

LEMAITRE VASCULAR INC
Form 10-Q
November 04, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

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)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

01803
(Zip Code)

(781) 221-2266

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant 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

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

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

The registrant had 18,583,768 shares of common stock, \$.01 par value per share, outstanding as of November 1, 2016.

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 September 30, 2016 (unaudited) and December 31, 2015</u> | 3 |
| <u>Unaudited Consolidated Statements of Operations for the three-month and nine-month periods ended September 30, 2016 and 2015</u> | 4 |
| <u>Unaudited Consolidated Statements of Comprehensive Income for the three-month and nine-month periods ended September 30, 2016 and 2015</u> | 5 |
| <u>Unaudited Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2016 and 2015</u> | 6 |
| <u>Notes to Unaudited Consolidated Financial Statements</u> | 7 |
| <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 18 |
| Item 2. <u>Operations</u> | |
| Item 3. <u>Quantitative and Qualitative Disclosure about Market Risk</u> | 28 |
| Item 4. <u>Controls and Procedures</u> | 28 |
| Part II. <u>Other Information:</u> | |
| Item 1. <u>Legal Proceedings</u> | 29 |
| Item 1A. <u>Risk Factors</u> | 30 |
| Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u> | 31 |
| Item 6. <u>Exhibits</u> | 32 |
| <u>Signatures</u> | 33 |
| <u>Index to Exhibits</u> | |

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

| | (unaudited) September 30, 2016 | December 31, 2015 |
|--|--|------------------------------|
| | (in thousands, except share data) | |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 34,650 | \$ 27,451 |
| Accounts receivable, net of allowances of \$234 at September 30, 2016, and \$243 at December 31, 2015 | 12,176 | 11,971 |
| Inventory | 17,430 | 15,205 |
| Prepaid expenses and other current assets | 3,979 | 3,557 |
| Total current assets | 68,235 | 58,184 |
| Property and equipment, net | 7,490 | 7,022 |
| Goodwill | 18,206 | 17,789 |
| Other intangibles, net | 5,872 | 6,336 |
| Deferred tax assets | 1,327 | 1,205 |
| Other assets | 176 | 168 |
| Total assets | \$ 101,306 | \$ 90,704 |
| Liabilities and stockholders equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,148 | \$ 1,366 |
| Accrued expenses | 10,308 | 8,837 |
| Acquisition-related obligations | 608 | 165 |
| Total current liabilities | 12,064 | 10,368 |
| Deferred tax liabilities | 1,680 | 1,678 |
| Other long-term liabilities | 872 | 774 |
| Total liabilities | 14,616 | 12,820 |
| 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 20,033,526 shares at September 30, 2016, and 19,748,321 shares at December 31, 2015 | 200 | 197 |
| Additional paid-in capital | 84,837 | 82,094 |

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-Q

| | | |
|---|------------|-----------|
| Retained earnings | 13,568 | 8,161 |
| Accumulated other comprehensive loss | (3,213) | (4,049) |
| Treasury stock, at cost; 1,452,810 shares at September 30, 2016 and 1,431,139 shares at December 31, 2015 | (8,702) | (8,519) |
| Total stockholders' equity | 86,690 | 77,884 |
| Total liabilities and stockholders' equity | \$ 101,306 | \$ 90,704 |

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.

Consolidated Statements of Operations

(unaudited)

| | Three months ended September 30, | | Nine months ended September 30, | |
|--|--|-----------|------------------------------------|-----------|
| | 2016 | 2015 | 2016 | 2015 |
| | (in thousands, except per share data) | | | |
| Net sales | \$ 23,216 | \$ 19,025 | \$ 65,863 | \$ 57,869 |
| Cost of sales | 6,197 | 5,509 | 19,121 | 18,106 |
| Gross profit | 17,019 | 13,516 | 46,742 | 39,763 |
| Sales and marketing | 6,541 | 5,489 | 19,353 | 16,866 |
| General and administrative | 3,595 | 3,455 | 10,343 | 10,375 |
| Research and development | 1,539 | 1,421 | 4,619 | 3,904 |
| Medical device excise tax | | 190 | | 554 |
| Gain on divestiture | | (360) | | (360) |
| Total operating expenses | 11,675 | 10,195 | 34,315 | 31,339 |
| Income from operations | 5,344 | 3,321 | 12,427 | 8,424 |
| Other income (expense): | | | | |
| Interest income | 24 | 3 | 55 | 7 |
| Foreign currency gain (loss) | (61) | (185) | (74) | (142) |
| Income before income taxes | 5,307 | 3,139 | 12,408 | 8,289 |
| Provision for income taxes | 2,078 | 1,047 | 4,415 | 3,061 |
| Net income | \$ 3,229 | \$ 2,092 | \$ 7,993 | \$ 5,228 |
| Earnings per share of common stock: | | | | |
| Basic | \$ 0.17 | \$ 0.12 | \$ 0.43 | \$ 0.30 |
| Diluted | \$ 0.17 | \$ 0.11 | \$ 0.42 | \$ 0.29 |
| Weighted-average shares outstanding: | | | | |
| Basic | 18,524 | 17,865 | 18,423 | 17,625 |
| Diluted | 19,248 | 18,497 | 19,103 | 18,136 |
| Cash dividends declared per common share | \$ 0.045 | \$ 0.040 | \$ 0.135 | \$ 0.120 |

See accompanying notes to consolidated financial statements.

