BIOVERIS CORP
Form 10-K
June 14, 2006

UNITED STATES

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, 2006
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)	(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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ( ) **No (X)**

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.

Yes ( ) **No (X)**

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 (X) **No ( )**

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained to the best of the 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 a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer ( ) **Accelerated filer (X)** **Non-accelerated filer ( )**

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act)

Yes ( ) **No (X)**

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of September 30, 2005, computed by reference to the closing sale price of such stock quoted on The Nasdaq National Market on such date, was approximately $119,832,828.

The number of shares outstanding of the registrant s Common Stock, $0.001 par value per share, as of May 31, 2006 was 27,237,821.

Documents Incorporated by Reference: Portions of the definitive Proxy Statement for our 2006 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, 2006

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As used herein, BioVeris , we , us and our refer to BioVeris Corporation and its subsidiaries. M-SERIES, TRICORDER, BIOVERIFY, and BIOVERIS are our trademarks. This Form 10-K also contains disclosures 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 and vaccine 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, inten 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, biosecurity, life science and industrial markets and other healthcare opportunities;

our ability to develop and introduce new or enhanced products;

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 and biosecurity funding, 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;

our 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, royalties, payment obligations 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, and IGEN LS, LLC, an affiliate of Roche Diagnostics GmbH and Roche Holding Ltd, which we collectively refer to in this Form 10-K as Roche;

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

We are a global integrated healthcare company developing proprietary technologies in diagnostics and vaccinology. We are dedicated to the commercialization of innovative products and services for healthcare providers, their patients and their communities.

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

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

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

agreements between certain affiliates of Roche and us became effective.

Diagnostics

We develop, manufacture and market our M-SERIES(R) 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 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 biosecurity, life science and industrial markets. The non-clinical diagnostics market includes biosecurity 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 biosecurity 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 a clinical analyzer that builds on the M-SERIES instruments we sell in the biosecurity and life science markets. We 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 as biosecurity tools for use 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. 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. We believe our M-SERIES product line for the life science market is ideally suited to perform immunogenicity testing by measuring low affinity antibodies with high sensitivity, all in the presence of the highly concentrated drug.

Vaccines

In fiscal 2005, we expanded our business model to target the field of vaccines. In connection with this effort, we have entered into the following license and option agreements:

An 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 satisfy a significant unmet medical need.

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.

An 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 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*.

A technology license agreement with Baxter Healthcare Corporation for exclusive patent rights to a broad portfolio of vaccine candidates. Vaccines covered by the Agreement include those for the prevention of diseases caused by Group A streptococci (GAS), GBS, Pneumococci, GBM, anthrax bacilli and urinary tract infection (UTI) associated with *E coli.* Under that agreement, we receive exclusive rights to patents or know-how related to the manufacture, production, use and commercialization of the vaccine candidates.

A license agreement with The Rockefeller University under which we receive an exclusive, worldwide license of patents and know-how to manufacture, use and commercialize a unique vaccine candidate for GAS, including pharmaceutical, therapeutic, diagnostic and vaccine applications thereof. GAS, also known as *Streptococcus pyogenes*, causes a range of mild to severe diseases in both children and adults and there is currently no vaccine for this disease. The technology from Rockefeller University is based on the use of bacterial polysaccharide in a new vaccine to elicit protective antibodies, which we believe will complement our existing carbohydrate conjugate vaccine platform.

An agreement with TheraCarb, Inc. of Edmonton, Alberta for exclusive patent rights to a vaccine candidate for *Candida albicans*, the most common fungal pathogen affecting humans. Under the agreement with TheraCarb, we acquired a first option for exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of *Candida albicans* infections. *Candida albicans* is the most common of the Candida species, which are ubiquitous, opportunistic pathogens that colonize more than half of all healthy individuals in the U.S., causing systemic disease in nearly 15% of those who are immunocompromised.

Under these license and option agreements, the Company paid certain upfront fees and may also make additional future payments for patent costs, milestone fees, including for initiating and completing human clinical trials and receiving regulatory approvals, and royalties on future sales.

In connection with our efforts to determine an individual s personal immune status through unique diagnostic test panels, we entered into a license and research agreement with Jewish General Hospital (JGH) in Montreal under which we received an exclusive, worldwide license to the use of a JGH database that contains demographic data and the serologic status of an immigrant population linked to numerous infectious diseases.

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 incorporate a number of technologies, including:

- ECL technology developed and owned by us;
- various improvements to ECL technology developed by Roche and licensed to us;
- polymerase chain reaction technology developed by Roche 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

In addition, we have rights to a portfolio of unique vaccine candidates.

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 immunodiagnostic and nucleic acid tests to be performed 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. 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 restricts our right to use such improvements in certain types of ECL products. 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 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.

Vaccines

In fiscal 2005, we expanded our business model to target the field of vaccines and have rights to certain vaccine candidates through the following license and option agreements:

An option agreement with Children s Hospital & Research Center at Oakland for exclusive patent rights to a unique vaccine candidate for *Neisseria meningitidis* serogroup B, which causes meningitis.

An agreement with the National Research Council of Canada for a license to patent rights to candidates for a GBS

Type II and Type V vaccine and a group B meningococcus vaccine.

An agreement with the University of Massachusetts at Amherst for exclusive patent rights to a unique vaccine candidate for Chlamydia.

A technology license agreement with Baxter Healthcare Corporation for exclusive patent rights to a broad portfolio of vaccine candidates. Vaccines covered by the Agreement include those for the prevention of diseases caused by GAS, GBS, Pneumococci, GBM, anthrax bacilli and UTI associated with *E coli.*

A license agreement with The Rockefeller University under which we receive an exclusive, worldwide license of patents and know-how to manufacture, use and commercialize a unique vaccine candidate for GAS, including pharmaceutical, therapeutic, diagnostic and vaccine applications thereof.

An agreement with TheraCarb, Inc. of Edmonton, Alberta for exclusive patent rights to a vaccine candidate for *Candida albicans*, the most common fungal pathogen affecting humans.

Products and Markets Using Our Technology

The following table summarizes the range of products that we have licensed, developed or are developing:

BioVeris Products	**Customer Application**	**Market**	**Status**
Diagnostics			
M-SERIES (Clinical analyzer and clinical diagnostic tests)	Screen, monitor and diagnose medical conditions	Clinical	Development

M-SERIES (M384 Analyzer and reagents)	Drug discovery and development	Life science	Product sales
M-SERIES (M1M Analyzer and reagents)	Drug discovery and development	Life science	Product sales
	Detection of food and beverage contaminants and bacteria, viruses and toxins	Biosecurity	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	Preventative medicine	Vaccine	Pre-clinical research
Chlamydia	Preventative medicine	Vaccine	Pre-clinical research
Group A streptococcus	Preventative medicine	Vaccine	Pre-clinical research
Pneumococcus	Preventative medicine	Vaccine	Pre-clinical research
Anthrax bacilli	Preventative medicine	Vaccine	Pre-clinical research
Urinary tract infection (*E coli)*	Preventative medicine	Vaccine	Pre-clinical research
Candida albicans	Preventative medicine	Vaccine	Pre-clinical research

The following table summarizes the range of products that our licensees have developed using our ECL technology. For a description of the commercial arrangements and license agreements that we have with our licensees see Business-Collaborations and License Arrangements.

