

LEMAITRE VASCULAR INC  
Form 10-Q  
August 10, 2012  
Table of Contents

**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 June 30, 2012

Or

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

For the transition period from            to            .

Commission File Number 001-33092

**LEMAITRE VASCULAR, INC.**

(Exact name of registrant as specified in its charter)

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-Q

<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>04-2825458</b> (I.R.S. Employer Identification No.)
<b>63 Second Avenue, Burlington, Massachusetts</b> (Address of principal executive offices)	<b>01803</b> (Zip Code)
<b>(781) 221-2266</b> (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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="checkbox"/>

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 15,155,154 shares of common stock, \$.01 par value per share, outstanding as of August 6, 2012.

**Table of Contents**

**LEMAITRE VASCULAR**

**FORM 10-Q**

**TABLE OF CONTENTS**

	Page
Part I. <u>Financial Information:</u>	
Item 1. <u>Financial Statements</u>	
<u>Consolidated Balance Sheets as of June 30, 2012 (unaudited) and December 31, 2011</u>	3
<u>Unaudited Consolidated Statements of Operations for the three-month and six-month periods ended June 30, 2012 and 2011</u>	4
<u>Unaudited Consolidated Statements of Comprehensive Income for the three-month and six-month periods ended June 30, 2012 and 2011</u>	5
<u>Unaudited Consolidated Statements of Cash Flows for the six-month periods ended June 30, 2012 and 2011</u>	6
<u>Notes to Unaudited Consolidated Financial Statements</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	19
Item 3. <u>Quantitative and Qualitative Disclosure about Market Risk</u>	31
Item 4. <u>Controls and Procedures</u>	31
Part II. <u>Other Information:</u>	
Item 1. <u>Legal Proceedings</u>	32
Item 1A. <u>Risk Factors</u>	32
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	33
Item 5. <u>Other Information</u>	33
Item 6. <u>Exhibits</u>	33
<u>Signatures</u>	35
<u>Index to Exhibits</u>	

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

	(unaudited) <b>June 30, 2012</b>	<b>December 31, 2011</b>
	(in thousands, except share data)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 20,162	\$ 20,132
Accounts receivable, net of allowances of \$283 at June 30, 2012 and \$211 at December 31, 2011	8,801	8,541
Inventory	9,127	8,003
Prepaid expenses and other current assets	2,578	3,011
<b>Total current assets</b>	<b>40,668</b>	<b>39,687</b>
Property and equipment, net	4,607	4,661
Goodwill	11,917	11,917
Other intangibles, net	2,568	2,985
Deferred tax assets	6	6
Other assets	233	431
<b>Total assets</b>	<b>\$ 59,999</b>	<b>\$ 59,687</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 937	\$ 981
Accrued expenses	5,980	5,539
Acquisition-related obligations	19	19
<b>Total current liabilities</b>	<b>6,936</b>	<b>6,539</b>
Deferred tax liabilities	989	989
Other long-term liabilities	101	71
<b>Total liabilities</b>	<b>8,026</b>	<b>7,599</b>
Stockholders' equity:		
Preferred stock, \$0.01 par value; authorized 3,000,000 shares; none outstanding		
Common stock, \$0.01 par value; authorized 37,000,000 shares; issued 16,325,286 shares at June 30, 2012, and 16,303,155 shares at December 31, 2011	163	163
Additional paid-in capital	64,416	64,619
Accumulated deficit	(5,230)	(6,440)
Accumulated other comprehensive loss	(618)	(606)
Treasury stock, at cost; 1,176,622 shares at June 30, 2012, and 975,700 shares at December 31, 2011	(6,758)	(5,648)
<b>Total stockholders' equity</b>	<b>51,973</b>	<b>52,088</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 59,999</b>	<b>\$ 59,687</b>

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-Q

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 six months ended	
	June 30, 2012	June 30, 2011	June 30, 2012	June 30, 2011
	(in thousands, except per share data)			
Net sales	\$ 14,361	\$ 15,112	\$ 28,289	\$ 29,710
Cost of sales	3,816	4,742	7,874	9,189
Gross profit	10,545	10,370	20,415	20,521
Sales and marketing	5,186	4,916	10,399	9,889
General and administrative	2,717	2,867	5,385	5,715
Research and development	1,135	1,040	2,270	2,312
Restructuring charges		650		1,655
Loss on divestitures	52		52	
Impairment charges				83
Total operating expenses	9,090	9,473	18,106	19,654
Income from operations	1,455	897	2,309	867
Other income (expense):				
Interest income	14	2	21	3
Foreign currency gain (loss)	(49)	5	(247)	144
Other income, net				8
Income before income taxes	1,420	904	2,083	1,022
Provision for income taxes	596	385	873	439
Net income	\$ 824	\$ 519	\$ 1,210	\$ 583
Net income per share of common stock:				
Basic	\$ 0.05	\$ 0.03	\$ 0.08	\$ 0.04
Diluted	\$ 0.05	\$ 0.03	\$ 0.08	\$ 0.04
Weighted-average shares outstanding:				
Basic	15,201	15,470	15,248	15,468
Diluted	15,636	16,071	15,681	16,064
Cash dividends declared per common share	\$ 0.025	\$ 0.020	\$ 0.050	\$ 0.040

See accompanying notes to consolidated financial statements.



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

	<b>Three months ended</b>		<b>Six months ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
	(in thousands)			
Net income	\$ 824	\$ 519	\$ 1,210	\$ 583
Other comprehensive income:				
Foreign currency translation adjustment, net	(305)	126	(12)	423
Total other comprehensive income	(305)	126	(12)	423
Comprehensive income	\$ 519	\$ 645	\$ 1,198	\$ 1,006

See accompanying notes to consolidated financial statements.



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

	<b>For the six months ended June 30,</b>	
	<b>2012</b>	<b>2011</b>
	(in thousands)	
<b>Operating activities</b>		
Net income	\$ 1,210	\$ 583
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,105	950
Stock-based compensation	530	530
Impairment charges		83
Provision for losses in accounts receivable	89	132
Provision for inventory write-downs	699	564
Loss on divestitures	52	
Noncash restructuring charges		724
Foreign currency transaction (gain) loss	276	(217)
Changes in operating assets and liabilities:		
Accounts receivable	(438)	(388)
Inventory	(1,895)	440
Prepaid expenses and other assets	424	258
Accounts payable and other liabilities	379	(2,561)
<b>Net cash provided by operating activities</b>	<b>2,431</b>	<b>1,098</b>
<b>Investing activities</b>		
Purchases of property and equipment	(584)	(754)
Payments related to acquisitions		(641)
Receipts related to divestitures	135	108
Purchase of technology and licenses	(68)	(26)
<b>Net cash used in investing activities</b>	<b>(517)</b>	<b>(1,313)</b>
<b>Financing activities</b>		
Proceeds from issuance of common stock	29	53
Purchase of treasury stock	(1,110)	(522)
Common stock cash dividend paid	(760)	(619)
<b>Net cash used in financing activities</b>	<b>(1,841)</b>	<b>(1,088)</b>
Effect of exchange rate changes on cash and cash equivalents	(43)	94
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>30</b>	<b>(1,209)</b>
Cash and cash equivalents at beginning of period	20,132	22,614
<b>Cash and cash equivalents at end of period</b>	<b>\$ 20,162</b>	<b>\$ 21,405</b>

Supplemental disclosures of cash flow information (see Note 14)

See accompanying notes to consolidated financial statements.



---

**Table of Contents**

**LeMaitre Vascular, Inc.**

**Notes to Consolidated Financial Statements**

**June 30, 2012**

**(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. We develop, manufacture, and market 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 balloon catheters, carotid shunts, laparoscopic cholecystectomy devices, radiopaque tape, remote endarterectomy devices, valvulotomes, vascular grafts, vascular patches, and vessel closure systems. In addition, we have rights to exclusively distribute in the United States, Canada, and most of Europe a biologic vascular patch manufactured by a third party through January 26, 2016. Our offices are located in Burlington, Massachusetts, Sulzbach, Germany, Milan, Italy, Madrid, Spain, 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 (GAAP) 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 GAAP 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 six months ended June 30, 2012 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, 2011, including the notes thereto, included in our Form 10-K filed with the Securities and Exchange Commission (SEC).

***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, Vascutech Acquisition LLC, LeMaitre Acquisition LLC, LeMaitre Vascular SAS, Biomateriali S.r.l., LeMaitre Vascular S.r.l., and LeMaitre Vascular Spain SL. Our wholly-owned subsidiary Biomateriali S.r.l. was dissolved in March 2012. All significant intercompany accounts and transactions have been eliminated in consolidation.