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

| | Three months ended | | Nine months ended | |
|--|---------------------------|-------------|--------------------------|-------------|
| | September 30, | | September 30, | |
| | 2016 | 2015 | 2016 | 2015 |
| | (in thousands) | | | |
| Net income | \$ 3,229 | \$ 2,092 | \$ 7,993 | \$ 5,228 |
| Other comprehensive income (loss): | | | | |
| Foreign currency translation adjustment, net | 312 | (508) | 836 | (1,668) |
| Total other comprehensive income (loss) | 312 | (508) | 836 | (1,668) |
| Comprehensive income | \$ 3,541 | \$ 1,584 | \$ 8,829 | \$ 3,560 |

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.

Consolidated Statements of Cash Flows

(unaudited)

| | Nine months ended September 30, 2016 2015 | |
|---|---|------------------|
| | (in thousands) | |
| Operating activities | | |
| Net income | \$ 7,993 | \$ 5,228 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 2,658 | 2,497 |
| Stock-based compensation | 1,195 | 1,088 |
| Provision for doubtful accounts | 52 | 156 |
| Provision for inventory write-downs | 280 | 462 |
| Gain on divestitures | | (360) |
| Foreign currency transaction (gain) loss | (1) | 130 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (68) | (1,078) |
| Inventory | (216) | (33) |
| Prepaid expenses and other assets | (390) | (791) |
| Accounts payable and other liabilities | 1,199 | 214 |
| Net cash provided by operating activities | 12,702 | 7,513 |
| Investing activities | | |
| Purchases of property and equipment and other assets | (1,830) | (1,558) |
| Proceeds from disposal of property and equipment | | 15 |
| Proceeds from divestitures, net of expenses | | 360 |
| Purchase of intellectual property | | (6) |
| Payments related to acquisitions | (2,368) | (1,426) |
| Net cash used in investing activities | (4,198) | (2,615) |
| Financing activities | | |
| Payments of deferred acquisition consideration | (249) | (1,100) |
| Proceeds from issuance of common stock | 1,384 | 3,718 |
| Purchase of treasury stock | (183) | (266) |
| Common stock cash dividend paid | (2,487) | (2,120) |
| Net cash used in financing activities | (1,535) | 232 |
| Effect of exchange rate changes on cash and cash equivalents | 230 | (193) |
| Net increase in cash and cash equivalents | 7,199 | 4,937 |
| Cash and cash equivalents at beginning of period | 27,451 | 18,692 |
| Cash and cash equivalents at end of period | \$ 34,650 | \$ 23,629 |

Supplemental disclosures of cash flow information (see Note 12)

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.

Notes to Consolidated Financial Statements

September 30, 2016

(unaudited)

1. Organization and Basis of Presentation

Description of Business

Unless the context indicates 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 include the following: valvulotomes, balloon catheters, carotid shunts, biologic patches, biologic vascular grafts, radiopaque marking tape, anastomotic clips, remote endarterectomy devices, laparoscopic cholecystectomy devices, synthetic vascular grafts, angioscopes and powered phlebectomy devices. Our offices are located in Burlington, Massachusetts; Mississauga, Canada; Sulzbach, Germany; Milan, Italy; Madrid, Spain; North Melbourne, Australia; Tokyo, Japan; and Shanghai, China.

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 nine months ended September 30, 2016 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, 2015, 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. All significant intercompany accounts and transactions have been eliminated in consolidation.

Recent Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board (FASB) issued an accounting standards update, ASU 2016-15, which changes the classification of certain cash receipts and cash payments within the statement of cash flows. The new standard is effective for us beginning January 31, 2018, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

In March 2016, the FASB issued a new standard, ASU 2016-09, which changes the accounting for certain aspects of share-based payments to employees. The new guidance requires excess tax benefits and tax deficiencies to be recorded in the income statement when the awards vest or are settled. In addition, cash flows related to excess tax benefits will no longer be separately classified as a financing activity apart from other income tax cash flows. The new standard is effective for us beginning January 31, 2017, with early adoption permitted.

We elected to early adopt the new guidance in the third quarter of fiscal year 2016, which required us to reflect any adjustments as of January 1, 2016, the beginning of the annual period that includes the interim period of adoption. The primary impact of adoption was the recognition of \$0.3 million of excess tax benefits in our provision for income taxes rather than additional paid-in capital for all periods in fiscal year 2016. We recorded this adjustment in the quarter ended September 30, 2016 as it was not material to the earlier periods previously reported. As allowed by the standard, we also made an election to account for award forfeitures as they occur, rather than estimating them at the time of grant. In connection with this election we recorded a net cumulative-effect adjustment to beginning retained earnings of \$0.1 million.

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 more likely than not, 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 intention is to permanently reinvest these earnings.

We recognize, measure, present and disclose in our financial statements any uncertain tax positions that we have taken, or expect to take on a tax return. We operate in multiple taxing jurisdictions, both within and without the United States, and may be subject to audits from various tax authorities. 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 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.

Our 2016 income tax expense varies from the statutory rate mainly due to the generation of federal and state tax credits, permanent items and lower statutory rates from our foreign subsidiaries. Additionally, in the third quarter of 2016, we recognized certain discrete items related to adjustments to prior period taxes resulting from a federal audit, which were partially offset by the benefit of the early adoption of stock-based compensation accounting guidance and stock option exercises. Our 2015 income tax expense varied from the statutory rate mainly due to certain permanent items, offset by lower statutory rates from our foreign entities and a discrete item for stock option exercises.

