

Since inception of the MSD joint venture through March 31, 2004, the equity method had been utilized by the Company to account for this investment. 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 (except for the period from March 31, 2004 through August 12, 2004, during which time the Company consolidated the financial results of MSD, as discussed below).

Effective March 31, 2004, the Company consolidated the financial results of MSD in accordance with FIN 46, which 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 it determined that MSD qualified as a variable interest entity and the Company was a primary beneficiary. The settlement agreement between the parties was determined to constitute a reconsideration event under FIN 46 and the Company has determined that it no longer meets the conditions to be designated as the primary beneficiary of MSD, as certain provisions of the settlement agreement reallocated the obligation to absorb the majority of MSD s future expected losses. Accordingly, beginning August 12, 2004, the Company has deconsolidated the financial results of MSD and resumed accounting for this investment on the equity method through December 13, 2004, the date of the sale of the Company s interests in MSD. See Note 1 for a discussion of consolidation accounting for MSD.

During the years ended March 31, 2005, 2004 and 2003 operating costs allocated to MSD by the Company in connection with shared personnel and facilities were approximately $743,000, $6.0 million and $11.9 million, respectively. Operating costs allocated to MSD for the year ended March 31, 2005 are net of a $476,000 write off of unpaid costs in connection with the settlement agreement, in which all claims against MSD, MST and Jacob Wohlstadter were dismissed and released.

For the years ended March 31, 2004 and 2003 and for the period from August 13, 2004 through December 13, 2004, these allocated operating costs reduced certain of the Company s operating costs and expenses and increased Equity in Loss of Joint Venture in the accompanying consolidated statements of operations. MSD-related losses included in the equity in loss of joint venture were $5.5 million, $19.6 million and $17.6 million for the years ended March 31, 2005, 2004 and 2003, respectively. At March 31, 2004, the Company s investment in joint venture had been eliminated as part of the consolidation of MSD s balance sheet. Summarized financial information for MSD is as follows (in thousands):

	Period April 1, 2004 through December 13, 2004	Years ended March 31,	
		2004	2003

Revenue	$ 10,091	$ 8,383	$ 3,247
Operating expense	23,263	28,528	21,357
Net loss	13,064	19,851	18,215

	December 13, 2004	March 31, 2004
Current assets	$ 36,365	$ 42,257
Total assets	44,840	49,894
Current liabilities	4,147	3,363
Total liabilities	5,629	3,363
Total members equity	39,211	46,531

The following is a summary of the Company s investment in the MSD joint venture (in thousands):

Balance at April 1, 2003	$ 9,164
Capital contribution	56,660
Equity in loss of joint venture	(19,616)
Valuation adjustment	(33,700)
Change in accounting principle	33,700
Balance at March 31, 2004	46,208
Capital contribution	5,045
Equity in loss of joint venture	(5,524)
Valuation adjustment	(35,077)
Sale of interests	(10,652)
Balance at March 31, 2005	$

Buyout of the Company s interest in MSD

Pursuant to the MSD joint venture agreement, MSD and MST had a joint right to purchase the Company s 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 set 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. Pursuant to the settlement, MST or MSD agreed to purchase, and the Company agreed to sell, its entire interest in MSD. The purchase of the Company s interests was completed on December 13, 2004 and accordingly, the Company no longer holds an equity interest in MSD.

As contemplated by the MSD joint venture agreement, the purchase price was to be equal to fair market value of the Company s interests less a discount factor of 7.5%. Fair market value has been determined in accordance with the valuation process set forth in the MSD joint venture agreement. In the settlement, the Company agreed to certain matters in connection with the valuation process, including the timetable for the appraisals. The Company and MSD each appointed an appraiser; a third appraiser was also appointed. The fair market value was determined to be approximately $9.9 million (the average of the two closest determinations, less the 7.5% discount factor).

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. Pursuant to the settlement, the Company paid MSD s share of such fees and costs, which approximated $85,000, which amount was included in the purchase price payable by MST for the Company s interests in MSD. In addition, as more fully described below, MSD s rental and expense payment obligations for subleased property for the period from March 1, 2004 through August 31, 2005, approximating $2.3 million, were included in the purchase price of the Company s interests in MSD in lieu of MSD making current payments.

As provided in the MSD joint venture agreement, MST is 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 or 5.5%, 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.

