BIO RAD LABORATORIES INC
Form 10-K
March 18, 2013
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K
(Mark One)

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

For the year ended December 31, 2012
OR

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

For the transition period from _____ to _____

Commission file number 1-7928

BIO-RAD LABORATORIES, INC.
(Exact name of registrant as specified in its charter)

Delaware	94-1381833
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1000 Alfred Nobel Drive, Hercules, California	94547
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (510) 724-7000
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Class A Common Stock Par Value $0.0001 per share	New York Stock Exchange
Class B Common Stock Par Value $0.0001 per share	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: NONE
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
ý Yes ¨ No
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
¨ Yes ý No
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. ý Yes ¨ No
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data

File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period
that the registrant was required to submit and post such files). ý 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 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. ý

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	ý		Accelerated filer	¨
Non-accelerated file	¨	(Do not check if a smaller reporting company)	Smaller reporting company	¨

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

As of June 30, 2012, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the Registrant's Class A Common Stock held by non-affiliates was approximately $1,954,098,590 and the aggregate market value of the registrant's Class B Common Stock held by non-affiliates was approximately $39,439,322.

As of March 12, 2013, there were 23,371,413 shares of Class A Common Stock and 5,127,654 of Class B Common Stock outstanding.

Documents Incorporated by Reference

	Document	Form 10-K Parts
(1)	Definitive Proxy Statement to be mailed to stockholders in connection with the registrant's 2013 Annual Meeting of Stockholders (specified portions)	III

BIO-RAD LABORATORIES, INC.

FORM 10-K DECEMBER 31, 2012

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PART I.

ITEM 1. BUSINESS

General

Founded in 1952 and incorporated in 1957, Bio-Rad Laboratories, Inc. (referred to in this report as “Bio-Rad,” “we,” “us,” and “our”) was initially engaged in the development and production of specialty chemicals used in biochemical, pharmaceutical and other life science research applications. We entered the field of clinical diagnostics with the development of our first test kit based on separation techniques and materials developed for life science research. Through internal research and development efforts and acquisitions we have expanded into various markets. Today, Bio-Rad manufactures and supplies the life science research, healthcare, analytical chemistry and other markets with a broad range of products and systems used to separate complex chemical and biological materials and to identify, analyze and purify their components.

As we broadened our product lines, we also expanded our geographical market. We have direct distribution channels in over 35 countries outside the United States through subsidiaries whose focus is sales, customer service and product distribution. In some regions, sales efforts are supplemented by distributors and agents.

Description of Business

Business Segments

Today, Bio-Rad operates in two industry segments designated as Life Science and Clinical Diagnostics. Both segments operate worldwide. Our Life Science segment and our Clinical Diagnostics segment generated 33% and 66%, respectively, of our net sales for the year ended December 31, 2012. We generated approximately 32% of our consolidated net sales for the year ended December 31, 2012 from U.S. sales and approximately 68% from sales in our remaining worldwide markets.

For a description of business and financial information on industry and geographic segments, see Note 14 on pages 73 through 75 of Item 8 of Part II of this report.

Life Science Segment

Our Life Science segment is at the forefront of discovery, creating advanced tools to answer complex biological questions. We are a market leader in the life sciences market, developing, manufacturing and marketing a range of more than 5,000 reagents, apparatus and laboratory instruments that serve a global customer base. Many of our products are used in established research techniques, biopharmaceutical production processes and food testing regimes. These techniques are typically used to separate, purify and identify biological materials such as proteins, nucleic acids and bacteria within a laboratory or production setting. We focus on selected segments of the life sciences market in proteomics (the study of proteins), genomics (the study of genes), biopharmaceutical production, cell biology and food safety. Based on the most recent studies, we currently estimate that the worldwide market for products in these selected segments was approximately $7 billion. Our principal life science customers include universities and medical schools, industrial research organizations, government agencies, pharmaceutical manufacturers, biotechnology researchers, food producers and food testing laboratories.