	Customer Application	**Market**	**Status**	**Licensee**
Licensee Products				
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 directly 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 our ECL technology is ideally suited for the 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 because 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, regulations, lack of sensitivity 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, most 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 under development will 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 would 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.

In connection with our efforts to determine an individual s personal immune status, we entered into a license and research agreement with Jewish General Hospital in Montreal under which BioVeris received an exclusive, worldwide license to the use of a JGH database that contains demographic data and the serologic status of an immigrant population linked to numerous infectious diseases.

We are also 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, including through collaborative arrangements.

Non-Clinical Diagnostics

Biosecurity. We are commercializing products in the emerging market segment for biosecurity, 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. We believe there will be an increasing opportunity to use our products as a biosecurity 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. Our presence in the biosecurity market may also provide us with the opportunity to sell products to other diagnostics markets. We believe that tests developed for the biosecurity field may also have utility in the clinical diagnostic markets by providing tests for patients exposed to biological agents or toxins. We expect that our non-clinical products for biosecurity 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 Biosecurity and Industrial Testing Products for a more detailed description of the government regulations to which we are subject in connection with our biosecurity products.

Our M-SERIES M1M Analyzer 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(TM) test kits for the detection of botulinum neurotoxins, anthrax, ricin, staphylococcal enterotoxins A and B, E. coli O157, and salmonella, 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. The M-SERIES M1M Analyzer was also designed for use by first responders, such as trauma centers, emergency medical workers, firefighters and police. We market the M-SERIES product family directly through our own sales, marketing and applications teams. Instrument systems originally designed for the biosecurity market are now also being used in life science.

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. The tests are used by various laboratories and field sites of the DOD. For risks related to our contracts with the government see ITEM 1A Risk Factors Risks Relating to Regulation and Government Contracts.

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(TM) and Biomek(R) 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:

our Cooperative Research and Development Agreement with the U.S. Army Medical Research Institute of Infectious Diseases for the development of tests for the detection of biological toxins;

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

the continued integration of our 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 1A Risk Factors Risks Relating to Regulation and Government Contracts.

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.

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 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 than other methods 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 test results.

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. 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, 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. We believe our M-SERIES product line for the life science market is 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 also typically sell proprietary reagents to customers. We market the M-SERIES product family directly through our own sales, marketing and applications teams. 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

In fiscal 2005, we expanded our business model to target the field of vaccines and have rights to certain vaccine candidates through license and option agreements.

Neisseria meningitidis serogroup B

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% of the individuals who contract meningococcal disease will die. Of the survivors, up to 20% 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% 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 entered into license and option agreements for exclusive patent rights to a unique vaccine candidate for *Neisseria meningitidis* serogroup B and now have candidates for vaccines against bacterial meningitis, including that of streptococcal, pneumococcal and meningococcal origin. We believe that the availability of an effective vaccine that would prevent meningococcal serogroup B, for use by various population groups, could satisfy a significant unmet medical need.

Group B Streptococcus

We have also entered into agreements under which we license patent rights to candidates for a GBS conjugate vaccine. GBS is a leading cause of sepsis, pneumonia, and meningitis among newborns. Approximately 25% 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%. 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 %. 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.

Chlamydia

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 vaccine technology licensed by us is 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.

We have licensed exclusive patent rights to a unique vaccine candidate for Chlamydia under which we received exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of all Chlamydial infections.

Group A Streptococcus

GAS, also known as *Streptococcus pyogenes*, causes a range of mild to severe diseases in both children and adults. Most infections are mild or noninvasive, accounting for more than 10 million cases annually in the U.S., and primarily include strep throat (pharyngitis) and impetigo (skin infection). Industry analysts have estimated that the potential market for an effective GAS vaccine could exceed $1 billion annually.

Invasive disease from GAS occurs when the organism spreads to deeper areas of the body (e.g., blood, muscles, lungs, bones, spinal cord and abdomen) and results in severe illness, which may include necrotizing fasciitis (flesh-eating bacteria) and Streptococcal Toxic Shock Syndrome (STSS). The Centers for Disease Control and Prevention estimates that approximately 11,000 cases of invasive disease occurred in the U.S. in 2003, which resulted in 1,700 deaths. While the overall mortality rate for invasive disease is between 10% and 13%, it increases to 25% for flesh-eating bacteria and to 45% for STSS, in spite of available antibiotics. There is currently no vaccine for this disease. The technology licensed by us is based on the use of bacterial polysaccharide in a new vaccine to elicit protective antibodies, which should complement our existing carbohydrate conjugate vaccine platform.

We received an exclusive, worldwide license of patents and know-how to manufacture, use and commercialize a unique vaccine candidate for GAS, including pharmaceutical, therapeutic, diagnostic and vaccine applications thereof.

Candida albicans

Candida albicans is the most common of the Candida species, which are ubiquitous, opportunistic pathogens that colonize more than half of all healthy individuals in the U.S., causing systemic disease in nearly 15% of those who are immunocompromised. Resulting diseases include:

Genital candidiasis, or vaginal yeast infections, which is the second most common cause of vaginitis. Vaginal candidiasis affects approximately 75% of all women at least once during their lifetime. While certain risk factors increase the likelihood of contracting vaginal candidiasis (e.g., pregnancy, diabetes, antibiotic use, birth control pill use, corticosteroid use, being immunocompromised), approximately 10% of women have recurring yeast infections without precipitating risk. Antifungal therapy has a high success rate; however, prolonged use of antifungal drugs, particularly through self-medication without formal diagnosis, has resulted in increased

drug resistance. The carbohydrate-based vaccine technology is expected to be a safe approach that provides long-lasting immunity for this vulnerable population.

Invasive or systemic candidiasis, which is common in newborns of low birth weight and immunocompromised people. Although relatively rare, systemic candidiasis represents the most serious Candida infection, with a mortality rate as high as 77% for those who are immunocompromised. This group includes patients scheduled to receive abdominal surgery; transplantations including bone marrow, kidney or heart; and immunosuppressive cancer therapy. A successful vaccine could be used to provide protection prior to initiating treatment of individuals who are at high risk of developing serious conditions due to *Candida albicans* and augment conventional antifungal drug therapy.

