MERIDIAN BIOSCIENCE INC Form 10-K November 29, 2006

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#### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### **FORM 10-K**

# FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

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

FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2006.

o TRANSITION REPORT PURSU	JANT TO SECTION 13 OR 15(d) OF THE SECURITIE	ES
<b>EXCHANGE ACT OF 1934</b>		
FOR THE TRANSITION PERIOD FROM	TO	

## Commission File No. 0-14902 MERIDIAN BIOSCIENCE, INC.

Incorporated under the Laws of Ohio Phone: (513) 271-3700 3471 River Hills Drive Cincinnati, Ohio 45244

IRS Employer ID

No. 31-0888197

Securities Registered Pursuant to Section 12(b) of the Act:

Common Shares, No Par Value

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.

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act.

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, and (2) has been subject to such filing requirements for the past 90 days.

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this Chapter) 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.

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 b Non-accelerated filer o

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

The aggregate market value of Common Shares held by non-affiliates as of March 31, 2006 was \$703,576,697 based on a closing sale price of \$26.98 per share on March 31, 2006. As of October 31, 2006, 26,158,687 no par value Common Shares were issued and outstanding.

## Documents Incorporated by Reference

Portions of the Registrant s Annual Report to Shareholders for the fiscal year ended September 30, 2006 furnished to the Commission pursuant to Rule 14a-3(b) as specified and portions of the Registrant s Proxy Statement filed with the Commission for its 2007 Annual Shareholders Meeting are incorporated by reference in Parts II and III as specified.

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#### FORWARD LOOKING STATEMENTS

The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements which may be identified by words such as estimates, anticipates, projects, plans, seeks, may, will, expects, intends, believes, should and similar expressions or the negative versions thereof and which also may be identified by their context. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. The Company

assumes no obligation to publicly update any forward-looking statements. These statements are subject to various risks, uncertainties and other factors that could cause actual results to differ materially, including, without limitation, the following: Meridian s continued growth depends, in part, on its ability to introduce into the marketplace enhancements of existing products or new products that incorporate technological advances, meet customer requirements and respond to products developed by Meridian s competition. While Meridian has introduced a number of internally developed products, there can be no assurance that it will be successful in the future in introducing such products on a timely basis. Ongoing consolidations of reference laboratories and formation of multi-hospital alliances may cause adverse changes to pricing and distribution. Costs and difficulties in complying with laws and regulations administered by the United States Food and Drug Administration can result in unanticipated expenses and delays and interruptions to the sale of new and existing products. Changes in the relative strength or weakness of the U.S. dollar can change expected results. One of Meridian s main growth strategies is the acquisition of companies and product lines. There can be no assurance that additional acquisitions will be consummated or that, if consummated, will be successful and the acquired businesses successfully integrated into Meridian s operations. In addition to the factors described in this paragraph, Part I, Item 1A Risk Factors contains a list of uncertainties and risks that may affect the financial performance of the Company.

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#### PART I.

This Annual Report on Form 10-K includes forward-looking statements about our business and results of operations that are subject to risks and uncertainties. See Forward-Looking Statements above. Factors that could cause or contribute to such differences include those discussed in Item 1A. In addition to the risk factors discussed herein, we are also subject to additional risks and uncertainties not presently known to us or that we currently deem immaterial. If any of these risks and uncertainties develops into actual events, our business, financial condition or results of operations could be adversely affected.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to we, us, our, the company, or our company refer to Meridian Bioscience, Inc. and all of its subsidiaries and predecessors as a combined entity.

# ITEM 1. BUSINESS

#### Overview

Meridian is a fully-integrated life science company whose principal businesses are (i) the development, manufacture, sale and distribution of diagnostic test kits, primarily for certain respiratory, gastrointestinal, viral and parasitic infectious diseases, (ii) the manufacture and distribution of bulk antigens, antibodies, and reagents used by researchers and other diagnostic manufacturers and (iii) the contract manufacture of proteins and other biologicals for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines. By exploiting revenue opportunities across research, clinical diagnostics, and therapeutic areas for key biologicals, Meridian can maximize revenues, efficiently invest in research and development, and increase profitability of manufacturing operations.

## **Operating Segments**

Meridian s reportable operating segments are US Diagnostics, European Diagnostics, and Life Science. The US Diagnostics operating segment consists of manufacturing operations in Cincinnati, Ohio, and the sale and distribution of diagnostics test kits in the US and countries outside of Europe, Africa and the Middle East. The European Diagnostics operating segment consists of the sale and distribution of diagnostics test kits in Europe, Africa and the Middle East. The Life Science operating segment consists of manufacturing operations in Memphis, Tennessee, Saco, Maine, and Boca Raton, Florida, and the sale and distribution of bulk antigens, antibodies, and bioresearch reagents domestically and abroad. The Life Science operating segment also includes contract services, including the contract manufacture of proteins and other biologicals for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines and contract

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research and development, which involves growth of proteins as part of the development process. Financial information for Meridian s operating segments is included in Note 9 to the consolidated financial statements contained herein.

Meridian s primary source of domestic and international revenues continues to be its core diagnostic products, which represented 79% of consolidated net sales for fiscal 2006. Meridian s diagnostic products provide accuracy, simplicity, and speed, enable early diagnosis and treatment of common, acute medical conditions, and provide for better patient outcomes at reduced costs. Meridian targets diagnostics for disease states that (i) are acute conditions where rapid diagnosis impacts patient outcomes, (ii) have opportunistic demographic and disease profiles, (iii) are underserved by current diagnostic products, and (iv) have difficult sample handling requirements. This approach has allowed Meridian to establish significant market share in its target disease states.

Meridian s website is www.meridianbioscience.com. Meridian makes available its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments thereto, free of charge through this website, as soon as reasonably practicable after such material has been electronically filed with or furnished to the Securities and Exchange Commission. These reports may also be read and copied at the SEC s public reference room at 100 F Street, N.E., Room 1580, Washington, DC 20549, phone 1-800-732-0330. The SEC maintains an internet site containing these filings and other information regarding Meridian at http://www.sec.gov.

# **US Diagnostics Operating Segment**

#### **Overview**

The US Diagnostics operating segment s business focuses on the development, manufacture, sale and distribution of diagnostic test kits, primarily for certain respiratory, gastrointestinal, viral and parasitic infectious diseases. In addition to diagnostic test kits, products also include transport media that store and preserve specimen samples from patient collection to laboratory testing. Third-party sales for this operating segment were \$65,721,000, \$53,485,000 and \$48,153,000 for fiscal 2006, 2005 and 2004, respectively, reflecting a compound annual growth rate of 18%. As of September 30, 2006, the US Diagnostics operating segment had 247 employees.

Meridian s diagnostic test kits utilize immunodiagnostic technologies, which test samples of blood, urine, stool, and other body fluids or tissue for the presence of antigens and antibodies of specific infectious diseases. Specific immunodiagnostic technologies used in Meridian s diagnostic test kits include enzyme immunoassay, immunofluorescence, particle agglutination/aggregation, immunodiffusion, complement fixation, and chemical

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stains. The enzyme immunoassay technology is used in multiple test formats; the Premierä products for large volume users and the Immuno*Card*â products for rapid, single test, low volume users.

Meridian s diagnostic products are used principally in the detection of respiratory diseases, such as pneumonia, valley fever, influenza, and Respiratory Syncytial Virus (RSV); gastrointestinal diseases, such as stomach ulcers (H. *pylori*), antibiotic-associated diarrhea (C. *difficile*) and pediatric diarrhea (Rotavirus and Adenovirus); viral diseases, such as Mononucleosis, Herpes Simplex, Chicken Pox and Shingles (Varicella-Zoster) and Cytomegalovirus (organ transplant infections); and parasitic diseases, such as Giardiasis, Cryptosporidiosis and Lyme. The primary markets and customers for these products are reference laboratories, hospitals, and physicians offices.

#### **Market Trends**

The global market for infectious disease tests continues to expand as new disease states are identified, new therapies become available, and worldwide standards of living and access to health care improve. More importantly, within this market there is a continuing shift from conventional testing, which requires highly trained personnel and lengthy turnaround times for test results, to more technologically advanced testing which can be performed by less highly trained personnel and completed in minutes or hours.

The increasing pressures to contain total health care costs have accelerated the increased use of diagnostic testing. With rapid and accurate diagnoses of infectious diseases, physicians can pinpoint appropriate therapies quickly, leading to faster recovery, shorter hospital stays and lower treatment expense. In addition, these pressures have led to a major consolidation among reference laboratories and the formation of multi-hospital alliances that have reduced the number of institutional customers for diagnostic products and resulted in changes in buying practices. Specifically, multi-year exclusive or primary source marketing or distribution contracts with institutional customers have become more common, replacing less formal distribution arrangements of shorter duration and involving lower product volumes.

# Sales and Marketing

The US Diagnostics operating segment s sales and distribution network consists of a direct sales force in the US and independent distributors in the US and abroad. The direct sales force consists of one director of sales, three regional sales managers, one director of corporate health systems, one director of managed health care, one international distribution manager, 24 technical sales representatives, and three inside sales representatives. Meridian utilizes two primary independent distributors in the US, who accounted for 47% of the US Diagnostics operating segment s third-party sales in fiscal 2006. Meridian drives the selling effort for key customers where these independent distributors are utilized.

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Consolidation of the US healthcare industry is expected to continue and potentially affect Meridian s customers. Industry consolidation puts pressure on pricing and aggregates buying power. In response, in the last five years, Meridian has entered into, extended, or renewed several exclusive multiple-year contracts with consolidated healthcare providers and supply agreements with major reference laboratories.

#### **Products and Markets**

Meridian has expertise in the development and manufacture of products based on multiple core diagnostic technologies, each of which enables the visualization and identification of antigen/antibody reactions for specific pathogens. As a result, Meridian is able to develop and manufacture diagnostic tests in a variety of formats that satisfy customer needs and preferences, whether in a hospital, commercial or reference laboratory or alternate site location. Meridian s product offering consists of approximately 150 medical diagnostic products. Meridian s products generally range in list price from \$1 per test to \$33 per test.

Meridian s product technologies include enzyme immunoassay, immunofluorescence, particle agglutination/aggregation, immunodiffusion, complement fixation and chemical stains.