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 September 30, 2016, the gross amount of unrecognized tax benefits exclusive of interest and penalties was \$382,000. We remain subject to examination until the statute of limitations expires for each respective tax jurisdiction. The statute of limitations will be open with respect to these tax positions until 2029. A reconciliation of beginning and ending amount of our unrecognized tax benefits is as follows:

| | 2016 |
|---|----------------|
| | (in thousands) |
| Unrecognized tax benefits as of December 31, 2015 | \$ 82 |

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-Q

| | | |
|---|----|-----|
| Additions for tax positions of current year | | 84 |
| Additions for tax positions of prior years | | 216 |
| Reductions for settlements with taxing authorities. | | |
| Reductions for lapses of the applicable statutes of limitations | | |
| Unrecognized tax benefits as of September 30, 2016 | \$ | 382 |

As of September 30, 2016, a summary of the tax years that remain subject to examination in our taxing jurisdictions is as follows:

| | |
|---------------|------------------|
| United States | 2013 and forward |
| Foreign | 2008 and forward |

3. Inventories

Inventories consist of the following:

| | September 30, 2016 | December 31, 2015 |
|-------------------|-----------------------|----------------------|
| | (in thousands) | |
| Raw materials | \$ 2,910 | \$ 3,062 |
| Work-in-process | 2,684 | 2,681 |
| Finished products | 11,836 | 9,462 |
| Total inventory | \$ 17,430 | \$ 15,205 |

We held inventory on consignment of \$1.3 million and \$1.1 million as of September 30, 2016 and December 31, 2015, respectively.

4. Acquisition and Divestitures

Our acquisitions, including those discussed below, have historically been made at prices above the fair value of the acquired identifiable assets, resulting in goodwill, due to expectations of synergies that will be realized by combining businesses. These synergies include the use of our existing sales channel to expand sales of the acquired businesses products, consolidation of manufacturing facilities, and the leveraging of our existing administrative infrastructure.

The fair market valuations associated with these transactions fall within Level 3 of the fair value hierarchy, due to the use of significant unobservable inputs to determine fair value. The fair value measurements were calculated using unobservable inputs, primarily using the income approach, specifically the discounted cash flow method. The amount and timing of future cash flows within our analysis was based on our due diligence models, most recent operational budgets, long range strategic plans and other estimates.

ProCol Biologic Graft

On March 18, 2016, we acquired the ProCol biologic vascular graft (ProCol) business for \$2.7 million from Hancock Jaffe Laboratories, Inc. (HJL) and CryoLife, Inc. (CRY). HJL was the owner and manufacturer of ProCol and CRY was the exclusive distributor of the ProCol graft. CRY also owned an option to purchase the ProCol business, which we acquired from CRY. We bought finished goods inventory and other ProCol related assets from CRY for \$2.0 million, which was paid in full at closing. We bought other ProCol assets from HJL for \$0.7 million, 50% of which was paid at closing, 25% of which was paid in the quarter ended September 30, 2016 and the remainder of which will be paid within one year of closing. Additional consideration is payable to HJL for a three-year period following the closing, calculated at 10% of ProCol revenues. This additional consideration was initially valued at \$0.3 million and

will be re-measured each reporting period until the payment requirement ends, with any adjustments reported in income from operations. For the nine months ended September 30, 2016, the amount of the adjustment was not material to our financial statements.

Assets acquired included inventory, intellectual property and a related license, the ProCol trade name, customer lists, non-compete agreements and certain equipment and supplies. We did not assume any liabilities. We accounted for the acquisition as a business combination.

The following table summarizes the preliminary purchase price allocation as of September 30, 2016:

| | Allocated Fair Value (in thousands) |
|--------------------------------------|---|
| Inventory | \$ 2,080 |
| Manufacturing equipment and supplies | 25 |
| Intangible assets | 620 |
| Goodwill | 318 |
| Purchase price | \$ 3,043 |

The goodwill is deductible for tax purposes over 15 years.

The following table reflects the preliminary allocation of the acquired intangible assets and related estimated useful lives:

| | Allocated Fair Value (in thousands) | Weighted Average Useful Life |
|--------------------------------|---|------------------------------------|
| Non-compete agreement | \$ 84 | 5.0 years |
| Tradename | 109 | 9.5 years |
| Intellectual property | 277 | 9.0 years |
| Customer relationships | 150 | 9.0 years |
| Total intangible assets | \$ 620 | |

The weighted-average amortization period of the acquired intangible assets was 8.6 years.

Tru-Incise Valvulotome

In May 2015, we entered into an asset purchase agreement with UreSil, LLC (UreSil) to acquire the production and distribution rights of UreSil's Tru-Incise valvulotome for sales outside the United States for a purchase price of approximately \$1.4 million. We paid \$1.1 million at the closing with the remaining \$0.3 million payable at various points in 2016 and 2017. We accounted for the acquisition as a business combination. Assets acquired included inventory and intellectual property. We did not assume any liabilities. The purchase accounting is complete.

The following table summarizes the purchase price allocation at the date of the acquisition:

| | Allocated Fair Value (in thousands) |
|-----------|---|
| Inventory | \$ 88 |

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-Q

| | |
|-------------------|----------|
| Intangible assets | 545 |
| Goodwill | 742 |
| Purchase price | \$ 1,375 |

The goodwill is deductible for tax purposes over 15 years.

The following table reflects the allocation of the acquired intangible assets and related estimated useful lives:

| | Allocated Fair Value | Weighted Average Useful Life |
|--------------------------------|---------------------------------|---|
| | (in thousands) | |
| Non-compete agreement | \$ 120 | 5.0 years |
| Tradename license | 17 | 3.0 years |
| Product technology | 391 | 7.0 years |
| Customer relationships | 17 | 3.0 years |
| Total intangible assets | \$ 545 | |

Other 2015 Items

Following the May 2015 Tru-Incise valvulotome acquisition, we entered into definitive agreements with seven UreSil distributors to terminate their distribution of the Tru-Incise valvulotome for aggregate termination fees of \$0.2 million. We recorded approximately \$0.2 million of intangible assets with a weighted-average amortization period of 3.0 years.

