

BIOVERIS CORP
Form 10-K
June 14, 2005

SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

For Fiscal Year Ended
Commission File Number

March 31, 2005
000-50583

BioVeris Corporation

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)

80-0076765
(IRS Employer Identification No.)

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

(301) 869-9800
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

NONE

Securities registered pursuant to Section 12(g) of the Act:

Common Stock \$0.001 par value
(Title of Class)

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

Yes ☐ 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. ☐

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

Yes ☐ No ☐

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

BIOVERIS CORPORATION

Annual Report On Form 10-K

For The Fiscal Year Ended March 31, 2005

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As used herein, BioVeris, we, us and our refer to BioVeris Corporation and its subsidiaries. M-SERIES, TRICORDER and BIOVERIS are our trademarks. This Form 10-K also contains disclosure relating to brand names, trademarks or service marks of other companies, and these brand names, trademarks or service marks are the property of those other holders.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

In addition to historical information, this Annual Report on Form 10-K contains forward-looking statements within the meaning of the "safe harbor" provision of the Private Securities Litigation Reform Act of 1995. All statements contained in this report that are not statements of historical fact, including statements about markets and potential markets, market growth for diagnostic products, potential impact of competitive products, our expectations regarding future revenue, the potential market for products in development, the description of our plans and objectives for future operations, assumptions underlying such plans and objectives, the need for and availability of additional capital and other forward-looking statements included in ITEM 7 Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A), are forward-looking statements. The words "may," "should," "will," "expect," "could," "anticipate," "believe," "estimate," "plan," "intend" and similar expressions have been used to identify certain of the forward-looking statements. In this Form 10-K we have based these forward-looking statements on management's current expectations, estimates and projections and they are subject to a number of risks, uncertainties and assumptions which could cause actual results to differ materially from those described in the forward-looking statements. The following factors are among those that may cause actual results to differ materially from our forward-looking statements:

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

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

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

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

changes in customer demand, the timing of significant orders or the demand for rapid testing products in each of our markets;

our ability to expand our manufacturing capabilities or find a suitable manufacturer on acceptable terms or in a timely manner;

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

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

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

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

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

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

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

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

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

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

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

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

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

changes in general economic, business and industry conditions.

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

PART I

ITEM 1. BUSINESS

Summary

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

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

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

Diagnostics

We develop, manufacture and market our M-SERIES® family of products, which can serve as a platform for diagnostic systems to be used for the detection and measurement of biological or chemical substances. We incorporate

our technologies into our instrument systems, tests and reagents, which are the biological and chemical components used to perform such tests. Using the M-SERIES platform, we intend to integrate technologies and products to develop small, expandable and modular systems that can perform a wide variety of immunodiagnostic and nucleic acid tests for the following markets:

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

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

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

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

The first clinical diagnostic system being developed by us is an M-SERIES clinical analyzer that builds on the M-SERIES instruments we sell in the biodefense and life science markets. We are developing the assays using, among other things, improvements licensed from an affiliate of Roche. We believe that these improvements will reduce product development timelines. We also believe that the clinical analyzer will provide results to a physician rapidly with the same levels of sensitivity, accuracy or consistency as a large instrument in a clinical reference laboratory or in a central laboratory, thereby permitting the physician to make a more timely decision regarding the patient's course of treatment. Among the applications that we plan to develop is a proprietary approach for determining an individual's personal immune status through unique diagnostic panels. We will seek approval from the FDA for the clinical analyzer and other *in vitro* diagnostics products at the appropriate stage of their product development. There can be no assurance that such approval will be obtained.

Our M-SERIES instruments are used in biodefense programs for homeland security, including by the Department of Defense, or DOD. We believe there will be an increasing opportunity to sell our products for biodefense tools by commercial, governmental and military organizations around the world, as well as in the public health sector.

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

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

Vaccines

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

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

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

Investor Information

We were organized as IGEN Integrated Healthcare, LLC, a Delaware limited liability company, on June 6, 2003, and converted to BioVeris Corporation, a newly formed Delaware corporation, on September 22, 2003. Our executive offices are located at 16020 Industrial Drive, Gaithersburg, Maryland 20877. Our Internet website is located at <http://www.bioveris.com>. Information contained on our website is not part of this Form 10-K or any other filing which may incorporate by reference this Form 10-K. We provide to the public on our website, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as amended, as soon as practicable after such material is filed electronically with, or furnished to, the Securities and Exchange Commission which we refer to in this Form 10-K as the SEC. Any report, proxy statement or other information we file with the SEC may be read and copied at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Information on the operation of the Public Reference Room is available by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site (<http://www.sec.gov>) that makes available reports, proxy statements and other information regarding issuers that file electronically with it.

Our Strategy

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

- pursue collaborative relationships to accelerate new product development and enhance global manufacturing and marketing capabilities;

- establish leadership positions in emerging markets;

develop and market product line extensions and an expanded menu of assays; and
maximize high value-added opportunities in vaccines.

Our Technology

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

ECL technology developed and owned by us;

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

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

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

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

ECL Technology

ECL technology is based on electrochemiluminescence that is protected by patents in the United States and internationally. ECL technology permits the detection and measurement of a biological or chemical substance within a given sample. It works by labeling the targeted substance within a sample using a compound and binding the newly labeled substance to magnetizable beads. The beads can then be separated from the rest of the sample using a magnet. When this newly labeled substance is stimulated, the label emits light at a particular wavelength.

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

ECL technology provides a uniform format that can be used to conduct a multitude of tests, including immunodiagnostic tests and nucleic acid tests. The essential component of an ECL technology-based system is the flow cell, which contains a magnet to separate the labeled substance from the sample being tested and a light detector to measure the electrochemiluminescence.

The flow cell has been designed so that it can be incorporated into a variety of instruments, ranging from large central laboratory random access systems to small batch systems.

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

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

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

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

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

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

Consistency: provides highly-reproducible measurements.

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

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

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

ECL technology is well established in the market, evidenced by the fact that our licensees have developed multiple product lines based on ECL technology and through 2003 had sold or placed over 10,000 systems with customers worldwide which generate over \$500 million in annual sales. Substantially all of these sales and placements have been made by Roche, one of the world's leading providers of clinical diagnostic products, which has a worldwide, non-exclusive, royalty-free license for our ECL technology for use with certain defined systems and immunoassay methods for the clinical diagnostics market. There can be no assurance that we will succeed in profitably developing, marketing and selling products based on ECL technology.

Improvements from Roche

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

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

certain PCR technology; and

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

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

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

PCR Technology

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

amount of virus possible in the blood or other clinical samples.

