

LEMAITRE VASCULAR INC

Form 10-Q

November 13, 2008

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2008

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 001-33092

**LEMAITRE VASCULAR, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**04-2825458**  
(I.R.S. Employer  
Identification No.)

**63 Second Avenue, Burlington, Massachusetts**  
(Address of principal executive offices)

**01803**  
(Zip Code)

**(781) 221-2266**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  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 the 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  (Do not check if a smaller reporting company)

Smaller reporting company

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

The registrant had 15,632,228 shares of common stock, \$.01 par value per share, outstanding as of November 10, 2008.

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**LEMAITRE VASCULAR**

**FORM 10-Q**

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**Table of Contents****Part I. Financial Information****Item 1. Financial Statements****LeMaitre Vascular, Inc.****Consolidated Balance Sheets**

	(unaudited) September 30 2008	December 31 2007
	(in thousands, except share data)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 13,163	\$ 6,397
Marketable securities	6,000	16,198
Accounts receivable, net of allowances of \$201 at September 30, 2008, and \$219 at December 31, 2007	6,788	7,020
Inventory	8,103	9,589
Prepaid expenses and other current assets	1,906	2,562
Total current assets	35,960	41,766
Property and equipment, net	2,524	2,891
Goodwill	10,922	10,942
Other intangibles, net	3,088	3,886
Other assets	1,077	1,372
Total assets	\$ 53,571	\$ 60,857
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Revolving line of credit	\$	\$ 262
Accounts payable	814	2,271
Accrued expenses	4,718	6,661
Acquisition-related obligations	952	851
Total current liabilities	6,484	10,045
Long-term debt	40	42
Deferred tax liabilities	1,382	996
Other long-term liabilities	438	1,188
Total liabilities	8,344	12,271
Stockholders equity:		
Preferred stock, \$0.01 par value; authorized 5,000,000 shares; none outstanding		
Common stock, \$0.01 par value; authorized 100,000,000 shares; issued 15,633,703 shares at September 30, 2008, and 15,516,412 shares at December 31, 2007	157	155
Additional paid-in capital	62,035	61,187
Accumulated deficit	(16,506)	(12,880)
Accumulated other comprehensive income (loss)	(255)	291
Treasury stock, at cost; 36,566 shares at September 30, 2008, and 26,852 shares at December 31, 2007	(204)	(167)
Total stockholders equity	45,227	48,586

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Total liabilities and stockholders equity	\$ 53,571	\$ 60,857
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See accompanying notes to consolidated financial statements.

**Table of Contents****LeMaitre Vascular, Inc.****Consolidated Statements of Operations****(unaudited)**

	For the three months ended		For the nine months ended	
	September 30 2008	September 30 2007	September 30 2008	September 30 2007
	(in thousands, except per share data)		(in thousands, except per share data)	
Net sales	\$ 12,023	\$ 10,144	\$ 36,609	\$ 30,342
Cost of sales	3,920	2,563	11,131	7,778
<b>Gross profit</b>	<b>8,103</b>	<b>7,581</b>	<b>25,478</b>	<b>22,564</b>
Sales and marketing	4,373	4,583	15,353	14,131
General and administrative	2,164	2,341	7,726	6,917
Research and development	1,203	1,144	4,027	3,416
Restructuring charges	163	1,054	1,143	1,059
Impairment charge	30		514	7
<b>Total operating expenses</b>	<b>7,933</b>	<b>9,122</b>	<b>28,763</b>	<b>25,530</b>
Income (loss) from operations	170	(1,541)	(3,285)	(2,966)
Other income (expense):				
Interest income	151	359	449	1,054
Interest expense	(15)		(47)	
Investment impairment	(110)		(110)	
Foreign currency gain (loss)	(257)	221	(91)	284
Other income (expense), net	2			(9)
<b>Loss before income taxes</b>	<b>(59)</b>	<b>(961)</b>	<b>(3,084)</b>	<b>(1,637)</b>
Provision for income taxes	77	393	542	119
<b>Net loss</b>	<b>\$ (136)</b>	<b>\$ (1,354)</b>	<b>\$ (3,626)</b>	<b>\$ (1,756)</b>
Net loss per share of common stock:				
Basic	\$ (0.01)	\$ (0.09)	\$ (0.23)	\$ (0.11)
Diluted	\$ (0.01)	\$ (0.09)	\$ (0.23)	\$ (0.11)
Weighted-average shares outstanding:				
Basic	15,608	15,410	15,552	15,376
Diluted	15,608	15,410	15,552	15,376

See accompanying notes to consolidated financial statements.

**Table of Contents****LeMaitre Vascular, Inc.****Consolidated Statements of Cash Flows****(unaudited)**

	<b>For the nine months ended September 30</b>	
	<b>2008</b>	<b>2007</b>
	<b>(in thousands)</b>	
<b>Operating activities</b>		
Net loss	\$ (3,626)	\$ (1,756)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,276	990
Stock-based compensation	552	406
Accretion of discount on marketable securities	(90)	(189)
Impairment charges	514	7
Provision for losses in accounts receivable	50	122
Provision for inventory write-downs	884	331
Loss on sales of marketable securities	10	2
Impairment loss on marketable securities	110	
Loss on disposal of property and equipment	5	5
Changes in operating assets and liabilities, net of effect of business acquisitions:		
Accounts receivable	48	(979)
Inventory	495	(1,659)
Prepaid expenses and other assets	757	604
Accounts payable and other liabilities	(2,872)	760
Net cash used in operating activities	(1,887)	(1,356)
<b>Investing activities</b>		
Purchase of property and equipment	(584)	(826)
Payments related to acquisitions	(602)	(2,936)
Purchase of technology and licenses	(105)	
Sales and maturities of marketable securities	11,632	7,603
Purchases of marketable securities	(1,656)	(12,109)
Other assets		(61)
Net cash provided by (used in) investing activities	8,685	(8,329)
<b>Financing activities</b>		
Proceeds from issuance of common stock	299	225
Repayment of revolving line of credit	(262)	(32)
Expenses associated with equity transactions		(121)
Purchase of treasury stock	(37)	
Net cash provided by financing activities		72
Effect of exchange rate changes on cash and cash equivalents	(32)	(261)
Net increase (decrease) in cash and cash equivalents	6,766	(9,874)
Cash and cash equivalents at beginning of period	6,397	17,626
Cash and cash equivalents at end of period	\$ 13,163	\$ 7,752

Supplemental disclosures of cash flow information (see Note 15)

See accompanying notes to consolidated financial statements.





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**LeMaitre Vascular, Inc.**

**Notes to Consolidated Financial Statements**

**September 30, 2008**

**(unaudited)**

**1. Organization and Basis for Presentation**

***Description of Business***

Unless the context requires otherwise, references to LeMaitre Vascular, we, our, and us refer to LeMaitre Vascular, Inc. and our subsidiaries. LeMaitre Vascular develops, manufactures, and markets medical devices and implants used primarily in the field of vascular surgery. We operate in a single segment in which our principal product lines are thoracic stent grafts, abdominal stent grafts, anastomotic clips, radiopaque tape, valvulotomes, carotid shunts, remote endarterectomy devices, covered stents, contrast injectors, balloon catheters, vascular grafts, vein strippers, cholangiogram catheters, and vascular access ports. We also distribute in 11 European countries an abdominal stent graft manufactured by a third party. Our offices are located in Burlington, Massachusetts, Sulzbach, Germany, Rome, Italy, Brindisi, Italy, and Tokyo, Japan.

***Basis of Presentation***

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments, consisting only of normal, recurring adjustments considered necessary for a fair presentation of the results of these interim periods have been included. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Actual results may differ from these estimates. Our estimates and assumptions, including those related to bad debts, inventories, intangible assets, sales returns and discounts, share-based compensation, and income taxes are updated as appropriate. The results for the three and nine months ended September 30, 2008 are not necessarily indicative of results to be expected for the entire year. The information contained in these interim financial statements should be read in conjunction with our audited consolidated financial statements as of and for the year ended December 31, 2007, including the notes thereto, included in our Form 10-K filed with the Securities and Exchange Commission (SEC).

Certain prior year amounts have been reclassified in the consolidated financial statements and accompanying notes to conform to the current period's presentation.

***Consolidation***

Our consolidated financial statements include the accounts of LeMaitre Vascular and the accounts of our wholly-owned subsidiaries, LeMaitre Vascular GmbH, LeMaitre Vascular GK (successor to LeMaitre Vascular KK, reorganized in June 2007), LeMaitre UK Acquisition LLC, Vascutech Acquisition LLC, LeMaitre Acquisition LLC, LeMaitre Vascular SAS (organized in 2007), Biomateriali S.r.l. (acquired in 2007), and LeMaitre Vascular S.r.l. (organized in 2007). All significant intercompany accounts and transactions have been eliminated in consolidation.

**2. Recent Accounting Pronouncements**

In March 2008 the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB statement No. 133* (SFAS No. 161). SFAS No. 161 requires enhanced disclosures regarding an entity's derivative instruments and related hedging activities. These enhanced disclosures include information regarding how and why an entity uses derivative instruments; how derivative instruments and related hedge items are accounted for under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and its related interpretations; and how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The adoption of SFAS No. 161 will not have a material impact on our financial position, results of operations, or liquidity as we do not currently have any derivative instruments.



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In December 2007 the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, (SFAS No. 141(R)). SFAS No. 141(R) replaces SFAS No. 141, *Business Combinations*, and requires the acquiring entity in a business combination to recognize the full fair value of assets acquired and liabilities assumed in the transaction; requires certain contingent assets and liabilities acquired to be recognized at their fair values on the acquisition date; requires contingent consideration to be recognized at its fair value on the acquisition date and changes in the fair value to be recognized in earnings until settled; requires the expensing of most transaction and restructuring costs; and generally requires the reversals of valuation allowances related to acquired deferred tax assets and changes to acquired income tax uncertainties to also be recognized in earnings. SFAS No. 141(R) is effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of 2009. The adoption of SFAS No. 141(R) will change our accounting treatment for business combinations on a prospective basis for business combinations entered into subsequent to December 31, 2008.

In December 2007 the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of Accounting Research Bulletin No. 51* (SFAS No. 160). SFAS No. 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest, and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS No. 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of 2009. We do not expect that the adoption of SFAS No. 160 will have a material effect on our consolidated results of operations and financial condition.

In December 2007 the FASB ratified Emerging Issues Task Force (EITF) Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 provides guidance on collaborative arrangements within the scope of this issue, including the classification of the payments between participants in the arrangement, the appropriate income statement presentation as well as disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of 2009. We are currently evaluating the potential impact of EITF 07-1 on our financial position and results of operations.