Enzyme Immunoassay (EIA)/Rapid tests - Products incorporating the EIA technology achieve extremely high levels of accuracy in detecting disease-related antigens or antibodies through the use of special color-based enzyme-substrate reactions. Meridian utilizes this technology in some of its multiple test format, the Premier<sup>TM</sup> product for large volume users, and in some of its single test formats, the ImmunoCard<sup>®</sup>, ImmunoCard STAT!<sup>®</sup> and MONOLERT<sup>®</sup> products for lower volume users.

*Immunofluorescence* - When the microscopic visualization of an antigen/antibody reaction is necessary or desired, immunofluorescence technology is frequently utilized. Fluorescing immunochemicals, in the presence of the target antigen or antibody, can be viewed via a fluorescent microscope. Meridian utilizes this technology in its MERIFLUOR® products.

Particle Agglutination/Aggregation - This technology utilizes microparticles (e.g., latex, red blood cells) coated with specific antigens or antibodies that form visible aggregates in the presence of a specimen containing the complementary antigen or antibody. This technology is rapid and economical and is used in Meridian s MERITE® and MONOSPOT® products.

*Other Technologies* - Meridian utilizes other technologies that include immunodiffusion, complement fixation, and chemical stains. Meridian also manufactures and markets specimen collection, transportation, preservation and concentration products, such as Para-Pak<sup>®</sup>, Macro-CON<sup>®</sup> and Spin-Con<sup>®</sup>.

Research and Development

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The US Diagnostics operating segment s research and development organization consists of 13 research scientists with expertise in biochemistry, immunology, mycology, bacteriology, virology, and parasitology. Research and development expenses for the US Diagnostics operating segment for fiscal 2006, 2005 and 2004 were \$3,342,000, \$3,043,000 and \$3,151,000, respectively. This research and development organization focuses its activities on new applications for Meridian s existing technologies, improvements to existing products and development of new technologies. Research and development efforts may occur in-house or with collaborative partners. Meridian believes that new product development is a key source for sustaining revenue growth. Meridian s internally developed products include Premierä Platinum HpSA, Premierä Platinum HpSA PLUS, Premierä Toxins A & B, and Immuno*Card*Ò Toxins A & B, which together accounted for 36% of the US Diagnostics operating segment s third-party sales during fiscal 2006.

We believe that the use of collaborative partners in the development of new products will complement our internal research and development staff in a manner that allows us to bring products to market more quickly than if development were to occur solely on an internal basis.

During October 2006, we executed a license agreement with Eiken Chemical Co., Ltd. that provides rights to Eiken s loop-mediated isothermal amplification technology for infectious disease testing in the United States and 18 other geographic markets. This is Meridian s first look at molecular testing for infectious diseases.

During August 2006, we entered into a partnership agreement with the Performance & Life Science Chemicals Division of Merck KGaA, Darmstadt, Germany and its American company EMD for the development of new clinical assays. Our first product under this agreement is expected to be launched during fiscal 2007.

## Manufacturing

Meridian s immunodiagnostic products require the production of highly specific and sensitive antigens and antibodies. Meridian produces substantially all of its own requirements including monoclonal antibodies and polyclonal antibodies, plus a variety of fungal, bacterial, and viral antigens. Meridian believes it has sufficient manufacturing capacity for anticipated growth.

#### Intellectual Property, Patents, and Licenses

Meridian owns or licenses US and foreign patents for approximately 25 products manufactured by the US Diagnostics operating segment, including Premierä Platinum HpSA and Premierä Platinum HpSA PLUS. In the absence of patent protection, Meridian may be vulnerable to competitors who successfully replicate Meridian s production and manufacturing technologies and processes. Meridian s employees are required to execute confidentiality and non-disclosure agreements designed to protect Meridian s proprietary products.

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#### **Government Regulation**

Meridian s diagnostic products are regulated by the Food & Drug Administration (FDA) as devices pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA). Under the FDCA, medical devices are classified into one of three classes (i.e., Class I, II or III). Class I and II devices are not expressly approved by the FDA, but, instead, are cleared for marketing. Class III devices generally must receive pre-market approval from the FDA as to safety and effectiveness.

Each of the diagnostic products currently marketed by Meridian in the United States has been cleared by the FDA pursuant to the 510(k) clearance process or is exempt from such requirements. Meridian believes that most, but not all, products under development will be classified as Class I or II medical devices and, in the case of Class II devices, will be eligible for 510(k) clearance.

A 510(k) clearance will be granted if the submitted data establishes that the proposed device is substantially equivalent to an existing Class I or Class II medical device or to a Class III medical device for which the FDA does not require pre-market approval. The 510(k) clearance process for substantially equivalent devices allows product sales to be made in the United States after the filing of an application and upon clearance by the FDA, typically within 90 to 120 days after submission. If the FDA requests additional information, the product cannot be sold in the United States until the application has been supplemented and upon acknowledgment by the FDA within 90 to 120 days of the supplemental application. In practice, the FDA has been granting clearance in about 90 days following submission of the supplemental information. If there are no existing FDA-approved products or processes comparable to a diagnostic product or process, approval by the FDA involves the more lengthy pre-market approval procedures except where the product qualifies for de novo 510(k). Under the Food and Drug Export Reform and Enforcement Act of 1996 (FDERA), unapproved FDA products can, under certain conditions, be sold outside of the United States prior to receiving clearance.

Sales of Meridian s diagnostic products in foreign countries are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ.

## **European Diagnostics Operating Segment**

The European Diagnostics operating segment s business focuses on the sale and distribution of diagnostic test kits, manufactured both by the US Diagnostics operating segment and by third-party vendors. Approximately 66% of third-party sales for fiscal 2006 were products purchased from the US Diagnostics operating segment. Third-party sales for this operating segment were \$19,828,000, \$17,818,000 and \$15,412,000 for fiscal 2006, 2005 and 2004, respectively, reflecting a compound annual growth rate of 13%. As of September 30, 2006,

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the European Diagnostics operating segment had 38 employees, including 16 employees in the direct sales force. The European Diagnostics operating segment s sales and distribution network consists of direct sales forces in Belgium, France, Holland, and Italy, and independent distributors in other European countries, Africa and the Middle East. The European Diagnostics operating segment maintains a distribution center in Milan, Italy. The primary markets and customers for this operating segment are hospitals and reference laboratories.

Due to the introduction of new products and improvements in general market conditions, sales in local currency, the Euro, increased 15% in fiscal 2006, compared to fiscal 2005, and 11% in fiscal 2005, compared to fiscal 2004. The European Diagnostics operating segment s functional currency is the Euro. The translation of Euros into US dollars is subject to exchange rate fluctuations.

# **Life Science Operating Segment**

#### **Overview**

The Life Science operating segment s business focuses on the development, manufacture, sale, and distribution of bulk antigens, antibodies, and reagents used by researchers and other diagnostic companies, as well as contract development and manufacturing services. Third-party sales for this operating segment were \$22,864,000, \$21,662,000 and \$16,041,000 for fiscal 2006, 2005 and 2004, respectively, reflecting a compound annual growth rate of 23%, including the OEM Concepts acquisition discussed below. As of September 30, 2006, the Life Science operating segment had 117 employees.

Most of the revenue for the Life Science operating segment currently comes from the manufacture, sale and distribution of bulk antigens, antibodies, and reagents used by researchers and other diagnostic companies. During fiscal 2006, 18% of third-party sales for this segment were to one customer, a substantial portion of which is under exclusive supply agreements that have annual automatic renewal provisions. Meridian has a long-standing relationship with this customer, and although there can be no assurances, Meridian intends to renew these supply agreements in the normal course of business.

The protein production facility serves as an enabling technology for process development and large-scale manufacturing for biologicals used in new drugs and vaccines. The size of the facility is intended to accommodate manufacturing requirements for Phase I and Phase II clinical trials. The customer base for this aspect of the Life Science business includes biopharmaceutical and biotechnology companies, as well as government agencies, such as the National Institutes of Health. Revenues for the Life Science operating segment, in the normal course of business, may be affected from quarter to quarter by the timing and nature of arrangements for contract services work, which may have longer production cycles than bioresearch reagents

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and bulk antigens and antibodies, as well as buying patterns of major customers. See Note 1(j) to the Consolidated Financial Statements herein for revenue recognition policies. Meridian s revenues for contract services were \$2,537,000, \$3,053,000, and \$1,528,000 in fiscal 2006, 2005, and 2004, respectively.

#### **Growth Strategies**

Growth strategies for the Life Science operating segment include (i) development of new product applications from existing technologies and (ii) acquisition or licensing of biologicals and technologies for development of new products. Contract manufacturing of proteins and other biologicals used in research for new drugs and vaccines is an example of a significant new product application built from Meridian s existing expertise in manufacturing bulk antigens and reagents using cell culture techniques.

#### Markets

The Life Science operating segment is represented by four product-line brands. The BIODESIGN brand represents monoclonal and polyclonal antibodies, as well as assay reagents. The OEM Concepts brand represents contract ascites and antibody production services. The Viral Antigens brand represents viral proteins. The cGMP biologics brand represents contract development and manufacturing services for drug and vaccine discovery and development. The customer base for bulk biomedical reagents (BIODESIGN, OEM Concepts, and Viral Antigens brands) is large and fragmented, and includes other diagnostic manufacturers as well as researchers in academia and the pharmaceutical and biotechnology industries. The market segments for drug and vaccine discovery and development are intended to be served via contract manufacturing in the protein production laboratory discussed above.

# Sales and Marketing

The Life Science operating segment applies sales and marketing efforts in two different manners that are designed to complement one another. An internal sales and marketing staff, as well as a website, have been built to market bulk biomedical reagents directly to a large and fragmented customer base. The website provides detailed technical information and capability to submit purchase orders. For major bulk biomedical reagent customers, scientific resources have been dedicated to establish sole-source supply arrangements. For drug and vaccine discovery and development, management and scientific resources are dedicated to each potential customer.

## Research and Development

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The Life Science operating segment s research and development organization consists of 7 research scientists. Research and development expenses for the Life Science operating segment for fiscal 2006, 2005 and 2004 were \$1,457,000, \$823,000 and \$1,226,000, respectively. This research and development organization focuses its activities on the protein production laboratory, and developing new biomedical reagents.