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

Multi/Unit Dose Cartridge Technology

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

Vaccines

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

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

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

Products and Markets Using Our Technology

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

BioVeris Products Diagnostics	Customer Application	Market	Status
M-SERIES (Clinical analyzer and clinical diagnostic tests)	Screen, monitor and diagnose medical conditions	Clinical	Development
BioVeris Detection System and Reagents	Detection of bacteria, viruses and toxins	Biodefense	Product sales
	Drug discovery and development	Life science	Product sales
M-SERIES (M384 Analyzer and Reagents)	Drug discovery and development	Life science	Product sales
M-SERIES (M1M Analyzers)	Drug discovery and development	Life science	Product sales
	Detection of food and beverage contaminants and bacteria, viruses and toxins	Biodefense	Product sales
Test Panel for BioVeris Detection System	Detection of food and beverage contaminants	Industrial	Product sales
Cell Culture Reagents	Biological research	Life science	Product sales

Vaccines

Neisseria meningitides serogroup B	Preventative medicine	Vaccine	Pre-clinical research
Group B streptococcus Type II and Type V	Preventative medicine	Vaccine	Pre-clinical research
Group B meningococcus	Preventative medicine	Vaccine	Pre-clinical research
Chlamydia	Preventative medicine	Vaccine	Pre-clinical research

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

Licensee Products	Customer Application	Market	Status	Licensee
Elecsys 2010/1010/ ECL module of E170	Screen, monitor and diagnose medical conditions	Clinical	Product sales	Roche

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NucliSens/NASBA QR	Screen, monitor and diagnose medical conditions	Clinical	Product sales	bioMérieux
	Screen, monitor and diagnose medical conditions	Life science	Product sales	bioMérieux
Picolumi	Screen, monitor and diagnose medical conditions	Clinical	Product sales	Eisai (Japan)
Sector product line	Drug discovery and development	Life science	Product sales	MSD

Our Products and Markets

Clinical Diagnostics

We plan to manufacture and sell products utilizing our technologies for the clinical *in vitro* diagnostics market either ourselves or through additional licensees. *In vitro* diagnostic testing, which is the process of analyzing blood, urine and other samples to screen for, monitor and diagnose diseases and other medical conditions or to determine the chemical and microbiological constituents of the samples is one type of testing used by the clinical diagnostics market. We believe that ECL technology is ideally suited for the blood-based immunodiagnostic and nucleic acid testing segments of the clinical diagnostics market. Clinical diagnostic testing is performed in many locations, including testing by clinical reference laboratories, central hospital laboratories, and blood banks, as well as testing at clinical point-of-care sites. Our products for the clinical *in vitro* diagnostics market will generally require approval or clearance by the FDA prior to the marketing of the products, which we will seek in the appropriate stage of product development. There can be no assurance that such approval will be obtained. See ITEM 1 Business Government Regulation Clinical Diagnostic Products for a more detailed description of the government regulations to which we are subject in connection with products for the clinical *in vitro* diagnostics market.

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

Most immunodiagnostic systems for clinical point-of-care sites have had limited market penetration because of the lengthy turnaround time for test results, the need for skilled labor to perform the tests and the high cost of the tests. We believe that the emergence of simple, more accurate and cost-effective diagnostic products is shifting the site of *in vitro* diagnostic testing from clinical reference laboratories and central hospital laboratories to alternative sites.

We are developing a new instrument system, a clinical analyzer that would be a part of our M-SERIES family of instruments. We plan to integrate ECL, PCR, and other technologies into a small, expandable and modular system for the performance of immunodiagnostic and nucleic acid tests. The clinical analyzer is being designed for ease of use and the ability to provide fast results and is expected to be marketed to clinical point-of-care sites bringing laboratory testing closer to the patient thereby providing the associated benefits described above. We believe that the clinical analyzer may also be used in clinical reference laboratories, central hospital laboratories, and blood banks, which presently constitute the majority of the clinical diagnostics market. Currently available immunoassay tests for use at the clinical point-of-care sites are often not as sensitive, accurate, or consistent as similar tests run in a central laboratory. We believe the clinical analyzer can provide rapid turn-around time with the same levels of sensitivity, accuracy and consistency as a large instrument in a clinical reference laboratory or a hospital central laboratory.

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

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

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

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

Non-Clinical Diagnostics

Biodefense. We are commercializing products in the emerging market segment for biodefense, which involves the detection of bacteria, viruses and toxins that may pose a military or public health threat, as well as for the detection of foodborne and waterborne disease causing pathogens. Our currently available instruments include the BioVeris Detection System and the M-SERIES M1R and M1M instruments. We believe there will be an increasing opportunity to use our products as a biodefense tool in commercial, governmental and military organizations around the world, as well as in public health, due to the early adoption of our products by key decision makers. We expect that our nonclinical products for biodefense will generally not require the approval of a U.S. government agency prior to marketing of the products in the United States. See ITEM 1 Business Government Regulation Biodefense and Industrial Testing Products for a more detailed description of the government regulations to which we are subject in connection with our biodefense products.

U.S. Army scientists at Fort Detrick and the Edgewood Chemical Biological Center (ECBC) have developed ECL technology-based biological tests designed to measure specific agents and toxins in environmental samples. We have a contract with the DOD pursuant to which the DOD may purchase these tests from us. Under the contract, the DOD may, at its option, make purchases of up to \$23.0 million over a period of up to 48 months through June 2007. As of March 31, 2005, the DOD had purchased approximately \$7.8 million of products under the contract. The tests are used by various laboratories and field sites of the DOD, as well as other U.S. government agencies. For risks related to our contracts with the government see ITEM 1 Risk Factors Risks Relating to Regulation and Government Contracts.

In June 2004, we introduced for sale our new M-SERIES M1M Analyzer which is designed to function in demanding field environments, as well as in the laboratory. The M1M is an automated analyzer designed for use with our BioVerify test kits for the detection of botulinum neurotoxins, anthrax, ricin, and staphylococcal enterotoxins A and B, among others. The system has easy-to-use sample handling and can detect biological agents quickly and with high sensitivity. System software reports positive or negative results automatically in a standard format. The M1M Analyzer was built with specification and configuration inputs from our customers and is designed to meet the needs of field, mobile and centralized laboratories. We also introduced the M-SERIES M1M Analyzer for use by first responders, such as trauma centers, emergency medical workers, firefighters and police.

The Automated Biological Agent Testing System (ABATS) program at the ECBC, Aberdeen Proving Ground, in conjunction with us and Beckman Coulter, has integrated an M-SERIES instrument system with Beckman Coulter's SAGIAN and Biomek® FX lab automation systems to automate sample preparation and plate handling for ECL technology-based immunoassays. This program is designed for high throughput detection of biological agents and incorporates reagents that are being manufactured by us. In 2004, the ABATS was transferred to Stations of Robotic Monitoring (STORM), a mobile, high-throughput laboratory that can be deployed rapidly to the scene of an accident or terrorist event.

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

in environmental samples.

We are also engaged in initiatives for product development for this market, including:

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

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

continued integration of ECL technology into the Air Force biological testing program.

Certain of our U.S. government contracts contain provisions that grant to the U.S. government a non-exclusive, non-transferable, irrevocable, paid-up license to use inventions made by us in the course of performing such contracts, or have such inventions used by or on behalf of the U.S. government, for research or other government purposes. See ITEM 1 Risk Factors Risks Relating to Regulation and Government Contracts.

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

Industrial. We manufacture and sell a panel of tests for the detection of foodborne and waterborne disease-causing pathogens, such as E. coli O157, Salmonella, Campylobacter and Listeria. These tests are used as a quality control method for testing food and beverage products, such as meat used in hamburger, for bacteria that have caused numerous outbreaks of gastrointestinal and kidney-related disease worldwide.

We expect that our products for industrial testing will generally not require the approval of a government agency prior to marketing of the products in the United States. See ITEM 1 Business Government Regulation Biodefense and Industrial Testing Products for a more detailed description of the government regulations to which we are subject in connection with our products for industrial testing.