As part of the settlement, the Company received a $2.0 million non-refundable prepayment from MSD for future amounts payable by MST to the Company for the purchase price in the form of a credit against amounts the Company agreed to pay MSD pursuant to the settlement. This prepayment was recorded as a deferred liability on the Company s balance sheet. 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 or 5.0%, in effect on the date that MST purchased the Company s 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 the Company pursuant to the buyout of its interest in MSD.

No further cash payments will be payable by MST to the Company 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, the Company will not receive any additional payments from MST for the purchase of its interests in MSD. As security for the payment obligation, the Company holds a security interest in the interests in MSD that have been purchased. MST 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 following table summarizes the adjustments provided in the joint venture and settlement agreements (in thousands):

Fair market value purchase price	$ 9,898
Add:	
Appraisal fees and costs	85
Rent payment obligations (March 1, 2004 through August 31, 2005)	2,335
Less:	
Prepayment credit	(2,000)
Total	$ 10,318
Note receivable-recorded at the fair value purchase price payments	$ 4,709

Upon closing of the sale of the Company s interests in MSD, the total purchase price balance was approximately $10.3 million (net of the $2.0 million prepayment by MSD). The Company recorded a note receivable which has a balance of approximately $4.7 million at March 31, 2005, and which represents the net present value of future payments that the Company expects to realize from the sale of its interests in MSD. Calculating the net present value of future payments that the Company expects to realize as payment for the purchase price requires assumptions about MSD, including the timing and amount of MSD s future financings and revenue, and an appropriate discount rate. If actual results differ from these assumptions, the net present value of future payments received by the Company could differ from the amount reflected on the balance sheet at March 31, 2005.

The Company had recorded an approximate $1.2 million liability at March 31, 2004 representing the estimated value of MSD s option to purchase the Company s interests in MSD. During the year ended March 31, 2005, this liability was offset against the book value of the Company s interests in MSD upon sale of the Company s interests, and utilizing the guidance of APB 18, the Company recorded non-cash impairment charges of $35.1 million representing the amount by which the book value of the Company s interests in MSD exceeded the fair value purchase price of those interests. During the year ended March 31, 2005, the Company recorded interest income on the amount due from the sale of its interests in MSD, net of the interest expense on the prepayment credit, of approximately $171,000.

The holder of the Company s Series B preferred stock is entitled to a pro-rata share of payments from the sale of the Company s MSD interests. This pro-rata share approximates 6.3% of the $9.9 million sale price, representing the proportionate amount of the Company s Class C interest in MSD that was funded by the sale of the Series B stock (including payments allocated to the $2.0 million prepayment).

Transitional services and subleases

When the MSD joint venture agreement expired, the Company was no longer required to provide research personnel and corporate services to MSD. The Company has continued, and expects that it 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. The Company bills MSD for the cost of these services on a periodic basis. In connection with the settlement agreement, all claims against MSD, MST and Jacob Wohlstadter were dismissed and released, including unpaid costs for transitional services of approximately $476,000.

MSD leases certain facilities and related equipment from the Company (including laboratory facilities located in the Company s 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, 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. 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 is required to pay its pro-rata share of all rental and other expenses the Company incurs under the prime lease. 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 described above, as part of the settlement, MSD s rental and expense payment obligations for the period from March 1, 2004 through August 31, 2005, which are expected to approximate $2.3 million, were included in the purchase price of the Company s interests in MSD in lieu of MSD making current payments.

The estimated future rent obligations of MSD of $693,000 for the period from April 1, 2005 through August 31, 2005 has been recorded as deferred rent and is included with current liabilities on the Company s balance sheet at March 31, 2005. Future rent payments that are related to MSD s rent obligations will be recorded against the deferred rent liability.

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 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 the Company an exclusive, worldwide, royalty-free license to use in the diagnostic field certain defined improvements developed by MSD in the MSD research program. However, the Company may not make, use or sell products, processes or services that use certain defined ECL 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.

Although the MSD joint venture agreement has expired, the license granted to the Company to use in the diagnostic field certain defined ECL improvements developed by MSD remains in effect. In addition, after the Company ceases to be a member of MSD, MSD may require the Company to distribute MSD s products pursuant to a mutually agreeable distribution agreement, and the Company will be required to pay to MST a royalty of 3% of net sales of MSD products sold by it.