#### Manufacturing and Government Regulation

The proteins that are produced in the protein production facility are intended to be used as injectibles. As such, they are produced under cGMP Regulations for Biologics and Human Drugs under the auspices of the FDA. Approval and licensing, following clinical trials, of these products is the responsibility of the applicant, who owns the rights to each protein. Typically, the customer is the applicant, not Meridian Life Science.

## Competition

## **Diagnostics**

The market for diagnostic tests is a multi-billion dollar international industry, which is highly competitive. Many of Meridian s competitors are larger with greater financial, research, manufacturing and marketing resources. Important competitive factors of Meridian s products include product quality, price, ease of use, customer service, and reputation. In a broader sense, industry competition is based upon scientific and technological capability, proprietary know-how, access to adequate capital, the ability to develop and market products and processes, the ability to attract and retain qualified personnel and the availability of patent protection. To the extent that Meridian s product lines do not reflect technological advances, Meridian s ability to compete in those product lines could be adversely affected. Companies competing in the diagnostic test industry generally focus on a limited number of tests or limited segments of the market. As a result, the diagnostic test industry is highly fragmented and segmented. Hundreds of companies in the United States alone supply immunodiagnostic tests. These companies range from multi-national health care companies, for which immunodiagnostics is one line of business, to small start-up companies. Of central importance in the industry are mid-sized medical diagnostic specialty companies, like Meridian, that offer multiple, broad product lines and have the ability to deliver new, high value products quickly to the marketplace. Among the companies with which Meridian competes in the marketing of one or more of its products are Abbott Laboratories Inc., Becton, Dickinson and Company, Diagnostic Products Corporation (acquired by Siemens in 2006), Quidel Corporation, and Inverness Medical.

Life Science

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The market for bulk biomedical reagents is highly competitive. Important competitive factors include product quality, price, customer service, and reputation. Meridian faces competitors, many of which have greater financial, research and development, sales and marketing, and manufacturing resources where sole-source supply arrangements do not exist. From time to time, customers may choose to manufacture their biomedical reagents in-house rather than purchase from outside vendors such as Meridian.

The market for contract manufacturing in a validated cGMP facility such as Meridian s protein production laboratory is also competitive. Important competitive factors include reputation, customer service, and price. Although the product application for this facility was built from Meridian s existing expertise in cell culture manufacturing techniques, Meridian faces competitors with greater experience in contract manufacturing in a cGMP environment.

## Acquisitions

Acquisitions have played an important role in the historical growth of Meridian s businesses. Meridian s acquisition objectives are to, among other things, (i) enhance product offerings, (ii) improve product distribution capabilities, (iii) provide access to new markets, and/or (iv) provide access to key biologicals or new technologies that lead to new products.

Recent examples of completed acquisitions include Gull Laboratories in fiscal 1999, Viral Antigens in fiscal 2000, and OEM Concepts in fiscal 2005. The Gull acquisition enhanced product offerings, expanded sales and distribution capabilities in Europe, and provided the initial access into the Life Science market for Meridian (through the BIODESIGN business). The Viral Antigens acquisition, coupled with the opening of the protein production facility, solidified Meridian s entry into the Life Science market. The OEM Concepts acquisition strengthened Meridian s Life Science business by adding custom ascites manufacturing capabilities and diversifying Meridian s customer base of major diagnostic manufacturing companies.

Although Meridian cannot provide any assurance that it will consummate any acquisitions in the future, Meridian expects that acquisitions will continue to serve as a source of new revenues and earnings growth in the future.

## **International Markets**

International markets are an important source of revenue for Meridian's operating segments. For all operating segments combined, international sales were \$34,557,000 or 32% of total fiscal 2006 sales, \$30,232,000 or 33% of total fiscal 2005 sales and \$24,916,000 or 31% of total fiscal 2004 sales. Domestic exports for the US Diagnostics and Life Science operating segments were \$14,728,000, \$12,414,000 and \$9,504,000 in fiscal

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2006, 2005 and 2004, respectively. Meridian expects to continue to look to international markets as a source of new revenues and growth in the future.

# Environmental

Meridian is a conditionally exempt small quantity generator of hazardous waste and has a US EPA identification number. All hazardous material is manifested and disposed of properly. Meridian is in compliance with applicable portions of the federal and state hazardous waste regulations and has never been a party to any environmental proceeding.

# ITEM 1A. RISK FACTORS

In addition to the other information set forth in this report, you should carefully consider the following factors which could materially affect our business, financial condition, cash flows or future results. Any one of these factors could cause the Company s actual results to vary materially from recent results or from anticipated future results. The risks described below are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

# Risks Affecting Growth and Profitability of our Business

# We may be unable to develop new products and services or acquire products and services on favorable terms.

The medical diagnostic and life science industries are characterized by ongoing technological developments and changing customer requirements. As such, our results of operations and continued growth depend, in part, on our ability in a timely manner to develop or acquire rights to, and successfully introduce into the marketplace, enhancements of existing products and services or new products and services that incorporate technological advances, meet customer requirements, and respond to products developed by our competition. We cannot provide any assurance that we will be successful in developing or acquiring such rights to products and services on a timely basis, or that such products and services will adequately address the changing needs of the marketplace, either of which could adversely affect our results of operations.

In addition, we must regularly allocate considerable resources to research and development of new products, services, and technologies. The research and development process generally takes a significant amount of time from design stage to product launch. This process is conducted in various stages. During each stage, there is a risk that we will not achieve our goals on a timely basis, or at all, and we may have to abandon a product in which we have invested substantial resources.

During 2006, 2005, and 2004, we incurred \$4,799,000, \$3,866,000, and \$4,377,000, respectively, in research and development expenses. We expect to continue to invest in our research and development activities.

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# We may be unable to successfully integrate operations or to achieve expected cost savings from acquisitions we make.

One of our main growth strategies is the acquisition of companies and/or products. Although additional acquisitions of companies and products may enhance the opportunity to increase net earnings over time, such acquisitions could result in greater administrative burdens, increased exposure to the uncertainties inherent in marketing new products, and financial risks of additional operating costs. The principal benefits expected to result from any acquisitions we make will not be achieved fully unless we are able to successfully integrate the operations of the acquired entities with our operations and realize the anticipated synergies, cost savings, and growth opportunities from integrating these businesses into our existing businesses. We cannot provide any assurance that we will be able to identify and complete additional acquisitions on terms we consider favorable or that, if completed, will be successfully integrated into our operations.

Revenues for our diagnostic operating segments may be impacted by our reliance upon two key distributors, seasonal factors and sporadic outbreaks, and changing diagnostic market conditions.

Key Distributors

Our US Diagnostic operating segment sales through two distributors were approximately \$31,003,000, or approximately 29% of total sales, in fiscal 2006, and approximately \$23,756,000, or approximately 26% of total sales for fiscal 2005. These parties distribute our products and other laboratory products to end-user customers. The loss of either of these distributors could negatively impact our sales and results of operations unless suitable alternatives were timely found or lost sales to one distributor were absorbed by another distributor. Finding a suitable alternative on satisfactory terms may pose challenges in our industry s competitive environment.

As an alternative, we could expand our efforts to distribute and market our products directly. This alternative, however, would require substantial investment in additional sales, marketing, and logistics resources, including hiring additional sales and customer service personnel, which would significantly increase our future selling, general, and administrative expenses.

Seasonal Factors and Sporadic Outbreaks

Our principal business is the sale of a broad range of diagnostic test kits for common respiratory, gastrointestinal, viral, and parasitic infectious diseases. Certain infectious diseases may be seasonal in nature, while others may be associated with sporadic outbreaks, such as food-borne illnesses. While we believe that the breadth of our diagnostic product lines reduces the risk that infections subject to seasonality and sporadic outbreaks will cause variability in diagnostic revenues, we can make no assurance that revenues will not be negatively impacted period over period by such factors.

Changing Diagnostic Market Conditions

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Changes in the healthcare delivery system have resulted in major consolidation among reference laboratories and in the formation of multi-hospital alliances, reducing the number of institutional customers for diagnostic test products. Due to such consolidation, we may not be able to enter into and/or sustain contractual or other marketing or distribution arrangements on a satisfactory commercial basis with institutional customers, which could adversely affect our results of operations.

Third party payors for medical products and services, including state and federal governments, are increasingly concerned about escalating health care costs and can indirectly affect the pricing or the relative attractiveness of our products by regulating the maximum amount of reimbursement they will provide for diagnostic testing services. If reimbursement amounts for diagnostic testing services are decreased in the future, such decreases may reduce the amount that will be reimbursed to hospitals or physicians for such services and consequently could place constraints on the levels of overall pricing, which could have a material effect on our sales and/or profit margins.

# Revenues for our Life Science operating segment may be impacted by customer concentrations and buying patterns.

Our Life Science operating segment s sales of purified antigens and reagents to one customer were 18% and 23%, respectively, of the Life Science operating segment s total sales for fiscal 2006 and fiscal 2005, or 4% and 5%, respectively, of our overall total sales for fiscal 2006 and fiscal 2005. A substantial portion of these sales are under exclusive supply agreements that have annual automatic renewal provisions. Although we have a long-standing relationship with this customer, we cannot provide any assurance that we will be able to renew these supply agreements, which could adversely affect our sales and results of operations.

Our Life Science operating segment has five other significant customers who purchase antigens, antibodies and reagents, which together comprised 20% and 29%, respectively, of the operating segment s total sales for fiscal 2006 and fiscal 2005. Any significant alteration of buying patterns from these customers could adversely affect our period over period sales and results of operations.

Revenues relating to research, development and manufacturing services for our Life Science operating segment are generated on a contract by contract basis. The nature of this business is such that each contract provides a unique product and/or service and corresponding revenue stream. Although we believe that future prospects for this business will generate targeted growth rates, there can be no assurance that future contracts will be secured, and if secured, will be profitable.

## Intense competition could adversely affect our profitability.

The markets for our products and services are characterized by substantial competition and rapid change. Hundreds of companies in the United States supply immunodiagnostic tests and purified reagents. These companies range from multinational healthcare entities, for which immunodiagnostics is one line of business,

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to small start-up companies. Many of our competitors have significantly greater financial, technical, manufacturing, and marketing resources than we do. We cannot provide any assurance that our products and services will be able to compete successfully with the products and services of our competitors.

We are dependent on international sales, and our financial results may be adversely impacted by foreign currency, regulatory or other developments affecting international markets.