***Recent Accounting Pronouncements***

In May 2011, the Financial Accounting Standards Board (FASB) amended existing rules covering fair value measurement and disclosure to clarify guidance and minimize differences between GAAP and International Financial Reporting Standards (IFRS). The new guidance requires us to provide information about valuation techniques and unobservable inputs used in Level 3 fair value measurements and provide a narrative description of the sensitivity of Level 3 measurements to changes in unobservable inputs. The guidance became effective on January 1, 2012. The adoption of this standard did not have a material impact on our results of operations or financial position.

In June 2011, new guidance was issued pertaining to the presentation of comprehensive income. The new rule eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. The standard is intended to provide a more consistent method of presenting non-owner transactions that affect the company's equity. Under the new guidance, an entity can elect to present items of net income and other



**Table of Contents**

comprehensive income in one continuous statement or in two separate, but consecutive, statements. The new guidance was effective for fiscal years that begin after December 15, 2011. The adoption of this standard did not have a material impact on our results of operations or financial position.

**2. Income Tax Expense**

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 recognize, measure, present and disclose in our financial statements uncertain tax positions that we have taken or expect to take on a tax return. 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. Within specific countries, we may be subject to audit by various tax authorities operating within the country and may be subject to different statutes of limitation expiration dates. 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.

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

We have reviewed the tax positions taken, or to be taken, in our tax returns for all tax years currently open to examination by a taxing authority. As of June 30, 2012, the gross amount of unrecognized tax benefits exclusive of interest and penalties was \$329,000. We have identified no uncertain tax positions for which it is reasonably possible that the total amount of unrecognized tax benefits will significantly increase or decrease within the twelve months ending June 30, 2013. There was no change in the liability during the six months ended June 30, 2012. We remain subject to examination until the statute of limitations expires for each respective tax jurisdiction. The U.S federal statute of limitations will be open with respect to these tax positions until 2015.

As of June 30, 2012, a summary of the tax years that remain subject to examination in our most significant tax jurisdictions is as follows:

United States Federal	2008 and forward
Germany	2007 and forward
Italy	2006 and forward
Japan	2005 and forward

**Table of Contents****3. Inventories**

Inventories consist of the following:

	June 30, 2012	December 31, 2011
		(in thousands)
Raw materials	\$ 2,025	\$ 2,034
Work-in-process	2,059	1,308
Finished products	5,043	4,661
Total inventory	\$ 9,127	\$ 8,003

**4. Acquisition and Divestitures*****Cardiva, S.L. Distribution Agreement***

In December 2010, we entered into a definitive agreement with Cardiva, S.L. (Cardiva) to terminate its distribution of our products in Spain and to acquire certain assets and rights from Cardiva effective as of June 30, 2011. We paid approximately \$1.2 million in exchange for this early termination, the purchase of their Spanish customer list for our products, certain customer contracts, their provision of sales and marketing services, and most of their remaining inventory. We recorded \$0.4 million of intangible assets, recognized a \$0.5 million restructuring charge related to the early termination of the distribution agreement, expensed \$0.1 million of transition services as selling expense, and recorded \$0.3 million of inventory. We allocated the payment to the tangible and intangible assets acquired based on the estimated fair value of each of these elements to the transaction. The weighted-average amortization period for these intangibles as of June 30, 2011 was 5.5 years. Additionally, we entered into a one-year consulting agreement beginning July 1, 2011 with an employee of Cardiva for \$0.2 million which was paid in full as of December 31, 2011.

***Marcom Medical ApS Distribution Agreement***

In December 2010, we entered into a definitive agreement with Marcom Medical ApS (Marcom) to terminate its distribution of our products in Denmark and to acquire certain assets and rights from Marcom effective as of June 30, 2011. We paid approximately \$0.2 million in exchange for this early termination, the purchase of their Danish customer list for our products, certain customer contracts, and minimal inventory. We recorded \$0.1 million of intangible assets and recognized a \$0.1 million restructuring charge related to the early termination of the distribution agreement. We allocated the payment to the tangible and intangible assets acquired based on the estimated fair value of each of these elements to the transaction. The weighted-average amortization period for these intangibles as of June 30, 2011 was 2.9 years.

***OptiLock Implantable Port***

On June 1, 2010, we sold our OptiLock Implantable Port product line to Minvasive Ltd. (Minvasive). In exchange for consideration of approximately \$0.2 million, Minvasive received our existing inventory, tangible and intangible assets, and a customer list associated with the product line. Payment terms included \$30,000 due at signing, with the remaining balance to be paid in the form of a royalty of 30% of Minvasive's OptiLock Implantable Port sales until the total consideration is paid in full. In 2014, any outstanding balance will become due in full. As a result of the transaction, we recorded the estimated present value of amounts due as a \$0.1 million receivable in other long term assets. All royalty payments received from Minvasive were applied to the receivable. In May 2012, Minvasive provided notice that it was filing for insolvency protection under German law. As a result, we wrote-off the remaining balance of approximately \$52,000 as a loss on divestitures during the three months ended June 30, 2012. We had received approximately \$60,000 under the terms of this agreement prior to the write-off.



**Table of Contents**

These intangible assets are being amortized over their useful lives ranging from 1 to 15 years. The weighted-average amortization period for these intangibles as of June 30, 2012, is 5.4 years. Amortization expense is included in general and administrative expense and is as follows:

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
	(in thousands)			
Amortization expense	\$ 237	\$ 233	\$ 478	\$ 456

Estimated amortization expense for the remainder of 2012 and each of the five succeeding fiscal years is as follows:

	Year ending December 31,					
	2012	2013	2014	2015	2016	2017
	(in thousands)					
Amortization expense	\$ 387	\$ 724	\$ 564	\$ 364	\$ 267	\$ 61

As a result of the AlboGraft Vascular Graft Prohibition Notices discussed in Note 9, we assessed the \$0.6 million of AlboGraft intangible assets and concluded that they were not impaired as of June 30, 2012. During the three months ended March 31, 2011, we determined that certain patents within our portfolio in the United States and Europe had no value based upon an analysis of expected economic benefits. As a result, we recorded an impairment charge of \$0.1 million for the write-down of these patents.

**6. Financing Arrangements**

As part of the purchase of Biomateriali S.r.l, we assumed a loan from the Italian government under a program that provides funding to certain businesses in Italy through a combination of grants and loans if certain requirements are met. The loan was stated to be payable in ten annual payments through 2018 of principal and interest at an interest rate of 0.74%. The present value of the loan was recorded as of the date the proceeds were received using our incremental borrowing rate. Interest was being imputed on the loan and the amortization was recorded as interest expense. The loan and grant became due in full as a result of the Biomateriali S.r.l plant closure. As a result, in December 2011, we incurred approximately \$0.1 million of restructuring charges related to additional interest and penalties charges, and we made the final payment to the Italian government of \$0.5 million in December 2011. In 2010, we had previously recorded approximately \$0.3 million of restructuring charges related to the expected repayment of the grants, the imputed interest on the outstanding loan balance, and certain additional interest and penalties.



**Table of Contents****7. Accrued Expenses**

Accrued expenses consist of the following:

	<b>June 30, 2012</b>	<b>December 31, 2011</b>
		(in thousands)
Compensation and related taxes	\$ 3,056	\$ 3,250
Income and other taxes	1,420	530
Restructuring		101
Professional fees	307	360
Other	1,197	1,298
 Total	 \$ 5,980	 \$ 5,539

**8. Restructuring Charges**

In October 2010, we adopted a reorganization plan that was designed to eliminate redundant costs resulting from our 2007 acquisition of Biomateriali and to improve efficiencies in our manufacturing operations. For the six months ended June 30, 2011, we incurred \$1.0 million of restructuring charges related to the closure of our Biomateriali manufacturing facility in Brindisi, Italy and the related transition of production to our existing corporate headquarters in Burlington, Massachusetts. The restructuring charges consisted of approximately \$0.3 million associated with the transfer of manufacturing equipment and \$0.7 million related to deferred rent charges upon exiting the Biomateriali facility. In March 2012, we completed the Biomateriali liquidation and dissolution process which resulted in a \$0.2 million charge related to a cumulative translation adjustment recorded within our Biomateriali subsidiary's balance sheet which we recorded as foreign currency loss.

In May 2011, we adopted a reorganization plan (the LifeSpan Plan) that was designed to eliminate redundant costs resulting from our 2010 acquisition of the LifeSpan vascular graft and to improve efficiencies in our manufacturing operations. We transitioned the production of our LifeSpan vascular graft from Laguna Hills, California to our existing corporate headquarters in Burlington, Massachusetts. The LifeSpan Plan resulted in the termination of 7 employees at the Laguna Hills facility, relocation of manufacturing equipment, and the hiring of approximately 4 employees to staff the required functions in Burlington. We incurred approximately \$11,000 of severance charges during the three months ended June 30, 2011.