Oropharyngeal candidiasis or thrush, which is common in infants and immunocompromised adults.

Esophagitis, which is common for immunocompromised people and occurs in the majority of people with AIDS.

Cutaneous candidiasis, which is common with heavily moistened skin and diaper rash.

We have entered into an agreement for exclusive patent rights to a vaccine candidate for *Candida albicans*, under which we acquired a first option for exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of *Candida albicans* infections.

Pneumococcus

Streptococcus pneumoniae, also called pneumococcus, causes an acute bacterial infection. Pneumococcus infections are among the leading causes worldwide of illness and death for young children, persons with underlying dehabilitating medical conditions and the elderly. Each year in the United States, pneumococcal disease accounts for a significant number of cases of meningitis, bacteremia, pneumonia, and acute otitis media.

Some pneumococci bacteria are encapsulated with their surfaces composed of complex polysaccharides and such encapsulated bacteria are pathogenic for humans. They are antigenic and form the basis for classifying pneumococci by serotypes of which ninety serotypes have been identified. After the widespread use of the 7-valent pnuemococcal vaccine, replacement serotypes have emerged. Serotype replacement identifies a continued need for pneumococcal vaccine development.

We received an exclusive, worldwide license of patents and know-how to manufacture, use and commercialize a unique vaccine candidate for pneumococcus.

Anthrax

Anthrax is caused by the spore-forming, non-motile gram-positive bacterium, *Bacillus anthracis*, a zoonotic disease in herbivores, such as sheep, goats, and cattle following ingestion of spores. Human infections are acquired through direct contact either with infected animals, animal products or intentional exposure. The most common naturally occurring cases of infection are cutaneous, followed by gastrointestinal and inhalational anthrax, the latter resulting in a fatality rate of greater than 80% if left untreated. Multiple U.S. government agencies have concluded that the use of anthrax will increase as an instrument of terrorism, that environmental contamination will spread, and that lower doses of spores than previously believed are required to induce inhalational anthrax.

We received an exclusive, worldwide license of patents and know-how to manufacture, use and commercialize a unique vaccine candidate for anthrax.

Urinary tract infection (E. coli)

UTI is the second most common bacterial infection in humans and the most frequent infection in women. 40-50% of adult women have at least one UTI in their lifetime, and more than half of sexually active young women who are starting a new method of contraception will develop a UTI within the first year. Recurrent UTI occurs in 25-50% of healthy women after their initial infection, in spite of antibiotic therapy. Worldwide, about 150 million UTIs are estimated to occur annually resulting in approximately $6 billion of direct healthcare costs. UTIs account for at least 8 million doctor visits annually in the U.S., resulting in approximately $1.6 billion in annual healthcare costs. UTIs are one of the most common reasons that antibiotics are prescribed, leading to greater drug resistance, including a spread of multidrug-resistant UTIs.

The urinary tract is the dominant site for nosocomial (hospital-acquired) infection, usually occurring as catheter-associated UTI, which accounts for more than 1 million infected patients annually in the U.S. Infections may occur in the bladder (cystitis) or kidneys (pyelonephritis). *E. coli* is the most frequent cause of nosocomial UTI, accounting for nearly half the infections.

We received an exclusive, worldwide license of patents and know-how to manufacture, use and commercialize a unique vaccine candidate for UTI (*E. coli*).

It is our intention to continue to license rights to or acquire other 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

Effective in February 2004, we granted Roche a worldwide, non-exclusive, royalty-free license to patents and information relating to our proprietary ECL technology, subject to certain limitations described in the relevant license agreement. The license may be used by Roche to commercially exploit only certain ECL products and is royalty-free provided such products are used in a specified field. Our right to terminate the license is restricted, except under certain circumstances.

Pursuant to the license agreement, the parties can jointly engage an independent field monitor to review Roche s compliance with the license on an annual basis. We and Roche have engaged a field monitor to review placements and sales of products and services by Roche in 2005. The field monitor has been tasked with preparing a written report, including a list of any sales or placements of products and services that were not within the licensed field and identifying sales or placements of products or services in violation of the license grant. Pursuant to the license agreement, Roche must pay to us, within 30 days after receiving the field monitor s report, 65% of all undisputed revenues earned through

out-of-field sales of products for 2005. Although Roche may not knowingly sell or actively market outside the field, they may continue the identified out-of-field sales until we notify Roche in writing that they are prohibited from making any further such sales. For a more complete description of the Roche license, refer to the agreement on file with the SEC.

We believe that the potential payment to us for out-of-field sales may be material to our financial position, results of operations and cash flows. Based on its 2005 Annual Report, Roche reported ECL (Elecsys) product sales for the year ending December 31, 2005 of CHF 989 million. For each 1% of Roche s total sales that were out-of-field during 2005, as determined by the field monitor, there would be approximately a $5.3 million positive impact on our financial position, results of operations and cash flows (using the currency conversion rate of Swiss Francs to U.S. Dollars at June 6, 2006 of 0.8232). Actual differences in the amount of Roche ECL (Elecsys) sales or placements or in the currency rates used would change this amount.

The amount and timing of any payment that we might receive from Roche relating to out-of-field sales in 2005 is uncertain because, among other things: (1) the amount of such sales and placements has not yet been determined; and

(2) there may be disputes between Roche and us concerning the agreement and/or the field monitor s findings. Although a field monitor has not been engaged to address 2004, we believe that we are entitled to payment for out-of-field sales during 2004. We are attempting to resolve this matter with Roche.

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; and

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 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). Our 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 from us 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. Our 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.

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, in December 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.

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 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 88 issued U.S. patents, and own or have exclusively licensed approximately 28 pending U.S. patent applications in the diagnostics field. Additionally, we own or have exclusively licensed approximately 438 granted foreign patents and approximately 49 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 have begun to expire; 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.

We also have exclusively licensed approximately 28 issued U.S. patents and pending U.S. patent applications in the field of vaccines. Additionally, we have exclusively licensed approximately 184 granted foreign patents and pending foreign patent applications in the field of vaccines.

Our business could be harmed if we lose our patent protection or if pending patents are not issued to us. See ITEM 1A Risk Factors Risks Relating to Us and Our Business The success of our business depends on patents that will expire over time and that must be actively pursued, obtained, maintained and protected and, ITEM 1A - Risk Factors Risks Relating to Us and Our Business - Our business could be harmed if we infringe, or our licensees are alleged to have infringed, the intellectual property of others.

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.