We sell products and services into approximately 60 countries. Approximately 32% of our net sales for fiscal 2006 and approximately 33% of our net sales for fiscal 2005 were attributable to international markets. Approximately 49% of our international sales were made in Euros, with the remaining 51% made in U.S. dollars. We are subject to the risks associated with fluctuations in the U.S. dollar-Euro exchange rates. We are also subject to other risks associated with international operations, including longer customer payment cycles, tariff regulations, requirements for export licenses, stability of foreign governments, and governmental requirements with respect to the importation and distribution of medical devices and antigens, antibodies and reagents, all of which may vary by country.

## **Risks Affecting our Manufacturing Operations**

We are subject to comprehensive regulation, and our ability to earn profits may be restricted by these regulations. Medical device diagnostics and the manufacture, sale, and distribution of bulk antigens, antibodies, and reagents are highly regulated industries. We cannot provide any assurance that we will be able to obtain necessary governmental clearances or approvals or timely clearances or approvals to market future products in the United States and other countries. Costs and difficulties in complying with laws and regulations administered by the U.S. Food and Drug Administration, the U.S. Department of Agriculture, the U.S. Department of Commerce, the U.S. Drug Enforcement Agency, or the Centers for Disease Control can result in unanticipated expenses and delays and interruptions to the sale of new and existing products. Contract manufacturing of proteins and other biologicals is regulated by the U.S. Food and Drug Administration.

Regulatory approval can be a lengthy, expensive, and uncertain process, making the timing and costs of approvals difficult to predict. The failure to comply with these regulations can result in delay in obtaining authorization to sell products, seizure or recall of products, suspension or revocation of authority to manufacture or sell products, and other civil or criminal sanctions.

Significant interruptions in production at our principal manufacturing facilities and/or third-party manufacturing facilities would adversely affect our business and operating results.

Approximately 79% of our diagnostics revenues and 71% of our Life Science revenues come from products and services manufactured at our Cincinnati, Ohio, Boca Raton, Florida, Memphis, Tennessee, and Saco, Maine facilities. Our global supply of these products and services is dependent on the uninterrupted and

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efficient operation of these facilities. In addition, we currently rely on a small number of third-party manufacturers to produce certain of our diagnostic products. The operations of our facilities or these third-party manufacturing facilities could be adversely affected by power failures, natural or other disasters, such as earthquakes, floods, or terrorist threats. Although we carry insurance to protect against certain business interruptions at our facilities, there can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all. Any significant interruption in the Company s or third-party manufacturing capabilities could materially and adversely affect our operating results.

# We are dependent on sole-source suppliers for certain critical components and products. A supply interruption could adversely affect our business.

Our products are made from a wide variety of raw materials that are generally available from alternate sources of supply. However, certain critical raw materials and supplies required for the production of some of our principal products are available only from a single supplier. In addition, certain finished products, for which Meridian acts as a distributor, are available only from a single supplier. If these suppliers become unable or unwilling to supply the required raw materials or products, we would need to find another source, and perform additional development work and obtain regulatory approvals for the use of the alternative raw materials for our products. Completing that development and obtaining such approvals could require significant time and resources, and may not occur at all. Any disruption in the supply of these raw materials or finished products could have a material adverse affect on us.

## Risks Related to Intellectual Property and Product Liability

# We may be unable to protect or obtain proprietary rights that we utilize or intend to utilize.

In developing and manufacturing our products, we employ a variety of proprietary and patented technologies. In addition, we have licensed, and expect to continue to license, various complementary technologies and methods from academic institutions and public and private companies. We cannot provide any assurance that the technologies that we own or license provide protection from competitive threats or from challenges to our intellectual property. In addition, we cannot provide any assurances that we will be successful in obtaining licenses or proprietary or patented technologies in the future.

# Product infringement claims by other companies could result in costly disputes and could limit our ability to sell our products.

Litigation over intellectual property rights is prevalent in the diagnostic industry. As the market for diagnostics continues to grow and the number of participants in the market increases, we may increasingly be subject to patent infringement claims. It is possible that a third-party may claim infringement against us. If found to infringe, we may attempt to obtain a license to such intellectual property, however, we may be unable to do so on favorable terms, or at all. Additionally, if our products are found to infringe on a third party s

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intellectual property, we may be required to pay damages for past infringement and lose the ability to sell certain products, causing our revenues to decrease.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may have to limit or cease sales of our products.

The testing, manufacturing, and marketing of medical diagnostic products involves an inherent risk of product liability claims. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease sales of our products. We currently carry product liability insurance at a level we believe is commercially reasonable, although there is no assurance that it will be adequate to cover claims that may arise. In certain customer contracts, we indemnify third parties for certain product liability claims related to our products. These indemnification obligations may cause us to pay significant sums of money for claims that are covered by these indemnifications. In addition, a defect in the design or manufacture of our products could have a material adverse affect on our reputation in the industry and subject us to claims of liability for injury and otherwise. Any substantial underinsured loss resulting from such a claim could have a material adverse affect on our profitability and the damage to our reputation in the industry could have a material adverse affect on our business.

# **Other Risks Affecting Our Business**

# Our business could be negatively affected if we are unable to attract, hire, and retain key personnel.

Our future success depends on our continued ability to attract, hire, and retain highly qualified personnel, including our executive officers and scientific, technical, sales, and marketing employees, and their ability to manage growth successfully. If such key employees were to leave and we were unable to obtain adequate replacements, our operating results could be adversely affected.

## Our bank credit agreement imposes restrictions with respect to our operations.

Our bank credit agreement contains a number of financial covenants that require us to meet certain financial ratios and tests. If we fail to comply with the obligations in the credit agreement, we would be in default under the credit agreement. If an event of default is not cured or waived, it could result in acceleration of the indebtedness under our credit agreement and under other instruments that contain cross-acceleration or cross-default provisions, any of which could have a material adverse effect on our business. At the present time, no borrowings are outstanding under the credit agreement.

# Should we be unable to renew our bank credit agreement on an ongoing basis, our growth potential could be adversely affected.

Our bank credit agreement provides us with access to funds that may be used for acquisitions or ongoing operating expenses. If we were unable to renew the credit agreement and unable to put into place a similar

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agreement, we could become unable to fund future growth and/or take advantage of acquisition opportunities. Such limitations on growth could have a material adverse affect on our business.

#### **Risks Related to Our Common Stock**

Our board of directors has the authority to issue up to 1,000,000 shares of undesignated preferred stock and to determine the rights, preferences, privileges and restrictions, including voting rights, of such shares without any future vote or action by the shareholders. The issuance of preferred stock under certain circumstances could have the effect of delaying or preventing a change in control of our company. Ohio corporation law contains provisions that may discourage takeover bids for our company that have not been negotiated with the board of directors. Such provisions could limit the price that investors might be willing to pay in the future for shares of the common stock. In addition, sales of substantial amounts of such shares in the public market could adversely affect the market price of the common stock and our ability to raise additional capital at a price favorable to us.

# ITEM 1B. <u>UNRESOLVED SEC STAFF COMMENTS</u>

None.

# ITEM 2. PROPERTIES

Meridian s corporate offices, diagnostics manufacturing facility and diagnostics research and development facility are located in three buildings totaling approximately 94,000 square feet on 6.2 acres of land in a suburb of Cincinnati. These properties are owned by Meridian. Meridian has approximately 51,000 square feet of manufacturing space and 9,000 square feet of warehouse space in the Cincinnati facility.

The distribution center in Italy conducts its operations in a two-story building in the Milan, Italy area consisting of approximately 18,000 square feet. This facility is owned by Meridian Bioscience Europe s.r.l. Meridian also rents office space in France and Belgium for sales and administration functions.

Meridian Life Science rents a 10,000 square foot facility that houses administration, distribution and manufacturing facilities in Saco, Maine under a lease that expires in 2006; administrative offices and a manufacturing facility in Memphis, Tennessee, which consists of two buildings totaling approximately 34,000 square feet, including approximately 27,000 square feet of manufacturing space; and approximately 11,100 square feet of space in Boca Raton, Florida that houses manufacturing operations. Meridian Life Science is currently evaluating the purchase of the leased facility in Maine or an extension of the lease.

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# ITEM 3. LEGAL PROCEEDINGS

Meridian is a party to litigation that it believes is in the normal course of business. The ultimate resolution of these matters is not expected to have a material adverse effect on Meridian s financial position, results of operations or cash flows. No provision has been made in the accompanying consolidated financial statements for these matters.

ITEM 4.

#### SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the fourth quarter of fiscal 2006.

PART II. ITEM 5.

# MARKET FOR REGISTRANT S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Common Stock Information on the inside back cover of the Annual Report to Shareholders for 2006 and Quarterly Financial Data relating to Meridian s dividends in Note 11 to the Consolidated Financial Statements are incorporated herein by reference. There are no restrictions on cash dividend payments.

Meridian s cash dividend policy is to set the indicated annual dividend rate between 75% and 85% of each fiscal year s expected net earnings. The declaration and amount of dividends will be determined by the Board of Directors in its discretion based upon its evaluation of earnings, cash flow requirements and future business developments and opportunities, including acquisitions.

Meridian paid dividends of \$0.425 per share, \$0.31 per share, and \$0.26 per share in fiscal 2006, fiscal 2005, and fiscal 2004, respectively.

On August 15, 2005, Meridian announced a three-for-two stock split, with fractional shares paid in cash. The split was effective on September 2, 2005 to shareholders of record as of August 29, 2005. All references in this Annual Report to number of shares and per share amounts reflect the stock split.

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## **EQUITY COMPENSATION PLAN INFORMATION**

The following table presents summary information as of September 30, 2006 with respect to all the Company s equity compensation plans, except the Plan under which common shares issued to Directors are not subject to forfeiture and are not appropriate for inclusion in the table.

	(a)  Number of  Securities to be	(c) Number of securities remaining available for future issuance	
	issued upon	Weighted- average exercise	under equity compensation
Plan Category	exercise of outstanding options, warrants and rights	price of outstanding options, warrants and rights	plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders <sup>(1)</sup>	1,270,272	\$ 8.26	588,667
Equity compensation plans not approved by security holders	9,525	3.87	
Total	1,279,797	\$ 8.22	588,667

(1) 1994 Director s Stock Option

Plan

1996 Stock Option Plan, as amended in 2001

1999 Director s Stock Option Plan

2004 Equity Compensation Plan, as amended

> ITEM 6. SELECTED FINANCIAL DATA

Incorporated by reference from inside front cover of the Annual Report to Shareholders for 2006.

