

MERIDIAN BIOSCIENCE INC

Form 10-Q

February 08, 2010

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**SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
Form 10-Q**

**þ QUARTERLY REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934  
For the Quarterly Period Ended December 31, 2009  
OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number 0-14902**

**MERIDIAN BIOSCIENCE, INC.**

Incorporated under the laws of Ohio

31-0888197

(I.R.S. Employer Identification No.)

3471 River Hills Drive

Cincinnati, Ohio 45244

(513) 271-3700

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

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☐ No ☐

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

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting  
company ☐

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

Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class

Outstanding January 31, 2010

Common Stock, no par value

40,604,296



**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES  
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*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 within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, 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 or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be*

*realized. 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. Recessionary pressures on the economy and the markets in which our customers operate, as well as adverse trends in buying patterns from customers can change expected results. 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 also 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. The Company cannot predict the possible effects of potential healthcare reform in the United States and similar initiatives in other countries on its results of operations. In addition to the factors described in this paragraph, Part I, Item 1A Risk Factors of our Form 10-K contains a list and description of uncertainties, risks and other matters that may affect the Company.*

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**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Operations (Unaudited)**  
(in thousands, except per share data)

<b>Three Months Ended December 31</b>	<b>2009</b>	<b>2008</b>
NET SALES	\$ 42,457	\$ 34,293
COST OF SALES	16,972	10,949
GROSS PROFIT	25,485	23,344
OPERATING EXPENSES		
Research and development	2,078	2,064
Selling and marketing	4,887	4,967
General and administrative	4,764	4,155
Total operating expenses	11,729	11,186
OPERATING INCOME	13,756	12,158
OTHER INCOME (EXPENSE)		
Interest income	31	262
Other, net	(118)	(148)
Total other income (expense)	(87)	114
EARNINGS BEFORE INCOME TAXES	13,669	12,272
INCOME TAX PROVISION	4,748	4,196
NET EARNINGS	\$ 8,921	\$ 8,076
BASIC EARNINGS PER COMMON SHARE	\$ 0.22	\$ 0.20
DILUTED EARNINGS PER COMMON SHARE	\$ 0.22	\$ 0.20
AVERAGE NUMBER OF COMMON SHARES OUTSTANDING BASIC	40,496	40,318
DILUTIVE COMMON SHARE OPTIONS	689	807
AVERAGE NUMBER OF COMMON SHARES OUTSTANDING DILUTED	41,185	41,125

ANTI-DILUTIVE SECURITIES:

Common share options	141	112
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DIVIDENDS DECLARED PER COMMON SHARE	\$ 0.17	\$ 0.14
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The accompanying notes are an integral part of these consolidated financial statements.

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**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Cash Flows (Unaudited)**  
**(dollars in thousands)**

<b>Three Months Ended December 31</b>	<b>2009</b>	<b>2008</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net earnings	\$ 8,921	\$ 8,076
Non-cash items:		
Depreciation of property, plant and equipment	762	731
Amortization of intangible assets	395	404
Stock based compensation	559	286
Deferred income taxes	(431)	(290)
Unrealized loss on auction-rate securities and rights, net	15	104
Change in accounts receivable, inventory, and prepaid expenses	6,194	(209)
Change in accounts payable, accrued expenses, and income taxes payable	(3,282)	(2,936)
Other	37	11
Net cash provided by operating activities	13,170	6,177
 <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisitions of property, plant and equipment	(880)	(618)
Purchases of short-term investments	(1,000)	
Proceeds from calls of auction-rate securities		425
Net cash used for investing activities	(1,880)	(193)
 <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Dividends paid	(6,885)	(5,644)
Proceeds and tax benefits from exercises of stock options	96	160
Other		(12)
Net cash used for financing activities	(6,789)	(5,496)
 Effect of Exchange Rate Changes on Cash and Equivalents	(71)	(24)
Net Increase in Cash and Equivalents	4,430	464
Cash and Equivalents at Beginning of Period	54,030	49,297
Cash and Equivalents at End of Period	\$ 58,460	\$ 49,761

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





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**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**  
**Consolidated Balance Sheets (Unaudited)**  
**(dollars in thousands)**  
**ASSETS**