On June 30, 2011, we terminated our relationship with our Spanish distributor resulting in a contract termination charge of \$0.5 million which we recorded as restructuring charges (see Note 4 for further details regarding the transaction).

On June 30, 2011, we terminated our relationship with our Danish distributor resulting in a contract termination charge of \$0.1 million which we recorded as restructuring charges (see Note 4 for further details regarding the transaction).

**Table of Contents**

The components of our restructuring charges are as follows:

	<b>Three months ended June 30, 2011</b>	<b>Six months ended June 30, 2011</b>
	(in thousands)	
Transfer of manufacturing equipment	\$ 52	\$ 332
Distributor contract termination charges	572	572
Non-cash asset write-off	15	724
Severance	11	11
Other		16
 Total	 \$ 650	 \$ 1,655

We did not incur restructuring charges during the six months ended June 30, 2012.

Activity related to accrued restructuring costs is as follows:

	<b>Six months ended June 30, 2012</b>
	(in thousands)
Balance at beginning of period	\$ 101
Plus:	
Current period restructuring costs	
Less:	
Payment of employee severance costs	101
 Balance at end of period	 \$

**9. Commitments and Contingencies***Purchase Commitments*

As of June 30, 2012, as part of our normal course of business, we have purchase commitments to purchase \$5.4 million of inventory through 2017.

*Acquisition Payments*

In 2007, we purchased certain patent applications and in-process research and development which included earn-out payments associated with the commercialization of The UnBalloon Non-Occlusive Modeling Catheter in the European Union and the United States as part of the consideration. The earn-out payments are payable quarterly at approximately the rate of two times sales for the four quarters. The European earn-out period was measured from December 23, 2009 through December 22, 2010. We recorded an intangible asset of approximately \$27,000 related to earn-out payments made on European sales. The United States earn-out period will be measured from January 1, 2012 through December 31, 2012. We recorded an intangible asset of approximately \$20,000 related to earn-out payments made on United States sales during the six months ended June 30, 2012. We consider the earn-out payments associated with the commercialization of the products in Europe and the United States to be contingent consideration that will be recorded as additional intangible assets in the periods that the contingency is resolved. In addition, there is a contingent payment of \$0.1 million related to one patent application which is payable upon the issuance of the patent. We

## Edgar Filing: LEMAITRE VASCULAR INC - Form 10-Q

consider the payment associated with the patent application approval to be contingent consideration that will be recorded as additional intangible assets in the period that the contingency is resolved.

## **Table of Contents**

### *AlboGraft Recall and Sales Prohibition*

In October 2011, we received complaints of two AlboGraft device failures which resulted in a voluntary recall of one production lot of our AlboGraft Vascular Graft. Subsequently, in February 2012, we received complaints of two additional AlboGraft device failures, which resulted in a voluntary recall of one additional production lot. We believe that we have isolated the root cause of these device failures and implemented corrective actions beginning with lots produced in November 2011. However, there can be no assurance that these failures will not reoccur or that other problems will not develop in the future. As a result of the recalled lots, we recognized \$0.2 million of inventory write-offs which we recorded to cost of sales during the year ended December 31, 2011.

Subsequent to the February 2012 recall, we received four additional complaints regarding our AlboGraft Vascular Graft. Although the investigation was inconclusive, we believe these complaints were unrelated to the product failures which resulted in the recalls and that they were isolated manufacturing defects, although there can be no assurance that this will prove to be the case and that these or other problems will not reoccur or develop in the future.

In March 2012, the relevant regulatory agency in the United Kingdom issued a Medical Device Alert advising doctors to use caution when implanting our AlboGraft Vascular Grafts. In April 2012, the relevant regulatory agencies in the United Kingdom and France issued Prohibition Notices which prohibited our ability to sell AlboGraft Vascular Grafts in these countries pending our ability to address the concerns of these regulatory agencies. The United Kingdom and France represented approximately 40% of our AlboGraft Vascular Graft sales volume and sales of AlboGraft in these countries were \$1.0 million for the year ended December 31, 2011. As a result of the Prohibition Notices, we recognized \$0.1 million of inventory write-offs, which we recorded to cost of sales during the three months ended March 31, 2012. In July 2012, the French regulatory agency rescinded its Prohibition Notice without qualification, and the United Kingdom regulatory agency rescinded its Prohibition Notice with the qualification that all AlboGraft devices must be tested prior to implant. Although we are seeking to remove the qualification in the United Kingdom, there can be no assurance that our efforts will be successful, nor can there be any assurance that additional countries will not also issue their own prohibition against sales of our AlboGraft device. Although the Prohibition Notices have been lifted, the fact that they were issued will likely continue to adversely affect sales in France and the United Kingdom and may concurrently and adversely affect our reputation and sales of our AlboGraft Vascular Grafts in those countries and in other jurisdictions as well as our financial condition and results of operations. As of June 30, 2012, we have approximately \$1.9 million of inventory and \$0.6 million of intangible assets related to the AlboGraft Vascular Graft.

### **10. Segment and Enterprise-Wide Disclosures**

The FASB 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 is prepared by us except for product sales by product line and by geographic location for local reporting purposes.

**Table of Contents**

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. Our German subsidiary (LeMaitre Vascular GmbH) records all sales in Europe excluding direct sales in France (LeMaitre Vascular SAS); Italy (LeMaitre Vascular S.r.l.); and Spain (LeMaitre Vascular Spain SL) beginning July 1, 2011, and to distributors worldwide, excluding distributor sales in North, South and Central America (LeMaitre Vascular, Inc.), France (LeMaitre Vascular SAS), Portugal (LeMaitre Vascular Spain SL), and Korea and Taiwan (LeMaitre Vascular GK). Net sales to unaffiliated customers by legal entity were as follows:

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
	(in thousands)			
LeMaitre Vascular, Inc.	\$ 9,676	\$ 9,415	\$ 19,150	\$ 18,417
LeMaitre Vascular GmbH	2,953	3,952	5,685	7,687
Other entities	1,732	1,745	3,454	3,606
Total	\$ 14,361	\$ 15,112	\$ 28,289	\$ 29,710

Upon our divestiture of the stent graft product lines, we reorganized our product categories from Vascular, Endovascular, and General Surgery to Open Vascular and Endovascular and Other as we re-focused our portfolio and sales channel on open vascular products. Net sales in these product categories were as follows:

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
	(in thousands)			
Open Vascular	\$ 11,851	\$ 11,436	\$ 23,256	\$ 22,196
Endovascular and Other	2,510	3,676	5,033	7,514
Total	\$ 14,361	\$ 15,112	\$ 28,289	\$ 29,710

**11. Share-based Compensation**

Our 2006 Stock Option and Incentive Plan allows for granting of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, unrestricted stock awards, and deferred stock awards to our officers, employees, directors, and consultants.

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

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
	(in thousands)			
Stock option awards to employees	\$ 151	\$ 138	\$ 291	\$ 271
Restricted common stock awards	116	129	239	259
Total share-based compensation	\$ 267	\$ 267	\$ 530	\$ 530



**Table of Contents**

We have computed the fair values of employee stock options for option grants issued during the six months ended June 30, 2011 using the Black-Scholes option model with the following assumptions:

	2011
Dividend yield	1.2%
Volatility	67.3%
Risk-free interest rate	2.1%
Weighted average expected option term (in years)	5.0
Weighted average fair value per share of options granted	\$ 3.42

We did not issue option grants during the six months ended June 30, 2012.

We did not issue restricted stock units during the six months ended June 30, 2012 and 2011.

**12. Net Income per Share**

The computation of basic and diluted net income per share was as follows:

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
	(in thousands, except per share data)			
<b>Basic:</b>				
Net income available for common stockholders	\$ 824	\$ 519	\$ 1,210	\$ 583
Weighted average shares outstanding	15,201	15,470	15,248	15,468
Basic net income per share	\$ 0.05	\$ 0.03	\$ 0.08	\$ 0.04
<b>Diluted:</b>				
Net income available for common stockholders	\$ 824	\$ 519	\$ 1,210	\$ 583
Weighted-average shares outstanding	15,201	15,470	15,248	15,468
Common stock equivalents	435	601	433	596
Shares used in computing diluted net income per common share	15,636	16,071	15,681	16,064
Diluted net income per share	\$ 0.05	\$ 0.03	\$ 0.08	\$ 0.04
Shares excluded in computing diluted net income as those shares would be anti-dilutive	602	63	587	65

**13. Stockholders Equity***Authorized Shares*

## Edgar Filing: LEMAITRE VASCULAR INC - Form 10-Q

On June 14, 2012, our stockholders approved an amendment (the Charter Amendment ) to the our Second Amended and Restated Certificate of Incorporation to reduce the number of authorized shares of common stock from 100,000,000 to 37,000,000 shares and of undesignated preferred stock from 5,000,000 to 3,000,000 shares. The Charter Amendment was previously approved by our Board of Directors on April 12, 2012, subject to approval by our stockholders. The Charter Amendment was filed with the Secretary of State of the State of Delaware on June 14, 2012.