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#### ITEM 7.

# MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Refer to Forward Looking Statements following the Index in front of this Form 10-K and Item 1A Risk Factors on pages 14 through 20 of this Annual Report.

#### **Operating Segments:**

Meridian s reportable operating segments are US Diagnostics, European Diagnostics, and Life Science. The US Diagnostics operating segment consists of manufacturing operations in Cincinnati, Ohio, and the sale and distribution of diagnostic test kits in the US and countries outside of Europe, Africa and the Middle East. The European Diagnostics operating segment consists of the sale and distribution of diagnostic test kits in Europe, Africa, and the Middle East. The Life Science operating segment consists of manufacturing operations in Memphis, Tennessee; Saco, Maine; and Boca Raton, Florida; the sale and distribution of bulk antigens, antibodies and bioresearch reagents domestically and abroad; and contract research and development and manufacturing services.

## **Results of Operations:**

## Overview

#### Fourth quarter

Net earnings for the fourth quarter of fiscal 2006 increased 27% to \$4,778,000, or \$0.18 per diluted share (increased 20%) from net earnings for the fourth quarter of fiscal 2005 of \$3,761,000, or \$0.15 per diluted share. This increase is primarily attributable to increased sales and continuing efforts to improve operating efficiency across all businesses. Net sales for the fourth quarter of fiscal 2006 were \$28,650,000, an increase of \$3,634,000 or 15% compared to the fourth quarter of fiscal 2005.

During the fourth quarter of fiscal 2006, Meridian determined that the carrying value of a supply contract related to the Life Science operating segment had become impaired and recorded such impairment to general and administrative expenses in the amount of \$826,000. The contract provides for the supply of biological materials to the United States Department of Defense. Changes in the Department s Critical Reagents Program lowered the amount of materials to be supplied under the contract in future periods.

#### Fiscal Year

Net earnings for fiscal 2006 increased 46% to \$18,325,000, or \$0.68 per diluted share (increased 31%) from net earnings for fiscal 2005 of \$12,565,000, or \$0.52 per diluted share. Results of operations for fiscal 2006

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compared to fiscal 2005 are discussed below.

Fiscal Year Ended September 30, 2006 Compared to Fiscal Year Ended September 30, 2005 Net sales

Overall, net sales increased 17% for fiscal 2006 compared to fiscal 2005. Net sales for the US Diagnostics operating segment increased \$12,236,000, or 23%, for the European Diagnostics operating segment increased \$2,010,000, or 11%, and for the Life Science operating segment increased \$1,202,000, or 6%.

For the US Diagnostics operating segment, 46% of the sales increase was related to growth in C. *difficile* products (increased \$5,682,000), reflecting the market expansion and gains in market share related to the 2005 launch of Immuno*Card*Ò *C. difficile* Toxins A & B. Sales of respiratory products (increased \$1,819,000) also contributed to the increase, driven by growth in international markets and favorable changes in insurance reimbursement policies. Meridian s respiratory products include diagnostic tests for influenza, Respiratory Syncytial Virus (RSV), and mycoplasma. H. *pylori* sales (increased \$996,000) contributed to the increase due to increased testing and positive results from focused marketing efforts on the managed care sector. Sales increases for parasitology products (increased \$1,019,000), fungal products (increased \$860,000), food borne products (increased \$632,000), rotavirus products (increased \$565,000) and microbiology products (\$480,000) also contributed to favorable variances to fiscal 2005.

For the European Diagnostics operating segment, the sales increase offsets currency translation losses in the amount of approximately \$662,000. Sales in local currency, the Euro, increased 15%. The local currency increase was driven by market increases in sales of H. *pylori* products (\$1,182,000). Increases in sales of C. *difficile* products (\$901,000), including Immuno*Card*Ò *C. difficile* Toxins A & B, also contributed to the increase. These increases reflect market recognition of the benefits of performing C. *difficile* testing for both Toxin A and Toxin B and increased benefits of rapid testing to hospital environments.

For the Life Science operating segment, the sales increase was primarily attributable to the inclusion of OEM Concepts for a full year in fiscal 2006, compared to eight months in fiscal 2005. This was partially offset by shifts in buying patterns by one large diagnostic manufacturing customer and one large defense customer, as well as the timing and number of contract services arrangements. Sales of made-to-order bulk antigens and antibodies to one customer provided sales of approximately \$4,073,000, \$5,000,000, and \$5,446,000 in fiscal 2006, 2005 and 2004, respectively. For all operating segments combined, international sales were \$34,557,000, or 32% of total sales, for fiscal 2006, compared to \$30,232,000, or 33% of total sales, in fiscal 2005. Combined domestic exports for the US Diagnostics and Life Science operating segments were \$14,728,000 for fiscal 2006, compared to \$12,414,000

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in fiscal 2005. The remaining international sales were generated by the European Diagnostics operating segment. *Gross Profit* 

Gross profit increased 18% for fiscal 2006 compared to fiscal 2005. Gross profit margins were 60% for fiscal 2006 compared to 59% for fiscal 2005. This increase reflects higher margins commanded by new rapid tests, such as Immuno*Card*® C. *difficile* Toxins A & B and operating efficiencies.

Meridian s overall operations consist of the sale of diagnostic test kits for various disease states and in alternative test formats, as well as bioresearch reagents, bulk antigens and antibodies, proficiency panels, and contract research and development and contract manufacturing services. Product sales mix shifts, in the normal course of business, can cause the consolidated gross profit margin to fluctuate by several points.

Operating Expenses

Operating expenses increased 9% for fiscal 2006 compared to fiscal 2005. The overall increase in operating expenses for fiscal 2006 is discussed below.

Research and development expenses increased 24% for fiscal 2006 compared to fiscal 2005, and as a percentage of sales, were 4% in fiscal 2006 and fiscal 2005. Of this increase, \$299,000 related to the US Diagnostics operating segment and \$634,000 related to the Life Science operating segment. The US Diagnostics operating segment increase was primarily attributable to increased stock compensation expense. For the Life Science operating segment, during fiscal 2005, research and development scientists were performing contract work for third-party customers, and thus, their related costs were classified in cost of sales. During fiscal 2006, their efforts and activities were primarily focused on internal research and development work, and therefore charged to research and development expense, rather than being classified in cost of sales or inventory. The increase for the Life Science operating segment reflects the classification of such costs.

Selling and marketing expenses increased 10%, for fiscal 2006 compared to fiscal 2005, and as a percentage of sales, decreased from 16% for fiscal 2005 to 15% for fiscal 2006. Of this increase, \$1,195,000 related to the US Diagnostics operating segment and \$475,000 related to the Life Science operating segment, partially offset by a decrease of \$135,000 for the European Diagnostics operating segment. The increase for the US Diagnostics operating segment was primarily attributable to sales administration fees to group purchasing organizations and incentive compensation associated with higher sales levels, as well as higher salaries and benefits costs. The increase for the Life Science operating segment was primarily due to business development costs and a full year of costs for the OEM Concepts business, acquired during the second quarter

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of fiscal 2005. The decrease for the European Diagnostics operating segment was primarily attributable to fluctuations in the Euro currency.

General and administrative expenses increased 5%, for fiscal 2006 compared to fiscal 2005, and as a percentage of sales, decreased from 17% in fiscal 2005 to 15% in fiscal 2006. Of this increase, \$18,000 related to the US Diagnostics operating segment, \$679,000 related to the Life Science operating segment and \$60,000 related to the European Diagnostics operating segment. The increase for the US Diagnostics operating segment was primarily attributable to increased salaries and benefits costs and increased stock compensation expense, offset by an insurance recovery received and decreased legal and professional fees related to efficiencies in reporting under the Sarbanes-Oxley Act. The increase for the Life Science operating segment was primarily attributable to the impairment of a supply contract related to the acquisition of OEM Concepts. See Note 1(i) to the consolidated financial statements contained herein.

Effective July 1, 2005, Meridian adopted the provisions of Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*, in accounting for its stock option plans. The amount of stock-based compensation expense reported for fiscal year 2006 and fiscal 2005 was \$1,082,000 and \$279,000, respectively.

Operating Income

Operating income increased 33% in fiscal 2006, as a result of the factors discussed above.

Other Income and Expense

Interest expense declined 83% for fiscal 2006 compared to fiscal 2005. This decrease was attributable to the positive effects of the debenture conversion and redemption transactions discussed under Liquidity and Capital Resources herein.

Interest income was \$1,123,000 for fiscal 2006, and related primarily to interest earned on proceeds from the September 2005 common share offering that have been primarily invested in tax-exempt securities.

Income Taxes

The effective rate for income taxes was 35% for fiscal 2006 and 36% for fiscal 2005. The decrease in the effective tax rate was primarily attributable to the favorable effects of tax-exempt interest and domestic production incentives under the American Jobs Creation Act.

Fiscal Year Ended September 30, 2005 Compared to Fiscal Year Ended September 30, 2004 -26-

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Net sales

Overall, net sales increased 17% for fiscal 2005 compared to fiscal 2004. Net sales for the US Diagnostics operating segment increased \$5,332,000, or 11%, for the European Diagnostics operating segment increased \$2,406,000, or 16%, and for the Life Science operating segment increased \$5,621,000, or 35%.

For the US Diagnostics operating segment, over 50% of the sales increase was related to growth in C. *difficile* products (increased \$2,974,000), reflecting the launch of the Company s new product, Immuno*Card*Ò *C. difficile* Toxins A & B. Sales of respiratory products (increased \$2,419,000) also contributed to the increase, driven by a larger customer base. Meridian s respiratory products include diagnostic tests for influenza, Respiratory Syncytial Virus (RSV), and mycoplasma (walking pneumonia).

For the European Diagnostics operating segment, the sales increase includes currency translation gains in the amount of approximately \$709,000. Sales in local currency, the Euro, increased 11%. The local currency increase was driven by improvements in general market conditions and a full year of sales from Immuno*Card*O C. *difficile* Toxins A & B rapid diagnostic test, launched in European markets in fiscal 2004.