Life Science. We provide products and services for the discovery and development of new drugs to the life science market. Our product development and marketing efforts center on two M-SERIES instruments the M384 and the M1M instruments each of which build on the ECL technology-based applications provided by the M-SERIES systems and the BIOVERIS Detection System.

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

validating targets identified through genomics;

screening of large numbers of compounds generated through combinatorial chemistry;

re-testing and optimization of lead compounds; and

clinical trial testing of drug candidates.

After identifying disease targets and synthesizing chemical compounds, researchers attempt to find compounds that are drug candidates. This drug discovery process involves developing an assay to determine whether a particular compound has the desired effect on a target and then screening compounds using that assay. We believe that the need of pharmaceutical and biotechnology companies to rapidly identify therapeutic targets, screen thousands of compounds per day against those targets and then optimize the leads has created new opportunities for ECL technology-based systems in the pharmaceutical and biotechnology industry. Our M-SERIES instruments are compatible with multi-well microplates that are commonly used in drug discovery and development laboratories and

can be fully integrated with many existing automation and robotic systems. These instruments were designed to enable researchers to test new biological targets against potential drug compounds with higher levels of accuracy and sensitivity. We believe they may also perform highly sensitive tests more quickly at a lower cost and this may permit a drug candidate to move more rapidly into the later stages of drug development, clinical trials and ultimately into the market.

We believe that the sensitivity and accuracy of these M-SERIES systems create advantages over many competitive detection technologies. They permit the user to:

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

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

have more confidence in the results the tests produce.

Our expertise in developing assays allows us to assist customers in determining whether a proposed assay is feasible and to assist with the development and performance of assays that comply fully with the FDA's Good Manufacturing Practices.

Immunogenicity testing is performed by pharmaceutical and biotechnology companies in order to characterize the ability of protein-based therapeutics to stimulate an immune response. We have recently introduced proprietary products for immunogenicity testing. Antibodies that result from an immune response to a protein-based drug can reduce its efficacy and cause significant side effects, such as allergic reactions. Because of serious side effects that have been reported over the last year, it has become increasingly necessary to determine if an immune response to protein-based drugs develops in patients by screening for the presence of antibodies, confirming their specificity, characterizing the type of antibodies present and determining whether they interfere with binding events.

Immunogenicity testing is done during pre-clinical studies and may continue through the clinical trials required for regulatory approval. In some cases the FDA requires additional testing after a drug has been approved. Our M-SERIES product line for the life science market is believed to be ideally suited to perform immunogenicity testing by measuring low affinity antibodies with high sensitivity, all in the presence of the highly concentrated drug.

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

While continuing to support our existing bio-pharmaceutical and academic customers, we may selectively pursue other commercial opportunities in the life science or other markets in support of our overall corporate strategy. Our products that will be sold only for research use in the life science market generally do not require the approval of a government agency prior to marketing of the products in the United States. See ITEM 1 Business Government Regulation Life Science Research Products for a more detailed description of the government regulations to which we are subject in connection with our products for the life science market.

Vaccines

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

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

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

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

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

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

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

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

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

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

Collaborations and License Arrangements

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

arrangements with Roche Diagnostics, bioMérieux, Eisai and MSD.

Roche Diagnostics

In connection with the merger and related transactions, Roche, one of the world's leading providers of clinical diagnostic products, has obtained a worldwide, royalty-free, non-exclusive license, which we refer to in this Form 10-K as the license agreement, to develop, make, reproduce, modify, use, sell and otherwise commercially exploit certain clinical

immunoassay instruments and assays using defined ECL technology owned by us in the human *in vitro* diagnostics field, including the continued sale and further development of its Elecsys products. We will not receive royalties or other payments as a result of product sales by Roche in accordance with the license agreement.

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

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

certain PCR technology; or

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

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

bioMérieux

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

Eisai

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

MSD

As part of the merger and related transactions, we assumed IGEN's interest in MSD, a joint venture formed in 1995 by IGEN and MST, which is a company established and wholly-owned by Mr. Jacob Wohlstadter, a son of our chief executive officer. An independent committee of IGEN's board of directors, with the advice of independent advisors and counsel, negotiated and approved the MSD agreements.

MSD develops, manufactures, markets and sells products utilizing a combination of MST's multi-array technology and our ECL technology. MSD's Sector line of instrumentation is used in drug discovery for high throughput screening, high content screening, multiplexing and target validation. MSD also manufactures and markets a line of its own

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

The joint venture agreement among MSD, MST and us, which we refer to in the Form 10-K as the MSD joint venture agreement, expired upon completion of the merger and related transactions. As a result, MSD and MST had the right to purchase our interests in MSD and pursuant to the settlement agreement we entered into with MSD, MST and Jacob Wohlstadter in August 2004, which is referred to in this Form 10-K as the settlement, on December 13, 2004 MST

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

Patents and Other Proprietary Rights

We pursue a policy of seeking patent protection to preserve our technology and our right to capitalize on the results of our research and development activities and, to the extent it may be necessary or advisable, to exclude others from appropriating our technology. We will also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

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

We own approximately 83 issued U.S. patents, and own or have exclusively licensed approximately 32 pending U.S. patent applications in the diagnostics field. Additionally, we own or have exclusively licensed approximately 165 granted foreign patents and approximately 88 pending foreign patent applications in the diagnostics field. These patents and patent applications are important to our business and cover various aspects of ECL technology and products, as well as the methods for their production and use.

The pending patent applications in the diagnostics field may not be granted and others may challenge our patents. Certain ECL patents will begin to expire in 2006; however, patent coverage for certain key aspects of our ECL technology will continue through 2022. We plan to continue to protect our technology with new patent filings, which could further extend our patent coverage.

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

Government Regulation

The research and development, manufacturing, marketing, sale and distribution of both existing and future products based on ECL technology are subject to comprehensive government regulation. Government regulation by various Federal, state, and local agencies, which includes detailed inspection of, and controls over, research and laboratory procedures, safety, clinical investigations, manufacturing, marketing, sampling, labeling, distribution, record keeping, storage and disposal practices, substantially increases the time, difficulty and costs incurred in obtaining and maintaining the clearance or approval to market newly developed and existing products. In particular, government regulatory actions can result in, among other things, delays in the release of our and our licensees' products, injunction, seizure or recall of our or our licensees' products, suspension or revocation of the authority necessary for their production and sale, and other civil or criminal sanctions, including monetary penalties that could be substantial.

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

Biodefense and Industrial Testing Products

Our biodefense products are subject to stringent Federal, state, local and foreign laws, regulations and policies governing their manufacture, storage, sale, distribution and export. In addition, the U.S. government has adopted, and is expected to continue to adopt, laws, regulations and rules governing the research, development, procurement and handling of pathogens that may be used in a bioterrorist attack or other agents that may cause a public health emergency and to permit government inspection and oversight of facilities engaged in the research, development, manufacture or sale of select

agents. Under several statutes recently enacted, the Department of Homeland Security, the FDA, the Department of Commerce and various other regulatory authorities have been charged with establishing and implementing programs designed to enhance the security of food and water supplies, as well as the environment, from terrorist attacks. These legislative initiatives include recordkeeping, registration, notification, import, export, manufacturing and various other compliance measures. This is a rapidly evolving regulatory landscape and many of the possible rules and regulations have not yet been proposed or adopted. We may be required to incur significant costs to comply with such laws and regulations in the future, and such laws or regulations may have a material adverse effect upon our ability to do business.