	<b>December 31, 2009</b>	<b>September 30, 2009</b>
<b>CURRENT ASSETS:</b>		
Cash and equivalents	\$ 58,460	\$ 54,030
Short-term investments	8,270	7,285
Accounts receivable, less allowances of \$232 and \$247	17,854	26,981
Inventories	26,766	23,284
Prepaid expenses and other current assets	2,897	3,632
Deferred income taxes	1,904	1,935
 Total current assets	 116,151	 117,147
 <b>PROPERTY, PLANT AND EQUIPMENT:</b>		
Land	890	894
Buildings and improvements	19,720	19,718
Machinery, equipment and furniture	31,531	30,997
Construction in progress	1,811	1,586
 Subtotal	 53,952	 53,195
Less: accumulated depreciation and amortization	33,369	32,721
 Net property, plant and equipment	 20,583	 20,474
 <b>OTHER ASSETS:</b>		
Goodwill	9,866	9,866
Other intangible assets, net	6,922	7,317
Restricted cash	1,000	1,000
Other assets	201	193
 Total other assets	 17,989	 18,376
 <b>TOTAL ASSETS</b>	 <b>\$ 154,723</b>	 <b>\$ 155,997</b>

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



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**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**  
**Consolidated Balance Sheets (Unaudited)**  
**(dollars in thousands)**  
**LIABILITIES AND SHAREHOLDERS' EQUITY**

	<b>December 31, 2009</b>	<b>September 30, 2009</b>
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 5,705	\$ 6,901
Accrued employee compensation costs	3,869	5,338
Other accrued expenses	3,287	3,803
Income taxes payable	602	710
 Total current liabilities	 13,463	 16,752
 DEFERRED INCOME TAXES	 834	 1,340
 COMMITMENTS AND CONTINGENCIES		
 SHAREHOLDERS' EQUITY:		
Preferred stock, no par value, 1,000,000 shares authorized, none issued		
Common shares, no par value, 71,000,000 shares authorized, 40,597,121 and 40,493,313 shares issued, respectively		
Additional paid-in capital	92,321	91,668
Retained earnings	47,551	45,515
Accumulated other comprehensive income	554	722
 Total shareholders' equity	 140,426	 137,905
 TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	 \$ 154,723	 \$ 155,997

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

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**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**  
**Consolidated Statement of Changes in Shareholders' Equity (Unaudited)**  
**(dollars and shares in thousands)**

	Common Shares Issued	Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Comprehensive Income (Loss)	Total Shareholders' Equity
<b>Balance at September 30, 2009</b>	40,493	\$ 91,668	\$ 45,515	\$ 722		\$ 137,905
Cash dividends paid			(6,885)			(6,885)
Exercise of stock options	9	94				94
Issuance of restricted shares	95					
Stock based compensation		559				559
Comprehensive income:						
Net earnings			8,921		\$ 8,921	8,921
Other comprehensive income taxes				89	89	89
Foreign currency translation adjustment				(257)	(257)	(257)
Comprehensive income					\$ 8,753	
<b>Balance at December 31, 2009</b>	40,597	\$ 92,321	\$ 47,551	\$ 554		\$ 140,426

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

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**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**  
**Notes to Consolidated Financial Statements**  
**Dollars in Thousands, Except Per Share Amounts**  
**(Unaudited)**

**1. Basis of Presentation:**

The consolidated financial statements included herein have not been audited by an independent registered public accounting firm, but include all adjustments (consisting of normal recurring entries), which are, in the opinion of management, necessary for a fair presentation of the results for such periods.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to the requirements of the Securities and Exchange Commission. Meridian believes that the disclosures included in these financial statements are adequate to make the information not misleading.

It is suggested that these consolidated interim financial statements be read in conjunction with the consolidated annual financial statements and notes thereto, included in Meridian's Annual Report on Form 10-K for the Year Ended September 30, 2009.

The results of operations for interim periods are not necessarily indicative of the results to be expected for the year. Further, in connection with preparation of the condensed consolidated financial statements, we evaluated subsequent events after the balance sheet date of December 31, 2009 through January 31, 2010.

**2. Significant Accounting Policies:**

**(a) *Revenue Recognition and Accounts Receivable***

Revenue is generally recognized from sales 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. Management estimates accruals for rebate agreements based on historical statistics, current trends, and other factors. Changes to the accruals are recorded in the period that they become known. Our rebate accruals were \$5,933 at December 31, 2009 and \$4,776 at September 30, 2009.

Life Science revenue for contract services may come from standalone arrangements for process development and/or optimization work (contract research and development services) or custom manufacturing, or multiple-deliverable arrangements that include process development work followed by larger-scale manufacturing (both contract research and development services and contract manufacturing services). Revenue is recognized based on each of the multiple deliverables in a given arrangement having distinct and separate fair values. Fair values are determined via consistent pricing between standalone arrangements and multiple deliverable arrangements, as well as a competitive bidding process. 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 and billed. For fixed fee arrangements, revenue is recognized upon completion and acceptance by the customer. For contract manufacturing services, revenue is generally recognized upon delivery of product and acceptance by the customer. In some cases, customers may request that we store on their behalf clinical grade biologicals that we produce under contract manufacturing agreements. These cases arise when customers do not have clinical grade storage facilities or do not want to risk contamination during transport. For such cases, revenue may be recognized on a bill-and-hold basis pursuant to the satisfaction of criteria in SEC Staff Accounting Bulletins Nos. 101 and 104 related to bill-and-hold revenue recognition.