In August 2015, we entered into a definitive agreement with Grex Medical Oy (Grex), our distributor in Finland to terminate their distribution of our products, and we began selling direct to hospitals in Finland as of January 1, 2016. The agreement required us to pay approximately \$0.2 million in exchange for the purchase of customer lists and a non-compete agreement.

Angioscope

In September 2014, we entered into an asset purchase agreement with Applied Medical Resource Corporation (Applied Medical) to acquire substantially all the assets related to Applied Medical's angioscope product line for a purchase price of \$0.4 million. We paid \$0.3 million at closing and the remaining \$0.1 million was paid in December 2015 and March 2016. We accounted for the acquisition as a business combination. Assets acquired included inventory, property and equipment and intellectual property. We recorded \$0.1 million of tangible assets, \$0.3 million of intangible assets and \$0.1 million of goodwill. The weighted-average amortization period for the acquired intangible assets was 7.5 years. The goodwill is deductible for tax purposes over 15 years. The purchase accounting is complete.

Xenotis Pty Ltd

In August 2014, we entered into a stock purchase agreement with the shareholders of Xenotis Pty Ltd (Xenotis) to acquire all of the capital stock of Xenotis for \$6.7 million, with a mechanism for a purchase price adjustment that was based on the net tangible assets of Xenotis at closing. Xenotis was the parent company of Bio Nova International, the manufacturer and marketer of the Omniflow II biosynthetic vascular graft for lower extremity bypass and AV access. We paid \$5.1 million at the closing and the remaining \$1.4 million was paid in August 2015. The net tangible asset purchase price adjustment of \$0.2 million was paid in November 2014. We accounted for the acquisition as a business combination. We recorded \$2.1 million of tangible assets, \$2.1 million of property and equipment, \$1.8 million of intangible assets and \$2.5 million of goodwill. The weighted-average amortization period for the acquired intangible assets was 5.0 years. Liabilities assumed included payables and debt totaling \$1.7 million; the accounts payable of \$0.6 million was paid in the ordinary course, and the assumed debt was paid in full in August 2014. The

purchase accounting is complete.

The goodwill of \$2.5 million is not deductible for tax purposes. In addition, we acquired deferred tax assets of \$2.4 million which consisted primarily of net operating loss carry-forwards and capital loss carry-forwards. We recorded a full valuation allowance on these deferred tax assets.

In September 2014, we entered into definitive agreements with eight former Xenotis distributors in Europe to terminate their distribution of our Omniflow II biosynthetic vascular graft, for aggregated termination fees of \$1.3 million. We paid approximately \$1.1 million in 2014 with the remainder paid in 2015. We recorded \$0.4 million of inventory and \$0.9 million of intangible assets. We allocated the payment to the tangible and intangible assets acquired based on the estimated fair value of each of these elements to the transactions. The weighted-average amortization period for the acquired intangible assets was 5.0 years.

5. Goodwill and Other Intangibles

Goodwill consists of the following:

| | (in thousands) |
|-------------------------------|----------------|
| Balance at December 31, 2015 | \$ 17,789 |
| Additions for acquisitions | 318 |
| Effects of currency exchange | 99 |
| Balance at September 30, 2016 | \$ 18,206 |

Other intangibles consist of the following:

| | September 30, 2016 | | | December 31, 2015 | | |
|--|----------------------------|-----------------------------|--------------------------|----------------------------|-----------------------------|--------------------------|
| | Gross Carrying Value | Accumulated Amortization | Net Carrying Value | Gross Carrying Value | Accumulated Amortization | Net Carrying Value |
| | (in thousands) | | | | | |
| Product technology and intellectual property | \$ 7,452 | \$ 3,825 | \$ 3,627 | \$ 7,113 | \$ 3,247 | \$ 3,866 |
| Trademarks, tradenames and licenses | 1,675 | 1,332 | 343 | 1,560 | 1,230 | 330 |
| Customer relationships | 4,015 | 2,527 | 1,488 | 3,801 | 2,143 | 1,658 |
| Other intangible assets | 1,389 | 975 | 414 | 1,297 | 815 | 482 |
| Total identifiable intangible assets | \$ 14,531 | \$ 8,659 | \$ 5,872 | \$ 13,771 | \$ 7,435 | \$ 6,336 |

These intangible assets are being amortized over their useful lives ranging from 1 to 13 years. The weighted-average amortization period for these intangibles as of September 30, 2016 is 7.9 years. Amortization expense is included in general and administrative expense and is as follows:

| | Three months ended | | Nine months ended | |
|----------------------|-----------------------|--------|-----------------------|----------|
| | September 30, 2016 | 2015 | September 30, 2016 | 2015 |
| | (in thousands) | | | |
| Amortization expense | \$ 385 | \$ 387 | \$ 1,170 | \$ 1,135 |

Estimated amortization expense for the remainder of 2016 and each of the five succeeding fiscal years is as follows:

| | Year ended December 31, | | | | | 2021 |
|----------------------|-------------------------|----------|----------|--------|--------|--------|
| | 2016 | 2017 | 2018 | 2019 | 2020 | |
| | (in thousands) | | | | | |
| Amortization expense | \$ 372 | \$ 1,305 | \$ 1,120 | \$ 930 | \$ 670 | \$ 497 |

6. Accrued Expenses

Accrued expenses consist of the following:

| | September 30, 2016 | December 31, 2015 |
|--------------------------------|--------------------|-------------------|
| | (in thousands) | |
| Compensation and related taxes | \$ 5,418 | \$ 6,062 |
| Income and other taxes | 2,785 | 483 |
| Professional fees | 131 | 530 |
| Other | 1,974 | 1,762 |
| Total | \$ 10,308 | \$ 8,837 |

7. Commitments and Contingencies

As of September 30, 2016, as part of our normal course of business, we have commitments to purchase \$4.2 million of inventory through 2017.