Clinical Diagnostics Segment

Our Clinical Diagnostics segment designs, manufactures, sells and supports test systems, informatics systems, test kits and specialized quality controls that serve clinical laboratories in the global diagnostics market. Our products currently address specific niches within the in vitro diagnostics (IVD) test market, and we focus on the higher margin, higher growth segments of this market.

We supply more than 3,000 different products that cover more than 300 clinical diagnostic tests to the IVD test market. Based on the most recent studies, we currently estimate that the worldwide sales for products in the markets we serve were approximately $10 billion. IVD tests are conducted outside the human body and are used to identify and measure substances in a patient's tissue, blood or urine. Our products consist of reagents, instruments and software, typically provided to our customers as an integrated package to allow them to generate reproducible test results. Revenue in this business is highly recurring, as laboratories typically standardize test methodologies, which are dependent on a particular supplier's equipment, reagents and consumable products. An installed base of diagnostic test systems creates an ongoing source of revenue through the sale of test kits for each sample analyzed on an installed system. Our principal clinical diagnostic customers include hospital laboratories, reference laboratories, transfusion laboratories and physician office laboratories.

Raw Materials and Components

We utilize a wide variety of chemicals, biological materials, electronic components, machined metal parts, optical parts, minicomputers and peripheral devices. Most of these materials and components are available from numerous sources and we have not experienced difficulty in securing adequate supplies.

Patents and Trademarks

We own numerous U.S. and international patents and patent licenses. We believe, however, that our ability to develop and manufacture our products depends primarily on our knowledge, technology and special skills. We pay royalties on the sales of certain products under several patent license agreements. We view these patents and license agreements as valuable assets.

Seasonal Operations and Backlog

Our business is not inherently seasonal. However, the European custom of concentrating vacation during the summer months usually tempers third quarter sales volume and operating income.

For the most part, we operate in markets characterized by short lead times and the absence of significant backlogs. Management has concluded that backlog information is not material to our business as a whole.

Sales and Marketing

We conduct our worldwide operations through an extensive direct sales force and service network, employing approximately 1,000 sales and service people around the world. Our sales force typically consists of experienced industry practitioners with scientific training, and we maintain a separate specialist sales force for each of our segments. Our direct sales approach contrasts with the distributor approach used by some of our competitors, allowing us to sell a broader range of our products and have more direct contact with our customers.

Our customer base is broad and diversified. Our worldwide customer base includes (1) prominent university and research institutions, providing us access to more than 150,000 scientists in the U.S. alone; (2) hospital, public health and commercial laboratories; (3) other leading diagnostic manufacturers; and (4) leading companies in the biotechnology, pharmaceutical, chemical and food industries. In 2012, no single customer accounted for more than two percent of our total net sales. Our sales are affected by certain external factors. For example, a number of our customers, particularly in the Life Science segment, are substantially dependent on government grants and research contracts for their funding. A significant reduction of government funding would have a detrimental effect on the results of this segment.

Most of our international sales are generated by our wholly-owned subsidiaries and their branch offices. Certain of these subsidiaries also have manufacturing facilities. Bio-Rad's international operations are subject to certain risks common to foreign operations in general, such as changes in governmental regulations, import restrictions and foreign exchange fluctuations. However, our international operations are principally in developed nations, which we regard as presenting no significantly greater risks to our operations than are present in the United States.

Competition

The markets served by our product groups are highly competitive. Our competitors range in size from start-ups to large multinational corporations with significant resources and reach. Reliable independent information on sales and market share of products produced by our competitors is not generally available. We believe, however, based on our own estimates, no one company is so dominant that it prevents other companies, including Bio-Rad, from competing effectively. We compete mainly in market segments where our products and technology offer customers specific advantages over the competition.

