BIOVERIS CORP
Form 10-K
June 07, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K
ANNUAL REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For Fiscal Year Ended March 31, 2007
Commission File Number 000-50583
BioVeris Corporation
(Exact name of registrant as specified in its charter)

DELAWARE	80-0076765
(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)

16020 INDUSTRIAL DRIVE, GAITHERSBURG, MD 20877
(Address of principal executive offices) (Zip Code)
301-869-9800
(Registrant s telephone number, including area code)

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

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes o **No** þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.
Yes o **No** þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes þ **No** o

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.
Large accelerated filer o **Accelerated filer** þ **Non-accelerated filer** o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act)
Yes o **No** þ

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of September 29, 2006, computed by reference to the closing sale price of such stock quoted on The Nasdaq National Market on such date, was approximately $192,172,350.

The number of shares outstanding of the registrant s Common Stock, $0.001 par value per share, as of May 25, 2007 was 27,247,902.

Documents Incorporated by Reference: Portions of the definitive Proxy Statement for our 2007 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, 2007
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As used herein, BioVeris , we , us and our refer to BioVeris Corporation and its subsidiaries. M-SERIES, TRICORDER, BIOVERIFY, and BIOVERIS are our trademarks. This Form 10-K also contains disclosures relating to brand names, trademarks or service marks of other companies, and these brand names, trademarks or service marks are the property of those other holders.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

In addition to historical information, this Annual Report on Form 10-K contains forward-looking statements within the meaning of the safe harbor provision of the Private Securities Litigation Reform Act of 1995. All statements contained in this report that are not statements of historical fact, including statements about the proposed merger transaction with Roche Holding Ltd and its wholly-owned subsidiaries and affiliates, which we collectively refer to in this Form 10-K as Roche, markets and potential markets, market growth for diagnostic and vaccine products, potential impact of competitive products, our expectations regarding future revenue, the potential market for products in development, the description of our plans and objectives for future operations, assumptions underlying such plans and objectives, the need for and availability of additional capital and other forward-looking statements included in ITEM 7 Management s Discussion and Analysis of Financial Condition and Results of Operations (MD&A), are forward-looking statements. The words may, should, will, expect, could, anticipate, believe, estimate, 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:

completion of the proposed merger transaction with Roche on a timely basis, if at all;

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

our ability to develop and introduce new or enhanced products;

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

our ability to expand the distribution and to maintain or increase sales of existing products, including as a result of proposed merger transaction with Roche;

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

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

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

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

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

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

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

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

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

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

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

any potential future disputes regarding the scope, permitted use, royalties, payment obligations and other material terms of our license agreements, including those with Roche, which we refer to in this Form 10-K as the Roche License, and 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

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

We were organized as IGEN Integrated Healthcare, LLC, a Delaware limited liability company, on June 6, 2003, and converted into BioVeris Corporation, a newly formed Delaware corporation on September 22, 2003. On February 13, 2004, IGEN International, Inc., which we refer to in this Form 10-K as IGEN, and Roche consummated a merger transaction pursuant to which Roche acquired IGEN and IGEN simultaneously distributed our common stock to its stockholders.

On April 4, 2007, we and an indirect wholly-owned subsidiary of Roche entered into an Agreement and Plan of Merger, which we refer to in this Form 10-K as the Merger Agreement. Pursuant to the proposed Merger Agreement, a subsidiary of Roche will be merged with and into us, with BioVeris surviving as an indirect wholly-owned subsidiary of Roche. The completion of the proposed merger is subject to a number of customary conditions, including, among others, approval by our stockholders, the absence of certain legal impediments to the consummation of the merger, the completion of a review by the Committee on Foreign Investment in the United States under Section 271 of the Defense Production Act of 1950, as amended, and the expiration or termination of the applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, which we refer to in this Form 10-K as the HSR Act, and under certain German anti-trust laws, and other customary conditions. The applicable waiting periods under the HSR Act and German anti-trust laws have expired and we have scheduled a special meeting of stockholders for June 25, 2007 at which our stockholders will vote on the Merger Agreement.

For more information about the Merger Agreement, see ITEM 8 Consolidated Financial Statements and Supplementary Data Notes to Consolidated Financial Statements Note 1. The foregoing description of the Merger Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Merger Agreement, a copy of which is filed with the Securities and Exchange Commission, which we refer to in this Form 10-K as the SEC, and the terms of which are incorporated herein by reference.

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 tests for the following markets:

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

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.

