

MERIDIAN BIOSCIENCE INC

Form 10-Q

February 11, 2008

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

**☐ QUARTERLY REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934  
For the Quarterly Period Ended December 31, 2007**

**OR**

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

**For the transition period from to  
Commission file number 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 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 ○ Accelerated filer ☐ Non-accelerated filer ○

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, 2008
Common Stock, no par value	40,079,848

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

<b>Three Months Ended December 31</b>	<b>2007</b>	<b>2006</b>
NET SALES	\$33,847	\$28,720
COST OF SALES	12,095	11,108
GROSS PROFIT	21,752	17,612
OPERATING EXPENSES:		
Research and development	1,536	1,315
Selling and marketing	4,690	4,195
General and administrative	4,333	4,044
Total operating expenses	10,559	9,554
OPERATING INCOME	11,193	8,058
OTHER INCOME (EXPENSE):		
Interest income	455	395
Interest expense		(30)
Other, net	(80)	64
Total other income (expense)	375	429
EARNINGS BEFORE INCOME TAXES	11,568	8,487
INCOME TAX PROVISION	4,112	2,914
NET EARNINGS	\$ 7,456	\$ 5,573
BASIC EARNINGS PER COMMON SHARE	\$ 0.19	\$ 0.14
DILUTED EARNINGS PER COMMON SHARE	\$ 0.18	\$ 0.14
AVERAGE NUMBER OF COMMON SHARES OUTSTANDING BASIC	39,910	39,284
DILUTIVE COMMON SHARE OPTIONS	1,057	956

AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	DILUTED	40,967	40,240
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ANTI-DILUTIVE SECURITIES:

Common share options	2	158
Shares from convertible debentures		231

DIVIDENDS DECLARED PER COMMON SHARE	\$ 0.11	\$ 0.08
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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>2007</b>	<b>2006</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net earnings	\$ 7,456	\$ 5,573
Non-cash items:		
Depreciation of property, plant and equipment	705	684
Amortization of intangible assets and deferred costs	426	409
Stock based compensation	273	423
Deferred income taxes	(188)	215
Loss on disposition of fixed assets		2
Change in accounts receivable, inventory, and prepaid expenses	1,863	347
Change in accounts payable, accrued expenses, and income taxes payable	(1,808)	(2,918)
Other	(177)	(132)
Net cash provided by operating activities	8,550	4,603
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisitions of property, plant and equipment	(736)	(364)
Acquisitions of license agreements		(265)
Proceeds from sales of short-term investments		4,000
Purchase of short-term investments	(5,000)	
Net cash provided by (used for) investing activities	(5,736)	3,371
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Dividends paid	(4,392)	(3,015)
Proceeds and tax benefits from exercise of stock options	598	922
Net cash used for financing activities	(3,794)	(2,093)
Effect of Exchange Rate Changes on Cash and Equivalents	90	35
Net Increase (Decrease) in Cash and Equivalents	(890)	5,916
Cash and Equivalents at Beginning of Period	49,400	36,348
Cash and Equivalents at End of Period	\$48,510	\$42,264

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, 2007</b>	<b>September 30, 2007</b>
<b>CURRENT ASSETS:</b>		
Cash and equivalents	\$ 48,510	\$ 49,400
Short term investments	5,000	
Accounts receivable, less allowances of \$223 and \$258	19,424	22,651
Inventories	20,042	18,171
Prepaid expenses and other current assets	1,971	2,147
Deferred income taxes	1,485	1,376
Total current assets	96,432	93,745
<b>PROPERTY, PLANT AND EQUIPMENT:</b>		
Land	895	890
Buildings and improvements	16,967	16,907
Machinery, equipment and furniture	25,090	24,619
Construction in progress	1,440	1,290
Subtotal	44,392	43,706
Less: accumulated depreciation and amortization	26,032	25,395
Net property, plant and equipment	18,360	18,311
<b>OTHER ASSETS:</b>		
Goodwill	9,965	9,964
Other intangible assets, net	9,032	9,457
Restricted cash	1,000	1,000
Other assets	222	221
Total other assets	20,219	20,642
<b>TOTAL ASSETS</b>	<b>\$ 135,011</b>	<b>\$ 132,698</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