Because of the breadth of its product lines, the Life Science segment does not face the same competitors for all of its products. Competitors in this market include GE Biosciences, Life Technologies, Merck Millipore, PerkinElmer and Thermo Fisher Scientific. We compete primarily based on meeting performance specifications.

Major competitors in the Clinical Diagnostics segment include Roche, Abbott Laboratories (Diagnostic Division), Siemens Medical Diagnostics Solutions, Danaher, Thermo Fisher, Becton Dickinson, bioMérieux, Ortho Clinical Diagnostics, Tosoh, Immucor and DiaSorin.

Research and Development

We conduct extensive research and development activities in all areas of our business, employing approximately 860 people worldwide in these activities. Research and development have played a major role in Bio-Rad's growth and are expected to continue to do so in the future. Our research teams are continuously developing new products and new applications for existing products. In our development of new products and applications, we interact with scientific and medical professionals at universities, hospitals and medical schools, and within our industry. We spent approximately $214.0 million, $186.4 million and $172.3 million on research and development activities during the years ended December 31, 2012, 2011 and 2010, respectively.

Regulatory Matters

The development, testing, manufacturing, marketing, post-market surveillance, distribution, advertising and labeling of certain of our products (primarily diagnostic products) are subject to regulation in the United States by the Center for Devices and Radiological Health of the United States Food and Drug Administration (FDA) and in other jurisdictions by state and foreign government authorities. FDA regulations require that some new products have pre-marketing clearance or approval by the FDA and require certain products to be manufactured in accordance with FDA's “good manufacturing practice” regulations, to be extensively tested and to be properly labeled to disclose test results and performance claims and limitations. The FDA has authority to take various administrative and legal actions against us for our, or our products', failure to comply with relevant legal or regulatory requirements, including issuing warning letters, initiating product seizures, requesting or requiring product recalls or withdrawals, and other civil or criminal sanctions, among other things.

As a multinational manufacturer and distributor of sophisticated instrumentation, we must meet a wide array of electromagnetic compatibility and safety compliance requirements to satisfy regulations in the United States, the European Community and other jurisdictions.

Our operations are subject to federal, state, local and foreign environmental laws and regulations that govern such activities as transportation of goods, emissions to air and discharges to water, as well as handling and disposal practices for solid, hazardous and medical wastes. In addition to environmental laws that regulate our operations, we are also subject to environmental laws and regulations that create liabilities and clean-up responsibility for spills, disposals or other releases of hazardous substances into the environment as a result of our operations or otherwise

impacting real property that we own or operate. The environmental laws and regulations could also subject us to claims by third parties for damages resulting from any spills, disposals or releases resulting from our operations or at any of our properties.

These regulatory requirements vary widely among countries.

Employees

At December 31, 2012, Bio-Rad had approximately 7,380 employees. Approximately seven percent of Bio-Rad's approximately 2,975 U.S. employees are covered by a collective bargaining agreement, which will expire on November 7, 2016. Many of Bio-Rad's non-U.S. full-time employees, especially in France, are covered by collective bargaining agreements. We consider our employee relations in general to be good.

Available Information

Bio-Rad files annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission (SEC) under the Securities Exchange Act of 1934, as amended. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, the SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including Bio-Rad, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at http://www.sec.gov.

Bio-Rad's website address is www.bio-rad.com. We make available, free of charge through our website, our Form 10-Ks, 10-Qs and 8-Ks, and any amendments to these forms, as soon as reasonably practicable after filing with the SEC. The information on our website is not part of this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

The following risk factors should be read carefully in connection with evaluating our business and the forward-looking information contained in this Annual Report on Form 10-K. We believe that any of the following risks could have a material affect on our business, operations, industry, financial position or our future financial performance. While we believe that we have identified and discussed below the key risk factors affecting our business, there may be additional risks and uncertainties that are not presently known or that are not currently believed to be significant that may adversely affect our business, operations, industry, financial position and financial performance in the future.