Biosecurity and Industrial Testing Products

Our biosecurity 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 life science products that will be sold for research use only, including the M-SERIES instruments, 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 distribution requirements and procedures on companies selling research use only products, such as the requirement that the seller receive specified representations 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 under development 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. A 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 our or 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 or our licensees products may be categorized as highly complex tests, in which case penetration of the point-of-care market would be reduced because a large percentage of laboratories do not 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.

While we expect that compliance with these laws and regulations may have a material effect on our financial results, capital requirements or competitive position, we presently 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, 2006, 2005, and 2004, agencies of the U.S. government accounted for 30%, 27% and 22% of our total revenue, respectively, and 43% and 39% of our total consolidated accounts receivable as of March 31, 2006 and 2005, 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 or our licensees 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 reduce 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 biosecurity 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 1A Risk Factors Risks Relating to Regulation and Government Contracts.

Competition

We compete in the non-clinical diagnostics markets, including biosecurity, 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, biosecurity 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 1A 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 1A 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 1A 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. Our direct sales group focuses on sales of the M-SERIES family of products, together with reagents and services, to various government agencies in the biosecurity market, food and beverage producers and contract testing laboratories in the industrial market and other potential customers in the life science market.

We also utilize several distributors for select markets or products. In addition to our direct and indirect sales and marketing efforts, our licensees and collaborators also conduct sales and marketing of products based on our technology. 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, 2006, we and our subsidiaries employed 219 individuals, of whom 145 were engaged in research, product development, manufacturing and operations support, and 74 in marketing, sales and applications support and general administration. Of our employees, 26 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 significant 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 9.

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 9.

Executive Officers of BioVeris Corporation

The names and ages of our executive officers at May 31, 2006 and their respective positions and offices with us are set forth below.

Samuel J. Wohlstadter, age 64, is our Chairman of the Board of Directors 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.

George V. Migausky, age 51, has served as our Vice President and Chief Financial Officer and Secretary to the Board of Directors 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.

ITEM 1A. RISK FACTORS

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 EXPECT TO HAVE FUTURE LOSSES AND NEGATIVE CASH FLOW.

We incurred net losses of $27.9 million, $77.6 million and $93.3 million for the years ended March 31, 2006, 2005 and 2004, 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 into the marketplace. 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 or accepted 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 $15.4 million at March 31, 2006. 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 biosecurity 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 or collectible from royalties and other contract revenues, which revenues are dependent upon the efforts and compliance of our licensees and collaborators, including Roche;
- 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 increase or decrease 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 or MST as payment for the purchase of our interests in MSD and the related accretion of income on the note receivable from MST;

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 healthcare 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.

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.

IF WE ARE UNABLE TO ESTABLISH NEW COLLABORATIONS, OR IF 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 that third parties, including our licensees, suppliers or others will not object to possible new 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.

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, including future payment obligations under license or option agreements;
- 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 our existing products. 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 biosecurity 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 demonstrates adequate safety and immune response. Statistically significant effectiveness of our vaccine product candidates cannot be demonstrated in humans, but instead must 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.

THE ACCOMPANYING CONSOLIDATED FINANCIAL STATEMENTS FOR FISCAL YEAR 2004 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 year 2004 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 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 for fiscal year 2004.

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 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.

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

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 are being applied against this credit and not paid to us in cash. No further cash payments will be payable by MSD to us pursuant to the buyout until the prepayment credit, which has a balance of $1.2 million at March 31, 2006, is no longer deemed outstanding.

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 $5.7 million at March 31, 2006. 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 or vaccine 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 CURRENT 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 current 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 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 vaccines, clinical testing or biosecurity 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 unable to pay for facility enhancements and improvements to meet our future growth needs, our business would suffer.

WE HAVE NO EXPERIENCE SELLING, MARKETING OR DISTRIBUTING CLINICAL DIAGNOSTIC OR VACCINE PRODUCTS. OUR FAILURE TO ESTABLISH AN EFFECTIVE SALES FORCE OR TO ESTABLISH AN EFFICIENT 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 success or failure will depend, in part, on our ability to pursue, obtain, and maintain adequate patent protection for ECL technology, vaccines 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.

OUR BUSINESS COULD BE HARMED IF WE HAVE FUTURE DISAGREEMENTS WITH ROCHE OVER THE SCOPE OF THE LICENSE AGREEMENT.

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, or any licensee, over the scope of the license agreement, such as disputes over the field, the types of products that Roche is permitted to develop and sell, or royalties owed, including payments for out-of-field sales by Roche of licensed products that employ ECL technology and which are outside the licensed field, 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 OUR LICENSEES 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, obligations owed and other material terms of the improvements license agreement or the PCR license agreements, such as disputes over the field, types of products that we are

permitted to develop and sell, other obligations 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.

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

Our research and development activities have 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 OUR 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 biosecurity 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 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. 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.

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, biosecurity 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 biosecurity 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 contracts 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, biosecurity and industrial markets. We may not be able to insure ourselves 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 24% of the outstanding shares of our common stock. Our chairman and chief executive officer owns approximately 19% 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 stockholdings, certain of our executive officers and directors could have significant influence over the outcome of potential transactions, including any acquisition transactions, that may be supported or opposed 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 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 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

Our principal administrative, marketing, manufacturing and research and development facilities consist of approximately 278,000 square feet located in several buildings in Gaithersburg, Maryland, of which approximately 131,000 square feet is currently under sublease. We have an additional 9,000 square feet of leased research and development, sales and office facilities in San Diego, California; the District of Columbia; and Oxfordshire, England.

Our leases expire at various times from 2007 through 2015. 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.

See ITEM 1A Risk Factors Risks Relating to Us and Our Business - We Have Limited Manufacturing Facilities For Our Current Products And We May Not Find Additional Facilities Suitable For Future Growth, Which Could Materially Adversely Affect Our Business And Prospects and ITEM 7 Management s Discussion and Analysis of Financial Condition and Results of Operations.

ITEM 3. LEGAL PROCEEDINGS

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 1A Risk Factors Risks Relating to Us and Our Business and ITEM 1A 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 EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

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, 2006, there were approximately 150 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 2006 and 2005.

Year ended March 31, 2006	**High**	**Low**
First quarter	$ 5.49	$ 4.11
Second quarter	6.09	4.20
Third quarter	6.34	4.35
Fourth quarter	5.10	3.72

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

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, 2006 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 compensation plans (excluding securities reflected in column (a)) (c)**
Equity compensation plans approved by security holders	438,000	$ 5.88	4,351,000
Equity compensation plans not approved by security holders			
Total	438,000	$ 5.88	4,351,000

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, 2006, Samuel J. Wohlstadter is the only holder of series B preferred stock.

The proceeds from the sale of series B preferred stock 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.