Trade accounts receivable are recorded in the accompanying consolidated balance sheet at invoiced amounts less provisions for rebates and doubtful accounts. The allowance for doubtful accounts represents our estimate of probable credit losses and is based on historical write-off experience. The allowance for doubtful accounts and related metrics, such as days sales outstanding, are reviewed monthly. Accounts with past due balances over 90 days are reviewed individually for collectibility. Customer invoices are charged off against the allowance when we believe it is probable that the invoices will not be paid.



**Table of Contents****(b) *Comprehensive Income (Loss)***

Our comprehensive income or loss is comprised of net earnings, foreign currency translation, changes in the fair value of forward exchange contracts accounted for as cash flow hedges (fiscal 2009 only), and changes in the fair value of available-for-sale (AFS) fixed income securities (fiscal 2009 only).

Assets and liabilities of foreign operations are translated using period-end exchange rates with gains or losses resulting from translation included in a separate component of accumulated other comprehensive income or loss. Revenues and expenses are translated using exchange rates prevailing during the period. We also recognize foreign currency transaction gains and losses on certain assets and liabilities that are denominated in the Euro currency. These gains and losses are included in other income and expense in the accompanying consolidated statements of operations. Comprehensive income for the interim periods was as follows:

	<b>Three Months Ended December 31,</b>	
	<b>2009</b>	<b>2008</b>
Net earnings	\$ 8,921	\$ 8,076
Hedging activity		(22)
Transfer of AFS securities to trading classification		270
Income taxes	89	(5)
Foreign currency translation adjustment	(257)	(234)
Comprehensive income	\$ 8,753	\$ 8,085

**(c) *Income Taxes***

The 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. We prepare 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 our tax returns, typically occurring in the third and fourth quarters of the current fiscal year for the preceding fiscal year's estimates.

We account for uncertain tax positions using a benefit recognition model with a two-step approach: (i) a more-likely-than-not recognition criterion and (ii) a measurement attribute that measures the position as the largest amount of tax benefit that is greater than 50% likely of being ultimately realized upon ultimate settlement. If it is not more likely than not that the benefit will be sustained on its technical merits, no benefit is recorded. We recognize accrued interest and penalties related to unrecognized tax benefits as a portion of our income tax provision in the consolidated statements of operations.

**(d) *Share-based Compensation***

We recognize compensation expense for all share-based awards made to employees based upon the fair value of the share-based award on the date of the grant.



**Table of Contents****(e) Cash, Cash Equivalents, and Investments**

Our investment portfolio includes the following components:

	<b>December 31, 2009</b>		<b>September 30, 2009</b>	
	<b>Cash and Equivalents</b>	<b>Other</b>	<b>Cash and Equivalents</b>	<b>Other</b>
Taxable investments				
Overnight repurchase agreements	\$ 11,936	\$	\$	\$
Money market funds	38,274		29,032	
Fixed-rate municipal note		1,000		
Tax-exempt investments				
Money market funds	151		10,383	
Student loan auction-rate securities and rights		7,270		7,285
Cash on hand				
Restricted		1,000		1,000
Unrestricted	8,099		14,615	
Total	\$ 58,460	\$ 9,270	\$ 54,030	\$ 8,285

Our investment portfolio includes student loan auction-rate securities, which are long-term student loan revenue bonds whose interest rates are reset every 35 days via a Dutch auction process. All of our auction-rate securities are backed by pools of student loans originated under the Federal Family Education Loan Program (FFELP). FFELP student loans are guaranteed by State guarantors who have reinsurance agreements with the US Department of Education. All of our student loan auction-rate securities were rated Aaa and AAA by Moody's and Standard & Poor's, respectively, at the time of purchase, and have continued to maintain these credit ratings through the present time.

The Dutch auction process historically provided the necessary liquidity mechanism to either purchase or sell these securities. Beginning in mid-February 2008, liquidity issues in the US credit markets resulted in the failure of auctions across a broad spectrum of tax-exempt securities, including student loan revenue bonds. Auctions for the student loan revenue bonds that we hold have continued to fail through the present time. The consequence of a failed auction is that we do not have access to the principal amount of our investments. Issuers are still required to make interest payments when due in the event of failed auctions. We have not experienced any missed interest payments to date.