**Table of Contents****14. Supplemental Cash Flow Information**

	<b>Six months ended</b>	
	<b>June 30,</b>	
	<b>2012</b>	<b>2011</b>
	(in thousands)	
Cash paid (refunded) for income taxes, net	\$ (41)	\$ 106
<b>Supplemental non-cash financing activities:</b>		
Common stock repurchased for RSU tax withholdings	\$ 22	\$ 27
Note receivable resulting from divestiture	\$	\$ 200

**15. Fair Value Measurements**

The fair value accounting guidance requires that assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

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. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

As of June 30, 2012, we had cash equivalents in a money market fund that was valued using Level 1 inputs (quoted market prices for identical assets) at a fair value of \$16.4 million.

We had no Level 2 or Level 3 assets being measured at fair value on a recurring basis as of June 30, 2012.

**Table of Contents****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 Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements include all statements other than statements of historical fact contained in this Quarterly Report, including statements about: our AlboGraft product complaints and recalls and our related remediation efforts; our AlboGraft U.K. and French Prohibition Notices and our expectations regarding appeals of qualifications on the repeals of such notices; the liquidity of our investment portfolio; our continued profitability; and the adequacy of our cash reserves for the next twelve months. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by such forward-looking statements. Moreover, the forward-looking statements represent our estimates and assumptions only as of the date hereof. Forward-looking statements are subject to risks and uncertainties; our failure to manage the anticipated growth of our business; and the unavailability of additional, required capital on acceptable terms. Further information on potential risk factors that could affect our business and financial results is detailed in Part II, Item IA. Risk Factors in this Quarterly Report on Form 10-Q. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. 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 other SEC filings, including our audited consolidated financial statements and the related notes contained in our Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the SEC on March 27, 2012.*

*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, AlboGraft, LifeSpan, and the LeMaitre Vascular logo are registered trademarks of LeMaitre Vascular, and UnBalloon is an unregistered trademark 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 for all peripheral vascular devices approximates \$3 billion, within which our core product lines address roughly \$750 million. We have grown our business by using a three-pronged strategy: competing in niche markets, expanding our worldwide direct sales force, and acquiring and developing complementary vascular devices. We currently manufacture most of our product lines in our Burlington, Massachusetts, headquarters.

Our products are used by vascular surgeons who treat peripheral vascular disease through both open surgical methods and endovascular techniques. In contrast to interventional cardiologists and interventional radiologists, neither of whom are 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 a wider range of treatment options to patients.

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

Our **Open Vascular** product category includes our balloon catheters, carotid shunts, remote endarterectomy devices, valvulotomes, vascular grafts, and vessel closure systems. We also report the results of our distribution of the Xenasure Biologic Patch in this category.

Our **Endovascular and Other** product category includes our contrast injection device, laparoscopic cholecystectomy devices, non-occlusive modeling catheter, and radiopaque marking tape. We divested our aortic stent grafts in June 2011 and terminated our distribution of the Endologix products in August 2011, each of which was previously reported in this product category.

## **Table of Contents**

We evaluate the sales performance of our various product lines utilizing criteria that varies 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 newer or faster growing products, we typically also focus upon new account generation and customer retention.

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.

Our business opportunities include the following:

the long-term growth of our sales force in North America, Europe and Japan, sometimes in connection with terminations of certain distributor relationships in order to expand our sales presence in new countries;

the addition of complementary products through acquisitions;

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

the introduction of our products in new markets upon obtainment of regulatory approvals in these markets.

We are currently pursuing each of these opportunities.

We sell our products primarily through a direct sales force. As of June 30, 2012 our sales force was comprised of 83 sales representatives in North America, the European Union and Japan. We also sell our products in other countries through distributors. Our worldwide headquarters is located in Burlington, Massachusetts. Our international operations are headquartered in Sulzbach, Germany. We also have sales offices located in Tokyo, Japan, Madrid, Spain, and Milan, Italy. In 2012, approximately 95% of our net sales were generated in markets in which we employ direct sales representatives.

In recent years we have experienced comparatively greater success in product markets characterized by low or limited competition, for example the market for valvulotome devices. In these markets, we believe that we have been able to increase selling prices without compromising market share. There can be no assurance that we will not meet resistance to increased selling prices in the future. In contrast, we have experienced comparatively lesser success in highly competitive product markets such as polyester and ePTFE vascular grafts, where we face stronger competition from larger companies with greater resources. While we believe that these challenging market dynamics can be mitigated by our strong relationships with our vascular surgeon customers, there can be no assurance that we will be successful in highly competitive markets.

Because we believe that direct-to-hospital sales engender closer customer relationships, and allow for higher selling prices and gross margins, we periodically enter into transactions with our distributors to transition their sales of our medical devices to our direct sales organization. In December 2010, we entered into a definitive agreement with Cardiva, S.L. to terminate its distribution of our products in Spain effective as of June 30, 2011. The agreement required us to pay approximately \$1.2 million in exchange for this early termination, the purchase of their customer list for our products, certain customer contracts, their provision of sales and marketing services, and \$0.3 million of inventory. We anticipate that the expansion of our direct sales organization to Spain may result in increased sales and marketing expenses during 2012.

Our strategy for growing our business includes the acquisition of complementary product lines and companies and occasionally the discontinuance or divestiture of products or activities that are no longer complementary:

In November 2010, we acquired our LifeSpan ePTFE Vascular Graft from Angiotech Pharmaceuticals, Inc. for \$2.8 million and related assets from Edwards LifeSciences for \$1.2 million.



## **Table of Contents**

In June 2011, we divested our TAArget and UniFit stent grafts to Duke Vascular, Inc. for \$0.6 million. In addition, Duke Vascular, Inc. assumed our future obligations for the associated UNITE and ENTRUST clinical trials.

In August 2011, we terminated our distribution of Endologix's aortic stent graft products in Europe in exchange for \$1.3 million. In addition to relying upon acquisitions to grow our business, we also rely on our product development efforts to bring differentiated technology and next-generation products to market. These efforts have led to the following recent product launches:

In November 2011, we launched the second-generation of The UnBalloon Non-Occlusive Modeling Catheter.

In December 2011, we launched the Over-The-Wire LeMaitre Valvulotome. In addition to our sales growth strategies, we have also executed several operational initiatives designed to consolidate and streamline manufacturing within our Burlington, MA facilities. We expect that these plant consolidations will yield improved control over our production capacity and our direct labor force as well as reduce redundant costs over the long-term. Our most recent manufacturing transitions included:

In October 2010, we adopted a reorganization plan that was designed to eliminate redundant costs resulting from our 2007 acquisition of Biomateriali and to improve efficiencies in manufacturing operations. We have completed the transition of AlboGraft vascular graft manufacturing to our existing corporate headquarters in Burlington, Massachusetts.

In May 2011, we adopted a reorganization plan that was designed to eliminate redundant costs resulting from our 2010 acquisition of the LifeSpan vascular graft and to improve efficiencies in manufacturing operations. We have completed this transition to our existing corporate headquarters in Burlington, Massachusetts.

In October 2011, we received complaints of two AlboGraft device failures which resulted in a voluntary recall of one production lot of our AlboGraft Vascular Graft. Subsequently, in February 2012, we received complaints of two additional AlboGraft device failures, which resulted in a voluntary recall of one additional production lot. We believe that we isolated the root cause of these device failures and implemented corrective actions beginning with lots produced in November 2011. However, there can be no assurance that these failures will not reoccur or that other problems will not develop in the future. As a result of the recalled lots, we recognized \$0.2 million of inventory write-offs which we recorded to cost of sales during the year ended December 31, 2011.

Subsequent to the February 2012 recall, we received four additional complaints regarding our AlboGraft Vascular Graft. Although the investigation was inclusive, we believe these complaints were unrelated to the product failures which resulted in the recalls and that they were isolated manufacturing defects, although there can be no assurance that this will prove to be the case and that these or other problems will not reoccur or develop in the future.