8. Segment and Enterprise-Wide Disclosures

Under Accounting Standards Codification Topic 280, *Segment Reporting*, operating segments are defined as components of an enterprise for which separate, discrete financial information is available and evaluated 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 sales by product line and by legal entity for local reporting purposes.

Most of our revenues are generated in the United States, Germany, and other European countries as well as in Canada and Japan. Substantially all of our assets are located in the United States. Net sales to unaffiliated customers by country were as follows:

| Three months ended | | Nine months ended | |
|--------------------|------|-------------------|------|
| September 30, | | September 30, | |
| 2016 | 2015 | 2016 | 2015 |

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-Q

| | (in thousands) | | | |
|-----------------|----------------|-----------|-----------|-----------|
| United States | \$ 13,718 | \$ 11,171 | \$ 37,180 | \$ 33,774 |
| Germany | 2,651 | 2,208 | 7,920 | 6,900 |
| Other countries | 6,847 | 5,646 | 20,763 | 17,195 |
| Net Sales | \$ 23,216 | \$ 19,025 | \$ 65,863 | \$ 57,869 |

9. 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 | | Nine months ended | |
|---------------------------------------|--------------------|--------------------|--------------------|--------------------|
| | September 30, 2016 | September 30, 2015 | September 30, 2016 | September 30, 2015 |
| | (in thousands) | | | |
| Stock option awards | \$ 354 | \$ 327 | \$ 809 | \$ 752 |
| Restricted stock units | 179 | 152 | 386 | 336 |
| Total share-based compensation | \$ 533 | \$ 479 | \$ 1,195 | \$ 1,088 |

Stock-based compensation is included in our statements of operations as follows:

| | Three months ended | | Nine months ended | |
|---------------------------------------|--------------------|--------------------|--------------------|--------------------|
| | September 30, 2016 | September 30, 2015 | September 30, 2016 | September 30, 2015 |
| | (in thousands) | | | |
| Cost of sales | \$ 46 | \$ 53 | \$ 117 | \$ 126 |
| Sales and marketing | 129 | 108 | 271 | 213 |
| General and administrative | 314 | 276 | 708 | 661 |
| Research and development | 44 | 42 | 99 | 88 |
| Total stock-based compensation | \$ 533 | \$ 479 | \$ 1,195 | \$ 1,088 |

During the nine months ended September 30, 2016 and 2015, respectively, we granted options to purchase 511,000 and 499,000 shares of our stock to employees and non-employee directors. We computed the weighted average fair values of employee stock options for option grants issued during the nine months ended September 30, 2016 and 2015 using the Black-Scholes option model with the following assumptions:

| | 2016 | 2015 |
|--|---------|---------|
| Dividend yield | 1.3% | 1.4% |
| Volatility | 34.5% | 28.6% |
| Risk-free interest rate | 1.2% | 1.8% |
| Weighted average expected option term (in years) | 5.5 | 5.6 |
| Weighted average fair value per share of options granted | \$ 4.04 | \$ 2.80 |

During the nine months ended September 30, 2016 and 2015, respectively, we awarded restricted stock units of 126,000 and 63,000 to employees. The weighted-average fair value per share of restricted stock unit awards issued for

the nine months ended September 30, 2016 was \$14.11. The weighted-average fair value per share of restricted stock unit grants issued for the nine months ended September 30, 2015 was \$11.32.

We issued approximately 285,000 and 721,000 shares of common stock following the exercise or vesting of underlying stock options or restricted stock units in the nine months ended September 30, 2016 and 2015, respectively.

10. Net Income per Share

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

| | Three months ended | | Nine months ended | |
|--|---------------------------------------|-------------|--------------------------|-------------|
| | September 30, | | September 30, | |
| | 2016 | 2015 | 2016 | 2015 |
| | (in thousands, except per share data) | | | |
| Basic: | | | | |
| Net income available for common stockholders | \$ 3,229 | \$ 2,092 | \$ 7,993 | \$ 5,228 |
| Weighted average shares outstanding | 18,524 | 17,865 | 18,423 | 17,625 |
| Basic earnings per share | \$ 0.17 | \$ 0.12 | \$ 0.43 | \$ 0.30 |
| Diluted: | | | | |
| Net income available for common stockholders | \$ 3,229 | \$ 2,092 | \$ 7,993 | \$ 5,228 |
| Weighted-average shares outstanding | 18,524 | 17,865 | 18,423 | 17,626 |
| Common stock equivalents, if dilutive | 724 | 632 | 680 | 510 |
| Shares used in computing diluted earnings per common share | 19,248 | 18,497 | 19,103 | 18,136 |
| Diluted earnings per share | \$ 0.17 | \$ 0.11 | \$ 0.42 | \$ 0.29 |
| Shares excluded in computing diluted earnings per share as those shares would be anti-dilutive | 76 | 40 | 44 | 81 |

11. Stockholders Equity
Share Repurchase Program

On July 25, 2016, our Board of Directors approved a stock repurchase program under which the Company is authorized to repurchase up to \$5.0 million of its common stock through transactions on the open market, in privately negotiated purchases or otherwise. This program may be suspended or discontinued at any time, and expires on the earlier of July 25, 2017 or when the authorized aggregate \$5.0 million repurchase limit is reached. We have not made any share repurchases under this program.