	December 31, 2007	September 30, 2007
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 4,374	\$ 4,704
Accrued payroll costs	4,116	7,541
Purchase business combination liability	153	152
Other accrued expenses	4,545	4,008
Income taxes payable	2,436	662
Total current liabilities	15,624	17,067
DEFERRED INCOME TAXES	2,611	2,683
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>SHAREHOLDERS EQUITY:</b>		
Preferred stock, no par value, 1,000,000 shares authorized, none issued		
Common shares, no par value, 71,000,000 shares authorized, 39,969,556 and 39,847,391 shares issued, respectively		
Additional paid-in capital	83,146	82,209
Retained earnings	33,134	30,375
Accumulated other comprehensive income	496	364
Total shareholders equity	116,776	112,948
<b>TOTAL LIABILITIES AND SHAREHOLDERS EQUITY</b>	<b>\$135,011</b>	<b>\$132,698</b>

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, 2007</b>	39,847	\$ 82,209	\$ 30,375	\$ 364		\$ 112,948
Adoption of FASB Interpretation No. 48			(305)			(305)
Dividends paid			(4,392)			(4,392)
Exercise of stock options, net of tax	122	664				664
Stock based compensation		273				273
Comprehensive income:						
Net earnings			7,456		\$ 7,456	7,456
Hedging activity				(75)	(75)	(75)
Other comprehensive income taxes				(74)	(74)	(74)
Foreign currency translation adjustment				281	281	281
Comprehensive income					\$ 7,588	
<b>Balance at December 31, 2007</b>	39,969	\$ 83,146	\$ 33,134	\$ 496		\$ 116,776

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**  
**(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, 2007.

The results of operations for the interim periods are not necessarily indicative of the results to be expected for the year.

**2. Significant Accounting Policies:**

***(a) Revenue Recognition***

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. We estimate 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 \$4,300,000 at December 31, 2007 and \$2,415,000 at September 30, 2007.

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 the nature of the arrangements, using the principles in EITF 00-21, *Revenue Arrangements with Multiple Deliverables*. The framework in EITF 00-21 is 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

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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.

**(b) Comprehensive Income**

Comprehensive income represents the net change in shareholders' equity during a period from sources other than transactions with shareholders. Our comprehensive income is comprised of net earnings, foreign currency translation, and changes in the fair value of forward exchange contracts accounted for as cash flow hedges.

Assets and liabilities of foreign operations are translated using period-end exchange rates with gains or losses resulting from translation included in 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 (in thousands):

	<b>Three Months Ended December 31,</b>	
	<b>2007</b>	<b>2006</b>
Net earnings	\$7,456	\$5,573
Hedging activity	(75)	(39)
Income taxes	(74)	(84)
Foreign currency translation adjustment	281	275
Comprehensive income	\$7,588	\$5,725

**(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 which are adjusted to actual upon filing of our tax returns, which typically occurs in the third and fourth quarters of the current fiscal year for the preceding fiscal year's estimates.

On October 1, 2007, we adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure of uncertain tax positions, assuming full knowledge of all relevant facts by the applicable tax authorities. The cumulative effect of adopting FIN 48, \$305,000, was charged to opening retained earnings. As of October 1, 2007, Meridian's liability for uncertain tax positions was \$856,000, including estimated penalties and interest. Meridian's liability for uncertain

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tax positions was increased to \$891,000 as of December 31, 2007, related to activity during the first quarter of fiscal 2008. This liability is included in current income taxes payable in the accompanying consolidated balance sheet. Penalties and interest are a component of the income tax provision. The full amount of \$891,000 would favorably affect our effective tax rate if recognized. The amount of Meridian's liability for uncertain tax positions expected to be paid or settled in the next 12 months is uncertain.

We are subject to examination by the tax authorities in the US (both federal and state) and the countries of Belgium, France, Holland and Italy. In the US, open tax years are for fiscal 2004 and forward. We are currently under examination by the IRS for fiscal 2006. This audit is expected to be completed during fiscal 2008. In countries outside the US, open tax years generally range from fiscal 2002 and forward. However, in Belgium, the utilization of local net operating loss carryforwards extends the statute of limitations for examination well into the foreseeable future.

***(d) Stock-based Compensation***

We account for stock-based compensation pursuant to SFAS No. 123R, *Share-Based Payment*. SFAS No. 123R requires recognition of compensation expense for all share-based awards made to employees and outside directors, based upon the fair value of the share-based award on the date of the grant.