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, the Company remains subject to limitations on its 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 the Company s employees have ceased. Certain of the Company s 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 of certain information;
- 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, the Company is 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 the Company, 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 December 13, 2004 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 agreement by MSD and MST to purchase the Company s interests in MSD, the Company was 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 the Company made to MSD in connection with the settlement was made in full and complete satisfaction of any obligation it had in connection with such expenses.

IGEN/MSD license agreement

Under the terms of the IGEN/MSD license agreement, which is one of the MSD agreements, IGEN granted to MSD a worldwide, perpetual, exclusive license (with certain exceptions) to the Company s 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 the Company. The IGEN/MSD license agreement survived the expiration of the MSD joint venture agreement and the termination of the Company s status as a member of MSD. In addition, when the Company ceased to be a member of MSD, it became 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 the Company 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, 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.

MSD/MST sublicense agreement

MST holds a worldwide, perpetual, non-exclusive sublicense from MSD, which is referred to as the MSD/MST sublicense agreement, to use the Company s 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 the Company is a member of MSD, it is 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 the Company received as part of the merger and related transactions.

The Company assumed IGEN s obligation under the MSD agreements to make its technology available for sublicense by MSD to MST, and these obligations survived the expiration of the MSD joint venture agreement and the termination of the Company s or MST s status as a member of MSD. The Company is not, however, obligated to make available for

sublicense by MSD to MST any technology or improvements to the Company s technology developed after the expiration of the MSD joint venture agreement or the termination of the Company s or MST s status as a member of MSD. In addition, the Company may terminate its participation in the MSD/MST sublicense agreement upon MSD s or MST s material breach, after notice and an opportunity to cure the breach.

Employment and consulting agreement

The Company assumed an employment agreement pursuant to which Jacob Wohlstadter is serving as the president and chief executive officer of MSD. The current term of the employment runs through November 30, 2006. The term of the employment agreement will automatically renew for a 12-month period on November 30 of each year unless either MSD or Jacob Wohlstadter gives notice of termination no later than 180 days prior to that renewal date. Most of the Company s obligations under the employment agreement have ended, except that it remains obligated to maintain in effect directors and officers liability insurance coverage for Jacob Wohlstadter, to pay or cause MSD to pay a gross-up for any parachute excise tax that may be imposed and to indemnify Jacob Wohlstadter against certain liabilities, including liability from the MSD joint venture relating to the period of IGEN s or the Company s involvement with MSD.

Jacob Wohlstadter had a consulting agreement with IGEN that the Company assumed and which terminated on August 15, 2004. Pursuant to the consulting agreement, Jacob Wohlstadter was entitled to receive such fees as the Company and Jacob Wohlstadter agree to when consulting services are requested by the Company. The Company did not ask Jacob Wohlstadter to perform, nor did he perform, any compensable consulting services during the years ended March 31, 2005, 2004 and 2003.

Certain indemnification agreements and obligations

Jacob Wohlstadter and JW Consulting Services, L.L.C., a company established and wholly-owned by Jacob Wohlstadter, have an indemnification agreement with IGEN that the Company assumed. Pursuant to the indemnification agreement, the Company will indemnify 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 the Company.

In addition, the Company 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 the Company made to MSD in connection with the settlement was made in full and complete satisfaction of the dispute.

The Company 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, or the preparation of MSD audited or unaudited financial statements requested by the Company.

In addition, the Company 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 the Company is (or its predecessor, IGEN, was) an issuer of publicly traded securities. The Company is 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.

4. 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 $240,000, $231,000 and $236,000 has been recognized in the accompanying consolidated financial statements for the years ended March 31, 2005, 2004, and 2003, 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 $1.0 million, $828,000 and $871,000 has been recognized in the accompanying consolidated financial statements for the years ended March 31, 2005, 2004 and 2003, respectively.

5. 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 $421,000, $1.0 million and $1.0 million for the years ended March 31, 2005, 2004 and 2003, 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 amount due from affiliated companies under the shared services arrangements was approximately $8,000 at March 31, 2005 and the affiliated companies had prepaid approximately $12,000 under the shared services arrangements at March 31, 2004. All such balances were settled subsequent to each respective year-end.

Since 1995, the Company had 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, the Company had also 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 the Company s Chief Executive Officer since December 2001, is a junior partner in that law firm. These two firms merged during 2004 creating the firm of Wilmer, Cutler, Pickering, Hale & Dorr LLP. The Company recorded approximately $2.2 million, $400,000 and $200,000 in legal fees with the combined law firm for the years ended March 31, 2005, 2004 and 2003, respectively.