Dividends

In February 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 2016 | | | |
| March 21, 2016 | April 4, 2016 | \$ 0.045 | \$ 825 |
| May 25, 2016 | June 8, 2016 | \$ 0.045 | \$ 829 |
| August 22, 2016 | September 2, 2016 | \$ 0.045 | \$ 833 |
| Fiscal Year 2015 | | | |
| March 20, 2015 | April 3, 2015 | \$ 0.040 | \$ 700 |
| May 22, 2015 | June 5, 2015 | \$ 0.040 | \$ 705 |
| August 20, 2015 | September 3, 2015 | \$ 0.040 | \$ 715 |
| November 20, 2015 | December 4, 2015 | \$ 0.040 | \$ 725 |

On October 24, 2016 our Board of Directors approved a quarterly cash dividend on our common stock of \$0.045 per share payable on December 5, 2016 to stockholders of record at the close of business on November 21, 2016, which will total approximately \$0.8 million.

12. Supplemental Cash Flow Information

| | Nine months ended September 30, 2016 2015 | |
|---|---|----------|
| | (in thousands) | |
| Cash paid for income taxes, net | \$ 2,809 | \$ 3,341 |
| Common stock repurchased for RSU tax withholdings | \$ 183 | \$ 266 |

13. 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 September 30, 2016, 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 \$16.0 million.

We had no Level 2 assets being measured at fair value on a recurring basis as of September 30, 2016.

As discussed in Note 4, we have contingent liabilities related to certain of our acquired businesses. These liabilities are or have been remeasured each reporting period using Level 3 techniques to assess the probability that we will be required to make future payments, and to estimate the amount of those payments. There were no material changes in estimated liabilities during the nine months ended September 30, 2016.

14. Accumulated Other Comprehensive Loss

| | Nine months ended | |
|--|--------------------------|-------------|
| | September 30, | |
| | 2016 | 2015 |
| | (in thousands) | |
| Beginning balance | \$ (4,049) | \$ (2,365) |
| Other comprehensive income (loss) before reclassifications | 836 | (1,668) |
| Amounts reclassified from accumulated other comprehensive loss | | |
| Ending Balance | \$ (3,213) | \$ (4,033) |

Changes to our accumulated other comprehensive loss consisted of foreign currency translation for the nine months ended September 30, 2016 and 2015.

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

This Quarterly Report on Form 10-Q contains forward-looking statements (within the meaning of the federal securities law) that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future net sales, projected costs, projected expenses, prospects and plans and objectives of management are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, would, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We have based these forward-looking statements on our current expectations and projections about future events. Although we believe that the expectations underlying any of our forward-looking statements are reasonable, these expectations may prove to be incorrect, and all of these statements are subject to risks and uncertainties. Should one or more of these risks and uncertainties materialize, or should underlying assumptions, projections, or expectations prove incorrect, our actual results, performance, or financial condition may vary materially and adversely from those anticipated, estimated, or expected. These risks and uncertainties include, but are not limited to: the risk that the Company may not realize the anticipated benefits of its strategic activities; risks related to the integration of acquisition targets; the risk that assumptions about the market for the Company's products and the productivity of the Company's direct sales force and distributors may not be correct; risks related to product demand and market acceptance of the Company's products; risks related to attracting, training and retaining sales representatives and other employees in new markets such as Finland and New Zealand; adverse or fluctuating conditions in the general domestic and global economic markets; and the risk that the Company is not successful in transitioning to a direct-selling model in new territories.

Forward-looking statements reflect management's analysis as of the date of this quarterly report. Further information on potential risk factors that could affect our business and financial results is detailed in Part II, Item 1A, Risk Factors in this Quarterly Report on Form 10-Q and in our other filings with the Securities and Exchange Commission, including under the section headed Risk Factors in our most recent Annual Report on Form 10-K. 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, 2015, as filed with the SEC on March 10, 2016. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

Unless the context indicates 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, Omniflow, and XenoSure are registered trademarks of LeMaitre Vascular or one of its subsidiaries. This Quarterly Report on Form 10-Q also includes the registered and unregistered trademarks of other persons, which are the property of their respective owners.

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, Europe and, to a lesser extent, Asia and the Pacific Rim. We estimate that the annual worldwide market for all peripheral vascular devices approximates \$4 billion, within which our core product lines address roughly \$820 million. We have grown our business by using a three-pronged strategy: competing for sales of niche products, expanding our worldwide direct sales force, and acquiring and developing complementary vascular devices. We have used acquisitions as a primary means of further accessing the larger peripheral vascular device market, and we expect to continue to pursue this strategy in the future. Additionally, we have increased our efforts to expand our

vascular device offerings through new product development. We currently manufacture most of our product lines at our Burlington, Massachusetts headquarters.

Our products are used primarily 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 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.

Our principal product lines include the following: biologic vascular patches, valvulotomes, carotid shunts, balloon catheters, anastomotic clips, radiopaque marking tape, biologic vascular grafts, laparoscopic cholecystectomy devices, remote endarterectomy devices, prosthetic vascular grafts, biosynthetic grafts and powered phlebectomy devices.

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 direct sales force in North America, Europe, Asia and the Pacific Rim;

the addition of complementary products through acquisitions;

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

the introduction of our products in new territories upon receipt of regulatory approvals in these territories;
and

the consolidation of product manufacturing into our facilities in our Burlington, Massachusetts corporate headquarters.

We sell our products primarily through a direct sales force. As of September 30, 2016 our sales force was comprised of 91 sales representatives in North America, Europe, Japan, China, Australia and New Zealand. 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; Mississauga, Canada; Madrid, Spain; Milan, Italy; Shanghai, China; and North Melbourne, Australia. During the three and nine months ended September 30, 2016, approximately 93% and 92%, respectively of our net sales were generated in territories in which we employ direct sales representatives.