***(e) Cash equivalents***

We consider short-term investments with original maturities of 90 days or less, including overnight repurchase agreements, investments in municipal variable rate demand notes that have a seven-day put feature and institutional money market funds to be cash equivalents.

***(f) Short-term investments***

Auction-rate securities are classified as short-term investments in the consolidated balance sheets and are accounted for as available-for-sale securities under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. As such, unrealized holding gains and losses are reported as a component of other comprehensive income until realized. The carrying value of these securities was equal to their fair value as of December 31, 2007. We did not hold any auction-rate securities at September 30, 2007.

***(g) Derivative financial instruments***

We account for foreign currency forward exchange contracts 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 accumulated other comprehensive income or loss 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. Cash flows from our hedging instruments are classified in Operating

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Activities, consistent with cash flows from the related items being hedged. See Note 6.

***(h) Reclassifications***

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

***(i) New Accounting Pronouncements***

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141(R), *Business Combinations*, as part of a joint project with the International Accounting Standards Board. Statement 141(R) provides for several significant changes to existing accounting practices for business combinations. Most notably, (i) acquisition-related transaction costs such as legal and professional fees, shall be expensed rather than accounted for as part of the acquisition cost; (ii) acquired in-process research and development shall be capitalized rather than expensed at the acquisition date; and (iii) contingent consideration shall be recorded at fair value at the acquisition date rather than the points in time that payment becomes probable. Statement 141(R) is effective for fiscal years beginning after December 15, 2008. Thus, for Meridian, it will affect any acquisitions after October 1, 2009.

**3. Inventories:**

Inventories are comprised of the following (in thousands):

	December 31, 2007	September 30, 2007
Raw materials	\$ 6,112	\$ 4,816
Work-in-process	4,536	5,141
Finished goods	9,394	8,214
	\$ 20,042	\$ 18,171

Effective July 1, 2007, we changed our method of accounting for certain inventories from the LIFO method to the FIFO method, so that substantially all of our inventories are reflected at the lower of cost or market with cost determined by the FIFO method. We changed to the FIFO method for these inventories because: it conformed substantially all of our worldwide inventories to a consistent basis of accounting; and it provides better comparability to our industry peers, many of whom use the FIFO method of accounting for inventories. In accordance with Statement of Financial Accounting Standards ( SFAS ) No. 154, *Accounting Changes and Error Corrections*, this change in accounting has been retrospectively applied to the three-month period ended December 31, 2006. The effect of this change was to increase gross profit and net earnings by \$15,000 and \$9,000, respectively.

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

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 the US and countries outside of Europe, Africa

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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; 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 60% and 57% of the US Diagnostics operating segment third-party sales during the three months ended December 31, 2007 and 2006, respectively. One customer accounted for 40% and 26% of the Life Science operating segment third-party sales during the three months ended December 31, 2007 and 2006, respectively. Segment information for the interim periods is as follows (in thousands):

	US Diagnostics	European Diagnostics	Life Science	Eliminations <sup>(1)</sup>	Total
<b>Three Months December 31, 2007</b>					
Net sales-					
Third-party	\$ 22,219	\$ 6,099	\$ 5,529	\$	\$ 33,847
Inter-segment	2,300		142	(2,442)	
Operating income	8,936	1,159	991	107	11,193
Total assets (December 31, 2007)	117,657	14,852	46,256	(43,754)	135,011
<b>Three Months December 31, 2006</b>					
Net sales-					
Third-party	\$ 18,954	\$ 5,255	\$ 4,511	\$	\$ 28,720
Inter-segment	2,220		269	(2,489)	
Operating income	7,091	976	34	(43)	8,058
Total assets (September 30, 2007)	115,297	13,600	45,410	(41,609)	132,698

(1) Eliminations consist of intersegment 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 \$1,492,000 and \$8,473,000, respectively, at December 31, 2007, and \$1,492,000 and \$8,472,000, respectively, at September 30, 2007.

**Table of Contents****5. Intangible Assets:**

A summary of our acquired intangible assets subject to amortization, as of December 31, 2007 and September 30, 2007 is as follows (in thousands):

	Wtd Avg Amort  Period (Yrs)	December 31, 2007		September 30, 2007	
		Gross	Accumulated	Gross	Accumulated
		Carrying Value	Amortization	Carrying Value	Amortization
Core products and cell lines	15	\$ 4,698	\$ 2,385	\$ 4,698	\$ 2,313
Manufacturing technologies	15	5,907	4,178	5,907	4,089
Trademarks, licenses and patents	12	2,270	1,730	2,270	1,694
Customer lists and supply agreements	13	10,644	6,194	10,641	5,963
		\$23,519	\$14,487	\$23,516	\$14,059

The actual aggregate amortization expense for these intangible assets for the three months ended December 31, 2007 and 2006 was \$426,000 and \$407,000, respectively.