6. COMMITMENTS

The Company leased office, laboratory and manufacturing facilities pursuant to operating leases expiring at various times from fiscal 2006 through fiscal 2011. Rent expense for these operating leases totaled approximately $3.4 million, $2.9 million and $2.9 million for the years ended March 31, 2005, 2004 and 2003, respectively,

including approximately $600,000 in fiscal 2005 of leased facilities for use in the Company s vaccine programs.

At March 31, 2005, the future minimum operating lease payments are as follows (in thousands):

2006	$ 3,003
2007	2,810
2008	2,783
2009	2,762
2010	2,179
2011 and thereafter	547
Total	$ 14,084

At March 31, 2005, the Company had committed to sponsor research of approximately $367,000 and $233,000 in fiscal 2006 and 2007, respectively. Subsequent to March 31, 2005, the Company entered into a sponsored research agreement under which it will pay up to $600,000 of research through December 31, 2006.

7. INCOME TAXES

Prior to the merger and related transactions, the Company s operating results historically had been included in IGEN s consolidated Federal and state income tax returns. For purposes of the Company s consolidated financial statements, 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, 2005, 2004 and 2003, 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 acquired 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,		
	2005	2004	2003
		(In thousands)	
Deferred tax assets:			
Accruals and reserves	$ **877**	$ 895	$ 551
Deferred revenue	**300**	321	219
Equipment and leasehold improvements	**1,711**	1,612	1,304
Investment in affiliate		1,466	1,954
Net operating loss carryforwards	**32,175**	3,243	
Capital loss carryforward	**15,247**		
Research and development credits	**626**	114	
Other	**(482)**	(416)	(238)
Total deferred tax assets	**50,454**	7,234	3,790
Less: valuation allowance	**(50,454)**	(7,234)	(3,790)
Net deferred tax assets	**$**	$	$

A valuation allowance equal to the total net deferred tax assets has been provided as of March 31, 2005, 2004 and 2003 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 $43.4 million and $3.4 million for the years ended March 31, 2005 and 2004, respectively. Net operating loss carryforwards as of March 31, 2005 approximate $83 million and $4.7 million in the U.S. and the United Kingdom, respectively. The U.S. losses will begin to expire in 2024 and the U.K. losses can be carried forward indefinitely. 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:

	Years Ended March 31,		
	2005	2004	2003
Income tax provision at federal statutory rate	**34.0%**	34.0%	34.0%
State and local taxes net of federal benefit	**4.6%**	4.6%	4.6%
Non-deductible items	**(0.3)%**	(0.1)%	(0.3)%
Change in valuation allowance	**(39.0)%**	(3.8)%	(39.9)%
Loss in tax attributes due to change control	**0.0%**	(35.5)%	0.0%
Other	**0.7%**	0.8%	1.6%
Effective tax rates	**0.0%**	0.0%	0.0%

8. EMPLOYEE SAVINGS PLAN

The Company has an Employee Savings Plan intended to qualify under Sections 401(a) and 401(k) of the Internal Revenue Code of 1986, as amended, and subject to the Employee Retirement Income Security Act of 1974, as amended. The Company made discretionary contributions of $343,000, $508,000 and $544,000 for the years ended March 31, 2005, 2004 and 2003, respectively. The Company is not obligated under any postretirement benefit plan.

9. LITIGATION

In June 2004, the Audit Committee of the Company s Board of Directors investigated a series of transactions whereby MSD, upon Jacob Wohlstadter s sole approval and without the Company s knowledge, purchased residential real property and luxury automobiles for approximately $7.0 million. On June 15, 2004, the Company filed an action in the Court of Chancery of the State of Delaware against Jacob Wohlstadter, MSD and MST and sought an order from the court confirming that the Company remained entitled to designate one of the two members of the MSD Board of Managers and prohibiting MSD from taking any actions outside the ordinary course of MSD s business without giving prior notice to the Company, pending the final outcome of the litigation. 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.

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 MSD Board of Managers. Jacob Wohlstadter also agreed to assume MSD s obligations with respect to a prospective approximately $4.1 million real property purchase. 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 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 19, 2004, all of the members of the Company s Board of Directors met to review the MSD litigation and related issues. As a result of its review, the Board of Directors, with all members participating, unanimously approved a resolution that delegated to the Joint Venture Oversight Committee (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 five independent directors, and provided that action of the JVOC should be by unanimous approval of its members.