For the Life Science operating segment, the sales increase was attributable to the acquisition of OEM Concepts (\$3,087,000 for eight months), revenues from contract research and development and contract services (increased \$1,525,000), and volume growth in make-to-order bulk antigens and antibodies. Sales of made-to-order bulk antigens and antibodies to one customer provided sales of approximately \$5,000,000 and \$5,446,000 in fiscal 2005 and fiscal 2004, respectively.

For all operating segments combined, international sales were \$30,232,000, or 33% of total sales, for fiscal 2005, compared to \$24,916,000, or 31% of total sales, in fiscal 2004. Combined domestic exports for the US Diagnostics and Life Science operating segments were \$12,414,000 for fiscal 2005, compared to \$9,504,000 in fiscal 2004. The remaining international sales were generated by the European Diagnostics operating segment. *Gross Profit* 

Gross profit increased 20% for fiscal 2005 compared to fiscal 2004. Gross profit margins were 59% for fiscal 2005 compared to 57% for fiscal 2004. This increase reflects higher margins commanded by new rapid tests, such as Immuno *Card*® C. *difficile* Toxins A & B and operating efficiencies.

Meridian s overall operations consist of the sale of diagnostic test kits for various disease states and in alternative test formats, as well as bioresearch reagents, bulk antigens and antibodies, proficiency tests, and contract services. Product sales mix shifts, in the normal course of business, can cause the consolidated gross profit margin to fluctuate by several points.

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#### **Operating Expenses**

Operating expenses increased 15% for fiscal 2005 compared to fiscal 2004. The overall increase in operating expenses for fiscal 2005 is discussed below.

Research and development expenses decreased 12% for fiscal 2005 compared to fiscal 2004, and as a percentage of sales, decreased to 4% in fiscal 2005, from 5% in fiscal 2004. Of this decrease, \$107,000 related to the US Diagnostics operating segment and \$404,000 related to the Life Science operating segment. For the Life Science operating segment, during fiscal 2005, research and development scientists were performing contract work for third-party customers, and thus, their related costs are classified in cost of sales. During fiscal 2004, their efforts and activities were primarily focused on internal research and development work. The decrease for the Life Science operating segment reflects the classification of such costs.

Selling and marketing expenses increased 19%, for fiscal 2005 compared to fiscal 2004, and as a percentage of sales, were 16% for fiscal 2005 and fiscal 2004. Of this increase, \$1,160,000 related to the US Diagnostics operating segment, \$802,000 related to the European Diagnostics operating segment, and \$468,000 related to the Life Science operating segment. The increase for the US Diagnostics operating segment was primarily attributable to higher salaries and benefits costs for additional sales and marketing personnel, costs of physician education and business development for H. *pylori* diagnostics, costs related to distributor incentives, and increased advertising for corporate branding and new products. The increase for the European Diagnostics operating segment was primarily due to higher sales commissions related to sales growth and currency translation. The increase for the Life Science operating segment was primarily due to the acquisition of OEM Concepts and additional marketing and business development resources.

General and administrative expenses increased 12%, for fiscal 2005 compared to fiscal 2004, and as a percentage of sales, decreased from 18% in fiscal 2004, to 17% in fiscal 2005. Of this increase, \$1,326,000 related to the US Diagnostics operating segment, \$517,000 related to the Life Science operating segment, partially offset by a decrease of \$196,000 related to the European Diagnostics operating segment. The increase for the US Diagnostics operating segment was primarily attributable to incentive compensation pursuant to Meridian s corporate incentive plan, increased legal and professional fees, primarily related to the audit of the Company s financial statements, and compliance with the Sarbanes-Oxley Act, and increased costs related to stock based compensation pursuant to the Company s stock option plans. The increase for the Life Science operating segment was primarily attributable to the acquisition of OEM Concepts, including amortization of acquired intangibles, partially offset by lower incentive compensation pursuant to Meridian s corporate incentive plan.

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Effective July 1, 2005, Meridian early adopted the provisions of Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*, in accounting for its stock option plans. Meridian would have otherwise been required to adopt SFAS No. 123R on October 1, 2005. Meridian elected to early adopt SFAS No. 123R in order to achieve a lower cost associated with performance-based stock options that were granted to certain employees in December 2004 than would have been recognized under its previous accounting method, the intrinsic value method under Accounting Principles Board Opinion No. 25. Pursuant to APB No. 25, stock compensation expense for the performance options would have been measured at Meridian s stock price at September 30, 2005, which was 90% higher than at the grant date. The fair value of these stock options, determined under a Black-Scholes model at the date of grant, was substantially lower. For this reason, Meridian believed that early adoption of SFAS No. 123R was in the best interests of shareholders. The amount of stock-based compensation expense reported for fiscal year 2005 was \$279,000. The amount of stock-based compensation expense that would have been reported in fiscal 2005 under a full year of APB No. 25 was \$604,000.

Operating Income

Operating income increased 38% in fiscal 2005, as a result of the factors discussed above.

Other Income and Expense

Interest expense declined 51% for fiscal 2005 compared to fiscal 2004. This decrease was attributable to the positive effects of the fiscal 2004 debenture exchange and redemption transactions and the fiscal 2005 debenture redemption and conversion transactions discussed under Liquidity and Capital Resources herein.

Income Taxes

The effective rate for income taxes was 36% for fiscal 2005 and 30% for fiscal 2004. The increase in the effective tax rate was primarily attributable to favorable book-to-return adjustments related to non-US sales activities in fiscal 2004. Book-to-return adjustments represent changes to prior estimates and generally are determined upon filing Meridian s tax returns, typically occurring in the third and fourth quarters. These adjustments are recorded in the period in which amounts previously estimated become known.

**Liquidity and Capital Resources:** 

Comparative Cash Flow Analysis

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Meridian s operating cash flow and financing requirements are determined by analyses of operating and capital spending budgets and consideration of acquisition plans. Meridian has historically maintained line of credit availability to respond quickly to acquisition opportunities.

Net cash provided by operating activities increased 22% in fiscal 2006 compared to fiscal 2005. This increase was primarily attributable to higher earnings levels, partially offset by higher investments in accounts receivable and inventories.

Net cash used in investing activities was \$8,689,000 for fiscal 2006, compared to \$9,647,000 for fiscal 2005. This decrease was primarily attributable to lower acquisition payments in fiscal 2006, in part offset by net purchases of short-term auction rate securities with certain of the proceeds from the September 2005 common share offering. Net cash used in financing activities was \$10,225,000 for fiscal 2006, compared to net cash provided by financing activities of \$22,618,000 for fiscal 2005. This decrease was primarily attributable to proceeds received from the September 2005 common share offering and increased dividend payments. Dividend payments were \$11,095,000 in fiscal 2006, compared to \$7,200,000 in fiscal 2005, reflecting increased dividend rates and common shares outstanding relating to the common share offering, stock option exercises and bond conversions in fiscal 2006 and fiscal 2005.

Net cash flows from operating activities are anticipated to fund working capital requirements, debt service, and dividends during fiscal 2007.

## Capital Resources

During August 2004, Meridian completed the renewal of its credit facility with its commercial bank. The amount of the credit facility is \$25,000,000, and includes \$2,500,000 of term debt and capital lease capacity and a \$22,500,000 line of credit that expires in September 2007. As of November 28, 2006, there were no borrowings outstanding on the line of credit portion of this facility.

As of September 30, 2004, Meridian had outstanding \$12,111,000 principal amount of convertible subordinated debentures due September 1, 2006, bearing interest at 7% and convertible at the option of the holder into common shares at a price of \$10.727. During fiscal 2005, Meridian made several calls for redemption of these debentures, with the aggregate amounts totaling \$1,812,000. Holders converted the remaining \$10,299,000 of 7% debentures into 959,768 common shares during fiscal 2005.

As of September 30, 2004, Meridian had outstanding \$3,889,000 principal amount of convertible subordinated debentures due September 1, 2013, bearing interest at 5% and convertible at the option of the holder into

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common shares at a price of \$9.67. Holders converted \$1,438,000 principal amount of debentures into 148,726 common shares during fiscal 2005 and \$648,000 principal amount of debentures into 67,004 common shares during fiscal 2006.

The 2005 conversion and redemption transactions reduced annual interest expense by \$920,000. The 2006 conversion and redemption transactions are expected to reduce annual interest expense by approximately \$32,000. The Viral Antigens acquisition, completed in fiscal 2000, provided for additional purchase consideration, contingent upon Viral Antigens earnings through September 30, 2006. The OEM Concepts acquisition, completed in fiscal 2005, provides for additional purchase consideration up to a remaining amount of \$2,005,000, contingent upon OEM Concepts future calendar-year sales and gross profit through December 31, 2008. Earnout consideration paid during fiscal 2006 was \$1,494,000. The amount of earnout consideration payable as of September 30, 2006 was \$853,000 for Viral Antigens and \$84,000 for OEM Concepts. Earnout consideration is payable each year, following the period earned.

Meridian s capital expenditures are estimated to be approximately \$5,000,000 for fiscal 2007, and may be funded with operating cash flows, availability under the \$25,000,000 credit facility discussed above, or proceeds from the September 2005 common share offering. Capital expenditures relate to manufacturing and other equipment of a normal and recurring nature as well as capacity expansion for the Maine facility.

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# **Known Contractual Obligations:**

Known contractual obligations and their related due dates were as follows as of September 30, 2006 (amounts in thousands):

		Less than			More than
	Total	1 Year	1-3 Years	4-5 Years	5 Years
Long-term debt	\$ 1,803	\$	\$	\$	\$ 1,803
Interest payments relating to long-term					,
debt	630	90	270	180	90
Operating leases (1)	1,798	561	1,039	198	
Purchase obligations (2)	9,402	8,451	951		
Viral Antigens earnout	853	853			
OEM Concepts earnout (3)	2,089	84	2,005		
Total	\$ 16,575	\$ 10,039	\$ 4,265	\$ 378	\$ 1,893

(1) Meridian and its subsidiaries are lessees of (i) office and warehouse buildings in Maine, Florida, Belgium, and France; (ii) automobiles for use by the diagnostic direct sales forces in the US and Europe; and (iii) certain office equipment such as facsimile machines and copier machines across all business units, under operating lease agreements that expire at various dates.

(2)

Meridian s purchase obligations are primarily outstanding purchase orders for inventory and service items. These contractual commitments are not in excess of expected production requirements over the next twelve months.