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

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

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

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

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

Vaccines

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

Neisseria meningitidis serogroup B and Y

Neisseria meningitidis serogroup C, in combination with certain other vaccines;

Haemophilus influenzae type b

Group A and Group B Streptococcus;

Chlamydia;

Candida albicans;

Pneumococcus;

Anthrax bacilli; and

Urinary tract infection (E coli).

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

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

Investor Information

We were organized as IGEN Integrated Healthcare, LLC, a Delaware limited liability company, on June 6, 2003, and converted to BioVeris Corporation, a newly formed Delaware corporation, on September 22, 2003. Our executive offices are located at 16020 Industrial Drive, Gaithersburg, Maryland 20877. Our Internet website is located at http://www.bioveris.com. Information contained on our website is not part of this Form 10-K or any other filing which may incorporate by reference this Form 10-K. We provide to the public on our website, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as amended, as soon as practicable after such material is filed electronically with, or furnished to, the 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; however, under the terms of the Merger Agreement, we currently have restrictions on our ability to pursue such relationships;
- 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 technologies, include:

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

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

ECL Technology

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

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

ECL technology provides a uniform format that can be used to conduct a multitude of tests, including immunodiagnostic tests and nucleic acid tests. The essential component of an ECL technology-based system is the flow cell, which contains a magnet to separate the labeled substance from the sample being tested and a light detector to measure the electrochemiluminescence. The flow cell has been designed so that it can be incorporated into a variety of instruments, ranging from large central laboratory random access systems to small batch systems.

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

- *Simplicity:* uniform testing format reduces time and labor in performing a test or series of tests and permits complete automation of the testing process.
- *Flexibility:* enables a single instrument to perform immunodiagnostic tests on large and small molecules and to perform nucleic acid tests, including in the form of DNA and RNA tests.

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

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

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

Consistency: provides highly-reproducible measurements.

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

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

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

ECL technology is well established in the market, evidenced by the fact that our licensees have developed multiple product lines based on ECL technology. There can be no assurance that we will succeed in profitably developing, marketing and selling products based on ECL technology.

Improvements from Roche

We acquired from Roche Diagnostics and its affiliates an irrevocable, worldwide, non-exclusive, fully-paid, royalty-free, perpetual license under certain patents covering technologies based on:

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

certain PCR technology; and

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

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

The improvements license agreement restricts our right to use such improvements in certain types of ECL products. In addition, the license does not permit us to develop, use, manufacture or sell ECL assays that contain labeling that make them useable on ECL instruments manufactured, sold or placed by Roche Diagnostics or its licenses or resellers, in the field.

PCR Technology

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

The PCR license agreements obtained by us from Roche and its affiliates will allow us to develop nucleic acid tests for several specified markets, including the human and animal *in vitro* diagnostics markets. We believe that nucleic acid tests are currently one of the fastest growing segments of the clinical diagnostics market and would complement our immunodiagnostic product line. We do not currently sell any product based on the PCR technology licensed from Roche. For more information about the license fee and royalty payments in connection with the PCR license agreements, see ITEM 8 Consolidated Financial Statements and Supplementary Data Notes to Consolidated Financial Statements Note 2.

Vaccines

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

Neisseria meningitidis serogroup B and Y

Neisseria meningitidis serogroup C, in combination with certain other vaccines;

Haemophilus influenzae type b

Group A and Group B Streptococcus;

Chlamydia;

Candida albicans;

Pneumococcus;

Anthrax bacilli; and

Urinary tract infection (E coli).

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

Products and Markets Using Our Technology

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

BioVeris Products

Diagnostics	Customer Application	Market	Status
M-SERIES (clinical diagnostics analyzer and tests)	Screen, monitor and diagnose medical conditions	Clinical	Development
M-SERIES (M384 Analyzer, reagents, biomarkers and antibody panels)	Drug discovery and development	Life science	Product sales
M-SERIES (M1M Analyzer, reagents, biomarkers and antibody panels)	Drug discovery and development	Life science	Product sales
M-SERIES (M1M(R) Analyzer and reagents)	Detection of food and beverage contaminants and bacteria, viruses and toxins	Biosecurity	Product sales
Cell culture reagents	Biological research		Product sales