In March 2012, the relevant regulatory agency in the United Kingdom issued a Medical Device Alert advising doctors to use caution when implanting our AlboGraft Vascular Grafts. In April 2012, the relevant regulatory agencies in the United Kingdom and France issued Prohibition Notices which prohibited our ability to sell AlboGraft Vascular Grafts in these countries pending our ability to address the concerns of these regulatory agencies. The United Kingdom and France represented approximately 40% of our AlboGraft Vascular Graft sales volume and sales of AlboGraft in these countries were \$1.0 million for the year ended December 31, 2011. As a result of the Prohibition Notices, we recognized \$0.1 million of inventory write-offs, which we recorded to cost of sales during the three months ended March 31, 2012. In July 2012, the French regulatory agency rescinded its Prohibition Notice without qualification, and the United Kingdom regulatory agency rescinded its Prohibition Notice with the qualification that all AlboGraft devices must be tested prior to implant. Although we are seeking to remove the qualification in the United Kingdom, there can be no assurance that our efforts will be successful, nor can there be any assurance that additional countries will not also issue their own prohibition against sales of our AlboGraft device. Although the Prohibition Notices have been lifted, the fact that they were issued will likely continue to adversely affect sales in France and the United Kingdom and may concurrently and subsequently adversely affect our



**Table of Contents**

reputation and sales of our AlboGraft Vascular Grafts in both countries and in other jurisdictions as well as our financial condition and results of operations. As of June 30, 2012, we have approximately \$1.9 million of inventory and \$0.6 million of intangible assets related to the AlboGraft Vascular Graft.

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies, primarily the Euro, affect our financial results. For the six months ended June 30, 2012, approximately 32% of our sales were from outside the Americas. 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, most of our foreign sales are denominated in local currency, and 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 we will receive less in U.S. dollars than we did before the rate increase went into effect.

The following table indicates the impact of foreign currency fluctuations and strategic changes to our business activities for each quarter during 2012 and the two most recently completed fiscal years:

(amounts in thousands)  
(unaudited)

	2012			2011			2010			
	Q2	Q1	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Total net sales	14,361	13,928	13,411	14,564	15,112	14,598	14,431	13,656	14,158	13,815
Impact of currency exchange rate fluctuations (1)	(470)	(146)	15	431	669	10	(420)	(418)	(336)	314
Net impact of acquisitions and distributed sales, excluding currency exchange rate fluctuations (2)			260	319	335	328	156			95
Net impact of discontinued products, excluding currency rate fluctuations (3)	(1,342)	(1,584)	(1,904)	(370)	(76)	(45)	(100)	(105)	(65)	

- (1) Represents the impact of the change in foreign exchange rates compared to the corresponding quarter of the prior year based on the weighted average exchange rate for each quarter.
- (2) Represents the impact of new sales of acquired products or businesses and newly distributed sales of other manufacturers during the current year period, measured for 12 months following the date of the event or transaction.
- (3) Represents the impact of sales related to discontinued and divested products, and discontinued distributed sales of other manufacturers products, during the comparable prior period, measured for 12 months following the date of the event or transaction.



**Table of Contents****Results of Operations****Comparison of the three and six months ended June 30, 2012 to the three and six months ended June 30, 2011**

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 percentage increase or decrease:

(unaudited)	Three months ended June 30,			Six months ended June 30,		
	2012	2011	Percent change	2012	2011	Percent change
	(\$ in thousands)			(\$ in thousands)		
Net sales	\$ 14,361	\$ 15,112	(5%)	\$ 28,289	\$ 29,710	(5%)
Net sales by product category:						
Open Vascular	\$ 11,851	\$ 11,436	4%	\$ 23,256	\$ 22,196	5%
Endovascular and other	2,510	3,676	(32%)	5,033	7,514	(33%)
Total	\$ 14,361	\$ 15,112	(5%)	\$ 28,289	\$ 29,710	(5%)
Net sales by geography:						
Americas	\$ 9,676	\$ 9,415	3%	\$ 19,150	\$ 18,417	4%
International	4,685	5,697	(18%)	9,139	11,293	(19%)
Total	\$ 14,361	\$ 15,112	(5%)	\$ 28,289	\$ 29,710	(5%)

**Net sales.** Net sales decreased 5% to \$14.4 million for the three months ended June 30, 2012, compared to \$15.1 million for the three months ended June 30, 2011. Sales decreases for the three months ended June 30, 2012 were primarily driven by the 2011 divestiture of our stent graft product lines which accounted for \$1.3 million of sales during the three months ended June 30, 2011 and a \$0.2 million decrease in polyester graft sales, and a weakening of the Euro which negatively impacted sales by \$0.5 million. These decreases were partially offset by higher average selling prices across nearly all product lines, increased sales in biologic patches of \$0.6 million, and increased sales of catheters of \$0.2 million which was partially driven by selected pricing discounts in new geographies.

Net sales decreased 5% to \$28.3 million for the six months ended June 30, 2012, compared to \$29.7 million for the six months ended June 30, 2011. Sales decreases for the six months ended June 30, 2012 were primarily driven by the 2011 divestiture of our stent graft product lines which accounted for \$2.9 million of sales during the six months ended June 30, 2011 and a \$0.3 million decrease in polyester graft sales, and a weakening of the Euro which negatively impacted sales by \$0.6 million. These decreases were partially offset by higher average selling prices across nearly all product lines, increased sales in biologic patches of \$0.9 million, and increased sales of catheters of \$0.5 million which was partially driven by selected pricing discounts in new geographies.

Direct-to-hospital net sales were 95% for the three months and six months ended June 30, 2012, compared to 93% and 94% for the three months and six months ended June 30, 2011, respectively.

**Net sales by geography.** Net sales in the Americas increased \$0.3 million for the three months ended June 30, 2012. The increase was largely the result of higher average selling prices across nearly all product lines and increases in the sales of biologic patches. International net sales decreased \$1.0 million for the three months ended June 30, 2012. The decrease was primarily driven by the divestiture of our stent graft product lines and a decrease in polyester graft sales, and was partially offset by increased sales of biologic patches of \$0.3 million which became available for sale in Europe in July 2011 and catheter sales to international distributors.

**Table of Contents**

Net sales in the Americas increased \$0.7 million for the six months ended June 30, 2012. The increase was largely the result of higher average selling prices across nearly all product lines and increases in the sales of biologic patches. International net sales decreased \$2.2 million for the three months ended June 30, 2012. The decrease was primarily driven by the divestiture of our stent graft product lines and a decrease in polyester graft sales, which was partially offset by increased sales of biologic patches of \$0.5 million which became available for sale in Europe in July 2011 and catheter sales to international distributors.

In April 2012, the regulatory agencies in the United Kingdom and France issued Prohibition Notices which prohibited us from selling our AlboGraft polyester grafts in those countries until further notice. In July 2012, the regulatory agencies substantially rescinded the Prohibition Notices allowing the products to return to market. See [Overview](#) above for a further discussion regarding these notices. Sales of AlboGraft in France and the United Kingdom were \$0.2 million for the six months ended June 30, 2012 and were \$0.5 million for the six months ended June 30, 2011. Sales of AlboGraft in France and the United Kingdom were \$1.0 million for the year ended December 31, 2011.

International direct-to-hospital net sales were 85% and 86% of total international net sales for the three months and six months ended June 30, 2012, compared to 82% and 84% for the three months and six months ended, June 30, 2011, respectively.

(unaudited)	Three months ended June 30,				Six months ended June 30,			
	2012	2011	\$ Change	Percent change	2012	2011	\$ Change	Percent change
	(\$ in thousands)				(\$ in thousands)			
Gross profit	\$ 10,545	\$ 10,370	\$ 175	1.7%	\$ 20,415	\$ 20,521	\$ (106)	(0.5%)
Gross margin	73.4%	68.6%	*	4.8%	72.2%	69.1%	*	3.1%

\* Not applicable

**Gross Profit.** Gross profit increased 1.7% to \$10.5 million for the three months ended June 30, 2012, while gross margin increased 4.8% to 73.4% in the same period. The gross margin increase was largely the result of favorable product and geographic mix driven largely by our exit from stent grafts, increased selling prices across most of our product lines, and a reduction in costs associated with the 2011 manufacturing start-up and transition costs related to the AlboGraft and Lifespan product lines. The gross profit increase was a result of our higher gross margin, and was partially offset by the divestiture of our stent graft product lines which generated \$1.3 million of revenue during the three months ended June 30, 2011.