The ongoing investigation by government agencies of possible violations by us of the United States Foreign Corrupt Practices Act and similar laws could have a material adverse effect on our business.

Based on an internal investigation, we identified conduct in certain of our overseas operations that may have violated the anti-bribery provisions of the United States Foreign Corrupt Practices Act (FCPA) and is likely to have violated the FCPA's books and records and internal controls provisions and our own internal policies. In May 2010, we voluntarily disclosed these matters to the U.S. Department of Justice (DOJ) and the Securities and Exchange Commission (SEC), each of which commenced an investigation. The Audit Committee of our Board of Directors (Audit Committee) assumed direct responsibility for reviewing these matters and hired experienced independent counsel to conduct an investigation and provide legal advice. We provided additional information to the DOJ and the SEC as the Audit Committee's investigation progressed. We continue to cooperate with the DOJ and SEC investigations and to provide information to them. The Audit Committee has determined to continue its investigation based on matters that arose in connection with an assessment of our accrual for royalties payable by us under certain patent licenses from a third party.

The DOJ and SEC investigations are also continuing and we are presently unable to predict the duration, scope or results of these investigations or whether either agency will commence any legal actions. The DOJ and the SEC have a broad range of civil and criminal sanctions under the FCPA and other laws and regulations including, but not limited to, injunctive relief, disgorgement, fines, penalties, modifications to business practices including the termination or modification of existing business relationships, the imposition of compliance programs and the retention of a monitor to oversee compliance with the FCPA. We are unable to estimate the outcome of this matter.

However, the imposition of any of these sanctions or remedial measures could have a material adverse effect on our business, including our results of operations, cash balance and credit rates. We have not to date determined whether any of the activities in question violated the laws of the foreign jurisdictions in which they took place.

On April 13, 2011, a shareholder derivative lawsuit was filed against each of our directors in the Superior Court for Contra Costa County, California. The case, which also names the Company as a nominal defendant, is captioned City of Riviera Beach General Employees' Retirement System v. David Schwartz, et al., Case No. MSC11-00854. In the complaint, the plaintiff alleges that our directors breached their fiduciary duties by failing to ensure that we had sufficient internal controls and systems for compliance with the FCPA. Purportedly seeking relief on our behalf, the plaintiff seeks an award of unspecified compensatory and punitive damages, costs and expenses (including attorneys' fees), and a declaration that our directors have breached their fiduciary duties. We and the individual defendants filed a demurrer requesting dismissal of the complaint in this case, as well as a motion to stay this matter pending resolution of the above-referenced investigations by the DOJ and SEC. Following a hearing on September 30, 2011, the court sustained our demurrer and dismissed the complaint, without prejudice, and granted the plaintiff additional time to file an amended complaint. The court denied our motion to stay this matter because it dismissed the complaint. The parties have agreed to a stipulated dismissal of this case, without prejudice, and to a tolling of the statute of limitations pending the resolution of the DOJ and SEC investigations.

We have identified four significant deficiencies in our internal control over financial reporting as of December 31, 2012 that, when aggregated, constitute a material weakness in our internal control over financial reporting as of December 31, 2012. Our failure to establish and maintain effective internal control over financial reporting could result in our failure to meet our reporting obligations and cause investors to lose confidence in our reported financial information, which in turn could cause the trading price of our common stock to decline.