### **3. Income Tax Expense**

We operate in multiple taxing jurisdictions, both within the United States and outside of the United States, and are or may be subject to audits from various tax authorities regarding transfer pricing, the deductibility of certain expenses, intercompany transactions, and other matters. Our income tax expense for the period varies from the amount that would normally be derived based upon statutory rates in the respective jurisdictions in which we operate. The significant reasons for this variation are our inability to record a tax benefit on our losses generated in the United States, coupled with a tax provision on foreign earnings, and the effect of tax-deductible goodwill, for which a deferred tax liability has been recorded. In addition, we recorded a one-time tax benefit of \$0.5 million related to the reorganization of our Japanese subsidiary in June 2007 for which a loss carry back was realized.

Our policy is to classify interest and penalties related to unrecognized tax benefits as income tax expense. This policy has been consistently applied in prior periods.

We have not identified any uncertain tax positions for which it is reasonably possible that the total amount of unrecognized tax benefits will significantly increase or decrease within the 12 months ending September 30, 2009, except with respect to matters that may be identified under audit that we cannot reasonably estimate as discussed in our audited consolidated financial statements as of and for the year ended December 31, 2007, including the notes thereto, included in our Form 10-K filed with the Securities and Exchange Commission. As of September 30, 2008, the liability for unrecognized tax benefits was approximately \$28,000. There was no change in the liability during the nine months ended September 30, 2008.

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As of January 1, 2008, a summary of the tax years that remain subject to examination in our most significant tax jurisdictions is:

United States federal	2006 and forward
Germany	2007
Japan	2004 and forward
Italy	2007
France	2007

**4. Inventories**

Inventories consist of the following:

	September 30, 2008	December 31, 2007
	(in thousands)	
Raw materials	\$ 2,138	\$ 2,374
Work-in-process	1,137	1,540
Finished products	4,828	5,675
Total inventory	\$ 8,103	\$ 9,589

**5. Goodwill and Other Intangibles**

The changes in the carrying amount of goodwill for the nine months ended September 30, 2008, are as follows:

	September 30, 2008
	(in thousands)
Beginning balance	\$ 10,942
Adjustments to purchase price on prior year acquisitions:	
Cardiovascular Innovations acquisition	5
Vascular Architects acquisition	(25)
Ending balance	\$ 10,922

In August 2008, we made the final installment payment of \$0.3 million, net of an indemnity claim and a prepayment discount, related to the Vascular Architects acquisition. The purchase price was adjusted for this indemnity claim and prepayment discount. The purchase accounting for the Vascular Architects acquisition has been finalized.

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The components of our identifiable intangible assets are as follows:

	September 30, 2008			December 31, 2007		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
	(in thousands)					
Patents	\$ 2,242	\$ 723	\$ 1,519	\$ 2,184	\$ 532	\$ 1,652
Trademarks and technology licenses	1,245	474	771	1,265	356	909
Customer relationships	850	197	653	1,233	92	1,141
Other intangible assets	179	34	145	190	6	184
<b>Total identifiable intangible assets</b>	<b>\$ 4,516</b>	<b>\$ 1,428</b>	<b>\$ 3,088</b>	<b>\$ 4,872</b>	<b>\$ 986</b>	<b>\$ 3,886</b>

Intangible assets are amortized over their estimated useful lives, ranging from 5 to 17 years. Amortization expense amounted to \$141,000 and \$65,000 for the three months ended September 30, 2008 and September 30, 2007, respectively. Amortization expense amounted to \$374,000 and \$183,000 for the nine months ended September 30, 2008 and September 30, 2007, respectively. Amortization expense is included in general and administrative expense. Estimated amortization expense for the remainder of 2008 and each of the five succeeding fiscal years is as follows:

	(in thousands)
2008 (remaining 3 months)	\$ 116
2009	436
2010	418
2011	409
2012	366
2013	283

We recognized impairment charges of \$30,000 and \$48,000 related to patents and trademarks which were deemed to have no value based upon a lack of future expected economic benefits in the three months ended September 30, 2008 and June 30, 2008, respectively. In January 2008, we were notified by one of the customers of our Biomateriali subsidiary that they would no longer purchase a certain product line from us, and, as a result, we incurred an impairment charge of \$435,000 due to the write-down of related intangible assets.

**6. Financing Arrangements**

We maintain a \$10.0 million revolving line of credit that provides for up to \$3.0 million in letters of credit. Loans made under this revolving line of credit bear interest at the bank's base rate or LIBOR plus 200 basis points, at our discretion, and are collateralized by substantially all of our assets. The loan agreement requires that we meet certain financial and operating covenants. As of September 30, 2008 and December 31, 2007, we did not have an outstanding balance under this facility and we were in compliance with these covenants.

In addition, at the acquisition date, Biomateriali had two existing revolving lines of credit with its bank for a total of approximately \$0.7 million to be used in connection with the financing of sales to certain customers. Loans made under these lines bear interest at 20% per annum. On December 31, 2007, we had \$0.3 million of borrowings outstanding under one of these lines of credit, which were paid in full in January 2008. One line of credit was closed in January 2008. A line of credit remains available to Biomateriali. As of September 30, 2008, we did not have an outstanding balance under this line of credit.

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Accrued expenses consist of the following:

	September 30, 2008	December 31, 2007
	(in thousands)	
Compensation and related taxes	\$ 2,787	\$ 3,146
Restructuring	78	1,129
Income and other taxes	428	673
Professional fees	366	811
Other	1,059	902
<b>Total</b>	<b>\$ 4,718</b>	<b>\$ 6,661</b>

**8. Restructuring Charges**

During the three months ended September 30, 2008, we incurred \$0.2 million of restructuring charges, primarily related to the termination of an agreement with a former Italian distributor and severance costs related to a reduction in force of eight employees that we initiated in the third quarter. During the nine months ended September 30, 2008, we incurred \$1.1 million of restructuring charges. Included in the restructuring charges for the nine months ended September 30, 2008 were \$0.7 million for contractual obligations associated with non-compete and consulting agreements related to a termination agreement with a former Italian distributor and \$0.4 million for severance costs related to the reduction in force of eight and 32 employees that we initiated in the third and first quarters, respectively.

In September 2007, the Company entered into termination agreements with our former Italian and Irish distributors. The restructuring charges for the three months ended September 2007 were \$1.1 million for contractual obligations associated with early termination charges, non-compete and consulting agreements related to the distributor terminations.

The components of the restructuring charges are follows:

	Three months ended		Nine months ended	
	September 30		September 30	
	2008	2007	2008	2007
	(in thousands)			
Severance	\$ 52	\$	\$ 431	\$ 5
Distributor termination costs	111	1,054	712	1,054
<b>Total</b>	<b>\$ 163</b>	<b>\$ 1,054</b>	<b>\$ 1,143</b>	<b>\$ 1,059</b>

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Activity related to accrued restructuring costs is as follows:

	Nine months ended September 30	
	2008	2007
	(in thousands)	
Balance at beginning of period	\$ 1,129	\$ 46
Plus:		
Current period restructuring costs	1,143	1,059
Other	21	20
Less:		
Payments for termination of contractual obligations	1,862	
Payment of employee severance costs	353	34
Balance at end of period	\$ 78	\$ 1,091

We expect that the remaining restructuring costs will be paid over the next 12 months.

**9. Comprehensive Loss**

The components of other comprehensive income (loss) generally include foreign exchange translation and unrealized gains and losses on marketable securities. The computation of comprehensive loss was as follows:

	Three months ended September 30		Nine months ended September 30	
	2008	2007	2008	2007
	(in thousands)			
Net loss	\$ (136)	\$ (1,354)	\$ (3,626)	\$ (1,756)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	10	25	(164)	3
Foreign currency translation adjustment	(636)	30	(382)	47
Total other comprehensive income (loss)	(626)	55	(546)	50
Comprehensive loss	\$ (762)	\$ (1,299)	\$ (4,172)	\$ (1,706)

On September 30, 2008, we recorded an investment impairment charge of \$0.1 million which were attributed to the other-than-temporary decline in one specific asset backed security which we hold as available-for-sale in our marketable securities portfolio.

**10. Commitments and Contingencies**

As part of our normal course of business, we have minimum inventory purchase commitments totaling \$2.9 million for 2008, \$3.8 million for 2009, and \$3.9 million for 2010. As of September 30, 2008, we had purchased approximately \$1.7 million toward fulfilling our 2008 purchase commitments.

In addition, there are potential contingent payments associated with the Biomateriali stock purchase agreement and product distribution agreement that could not be determined beyond a reasonable doubt as of September 30, 2008. These contingent payments could total up to \$2.1 million based upon the exchange rate effective on September 30, 2008. Due to the uncertainty of the future payouts, they have not been recorded as part of the purchase price for Biomateriali. When the contingencies are resolved, they may result in recognition of an additional cost and the purchase price may be adjusted at that time.





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In March 2008, we provided notice of an indemnity claim to the sellers of Biomateriali, contending that the sellers breached certain representations and warranties in the purchase agreement by failing to adequately disclose material information regarding a customer relationship. In 2008, we made additional indemnity claims regarding inventory and government subsidies to the sellers of Biomateriali. We have demanded the payment of damages of approximately \$1.1 million, based upon the exchange rate effective on September 30, 2008, and have ceased making certain post-closing payments to the sellers pending resolution of these indemnity claims. As of September 30, 2008, we had not adjusted the purchase accounting related to Biomateriali for these claims.

**11. Segment and Enterprise-Wide Disclosures**

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, establishes standards for reporting information regarding operating segments in annual financial statements. Operating segments are identified as components of an enterprise about which separate, discrete financial information is available for evaluation by the chief operating decision-maker in making decisions on how to allocate resources and assess performance. We view our operations and manage our business as one operating segment. No discrete operating information other than product sales is prepared by us, except by geographic location, for local reporting purposes.