Gross profit decreased 0.5% to \$20.4 million for the six months ended June 30, 2012, while gross margin increased 3.1% to 72.2% in the same period. The gross margin increase was largely the result of a reduction in costs related to the closure of our factory in Brindisi, Italy in March 2011, a reduction in costs associated with the 2011 manufacturing start-up and transition costs related to the AlboGraft and Lifespan product lines, increased selling prices across most of our product lines, and favorable product and geographic mix driven largely by our exit from stent grafts. The gross margin increase was partially offset by additional inventory write-offs associated with our AlboGraft product line and manufacturing inefficiencies. The gross profit decrease was largely the result of the divestiture of our stent graft product lines which generated \$2.9 million of revenue during the six months ended June 30, 2011 and was partially offset by the increase in gross margin.

Commencing in 2013, we will be subject to a medical device tax of 2.3% on sales within the United States.

**Table of Contents**

(unaudited)	Three months ended June 30,				Six months ended June 30,			
	2012	2011	\$ change	Percent change	2012	2011	\$ change	Percent change
	(\$ in thousands)				(\$ in thousands)			
Sales and marketing	\$ 5,186	\$ 4,916	\$ 270	5%	\$ 10,399	\$ 9,889	\$ 510	5%
General and administrative	2,717	2,867	(150)	(5%)	5,385	5,715	(330)	(6%)
Research and development	1,135	1,040	95	9%	2,270	2,312	(42)	(2%)
Restructuring charges		650	(650)	*		1,655	(1,655)	*
Loss on divestitures	52		52	*	52		52	*
Impairment charge				*		83	(83)	*
<b>Total</b>	<b>\$ 9,090</b>	<b>\$ 9,473</b>	<b>\$ (383)</b>	<b>(4%)</b>	<b>\$ 18,106</b>	<b>\$ 19,654</b>	<b>\$ (1,548)</b>	<b>(8%)</b>

	Three months ended June 30,			Six months ended June 30,		
	2012	2011	Change	2012	2011	Change
	of Net Sales			of Net Sales		
Sales and marketing	36%	33%	3%	37%	33%	4%
General and administrative	19%	19%	0%	19%	19%	0%
Research and development	8%	7%	1%	8%	8%	0%
Restructuring charges	0%	4%	(4%)	0%	6%	(6%)
Loss on divestitures	0%	0%	0%	0%	0%	0%
Impairment charge	0%	0%	0%	0%	0%	0%

\* Not a meaningful percentage relationship.

**Sales and marketing.** For the three months ended June 30, 2012, sales and marketing expenses increased 5% to \$5.2 million. Selling expenses increased \$0.1 million while marketing expenses increased by \$0.2 million. Selling expense increases were largely driven by \$0.1 million of additional sales meetings and related travel costs. Marketing expenses increases were largely driven by \$0.2 million of additional advertising costs and \$0.1 million of increased personnel costs. These increases were partially offset by changes in foreign currency exchange rates of \$0.2 million. As a percentage of net sales, sales and marketing expenses were 36% in the three months ended June, 2012.

For the six months ended June 30, 2012, sales and marketing expenses increased 5% to \$10.4 million. Selling expenses increased \$0.3 million while marketing expenses increased by \$0.2 million. Selling expense increases were largely driven by \$0.2 million of additional sales meetings and related travel costs, selling costs associated with our Spanish subsidiary of \$0.2 million, and \$0.1 million of additional sales sample costs. These increases were partially offset by \$0.1 million of transition services related to the LifeSpan acquisition incurred in the prior year period. Marketing expense increases were largely driven by \$0.2 million of additional advertising costs and \$0.1 million of increased personnel costs. These increases were partially offset by changes in foreign currency exchange rates of \$0.3 million. As a percentage of net sales, sales and marketing expenses were 37% in the six months ended June, 2012.

**General and administrative.** For the three months ended June 30, 2012, general and administrative expenses decreased 5% to \$2.7 million. The decrease was largely the result of a decrease in compensation costs of \$0.1 million and changes in foreign currency exchange rates of \$0.1 million. As a percentage of net sales, general and administrative expenses were 19% in the three months ended June 30, 2012.

For the six months ended June 30, 2012, general and administrative expenses decreased 6% to \$5.4 million. The decrease was largely the result of a decrease in compensation costs of \$0.2 million, the closure of our Biomaterials facility in March 2011 which incurred general and administrative costs of \$0.1 million in the prior year period, and by changes in foreign currency exchange rates of \$0.1 million. As a percentage of net sales, general and administrative expenses were 19% in the six months ended June 30, 2012.

**Research and development.** For the three months ended June 30, 2012, research and development costs increased 9% to \$1.1 million. Product development costs increased \$0.1 million primarily due to increased product engineer related compensation. Clinical and regulatory expenses decreased \$0.1 million, primarily due to a



**Table of Contents**

reduction in costs associated with the suspension of enrollment in our UNITE and ENTRUST stent graft trials in October 2010. As a percentage of net sales, research and development expenses were 8% for the three months ended June 30, 2012.

For the six months ended June 30, 2012, research and development costs were relatively flat compared to the prior year. Product development costs increased \$0.2 million primarily due to increased product engineer compensation. Clinical and regulatory expenses decreased \$0.2 million, primarily due to a reduction in costs associated with the suspension of enrollment in our UNITE and ENTRUST stent graft trials in October 2010. On June 30, 2011, Duke Vascular, Inc. assumed all future obligations of the UNITE and ENTRUST trials as part of our stent graft divestiture agreement. As a percentage of net sales, research and development expenses were 8% for the six months ended June 30, 2012.

**Restructuring.** We did not incur any restructuring charges in the six months ended June 30, 2012.

In October 2010, we adopted a reorganization plan that was designed to eliminate redundant costs resulting from our 2007 acquisition of Biomateriali and to improve efficiencies in our manufacturing operations. For the six months ended June 30, 2011, we incurred \$1.0 million of restructuring charges related to the closure of our Biomateriali manufacturing facility in Brindisi, Italy and the related transition of production to our existing corporate headquarters in Burlington, Massachusetts. The restructuring charges consisted of approximately \$0.3 million associated with the transfer of manufacturing equipment and \$0.7 million related to deferred rent charges upon exiting the Biomateriali facility. In March 2012, we completed the Biomateriali liquidation and dissolution process.

In May 2011, we adopted a reorganization plan that was designed to eliminate redundant costs resulting from our 2010 acquisition of the LifeSpan vascular graft and to improve efficiencies in manufacturing operations. We transitioned the production of our LifeSpan vascular graft from Laguna Hills, California to our existing corporate headquarters in Burlington, Massachusetts. We incurred approximately \$11,000 of severance charges during the three months ended June 30, 2011.

On June 30, 2011, we terminated our relationship with our Spanish and Danish distributors resulting in contract termination charges of \$0.5 million and \$0.1 million, respectively, which we recorded as restructuring charges during the three months ended June 30, 2011.

**Impairment charge.** We did not incur any impairment charges in the six months ended June 30, 2012. Impairment charges were \$0.1 million for the six months ended June 30, 2011 as we determined that certain patents within our portfolio in the U.S. and Europe had no value based upon an analysis of expected economic benefits.

**Loss on divestitures.** We recorded a \$0.1 million write-off on a note receivable associated with our Optilock divestiture in 2010 as the acquirer provided notice that it was filing for insolvency protection under German law in the three months ended June 30, 2012.

**Foreign exchange gains / losses.** Foreign exchange losses for the six months ended June 30, 2012 was \$0.2 million and was primarily the result of a cumulative translation adjustment recorded at our Biomateriali subsidiary upon the liquidation and dissolution of that legal entity as well as the general weakening of the Euro. Foreign exchange gains for the six months ended June 30, 2011 were \$0.1 million.

**Income tax expense.** We recorded a provision for taxes of \$0.6 million on pre-tax income of \$1.4 million for the three months ended June 30, 2012, compared to \$0.4 million on pre-tax income of \$0.9 million for the three months ended June 30, 2011. We recorded a provision for taxes of \$0.9 million on pre-tax income of \$2.1 million for the six months ended June 30, 2012, compared to \$0.4 million on pre-tax income of \$1.0 million for the six months ended June 30, 2011. Our current period provision is based on the estimated annual effective tax rate for 2012 of 41.2% and is comprised of estimated federal and state income taxes of approximately \$1.0 million, as well as a foreign income tax benefit of \$0.1 million. Our income tax expense for the current period varies from the statutory rate amounts mainly due to certain permanent items, from lower statutory rates at our foreign German entity and certain discrete items. Our June 30, 2011 provision was based on the estimated annual effective tax rate for 2011 of 36.3%, which included estimated federal and state income taxes of approximately \$0.3 million, as well

---

## **Table of Contents**

as foreign income taxes of approximately \$0.1 million. Our 2011 income tax expense varied from the statutory rate amounts mainly due to the generation of United States research and development tax credits, from lower statutory rates at our foreign German entity, offset by certain discrete items. We monitor the mix of profitability by tax jurisdiction and adjust our annual expected rate on a quarterly basis as needed. While it is often difficult to predict the final outcome or timing of the resolution of any particular tax matter, we believe that our tax reserves reflect the probable outcome of known contingencies.