During the year ended March 31, 2006, we paid dividends of approximately $54,000 in respect of shares of series B preferred stock.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read 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, 2006, 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 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, 2003 and 2002 have been derived from audited 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 1A Risk Factors and ITEM 8 Consolidated Financial Statements and Supplementary Data.

	Years ended March 31,					
	2006	2005 (1)	2004 (1)	2003		2002	
	(In thousands, except per share data)						
Consolidated Statements of Operations Data:							
Revenues:							
Product sales	$ **19,054**	$ 24,662	$ 18,741	$ 16,487		$ 12,077	
Royalty income	**1,561**	1,249	1,060	1,107		1,050	
Contract fees	**-**	388	155	180		116	
Total	**20,615**	26,299	19,956	17,774		13,243	
Operating costs and expenses:							
Product costs (2)	**8,706**	12,860	12,247	8,005		5,361	
Research and development	**17,695**	21,485	19,821	22,766		26,829	
Selling, general and administrative	**24,688**	32,212	18,656	20,453		19,217	
Merger related costs	**-**	-	75,702	-		-	
Total operating costs and expenses	**51,089**	66,557	126,426	51,224		51,407	
Loss from operations	**(30,474)**	(40,258)	(106,470)	(33,450)		(38,164)	
Interest income	**3,851**	3,191	130	-		-	
Other, net	**(1,230)**	95	(1,063)	154		(39)	
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	**(27,853)**	(77,573)	(127,019)	(50,894)		$ (49,150)	
Cumulative effect of a change in accounting principle (1)	**-**	-	33,700	-		-	
Net loss	$ **(27,853)**	$ (77,573)	$ (93,319)	$ (50,894)		$ (49,150)	
Net loss per common share before cumulative effect of a change in accounting principle (basic and diluted)	$ **(1.04)**	$ (2.90)	$ (4.75)	$ (1.90)		$ (1.84)	
Cumulative effect of a change in accounting principle (1)	**-**	-	1.26	-		-	
Net loss (basic and diluted)	$ **(1.04)**	$ (2.90)	$ (3.49)	$ (1.90)		$ (1.84)	
Shares used in computing net loss per common share	**26,810**	26,728	26,728	26,728	(4)	26,728	(4)

	March 31				
	2006	2005	2004(1)	2003	2002
	(In thousands)				
Consolidated Balance Sheet Data :					
Cash, cash equivalents and short-term investments (5)	$ **69,631**	$ 95,629	$ 182,509	$ -	$ -
Working capital	**72,184**	98,639	169,184	4,733	1,193
Total assets	**105,853**	134,165	232,814	29,160	21,518
Long-term obligations	**546**	1,890	54	60	96
Minority interest	**-**	-	54	-	-
Series B preferred stock	**7,500**	7,500	7,500	-	-
Stockholders equity	**89,063**	115,254	193,826	-	-
Net investment by parent (5)	**-**	-	-	20,665	14,151

(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 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.

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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 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, for the period April 1, 2004 through August 12, 2004, we consolidated the financial results of MSD and beginning August 13, 2004, we deconsolidated the financial results of MSD and 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 were filed as Exhibit 99.9 to the Form 10-K for the year ending March 31, 2005.

(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.

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Supplemental Consolidated Statement of Operations Data:

	Year Ended March 31, 2006 BioVeris and Wholly-Owned Subsidiaries	Year Ended March 31, 2005 BioVeris and Wholly-Owned Subsidiaries	MSD	Consolidating Eliminations	Consolidated
	(In thousands, except per share data)				
Revenues:					
Product sales	$ 19,054	$ 20,703	$ 3,959	$ -	$ 24,662
Royalty income	1,561	1,249	-	-	1,249
Contract fees	-	32	356	-	388
Total	20,615	21,984	4,315	-	26,299
Operating costs and expenses:					
Product costs	8,706	9,167	3,693	-	12,860
Research and development	17,695	17,877	3,705	(97)	21,485
Selling, general and administrative	24,688	27,710	4,502	-	32,212
Merger related costs	-	-	-	-	-
Total operating costs and expenses	51,089	54,754	11,900	(97)	66,557
Loss from operations	(30,474)	(32,770)	(7,585)	97	(40,258)
Interest income	3,851	3,111	80	-	3,191
Other, net	(1,230)	95	-	-	95
Loss on joint venture impairments	-	(35,077)	-	-	(35,077)
Equity in loss of joint venture	-	(12,932)	-	7,408	(5,524)
Net loss	$ (27,853)	$ (77,573)	$ (7,505)	$ 7,505	$ (77,573)
Net loss per common share	$ (1.04)	$ (2.90)	$ (0.28)	$ 0.28	$ (2.90)
Shares used in computing net loss per common share	26,810	26,728	26,728	26,728	26,728

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

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 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 biosecurity, life science and industrial markets. The non-clinical diagnostics market includes biosecurity 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 biosecurity 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 a clinical analyzer that builds on the M-SERIES instruments we sell in the biosecurity and life science markets. We 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 as biosecurity tools for use 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. 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. We believe our M-SERIES product line for the life science market is ideally suited to perform immunogenicity testing by measuring low affinity antibodies with high sensitivity, all in the presence of the highly concentrated drug.

In fiscal 2005, we expanded our business model to target the field of vaccines and have rights to certain vaccine candidates through license and option agreements. These vaccine candidates include:

Neisseria meningitidis serogroup B;

Group B Streptococcus;

Chlamydia;

Group A Streptococcus;

Candida albicans;

Pneumococcus;

Anthrax bacilli; and

Urinary tract infection (E coli).

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

In connection with our efforts to determine an individual s personal immune status through unique diagnostic test panels, we entered into a license and research agreement with Jewish General Hospital (JGH) in Montreal under which we received an exclusive, worldwide license to the use of a JGH database that contains demographic data and the serologic status of an immigrant population linked to numerous infectious diseases.

Roche / IGEN Transaction

On February 13, 2004, IGEN and Roche consummated a merger and certain 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.

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 determined that we no longer met the conditions to be designated as the primary beneficiary of MSD, as through the provisions of the settlement agreement, we 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 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 had 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, certain of our revenues and expenses for the year ended March 31, 2006 have decreased.

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 was 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 prepayment credit, which has a balance of approximately $1.2 million at March 31, 2006, is no longer deemed outstanding.

Upon the sale of our interests in MSD, we recorded a discounted note receivable of $4.5 million that had a balance at March 31, 2006 of approximately $5.7 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, which are updated periodically, 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, 2006. 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.

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 .