Most of our revenues were generated in the United States, Europe, and Japan, and substantially all of our assets are located in the United States. We analyze our sales using a number of approaches, including sales by legal entity. LeMaitre Vascular GmbH, our German subsidiary, records all sales in Europe and to distributors worldwide, excluding sales in France (LeMaitre Vascular SAS); Italy (LeMaitre Vascular S.r.l.); Japan, Korea, and Taiwan (LeMaitre Vascular GK); and worldwide sales of Biomateriali S.r.l. products. Net sales to unaffiliated customers by legal entity were as follows:

	Three months ended		Nine months ended	
	September 30, 2008		September 30, 2008	
	2008	2007	2008	2007
	(in thousands)		(in thousands)	
LeMaitre Vascular, Inc.	\$ 6,805	\$ 6,236	\$ 20,061	\$ 18,232
LeMaitre Vascular GmbH	3,927	3,583	12,486	11,407
Other entities	1,291	325	4,062	703
Total	\$ 12,023	\$ 10,144	\$ 36,609	\$ 30,342

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We sell products in three product categories; Endovascular & Dialysis Access, Vascular, and General Surgery, and have also derived a limited amount of revenue from manufacturing devices under OEM arrangements. Net sales in these product categories were as follows:

	Three months ended September 30, 2008		Nine months ended September 30, 2008	
	2008	2007	2008	2007
	(in thousands)		(in thousands)	
Endovascular & Dialysis Access	\$ 3,966	\$ 3,211	\$ 11,836	\$ 10,256
Vascular	6,987	5,982	21,600	17,216
General Surgery	1,000	951	2,926	2,870
Total Branded Products	11,953	10,144	36,362	30,342
OEM	70		247	
Total	\$ 12,023	\$ 10,144	\$ 36,609	\$ 30,342

**12. Share-based Compensation**

Our 2006 Stock Option and Incentive Plan (the 2006 Plan) allows for granting of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units (RSUs), unrestricted stock awards, and deferred stock awards to officers, employees, directors, and consultants of the company. We account for our share-based compensation plans in accordance with SFAS No. 123(R), *Share-Based Payment*.

The components of share-based compensation expense are as follows:

	Three months ended September 30		Nine months ended September 30	
	2008	2007	2008	2007
	(in thousands)		(in thousands)	
Stock option awards to employees under SFAS No. 123(R)	\$ 82	\$ 72	\$ 209	\$ 187
Restricted stock awards under SFAS No. 123(R)	127	96	344	219
Employee stock purchase plan			7	
Stock option awards to non-employees under SFAS No. 123			(8)	
Total share-based compensation	\$ 209	\$ 168	\$ 552	\$ 406

We have computed the fair values of employee stock options for option grants made during the nine months ended September 30, 2008 and 2007 using the Black-Scholes option model with the following weighted-average assumptions and weighted-average fair values:

	2008	2007
Dividend yield	0.0%	0.0%
Volatility	52.1%	65.0%
Risk-free interest rate	3.2%	4.9%
Weighted average expected option term (in years)	4.7	5.0
Weighted average fair value per share of options granted	\$ 1.61	\$ 3.59

The weighted-average fair value per share of restricted stock unit grants issued for the nine-months ended September 30, 2008 and 2007 were \$3.58 and \$6.09, respectively.

**Table of Contents****13. Net Loss per Share**

The computation of basic and diluted net loss per share is as follows:

	Three months ended September 30		Nine months ended September 30	
	2008	2007	2008	2007
	(in thousands, except per share data)			
<b>Basic:</b>				
Net loss	\$ (136)	\$ (1,354)	\$ (3,626)	\$ (1,756)
Weighted average shares outstanding	15,608	15,410	15,552	15,376
Net loss per share	\$ (0.01)	\$ (0.09)	\$ (0.23)	\$ (0.11)
<b>Diluted:</b>				
Net loss	\$ (136)	\$ (1,354)	\$ (3,626)	\$ (1,756)
Weighted average shares of common stock	15,608	15,410	15,552	15,376
Net loss per share	\$ (0.01)	\$ (0.09)	\$ (0.23)	\$ (0.11)
<b>Calculation of weighted average shares</b>				
Weighted-average shares of common stock outstanding	15,608	15,410	15,552	15,376
Weighted-average shares of common stock issuable upon exercise of outstanding stock options				
Shares used in computing diluted net loss per common share	15,608	15,410	15,552	15,376

For the three months and nine months ended September 30, 2008, 1,199,776 and 1,136,773 weighted-average shares of restricted common stock and options to purchase common stock, respectively, were excluded from the computation of diluted net loss per share, as their effect would have been anti-dilutive. For the three months and nine months ended September 30, 2007, 362,000 and 365,000 weighted-average shares of restricted common stock and options to purchase common stock were excluded from the computation of diluted net income (loss) per share, as their effect would have been anti-dilutive.

We have never declared cash dividends and do not expect to do so in the foreseeable future.

**14. Stockholders Equity****Undesignated Preferred Stock**

We have 5,000,000 shares of undesignated preferred stock authorized. There were no shares designated, issued, or outstanding as of September 30, 2008 or as of December 31, 2007.

**Employee Stock Purchase Plan**

Our employee stock purchase plan enables eligible employees to purchase shares of our common stock. Eligible employees may purchase shares during six-month offering periods commencing on February 1 and August 1 of each year at a price per share equal to 90 percent of the fair market value of our common stock on the last date of each six-month offering period. Participating employees may elect to have up to ten percent of their base pay withheld and applied toward the purchase of such shares. The rights of participating employees terminate upon voluntary withdrawal from the plan at any time or upon termination of employment. On February 1, 2008, 13,103 shares were purchased at a purchase price of \$4.96 per share. On July 31, 2008, 9,034 shares were purchased at a purchase price of \$3.02 per share. As of September 30, 2008, 214,085 shares were reserved and are available for issuance under this plan.



**Table of Contents****15. Supplemental Cash Flow Information**

	For the nine months ended September 30	
	2008	2007
	(in thousands)	
Cash paid for income taxes, net	\$ 122	\$ 622
Cash paid for interest	\$	\$ 1
<b>Supplemental non-cash financing activities:</b>		
Common stock repurchased for RSU tax withholdings	\$ 37	\$

**16. Fair Value Measurements**

On January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements* (SFAS No. 157), for our financial assets and liabilities. The adoption of SFAS No. 157 did not impact our financial position, results of operations, or liquidity. In accordance with FASB Staff Position No. 157-2, *Effective Date of FASB Statement No. 157* (FSP FAS 157-2), we elected to defer until January 1, 2009 the adoption of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities that are not recognized or disclosed at fair value in the financial statements on a recurring basis. The adoption of SFAS No. 157 for those assets and liabilities within the scope of FSP FAS 157-2 is not expected to have a material impact on our financial position, results of operations, or liquidity. SFAS No. 157 provides a framework for measuring fair value and requires expanded disclosures regarding fair value measurements. SFAS No. 157 defines fair value as the price that would be received for an asset or the exit price that would be paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. SFAS No. 157 also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available. The following summarizes the three levels of inputs required by the standard that we use to measure fair value, as well as the assets and liabilities that we value using those levels of inputs.

- Level 1: Quoted prices in active markets for identical assets or liabilities. Our Level 1 assets are comprised of investments in marketable securities. We do not have any Level 1 liabilities.
- Level 2: Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities. We do not have any Level 2 assets or liabilities.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. We do not have any Level 3 assets or liabilities.

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### **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*This Quarterly Report on Form 10-Q contains forward-looking statements (within the meaning of the federal securities law) that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Quarterly Report on Form 10-Q regarding our strategy, future operations, future financial position, future net sales, projected costs, projected expenses, prospects, and plans and objectives of management are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, would, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We have based these forward-looking statements on our current expectations and projections about future events. Although we believe that the expectations underlying any of our forward-looking statements are reasonable, these expectations may prove to be incorrect, and all of these statements are subject to risks and uncertainties. Should one or more of these risks and uncertainties materialize, or should underlying assumptions, projections, or expectations prove incorrect, actual results, performance, or financial condition may vary materially and adversely from those anticipated, estimated, or expected. We have identified below some important factors that could cause our forward-looking statements to differ materially from actual results, performance, or financial conditions:*

*the unpredictability of our quarterly net sales and results of operations;*

*the ability to keep pace with a rapidly evolving marketplace and to develop or acquire and then successfully market new and enhanced products;*

*our ability to successfully identify, acquire, and integrate new products, businesses, and technologies and realize expected benefits;*

*a highly competitive market for medical devices;*

*the effect of a disaster at any of our manufacturing facilities;*

*the loss of any significant suppliers, especially sole-source suppliers;*

*the loss of any distributor or any significant customer, especially in regard to any product that has a limited distributor or customer base;*

*our ability to adequately grow our operations and attain sufficient operating scale;*

*our ability to obtain adequate profit margins;*

*our ability to effectively protect our intellectual property and not infringe on the intellectual property of others;*

*possible product liability lawsuits and product recalls;*

*inadequate levels of third-party reimbursement to healthcare providers;*

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*our ability to initiate, complete, or achieve favorable results from clinical studies of our products;*

*our ability to obtain and maintain U.S. and foreign regulatory clearance for our products and our manufacturing operations;*

*our ability to raise sufficient capital when necessary or at satisfactory valuations;*

*loss of key personnel; and*

*other factors discussed elsewhere in this Quarterly Report on Form 10-Q.*

*For more information regarding these and other uncertainties and factors that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements, or that otherwise could materially adversely affect our business, financial condition, or operating results, see our annual report on Form 10-K for the fiscal year ended December 31, 2007, under the heading Part I Item 1A. Risk Factors and those risk factors included under the heading Part II Item 1A. Risk Factors in this quarterly report.*

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*All forward-looking statements included in this report are expressly qualified in their entirety by the foregoing cautionary statements. We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the uncertainties and factors described above, as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown uncertainties and factors, including those described above. The risks and uncertainties described above are not exclusive, and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update, amend, or clarify forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our annual reports on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.*

*The following discussion and analysis should be read in conjunction with our consolidated financial statements and the related notes included in this report and our audited consolidated financial statements and the related notes contained in our Annual Report on Form 10-K for the year ended December 31, 2007, as filed with the Securities and Exchange Commission.*

*Unless the context requires otherwise, references to LeMaitre Vascular, we, our, and us in this Quarterly Report on Form 10-Q refer to LeMaitre Vascular, Inc. and its subsidiaries.*

*LeMaitre, AnastoClip, EndoFit, Expandable LeMaitre Valvulotome, Flexcel, Glow N Tell, Grice, Inahara-Pruitt, InvisiGrip, LeverEdge, MollRing Cutter, NovaSil, OptiLock, Periscope, Pruitt, Pruitt-Inahara, Reddick, TT, UniFit, VascuTape, and the LeMaitre Vascular logo are registered trademarks of LeMaitre Vascular, and Albograft, aSpire, Biomateriali, EndoHelix, EndoRE, F3, Martin, TAArget, and VCS are unregistered trademarks of LeMaitre Vascular. This Quarterly Report on Form 10-Q also includes the registered and unregistered trademarks of other persons.*

**Overview**

We are a medical device company that develops, manufactures, and markets medical devices and implants for the treatment of peripheral vascular disease. Our principal product offerings are sold throughout the world, primarily in the United States, the European Union, and, to a lesser extent, Japan. We estimate that the annual worldwide market addressed by our 14 current product lines exceeds \$1 billion and that the annual worldwide market for all peripheral vascular devices exceeds \$3 billion and is growing at 8 percent per year. We have used acquisitions as a primary means of further accessing the peripheral vascular device market, and we expect to continue to pursue this strategy in the future. We currently manufacture our product lines in our Burlington, Massachusetts, headquarters with the exception of the LeverEdge Contrast Injector (acquired in April 2007) and the Vascular Architects products (acquired in September 2007), for which a portion of the manufacturing is currently outsourced. In addition, our Albograft vascular grafts (acquired in December 2007) are manufactured at our facility in Brindisi, Italy.