We have assessed the need for a valuation allowance against our deferred tax assets at June 30, 2012 and concluded that we continue to carry a valuation allowance against \$4.4 million of state and foreign deferred tax assets, which based on the weight of available evidence, we believe it is more likely than not that such assets will not be realized.

We expect that our effective tax rate will remain fairly constant throughout the remainder of 2012.

## **Liquidity and Capital Resources**

At June 30, 2012, our cash and cash equivalents were \$20.2 million as compared to \$20.1 million at December 31, 2011. Our cash and cash equivalents are highly liquid investments with maturities of 90 days or less at the date of purchase and consist of money market funds, and are stated at cost, which approximates fair value. We did not hold any marketable securities nor any mortgage asset-backed or auction-rate securities in our investment portfolio as of June 30, 2012. In the event of a temporary decline in market value, we have the intent and ability to hold our investments for a sufficient period of time to allow for recovery of the principal amounts invested. We continually monitor the asset allocation of our holdings in an attempt to mitigate our credit and interest rate exposures, and we intend to continue to closely monitor developments in the credit markets and make appropriate changes to our investment policy as necessary.

## ***Operating and Capital Expenditure Requirements***

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 public offerings and private placements of equity securities, short-term borrowings, and funds generated from our operations.

We recognized operating income of \$2.3 million for the six months ended June 30, 2012. For the year ended December 31, 2011, we recognized operating income of \$3.7 million. Although it is our intention to generate an operating profit on an ongoing basis, excluding the impact of acquisitions, divestitures and distributor terminations, there can be no assurance that we will generate an operating profit in the future due to our continued investment in growing our business. 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. These factors include, but are not limited to, the following:

the revenues generated by sales of our products;

payments associated with potential future quarterly cash dividends to our common stockholders;

payments associated with our stock repurchase plan;

payments associated with U.S income taxes or other taxes, such as the medical device tax;

the costs associated with expanding our manufacturing, marketing, sales, and distribution efforts;

the rate of progress and cost of our research and development activities;

## Edgar Filing: LEMAITRE VASCULAR INC - Form 10-Q

the costs of obtaining and maintaining FDA and other regulatory clearances of our existing and future products;

the effects of competing technological and market developments; and

the number, timing, and nature of acquisitions and other strategic transactions.

Our cash balances may decrease as we continue to use cash to fund our operations, make acquisitions, make purchases under our share repurchase program, make payments under our quarterly dividend program, and make deferred payments related to prior acquisitions. We believe that our cash, cash equivalents, investments and the interest we earn on these balances will be sufficient to meet our anticipated cash requirements for at least the next

**Table of Contents**

twelve months. If these sources of cash are insufficient to satisfy our liquidity requirements beyond the next twelve months, we may seek to sell additional equity or debt securities or borrow from a financial institution. The sale of additional equity and debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of debt securities, such securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all.

**Italian Loan and Grant**

As part of the purchase of Biomateriali S.r.l, we assumed a loan from the Italian government under a program that provides funding to certain businesses in Italy through a combination of grants and loans if certain requirements are met. The loan was stated to be payable in ten annual payments through 2018 of principal and interest at an interest rate of 0.74%. The present value of the loan was recorded as of the date the proceeds were received using our incremental borrowing rate. Interest was being imputed on the loan and the amortization was recorded as interest expense. The loan and grant became due in full as a result of the Biomateriali S.r.l plant closure. As a result, in December 2011, we incurred approximately \$0.1 million of restructuring charges related to additional interest and penalties charges, and we made the final payment to the Italian government of \$0.5 million in December 2011. In 2010, we had previously recorded approximately \$0.3 million of restructuring charges related to the expected repayment of the grants, the imputed interest on the outstanding loan balance, and certain additional interest and penalties.

**Stock Repurchase Plan**

In July 2009, our Board of Directors authorized a repurchase of our common stock from time to time on the open market or in privately negotiated transactions. In November 2011, our Board of Directors increased this authorization to \$10.0 million and extended the program through December 31, 2013. The timing and number of any shares repurchased will be determined based on our evaluation of market conditions and other factors. Repurchases may also be made under a Rule 10b5-1 plan, which would permit shares to be repurchased when we might otherwise be precluded from doing so under insider trading laws. The repurchase program may be suspended or discontinued at any time and will conclude no later than December 31, 2013, unless otherwise extended by our Board of Directors. The repurchase program is being funded using our available cash and cash equivalents. We have the authority to purchase \$4.2 million shares of our common stock remaining under the repurchase program as of June 30, 2012. The following is a summary of the stock repurchase activity for the six months ended:

	June 30, 2012		June 30, 2011	
	Shares Purchased	Total Purchased	Shares Purchased	Total Purchased
	(\$ in thousands)			
Share repurchases	196,121	\$ 1.084	71,405	\$ 490

**Dividends**

On February 28, 2011, our Board of Directors approved a policy for the payment of quarterly cash dividends on our common stock. Future declarations of quarterly dividends and the establishment of future record and payment dates are subject to approval by our Board of Directors on a quarterly basis. The dividend activity for the periods presented is as follows:

Record Date	Payment Date	Per Share Amount	Dividend Payment (in thousands)
Fiscal Year 2012			
March 20, 2012	April 3, 2012	\$ 0.025	\$ 381
May 18, 2012	June 4, 2012	\$ 0.025	\$ 379
Fiscal Year 2011			
March 22, 2011	April 5, 2011	\$ 0.020	\$ 309
May 20, 2011	June 6, 2011	\$ 0.020	\$ 310





**Table of Contents**

On July 25, 2012, our Board of Directors approved a quarterly cash dividend on our common stock of \$0.025 per share payable on September 4, 2012, to stockholders of record at the close of business on August 17, 2012, which will total approximately \$0.4 million.

**Cash Flows**

	Six months ended June 30, (in thousands)		
	2012	2011	Net Change
Cash and cash equivalents	\$ 20,162	\$ 21,405	\$ (1,243)
Cash flows provided by (used in):			
Operating activities	\$ 2,431	\$ 1,098	\$ 1,333
Investing activities	(517)	(1,313)	796
Financing activities	(1,841)	(1,088)	(753)

**Net cash provided by operating activities.** Net cash provided by operating activities was \$2.4 million for the six months ended June 30, 2012, and consisted of \$1.2 million net income, adjusted for non-cash items of \$2.8 million (including depreciation and amortization of \$1.1 million, provision for inventory write-offs of \$0.7 million, stock-based compensation of \$0.5 million, and the effects of foreign currency translations of \$0.3 million) and was offset by changes in working capital of \$1.5 million. The net cash used by changes in working capital was principally the result of an increase in inventory of \$1.9 million, an increase of accounts receivable, and a decrease in accounts payable and other liabilities.

Net cash provided by operating activities was \$1.1 million for the six months ended June 30, 2011, and consisted of \$0.6 million net income, adjusted for non-cash items of \$2.8 million (including depreciation and amortization of \$1.0 million, the noncash restructuring charges associated with our exit of our Brindisi, Italy factory of \$0.7 million, provision for inventory write-offs of \$0.6 million, stock-based compensation of \$0.5 million, and impairment charges of \$0.1 million) and was offset by changes in working capital of \$2.3 million. The net cash used by changes in working capital was principally the result of an increase in accounts payable and other liabilities, and partially offset by a decrease in inventories.

**Net cash used in investing activities.** Net cash used in investing activities was \$0.5 million for the six months ended June 30, 2012. This was primarily driven by the purchase of property and equipment and was partially offset by the \$0.1 million payment of a note receivable related to our stent graft divestiture in 2011.

Net cash used in investing activities was \$1.3 million for the six months ended June 30, 2011. This was due to the purchase of property and equipment of \$0.8 million, primarily related to transfer of our manufacturing plant in Brindisi, Italy to Burlington, Massachusetts and \$0.6 million of acquisition related payments, primarily related to the LifeSpan Vascular Graft acquisition and the Spanish and Danish distributor buyouts.

**Table of Contents**

**Net cash used in financing activities.** Net cash used in financing activities was \$1.8 million for the six months ended June 30, 2012, driven primarily by the purchase of \$1.1 million of our outstanding shares under our stock repurchase plan and the payment of common stock dividends of \$0.8 million.