Life Science Research Products

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

Clinical Diagnostic Products

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

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

The FDA will clear a device under section 510(k) if the submitted information establishes that the proposed device is substantially equivalent to a legally marketed class I or II medical device, or to a class III medical device for which the FDA has not yet called for a pre-market approval application. Commercial distribution can begin only after the FDA issues an order that the device is substantially equivalent to a device that is legally marketed and not subject to a pre-market approval requirement. The FDA may determine that a proposed device is not substantially equivalent to a legally marketed device, in which case a pre-market approval will be required to market the device, unless additional information can be submitted to support a substantial equivalence determination, or the FDA, pursuant to a timely request, makes a risk-based determination that a device that is not a substantially equivalent device can be classified into class I or II. An FDA request for additional data could require that clinical studies of the device's safety and effectiveness be performed. Clearance, if obtained, may be conditioned on labeling restrictions or conducting a lengthy post-market surveillance study.

A pre-market approval application must be filed and approved before a device can be marketed if a proposed device is not substantially equivalent to a legally marketed device, as discussed above, or if it is a class III device that was in commercial distribution prior to May 28, 1976, for which the FDA has called for pre-market approval. A pre-market approval application must be supported by valid scientific evidence, which typically includes extensive pre-clinical data and well controlled or partially controlled clinical trials, to demonstrate the safety and effectiveness of the device. Obtaining approval can take several years and approval may be conditioned on, among other things, substantial restrictions on indications for use and the conduct of postmarket surveillance studies. Generally, the pre-market approval process requires much more extensive pre-filing testing than does the section 510(k) pre-market notification procedure and involves a significantly longer FDA review after the date of filing. In responding to a pre-market approval application, the FDA may grant marketing approval, may request additional information, may set restrictive limits on claims for use or may deny the application altogether.

After the pre-market clearance or approval for the medical device has been received, it may still be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the device reaches the market. The FDA may require post-market surveillance programs to monitor the effect of medical devices that have been sold, and has the power to prevent or limit further marketing of medical devices based on the results of these post-marketing programs. In addition, the FDA's medical device reporting regulation requires reports to the FDA whenever information reasonably suggests that a marketed device may have caused or contributed to death or serious injury, or when a device malfunctions and if the malfunction were to recur, the device would be likely to cause or contribute to a death or a serious injury.

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

We and our licensees' clinical diagnostic products will be affected by the Clinical Laboratory Improvement Amendments of 1988, which is intended to insure the quality and reliability of medical testing and may have the effect of discouraging, or increasing the cost of, clinical diagnostic testing.

The regulations establish numerous requirements applicable to clinical diagnostics. Under these regulations, the specific requirements that a laboratory must meet depend upon the complexity of the tests performed by the laboratory. Under the clinical laboratory improvement regulations, all laboratories performing moderately complex or highly complex tests will be required to comply with stringent standards and requirements. Because the regulations interpretation is uncertain, it is possible that certain of our licensees' products may be categorized as highly complex tests, in which case penetration of the point-of-care market would be reduced because not all laboratories would meet the standards required to conduct such tests. In addition, future changes in regulations or interpretations made by the U.S. Department of Health and Human Services, FDA, Centers for Medicare & Medicaid Services or other regulatory bodies may adversely affect us and our licensees.

In addition to the foregoing, we will be, and our licensees are, subject to numerous Federal, state and local laws and regulations relating to such matters as safe working conditions, laboratory and manufacturing practices, fire hazard control, and environmental protection, including disposal of hazardous or potentially hazardous substances.

We do not expect compliance with these laws and regulations to have a material effect on our financial results, capital requirements or competitive position, and we have no plans for material capital expenditures relating to such matters. However, we and our licensees may be required to incur significant costs to comply with such laws and regulations in the future, and such laws or regulations may have a material adverse effect upon us and our licensees' ability to do business.

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

Vaccines

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

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

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

Government Contracts and Regulation

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

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

During the years ended March 31, 2005, 2004, and 2003, agencies of the U.S. government accounted for 27%, 22% and 26% of total revenue, respectively, and 39% and 26% of total consolidated accounts receivable as of March 31, 2005 and 2004, respectively.

Environmental Regulation

Our operations are subject to stringent foreign, Federal, state and local laws, rules and regulations relating to the protection of the environment, including those governing the use, handling and disposal of hazardous, radioactive and infectious materials and wastes, the discharge of pollutants into the air and water and the cleanup of contaminated sites. Some of our operations will require permits, and these permits will be subject to modification, renewal and revocation by issuing authorities. Although we believe that we are in compliance with these laws and regulations in all material respects, we may be required to incur significant costs to maintain or achieve compliance if additional or stricter environmental and health and safety requirements are imposed in the future or in the event of any noncompliance at our facilities.

Reimbursement

Third-party payors, such as governmental programs and private insurance plans, can indirectly affect the pricing or the relative attractiveness of our products by regulating the maximum amount of reimbursement they will provide for diagnostic testing services. In recent years, healthcare costs have risen substantially, and third-party payors have come under increasing pressure to reduce such costs. In this regard, the Federal government, in an effort to reduce healthcare costs, may take actions that may involve reductions in reimbursement rates. If the reimbursement amounts for diagnostic testing services are decreased in the future, it may decrease the amount which physicians, clinical laboratories and hospitals are able to charge patients for such services and consequently the price we and our collaborators will be able to charge for products.

Seasonal Aspects, Backlog and Renegotiation

There are no significant seasonal aspects to our business. Orders for our products are generally filled on a current basis, and order backlog is not material to our business. A material portion of our business is subject to contracts that may be terminated at the election of the government.

In the event our biodefense business expands, the portion of our business subject to contracts that may be terminated at the election of the government is likely to expand. For a further description of risks related to our contracts with the government, see ITEM 1 Risk Factors Risks Relating to Regulation and Government Contracts.

Competition

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

- the time required to run tests with the product;
- the level of sensitivity, accuracy and consistency of the product;
- the relative ease of use of the product;
- the quality of support and services for the product;
- flexibility and expandability of the product;
- product time-to-market;
- product safety;
- market acceptance of product; and
- product price.

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

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

Manufacturing

Our current commercial manufacturing operations consist of the manufacture of the M-SERIES family of products and reagents, biodefense and industrial testing products, and cell culture research biologicals. We operate a qualified ISO 9001 facility. We use a variety of suppliers and believe that we do not depend on any supplier that cannot be replaced in the ordinary course of business. Any changes in source of supply may require additional engineering or technical development, with costs and delays that could be significant, to ensure consistent and acceptable performance of the products.

We do not manufacture any clinical diagnostic products. We are presently evaluating plans for future manufacturing of our clinical diagnostic products. These plans may include direct and third-party manufacturing.

See ITEM 1 Business Risk Factors Risks Relating to Us and Our Business We have limited manufacturing experience, which puts us at a competitive disadvantage and could have a material adverse effect on our business, financial condition and revenue, ITEM 1 Business Risk Factors - Risks Relating to Us and Our Business We have limited manufacturing facilities for our products and we may not find additional facilities suitable for future growth, which could materially adversely affect our business and prospects and ITEM 1 Business Risk Factors Risks Relating to Us and Our Business We depend on a limited number of suppliers for materials used in the manufacturing of our products, and any interruption in the supply of those materials could hamper our ability to manufacture products and meet customer orders.