Historically we have experienced success in lower-rivalry niche product segments, for example the market segments for biologic vascular patches and valvulotome devices. In the biologic vascular patch market segment the number of competitors is limited, and we believe that we have been able to increase segment share and to a lesser extent increase selling prices, mainly due to strong sales service. In the valvulotome market segment, we believe that we have been able to materially increase our selling prices without losing significant market share. In contrast, we have experienced less success in highly competitive segments such as polyester grafts, where we face stronger competition from larger companies with greater resources and lower production costs. We have also experienced less success in segments such

as carotid shunts, where unit sales in the overall market may be declining. While we believe that these challenging market dynamics can be mitigated by our strong relationships with vascular surgeons, there can be no assurance that we will be successful in other highly competitive market segments.

In recent years we have also experienced success in geographic markets outside of the United States, such as Europe, where we generally offer comparatively lower average selling prices. If we continue to seek growth opportunities outside of the United States, we will likely experience downward pressure on our gross margin.

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:

During 2014, we entered into definitive agreements with eight former Xenotis distributors in Europe in order to terminate their distribution of our Omniflow II biosynthetic vascular grafts and we began selling direct to hospitals in those geographies. The agreements required us to pay approximately \$1.3 million in exchange for the purchase of customer lists and inventory.

During 2015, we entered into definitive agreements with seven former UreSil, LLC distributors in Europe in order to terminate their distribution of our Tru-Incise valvulotome and we began selling direct-to-hospital in those geographies. The termination fee was approximately \$0.2 million

In August 2015, we entered into a definitive agreement with Grex Medical Oy (Grex), our distributor in Finland, in order to terminate their distribution of our products and we began selling direct-to-hospital in Finland as of January 1, 2016. The termination fee was approximately \$0.2 million.

We anticipate that the expansion of our direct sales organization in China will result in increased sales, marketing and regulatory expenses during 2016. As of September 30, 2016 we had five employees in China.

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 August 2014, we acquired all of the capital stock of Xenotis Pty Ltd (Xenotis) for \$6.7 million plus the assumption of \$1.1 million of debt. Xenotis is the parent company of Bio Nova International, the manufacturer and marketer of the Omniflow II biosynthetic vascular graft for lower extremity bypass and AV access.

In September 2014, we acquired substantially all of the assets related to the angioscope product line from Applied Medical Resource Corporation for \$0.4 million.

In September 2014, we terminated our UnBalloon non-occlusive modeling catheter product line.

In May 2015, we acquired the production and distribution rights of UreSil LLC's Tru-Incise valvulotome for sales outside of the United States for \$1.4 million.

In July 2015, we entered into an asset sales agreement with Merit Medical Ireland Limited to sell our inventory, intellectual property and customer lists associated with The UnBalloon, our non-occlusive modeling catheter product line for \$0.4 million.

In December 2015, we terminated our InvisiGrip vein stripper product line, and wrote down \$0.1 million of related inventory in Q3 2015.

In March 2016, we acquired substantially all of the assets as well as the production and distribution rights of the ProCol business from Hancock Jaffe Laboratories and CryoLife, Inc. for \$2.7 million plus 10% of net sales for three years following the closing. ProCol is a biologic vascular graft used for dialysis access, and is approved for sale in the United States.

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 developments:

In June 2014, we launched the 1.5mm HYDRO LeMaitre Valvulotome.

In October 2014, we launched the LeMaitre Aortic Occlusion Catheter.

In December 2014, we launched the LeMills Valvulotome.

In December 2015, we launched the 15-cm AnastoClip AC.

In addition to our sales growth strategies, we have also executed several operational initiatives designed to consolidate and streamline manufacturing within our Burlington, Massachusetts facilities. We expect that these plant consolidations will result in improved control over our production capacity as well as reduced costs over the long-term. Our most recent manufacturing transitions included:

In January 2014, we initiated a project to transfer the manufacturing of the newly acquired Clinical Instruments devices to our facility in Burlington. We closed the Clinical Instruments facility in March 2014 and completed the manufacturing transfer during Q2 2014.

In March 2015, we initiated a project to transfer the manufacturing of the newly acquired angioscope product line to our facility in Burlington. We had been purchasing the devices from Applied Medical since the September 2014 acquisition and completed the transition of manufacturing to our Burlington facility in December 2015.

In May 2015, we initiated a project to transfer the manufacturing of the newly acquired Tru-Incise valvulotome product line to our facility in Burlington. We have been purchasing the devices from UreSil, LLC since the acquisition. We currently expect the transition of manufacturing to be completed in early 2017.

In March 2016, we initiated a project to transfer the manufacturing of the newly acquired ProCol biologic product line to our facility in Burlington. We have an agreement to purchase the product from the seller, Hancock Jaffe Laboratories, for up to three years following the closing. We currently expect the establishment of the production line and transition of manufacturing to be completed in the first half of 2018. Our execution of these business opportunities may affect the comparability of our financial results from period to period and may cause substantial fluctuations from period to period, as we incur related process engineering and other charges, as well as longer term impacts to revenues and operating expenditures.

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies, primarily the Euro, affect our financial results. For the nine months ended September 30, 2016, approximately 44% of our sales took place outside the United States. 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 exposure to exchange rate fluctuations. However, as most of our foreign sales are denominated in local currency, 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 revenue in U.S. dollars than we did before the rate increase went into effect. For the three months ended September 30, 2016, the effects of changes in foreign exchange rates increased sales by approximately \$0.1 million, and for the nine months ended September 30, 2016 reduced sales by approximately \$28,000, as compared to rates in effect for the three and nine months ended September 30, 2015, respectively.