#### (3) OEM Concepts

earnout
obligation is
contingent upon
OEM Concepts
future
calendar-year
sales and gross
profit through
December 31,
2008.

#### **Other Commitments and Off-balance Sheet Arrangements:**

#### License Agreements

Meridian has entered into various license agreements that require payment of royalties based on a specified percentage of sales of related products (1% to 8%). Meridian expects that payments under these agreements will amount to as much as \$1,012,000 in fiscal 2007. These royalty payments primarily relate to the US Diagnostics operating segment. During October 2006, Meridian entered into a license agreement with Eiken Chemical Co., Ltd., that provides rights to Eiken s loop-mediated isothermal amplification technology for infectious disease testing in the United -32-

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States and 18 other geographic markets. The agreement calls for payments of up to 200,000,000 Japanese Yen (approximately \$1,700,000) based on the achievement of certain milestones and on-going royalties once products are available for commercial sale. Payments made during product development are expected to occur over a five-year period beginning in fiscal 2007.

## Derivative financial instruments

Meridian accounts for its derivative financial instruments in accordance with SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, as amended. These instruments are designated as cash flow hedges, and therefore, the effective portion of the net gain or loss on the derivative instrument is reported as a component of other comprehensive income and reclassified into earnings in the same period or periods during which the hedged transaction affects earnings. For the ineffective portion of the hedge, gains or losses are charged to earnings in the current period. All derivative instruments are recognized as either assets or liabilities at fair value in the consolidated balance sheets. See Note 6 to the consolidated financial statements contained herein.

## **Market Risk Exposure:**

Meridian has market risk exposure related to foreign currency transactions. Meridian is exposed to foreign currency risk related to its European distribution operations, including foreign currency denominated intercompany receivables.

## **Critical Accounting Policies:**

The consolidated financial statements included in this Annual Report on Form 10-K have been prepared in accordance with accounting principles generally accepted in the United States. Such accounting principles require management to make judgments about estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Management believes that the following accounting policies are critical to understanding the accompanying consolidated financial statements because the application of such polices requires the use of significant estimates and assumptions and the carrying values of related assets and liabilities are material.

## Revenue Recognition

Meridian s revenues are derived primarily from product sales. Revenue is generally recognized when product is shipped and title has passed to the buyer. Revenue for the US Diagnostics operating segment is reduced at the date of sale for estimated rebates that will be claimed by customers. Rebate agreements are in place with certain independent national distributors and are designed to reimburse such distributors for their cost in

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handling Meridian s products. Management estimates rebate accruals based on historical statistics, current trends, and other factors. Changes to these rebate accruals are recorded in the period that they become known.

Life Science operating segment revenue for contract services may come from standalone arrangements for process development and/or optimization work (contract research and development services), or multiple-deliverable arrangements that include process development work followed by larger-scale manufacturing (contract manufacturing services). Revenue is recognized based on the nature of the arrangements, using the principles in EITF 00-21, *Revenue Arrangements with Multiple Deliverables*. Contract research and development services may be performed on a time and materials basis or fixed fee basis. For time and materials arrangements, revenue is recognized as services are performed. For fixed fee arrangements, revenue is recognized upon completion and acceptance by the customer. For contract manufacturing services, revenue is recognized upon delivery of product and acceptance by the customer.

#### Inventories

Meridian s inventories are carried at the lower of cost or market. Cost is determined on a first-in, first-out basis, except for certain inventories in the Viral Antigens business for which cost is determined on a last-in, first-out basis. Meridian establishes reserves against cost for excess and obsolete materials, finished goods whose shelf life may expire before sale to customers, and other identified exposures. Management estimates reserves based on assumptions about future demand and market conditions. If actual market conditions were less favorable than such estimates, additional inventory write-downs would be required and this would negatively affect gross profit margin and overall results of operations. Changes to inventory reserves are recorded in the period that they become known. For the Viral Antigens purchase business combination, Meridian elected to use last-in, first-out accounting for inventories for financial reporting purposes. Under last-in, first-out accounting, the stepped-up inventory value will be charged to earnings in periods in which inventory quantities decline below those on hand at the acquisition date. To date, inventory quantities have remained above levels on hand at the acquisition date.

#### Intangible Assets

Meridian s intangible assets include identifiable intangibles and goodwill. Identifiable intangibles include customer lists, supply agreements, manufacturing technologies, patents, licenses, and trade names. All of Meridian s identifiable intangibles have finite lives.

SFAS No. 142, *Goodwill and Other Intangible Assets* provides that goodwill and intangible assets with indefinite lives are subject to an annual impairment review (or more frequently if impairment indicators arise)

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by applying a fair-value based test. There have been no impairments from the analyses required by SFAS No. 142. Identifiable intangibles with finite lives are subject to impairment testing as prescribed by SFAS No. 144, *Accounting for the Impairment or Disposal of Long-lived Assets*. Pursuant to the provisions of SFAS No. 144, identifiable intangibles with finite lives are reviewed for impairment when events or circumstances indicate that such assets may not be recoverable at their current carrying value. Whether an event or circumstance triggers impairment is determined by comparing an estimate of the asset s undiscounted future cash flows to its carrying value. If impairment has occurred, it is measured by a fair-value based test. During fiscal 2006, Meridian determined that the carrying value of a supply contract related to the Life Science operating segment had become impaired and recorded such impairment in the amount of \$826,000 to general and administrative expenses. The contract provides for the supply of biological materials to the United States Department of Defense. Changes in the Department s Critical Reagents Program lowered the amount of materials to be supplied under the contract in future periods. There have been no events or circumstances indicating that the carrying value of other such assets may not be recoverable.

Meridian s ability to recover its intangible assets, both identifiable intangibles and goodwill, is dependent upon the future cash flows of the related acquired businesses and assets. The application of SFAS Nos. 142 and 144 requires management to make judgments and assumptions regarding future cash flows, including sales levels, gross profit margins, operating expense levels, working capital levels, and capital expenditures. With respect to identifiable intangibles, management also makes judgments and assumptions regarding useful lives.

Management considers the following factors in evaluating events and circumstances for possible impairment: (i) significant under-performance relative to historical or projected operating results, (ii) negative industry trends, (iii) sales levels of specific groups of products (related to specific identifiable intangibles), (iv) changes in overall business strategies and (v) other factors.

If actual cash flows are less favorable than projections, impairment of intangible assets could take place. If impairment were to occur, this would negatively affect overall results of operations.

#### Income Taxes

Pursuant to SFAS No. 109, *Accounting for Income Taxes*, Meridian s provision for income taxes includes federal, foreign, state, and local income taxes currently payable and those deferred because of temporary differences between income for financial reporting and income for tax purposes. Meridian prepares estimates of permanent and temporary differences between income for financial reporting purposes and income for tax purposes. These differences are adjusted to actual upon filing of Meridian s tax returns, typically occurring in the third and fourth quarters of the current fiscal year for the preceding fiscal year s estimates.

Meridian s deferred tax assets include net operating loss carryforwards in foreign jurisdictions. The realization of tax benefits related to net operating loss carryforwards is dependent upon the generation of future taxable

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income in the applicable jurisdictions. Management assesses the level of deferred tax asset valuation allowance by taking into consideration historical and future projected operating results, future reversals of taxable temporary differences, as well as tax planning strategies. The amount of net deferred tax assets considered realizable could be reduced in future years if estimates of future taxable income during the carryforward period are reduced. Undistributed earnings in Meridian s foreign subsidiaries are considered by management to be permanently re-invested in such subsidiaries. Consequently, US deferred tax liabilities on such earnings have not been recorded. Management believes that such US taxes would be largely offset by foreign tax credits for taxes paid in applicable foreign jurisdictions.

From time to time, Meridian s tax returns in federal, state, and foreign jurisdictions are examined by the applicable tax authorities. Meridian s tax provisions take into consideration the judgmental nature of certain tax positions through the establishment of reserves for differences between the probable tax determinations and the as filed tax positions of certain assets and liabilities. To the extent that tax benefits result from the completion of these examinations or the passing of statutes of limitation, they will affect tax liabilities in the period known. Meridian believes that the results of any tax authority examinations would not have a significant adverse impact on financial condition or results of operation.

## **Recent Accounting Pronouncements:**

See Note 1(q) to the Consolidated Financial Statements.

ITEM 7A.

#### **OUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

See Market Risk Exposure and Capital Resources under Item 7 above.

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# ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Consolidated Statements of Cash Flows for the years ended September 30, 2006, 2005 and 2004	45
Consolidated Balance Sheets as of September 30, 2006 and 2005	46
Consolidated Statements of Shareholders Equity for the years ended September 30, 2006, 2005 and 2004	48
Notes to Consolidated Financial Statements	49
Schedule No. II Valuation and Qualifying Accounts for the years ended September 30, 2006, 2005 and 2004  All other supplemental schedules are omitted due to the absence of conditions under which they are required or because the information is shown in the Consolidated Financial Statements or Notes thereto.  -37-	76

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## Management s Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f).

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

Under the supervision and with the participation of our management, including the Chief Executive Officer and the Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework and criteria in *Internal Control - Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on management s evaluation and those criteria, the Company concluded that its system of internal control over financial reporting was effective as of September 30, 2006.

Grant Thornton LLP, the independent registered public accounting firm that audited the consolidated financial statements as of and for the years ended September 30, 2006 and September 30, 2005, included in this Annual Report on Form 10-K, has issued an attestation report on management s assessment of the Company s internal control over financial reporting, which appears on pages 39-40.

/s/ William J. Motto

William J. Motto Chairman of the Board and Chief Executive Officer November 29, 2006

/s/ Melissa Lueke

Melissa Lueke Vice President and Chief Financial Officer November 29, 2006

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#### Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders of

Meridian Bioscience, Inc.

We have audited the accompanying consolidated balance sheets of Meridian Bioscience, Inc. (an Ohio Corporation) and subsidiaries as of September 30, 2006 and 2005, and the related consolidated statements of operations, shareholders equity, and cash flows for each of the two years in the period ended September 30, 2006. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Meridian Bioscience, Inc. and subsidiaries as of September 30, 2006 and 2005, and the results of their operations and their cash flows for each of the two years in the period ended September 30, 2006 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Meridian Bioscience, Inc. s internal control over financial reporting as of September 30, 2006, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated November 27, 2006 expressed an unqualified opinion on Management s assessment of the effectiveness of the Company s internal control over financial reporting and an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

Our audit was conducted for the purpose of forming an opinion on the consolidated financial statements taken as a whole. The accompanying Schedule II is presented for purposes of additional analysis and is not a required part of the basic financial statements. The information for each of the two years ended September 30, 2006 included in this schedule has been subjected to the auditing procedures applied in our audits of the basic financial statements as of September 30, 2006 and 2005 and for each of the two years in the period ended September 30, 2006 and, in our opinion, is fairly stated in all material respects in relation to the basic financial statements taken as a whole.