Sales and Marketing

We maintain a direct sales and marketing group in the United States and Europe that consists of approximately 34 people. Our direct sales group focuses on sales of the M-SERIES family of products and the BIOVERIS Detection System, together with reagents and services, to various government agencies in the biodefense market, food and beverage producers and contract testing laboratories in the industrial market and other potential customers in the life science market.

In addition to our direct and indirect sales and marketing efforts, our licensees and collaborators also conduct sales and marketing of our products. See ITEM 1 Business-Collaborations and License Arrangements.

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

Human Resources

As of May 31, 2005, we and our subsidiaries employed 221 individuals, of whom 157 were engaged in research, product development, manufacturing and operations support, and 64 in marketing, sales and applications support and general administration. Of our employees, 23 have Ph.D. degrees. None of our employees is covered by a collective bargaining agreement, and management considers relations with its employees to be satisfactory.

Operating Segment

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

Geographic Segments

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

Executive Officers of BioVeris Corporation

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

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

Samuel J. Wohlstadter is our Chairman of the Board and Chief Executive Officer. He was one of the founders of IGEN and, from IGEN's formation in 1982 until its merger with Roche, he was IGEN's Chairman of the Board and Chief Executive Officer. Mr. Wohlstadter has been a venture capitalist for more than 25 years and has experience in founding, supporting and managing high technology companies, including Amgen Inc., a biotechnology company, and Applied Biosystems, Inc., a medical and biological research products company. Mr. Wohlstadter is also Chief

Executive Officer of Hyperion Catalysis International, an advanced materials company, which he founded in 1981; of Wellstat Therapeutics Corporation, a drug discovery company, which he founded in 1985; of Proteinix Corporation, a development stage company organized to conduct research in intracellular metabolic processes, which he founded in 1988; and of Wellstat Biologics Corporation, a drug discovery company, which commenced operations in 1994.

Richard J. Massey, Ph.D. is our President and Chief Operating Officer. He was one of the founders of IGEN and, from February 1992 until IGEN's merger with Roche, he was IGEN's President and Chief Operating Officer. He served as Senior Vice President of IGEN from 1985 to 1992. From 1981 until he joined IGEN in 1983, Dr. Massey was a faculty member in the Microbiology and Immunology Department at Rush Medical Center in Chicago. Prior to that, he was Senior Research Scientist at the Frederick Cancer Research Center/National Cancer Institute.

George V. Migausky has served as our Vice President and Chief Financial Officer since September 2003. From 1985 until the completion of IGEN's merger with Roche, he was IGEN's Vice President and Chief Financial Officer. Between 1985 and 1992, in addition to serving as IGEN's Chief Financial Officer on a part-time basis, Mr. Migausky also served as financial advisor to several other privately held companies. Prior to joining IGEN in 1985, he spent nine years in financial management and public accounting positions, most recently as a Manager with the High Technology Group of Deloitte & Touche.

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

Risks Relating to Us and Our Business

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

We incurred net losses of \$77.6 million, \$93.3 million and \$50.9 million for the years ended March 31, 2005, 2004 and 2003, respectively. We expect to continue to incur operating losses and negative cash flow as a result of our expenses for manufacturing, marketing and sales capabilities, research and product development, and general and administrative costs.

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

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

- upgrade and enhance the M-SERIES family of products;

- introduce new products into the market;

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

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

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

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

- our design or approach may not be successful;

- our products may not be compatible with existing technology or may rely on technology that has become obsolete;

- our products may be found ineffective or fail to meet the applicable regulatory standards or receive necessary regulatory clearances;

our estimates of the market size and potential for our products may prove incorrect;
third parties may market superior or equivalent products;
our products may not be recognized in the market due to unfamiliar brand names; or
our product development costs may outweigh potential future cash flows associated with those products.

Our business, business prospects and financial results would be hurt if our products are not accepted as alternatives to other existing or new products and do not gain market acceptance.

In addition, we have licensed certain PCR technology from Roche that we plan to integrate into certain of our new instrument systems. Although we do not currently sell any product based on the PCR technology licensed from Roche, any products that we may develop using PCR technology will be also subject to the risks of failure inherent in the development of products based on new technologies as described above.

We have recorded a net book value for the PCR licenses of \$17.3 million at March 31, 2005. If we are unable to successfully develop any products using PCR technology because such PCR technology has become obsolete or the future cash flows attributable to products using PCR technology are insufficient to realize the remaining carrying value of the license, we would be required to write off the remaining net book value or record an impairment of the value of the PCR license. Such a write-off or the recording of such an impairment could have a material adverse effect on our future results of operations.

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

Our quarterly operating results will depend upon:

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

- the success of M-SERIES system upgrades and enhancements and customer acceptance of those enhancements and upgrades;

- costs incurred related to expansion into the field of vaccines;

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

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

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

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

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

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

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

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

the amount that we may record related to the potential impairment of the license to use PCR technology;

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

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

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

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

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

One aspect of our strategy is to enter into collaborative relationships with established healthcare and other companies to assist us in developing our technologies or manufacturing or marketing our products for certain markets. We may not be able to enter into collaborations on terms that are favorable to us, if at all. In addition, we cannot assure you that third parties, including our licensees, suppliers or others will not object to possible new collaborations. See ITEM 1 Business Risk Factors Risks Relating to Us and Our Business We and MSD may have different views of the scope of the exclusive license to our technology previously granted to MSD and the scope of MSD's rights under the former joint venture agreement with us, which could affect our ability to expand our business directly or through collaborations.

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

- may decide not to, or may fail to successfully, develop, market or sell products based on our technology;

- may not devote sufficient resources to the development, marketing or sale of these products based on our technology; or

- may terminate their agreements with us.

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

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

Until February 13, 2004, our assets and businesses had historically been owned, operated and fully integrated with IGEN. Our accompanying consolidated financial statements for fiscal years 2004 and 2003 have been prepared and are presented as if we had been operating as a separate entity. In order to fairly present our operating results, these financial statements reflect the application of certain estimates and allocations. Our consolidated statements of operations for fiscal 2004 and 2003 include all revenues and costs that are directly attributable to our businesses, as well as certain expenses of IGEN that have been allocated to us using various assumptions. These expenses include an allocated share of general and administrative salaries as well as certain other shared costs (primarily facility, human resources, legal, accounting and other administrative costs) which were allocated based upon percentage of total revenue or percentage of total headcount, as appropriate. While management believes that the allocation methodologies are reasonable and appropriate, different allocation methodologies would result in changes to our operating results.

Upon completion of the merger and related transactions between Roche and IGEN, we became an independent, publicly-traded company and operate on a stand-alone basis. The financial information in the accompanying

consolidated financial statements for fiscal 2004 and 2003 may not reflect our financial position, results of operations and cash flows in the future or what they would have been had we been operating as a stand-alone entity in the past.

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

We have broad discretion in determining the future strategy and focus of our business and may enter new healthcare fields in which we have limited or no experience. During fiscal 2005, we expanded our business model to target the field of

vaccines. A significant change in the focus of our business could result in a loss of our investment, the incurrence of additional costs, including research and development costs, and exposure to additional or different business risks. Incurrence of additional costs and exposure to additional risks could materially adversely affect our business.