**6. Hedging Transactions:**

We designate forward exchange contracts as cash flow hedges under SFAS No. 133. The purpose of these contracts is to hedge cash flows related to forecasted intercompany sales denominated in the Euro currency.

The following table presents our hedging portfolio as of December 31, 2007 (in thousands).

Notional Amount	Contract Value	Estimated Fair Value	Average Exchange Rate	Maturity
3,600	\$4,958	\$ 5,252	1.3772	FY 2008
900	\$1,289	\$ 1,309	1.4322	FY 2009

At December 31 2007, \$346,000 of unrealized losses were included in accumulated other comprehensive income in the consolidated balance sheet, compared to unrealized losses of \$270,000 at September 30, 2007. This amount is expected to be reclassified into net earnings during the next 12 months. The estimated fair value of forward contracts outstanding at December 31, 2007 and September 30, 2007 is based on quoted amounts provided by the counterparties to these contracts.

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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.

**Overview:**

For the first quarter of fiscal 2008, we continued our consistency in delivering double-digit sales and earnings growth. Our diagnostics operating segments continue to provide the largest share of consolidated revenues, 84%, for both the first quarter of fiscal 2008 and 2007.

Our sales growth continues to be organic and driven by new diagnostic products, market expansions, increased market share in targeted disease states, and volume increases for antibodies, antigens and reagents supplied to large diagnostic manufacturing companies. During the first quarter of fiscal 2008, we received FDA clearance to begin marketing and distributing Influenza and Respiratory Syncytial Virus tests using our proprietary TRU<sup>®</sup> rapid test technology that improves laboratory technician safety and reduces laboratory testing space requirements. These products are expected to improve gross profit margins for our upper respiratory diagnostic products in the latter half of fiscal 2008 and into fiscal 2009 as certain existing upper respiratory products sold by us are manufactured by an outside vendor.

ImmunoCard STAT!<sup>®</sup> EHEC, a rapid test developed in collaboration with Merck for detection of toxin-producing *E. coli* in patients that may have ingested contaminated produce or meat products, was launched in fiscal 2007 and continues to contribute to significant growth in fiscal 2008 to date. We expect to launch two Epstein-Barr virus (Mononucleosis) tests using our proprietary TRU<sup>®</sup> rapid test technology later this fiscal year.

Besides these new diagnostic products, we continue to see growth in the *C. difficile* and *H. pylori* testing markets where we hold market leadership positions. The *C. difficile* market has expanded as testing increases due to more virulent strains of this toxin and heightened focus by hospitals on this dangerous pathogen. New AGA guidelines are creating increased focus on direct antigen testing for *H. pylori* as this infection is a known cause of ulcers. Our line of patented *H. pylori* products includes both rapid and batch method noninvasive direct testing formats.

Finally, buying patterns of one of our major distributors of diagnostic products in the US and one of our major diagnostic manufacturer customers in our Life Science operating segment also contributed to the volume increases during the first quarter of fiscal 2008. These buying patterns resulted in a favorable sales mix that was more heavily weighted towards higher margin rapid diagnostic tests and bulk antigens and reagents for these customers. This sales mix led to the overall gross profit margin of 64% for the first quarter of fiscal 2008.

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**Operating Segments:**

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 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; 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. We believe that the overall breadth of our product lines serve to reduce the variability in consolidated sales from quarter to quarter.

**Results of Operations:**

***Three Months Ended December 31, 2007 Compared to Three Months Ended December 31, 2006***

*Net sales*

Overall, net sales increased 18% to \$33,847,000 for the first quarter of fiscal 2008 compared to the first quarter of fiscal 2007. Net sales for the US Diagnostics operating segment increased \$3,265,000, or 17%, for the European Diagnostics operating segment increased \$844,000, or 16%, and for the Life Science operating segment increased \$1,018,000, or 23%.