Our products are used by vascular surgeons who treat peripheral vascular disease through both open surgical methods and more recently adopted endovascular techniques. Unlike interventional cardiologists and interventional radiologists, who are not typically certified to perform open surgical procedures, vascular surgeons can perform both open surgical and minimally invasive endovascular procedures, and are therefore uniquely positioned to provide patients with a wider range of treatment options.

We believe that the purchasing volume of the vascular surgeon will increase and that the changing product needs of the vascular surgeon present us with attractive opportunities to sell new devices. As a result, we have sought out and acquired new products and businesses that address these needs, such as our acquisition of the contrast injector in April 2007, the remote endarterectomy suite of products in September 2007, our four-year exclusive agreement to distribute the Endologix Powerlink System in 11 European countries, which commenced January 1, 2007, and the acquisition of a line of polyester vascular grafts in December 2007.



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Below is a listing of our product lines and product categories:

Our **Endovascular & Dialysis Access** product category includes our TAArget Thoracic Stent Graft, UniFit Abdominal Stent Graft, VascuTape Radiopaque Tape, AnastoClip Vessel Closure System, LeverEdge Contrast Injector, and aSpire Covered Stent. We also report our distribution sales of the Endologix Powerlink System within this product category.

Our **Vascular** product category includes our Expandable LeMaitre Valvulotome; Flexcel, Pruitt-Inahara, and Pruitt F3 Carotid Shunts; InvisiGrip Vein Stripper; LeMaitre Balloon Catheters; five remote endarterectomy products, which include our Martin Dissector, Periscope Dissector, EndoHelix Retrieval Device, MollRing Cutter Transection Device, and Ring Dissector; and our Albograft line of polyester prosthetic grafts.

Our **General Surgery** product category includes our Reddick Cholangiogram Catheter and its accessories and our OptiLock Implantable Port.

Our **OEM** category includes sales of a dacron product to a cardiac device manufacturer.

We evaluate the sales performance of our various product lines utilizing criteria that vary based upon the position of each product line in its expected life cycle. For established products, we typically review unit sales and selling prices. For faster growing products, we typically also focus on new account generation and customer retention.

Our business strategies include the following:

the addition of complementary products through further acquisitions;

the updating of existing products and the introduction of new products through research and development;

the maintenance or expansion of our sales teams in North America, Europe, and Japan; and

the introduction of our products in new markets via regulatory approvals.

We are currently pursuing all of these strategies.

To assist us in evaluating our business strategies, we regularly monitor long-term technology trends in the peripheral vascular device market. Additionally, we consider the information obtained from discussions with the medical community in connection with the demand for our products, including potential new product launches. We also use this information to help determine our competitive position in the peripheral vascular device market and our manufacturing capacity requirements.

We sell our products primarily through a direct sales force. Our sales force was comprised of 49 sales representatives in North America, the European Union, and Japan as of September 30, 2008. We also sell our products through a network of distributors in various countries outside of the United States and Canada. In 2007, approximately 90% of our net sales were direct-to-hospital. For the nine-months ended September 30, 2008, approximately 88% of our net sales were direct-to-hospital.

Our worldwide headquarters are in Burlington, Massachusetts. Our international operations are headquartered in Sulzbach, Germany. We also have sales offices located in Tokyo, Japan, and Rome, Italy, and a manufacturing facility in Brindisi, Italy. For the nine months ended September 30, 2008, approximately 45% of our net sales were denominated in currencies other than the U.S. dollar. Accordingly, our results of operations are influenced by changes in currency exchange rates. Increases or decreases in the value of the U.S. dollar, as compared to other

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currencies in which our net sales are denominated, will directly affect our reported results as we translate those currencies into U.S. dollars for reporting purposes.

Our strategy for growing our business includes the acquisition of complementary product lines and companies and occasionally the discontinuance of products or activities that are no longer complementary. These actions may affect the comparability of our financial results from period to period and may cause substantial fluctuations period to period.

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The following table indicates the impact of foreign currency fluctuations and changes to our business activities for each of the quarters listed:

(amounts in thousands) (unaudited)	2008				2007				2006		
	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Total net sales	12,023	12,739	11,847	11,104	10,144	10,315	9,883	8,757	8,540	8,760	8,571
Impact of currency exchange rate fluctuations (1)	452	836	674	439	253	267	322	232	135	(1)	(287)
Net impact of acquisitions, distributed sales and discontinued products, excluding currency exchange rate fluctuations (2)	703	929	1,133	1,116	635	567	455	(252)	(383)	(107)	37

- (1) Represents the impact of the change in foreign exchange rates over the corresponding quarter of the prior year based on the weighted average exchange rate for each quarter.
- (2) Represents the impact of sales of products of acquired businesses and distributed sales of other manufacturers' products, net of sales related to discontinued products and other activities, based on 12 months' sales following the date of the event or transaction, and shown in the current period only.

**Results of Operations****Comparison of the three and nine months ended September 30, 2008, to the three and nine months ended September 30, 2007**

The following tables set forth, for the periods indicated, our results of operations, net sales by product category, net sales by geography, and the change between the specified periods expressed as a percent increase or decrease:

(unaudited)	Three months ended September 30			Nine months ended September 30		
	2008	2007	Percent change	2008	2007	Percent change
	(\$ in thousands)			(\$ in thousands)		
Net sales	\$ 12,023	\$ 10,144	19%	\$ 36,609	\$ 30,342	21%
Net sales by product category:						
Endovascular & Dialysis Access	\$ 3,966	\$ 3,211	24%	\$ 11,836	\$ 10,256	15%
Vascular	6,987	5,982	17%	21,600	17,216	25%
General Surgery	1,000	951	5%	2,926	2,870	2%
Total Branded Products	11,953	10,144	18%	36,362	30,342	20%
OEM	70		*	247		*
Total	\$ 12,023	\$ 10,144	19%	\$ 36,609	\$ 30,342	21%
Net sales by geography:						
United States and Canada	\$ 6,805	\$ 6,236	9%	\$ 20,061	\$ 18,232	10%
Outside the United States and Canada	5,218	3,908	34%	16,548	12,110	37%
Total	\$ 12,023	\$ 10,144	19%	\$ 36,609	\$ 30,342	21%

\* Not a meaningful percentage relationship.

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**Net sales.** Net sales increased 19% to \$12.0 million and 21% to \$36.6 million, for the three and nine months ended September 30, 2008, respectively, compared to \$10.1 million and \$30.3 million for the three and nine months ended September 30, 2007, respectively. Sales growth for the three months ended September 30, was driven by the inclusion of the sales of Biomateriali acquired in December 2007 and the EndoRE suite of products acquired in September of 2007. Sales growth was also driven by the positive effects of currency exchange rate fluctuations, higher average selling prices across nearly all product lines, and greater sales of the recently improved TAArget and UniFit stent grafts, Powerlink System, and embolectomy balloon catheters. Strong performance in our endovascular and dialysis access category for the three months ended September 30, 2008 was driven primarily by our newly redesigned TAArget and UniFit stent grafts. Sales growth for the nine months ended September 30, 2008 was driven by the inclusion of Biomateriali and the EndoRE suite of products, as well as the LeverEdge contrast injector acquired in April 2007. Sales growth for the nine months was driven by the positive effects of currency exchange rate fluctuations, higher average selling prices across nearly all product lines, and greater sales of the Powerlink System, valvulotomes and embolectomy balloon catheters. Strong performance in our vascular category for the nine months ended September 30, 2008 reflected in part the addition of our recently acquired prosthetic vascular grafts and suite of remote endarterectomy products.

Direct-to-hospital net sales were 89% during the three months ended September 30, 2008 and 2007. Direct to hospital total net sales decreased to 87% of total net sales during the nine months ended September 30, 2008, from 89% in the year earlier period. In 2008, direct-to-hospital sales growth was increased by our recent direct sales initiatives in France, Italy, Sweden and Ireland, and offset by the inclusion of our sales of prosthetic vascular grafts to a distributor in Europe.

The impact of foreign currency fluctuations and changes in business activities are presented in the table in the Overview section above.

**Net sales by geography.** Net sales in the United States and Canada increased 9% to \$6.8 million and 10% to \$20.1 million, for the three and nine months ended September 30, 2008, respectively. Increases were largely a result of the inclusion of the EndoRE suite of products, higher average selling prices across nearly all product lines, strong valvulotome and embolectomy balloon catheter sales, and increased sales representative efficiency. Net sales outside of the United States and Canada increased 34% to \$5.2 million and 37% to \$16.5 million, for the three and nine months ended September 30, 2008, respectively. Increases were attributable to the positive effects of currency exchange rate fluctuations, the inclusion of the prosthetic vascular graft product line, and increased sales of the recently improved TAArget and UniFit stent grafts as well as the Powerlink system.

Direct-to-hospital net sales outside of the United States and Canada increased to 76% during the three months ended September 30, 2008, from 74% of net sales in the year earlier period. Direct to hospital net sales outside of the United States and Canada were 72% during the nine months ended September 30, 2008 and 2007. Direct-to-hospital sales growth was increased of our recent direct sales initiatives in France, Italy, Sweden and Ireland, and offset by the inclusion of our sales of prosthetic vascular grafts to a distributor in Europe.

**Gross profit:**

(unaudited)	Three months ended September 30				Nine months ended September 30			
	2008	2007	\$ Change	Percent change	2008	2007	\$ Change	Percent change
Gross profit	\$ 8,103	\$ 7,581	\$ 522	6.9%	\$ 25,478	\$ 22,564	\$ 2,914	12.9%
Gross margin	67.4%	74.7%	*	(7.3)%	69.6%	74.4%	*	(4.8)%

Gross profit increased 7% to \$8.1 million and 13% to \$25.5 million, for the three and nine months ended September 30, 2008, respectively. Our gross margin decreased 7% to 67.4% and 5% to 69.6%, for the three and nine months ended September 30, 2008, respectively. Increased gross profit was driven by higher sales versus prior



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**Research and development.** Research and development expenses increased over the previous year by \$0.1 million to \$1.2 million and by \$0.6 million to \$4.0 million, for the three and nine months ended September 30, 2008, respectively. Increases were largely a result of the UNITE Trial, which did not commence patient enrollment until June 2007, as well as other increased clinical and regulatory spending as we seek to obtain clearances to sell new products or existing products in new markets. We launched our 9 French Pruitt F3 Carotid Shunt and our 5 French Plus Over-the-Wire Embolectomy Catheter during the quarter ended September 30, 2008. We anticipate that research and development expenses will continue to increase as more UNITE Trial patients are enrolled, as new products follow the regulatory pathways, and as more product development is undertaken.