In connection with our assessment of the effectiveness of internal control over financial reporting and the preparation of our financial statements for the year ended December 31, 2012, our management identified four significant deficiencies in our internal control over financial reporting as of December 31, 2012 that, when aggregated, constitute a material weakness in our internal control over financial reporting as of December 31, 2012. A significant deficiency is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness, yet important enough to merit attention by those responsible for oversight of our financial reporting. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The four significant deficiencies that we identified are the result of: (i) an inadequate accounting close process, including our failure to review and adjust a contingency accrual with respect to royalties owed to a third party in a timely manner, inadequate supporting documentation for certain key transactions and account reconciliations at some of our foreign locations, and our lack of adequate financial statement review at our German subsidiary; (ii) an inadequate revenue recognition process, including the unauthorized execution of distributor contracts at our Chinese subsidiary, our lack of controls over pricing and our ineffective methods of analyzing credit risk, and in some instances, the lack of sufficient documentation for the timing of revenue recognition; (iii) an inadequate reagent rental process at certain of our international subsidiaries, including our failure to provide management review of reagent rental agreements, our failure to monitor ongoing compliance with agreement terms, and our lack of timely reconciliations of our reagent rental equipment; and (iv) inadequate expenditure controls at our German subsidiary, including our lack of compliance with controls for vendor management and transaction approvals, and insufficient segregation of duties.

We cannot assure you that we will be able to remediate these significant deficiencies and the resulting material weakness or that additional significant deficiencies or material weaknesses in our internal control over financial

reporting will not be identified in the future. Any failure to maintain or implement new or improved internal controls, or any difficulties that we may encounter in their maintenance or implementation, could result in additional significant deficiencies or material weaknesses, result in material misstatements in our financial statements and cause us to fail to meet our reporting obligations, which in turn could cause the trading price of our

common stock to decline. Any such failure has and could in the future adversely affect the results of our periodic management evaluations and annual auditor attestation reports regarding the effectiveness of our internal control over financial reporting required by Section 404 of the Sarbanes-Oxley Act of 2002.

Adverse changes in general domestic and worldwide economic conditions and instability and disruption of credit markets could adversely affect our operating results, financial condition or liquidity.

The continuing slow economic growth in developed nations may adversely affect our future results of operations. Demand for our products and services could change more dramatically than in previous years based on activity, funding, reimbursement constraints and support levels from government, universities, hospitals and private industry, including diagnostic laboratories. The need for certain sovereign nations with large annual deficits to curtail spending could lead to slower growth of, or even a decline in, our business. Although signs of limited recovery may exist in some markets, there are continued concerns about systemic economic imbalance, the availability and cost of credit, declining asset values and geopolitical issues that contribute to increased market volatility and uncertain expectations for the global economy. These conditions, combined with greater volatility in business activity levels and consumer confidence, high unemployment and volatile oil prices, contributed to unprecedented levels of volatility in the capital markets in recent years. Continuing or recurring disruptions in the capital and credit markets may adversely affect our business, results of operations, cash flows and financial condition.

As a result of these market conditions, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many private sector investors to reduce and, in some cases, cease to provide credit to governments, businesses and consumers. These factors have led to depressed spending by some governments, businesses and consumers. Our customers and suppliers may experience cash flow concerns and, as a result, customers may modify, delay or cancel plans to purchase our products and suppliers may increase their prices, reduce their output or change terms of sales. Additionally, if customers' or suppliers' operating and financial performance deteriorates, or if they are unable to make scheduled payments or obtain credit, customers may not be able to pay, or may delay payment of, amounts owed to us. Sovereign nations either delaying payment for goods and services or renegotiating their debts could impact our liquidity. The situation in these sovereign nations is continuously evolving and we have no greater knowledge of the situation other than what is publicly reported. As of December 31, 2012 and December 31, 2011, we had accounts receivable, net of allowance for doubtful accounts, in Spain, Italy, Greece and Portugal of $64.8 million and $82.1 million, respectively. The decrease from December 31, 2011 was primarily associated with large payments made in June 2012 of approximately $21 million by public agencies in Spain that represented Spanish balances that were significantly past due.

Suppliers may restrict credit or impose less favorable payment terms. Any inability of current and/or potential customers to pay us for our products or any demands by suppliers for accelerated payment terms may adversely affect our earnings and cash flow. Additionally, strengthening of the U.S. dollar associated with the global financial crisis may adversely affect the results of our international operations when those results are translated into U.S. dollars.