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

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

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

- for research and development to successfully develop our technologies;

- To obtain regulatory approval for our products;

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

- to respond to innovations that our competitors develop;

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

- to make new arrangements to market our technology;

- to manufacture products ourselves or through a third party;

- to provide funding for expanded or new facilities; and

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

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

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

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

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

WE MAY EXPERIENCE DESIGN, DEVELOPMENT, IMPLEMENTATION AND OTHER DIFFICULTIES THAT COULD DELAY OR PREVENT OUR INTRODUCTION OF NEW OR ENHANCED PRODUCTS OR AFFECT THE PERFORMANCE OF EXISTING PRODUCTS, WHICH COULD ADVERSELY AFFECT OUR BUSINESS. IN ADDITION, IF THE MARKETS FOR OUR PRODUCTS CHANGE OR EVOLVE IN AN UNEXPECTED MANNER, OUR BUSINESS COULD BE MATERIALLY ADVERSELY AFFECTED.

The development of new or enhanced products is a complex and uncertain process that requires the accurate anticipation of technological and market trends as well as precise technological execution. We may experience design, development, implementation and other difficulties that could delay or prevent our introduction of new or enhanced products, or

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

We expect the markets for our products to change and evolve. These changes could facilitate the market demand for our new or enhanced products, including the need for products that could be utilized in clinical point-of-care sites and field-testing of environmental samples in the biodefense market. If market demand does not change or evolve as we anticipate or if we are not able to develop products that meet the evolving market demand, our business prospects would be adversely affected.

In addition, the markets for our products are characterized by evolving industry standards and government regulations, the need for updated and effective technology and new product introductions. Our success will depend in part upon our ability to profitably enhance existing products and develop and introduce new products. We may not be able to avoid the obsolescence of our products due to technological change and evolving industry standards and government regulations.

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

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

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

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

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

Any factor adversely affecting the pricing or demand of M-SERIES products, including market acceptance of competing products, could cause our revenues to decline, resulting in adverse financial results and negatively affecting

our business prospects.

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

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

Pursuant to the settlement, MST purchased our entire interests in MSD and is required to pay us the outstanding purchase price over time, plus simple (cumulated, not compounded) interest at the fixed annual rate of 5.5%. The purchase price is payable over time in installments equal to the sum of 5% of MSD net sales, as determined in accordance with the MSD agreements, and 20% of the net proceeds realized by MSD from the sale of its debt or equity securities in any third-party financing after the date of the sale of our interests in MSD. We received a prepayment credit of \$2.0 million against our payment obligations to MSD in connection with the settlement, and therefore the initial installment payments will be applied against this credit and not paid to us in cash.

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

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

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

Our business will be subject to intensive competition from established companies, development stage companies and research and academic institutions, and we expect this competition to intensify. Many of these companies and institutions have one or more competitive advantages over us, including, among other things:

- more money to invest;

- more established diagnostic or vaccine products;

- longer-standing relationships with customers;

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

- a larger, more experienced workforce; and

- more experience in obtaining regulatory approval for clinical testing or vaccine products.

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

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

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

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

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

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

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

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

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

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

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

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

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

FAILURE TO MANAGE OUR GROWTH COULD ADVERSELY AFFECT OUR BUSINESS.

We expect to grow by increasing our presence in existing markets and introducing new products we develop into new potential markets. Our growth strategy will place a strain on our management and our operating and financial systems.

As we grow, our personnel, systems, manufacturing capabilities and resources, procedures and controls may be inadequate to support future operations and we will need to hire, train and retain additional personnel. We may also need to improve and expand our financial and management controls, reporting systems and operating systems as well as other aspects of our infrastructure, including research and development or manufacturing facilities. We may encounter difficulties integrating additional personnel, as well as improving, expanding and integrating new systems or facilities, which could adversely affect our business.

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

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

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

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

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

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

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

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

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

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

- be required to alter, or abandon products or processes;

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

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

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

- be required to pay damages that could be substantial.

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

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

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

Our success or failure will also depend, in part, on the patent rights and technology of others, including patents and technology being licensed to us from affiliates of Roche. We have been licensed by affiliates of Roche to exploit certain improvements from Roche Diagnostics and certain PCR technology, subject to certain limitations. Although the terms of the improvements license agreement and the PCR license agreements were negotiated in an effort to minimize the areas of potential future disputes, there are no assurances that we and Roche will continue to agree on the scope, permitted use and other material terms of the improvements license agreement or the PCR license agreements. Future disputes with Roche over the scope, permitted use and other material terms of the improvements license agreement or the PCR license agreements, such as disputes over the field or types of products that we are permitted to develop and sell, may lead to lengthy and costly legal proceedings, or could interfere with or preclude us from proceeding with one or more development programs, whether conducted independently or through a collaborative arrangement. In addition, third parties may object to the scope, permitted use and other material terms of one or more of the licenses granted to us by certain Roche affiliates.

We also license technology from other companies and academic institutions. Because access to this technology is necessary to operate our business, we must be certain that we comply with these license agreements.

Our business could be harmed if we breached any of these license agreements and lost the rights to use this patented technology or if we were unable to renew existing licenses on acceptable terms, if at all, or get additional licenses that we may need on acceptable terms, if at all. In addition, we may need to litigate the scope and validity of patents held by others and such litigation could be a substantial cost for us.

WE AND MSD MAY HAVE DIFFERENT VIEWS OF THE SCOPE OF THE EXCLUSIVE LICENSE TO OUR TECHNOLOGY PREVIOUSLY GRANTED TO MSD AND THE SCOPE OF MSD'S RIGHTS UNDER THE FORMER JOINT VENTURE AGREEMENT WITH US, WHICH COULD AFFECT OUR ABILITY TO EXPAND OUR BUSINESS DIRECTLY OR THROUGH COLLABORATIONS.

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

WE RELY ON TRADE SECRETS AND OTHER INFORMATION THAT CANNOT BE PROTECTED BY PATENTS, WHICH COULD HARM OUR BUSINESS IF THEY WERE DISCLOSED TO OR INDEPENDENTLY DEVELOPED BY OTHERS.

In addition to patents, we also rely in our business on trade secrets, know-how and other proprietary information. If this information were disclosed to or independently developed by competitors, our business would suffer.

We seek to protect this information, in part, by entering into confidentiality agreements with licensees, employees and consultants that prohibit these parties from disclosing our confidential information. These agreements may not provide

adequate protection for our trade secrets, know-how and other proprietary information or ensure that the information we share with others during the course of our business will remain confidential. We may not have sufficient legal remedies under the agreements or otherwise to correct or compensate for unauthorized disclosures or sufficient resources to seek redress.

If we are not able to be adequately redressed for the unauthorized disclosure of our trade secrets, know-how or other proprietary information, our competitive position may be undermined and our business may suffer.

WE DEPEND ON A LIMITED NUMBER OF SUPPLIERS FOR MATERIALS USED IN THE MANUFACTURING OF OUR PRODUCTS, AND ANY INTERRUPTION IN THE SUPPLY OF THOSE MATERIALS COULD HAMPER OUR ABILITY TO MANUFACTURE PRODUCTS AND MEET CUSTOMER ORDERS.