Life
science

Vaccines	Customer Application	Market	Status
Neisseria meningitides serogroup B, Y and C (combination only)	Preventative medicine	Vaccine	Pre-clinical research
Haemophilus influenzae type b	Preventative medicine	Vaccine	Pre-clinical research
Group A & B streptococcus	Preventative medicine	Vaccine	Pre-clinical research
Chlamydia	Preventative medicine	Vaccine	Pre-clinical research
Group A streptococcus	Preventative medicine	Vaccine	Pre-clinical research
Pneumococcus	Preventative medicine	Vaccine	Pre-clinical research
Anthrax bacilli	Preventative medicine	Vaccine	Pre-clinical research
Urinary tract infection (*E. coli)*	Preventative medicine	Vaccine	Pre-clinical research
Candida albicans	Preventative medicine	Vaccine	Pre-clinical research

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

Licensee Products	Customer Application	Market	Status	Licensee
Elecsys 2010 /ECL module of E170 / cobas e 601 /cobas e 411	Screen, monitor and diagnose medical conditions	Clinical	Product sales	Roche
NucliSens/NASBA QR	Screen, monitor and diagnose medical conditions	Clinical	Product sales	bioMérieux
	Screen, monitor and diagnose medical conditions	Life science	Product sales	bioMérieux
Picolumi	Screen, monitor and diagnose medicak conditions	Clinical	Product sales	Eisai (Japan)
Sector product line	Drug discovery and development	Life science	Product sales	MSD

Our Products and Markets

Non-Clinical Diagnostics

Biosecurity. We are commercializing products in the emerging market segment for biosecurity, which involves the detection of bacteria, viruses and toxins that may pose a military or public health threat, as well as for the detection of foodborne and waterborne disease causing pathogens. We believe there will be an increasing opportunity to use our products as a biosecurity tool in commercial, governmental and military organizations around the world, as well as in public health, due to the early adoption of our products by key decision makers. Our presence in the biosecurity market may also provide us with the opportunity to sell products to other diagnostics markets. We believe that tests developed for the biosecurity field may also have utility in the clinical diagnostic markets by providing tests for patients exposed to biological agents or toxins. We expect that our non-clinical products for biosecurity will generally not require the approval of a U.S. government agency prior to marketing of the products in the United States. See ITEM 1 Business Government Regulation Biosecurity and Industrial Testing Products for a more detailed description of the government regulations to which we are subject in connection with our biosecurity products.

Our M-SERIES M1M Analyzer is designed to function in demanding field environments, as well as in the laboratory. The M1M is an automated analyzer designed for use with our BioVerify(TM) test kits for the detection of botulinum neurotoxins, anthrax, ricin, staphylococcal enterotoxins A and B, E. coli O157, and salmonella, among others. The system has easy-to-use sample handling and can detect biological agents quickly and with high sensitivity. System software reports positive or negative results automatically in a standard format. The M1M Analyzer was built with specification and configuration inputs from our customers and is designed to meet the needs of field, mobile and centralized laboratories. The M-SERIES M1M Analyzer was also designed for use by first responders, such as trauma centers, emergency medical workers, firefighters and police. We market the M-SERIES product family directly through our own sales, marketing and applications teams. M1M instrument systems originally designed for the biosecurity market are now also being used in life science.

U.S. Army scientists at Fort Detrick and the Edgewood Chemical Biological Center (ECBC) have developed ECL technology-based biological tests designed to measure specific agents and toxins in environmental samples. We have a contract with the DOD pursuant to which the DOD may purchase these tests from us. The tests are used by various laboratories and field sites of the DOD. For risks related to our contracts with the government see ITEM 1A Risk Factors Risks Relating to Regulation and Government Contracts.

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

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

- our Cooperative Research and Development Agreement with the U.S. Army Medical Research Institute of Infectious Diseases for the development of tests for the detection of biological toxins; and
- the continued integration of our ECL technology into the Air Force biological testing program.

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

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

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

- validating targets identified through genomics;
- screening large numbers of compounds generated through combinatorial chemistry;
- re-testing and optimization of lead compounds; and
- clinical trial testing of drug candidates.

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

researchers to test new biological targets against potential drug compounds with higher levels of accuracy and sensitivity. We believe they may also perform highly sensitive tests more quickly at a lower cost than other methods and this may permit a drug candidate to move more rapidly into the later stages of drug development, clinical trials and ultimately into the market.

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

- more quickly adapt the ECL technology to develop and then perform the specific, desired assays, compared to the longer periods required by other existing competing technologies;
- reduce the use of rare components, such as proprietary compounds, antibodies or clinical trial samples, that must be used to run assays; and
- have more confidence in the test results.