Furthermore, the disruption in the credit markets could impede our access to capital, especially if we are unable to maintain our current credit ratings. Should we have limited access to additional financing sources when needed, we may decide to defer capital expenditures or seek other higher cost sources of liquidity, which may or may not be available to us on acceptable terms. Continued turbulence in the U.S. and international markets and economies, and prolonged declines in business and consumer spending may adversely affect our liquidity and financial condition, and the liquidity and financial condition of our customers, including our ability to refinance maturing liabilities and access the capital markets to meet liquidity needs.

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We cannot assure you that we will be able to integrate acquired companies, products or technologies into our company successfully, or we may not be able to realize the anticipated benefits from the acquisitions.

As part of our overall business strategy, we pursue acquisitions of and investments in complementary companies, products and technologies. In order to be successful in these activities, we must, among other things:

- assimilate the operations and personnel of acquired companies;
- retain acquired business customers;
- minimize potential disruption to our ongoing business;
- retain key technical and management personnel;
- integrate acquired companies into our strategic and financial plans;
- accurately assess the value of target companies, products and technologies;
- comply with new regulatory requirements;
- harmonize standards, controls, procedures and policies;
- minimize the impact to our relationships with our employees and customers; and
- assess, document and remediate any deficiencies in disclosure controls and procedures and internal control over financial reporting.

The benefits of any acquisition may prove to be less than anticipated and may not outweigh the costs reported in our financial statements. Completing any potential future acquisition could cause significant diversion of our management's time and resources. If we acquire new companies, products or technologies, we may be required to assume contingent liabilities or record impairment charges for goodwill and other intangible assets over time. We cannot assure you that we will successfully overcome these risks or any other problems we encounter in connection with any acquisitions, and any such acquisitions could adversely affect our business, financial position or operating results.

The industries and market segments in which we operate are highly competitive, and we may not be able to compete effectively with larger companies with greater financial resources than we have.

The life science and clinical diagnostics markets are each highly competitive. Some of our competitors have greater financial resources than we do and are less leveraged than we are, making them better equipped to license technologies and intellectual property from third parties or to fund research and development, manufacturing and marketing efforts. Moreover, competitive and regulatory conditions in many markets in which we operate restrict our ability to fully recover, through price increases, higher costs of acquired goods and services resulting from inflation and other drivers of cost increases. Our competitors can be expected to continue to improve the design and performance of their products and to introduce new products with competitive price and performance characteristics. Maintaining these advantages will require us to continue to invest in research and development, sales and marketing and customer service and support. We cannot assure you that we will have sufficient resources to continue to make such investments or that we will be successful in maintaining such advantages.

We have significant international operations which subject us to various risks such as general economic and market conditions in the countries in which we operate.

A significant portion of our sales are made outside of the United States. Our foreign subsidiaries generated 68% of our net sales for the year ended December 31, 2012. Our international operations are subject to risks common to foreign operations, such as general economic and market conditions in the countries in which we operate, changes in governmental regulations, political instability, import restrictions, additional scrutiny over certain financial instruments and currency exchange rate risks. We cannot assure you that shifts in currency exchange rates, especially significant strengthening of the U.S. dollar compared to the Euro, will not have a material adverse effect on our

operating results and financial condition.

We are dependent on government funding and the capital spending programs of our customers, and the effect of healthcare reform on government funding and our customers' ability to purchase our products is uncertain.

Our customers include universities, clinical diagnostics laboratories, government agencies, hospitals and pharmaceutical, biotechnology and chemical companies. The capital spending programs of these institutions and companies have a significant effect on the demand for our products. Such programs are based on a wide variety of factors, including the resources available to make such purchases, the availability of funding from grants by governments or government agencies, the spending priorities for various types of equipment and the policies regarding capital expenditures during industry downturns or recessionary periods. If government funding to our customers were to decrease, or if our customers were to decrease or reallocate their budgets in a manner adverse to us, our business, financial condition or results of operations could be materially adversely affected.