**Restructuring.** Restructuring charges incurred in 2008 were a result of payments related to non-compete and consulting agreements made with our recently terminated Italian distributor of approximately \$0.7 million, as well as, severance costs of \$0.4 million resulting from the reduction in force of eight and 32 employees in the third and first quarters, respectively. In September 2007, we entered into termination agreements with our former Italian and Irish distributors resulting in \$1.1 million of restructuring expenses.

**Impairment charge.** In January 2008, we were notified by one of our Biomateriali customers that they would no longer purchase a certain product line from us. As a result, we recorded an impairment charge of \$0.4 million to write-down intangible assets related to that customer relationship in the quarter ended March 31, 2008. We recognized impairment charges of \$30,000 and \$48,000 related to patents and trademarks which were deemed to have no value based upon a lack of future expected economic benefits in the three months ended September 30, 2008 and June 30, 2008, respectively.

**Interest income.** Interest income was \$0.2 million for the three months and \$0.4 million for the nine months ended September 30, 2008, compared to \$0.4 million and \$1.1 million for the three and nine months ended September 30, 2007, due to lower average cash balances in the quarter and year-to-date periods, as well as a less favorable interest rate market in 2008.

**Interest expense.** Interest expense increased to \$15,000 for the three months ended and \$47,000 for the nine months ended September 30, 2008, from \$0 in the comparable periods in the prior year, primarily due to interest expense related to deferred Biomateriali acquisition payments.

**Investment Impairment.** On September 30, 2008, we recorded an investment impairment charge of \$0.1 million which were attributed to the other-than-temporary decline in one specific asset backed security which we hold as available-for-sale in our marketable securities portfolio. There were no investment impairment charges for the three months and nine months ending September 30, 2007.

**Foreign exchange gains / losses.** Foreign exchange losses were \$0.3 million for the three months ended and \$0.1 million for the nine months ended September 30, 2008, compared to foreign exchange gains of \$0.2 million and \$0.3 million in the comparable periods in the prior year due to the comparatively weaker U.S. dollar.

**Income tax expense.** Our provision for income taxes for the three months ended September 30, 2008, was \$0.1 million compared to \$0.4 million for the three months ended September 30, 2007. Our provision for income taxes for the nine months ended September 30, 2008, was \$0.5 million compared to \$0.1 million for the nine months ended September 30, 2007. In 2007, we recorded a one-time tax benefit of \$0.5 million related to the reorganization of our Japanese subsidiary in June 2007 for which a loss carry back was realized. In 2008, the income tax provision was driven by taxable earnings in a foreign subsidiary and the recording of a deferred tax liability related to the amortization of goodwill for U.S. tax reporting purposes, which could not be offset by existing deferred tax assets. We monitor the mix of profitability by tax jurisdiction and adjust our annual expected rate on a quarterly basis as needed.

## **Liquidity and Capital Resources**

At September 30, 2008, our cash and cash equivalents and marketable securities were \$19.2 million as compared to \$22.6 million at December 31, 2007. Our cash and cash equivalents are primarily highly liquid investments with maturities of 90 days or less at the date of purchase, consist of time deposits and investments in money market funds with commercial banks and financial institutions, commercial paper, and U.S. government obligations, and are stated at cost, which approximates fair value. Our marketable securities are primarily

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marketable debt securities, corporate bonds, and U.S. government securities that we classify as available-for-sale and are carried at fair market value. We did not hold any auction-rated securities in our investment portfolio as of September 30, 2008.

The majority of our marketable securities have remaining maturities of two years or less. Our investment portfolio includes \$1.9 million of asset-backed securities collateralized by first-lien mortgages, credit card debt, and auto loans. In the event of a temporary decline in market value, we have the intent and ability to hold our debt investments for a sufficient period of time to allow for recovery of the principal amounts invested. In September 2008, we recognized a loss of \$0.1 million on an asset-backed security which experienced an other-than-temporary decline in market value. We continually monitor the credit risk in our portfolio and attempt to mitigate our credit and interest rate exposures. We intend to continue to closely monitor future developments in the credit markets and make appropriate changes to our investment policy as necessary. Although the global financial markets are currently experiencing a highly unusual degree of volatility which makes forecasting liquidity extremely difficult, based on our ability to liquidate our investment portfolio, we do not anticipate any liquidity constraints as a result of the current credit environment.

We require cash to pay our operating expenses, make capital expenditures, and pay our long-term liabilities. Since our inception, we have funded our operations through private placements of equity securities, short-term borrowings, and funds generated from our operations. In October 2006 we completed our initial public offering of our common stock at a price to the public of \$7.00 per share. We sold 5,500,000 shares and received aggregate net proceeds of approximately \$35.8 million, after deducting underwriting discounts and commission of approximately \$2.7 million.

Of the \$35.8 million of net proceeds we received in our initial public offering, we have spent \$18.9 million as of September 30, 2008, including \$4.2 million to pay down all outstanding indebtedness under two term loans and a revolving line of credit, \$0.3 million to pay down the revolving line of credit of our Biomateriali subsidiary (which was outstanding on the acquisition date), \$1.3 million for payment of expenses related to our initial public offering, \$5.7 million for acquisitions, \$1.9 million for the early termination of our Italian distributor relationship, \$0.8 million for the purchase and licensing of technology (of which \$0.4 million was expensed on the date of acquisition as in-process research and development), and \$1.7 million for capital equipment additions. Our cash balances may decrease as we continue to use cash to fund our operations, make acquisitions, and make deferred payments related to prior acquisitions.

***Net cash used in operating activities.*** Net cash used in operating activities was \$1.9 million for the nine months ended September 30, 2008, and consisted of the \$3.6 million net loss, adjusted for non-cash items of \$3.3 million (including depreciation and amortization of \$1.3 million, provision for inventory write-offs of \$0.9 million, stock-based compensation of \$0.6 million, and an intangibles impairment charge of \$0.5 million) and net cash used from changes in working capital of \$1.6 million. The net cash used from changes in working capital was principally the result of a reduction in accounts payable and accrued expenses and to a lesser extent an increase in inventories.

***Net cash provided by investing activities.*** Net cash provided by investing activities was \$8.7 million for the nine months ended September 30, 2008. This was primarily due to sales and maturities of marketable securities of \$11.6 million, partially offset by purchases of marketable securities of \$1.7 million, of property and equipment of \$0.6 million, payments made related to prior year acquisitions of \$0.6 million, and the purchase of technology and other intangibles of \$0.1 million.

***Net cash used in financing activities.*** Financing activities were cashflow neutral for the nine months ended September 30, 2008. This was primarily due to the repayment of the revolving line of credit of our Italian subsidiary of \$0.3 million, which was offset by the proceeds from the issuance of common stock pursuant to the exercise of common stock options and the employee stock purchase plan of \$0.3 million.

We recognized a net operating profit of \$170,000 for the three months ending September 30, 2008; however, we recognized a net operating loss of \$3.3 million for the nine months ended September 30, 2008. Although it is our intention to continue to generate an operating profit, there can be no assurance that we will not generate a net operating loss in the future due to our investment in growing our business, as well as the cost of operating as a public company. We expect to fund any increased costs and expenditures from our existing cash and cash equivalents and marketable securities; though, our future capital requirements depend on numerous factors.

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These factors include, but are not limited to, the following: the revenues generated by sales of our products; the costs associated with expanding our manufacturing, marketing, sales, and distribution efforts; the rate of progress and cost of our research and development activities; litigation; the costs of obtaining and maintaining FDA and other regulatory clearances of our products and products in development; the effects of competing technological and market developments; the costs associated with being a public company, including consulting expenses associated with compliance with Section 404 of the Sarbanes-Oxley Act of 2002; and the number, timing, and nature of acquisitions and other strategic transactions.

We maintain a \$10.0 million revolving line of credit that provides for up to \$3.0 million in letters of credit. The loan agreement requires that we meet certain financial and operating covenants. As of September 30, 2008, we did not have an outstanding balance under this facility and were in compliance with these covenants. We believe that our current cash and cash equivalents and marketable securities will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. However, we may require additional funds in order to make acquisitions. We may seek financing of future cash needs through the sale of equity securities and issuance of debt. We cannot assure you that additional financing will be available when needed or that, if available, such financing will be obtained on terms favorable to us or our stockholders. Insufficient funds may require us to delay, scale back, or eliminate some or all of our business operations or may adversely affect our ability to operate as a going concern. If additional funds are obtained by issuing equity or debt securities, substantial dilution to existing stockholders may occur.

**Contractual Obligations.** Our principal contractual obligations consist of purchase commitments, operating leases, and capital leases. The following table summarizes our commitments to settle contractual obligations as of September 30, 2008:

	Total	Less than 1 year (in thousands)	1-3 years	3-5 years
<b>Contractual obligations</b>				
Operating leases	\$ 1,984	\$ 1,057	\$ 800	\$ 127
Purchase commitments for inventory	8,907	3,728	5,179	
Acquisition-related obligations	959	959		
FIN48 unrecognized tax benefits	28	28		
<b>Total contractual obligations</b>	<b>\$ 11,878</b>	<b>\$ 5,772</b>	<b>\$ 5,979</b>	<b>\$ 127</b>

The commitments under our operating leases shown above consist primarily of lease payments for our Burlington, Massachusetts, corporate headquarters and manufacturing facility and a separate manufacturing and storage facility in Burlington, Massachusetts, each expiring in 2009; our Sulzbach, Germany office, expiring in 2010; and our Tokyo, Japan office, expiring in 2010.

In addition to the contractual obligations detailed above, there are potential contingent payments associated with the Biomateriali stock purchase agreement and product distribution agreement that could not be resolved beyond a reasonable doubt as of September 30, 2008. These contingent payments could total up to \$2.1 million based upon the exchange rate effective on September 30, 2008. Due to the uncertainty of the future payouts, they have not been recorded as part of the purchase price for Biomateriali. When the contingencies are resolved, they may result in recognition of an additional cost, and the purchase price would be adjusted at that time.

**Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements as of September 30, 2008.



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### **Critical Accounting Policies and Estimates**

We have adopted various accounting policies to prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. Our most significant accounting policies are described in note 1 to our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007. The preparation of our consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. Our estimates and assumptions, including those related to bad debts, inventories, intangible assets, sales returns and discounts, and income taxes are reviewed on an ongoing basis and updated as appropriate. Actual results may differ from those estimates.