Our auction-rate securities were purchased through UBS Financial Services, Inc. During November 2008, we accepted an offer from UBS, AG (UBS) of Auction Rate Security Rights. These rights permit us to require UBS between June 30, 2010 and July 2, 2012 (the exercise period) to purchase our auction-rate securities at par value. In exchange, UBS is granted the right, at their sole discretion, to sell or otherwise dispose of our auction-rate security investments until July 2, 2012 as long as we receive a payment of par value upon the sale or disposition. In addition, the rights permit us to establish a demand revolving credit line in an amount equal to the par value of the securities at a net no cost. We are still able to sell the auction-rate securities on our own, but in such a circumstance, we would lose the par value support from UBS. In February 2010, we notified UBS that we would be exercising our Auction Rate Security Rights effective June 30, 2010. Pursuant to the terms of the Auction Rate Security Rights, we expect to receive the par value of our auction-rate securities on July 1, 2010.

Upon executing the settlement agreement with UBS, we recognized the Auction Rate Security Rights as a stand-alone financial instrument and elected the fair value option. We also transferred the student loan auction-rate securities from the available-for-sale classification, to the trading classification. Adjustments to the fair value of student loan auction-rate securities and Auction Rate Security Rights are recorded to other income and expense in each accounting period. As of December 31, 2009, the fair value of the student-loan auction rate securities was \$6,682 compared to a par value of \$7,275. As of December 31, 2009, the fair value of the Auction Rate Security Rights was \$588. The

student loan auction-rate securities and Auction Rate Security Rights are included in current assets in the accompanying consolidated balance sheet based on the earliest exercise date of June 30, 2010.

**Table of Contents****(f) *Reclassifications***

Certain reclassifications have been made to the prior period financial statements to conform to the current fiscal period presentation.

**3. Inventories:**

Inventories are comprised of the following:

	<b>December 31, 2009</b>	<b>September 30, 2009</b>
Raw materials	\$ 6,120	\$ 6,079
Work-in-process	5,891	5,916
Finished goods	15,866	12,314
<b>Gross inventory</b>	<b>27,877</b>	<b>24,309</b>
Less: Reserves	(1,111)	(1,025)
<b>Net inventory</b>	<b>\$ 26,766</b>	<b>\$ 23,284</b>

**4. Major Customers and Segment Information:**

Meridian was formed in 1976 and functions as a fully integrated research, development, manufacturing, marketing and sales organization with primary emphasis in the field of life science. Our principal businesses are (i) the development, manufacture 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 under clinical cGMP conditions for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines.

Our 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 North America, South America and the Pacific Rim. The European Diagnostics operating segment consists of the sale and distribution of diagnostic test kits in Europe, Scandinavia, 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 the contract development and manufacture of cGMP clinical grade proteins and other biologicals for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines.

Two customers accounted for 68% and 59% of the US Diagnostics operating segment third-party sales during the three months ended December 31, 2009 and 2008, respectively. Two customers accounted for 34% and 32% of the Life Science operating segment third-party sales during the three months ended December 31, 2009 and 2008, respectively.

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Segment information for the interim periods is as follows:

	US Diagnostics	European Diagnostics	Life Science	Eliminations(1)	Total
<b>Three Months Ended December 31, 2009</b>					
Net sales					
Third-party	\$ 30,704	\$ 6,294	\$ 5,459	\$	\$ 42,457
Inter-segment	2,927	1	92	(3,020)	
Operating income	12,130	970	904	(248)	13,756
Total assets (December 31, 2009)	131,963	17,959	55,670	(50,869)	154,723
<b>Three Months Ended December 31, 2008</b>					
Net sales					
Third-party	\$ 23,485	\$ 5,671	\$ 5,137	\$	\$ 34,293
Inter-segment	2,488		188	(2,676)	
Operating income	10,387	850	847	74	12,158
Total assets (September 30, 2009)	131,587	18,220	55,592	(49,402)	155,997

(1) Eliminations consist of inter-segment transactions.

Transactions between operating segments are accounted for at established intercompany prices for internal and management purposes with all intercompany amounts eliminated in consolidation. Total assets for the US Diagnostics and Life Science operating segments include goodwill of \$1,381 and \$8,485, respectively, at December 31, 2009 and September 30, 2009.