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

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

During 2007, we introduced for sale eight new products for use in life science research. These new products are focused on meeting the demand among pharmaceutical and biotechnology companies for a means to measure potential immune response to protein-based therapeutics that are in development. Two of the new products are pharmacodynamic biomarkers designed to measure cytokine levels that may be elevated in response to a drug treatment. These cytokine products detect human IL-2 and TNF-a, molecules that are up-regulated in inflammation and in many immune responses. In addition, six of the new products can be used for immunogenicity testing, assay development, and hybridoma screening. These products compose a panel of antibodies that are prelabeled with our detection label BV-TAG *Plus* and may be used to quantitate and characterize the following mouse antibodies: IgM, IgG, IgG1, IgG2a, IgG2b, and IgG3.

Our M-SERIES life science customers include many of the major pharmaceutical and biotechnology companies in the United States and Europe. In addition to the M-SERIES instruments we sell or lease, we also typically sell proprietary reagents to customers. We market the M-SERIES product family directly through our own sales, marketing and applications teams. We believe that our presence in the life science market provides us with the opportunity to identify novel tests that may have utility in the clinical diagnostics market.

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

Clinical Diagnostics

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

Point-of-Care Systems. Many diagnostic tests performed today involve a follow-up treatment decision by the physician because the test and treatment process are usually decoupled. In most situations, samples of blood are drawn from a patient in the physician s office, emergency room or hospital room and sent to a laboratory at another location where the tests are performed. Test results are normally returned to the physician several hours or even several days later. We believe that there is demand among physicians, patients and third-party payers for clinical diagnostic products that reduce turnaround time by bringing laboratory testing closer to the patient and providing the physician with fast, quality and cost-effective results thereby permitting the physician to deliver prompt feedback to the patient. Most immunodiagnostic systems for clinical point-of-care sites have had limited market penetration because of the lengthy turnaround time for test results, the need for skilled labor to perform the tests, regulations, lack of sensitivity and the high cost of the tests. We believe that the emergence of simple, more accurate and cost-effective diagnostic products is shifting the site of *in vitro* diagnostic testing from clinical reference laboratories and central hospital laboratories to alternative sites.

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

We have also explored 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 may pursue opportunities for the clinical reference and central hospital laboratory market segment, including through collaborative arrangements.

Vaccines

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

Neisseria meningitidis serogroup B, serogroup Y and serogroup C (for combinations only)

Meningococcal disease is a bacterial infection that strikes approximately 1.2 million people worldwide each year, causing meningitis or sepsis in the majority of cases. Approximately 10% of the individuals who contract meningococcal disease will die. Of the survivors, up to 20% suffer long-term permanent disabilities such as hearing loss, brain damage and limb amputations. Meningococcal disease often begins with symptoms that can be mistaken for common viral illnesses, such as the flu. It can progress very rapidly and kill an otherwise healthy young person in 48 hours or less. Communitywide outbreaks of meningococcal disease can persist for several months and controlling them remains a major challenge in public health.

Currently, there is no effective vaccine available against disease caused by meningococcal serogroup B, which is responsible for one-third of meningococcal disease in the United States and up to 70% in Europe and Canada. The availability of an effective vaccine that would prevent meningococcal serogroup B for use by various population groups is expected to be in high demand for both mass immunization and catch-up vaccination programs.

We have entered into license and option agreements for exclusive patent rights to unique vaccine candidate for *Neisseria meningitidis* serogroup B and serogroup Y and now have candidates for vaccines against bacterial meningitis, including that of streptococcal, pneumococcal and meningococcal origin. We have also entered into a license agreement for nonexclusive, worldwide patent rights and know-how to use *Neisseria meningitidis* group C vaccine as a component in new vaccine candidates for the prevention of meningitis and sepsis. The new combination vaccine candidates would consist of the *Neisseria meningitidis* group C components and additional vaccine candidates to protect against other disease causing organisms.

We believe that the availability of an effective vaccine that would prevent meningococcal disease, for use by various population groups, could satisfy a significant unmet medical need. These vaccine candidates, which may be used in combination with other vaccines, are expected to have the advantage of reducing the number of injections that a child would receive during a single office visit.

Haemophilus influenzae type b

Haemophilus influenzae type b (Hib) disease predominantly occurred as meningitis during the pre-vaccine era in the United States, originally accounting for 50-65 percent of cases. Presently there are licensed Hib vaccines available and recommended as part of the childhood immunization schedule, but none are licensed in combination with other bacterial vaccines for infants in the United States.