We depend on vendors to supply key materials that we use in our products. Some of these materials are available only from limited sources. From time to time, suppliers may extend lead time, limit supplies or increase prices due to capacity constraints or other factors. In the event of a reduction in, interruption of, or degradation in, the quality of the supply of any of the materials required by us, or an increase in the cost of obtaining those materials, we would be forced to locate an alternative source of supply. If no alternative source were available or if an alternative source were not available on a timely basis, at a reasonable cost or otherwise on acceptable terms, our ability to manufacture one or more of our products would be delayed or halted.

Any changes in sources of supply may require additional engineering or technical development to ensure consistent and acceptable performance of our products. If any of these events occur, our product costs may increase, we might be unable to deliver products in a timely fashion, we could lose sales as well as customers, and our business would be significantly harmed as a result.

WE DEPEND ON HIGHLY TRAINED AND SKILLED EMPLOYEES AND MANAGEMENT, AND WE MAY NOT BE ABLE TO ATTRACT AND RETAIN SUFFICIENT PERSONNEL, WHICH COULD ADVERSELY AFFECT OUR BUSINESS.

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

In addition to scientists, we also need to hire managers who have regulatory, manufacturing and marketing capabilities. If we are not able to hire managers with these skills, or develop expertise in these areas, our business could suffer.

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

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

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

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

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

Risks Relating to Regulation and Government Contracts

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

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

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

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

In addition to unfavorable termination provisions, certain of our U.S. government contracts contain provisions that grant to the U.S. government a non-exclusive, non-transferable, irrevocable, paid-up license to use inventions made by us in the course of performing such contracts, or have such inventions used by or on behalf of the U.S. government, for research or other government purposes. New U.S. government contracts we enter into may also include similar provisions.

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

The manufacture, packaging, labeling, advertising, promotion, distribution and sale of clinical diagnostic products and vaccines are subject to governmental regulation by national and local government agencies in the United States and abroad. The FDA regulates many of the areas in which we conduct our research and in which we are and expect to be developing, manufacturing and marketing products. In particular, we must obtain FDA clearance or approval before

we can market clinical diagnostic or vaccine products. The process of obtaining necessary clearances or approvals is often costly, time consuming and uncertain.

We may begin to distribute reagents specifically for research use under an exemption. If the FDA disagrees with our classification of, or the manner in which we market and sell those reagents, it may impose restrictions on our business operations and subject us to sanctions that could adversely affect our business prospects. We have very limited experience

obtaining FDA clearance and approval and may not be successful in obtaining FDA clearance or approval for any of our clinical diagnostic products, which would materially adversely affect our business prospects. Further, clearance or approval may place substantial restrictions on the indications for which the product may be marketed or to whom it may be marketed.

To obtain permission from the FDA to market clinical diagnostic products in the U.S., we, or the companies we work with, will need to either obtain Section 510(k) pre-market notification clearance or approval of a pre-market approval application from the FDA. To obtain clearance for marketing, we, or the companies we work with, must demonstrate substantial equivalence to a similar legally marketed product by submitting a pre-market notification to the FDA. The FDA may require preclinical and clinical data to support a substantial equivalence determination. Clinical trials for gathering supporting data can take extended periods of time to complete and there can be no assurance that the FDA will find a device substantially equivalent.

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

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

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

We expect that certain of our future products will be subject to continuing FDA requirements, including compliance with the FDA's Good Manufacturing Practices and the FDA's medical device reporting regulations. We expect that we may need to spend a substantial amount of money to comply on an ongoing basis with government regulations. Government agencies, such as the FDA, Department of Homeland Security, Department of Commerce and the Environmental Protection Agency, or EPA, regulate many of our products as well as products that we plan to develop, manufacture, market and sell, including products for the clinical diagnostics, biodefense and industrial markets. The costs of complying with governmental regulations and any restrictions that government agencies might impose could have a significant impact on our business. If we increase our manufacturing and expand our product offerings, these costs will increase.

Whether we directly manufacture products or contract with another company to manufacture products based on our technology, the FDA and other government agencies will continually review and periodically inspect the manufacturing process. If any of these agencies were to discover a problem with our products, the manufacturing process or the manufacturing facility, they could place restrictions on these products and on the manufacturer and impose sanctions. For example, the FDA could require us to recall, or even totally withdraw, a product from the market or close a manufacturing facility.

In addition to FDA regulations, the process of manufacturing products is subject to a variety of environmental laws and regulations, including laws and regulations governing the use, management and disposal of hazardous, radioactive and infectious materials and wastes, the discharge of pollutants into the air and water, and the cleanup of contaminated sites. We could incur substantial costs, including cleanup costs, fines and penalties, claims for damages, such as personal injury or property damages, and loss of permits required for our operations, if we fail to comply with these

laws or regulations. Our operations are also subject to various employee health and safety laws and regulations, including those concerning occupational injury and illness and employee exposure to hazardous, radioactive and infectious materials.

While we have procedures in place to protect employees from exposure to such materials, we cannot assure you that potentially harmful exposure will not occur or that we will not be liable to employees as a result. In addition, because of the limited information currently available regarding some of the hazardous, radioactive and infectious materials used in our businesses, there may be unknown risks involved with the use of and exposure to such materials. In some circumstances there may be no body of knowledge or standard protocols for dealing with these risks. Costs associated

with such environmental, health and safety matters could have a material adverse effect on our business and financial condition.

Our biodefense products are subject to stringent Federal, state, local and foreign laws, regulations and policies governing their manufacture, storage, sale, distribution and export. In addition, the U.S. government has adopted, and is expected to continue to adopt, laws, regulations and rules governing the research, development, procurement and handling of pathogens that may be used in a bioterrorist attack or other agents that may cause a public health emergency and to permit government inspection and oversight of facilities engaged in the research, development, manufacture or sale of select agents. Under several statutes recently enacted, the Department of Homeland Security, FDA, Department of Commerce and various other regulatory authorities have been charged with establishing and implementing programs designed to enhance the security of food and water supplies, as well as the environment, from terrorist attacks. These legislative initiatives include recordkeeping, registration, notification, import, export, manufacturing and various other compliance measures. This is a rapidly evolving regulatory landscape and many of the possible rules and regulations have not yet been proposed or adopted. We may be required to incur significant costs to comply with such laws and regulations in the future, and such laws or regulations may have a material adverse effect upon our ability to do business. In addition, the DOD or other government agencies may require additional security measures to be implemented at our facility, which could cause us to incur substantial additional costs.

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

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

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

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

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

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

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

decrease because fewer tests would be performed or prices would be lowered, or both. Reduced sales or royalty income would hurt our business and business prospects.

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

Risks Relating to the Industry

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

Product liability is a major risk in marketing products for vaccines and for the clinical diagnostics, biodefense and industrial markets. We may not be able to insure adequately against risk of product liability. We may face product liability for claims and lawsuits brought by customers. Damages awarded in product liability cases can be very large. While we have product liability insurance, this coverage is limited.

We may not have adequate product liability insurance to cover us against our potential liabilities or be able to maintain current levels of product liability insurance on acceptable terms, if at all. Claims or losses in excess of our product liability insurance coverage or not covered by our product liability insurance could have a material adverse effect on our financial condition.