**5. Intangible Assets:**

A summary of our acquired intangible assets subject to amortization, as of December 31, 2009 and September 30, 2009 is as follows:

	Wtd Avg Amort Period (Yrs)	December 31, 2009		September 30, 2009	
		Gross Carrying Value	Accumulated Amortization	Gross Carrying Value	Accumulated Amortization
Core products and cell lines	15	\$ 4,698	\$ 2,964	\$ 4,698	\$ 2,892
Manufacturing technologies	13	6,057	4,862	6,057	4,780
Trademarks, licenses and patents	7	2,772	2,013	2,772	1,974
Customer lists and supply agreements	11	11,038	7,804	11,040	7,604

\$ 24,565      \$ 17,643      \$ 24,567      \$ 17,250

The actual aggregate amortization expense for these intangible assets for the three months ended December 31, 2009 and 2008 was \$395 and \$404, respectively.

**Table of Contents****6. Hedging Transactions:**

Prior to February 1, 2009, we managed exchange rate risk related to forecasted intercompany sales denominated in the Euro currency through the use of forward exchange contracts and designated such forward contracts as cash flow hedges. As such, the effective portion of the gain or loss on the derivative instrument was reported as a component of other comprehensive income and reclassified into revenues in the Consolidated Statement of Operations in the same period or periods during which the hedged transaction affected earnings. As of December 31, 2009 and September 30, 2009, we had no such contracts outstanding.

The gain reclassified from accumulated other comprehensive income into income on the effective portion of these foreign exchange contracts was \$85 for the three months ended December 31, 2008. Gains and losses on the derivative instruments representing either hedge ineffectiveness or hedge components excluded from the assessment of effectiveness were recognized in current earnings. For the three months ended December 31, 2008, no portion of the gain was excluded from other comprehensive income due to effectiveness testing. All such forward contracts were recognized as either other assets or other accrued expenses at fair value in the consolidated balance sheet.

**7. Fair Value Measurements:**

We value certain financial assets and liabilities at fair value. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value hierarchy prioritizes inputs to valuation techniques used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities that are accessible at the measurement date for assets and liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly. These include quoted prices for identical or similar assets or liabilities in markets that are not active, that is, markets in which there are few transactions for the asset or liability, the prices are not current, or price quotations vary substantially either over time or among market makers, or in which little information is released publicly and inputs that are derived principally from or corroborated by observable market data by correlation or other means.

Level 3: Unobservable inputs, developed using the Company's estimates and assumptions, which reflect those that the market participants would use. Such inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

Determining where an asset or liability falls within the hierarchy depends on the lowest level input that is significant to the fair value measurement as a whole. In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in the assessment of fair value.

Financial assets and liabilities carried at fair value at December 31, 2009 and September 30, 2009 and are classified in the tables below into one of the three categories described above:

Balances as of December 31, 2009

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Money market funds	\$ 38,425	\$	\$	\$ 38,425
Student loan auction-rate securities			6,682	6,682
UBS Auction-Rate Security Rights			588	588
<b>Total</b>	<b>\$ 38,425</b>	<b>\$</b>	<b>\$ 7,270</b>	<b>\$ 45,695</b>

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Balances as of September 30, 2009

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Money market funds	\$ 39,415	\$	\$	\$ 39,415
Student loan auction-rate securities			6,708	6,708
UBS Auction-Rate Security Rights			577	577
<b>Total</b>	<b>\$ 39,415</b>	<b>\$</b>	<b>\$ 7,285</b>	<b>\$ 46,700</b>

The failed auction status and lack of liquidity for our student loan auction-rate securities and the non-transferability of our UBS Auction Rate Security Rights requires the use of a valuation methodology that relies exclusively on Level 3 inputs including market, tax status, credit quality, duration, recent market observations and overall capital market liquidity. The valuation of our student loan auction-rate securities and UBS Auction Rate Security Rights is subject to uncertainties that are difficult to predict. Factors that may impact the valuations include changes to credit ratings of the securities as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity. The following table provides a summary of changes in fair value of our auction-rate securities and UBS Auction Rate Security Rights for the three months ended December 31, 2009 and December 31, 2008.