Healthcare reform and the growth of managed care organizations have been and continue to be significant factors in the clinical diagnostics market. The trend towards managed care, together with healthcare reform of the delivery system in the United States and efforts to reform in Europe, has resulted in increased pressure on healthcare providers and other participants in the healthcare industry to reduce costs. Consolidation among healthcare providers has resulted in fewer, more powerful groups, whose purchasing power gives them cost containment leverage. These competitive forces place constraints on the levels of overall pricing, and thus could have a material adverse effect on our profit margins for products we sell in clinical diagnostics markets.

In the United States, 2010 reform measures, in particular, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, impose significant new programs and responsibilities affecting U.S. pharmaceutical and medical device industries. The PPACA, among other things, establishes annual fees and taxes on manufacturers of certain medical devices, including our devices, and promotes programs that increase the federal government's comparative effectiveness research, which may be used to evaluate the selection of medical services by clinicians and others. PPACA also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule of 1.75% for the years 2011 through 2015. In addition, a productivity adjustment is made to the fee schedule payment amount. These changes in payments apply to some or all of the clinical laboratory test services we furnish to Medicare beneficiaries.
In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. To the extent that the healthcare industry seeks to address the need to contain costs stemming from reform measures such as those contained in PPACA and ATRA, or in future legislation, by limiting the number of clinical tests being performed, our results of operations could be materially and adversely affected. If these changes in the healthcare markets in the United States and Europe continue, we could be forced to alter our approach in selling, marketing, distributing and servicing our products.

Our failure to improve our product offerings and develop and introduce new products may negatively impact our business.

Our future success depends on our ability to continue to improve our product offerings and develop and introduce new product lines and extensions that integrate new technological advances. If we are unable to integrate technological advances into our product offerings or to design, develop, manufacture and market new product lines and extensions successfully and in a timely manner, our operating results will be adversely affected. We cannot assure you that our product and process development efforts will be successful or that new products we introduce will achieve market acceptance.

If we experience a disruption of our information technology systems, or if we fail to successfully implement, manage and integrate our information technology and reporting systems, it could harm our business.

Our information technology (IT) systems are an integral part of our business, and a serious disruption of our IT systems could have a material adverse effect on our business and results of operations. We depend on our IT systems to process orders, manage inventory and collect accounts receivable. Our IT systems also allow us to efficiently purchase products from our suppliers and ship products to our customers on a timely basis, maintain cost-effective operations and provide customer service. We cannot assure you that our contingency plans will allow us to operate at our current level of efficiency.

Our ability to implement our business plan in a rapidly evolving market requires effective planning, reporting and analytical processes. We expect that we will need to continue to improve and further integrate our IT systems, reporting systems and operating procedures by training and educating our employees with respect to these improvements and integrations on an ongoing basis in order to effectively run our business. We are currently in the process of implementing a global single instance Enterprise Resource Planning (ERP) platform. If we fail to successfully manage and integrate our IT systems, reporting systems and operating procedures, including the ERP platform, it could adversely affect our business or operating results.

Risks relating to intellectual property rights may negatively impact our business.

We rely on a combination of copyright, trade secret, patent and trademark laws and third-party nondisclosure agreements to protect our intellectual property rights and products. However, we cannot assure you that our intellectual property rights will not be challenged, invalidated, circumvented or rendered unenforceable, or that meaningful protection or adequate remedies will be available to us. For instance, it may be possible for unauthorized third parties to copy our intellectual property, to reverse engineer or obtain and use information that we regard as proprietary, or to develop equivalent technologies independently. Additionally, third parties may assert patent, copyright and other intellectual property rights to technologies that are important to us. If we are unable to license or otherwise access protected technology used in our products, or if we lose our rights under any existing licenses, we could be prohibited from manufacturing and marketing such products. We may find it necessary to enforce our patents or other intellectual property rights or to defend ourselves a