Our 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 biosecurity 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 or collectible from royalties and other contract revenues, which revenues are dependent upon the efforts and compliance of our licensees, including Roche;

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 increase or decrease 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 or MST as payment for the purchase of our interests in MSD and the related accretion of income on the note receivable from MST;

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 healthcare 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, 2006 and 2005

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

Revenues. Consolidated revenues for the fiscal year ended March 31, 2006 decreased by approximately $5.7 million, or 22%, to $20.6 million from $26.3 million in fiscal 2005. Of this $5.7 million decrease, $4.3 million represents MSD

revenues which were consolidated with BioVeris revenues during fiscal 2005.

Consolidated product sales were $19.1 million in fiscal 2006, a decrease of 23% over the prior year s product sales of $24.7 million. Of this $5.6 million decrease, $4.0 million represents MSD product sales. BioVeris s sales of biosecurity products for fiscal 2006 were $8.6 million, a decrease of $800,000 from the prior year. Sales of products for the life science market were $10.5 million for fiscal 2006, a decrease of $800,000 from the prior year. These changes in product sales reflect the change of orders and product deliveries for biosecurity and life science products, which are based on our customers requirements.

Sales of our products for the biosecurity and life science markets are subject to a number of uncertainties, including the fact that we generally are not a party to significant long-term contracts for the sale of our products that would provide predictable sales. Therefore, the volume and timing of product orders from our biosecurity and 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.

Operating Costs and Expenses. Consolidated product costs were $8.7 million (46% of total product sales) for fiscal 2006 compared to $12.9 million (52% of total product sales) for fiscal 2005. The current year decrease of $4.2 million consists of $3.7 million due to the consolidation of MSD s product costs, and a $500,000 reduction in Bioveris costs. BioVeris product costs in fiscal 2006, as a percentage of total product sales, were 46% compared to 44% in fiscal 2005.

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. In addition, our product costs in fiscal 2007, as a percentage of total product sales, is expected to increase due to costs that may be incurred in connection with detection module upgrades for certain existing customers. These voluntary upgrades, which may cost approximately $1.0 million, are planned to enhance overall customer satisfaction.

Consolidated research and development expenses were $17.7 million for fiscal 2006, which represents a decrease of 18% over the prior year costs of $21.5 million. The $3.8 million decrease consists of $3.7 million due to the consolidation of MSD s research and development expenses, and a $100,000 reduction in BioVeris costs.

Research and development expenses primarily relate to ongoing development costs and product enhancements associated with vaccines, 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 biosecurity testing products, and development of a proprietary approach for determining an individual s personal immune status through unique diagnostic test panels.

We have expanded our business model to target the field of vaccines which will require substantial research and development expenditures. For example, we have entered into several license and option agreements for patent rights to unique vaccine candidates. Under these agreements, we are responsible for conducting or sponsoring the research and development of these vaccine candidates and may be required to make additional payments for patent costs, milestone fees, including for initiating and completing human clinical trials and receiving regulatory approvals, and royalties on future sales. Payments on these agreements totaled $1.6 million and $300,000 in the years ended March 31, 2006 and 2005, respectively.

Consolidated selling, general and administrative expenses were $24.7 million in fiscal 2006, which represents a decrease of 23% over the prior year costs of $32.2 million. The $7.5 million decrease consists of $4.5 million due to the consolidation of MSD s selling, general and administrative expenses, and a $3.0 million reduction in BioVeris costs. BioVeris decrease in selling, general and administrative costs of $3.0 million was primarily attributable to lower professional fees in the current year. Professional fees in the prior year included costs associated with our litigation and settlement with MSD.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, 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 ongoing 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.

Since 1995 we had engaged the law firm of Wilmer, Cutler, Pickering, Hale & Dorr 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 recorded approximately $300,000 and $2.2 million in legal fees with that law firm for the years ended March 31, 2006 and 2005, 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. 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 $476,000 and $421,000 for the years ended March 31, 2006 and 2005, 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 $256,000 and $8,000 at March 31, 2006 and 2005, respectively. All such balances due were paid subsequent to each respective fiscal year end.

Interest Income. Interest income was $3.9 million and $3.2 million in fiscal 2006 and 2005, respectively, including $1.9 million and $200,000, respectively, from the accretion of income related to the note receivable from MSD. During fiscal 2006, we recorded an out of period adjustment of $600,000 to reduce accumulated other comprehensive loss and interest income in order to reflect the amortization related to prior periods of the purchase price premium of short-term investments. The impact of this adjustment on current and prior interim and annual periods was not material, as the adjustment was comprised of relatively small amounts related to each of the quarterly reporting periods dating back to the quarter ended June 30, 2004. For all periods, comprehensive loss was not impacted by this adjustment.

Other Income / Expense. Other expense was $1.2 million and other income was $100,000 in fiscal 2006 and 2005, respectively. The 2006 amount includes approximately $600,000 of foreign currency losses and $300,000 for the write-off of furniture and equipment.

Loss on Joint Venture Impairments. In fiscal 2005, 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 were 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 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 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 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 for the year ended March 31, 2005.

Net Loss. The net loss for fiscal year 2006 was $27.8 million ($1.04 per common share), compared to a net loss of $77.6 million ($2.90 per common share) in fiscal year 2005, a decrease of $49.8 million. The decrease in the net loss is primarily caused by the prior year s non-cash charges of $35.1 million representing the amount by which the book value of our interests in MSD exceeded the fair market value purchase

price, MSD s consolidated losses of $7.5 million in the prior year and a decrease in operating expenses in the current year of approximately $3.7 million.

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 biosecurity 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 biosecurity and life science products, which are based on our customers requirements.

Sales of our products for the biosecurity and life science market are subject to a number of uncertainties, including the fact that we are generally not a party to significant long-term contracts for the sale of our products that would provide predictable sales. Therefore, the volume and timing of product orders from our biosecurity and 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.

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 fiscal 2005 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.

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 fiscal 2005 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.

In fiscal 2005, we expanded our business model to target the field of vaccines which will require substantial research and development expenditures. For example, we have entered into several license and option agreements for patent rights to unique vaccine candidates. Under these agreements, we are responsible for conducting or sponsoring the research and development of these vaccine candidates and may be required to make additional payments for patent costs, milestone fees, including for initiating and completing human clinical trials and receiving regulatory approvals, and royalties on future sales. Payments on these agreements totaled $250,000 in the year ended March 31, 2005.

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

fiscal 2005. 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.

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, was formerly 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 former 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 $1.0 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 $100,000 in fiscal 2005 and 2004, respectively. Interest income for fiscal 2005 includes $200,000 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 $100,000 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 were 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 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 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 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.