	<b>Student loan auction-rate securities</b>	<b>UBS Auction Rate Security Rights</b>	<b>Total Level 3</b>
Balance at September 30, 2009	\$ 6,708	\$ 577	\$ 7,285
Unrealized gains (losses) included in current period earnings	(26)	11	(15)
<b>Total at December 31, 2009</b>	<b>\$ 6,682</b>	<b>\$ 588</b>	<b>\$ 7,270</b>

	<b>Student loan auction-rate securities</b>	<b>UBS Auction Rate Security Rights</b>	<b>Total Level 3</b>
Balance at September 30, 2008	\$ 7,480	\$	\$ 7,480
Acquire UBS Auction Rate Security Rights		660	660
Proceeds from redemptions of auction-rate securities	(425)		(425)
Unrealized losses included in current period earnings	(494)		(494)
<b>Total at December 31, 2008</b>	<b>\$ 6,561</b>	<b>\$ 660</b>	<b>\$ 7,221</b>

## ITEM 2. 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-Q. In the discussion that follows, all amounts are in thousands (both tables and text), except per share data.*

**Overview:**

Our consolidated sales increased 24% to \$42,457 for the first quarter of fiscal 2010. Sales growth was driven by Upper Respiratory volumes in our Diagnostic operating segments, volume growth in Foodborne and *H. pylori* products for our US Diagnostics operating segment, and improved growth in our Life Science operating segment. Sales of influenza products within our Upper Respiratory family comprised approximately 19% of consolidated sales. Sales of *C. difficile* products were down 20%+ for our Diagnostic operating segments as a result of distributor buying patterns in our US Diagnostics operating segment in fiscal 2009 and increased competition from new immunoassays and emerging molecular technologies. January sales of *C. difficile* products showed positive growth as the effects of distributor buying patterns from the first quarter of fiscal 2009 began to turn around. We expect that sales of *C. difficile* products will be flat until the launch of our *illumigene*<sup>TM</sup> molecular product later this fiscal year.



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Our consolidated gross profit, operating income and net earnings margins for the first quarter of fiscal 2010 reflect a drag caused by the effects of a higher mix of lower margin Upper Respiratory products and a lower mix of higher margin *C. difficile* products. Despite the mix of Upper Respiratory products, we continue to increase sales of our own manufactured influenza and respiratory syncytial virus products (TRU FLU® and TRU RSV®) for our US Diagnostics operating segment. Sales of these products were 44% of our total influenza and respiratory syncytial virus products for the first quarter of fiscal 2010 compared to approximately 25% for all of fiscal 2009. We expect this percentage to continue to increase, yielding continuing improvements in gross profit margins. Our TRU® format, with its sample tube and test device, offers better containment of the specimen sample compared to card-type devices. Customers continue to react positively to this feature.

### **Upper Respiratory Products**

The novel A (H1N1) influenza outbreak in the Northern hemisphere created an early start to the 2009-2010 influenza season that has continued into the first quarter of our fiscal 2010. For our US Diagnostics operating segment, sales of influenza products comprised 24% of total sales for the first quarter of fiscal 2010. We believe that our US distributors have stocked inventories of influenza products in anticipation of further outbreaks over the coming months.

The novel A (H1N1) influenza pandemic also created an increased interest in influenza testing in European markets where rapid testing has not been traditionally performed, resulting in sales growth of approximately 75% in this operating segment on an organic basis (excluding currency) for the first quarter of fiscal 2010 for this product family.

We expect influenza product sales to moderate somewhat during the remainder of our fiscal year, in light of current inventory levels at our US distributors and expectations of lighter novel A (H1N1) influenza activity as we emerge from the pandemic. To put this in some perspective, sales of influenza products accounted for 14% of the total sales of our US Diagnostics operating segment for all of fiscal 2009, compared to 24% for the first quarter of fiscal 2010.

During the first quarter of fiscal 2010, we also saw significant sales growth in our US Diagnostics export area for both influenza and mycoplasma.

### **Foodborne Products**

During the first quarter of fiscal 2010, sales of our Foodborne products grew 40%+ for our US Diagnostics operating segment and 20% for our European Diagnostics operating segment on an organic basis. We continue to see significant volume growth coming from new products launched over the last few fiscal years (ImmunoCard STAT!® EHEC launched in fiscal 2007, and Premier™ CAMPY and ImmunoCard STAT!® CAMPY launched in fiscal 2009). This disease family is expected to continue to generate significant sales growth in fiscal 2010.

### **C. difficile Products**

Sales of *C. difficile* products for our US Diagnostics operating segment were impacted by distributor buying patterns during the first quarter of fiscal 2009, where one of our distributors stocked higher than normal inventory levels in advance of our January 1<sup>st</sup> price increase. This distributor did not stock higher than normal inventory levels for our *C. difficile* products during the current quarter.

The *C. difficile* market also continues to experience considerable confusion around the relative benefits of the various test methods available (toxin testing, antigen testing and molecular testing). Several new competitive products, including molecular assays, have been introduced into this market, causing competitive pressures for our products. These competitive factors resulted in significant sales declines in both of our Diagnostic operating segments.