Certain of our more critical accounting policies require the application of significant judgment by management in selecting the appropriate assumptions for calculating financial estimates. By their nature, these judgments are subject to an inherent degree of uncertainty. These judgments are based on our historical experience, terms of existing contracts, observance of trends in the industry, and information provided by physicians who use our products and information available from other outside sources, as appropriate. Different, reasonable estimates could have been used in the current period. Additionally, changes in accounting estimates are reasonably likely to occur from period to period. Both of these factors could have a material impact on the presentation of our financial condition, changes in financial condition, or results of operations.

We believe that the following financial estimates and related accounting policies are both important to the portrayal of our financial condition and results of operations and require subjective or complex judgments. Further, we believe that the items discussed below are properly recorded in our consolidated financial statements for all periods presented. Management has discussed the development, selection, and disclosure of our most critical financial estimates with the audit committee of our board of directors and our independent registered public accounting firm. The judgments about those financial estimates are based on information available as of the date of our consolidated financial statements. Those financial estimates and related policies include:

#### ***Revenue Recognition***

We recognize revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. We generally use customer purchase orders or contracts to determine the existence of an arrangement. Substantially all sales transactions are based on prices that are determinable at the time that the customer's purchase order is accepted by us. In order to determine whether collection is reasonably assured, we assess a number of factors, including past transaction history with the customer and the creditworthiness of the customer. If we determine that collection is not reasonably assured, we would defer the recognition of revenue until collection becomes reasonably assured, which is generally upon receipt of payment. We provide for product returns at the time revenue is recognized in accordance with Statement of Financial Accounting Standards (SFAS) No. 48, *Revenue Recognition When Right of Return Exists*, based on our history of product returns.

#### ***Accounts Receivable***

Our accounts receivable are with customers based in the United States and internationally. Accounts receivable generally are due within 30 to 90 days of invoice and are stated at amounts due from customers, net of an allowance for doubtful accounts and sales returns. We perform ongoing credit evaluations of the financial condition of our customers and adjust credit limits based upon payment history and the current creditworthiness of the customers, as determined by a review of their current credit information. We continuously monitor aging reports, collections, and payments from customers and maintain a provision for estimated credit losses based upon historical experience and any specific customer collection issues that we identify.

We write off accounts receivable when they become uncollectible. While such credit losses have historically been within our expectations and allowances, we cannot guarantee the same credit loss rates will be experienced in the future. The allowance for doubtful accounts is our best estimate of the amount of probable credit losses in our existing accounts receivable. We review our allowance for doubtful accounts on a monthly basis, and all past-due balances are reviewed individually for collectability. The provision for the allowance for doubtful accounts is recorded in general and administrative expenses.

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**Table of Contents*****Inventory***

Inventory consists of finished products, work-in-process, and raw materials. We value inventory at the lower of cost or market value. Cost includes materials, labor, and manufacturing overhead and is determined using the first-in, first-out (FIFO) method. On a quarterly basis, we review inventory quantities on hand and analyze the provision for excess and obsolete inventory based primarily on product expiration dating and our estimated sales forecast, which is based on sales history and anticipated future demand. Our estimates of future product demand may not be accurate, and we may understate or overstate the provision required for excess and obsolete inventory. Accordingly, any significant unanticipated changes in demand could have a significant impact on the value of our inventory and results of operations.

***Share-based Compensation***

Determining the appropriate fair value model and calculating the fair value of employee stock options requires judgment. We use the Black-Scholes option pricing model to estimate the fair value of these share-based awards consistent with the provisions of SFAS No. 123(R), *Share-Based Payment*. We estimate expected volatility based on the historical volatility of the company's stock. The expected lives of the options were estimated using the simplified method for plain vanilla options. The risk-free interest rate is based on U.S. Treasury zero-coupon issues with a remaining term which approximates the expected life assumed at the date of grant. Changes in these input variables would affect the amount of expense associated with stock-based compensation. The compensation expense recognized for all stock-based awards is net of estimated forfeitures. We estimate forfeiture rates based on historical analysis of option forfeitures. If actual forfeitures should vary from estimated forfeitures, adjustments to compensation expense may be required.

***Valuation of Goodwill and Other Intangibles***

When we acquire another company, the purchase price is allocated, as applicable, among acquired tangible net assets, identifiable intangible assets, and goodwill as required by U.S. GAAP. Goodwill represents the excess of the aggregate purchase price over the fair value of net assets of the acquired businesses. Goodwill is tested for impairment annually or more frequently if changes in circumstance or the occurrence of events suggest impairment exists. We evaluate the carrying value of goodwill based on a single reporting unit annually as of December 31 and more frequently if certain indicators are present or changes in circumstances suggest that impairment may exist. The test for impairment requires us to make several estimates about fair value, principally related to the determination that we operate as a single reporting unit and therefore that fair value is based on the our market capitalization. Our estimates associated with the goodwill impairment tests are considered critical due to the amount of goodwill recorded on our consolidated balance sheets and the judgment required in determining fair value amounts. Goodwill was \$10.9 million as of September 30, 2008 and as of December 31, 2007. We have determined that no impairment indicators existed as of September 30, 2008.

Other intangible assets consist primarily of purchased developed technology, patents, customer relationships, and trademarks and are amortized over their estimated useful lives, ranging from 5 to 17 years. We review these intangible assets for impairment as changes in circumstance or the occurrence of events suggest the remaining value may not be recoverable. The evaluation of asset impairments related to other intangible assets requires us to make assumptions about future cash flows over the life of the asset being evaluated. These assumptions require significant judgment and actual results may differ from assumed or estimated amounts. In January 2008 we were notified by one of the customers of our Biomaterials subsidiary that they would no longer purchase a certain product line from us, and, as a result, we recorded an impairment charge of \$0.4 million related to the write-down of certain acquired intangible assets related to that customer relationship. We recognized impairment charges of \$30,000 and \$48,000 related to patents and trademarks which were deemed to have no value based upon a lack of future expected economic benefits in the three months ended September 30, 2008 and June 30, 2008, respectively. Other intangible assets, net of accumulated amortization, were \$3.1 million as of September 30, 2008, and \$3.9 million as of December 31, 2007.

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**Table of Contents*****Contingencies***

In the normal course of business, we are subject to proceedings, lawsuits, and other claims and assessments for matters related to, among other things, patent infringement, business acquisitions, employment, and product recalls. We assess the likelihood of any adverse judgments or outcomes to these matters as well as potential ranges of probable losses. A determination of the amount of reserves required, if any, for these contingencies is made after careful analysis of each individual issue. The required reserves may change in the future due to new developments in each matter or changes in approach, such as a change in settlement strategy in dealing with these matters. We record charges for losses that are probable in connection with litigation and claims against us when we can reasonably estimate these losses. At September 30, 2008, we were not subject to any material litigation, claims, or assessments.

***Restructuring***

We record restructuring charges incurred in connection with reductions in force, consolidation or relocation of operations, exited business lines, shutdowns of specific sites, and the termination of distributor relationships. These restructuring charges, which reflect our commitment to a termination or exit plan that will begin within 12 months, are based on estimates of the expected costs associated with site closure, legal matters, contract terminations, or other costs directly related to the restructuring. If the actual cost incurred exceeds the estimated cost, an additional charge to earnings will result. If the actual cost is less than the estimated cost, a credit to earnings will be recognized.

***Accounting for Income Taxes***

As part of the process of preparing our consolidated financial statements we are required to determine our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax expense together with assessing temporary differences resulting from recognition of items for income tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within our consolidated balance sheet. We must then assess the likelihood that our deferred tax assets will be recovered from taxable income during the carryback period or in the future; and to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must reflect this increase as an expense within the tax provision in the statement of operations. We do not provide for income taxes on undistributed earnings of foreign subsidiaries, as our current intention is to permanently reinvest these earnings.

We operate in multiple taxing jurisdictions, both within the United States and outside of the United States and may be subject to audits from various tax authorities regarding transfer pricing, the deductibility of certain expenses, intercompany transactions, and other matters. Management's judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities, liabilities for uncertain tax positions, and any valuation allowance recorded against our net deferred tax assets. We will continue to monitor the realizability of our deferred tax assets and adjust the valuation allowance accordingly.

***Marketable Securities***

We account for our investments in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Our investments, primarily marketable debt securities, commercial paper, and U.S. government securities, were classified as available-for-sale and were carried at fair market value at September 30, 2008. The unrealized gains (losses) on available-for-sale securities are recorded in accumulated other comprehensive income (loss). We consider all highly liquid investments with original maturities of 90 days or less at the time of purchase to be cash equivalents, and investments with original maturities of greater than 90 days to be short-term investments. When a marketable security incurs a significant unrealized loss for a sustained period of time, we review the instrument to determine if it is other-than-temporarily impaired.

**Table of Contents*****Off-Balance Sheet Arrangements***

We did not have any off-balance sheet arrangements as of September 30, 2008. We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As a result, we are not materially exposed to any financing, liquidity, market, or credit risk that could arise if we had engaged in these relationships.

**New Accounting Pronouncements**

In March 2008 the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB statement No. 133 (SFAS No. 161)*. SFAS No. 161 requires enhanced disclosures regarding an entity's derivative instruments and related hedging activities. These enhanced disclosures include information regarding how and why an entity uses derivative instruments; how derivative instruments and related hedge items are accounted for under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and its related interpretations; and how derivative instruments and related hedge items affect an entity's financial position, financial performance, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The adoption of SFAS No. 161 will not have a material impact on our financial position, results of operations, or liquidity.

In December 2007 the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, (SFAS No. 141(R)). SFAS No. 141(R) replaces SFAS No. 141, *Business Combinations*, and requires the acquiring entity in a business combination to recognize the full fair value of assets acquired and liabilities assumed in the transaction; requires certain contingent assets and liabilities acquired to be recognized at their fair values on the acquisition date; requires contingent consideration to be recognized at its fair value on the acquisition date and changes in the fair value to be recognized in earnings until settled; requires the expensing of most transaction and restructuring costs; and generally requires the reversals of valuation allowances related to acquired deferred tax assets and changes to acquired income tax uncertainties to also be recognized in earnings. SFAS No. 141(R) is effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of 2009. The adoption of SFAS No. 141(R) will change our accounting treatment for business combinations on a prospective basis for business combinations entered into subsequent to December 31, 2008.

In December 2007 the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an amendment of Accounting Research Bulletin No. 51* (SFAS No. 160). SFAS No. 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest, and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS No. 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of 2009. We do not expect that the adoption of SFAS No. 160 will have a material effect on our consolidated results of operations and financial condition.