Net cash used in financing activities was \$1.1 million for the six months ended June 30, 2011 which was primarily driven by the payment of common stock dividends of \$0.6 million and the purchase of \$0.5 million of our outstanding shares under our stock repurchase plan.

**Contractual obligations.** Our principal contractual obligations consist of operating leases and inventory purchase commitments. The following table summarizes our commitments to settle contractual obligations as of June 30, 2012:

Contractual obligations	Total	Less than 1 year	1-3 years (in thousands)	3-5 years	More than 5 years
Operating leases	\$ 3,786	\$ 960	\$ 1,456	\$ 1,139	\$ 231
Purchase commitments for inventory	5,397	1,660	2,138	1,599	
<b>Total contractual obligations</b>	<b>\$ 9,183</b>	<b>\$ 2,620</b>	<b>\$ 3,594</b>	<b>\$ 2,738</b>	<b>\$ 231</b>

The commitments under our operating leases consist primarily of lease payments for our Burlington, Massachusetts, corporate headquarters and manufacturing facility, expiring in 2017; our Sulzbach, Germany office, expiring in 2016; our Tokyo, Japan office, expiring in 2013; and our Milan, Italy office, expiring in 2016; and our Madrid, Spain office, expiring in 2014. They also include automobile and equipment leases.

The purchase commitments for inventory are intended to be used in operations in the normal course of business and do not represent excess commitments or loss contracts.

**Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements as of June 30, 2012. 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.

**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, 2011. There has been no material changes in our critical accounting policies during the six months ended June 30, 2012. 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.

## **Table of Contents**

### **Recent Accounting Pronouncements**

In May 2011, the Financial Accounting Standards Board (FASB) amended existing rules covering fair value measurement and disclosure to clarify guidance and minimize differences between accounting principles generally accepted in the United States (GAAP) and International Financial Reporting Standards (IFRS). The new guidance requires us to provide information about valuation techniques and unobservable inputs used in Level 3 fair value measurements and provide a narrative description of the sensitivity of Level 3 measurements to changes in unobservable inputs. The guidance became effective on January 1, 2012. The adoption of this standard did not have a material impact on our results of operations or financial position.

In June 2011, new guidance was issued pertaining to the presentation of comprehensive income. The new rule eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. The standard is intended to provide a more consistent method of presenting non-owner transactions that affect the company's equity. Under the new guidance, an entity can elect to present items of net income and other comprehensive income in one continuous statement or in two separate, but consecutive, statements. The new guidance became effective for fiscal years that begin after December 15, 2011. The adoption of this standard did not have a material impact on our results of operations or financial position.

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

This item is not applicable to us as a smaller reporting company.

### **Item 4. Controls and Procedures 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 Exchange Act of 1934 is reported, processed, and summarized within the time periods specified in the SEC's rules and forms. As of June 30, 2012, or the Evaluation Date, 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). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective at the reasonable assurance level.

### **Changes in Internal Control**

There have been no changes in our internal control over financial reporting for the quarter ended June 30, 2012, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Inherent Limitations of Internal Controls**

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future

**Table of Contents**

conditions. Over time, a control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

**Part II. Other Information****Item 1. Legal Proceedings.**

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, employment matters commercial arrangements and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of August 10, 2012, that, management believes might have a material adverse effect on our financial position, results of operations or cash flows.

**Item 1A. Risk Factors**

*In Part I-Item 1A ( Risk Factors ) of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, which was filed with the Securities and Exchange Commission on March 27, 2012, we describe risk factors related to LeMaitre Vascular. The following risk factor includes a substantive change from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2011. You should carefully review this risk factor and the risks factors 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.*

*Even after our products have received marketing approval or clearance, product approvals and clearances can be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval.*

Our products, marketing, sales and development activities, and manufacturing processes are subject to extensive and rigorous regulation by the FDA, by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. These authorities have been increasing their scrutiny of our industry. If those regulatory bodies feel that we have failed to comply with regulatory standards or if we encounter unforeseen problems following initial approval of our products, there can be no assurance that any approval will not be subsequently withdrawn or conditioned upon extensive post-market study requirements, even after products have received marketing approval or clearance. Further, due to the increased scrutiny of our industry by the various regulatory agencies and the interconnectedness of the various regulatory agencies, particularly within the European Union, there is also no assurance that withdrawal of any of our product approvals by any single regulatory agency will not precipitate one or more additional regulatory agencies from also withdrawing approval of any such product.

In October 2011, we received complaints of two AlboGraft device failures which resulted in a voluntary recall of one production lot of our AlboGraft Vascular Graft. Subsequently, in February 2012, we received complaints of two additional AlboGraft device failures, which resulted in a voluntary recall of one additional production lot. Subsequent to the February 2012 recall, we received four additional complaints regarding our AlboGraft Vascular Graft. In March 2012, the relevant regulatory agency in the United Kingdom issued a Medical Device Alert advising doctors to use caution when implanting our AlboGraft Vascular Grafts. In April 2012, the relevant regulatory agencies in the United Kingdom and France issued Prohibition Notices which prohibited our ability to sell AlboGraft Vascular Grafts in these countries. In July 2012, the relevant regulatory agencies in the United Kingdom and France rescinded their Prohibition Notices allowing our Albograft to be sold within these counties. While the French regulatory agency rescinded its prohibition notice without qualification, the United Kingdom regulatory agency required that all AlboGraft devices must be tested prior to implant.

Although we are seeking to remove the qualification in the United Kingdom, there can be no assurance that our efforts will be successful, nor can there be any assurance that additional countries will not also issue their own prohibitions against sales of our AlboGraft devices. Although the Prohibition Notices have been substantially lifted, the fact that they were issued will likely continue to adversely affect sales in France and the United Kingdom and may concurrently and subsequently adversely affect our reputation and sales of our AlboGraft Vascular Grafts in both countries and in other jurisdictions as well as our financial condition and results of operations. As of June 30, 2012, we have approximately \$1.9 million of inventory and \$0.6 million of intangible assets related to the AlboGraft Vascular Graft.

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

None.

**Issuer Purchases of Equity Securities**

Period	Issuer Purchases of Equity Securities			
	Total Number of Shares (or Units) Purchased (1)	Average Price Paid Per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Program (2)	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that may yet be Purchased under the Plans or Program
April 1, 2012 through April 30, 2012	22,521	\$ 5.65	20,126	\$ 4,617,012
May 1, 2012 through May 31, 2012	52,493	\$ 5.17	50,808	\$ 4,354,511
June 1, 2012 through June 30, 2012	19,769	\$ 5.52	19,725	\$ 4,245,692
Total	94,783	\$ 5.36	90,659	\$ 4,245,692

- (1) For the three months ended June 30, 2012, we repurchased 4,124 shares of our common stock to satisfy the employees' obligations with respect to withholding taxes in connection with the vesting of restricted stock units.
- (2) In July 2009, our Board of Directors authorized the repurchase of up to \$1.0 million shares of our common stock from time to time on the open market or in privately negotiated transactions. In October 2009, our Board of Directors increased this amount to \$2.0 million, in July 2010, our Board of Directors further increased this amount to \$5.0 million, and in November 2011, our Board of Directors further increased this amount to \$10.0 million. The expiration date of this program is December 31, 2013.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.3	Amendment to Second Amended and Restated Certificate of Incorporation.	8-K	6/15/2012	3.3	
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a).				X
31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a).				X

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-Q

- |      |  |   |
|------|--|---|
| 32.1 | Certification by the Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350).* | X |
| 32.2 | Certification by the Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350).* | X |

**Table of Contents**

101.INS	XBRL Instance Document.+
101.SCH	XBRL Taxonomy Extension Schema Document.+
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.+
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.+
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.+
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.+

\*The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q, are not deemed filed with the SEC and are not to be incorporated by reference into any filing of LeMaitre Vascular, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

+ The XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.



**Table of Contents**

**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 August 10, 2012.

LEMAITRE VASCULAR, INC

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

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

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit</b>	<b>Exhibit Description</b>	<b>Incorporated by Reference</b>			<b>Filed</b>
		<b>Form</b>	<b>Date</b>	<b>Number</b>	<b>Herewith</b>
3.3	Amendment to Second Amended and Restated Certificate of Incorporation.	8-K	6/15/2012	3.3	
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a).				X
31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a).				X
32.1	Certification by the Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350).*				X
32.2	Certification by the Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350).*				X
101.INS	XBRL Instance Document.+				
101.SCH	XBRL Taxonomy Extension Schema Document.+				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.+				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.+				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.+				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.+				

\* The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q, are not deemed filed with the SEC and are not to be incorporated by reference into any filing of LeMaitre Vascular, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

+ The XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.