We expect to combat the competitive pressures in this disease family with our strong position in toxin testing and the launch of our *illumigene*™ molecular *C. difficile* product. Our new molecular test for *C. difficile* on our *illumigene*™ platform is currently in clinical trials. We are targeting revenue contributions from the launch of this technology later this fiscal year.

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**H. pylori Products**

During the first quarter of fiscal 2010, sales of our *H. pylori* products grew 30%+ for our US Diagnostics operating segment and 3% for our European Diagnostics operating segment on an organic basis. Although the sales growth rate for our US Diagnostics operating segment reflects a level of buying pattern difference in our national reference lab customer base, our partnerships with managed care companies in promoting the health and economic benefits of a test and treat strategy is beginning to move physician behavior away from serology-based testing to direct antigen testing.

**Life Science**

Sales for our Life Science operating segment increased 6% for the first quarter of fiscal 2010. This increase reflects growth from our two largest diagnostic manufacturing customers, as well as growth in contract research and development work and contract manufacturing work in our cGMP clinical facilities. We expect high single-digit growth for this operating segment during the remainder of fiscal 2010.

**Significant Customers**

Two national distributors in our US Diagnostics operating segment accounted for 68% and 59% of total sales for this operating segment for the first quarter of fiscal 2010 and 2009, respectively. The higher percentage of sales during the first quarter of fiscal 2010 reflects inventory stocking of influenza and other products for these national distributors.

Two diagnostic manufacturing customers in our Life Science operating segment accounted for 34% and 32% of total sales for this operating segment for the first quarters of fiscal 2010 and 2009, respectively.

**Foreign Currency**

Sales growth for our European Diagnostics operating segment included currency translation gains in the amount of approximately \$600 for the first quarter of fiscal 2010. Sales for this operating segment were flat on an organic basis for the first quarter of fiscal 2010.

**Operating Segment Revenues**

Our 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 North America, South America and the Pacific Rim. The European Diagnostics operating segment consists of the sale and distribution of diagnostic test kits in Europe, Scandinavia, 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 the contract development and manufacture of cGMP clinical grade proteins and other biologicals for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines.

Revenues for the Diagnostics operating segments, in the normal course of business, may be affected from quarter to quarter by buying patterns of major distributors, seasonality and strength of certain diseases and foreign currency exchange rates. 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 and bulk antigens and antibodies, as well as buying patterns of major customers.

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Revenues for our each of our operating segments are shown below.

	Three Months Ended December 31		
	2009	2008	Inc (Dec)
US Diagnostics	\$ 30,704	\$ 23,485	+31%
European Diagnostics	6,294	5,671	+11%
Life Science	5,459	5,137	+6%
Consolidated	\$ 42,457	\$ 34,293	+24%
International			
US Export	\$ 1,729	\$ 1,099	+57%
Life Science Export	2,460	2,369	+4%
European Diagnostics	6,294	5,671	+11%
Total	\$ 10,483	\$ 9,139	+15%
% of total sales	25%	27%	

**Gross Profit**

	Three Months Ended December 31,		
	2009	2008	Inc (Dec)
Gross Profit	\$ 25,485	\$ 23,344	+9%
Gross Profit Margin	60%	68%	-8 points%

Gross profit margin for the first quarter of fiscal 2010 reflects a drag of approximately seven points related to the strong mix of Upper Respiratory sales. As we move forward, we expect that our internally developed and manufactured TRU FLU® and TRU RSV® products will improve overall gross profit margins for the Upper Respiratory product family, as these products now contribute in excess of 40% of total influenza and respiratory syncytial virus product sales for our US Diagnostics operating segment.

Our 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, 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.

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	<b>Research &amp; Development</b>	<b>Sales &amp; Marketing</b>	<b>General &amp; Administrative</b>	<b>Total Operating Expenses</b>
Q1 2009 Expenses	\$ 2,064	\$ 4,967	\$ 4,155	\$ 11,186
% of Sales	6%	14%	12%	33%
Fiscal 2010 Increases (Decreases):				
US Diagnostics	(105)	(6)	613	502
European Diagnostics		(32)	37	5
Life Science	119	(42)	(41)	36
Q1 2010 Expenses	\$ 2,078	\$ 4,887	\$ 4,764	\$ 11,729
% of Sales	5%	12%	11%	28%
% Increase (Decrease)	1%	-2%	15%	5%

We continue to closely control spending for each of our operating segments. For our US Diagnostics operating segment, we have continued to invest in the development of our *illumigene*<sup>TM</sup> molecular platform, and our first product, *C. difficile*, is currently in clinical trials. The increase in general and administrative expenses for our US Diagnostics operating segment includes stock based compensation costs related to a time-vested restricted stock grant in November 2009. This grant has four-year cliff vesting provisions.