In December 2007 the FASB ratified Emerging Issues Task Force (EITF) Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 provides guidance on collaborative arrangements within the scope of this issue on the classification of the payments between participants in the arrangement, the appropriate income statement presentation as well as disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of 2009. We are currently evaluating the potential impact of EITF 07-01 on our financial position and results of operations.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to various market risks arising from adverse changes in market rates and prices, such as foreign exchange fluctuations and interest rates, which could impact our results of operations and financial position. We do not currently engage in any hedging or other market risk management tools, and we do not enter into derivatives or other financial instruments for trading or speculative purposes.

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**Foreign Currency Exchange Rate Risk.** Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies, primarily the euro, could adversely affect our financial results. For the three and nine months ended September 30, 2008, approximately 43% and 45%, respectively, of our sales were denominated in foreign currencies. We expect that foreign currencies will continue to represent a similarly significant percentage of our sales in the future. Selling, marketing, and administrative costs related to these sales are largely denominated in the same respective currency, thereby partially mitigating our transaction risk exposure. We therefore believe that the risk of a significant impact on our operating income from foreign currency fluctuations is moderated. However, for sales not denominated in U.S. dollars, if there is an increase in the rate at which a foreign currency is exchanged for U.S. dollars, it will require more of the foreign currency to equal a specified amount of U.S. dollars than before the rate increase. In such cases and if we price our products in the foreign currency, we will receive less in U.S. dollars than we did before the rate increase went into effect. If we price our products in U.S. dollars and competitors price their products in local currency, an increase in the relative strength of the U.S. dollar could result in our price not being competitive in a market where business is transacted in the local currency.

The majority of sales recorded in foreign currencies for the quarter ended September 30, 2008 were denominated in the euro. Our principal exchange rate risk therefore exists between the U.S. dollar and the euro. Fluctuations from the beginning to the end of any given reporting period result in the re-measurement of our foreign currency-denominated receivables and payables, generating currency transaction gains or losses that impact our non-operating income/expense levels in the respective period and are reported in other (income) expense, net in our consolidated financial statements. We recorded \$257,000 foreign currency loss and \$221,000 foreign currency gain for the three months ended September 30, 2008 and 2007, respectively, and \$91,000 foreign currency loss and \$284,000 foreign currency gain for the nine months ended September 30, 2008 and 2007, respectively, related mainly to the re-measurement of our foreign currency-denominated receivables and payables. We do not currently hedge our exposure to foreign currency exchange rate fluctuations. We may, however, hedge such exposure to foreign currency exchange rate fluctuations in the future.

**Interest Rate Risk.** Our exposure to interest rate risk at September 30, 2008 is related primarily to our investment portfolio. Our investment portfolio includes fixed rate debt instruments of the U.S. government and corporate issuers and consists primarily of short-term investments. The primary objective of our investments in debt instruments is to preserve principal while maximizing yields. A change in prevailing interest rates may cause the fair value of our investments to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing rate rises, the fair value of the principal amount of our investment will probably decline. To minimize this risk, investments are generally held to maturity. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments.

**Credit Risk.** In addition to a decline in interest rates, other economic variables, such as equity market fluctuations and changes in relative credit risk, could result in a decline in the fair value of our investment portfolio. The majority of our marketable securities have remaining maturities of two years or less. Our investment portfolio includes \$1.9 million of asset-back securities collateralized by first-lien mortgages, credit card debt, and auto loans. We did not hold any auction-rated securities in our investment portfolio as of September 30, 2008. In the event of a temporary decline in market value, we have the intent and ability to hold our debt investments for a sufficient period of time to allow for recovery of the principal amounts invested. We continually monitor the credit risk in our portfolio and mitigate our credit and interest rate exposures in accordance with our policies. We intend to continue to closely monitor future developments in the credit markets and make appropriate changes to our investment policy as deemed necessary. Based on our ability to liquidate our investment portfolio, we do not anticipate any liquidity constraints as a result of the current credit environment.

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**Item 4. Controls and Procedures**

**Effectiveness of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in reports we file or submit under the Securities and Exchange Act of 1934 is processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Our management, with the participation of the Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, the chief executive officer and chief financial officer have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Report.

*Remediation of Prior Material Weakness in Internal Control Over Financial Reporting*

As of December 31, 2007, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Due to the identification of a material weakness in internal control over financial reporting with respect to the determination of certain accruals and the related inadequate reconciliation and review procedures of the financial statement close process, as described below, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2007, our disclosure controls and procedures were not effective. A material weakness in internal control over financial reporting is a significant deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected by employees on a timely basis in the normal course of their assigned functions.

Since December 31, 2007, we have implemented enhancements to our internal control over financial reporting to address the material weakness described above and to provide reasonable assurance that errors and control deficiencies of this type will not recur. These steps included:

Hiring new finance personnel.

Providing additional training for finance personnel.

Instituting policies and procedures to enhance systematic review of certain accruals, reconciliations, and the review of the financial statement close.

We will continue to monitor the effectiveness of these procedures and will continue to make any changes that management deems appropriate.

**Changes in Internal Control over Financial Reporting**

There was no change in the Company's internal control over financial reporting that occurred during the fiscal quarter ended September 30, 2008, that has materially affected, or is reasonably likely to materially affect the Company's internal control over financial reporting. In addition, the quarter ended September 30, 2008 was the third full quarter that included the results of Biomateriali S.r.l., acquired on December 20, 2007, in our consolidated financial statements, and as such we incorporated Biomateriali into our corporate closing and consolidation process. We are still in the process of integrating Biomateriali's financial operations, and our management has not yet conducted testing related to our internal controls over financial reporting at Biomateriali.

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**Part II. Other Information**

**Item 1. Legal Proceedings.**

We are not party to any material pending or threatened litigation.

**Item 1A. Risk Factors**

*Our operating results and financial condition have varied in the past and may in the future vary significantly depending on a number of factors. In addition, this Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, including statements about our future plans, objectives, intentions and expectations. Many factors, including those described below, could cause actual results to differ materially from those discussed in any forward-looking statements.*

*In Part I-Item 1A ( Risk Factors ) of our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, which was filed with the Securities and Exchange Commission on March 31, 2008, we describe risk factors related to LeMaitre Vascular. The following risk factors are either new or have changed materially from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2007. You should carefully review these risks and those described in our Annual Report on Form 10-K and in other reports we file with the Securities and Exchange Commission in evaluating our business.*

***We may experience significant fluctuations in our quarterly results and we may not maintain our operating profitability.***

As of September 30, 2008, we had an accumulated deficit of approximately \$16.5 million. While we reported positive operating income in the three months ended September 30, 2008, we had an operating loss and a net loss for the nine months ended September 30, 2008. Although we intend to maintain operating profitability through the remainder of 2008 and into 2009, there can be no assurance that we will be successful in doing so. We cannot assure you that we will achieve significant net sales or achieve and maintain net profitability. Our recent operating profitability results from extensive operating expense reduction. Control of operating expenses will need to be maintained in order to maintain and improve operating profitability, and decreased discretionary investment levels may inhibit future growth in net sales and earnings. We intend to increase operating expenses through the remainder of 2008 and in 2009 in areas such as research and development and clinical and regulatory affairs. Our ability to achieve and maintain profitability will be influenced by many factors, including:

the level and timing of future sales, manufacturing costs and operating expenditures;

market acceptance of our new products;

the productivity of our direct sales force and distributors;

the cost of our clinical studies;

our ability to successfully acquire and develop competitive products;

our ability to successfully integrate acquired businesses, products, or technologies;

the impact on our business of competing products, technologies, and procedures;

our ability to obtain regulatory approvals for our products in new markets;

market and regulatory developments; and

the cost of intellectual property challenges, if any.



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***There can be no assurance that we will continue to increase our cash and marketable securities balance in the near term, and, as a result, we may require additional capital, which may not be available on terms acceptable to us or at all. Failure to attract additional capital on terms acceptable to us could impair our growth.***

While we reported an increase to our cash and marketable securities in the three months ended September 30, 2008, we had negative cash flow from operations in the nine months ended June 30, 2008, and we may require additional capital to execute our strategies and further expand our business. In particular, we depend on access to capital to acquire products and technologies that complement our existing product lines. If our cash reserves, together with cash available under our credit facility and cash generated internally are insufficient to fund our operations or our capital requirements, particularly those related to potential future acquisitions, we will require additional debt or equity financing. The availability of such financing depends in large measure on capital markets and liquidity factors over which we can exert little control. Events over the past several months, including recent failures and near failures of a number of large financial service companies have made the capital markets increasingly volatile. As a result, many medical device companies are finding financing to be increasingly expensive and difficult to obtain. Equity financing, if available, may be dilutive to our stockholders. If we raise additional capital through the issuance of debt, this debt will be senior to our outstanding shares of capital stock upon our liquidation. Financing may not be available or, if available, may not be available on terms acceptable to us and could result in significant stockholder dilution. In addition, covenants in debt financing arrangements may restrict our ability to operate our business or obtain additional debt financing. These covenants may also require us to attain certain levels of financial performance and we may not be able to do so; any such failure may result in the acceleration of such debt and the foreclosure by our creditors on the collateral we used to secure the debt. We may also elect to raise additional funds through collaboration, licensing, marketing, or similar arrangements, and these arrangements may require us to relinquish valuable rights to our products or proprietary technologies, or grant licenses that are not favorable to us. If we fail to obtain sufficient additional capital in the future, we could be forced to curtail our growth strategy by reducing or delaying capital expenditures and acquisitions, delaying or postponing our product development efforts (including clinical studies), selling assets, restructuring our operations, or refinancing our indebtedness.

***Fluctuations in foreign currency exchange rates could result in declines in our reported sales and earnings.***

For the nine months ended September 20, 2008, 45% of revenues were derived from sales occurring outside of the United States. Because the majority of our sales outside of the United States are denominated in local currencies, our reported sales and earnings are subject to fluctuations in foreign exchange rates. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our sales and earnings. At present, we manufacture very few of our products outside the United States and we do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. Over recent months, the value of foreign currencies against the U.S. dollar has fluctuated dramatically. For example, the value of the euro against the U.S. dollar declined by nearly 10% during the month of October, 2008, which could be expected to have a negative impact on sequential revenue and earnings growth as euro-denominated revenues are translated into U.S. dollars at a reduced value.

***Our results of operations are substantially dependent on businesses and assets that we acquired from third parties, and if we experience difficulties in completing the integration of these acquisitions into our business, or if we do not realize the anticipated benefits of these acquisitions, then our financial condition and results of operations could be adversely affected.***

Since 1998 we have completed ten acquisitions. Our operating results are largely dependent on these acquired product lines, and this dependence exposes us to risks and uncertainties.