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As noted in Note 8, the Company adopted SFAS No. 123R, *Share-Based Payment*, effective July 1, 2005. /s/ Grant Thornton LLP Cincinnati, Ohio November 27, 2006

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## Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders of

Meridian Bioscience, Inc.

We have audited management s assessment, included in the accompanying Report of Management on Internal Control over Financial Reporting, that Meridian Bioscience, Inc. (an Ohio Corporation) and subsidiaries (the Company) maintained effective internal control over financial reporting as of September 30, 2006, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions. A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

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

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In our opinion, management s assessment that Meridian Bioscience, Inc. and subsidiaries maintained effective internal control over financial reporting as of September 30, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Meridian Bioscience, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of September 30, 2006, based on the COSO criteria.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Meridian Bioscience, Inc. and subsidiaries as of September 30, 2006 and 2005 and the related consolidated statements of operations, shareholders equity, and cash flows for each of the two years in the period ended September 30, 2006, and our report dated November 27, 2006 expressed an unqualified opinion on those financial statements.

/s/ Grant Thornton LLP Cincinnati, Ohio November 27, 2006

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## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Meridian Bioscience, Inc.:

In our opinion, the consolidated statements of operations, shareholders—equity and cash flows listed in the accompanying index present fairly, in all material respects, the results of operations and cash flows of Meridian Bioscience, Inc. and its subsidiaries for the year ended September 30, 2004, in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and financial statements schedule based on our audit. We conducted our audit of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Cincinnati, Ohio

November 12, 2004, except for Note 12, as to which the date is December 6, 2005

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# CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share data) Meridian Bioscience, Inc. and Subsidiaries

For the Year Ended September 30,	2006	2005	2004
Net Sales Cost of Sales	\$ 108,413 43,742	\$ 92,965 38,184	\$ 79,606 33,949
Gross Profit	64,671	54,781	45,657
Operating Expenses:			
Research and development	4,799	3,866	4,377
Selling and marketing	16,530	14,995	12,565
General and administrative	16,461	15,704	14,057
Total operating expenses	37,790	34,565	30,099
Operating Income	26,881	20,216	14,658
Other Income (Expense):			
Interest income	1,123	43	31
Interest expense	(128)	(770)	(1,557)
Other, net	177	107	63
Total other income (expense)	1,172	(620)	(1,463)
Earnings Before Income Taxes	28,053	19,596	13,195
Income Tax Provision	9,728	7,031	4,010
Net Earnings	\$ 18,325	\$ 12,565	\$ 9,185
Earnings Per Share Data:			
Basic earnings per common share	\$ 0.70	\$ 0.54	\$ 0.41
Diluted earnings per common share	0.68	0.52	\$ 0.40
Common shares used for basic earnings per common share	26,088	23,474	22,294
Effect of dilutive stock options	688	630	595
Common shares used for diluted earnings per common share	26,776	24,104	22,889
Dividends declared per common share	\$ 0.425	\$ 0.310	\$ 0.260
Anti-dilutive Securities:			

Common share options	21	1	218
Convertible debentures	186	253	1,532

All share and per share data has been adjusted for the three-for-two stock split that occurred on September 2, 2005. The accompanying notes are an integral part of these consolidated financial statements.

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# CONSOLIDATED STATEMENTS OF CASH FLOWS (dollars in thousands) Meridian Bioscience, Inc. and Subsidiaries

For the Year Ended September 30,	2006	2005	2004	
Cash Flows From Operating Activities				
Net earnings	\$ 18,325	\$12,565	\$ 9,185	
Non-cash items:				
Depreciation of property, plant and equipment	2,717	2,597	2,615	
Amortization of intangible assets and deferred issuance costs	2,572	1,655	1,462	
Deferred income taxes	42	(279)	506	
Stock compensation expense	1,082	279	126	
(Gain) loss on disposition of fixed assets	38	(7)	(37)	
Change in current assets, net of acquisition Change in current liabilities, net of acquisition	(3,133) 920	(991) 2,455	(3,370) 1,683	
Other, net	(408)	(87)	483	
Other, net	(400)	(07)	403	
Net cash provided by operating activities	22,155	18,187	12,653	
<b>Cash Flows From Investing Activities</b>				
Earnout payments	(1,494)	(678)	(456)	
Acquisitions of property, plant and equipment	(3,120)	(2,590)	(2,385)	
Proceeds from dispositions of property, plant and equipment	47	14	68	
Acquisition of OEM Concepts, Inc.		(6,383)		
Purchases of short-term investments	(6,000)			
Sales of short-term investments	2,000			
Other intangibles acquired	(122)	(10)	(270)	
Net cash used in investing activities	(8,689)	(9,647)	(3,043)	
Cash Flows From Financing Activities				
Net activity on revolving credit facility			(463)	
Issuance of debt obligations			930	
Repayment of debt obligations	<b>(790)</b>	(3,061)	(5,612)	
Debt issuance costs paid			(311)	
Dividends paid	(11,095)	(7,200)	(5,793)	
Proceeds and tax benefits from exercises of stock options	1,660	3,302	1,458	
Proceeds from issuance of common shares		29,925		
Common share issuance costs		(345)	(26)	
Other		(3)	(36)	
Net cash provided by (used in) financing activities	(10,225)	22,618	(9,827)	
Effect of Exchange Rate Changes on Cash and Equivalents	22	(56)	117	
Net Increase (Decrease) in Cash and Equivalents	3,263	31,102	(100)	
Cash and Equivalents at Beginning of Period	33,085	1,983	2,083	
Cash and Equivalents at End of Period	\$ 36,348	\$33,085	\$ 1,983	

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

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# **CONSOLIDATED BALANCE SHEETS (dollars in thousands)**

Meridian Bioscience, Inc. and Subsidiaries

As of September 30,	2006	2005
Assets		
Current Assets:		
Cash and equivalents	\$ 36,348	\$ 33,085
Short term investments	4,000	17.066
Accounts receivable, less allowances of \$408 in 2006 and \$360 in 2005	19,645	17,366
Inventories Pranaid expanses and other current assets	17,680 2,109	16,785 1,666
Prepaid expenses and other current assets  Deferred income taxes	2,109 1,387	1,000
Deferred income taxes	1,307	1,236
Total current assets	81,169	70,160
Property, Plant and Equipment, at Cost:		
Land	701	693
Buildings and improvements	15,963	15,510
Machinery, equipment and furniture	22,902	21,053
Construction in progress	870	433
Constitution in progress	0.70	
Subtotal	40,436	37,689
Less-accumulated depreciation and amortization	22,629	20,229
Net property, plant and equipment	17,807	17,460
Other Assets:		
Deferred debenture offering costs, net	106	164
Goodwill	9,864	8,779
Other intangible assets, net	10,816	13,249
Restricted cash	1,000	600
Other assets	193	157
Total other assets	21,979	22,949
Total assets	\$ 120,955	\$ 110,569
The accompanying notes are an integral part of these consolidated financial statements.  -46-		

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# CONSOLIDATED BALANCE SHEETS (dollars in thousands)

Meridian Bioscience, Inc. and Subsidiaries

As of September 30,	2006	2005
Liabilities and Shareholders Equity		
Current Liabilities: Current portion of long-term debt Accounts payable Accrued payroll costs Purchase business combination liability Other accrued expenses Income taxes payable	\$ 3,671 7,896 937 3,955 4,158	\$ 556 2,949 7,707 1,313 3,993 3,273
Total current liabilities	20,617	19,791
Long-term Obligations: Bank debt Convertible subordinated debentures  Deferred Income Taxes Commitments and Contingencies  Shareholders Equity: Preferred stock, no par value, 1,500,000 shares authorized, none issued Common shares, no par value, 50,000,000 shares authorized, 26,157,185 and 25,940,080 shares issued	1,803 3,758	233 2,451 4,326
Treasury stock, at cost, zero and 12,450 shares Additional paid-in capital Retained earnings Accumulated other comprehensive loss  Total shareholders equity  Total liabilities and shareholders equity	74,950 19,917 (90) 94,777 \$ 120,955	(32) 71,568 12,687 (455) 83,768 \$110,569
The accompanying notes are an integral part of these consolidated financial statements.  -47-		

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# **CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY** (Dollars and shares in thousands except per share data)

## Meridian Bioscience, Inc. and Subsidiaries

				Additional		Accumulat Other	ed	
	Common Shares	Shares Held in	Treasur	ryPaid-in	Retained	Compreher Income	ns <b>Øø</b> mpreher Income	sive
	Issued	Treasur	y Stock	Capital	Earnings	(Loss)	(Loss)	Total
Balance at September 30, 2003	22,094	(12)	\$ (32)	\$24,176	\$ 3,930	\$ (590)		\$27,484
Cash dividends paid \$0.26 per share Exercise of stock options,					(5,793)			(5,793)
net of tax Stock compensation	363			1,670				1,670
expense Cost of shelf registration				126				126
statement				(36)				(36)
Comprehensive income: Net earnings					9,185		\$ 9,185	9,185
Foreign currency translation adjustment						296	296	296
Comprehensive income							\$ 9,481	
Balance at September 30, 2004	22,457	(12)	(32)	25,936	7,322	(294)		32,932
Cash dividends paid \$0.31 per share Exercise of stock options,					(7,200)			(7,200)
net of tax Stock compensation	575			3,956				3,956
expense Debenture conversions	1,108			279 11,817				279 11,817
Common share offering,	1,800							
net Comprehensive income:	1,000			29,580	12.565		¢ 12 565	29,580
Net earnings Foreign currency					12,565		\$ 12,565	12,565
translation adjustment						(161)	(161)	(161)
Comprehensive income							\$ 12,404	

Balance at

**September 30, 2005** 25,940 (12) (32) 71,568 12,687 (455)