We have entered into a license agreement for exclusive patent rights to a unique vaccine candidate for Hib under which we received exclusive rights, subject to potential future modification, to patents and know-how related to the manufacture, production, use, marketing, distribution and sale of the vaccine or vaccine combination candidates. As with *Neisseria meningitidis* serogroup B, serogroup Y and serogroup C, this vaccine candidate for Hib may be used in combination with other vaccines, and is expected to have the advantage of reducing the number of injections that a child would receive during a single office visit.

Group A Streptococcus

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

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

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

Group B Streptococcus

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

Chlamydia

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

There is no vaccine currently available to protect against Chlamydia. The vaccine technology licensed by us is expected to cover all Chlamydial infections, including those caused by *Chlamydia psittaci*, which often results in pneumonia and endocarditis in humans, and *Chlamydia pneumoniae*, which is responsible for some pneumonia, bronchitis, pharyngitis, laryngitis, and sinusitis. In addition, *C. pneumoniae* infections have been implicated by some investigators to be associated with atherosclerotic vascular disease, Alzheimer s disease, asthma and reactive arthritis. We have licensed exclusive patent rights to a unique vaccine candidate for Chlamydia under which we received exclusive rights to commercialize products for possible use in the prevention, diagnosis and treatment of all Chlamydial infections.

Candida albicans

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

Genital candidiasis, or vaginal yeast infections, which is the second most common cause of vaginitis. Vaginal candidiasis affects approximately 75% of all women at least once during their lifetime. While certain risk factors increase the likelihood of contracting vaginal candidiasis (e.g., pregnancy, diabetes, antibiotic use, birth control pill use, corticosteroid use, being immunocompromised), approximately 10% of women have recurring yeast infections without precipitating risk. Antifungal therapy has a high success rate; however, prolonged use of antifungal drugs, particularly through self-medication without formal diagnosis, has resulted in increased drug resistance. The carbohydrate-based vaccine technology is expected to be a safe approach that provides long-lasting immunity for this vulnerable population.

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

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

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

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

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

Pneumococcus

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

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

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

Anthrax

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

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

Urinary tract infection (E. coli)

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

of multidrug-resistant UTIs.

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

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

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. Under the terms of the Merger Agreement, we currently have restrictions on our ability to pursue such relationships. In addition, we have license arrangements with Roche Diagnostics, bioMérieux, Eisai and MSD.

Roche Diagnostics

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

Pursuant to the Roche License, we and Roche have engaged a field monitor to review placements and sales of products and services by Roche in 2005. The field monitor was tasked with preparing a written report, including a list of any sales or placements of products and services that were not within the licensed field and identifying sales or placements of products or services in violation of the license grant. While the field monitor s work has been completed, they will not issue their written report pending the completion of the proposed merger between us and Roche. Although Roche may not knowingly sell or actively market outside the field, they may continue the identified out-of-field sales until the Company notifies Roche in writing that they are prohibited from making any further such sales. The Company has notified Roche that it is prohibited from making any further sales to certain types of customers. For a more complete description of the Roche License, refer to the agreement on file with the SEC.

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

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

certain PCR technology; and

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

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

bioMérieux

bioMérieux, Inc., or bioMérieux, has a license from us for the development and worldwide use, manufacture and sale of ECL technology-based nucleic acid test systems on a non-exclusive basis for certain segments of the clinical diagnostics and life science markets. bioMérieux specializes in products for central hospital laboratories and blood banks and has incorporated its proprietary nucleic acid sequence-based amplification technology and ECL technology into its NucliSens line of diagnostic virology products, which are marketed with test kits for the detection of HIV-1 RNA and CMV (cytomegalovirus). Our agreement with bioMérieux extends until September 2011 and we receive royalty payments from bioMérieux on the relevant product sales by bioMérieux.

Eisai

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

MSD

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

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

The joint venture agreement among MSD, MST and us, which we refer to in the Form 10-K as the MSD joint venture agreement, expired upon completion of the IGEN merger and related transactions. As a result, MSD and MST had the right to purchase our interests in MSD and pursuant to the settlement agreement we entered into with MSD, MST and Jacob Wohlstadter in August 2004, which is referred to in this Form 10-K as the settlement, in December 2004 MST purchased our interests in MSD. For a more complete description of this purchase and the MSD agreements, see ITEM 7 Management s Discussion and Analysis of Financial Condition and Results of Operations and ITEM 8 Consolidated Financial Statements and Supplementary Data Notes to Consolidated Financial Statements Note 5.

Patents and Other Proprietary Rights

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

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

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

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

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

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

Government Regulation

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