Liquidity and Capital Resources

At March 31:	**2006**	2005	2004
	(In Thousands)		
Cash, cash equivalants and short-term investments	**$ 69,631**	$ 95,629	$ 182,509
Working capital	**72,184**	98,639	169,184
Year Ended March 31:			
Cash provided by (used in):			
Operating activities	**(24,450)**	(31,059)	(29,648)
Investing activities	**12,458**	(59,789)	(78,080)
Financing activities	**(54)**	(49,922)	290,237
Capital expenditures (included in investing activities above)	**(1,028)**	(1,855)	(1,920)

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.

Effective in February 2004, we granted Roche a worldwide, non-exclusive, royalty-free license to patents and information relating to our proprietary ECL technology, subject to certain limitations described in the relevant license agreement. The license may be used by Roche to commercially exploit only certain ECL products and is royalty-free provided such products are used in a specified field. Our right to terminate the license is restricted, except under certain circumstances.

Pursuant to the license agreement, the parties can jointly engage an independent field monitor to review Roche s compliance with the license on an annual basis. We and Roche have engaged a field monitor to review placements and sales of products and services by Roche in 2005. The field monitor has been tasked with preparing a written report, including a list of any sales or placements of products and services that were not within the licensed field and identifying sales or placements of products or services in violation of the license grant. Pursuant to the license agreement, Roche must pay to us, within 30 days after receiving the field monitor s report, 65% of all undisputed revenues earned through out-of-field sales of products for 2005. Although Roche may not knowingly sell or actively market outside the field, they may continue the identified out-of-field sales until we notify Roche in writing that they

are prohibited from making any further such sales. For a more complete description of the Roche license, refer to the agreement on file with the SEC.

We believe that the potential payment to us for out-of-field sales may be material to our financial position, results of operations and cash flows. Based on its 2005 Annual Report, Roche reported ECL (Elecsys) product sales for the year ending December 31, 2005 of CHF 989 million. For each 1% of Roche s total sales that were out-of-field during 2005, as determined by the field monitor, there would be approximately a $5.3 million positive impact on our financial position, results of operations and cash flows (using the currency conversion rate of Swiss Francs to U.S. Dollars at June 6, 2006 of 0.8232). Actual differences in the amount of Roche ECL (Elecsys) sales or placements or in the currency rates used would change this amount.

The amount and timing of any payment that we might receive from Roche relating to out-of-field sales in 2005 is uncertain because, among other things: (1) the amount of such sales and placements has not yet been determined; and (2) there may be disputes between Roche and us concerning the agreement and/or the field monitor s findings. Although a field monitor has not been engaged to address 2004, we believe that we are entitled to payment for out-of-field sales during 2004. We are attempting to resolve this matter with Roche.

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, the business plan for our clinical diagnostic and vaccine products, including immunodiagnostic and PCR technology-based products, is evolving and does not have definitive product introduction timelines or budgets and we 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 us with 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, which we have the ability to do. 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.

Cash Used in Operating Activities

Net cash used for operations was $24.4 million, $31.1 million, $29.6 million during the years ended March 31, 2006, 2005 and 2004, respectively. The decrease in cash used for operations in the current fiscal year resulted primarily from a lower net loss offset by changes in non-cash adjustments to the net loss partially offset by higher working capital requirements in the current fiscal 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 in Investing Activities

We used approximately $1.0 million, $1.9 million and $1.9 million of cash for the acquisition of equipment and leasehold improvements during the years ended March 31, 2006, 2005 and 2004, respectively. Our investments in MSD totaled $3.0 million and $56.7 million (including a $37.5 million payment to MSD following the completion of the merger and related transactions) for the years ended March 31, 2005 and 2004, respectively.

During fiscal 2006, we purchased $15.2 million of short-term investments and received proceeds of $28.7 million from the sales and maturities of short-term investments. During fiscal 2005, we purchased $108.7 million of short-term investments and received proceeds of $53.8 million from the sales and maturities 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 have not been required to pay any such royalties. 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 the year ended March 31, 2006, we paid dividends of approximately $54,000 in respect of shares of Series B preferred stock.

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 consolidated 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.

MSD

As part of the settlement with MSD, in August 2004, 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 a 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.

During the years ended March 31, 2006, 2005 and 2004, operating costs allocated to MSD by us in connection with shared personnel and facilities totaled $700,000, $700,000 and $6.0 million, respectively. The costs allocated for fiscal 2005 are net of a $500,000 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 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 may be required in a variety of areas, such as product development programs, sponsored research and the build-out of new facilities. We have not, at this time, made material commitments for any such capital expenditures and have not secured additional sources to fund such commitments if they become necessary in the future.

As of March 31, 2006, our material future obligations were as follows (in thousands):

Years Ended March 31,	Operating Lease Payments	Sponsored Research	Total
2007	$ 4,230	$ 704	$ 4,934
2008	4,208	130	4,338
2009	4,122	98	4,220
2010	3,531	-	3,531
2011	1,734	-	1,734
2012 and thereafter	5,402	-	5,402
	23,227	932	24,159
Less sublease income	(4,760)	-	(4,760)
Total	$ 18,467	$ 932	$ 19,399

Subsequent to March 31, 2006, we sub-leased a facility to a third party under an arrangement that will further reduce our annual operating lease payments by approximately $300,000 in fiscal 2007.

Under vaccine license agreements, we are responsible for conducting or sponsoring the research and development of vaccine candidates and may be required to make additional payments for patent costs, milestone fees, including for initiating and completing human clinical trials and receiving regulatory approvals, and royalties on future sales.

Off-Balance Sheet Arrangements

As of March 31, 2006, we had no off-balance sheet arrangements, as defined by SEC Regulation S-K, Item 303 (a) (4).

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. Significant changes to these estimates could have a material impact on our consolidated financial statements. Our critical accounting policies 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 fiscal 2004 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. 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 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.

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 determined that we no longer meet the conditions to be designated as the primary beneficiary of MSD. Factors used in this evaluation included:

We no longer had a significantly large variable interest in MSD to be the primary beneficiary. We held 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 ceased 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 discounted note receivable which had an original balance of $4.5 million. This note receivable has a balance of approximately $5.7 million at March 31, 2006, which represents the net present value of future payments that we expect to realize from the sale of our interests in MSD. We accrete to fair value using the effective interest method. 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 consolidated balance sheet at March 31, 2006.

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 2004, the FASB issued SFAS 123R, Share-Based Payment. SFAS 123R replaces SFAS No. 123, Accounting for Stock Issued to Employees, and supersedes 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.