For the US Diagnostics operating segment, the sales growth was primarily related to volume increases across *C. difficile* products, *H. pylori* products, and food borne products. Volume increases for *C. difficile* products were driven by market share growth and buying patterns of one national distributor. Volume increases for *H. pylori* products continue to be driven by increased managed care efforts and issuance of AGA guidelines recommending direct testing. Volume increases for food borne products were driven by the fiscal 2007 launch of ImmunoCard STAT!<sup>®</sup> EHEC. Two national distributors accounted for 60% and 57% of total sales for the US Diagnostics operating segment for the first quarters of fiscal 2008 and 2007, respectively.

For the European Diagnostics operating segment, the sales increase includes currency translation gains in the amount of \$670,000. Sales in local currency increased 3% for the first quarter of fiscal 2008. The increase in local currency was primarily driven by volume growth in *C. difficile* and *H. pylori* products.

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For the Life Science operating segment, sales growth for the quarter was driven by buying patterns from one diagnostic manufacturing customer for whom we supply bulk viral antigens and assay reagents. Sales to this customer accounted for 40% and 26% of total Life Science operating segment sales for the first quarters of fiscal 2008 and 2007, respectively. This customer recently reduced their forecasted antigen requirements due to their internal inventory management initiatives and their market factors. We believe the impact during calendar 2008 could be a reduction of revenue of up to \$1.8 million. This matter does not affect our fiscal 2008 guidance regarding expectations for net sales of \$140 to \$142 million and diluted earnings per share of \$0.72 to \$0.75.

For all operating segments combined, international sales were \$9,460,000, or 28% of total sales, for the first quarter of fiscal 2008, compared to \$8,533,000, or 30% of total sales, for the first quarter of fiscal 2007. Combined domestic exports for the US Diagnostics and Life Science operating segments were \$3,361,000 for the first quarter of fiscal 2008, compared to \$3,278,000 for the first quarter of fiscal 2007. The remaining international sales were generated by the European Diagnostics operating segment.

*Gross Profit*

Gross profit increased 24% to \$21,752,000 for the first quarter of fiscal 2008 compared to the first quarter of fiscal 2007. Gross profit margins improved 3 points for the first quarter of fiscal 2008 compared to the first quarter of fiscal 2007. This improvement was driven by a favorable sales mix that was more heavily weighted towards higher margin rapid diagnostic tests and bulk antigens and reagents for certain customers, and automation initiatives and related efficiencies in diagnostic production areas.

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, 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 11% to \$10,559,000, for the first quarter of fiscal 2008 compared to the first quarter of fiscal 2007. The overall increase in operating expenses for the first quarter of fiscal 2008 is discussed below.

Research and development expenses increased 17% to \$1,536,000 for the first quarter of fiscal 2008 compared to the first quarter of fiscal 2007, and as a percentage of sales, were 5% for the first quarters of fiscal 2008 and fiscal 2007. Of this increase, \$364,000 related to the US Diagnostics operating segment offset by a \$143,000 decrease related to the Life Science operating segment. The increase for the US Diagnostics operating segment was primarily related to salaries and benefits for additional headcount for new product development, as well as related supplies and clinical trial costs.

Selling and marketing expenses increased 12% to \$4,690,000 for the first quarter of fiscal 2008

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compared to the first quarter of fiscal 2007, and as a percentage of sales, decreased from 15% for the first quarter of fiscal 2007 to 14% for the first quarter of fiscal 2008. Of this increase, \$539,000 related to the US Diagnostics operating segment and \$41,000 related to the European Diagnostics operating segment, offset by a decrease of \$85,000 related to the Life Science operating segment. The increase for the US Diagnostics operating segment relates to salaries and benefits, including incentive compensation tied to sales growth.

General and administrative expenses increased 7% to \$4,333,000 for the first quarter of fiscal 2008 compared to the first quarter of fiscal 2007, and as a percentage of sales, were 13% for the first quarter of fiscal 2008 and 14% for the first quarter of fiscal 2007. Of this increase, \$64,000 related to the US Diagnostics operating segment, \$72,000 related to the European Diagnostics segment, and \$153,000 related to the Life Science operating segment.

*Operating Income*

Operating income increased 39% to \$11,193,000 for the first quarter of fiscal 2008, as a result of the factors discussed above.