**Operating Income**

Operating income increased 13% to \$13,756 for the first quarter of fiscal 2010, as a result of the factors discussed above.

**Other Income and Expense**

Interest income decreased 88% during for the first quarter of fiscal 2010 compared to the first quarter of fiscal 2009. This decrease was driven by lower interest yields due to a higher concentration of investments in money market funds in fiscal 2010 and lower interest rates in the current interest rate environment.

**Income Taxes**

The effective rate for income taxes was 35% for the first quarter of fiscal 2010 compared to 34% for the first quarter of fiscal 2009. For the fiscal year ending September 30, 2010, Meridian expects the effective tax rate to be approximately 35%.

**Liquidity and Capital Resources****Comparative Cash Flow Analysis**

Our cash flow and financing requirements are determined by analyses of operating and capital spending budgets, consideration of acquisition plans, and consideration of common share dividends. We have historically maintained a credit facility to augment working capital requirements and to respond quickly to acquisition opportunities. This credit facility has been supplemented by the proceeds from a September 2005 common share offering, which are invested in overnight repurchase agreements, institutional money-market mutual funds, municipal debt obligations and tax-exempt auction-rate securities.

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We have an investment policy that guides the holdings of our investment portfolio. Our objectives in managing the investment portfolio are to (i) preserve capital, (ii) provide sufficient liquidity to meet working capital requirements and fund strategic objectives such as acquisitions, and (iii) capture a market rate of return commensurate with market conditions and our policy's investment eligibility criteria. As a result of conditions in the financial markets, we have chosen to keep the maturity of our investment portfolio very short. As we look forward, we will continue to manage the holdings of our investment portfolio with preservation of capital being the primary objective.

Except as otherwise described herein, we do not expect current conditions in the financial markets, or overall economic conditions to have a significant impact on our liquidity needs, financial condition, or results of operations. We intend to continue to fund our working capital requirements and dividends from current cash flows from operating activities. We also have additional sources of liquidity through our investment portfolio and a \$30,000 bank credit facility, if needed. To date, we have not experienced any significant deterioration in the aging of our customer accounts receivable nor in our vendors' ability to supply raw materials and services and extend normal credit terms. Our liquidity needs may change if overall economic conditions worsen and/or liquidity and credit within the financial markets remains tight for an extended period of time, and such conditions impact the collectability of our customer accounts receivable, or impact credit terms with our vendors, or disrupt the supply of raw materials and services.

Net cash provided by operating activities increased 113% for the first quarter of fiscal 2010 to \$13,170. This increase was primarily attributable to higher earnings levels and improved net working capital changes. Net cash flows from operating activities are anticipated to be adequate to fund working capital requirements, capital expenditures and dividends during the next 12 months.

***Capital Resources***

We have a \$30,000 credit facility with a commercial bank which expires on September 15, 2012. As of January 31, 2010, there were no borrowings outstanding on this facility and we had 100% borrowing capacity available to us. We have had no borrowings outstanding under this facility during the first three months of fiscal 2010, or during the full year of fiscal 2009.

Our capital expenditures are estimated to be approximately \$5,000 for fiscal 2010 and may be funded with operating cash flows, availability under the \$30,000 credit facility, or cash and investments on-hand. Capital expenditures relate to manufacturing and other equipment of a normal and recurring nature, as well as the build out of the recently purchased property in the Village of Newtown, Ohio.

We do not utilize any special-purpose financing vehicles or have any undisclosed off balance sheet arrangements.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

There have been no material changes in the Company's exposure to market risk since September 30, 2009.

**ITEM 4. CONTROLS AND PROCEDURES**

As of December 31, 2009, an evaluation was completed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(b) and 15d-15(b) promulgated under the Securities Exchange Act of 1934, as amended. Based on that evaluation, our management, including the CEO and CFO, concluded that our disclosure controls and procedures were effective as of December 31, 2009. There have been no changes in our internal control over financial reporting identified in connection with the evaluation of internal control that occurred during the first fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, or in other factors that could materially affect internal control subsequent to December 31, 2009.

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**PART II. OTHER INFORMATION**

**ITEM 1A. RISK FACTORS**

There have been no material changes from risk factors as previously disclosed in the Registrant's Form 10-K in response to Item 1A to Part I of Form 10-K.

**ITEM 6. EXHIBITS**

- 31.1 Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a)
- 31.2 Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a)
- 32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**MERIDIAN BIOSCIENCE, INC.**

Date: February 8, 2010

/s/ Melissa Lueke  
Melissa Lueke  
Executive Vice President and Chief  
Financial Officer

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