For example, following our acquisition of Biomateriali S.r.l. in December 2007, we were informed by Sorin Biomedica SpA, that Sorin would be reducing its purchases under an existing private label manufacturing program with Biomateriali. We estimate that this change in purchase volume will result in a \$550,000 reduction, approximately, in annual net sales of Biomateriali compared to annual net sales for the year preceding the acquisition. We can provide no assurance that similar changes in purchasing volume will not occur in the future in regard to Sorin or any other private label customer of, or distributor for, a company that we acquire.

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In March 2008, we provided notice of an indemnity claim under the Biomateriali purchase agreement to the sellers of Biomateriali, contending that the sellers breached certain representations and warranties in the purchase agreement by failing to adequately disclose material information regarding the Sorin customer relationship. We have since made other indemnity claims related to inventory and government subsidies. We have demanded the payment of damages of approximately \$1.1 million (denominated in euros) and have ceased making certain post-closing payments to the sellers pending resolution of this indemnity claim.

There are also a number of contingent liabilities that we may face relating to the Biomateriali acquisition. For example, if our distribution agreement with Edwards Lifesciences AG is terminated or expires, we may be obligated to make payments to the sellers of approximately \$1.1 million to \$2.2 million. Further, upon termination of the distribution agreement we may be obligated to either buy back non-expired inventory from Edwards at the original sales price for that inventory or direct the sale of that inventory to third parties. Currently, we have no specific plan to terminate this agreement; however, we may elect to terminate or modify the agreement prior to its expiration, which could result in a payment to the sellers of less than the full \$2.2 million and possibly the repurchase of inventory.

We also may experience other difficulties related to our acquisitions. For example, in connection with our acquisition of our TAArget and UniFit Stent Graft product lines, we acquired an ongoing clinical study related to the UniFit Abdominal Stent Graft. Our experience in conducting clinical studies is limited and we have experienced and may further experience difficulties or delays in transitioning this study or future studies. Any difficulties or delays we experience in connection with this clinical study could negatively impact our ability to obtain regulatory approval to market the UniFit Abdominal Stent Graft in certain markets. In addition, the products that we have acquired may need to be improved in order to gain broader market acceptance or may not compete effectively with existing products. We have limited experience with certain technologies underlying the acquired products. There can be no assurance that we will be successful developing the desired product improvements in a timely manner, if at all.

In addition, in April 2003, we acquired the Expedial Vascular Access Graft product line from Credent Limited, a UK company. In May 2004, we commenced a clinical study in the United States to collect data to submit to the FDA in support of 510(k) clearance for this device. In July 2006, as a result of our review of preliminary clinical study results and less-than-planned sales of the Expedial product in Europe, we decided to cease the production and sale of this device. There can be no assurance that we will not experience similar clinical setbacks in connection with future clinical programs we may acquire.

Any of these difficulties could negatively impact our ability to realize the intended and anticipated benefits that we currently expect from our acquisitions and could have a material adverse effect on our financial condition and results of operations.

***Our stent graft products require, are in, or have recently completed, clinical studies. If our clinical study applications are not approved, if our ongoing clinical studies are not successful, if the FDA or other regulatory agencies do not accept or approve the results of such studies, or if the FDA or other regulatory agencies find reason to interrupt or discontinue such studies, these products may not come to market on a timely basis or at all, and our business prospects may suffer.***

We have recently applied for FDA approval to commence a feasibility study of our TAArget Thoracic Stent Graft, which we call ENTRUST, and we cannot assure you that the FDA will permit us to begin this feasibility study. We also currently have an ongoing clinical study to support a possible PMA application for our UniFit Abdominal Stent Graft, and we completed a Chinese clinical study to support approval from the Chinese State Food and Drug Administration (the SFDA) of our TAArget Thoracic Stent Graft for marketing in China. We cannot assure you that the ongoing UniFit study will be successful or that the FDA or SFDA or other relevant regulatory agencies will accept the results of the applicable study and approve or clear the devices for sale. Further, we continue to evaluate the potential financial benefits and costs of our clinical studies and the products being evaluated in them. If we determine that the costs associated with obtaining regulatory approval of a product exceed the potential financial benefits of that product, or if the projected development timeline is inconsistent with our investment horizon, we may choose to discontinue a clinical study and/or the development of a product.

In May 2008, we submitted an IDE application to the FDA to begin a feasibility study, which we call the ENTRUST study, to evaluate the safety of the TAArget Thoracic Stent Graft in the treatment of thoracic aortic

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aneurysms. Because the TAArget Thoracic Stent Graft is a significant risk device for regulatory purposes, we cannot start our feasibility study for the device until we receive the FDA's approval of our application. In July 2008, we received a letter from the FDA indicating that it could not approve our application until deficiencies identified in the letter are resolved to the FDA's satisfaction. We are working with the FDA to seek to resolve these deficiencies and resubmit an application, although there can be no assurance that the FDA will approve our application.

In May 2006, we submitted an investigational device exemption, or IDE, supplemental application to the FDA to begin a pivotal clinical trial to evaluate the safety and effectiveness of the UniFit Abdominal Stent Graft in the treatment of aorto, aorto-iliac, and/or iliac aneurysms. In May 2007, we received final approval from the FDA to commence the pivotal trial, which we refer to as the UNITE study, and as of September 30, 2008, we had enrolled 18 patients in the trial. We plan to enroll 90 patients at 14 institutions. The primary effectiveness endpoint of the study is based on aneurysm exclusion as evaluated through one-year follow-up. If the institutions participating in any of our clinical studies or trials do not enroll a sufficient number of patients to provide the clinical data necessary to obtain regulatory approval of the device being evaluated, or do not enroll patients in a timely fashion, the approval or clearance of that device for sale may be prevented or delayed.

In January 2008, the FDA audited the conduct of the feasibility study and pivotal clinical trial of our UniFit Abdominal Stent Graft. As a result of this audit, the FDA issued a formal notification, or Form FDA-483, listing nine observations. Specifically, the FDA observed that we had not adequately supervised participating sites, made all required reports to those sites and the FDA, or adequately maintained all records required by FDA regulations. In June 2008, the FDA issued a public Warning Letter regarding many of the matters cited in the Form FDA-483. After receiving this Warning Letter, we submitted a response letter to the FDA detailing our implementation of corrective actions, and in July 2008, we received a letter from the FDA indicating that the corrective actions that we have developed and implemented appear to be adequate. However, our corrective actions remain subject to verification as part of any future inspection, and we cannot assure you that we will continue to be successful in implementing these changes or that the FDA will agree that our implementation is adequate. If the FDA finds that we are not in substantial compliance with IDE requirements, they may take enforcement action against us, and the conduct of our clinical trial could be interrupted or discontinued.

Our ability to market our stent graft products in the United States will depend upon a number of factors, including our ability to demonstrate the safety and effectiveness of our products with valid clinical data. Our ability to market our products outside of the United States is also subject to regulatory approval, including our ability to demonstrate the safety of our products in the clinical setting. Our products may not be found to be safe and, where required, effective in clinical studies, and may not ultimately be approved for marketing by U.S. or foreign regulatory authorities. In particular, if we do not meet our study success criteria or obtain FDA approval or clearance with respect to our products, our future growth may be significantly hampered. The products for which we are currently conducting studies are already approved for sale outside of the United States. As a result, while our studies are ongoing, unfavorable data may arise in connection with usage of our products outside the United States, which could adversely impact the approval of such products in the United States. Conversely, unfavorable data from clinical studies in the United States may adversely impact sales of our products outside of the United States. Our failure to develop safe and effective new products that are approved for marketing on a timely basis would have a negative impact on our sales and our business prospects may suffer materially.

***We rely on an independent distributor to market and sell our Albograft Vascular Graft.***

Our Albograft Vascular Graft is sold exclusively by Edwards Lifesciences AG pursuant to a distribution agreement that terminates on December 31, 2011. During the term of this agreement, our success with this product depends largely upon the performance of Edwards, in particular its sales and service expertise and relationships with its customers in the marketplace. We do not control Edwards. Although our distribution agreement with Edwards requires Edwards to make minimum unit purchases, there can be no assurance that Edwards will order such volumes. Edwards may devote insufficient efforts to selling the Albograft Vascular Graft and may not be successful in implementing our marketing plans, in which event our Biomaterials subsidiary could fail to achieve profitability and our operations could be adversely affected.

The distribution agreement may be terminated by one or both of the parties to the agreement upon the occurrence of certain events, including a failure by Edwards to order their contractual purchase commitment. Upon termination of the distribution agreement, we may be obligated to either purchase non-expired inventory from Edwards at the original sales price for that inventory or direct the sale of that inventory to third parties, and under

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certain circumstances we may need to make a negative adjustment to net sales. We may also be required to continue to sell products to Edwards following a termination to allow Edwards to honor its pre-termination contractual commitments.

Following a termination, in the absence of cooperation by Edwards, a failure by us to maintain or to quickly re-establish Edwards' close relationships with the physicians who use our products could cause a decline in sales. On the logistical side, if Edwards entered into an agreement with a customer relating to sales of the Albograft Vascular Graft or successfully completed a customer's internal approval process, it may be difficult or impossible to assign Edwards' rights under such agreements or approvals, and sales to that customer may be discontinued altogether or may be delayed until a new agreement is entered into or a new approval is obtained. As a result of the above risks, there can be no assurance that we would be successful in transitioning to a direct sales model for the Albograft Vascular Graft, and difficulties that we might encounter in this transition could negatively affect our business.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**  
**Recent Sales of Unregistered Securities**

None

**Issuer Purchases of Equity Securities**

For the three months ended September 30, 2008, we repurchased 5,767 shares of our common stock in conjunction with the forfeiture of shares to satisfy the employees' obligations with respect to withholding taxes in connection with the vesting of restricted stock units.

Period	Issuer Purchases and Other Acquisitions of Equity Securities			
	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares that may yet be Purchased
July 1, 2008 through September 30, 2008	5,767	\$ 3.43	N/A	N/A
Total	5,767	\$ 3.43	N/A	

**Item 3. Defaults upon Senior Securities**

None

**Item 4. Submission of Matters to a Vote of Securities Holders**

None

**Item 5. Other Information**

None

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**Item 6. Exhibits**

(a) Exhibits

- Exhibit 31.1 Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- Exhibit 31.2 Certification of the Chief Financial Officer Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- Exhibit 32.1 Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- Exhibit 32.2 Certification of the 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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**SIGNATURES**

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 on November 13, 2008.

LEMAITRE VASCULAR

*/s/ George W. LeMaitre*  
George W. LeMaitre  
Chairman and Chief Executive Officer

*/s/ Joseph P. Pellegrino, Jr.*  
Joseph P. Pellegrino, Jr.  
Chief Financial Officer

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**EXHIBIT INDEX**

- 31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification pursuant to 18 U.S.C. Section 1350
- 32.2 Certification pursuant to 18 U.S.C. Section 1350