Risks Relating to Our Common Stock

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

Our executive officers and directors, in the aggregate, own approximately 23% of the outstanding shares of our common stock. Our chairman and chief executive officer owns approximately 18% of the outstanding shares of our common stock. As a result, certain of our executive officers or directors may have significant influence over the election of directors and may be able to significantly influence the outcome of proposed corporate actions supported or opposed by other stockholders. In addition, as a result of their shareholdings, certain of our executive officers and directors could have significant influence over the outcome of potential transactions, including acquisition transactions, that may be supported by other stockholders.

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

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

classify our board of directors into three classes, with directors of each class serving for a staggered three-year period;

provide that our directors may be removed only for cause and only upon the approval of the holders of at least a majority of the voting power of all our shares entitled to vote generally in the election of such directors then outstanding, voting together as a single class;

prohibit our stockholders from calling special meetings and prohibit action by our stockholders by written consent;

require at least 66 2/3% of the voting power of all our shares entitled to vote generally in the election of directors then outstanding, voting together as a single class, to alter, amend or repeal certain provisions, including the provisions relating to our classified board, the election, appointment and removal of our directors and action by

stockholders by written consent described above;

permit our board of directors to fill vacancies and newly created directorships on our board of directors; and

contain advance notice requirements for stockholder proposals.

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

preferred stock with voting and other rights that could adversely affect the voting power of the holders of our common stock or otherwise make it more difficult for a third party to gain control of us. Such provisions would make the removal of incumbent directors more difficult and time-consuming and may have the effect of discouraging a tender offer or other takeover attempt not previously approved by our board of directors.

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

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

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

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

Your investment in our common stock could be diluted if we issue additional shares of our common stock or securities convertible into, or exercisable for, shares of our common stock in the future, which we may need to do to raise funds for our business. Sales of additional shares of our common stock or the conversion of securities into, or the exercise of securities for, shares of our common stock could cause the market price of our common stock to decrease.

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

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

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

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

ITEM 2. PROPERTIES

Our principal administrative, marketing, manufacturing and research and development facilities consist of approximately 165,000 square feet located in five buildings in Gaithersburg, Maryland. We have an additional 21,000 square feet of leased research and development, sales and office facilities in McLean, Virginia; San Diego, California; the District of Columbia; and Oxfordshire, England.

Our leases expire at various times from 2005 through 2010. We believe that current facilities should be adequate for immediate business requirements but additional facilities may be required if we successfully expand our business operations. We are evaluating new facilities for development, manufacturing and other corporate uses and if we secure new space, it would result in additional facilities costs.

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

ITEM 3. LEGAL PROCEEDINGS

In June 2004, the Audit Committee of our Board of Directors investigated a series of transactions whereby MSD, upon Jacob Wohlstadter's sole approval and without our knowledge, purchased residential real property and luxury automobiles for approximately \$7.0 million. On June 15, 2004, we filed an action in the Court of Chancery of the State of Delaware against Jacob Wohlstadter, MSD and MST and sought an order from the court confirming that we remained entitled to designate one of the two members of the MSD Board of Managers and prohibiting MSD from taking any actions outside the ordinary course of MSD's business without giving prior notice to us, pending the final outcome of the litigation. On June 17, 2004, the court ordered that, pending the court's final determination of the lawsuit, our representative on the MSD Board of Managers was to remain on the MSD Board of Managers and that MSD was not to engage in any transaction outside the ordinary course of business which had a value in excess of \$10,000 without the approval of both members of the MSD Board of Managers.

On June 17, 2004, MSD received \$2.9 million from Jacob Wohlstadter as consideration for the proposed sale by MSD to Jacob Wohlstadter of real property and automobiles, pending approval by the MSD Board of Managers. Jacob Wohlstadter also agreed to assume MSD's obligations with respect to a prospective approximately \$4.1 million real property purchase. Also on June 17, 2004, we were informed by the staff of the SEC that it had commenced an informal inquiry as to certain issues relating to MSD.

On July 14, 2004, we filed a second action with the court against MSD, MST and Jacob Wohlstadter. The action alleged, among other things, breach of fiduciary duty and contract, and sought relief including the dissolution of MSD and the appointment of a liquidating trustee. Also in July 2004, the Audit Committee retained an independent special counsel to investigate whether our management had any prior knowledge of the real property and automobile transactions of MSD described above. This special counsel reported to the Audit Committee that there was no evidence that any member of our management knew of the MSD transactions at issue before they occurred.

On July 19, 2004, all of the members of our Board of Directors met to review the MSD litigation and related issues. As a result of its review, the Board of Directors, with all members participating, unanimously approved a resolution that delegated to the Joint Venture Oversight Committee (JVOC) the power and authority to (i) initiate, review, evaluate and determine the course of action we should pursue with respect to the pending litigation and any additional litigation against MSD, (ii) communicate and negotiate the terms of any proposed settlement of such litigation and any other matters with respect to MSD and (iii) otherwise deal with MSD in a manner the JVOC deemed to be in the best interests of our company and our stockholders. The resolution also appointed Messrs. Quinn and Crowley as additional members of the JVOC, resulting in the JVOC consisting of five independent directors, and provided that action of the JVOC should be by unanimous approval of its members.

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

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

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

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

MSD provided the representation letters requested by its and our auditors in connection with MSD's financial statements for the year ended December 31, 2003 and a copy of its audited financial statements for the year ended December 31, 2003, enabling us to file our Annual Report on Form 10-K for the fiscal year ended March 31, 2004.

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

we paid MSD \$3.0 million in satisfaction of all amounts that we allegedly owed to MSD pursuant to existing agreements between us and MSD. The \$3.0 million payment was net of a \$2.0 million credit, which represents a non-refundable pre-payment by MSD to us for future amounts payable by MSD to us pursuant to the buyout of our interests in MSD.

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

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

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

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

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

PART II

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

Common Stock

Our common stock began trading on February 17, 2004 and is quoted on The Nasdaq National Market under the symbol BIOV. Prior to that time, there was no public market for our common stock. As of May 31, 2005, there were approximately 164 holders of record of our common stock. The number of record holders is based on the actual number of holders in our books and does not include holders of our common stock in street name or individual participants in security position listings maintained by depositary trust companies.

The following table sets forth the range of high and low bid price per share of our common stock as quoted on The Nasdaq National Market for fiscal 2005 and 2004.

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

Third quarter	7.46	5.80
Fourth quarter	7.58	4.91

Year ended March 31, 2004

Fourth quarter (commencing with our first day of trading on February 17, 2004)	\$ 15.85	\$ 11.85
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No cash dividends have been paid on our common stock to date, and we currently intend to retain any earnings for development of our business.

2003 Stock Incentive Plan

In September 2003, our Board of Directors adopted the 2003 stock incentive plan pursuant to which 5.3 million shares of our common stock have been reserved for issuance upon the exercise of options granted under the plan. The 2003 stock incentive plan was approved by IGEN stockholders prior to the completion of the merger and related transactions on February 13, 2004. The following table sets forth certain information as of March 31, 2005 with respect to the equity compensation plans (including individual compensation arrangements) under which our equity securities are authorized for issuance, aggregated by (i) all compensation plans previously approved by our security holders, and (ii) all compensation plans not previously approved by our security holders.

		Number of securities remaining available for future issuance under equity
Number of securities to	Weighted-average	