Following extensive negotiations and the unanimous approval of the JVOC, on August 12, 2004 the parties entered into an agreement to settle the lawsuits involving MSD, MST and Jacob Wohlstadter. Pursuant to the terms of the settlement agreement:

the two lawsuits against MSD, MST and Jacob Wohlstadter were suspended and then dismissed with prejudice.

subject to certain exceptions, the parties waived all present and future claims against each other and any of their respective affiliates.

MSD or MST agreed to purchase the Company s interests in MSD pursuant to the buyout process set forth in the MSD joint venture agreement in accordance with certain agreed-upon terms and procedures.

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 and a copy of its audited financial statements for the year ended December 31, 2003, enabling the Company to file its Annual Report on Form 10-K for the fiscal year ended March 31, 2004.

the Company paid the fees of MSD s independent auditor in connection with the audit of MSD and agreed to indemnify MSD, MST and Jacob Wohlstadter against any losses, costs, fees and expenses arising out of any future audits of MSD, the preparation of MSD financial statements requested by the Company or with respect to regulatory or legal proceedings and investigations resulting from the fact that BioVeris is a public company.

the Company paid MSD $3.0 million in satisfaction of all amounts that the Company allegedly owed to MSD pursuant to existing agreements between it and MSD. The $3.0 million payment was 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 pursuant to the buyout of the Company s interests in MSD.

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 it 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 currently engaged in the development, manufacturing and marketing of products for the detection and measurement of biological and chemical substances.

Product sales by region are as follows:

	Years Ended March 31,		
	2005	2004	2003
	(In thousands)		
BioVeris and Wholly-Owned Subsidiaries:			
United States	**$ 16,270**	$ 13,585	$ 11,993
United Kingdom	**3,993**	1,607	1,823
All other foreign	**440**	3,549	2,671
Total	**20,703**	$ 18,741	$ 16,487

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

Product sales by market are as follows:

	Years Ended March 31,		
	2005	2004	2003
	(In thousands)		
BioVeris and Wholly-Owned Subsidiaries:			
Life Sciences	**$ 11,335**	$ 12,635	$ 11,895

Biodefense	**9,368**	6,106	4,592
Total	**20,703**	$ 18,741	$ 16,487

11. QUARTERLY OPERATING RESULTS (Unaudited)

	First	Second	Third	Fourth
	(In thousands, except per share data)			
For the years ended March 31,				
2005 (1)				
Revenue	$ 8,245	$ 7,851	$ 5,299	$ 4,904
Loss from operations	(13,245)	(10,190)	(8,784)	(8,039)
Net loss (2)	(12,851)	(45,618)	(11,974)	(7,130)
Net loss per common share	(0.48)	(1.71)	(0.45)	(0.27)
2004				
Revenue	$ 5,073	$ 5,951	$ 3,784	$ 5,148
Loss from operations (3)	(7,368)	(6,817)	(12,367)	(79,918)
Net loss (2)	(12,518)	(11,299)	(15,984)	(53,518)
Net loss per common share (4)	(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 (4)	(0.48)	(0.52)	(0.42)	(0.48)

(1) The Company adopted FIN 46 as of March 31, 2004 and determined that MSD qualified as a variable interest entity. Accordingly, beginning March 31, 2004, the Company consolidated the financial results of MSD. The Company has historically recorded approximately 100% of MSD s losses. On August 12, 2004, BioVeris, MSD and MST entered into a settlement agreement that resolved litigation between the parties and constituted a reconsideration event under FIN 46. The Company has determined that it no longer met the conditions to be designated as the primary beneficiary of MSD, as certain provisions of the settlement agreement reallocated the obligation to absorb the majority of MSD s future expected losses. Accordingly, for the period April 1, 2004 through August 12, 2004, the Company has consolidated the financial results of MSD and beginning August 13, 2004, has deconsolidated the financial results of MSD and has accounted for this investment on the equity method through December 13, 2004, the date of the sale of its interests in MSD.

(2) See Note 3 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) Operating costs and expenses for the fourth quarter include certain nonrecurring costs of $75.7 million in connection with the merger and related transactions, which consisted of an allocated one-time, non-cash 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.

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

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.