*Other Income and Expense*

Interest income increased 15% to \$455,000 for the first quarter of fiscal 2008, compared to \$395,000 for the first quarter of fiscal 2007. This increase was driven by higher average investment balances during the first quarter of fiscal 2008, somewhat offset by lower interest yields in the current interest rate environment. We currently invest in short-term fixed income securities such as overnight repurchase agreements, institutional money-market mutual funds, municipal variable rate demand notes with a seven-day put feature and municipal auction rate securities with a 35-day interest rate reset interval.

*Income Taxes*

The effective rate for income taxes was 35.5% for the first quarter of fiscal 2008 compared to 34.3% for the first quarter of fiscal 2007. The increase in the effective tax rate was primarily attributable to additional federal research and development tax credits recorded in the first quarter of fiscal 2007 upon renewal and extension by Congress and the President in December 2006. For the fiscal year ending September 30, 2008, Meridian expects the effective tax rate to range from 35% to 36%.

Effective October 1, 2007, we adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*. FIN 48 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure of uncertain tax positions, assuming full knowledge of all relevant facts by the applicable tax authorities. The cumulative effect of adopting FIN 48, \$305,000, was charged to opening retained earnings. See Note 2 to the consolidated financial statements herein.

**Liquidity and Capital Resources:**

*Comparative Cash Flow Analysis*

Our cash flow and financing requirements are determined by analyses of operating and capital

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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 short-term fixed income securities such as overnight repurchase agreements, institutional money-market mutual funds, municipal variable rate demand notes with a seven-day put feature and municipal auction rate securities.

Net cash provided by operating activities increased 86% to \$8,550,000 for the first quarter of fiscal 2008 compared to the first quarter of fiscal 2007. This increase was driven by growth in net earnings for the first quarter and working capital improvements relative to accounts receivable collections.

Net cash used in investing activities was \$5,736,000 for the first quarter of fiscal 2008 compared to net cash provided by investing activities of \$3,371,000 for the first quarter of fiscal 2007. The change primarily related to purchases of short-term investment securities during the first quarter of fiscal 2008 versus proceeds from the sales of such securities during the first quarter of fiscal 2007.

Net cash used for financing activities was \$3,794,000 for the first quarter of fiscal 2008 compared to \$2,093,000 for the first quarter of fiscal 2007. The increase primarily related to increased dividends paid on common shares.

Net cash flows from operating activities are anticipated to fund working capital requirements and dividends during fiscal 2008.

***Capital Resources***

Meridian has a \$30,000,000 credit facility with a commercial bank which expires on September 15, 2012. As of January 31, 2008, there were no borrowings outstanding on this facility.

The OEM Concepts acquisition, completed in fiscal 2005, provides for additional purchase consideration up to a maximum remaining amount of \$1,818,000, contingent upon future calendar-year sales and gross profit of OEM Concepts products through December 31, 2008. Earnout consideration is payable each year, following the period earned. Earnout consideration in the amount of \$153,000 related to calendar 2007 is included in the accompanying consolidated balance sheet in purchase business combination liabilities. Such earnout consideration is expected to be paid from operating cash flows during the second quarter of fiscal 2008.

Our capital expenditures are estimated to be \$5,000,000 for fiscal 2008 and may be funded with operating cash flows, availability under the \$30,000,000 credit facility, or cash equivalents and short-term investments on-hand. Capital expenditures relate to manufacturing equipment to further automation initiatives, computer system improvements, and capacity expansion for the Maine facility.

We do not utilize any special-purpose financing vehicles or have any undisclosed off balance sheet arrangements. Similarly, we do not hold any fair-value contracts for which a lack of marketplace quotations would necessitate the use of fair value techniques.

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**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, 2007.

**ITEM 4. CONTROLS AND PROCEDURES**

As of December 31, 2007, 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, 2007. There have been no changes in our internal controls over financial reporting identified in connection with the evaluation of internal controls that occurred during the first fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting, or in other factors that could materially affect internal controls subsequent to December 31, 2007, other than we implemented, as planned, new enterprise resource planning and general ledger and financial reporting systems for our Life Science facilities during the first quarter of fiscal 2008. These new system implementations provide the appropriate foundation to support future growth in our Life Science operating segment.

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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**

3.1 Amended and Restated Code of Regulations

10.1 2004 Equity Compensation Plan Amended and Restated as of January 22, 2008 (incorporated by reference from Exhibit 10.1 of the Registrant's filing of its Current Report on Form 8-K dated January 22, 2008)

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 11, 2008

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

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