The SEC issued Staff Accounting Bulletin (SAB) No. 107, Share-Based Payment in March 2005 in order to provide implementation guidance related to SFAS 123R. SAB 107 provides guidance on numerous issues such as valuation methods (including assumptions such as expected volatility and expected term), the classification of compensation expense, capitalization of compensation cost related to share-based payment arrangements, the accounting for income tax effects of share-based payment arrangements upon adoption of SFAS 123R, and disclosures in MD&A subsequent to adoption of SFAS 123R. We are assessing the impact of SAB on its implementation of SFAS 123R.

In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections, a replacement of APB

Opinion No. 20 and FASB Statement No. 3. SFAS 154 changes the requirements for the accounting for and reporting of a change in accounting principle. APB Opinion No. 20 previously required that most voluntary changes in accounting principle be recognized by including the cumulative effect of the change in the net income of the period. SFAS 154 requires retrospective application to prior periods financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. The provisions of SFAS 154 will be effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We are currently evaluating the provisions of SFAS 154 and do not believe that its adoption will have a material impact on our financial condition, results of operation and liquidity.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to changes in exchange rates where we sell products directly 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, 2006 had cash, cash equivalents and short-term investments of $69.6 million, which is approximately 66% 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, 2006, we had invested $39.9 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 interest rates. Based on our cash, cash equivalents and short-term investments balance at March 31, 2006, a 1% movement in interest rates would have an approximately $800,000 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 **Page**

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of BioVeris Corporation:

We have completed integrated audits of BioVeris Corporation s March 31, 2006 and 2005 consolidated financial statements and of its internal control over financial reporting as of March 31, 2006, and an audit of its March 31, 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 and supplementary data

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, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 2006 in conformity with accounting principles generally accepted in the United States of America. These consolidated financial statements and supplementary data are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements and supplementary data 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, 2006 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, 2006, based on criteria established in *Internal*

Control Integrated Framework issued by the 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 on 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 provides 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 or 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, 2006

BIOVERIS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	Years Ended March 31,		
	2006	2005	2004
REVENUES:			
Product sales	$ **19,054**	$ 24,662	$ 18,741
Royalty income	**1,561**	1,249	1,060
Contract fees	**-**	388	155
Total	**20,615**	26,299	19,956
OPERATING COSTS AND EXPENSES:			
Product costs	**8,706**	12,860	12,247
Research and development	**17,695**	21,485	19,821
Selling, general, and administrative	**24,688**	32,212	18,656
Merger related costs	**-**	-	75,702
Total	**51,089**	66,557	126,426
LOSS FROM OPERATIONS	**(30,474)**	(40,258)	(106,470)
INTEREST INCOME	**3,851**	3,191	130
OTHER, NET	**(1,230)**	95	(1,063)
LOSS ON JOINT VENTURE IMPAIRMENTS	-	(35,077)	-
EQUITY IN LOSS OF JOINT VENTURE	**-**	(5,524)	(19,616)
NET LOSS BEFORE CUMULATIVE EFFECT OF A CHANGE IN ACCOUNTING PRINCIPLE	**(27,853)**	(77,573)	(127,019)
CUMULATIVE EFFECT OF A CHANGE IN ACCOUNTING PRINCIPLE	**-**	-	33,700
NET LOSS	$ **(27,853)**	$ (77,573)	$ (93,319)
Net loss per common share before cumulative effect of a change in accounting principle (basic and diluted)	$ **(1.04)**	$ (2.90)	$ (4.75)
Cumulative effect of a change in accounting principle	**-**	-	1.26
Net loss per common share (basic and diluted)	$ **(1.04)**	$ (2.90)	$ (3.49)
COMMON SHARES OUTSTANDING (basic and diluted)	**26,810**	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, 2006	2005
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ **29,693**	$ 41,739
Short-term investments	**39,938**	53,890
Accounts receivable, net	**3,360**	4,483
Inventory, net	**5,429**	5,235
Other current assets	**2,508**	2,813
Total current assets	**80,928**	108,160
Equipment and leasehold improvements, net	**3,456**	3,636
OTHER NONCURRENT ASSETS:		
Note receivable, net	**5,666**	4,709
Technology licenses	**15,356**	17,306
Other	**447**	354
TOTAL ASSETS	$ **105,853**	$ 134,165
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ **5,362**	$ 6,457
Accrued wages and benefits	**1,862**	1,713
Other current liabilities	**1,520**	1,351
Total current liabilities	**8,744**	9,521
NONCURRENT DEFERRED LIABILITIES	**546**	1,890
Total liabilities	**9,290**	11,411
COMMITMENTS (see Note 6) and CONTINGENCIES		
MINORITY INTEREST	**-**	-
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, 27,238,000 and 26,728,000 shares issued and outstanding, respectively	**27**	27
Additional paid-in capital	**205,997**	203,464
Deferred compensation	**(1,688)**	-
Accumulated other comprehensive loss	**(128)**	(999)
Accumulated deficit	**(115,145)**	(87,238)
Total stockholders equity	**89,063**	115,254
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ **105,853**	$ 134,165

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

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BIOVERIS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended March 31,		
	2006	2005	2004
OPERATING ACTIVITIES**:**			
Net loss	$ **(27,853)**	$ (77,573)	$ (93,319)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	**3,778**	6,229	3,385
Loss on disposal of equipment	**271**	138	58
Equity in loss of joint venture	-	5,524	19,616
Joint venture impairments	-	35,077	33,700
Accretion of interest on note receivable	**(1,860)**	(171)	-
Amortization of premium on short-term investments	**1,337**	-	-
Change in accounting principle	-	-	(33,700)
Stock based compensation	**845**	-	38,800
Minority interest	-	-	54
Changes in assets and liabilities:			
Decrease (increase) in accounts receivable	**790**	(988)	2,017
(Increase) decrease in inventory	**(1,085)**	(1,516)	158
Decrease (increase) in other assets	**545**	1,139	(173)
(Decrease) increase in accounts payable and accrued expenses	**(814)**	1,306	(1,708)
(Decrease) increase in other liabilities	**(404)**	(224)	1,464
Net cash used in operating activities	**(24,450)**	(31,059)	(29,648)
INVESTING ACTIVITIES:			
Expenditures for equipment and leasehold improvements	**(1,028)**	(1,855)	(1,920)
Purchases of short-term investments	**(15,215)**	(108,706)	-
Sales and maturities of short-term investments	**28,701**	53,817	-
Investments in joint venture (net)	-	(3,045)	(56,660)
Purchase of technology licenses	-	-	(19,500)
Net cash provided by (used in) investing activities	**12,458**	(59,789)	(78,080)
FINANCING ACTIVITIES:			
Payment of distribution gain	-	(20,000)	-
(Deconsolidation) consolidation of joint venture cash and cash equivalents	-	(29,222)	35,111
Sale of preferred stock	-	-	7,500
Cash contributed by Parent, net			