12. 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				
2003	$ 89	$ 135	$ (76)	$ 148
2004	148	60		208
2005	208	20	(1)	227
Inventory reserve				
2003	$ 323	$ 102	$ (112)	$ 313
2004	313	402		715
2005	715	329	(773)	271
Income tax valuation				
2003	$ 3,478	$ 312	$	$ 3,790
2004	3,790	3,444		7,234
2005	7,234	43,220		50,454

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

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

None

ITEM 9A. CONTROLS AND PROCEDURES.

Controls and Procedures

We have carried out an evaluation, under the supervision and the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Securities Exchange Act), as of March 31, 2005. Based upon this evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2005, our disclosure controls and procedures were effective.

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures will prevent all errors or fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met and our disclosure controls and procedures are designed to provide this reasonable assurance. Based upon the evaluation discussed above, our principal executive officer and principal financial officer concluded that, as of March 31, 2005, our disclosure controls and procedures were effective at providing such reasonable assurance. Because of inherent limitations in all control systems, no evaluation of control can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected .

Changes in Internal Control over Financial Reporting

During the fourth quarter of the year ended March 31, 2005, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially effect, our internal control over financial reporting.

Management s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, a company s principal executive and principal financial officers and effected by a company s board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisitions, use or disposition of our assets that could have a material effect on the financial statements.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention of timely detection of unauthorized acquisitions, use, or disposition of the company s assets that could have a material effect on the financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in condition, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of March 31, 2005. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework.

Based on our assessment, our management has concluded that, as of March 31, 2005, our internal control over financial reporting is effective based on those criteria. Our management s assessment of the effectiveness of our internal control over financial reporting as of March 31, 2005 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears in Part II Item 8 Consolidated Financial Statements and Supplementary Data.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required under this item may be found under Executive Officers of BioVeris Corporation in Part I, Item 1 Business of this annual report on Form 10-K, as well as under sections captioned Election of Directors, Directors, Section 16(a) Beneficial Ownership Reporting Compliance and Governance in our Proxy Statement (the 2005 Proxy Statement), which will be filed with the SEC not later than 120 days after the close of our fiscal year ended March 31, 2005, and which is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required under this item may be found under the section captioned Compensation and Other Information Concerning Directors and Officers in the 2005 Proxy Statement, and is incorporated herein by reference.

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

The information required under this item may be found under the section captioned Securities Ownership of Certain Beneficial Owners and Management in the 2005 Proxy Statement, and is incorporated herein by reference.

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 and Supplementary Data Notes to Consolidated Financial Statements Note 2.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required under this item may be found under the section captioned Certain Relationships and Related Transactions in the 2005 Proxy Statement, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required under this item may be found under the section captioned Audit Fees and Pre-approval of Services by the Independent Auditor in the 2005 Proxy Statement, and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this Annual Report on Form 10-K.

(1) Consolidated Financial Statements.

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

(2) Financial Statement Schedules.

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) Exhibits.

The following exhibits are referenced or included as part of this Annual Report on Form 10-K.

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 July24, 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 30, 1995 between MesoScale 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 30, 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[15]	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.
10.36[15]	Agreement dated August 12, 2004, among BioVeris Corporation, MesoScale Diagnostics, LLC., Meso Scale Technologies, LLC., Jacob N. Wohlstadter and Richard J. Massey.
10.37[16]	Charter for the Governance and Nominating Committee of the Board of Directors dated November 15, 2004.
14.1[15]	Corporate Code of Conduct and Business Ethics.
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.
23.4	Consent of Aronson & Company. 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, 2004 and years ended 2003 and 2002 (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.

(15) Previously filed as an exhibit to BioVeris Corporation s Form 10-K for the fiscal year ended March 31, 2004, filed August 16, 2004.

(16)

Previously filed as an exhibit to BioVeris Corporations Form 10-Q for the quarter ended September 30, 2004, filed November 15, 2004.

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

Date: June 13, 2005

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	June 13, 2005
/s/ George V. Migausky George V. Migausky	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	June 13, 2005
/s/ Richard J. Massey Richard J. Massey	President, Chief Operating Officer; Director	June 13, 2005
/s/ William J. Crowley Jr. William J. Crowley Jr.	Director	June 13, 2005
/s/ John Quinn John Quinn	Director	June 13, 2005
/s/ Anthony Rees Anthony Rees	Director	June 13, 2005
/s/ Joop Sistermans Joop Sistermans	Director	June 13, 2005