Net Sales and Expense Components

The following is a description of the primary components of our net sales and expenses:

Net sales. We derive our net sales from the sale of our products, less discounts and returns. Net sales include the shipping and handling fees paid for by our customers. Most of our sales are generated by our direct sales force and are shipped and billed to hospitals or clinics throughout the world. In countries where we do not have a direct sales force, sales are primarily generated by shipments to distributors, who in turn sell to hospitals and clinics. In certain cases our products are held on consignment at a hospital or clinic prior to purchase; in those instances we recognize revenue at the time the product is used in surgery rather than at shipment.

Cost of sales. We manufacture nearly all of the products that we sell. Our cost of sales consists primarily of manufacturing personnel, raw materials and components, depreciation of property and equipment, and other allocated manufacturing overhead, as well as freight expense we pay to ship products to customers.

Sales and marketing. Our sales and marketing expense consists primarily of salaries, commissions, stock based compensation, travel and entertainment, attendance at medical society meetings, training programs, advertising and

product promotions, direct mail and other marketing costs.

General and administrative. General and administrative expense consists primarily of executive, finance and human resource expense, stock based compensation, legal and accounting fees, information technology expense, intangible asset amortization expense and insurance expense.

Research and development. Research and development expense includes costs associated with the design, development, testing, enhancement and regulatory approval of our products, principally salaries, laboratory testing

and supply costs. It also includes costs associated with design and execution of clinical studies, regulatory submissions and costs to register, maintain, and defend our intellectual property, and royalty payments associated with licensed and acquired intellectual property.

Other income (expense). Other income (expense) primarily includes interest income and expense, foreign currency gains (losses), and other miscellaneous gains (losses).

Income tax expense. We are subject to federal and state income taxes for earnings generated in the United States, which include operating losses in certain foreign jurisdictions for certain years depending on tax elections made, and foreign taxes on earnings of our wholly-owned foreign subsidiaries. Our consolidated tax expense is affected by the mix of our taxable income (loss) in the United States and foreign subsidiaries, permanent items, discrete items, unrecognized tax benefits, and amortization of goodwill for U.S tax reporting purposes.

Results of Operations

Comparison of the three and nine months ended September 30, 2016 to the three and nine months ended September 30, 2015.

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

| (unaudited) | Three months ended September 30, | | | Nine months ended September 30, | | |
|-------------------------|-------------------------------------|-----------|-------------------|------------------------------------|-----------|-------------------|
| | 2016 | 2015 | Percent change | 2016 | 2015 | Percent change |
| | (\$ in thousands) | | | | | |
| Net sales | \$ 23,216 | \$ 19,025 | 22% | \$ 65,863 | \$ 57,869 | 14% |
| Net sales by geography: | | | | | | |
| Americas | \$ 14,528 | \$ 11,916 | 22% | \$ 39,594 | \$ 35,870 | 10% |
| International | 8,688 | 7,109 | 22% | 26,269 | 21,999 | 19% |
| Total | \$ 23,216 | \$ 19,025 | 22% | \$ 65,863 | \$ 57,869 | 14% |

Net sales. Net sales increased 22% or \$4.2 million to \$23.2 million for the three months ended September 30, 2016, compared to \$19.0 million for the three months ended September 30, 2015. Sales increases for the three months ended September 30, 2016 occurred across multiple product lines, primarily driven by increased sales of our biologic vascular patches of \$2.0 million (of which we estimate that \$1.4 million was related to a safety alert/recall initiated by a competitor), valvulotomes of \$1.1 million and our recently acquired ProCol biologic vascular graft of \$0.3 million. These and other product line increases were partially offset by decreased sales of radiopaque tape, carotid shunts and cholangiogram catheters of \$0.1 million each.

Net sales increased 14% or \$8.0 million to \$65.9 million for the nine months ended September 30, 2016, compared to \$57.9 million for the nine months ended September 30, 2015. Sales increases for the nine months ended September 30, 2016 were primarily driven by increased sales of our biologic vascular patches of \$3.8 million (of which we estimate that \$1.7 million was related to a safety alert/recall initiated by a competitor), valvulotomes of \$2.0 million, vessel closure systems of \$0.8 million and our recently acquired ProCol biologic vascular graft of \$0.7 million. These and other product line increases were partially offset by decreased sales of radiopaque tape of \$0.6 million (related to

the inclusion in the 2015 period of \$0.6 million of OEM tape sales).

Direct-to-hospital net sales were 92% for the nine months ended September 30, 2016, versus 93% for the nine months ended September 30, 2015.

Net sales by geography. Net sales in the Americas increased \$2.6 million for the three months ended September 30, 2016. The increase was primarily driven by biologic vascular patches, valvulotomes, our recently acquired ProCol biologic vascular graft and vessel closure systems. These increases were partially offset by

decreases in sales of carotid shunts and radiopaque tape. International net sales increased \$1.6 million for the three months ended September 30, 2016. The increase occurred across multiple product lines but was primarily driven by increased sales of biologic vascular patches, valvulotomes, powered phlebectomy devices and ePTFE vascular grafts.

Net sales in the Americas increased \$3.7 million for the nine months ended September 30, 2016. The increase was primarily driven by biologic vascular patches, valvulotomes, our recently acquired ProCol biologic vascular graft and vessel closure systems, and was partially offset by decreased sales of radiopaque tape and carotid shunts. International net sales increased \$4.3 million for the nine months ended September 30, 2016. The increase occurred across most product lines but was primarily driven by sales of our biologic vascular patches, valvulotomes, ePTFE vascular grafts and shunts.

| (unaudited, \$ in thousands) | Three months ended | | | | Nine months ended | | | |
|------------------------------|--------------------|-----------|----------|----------------|-------------------|-----------|----------|----------------|
| | September 30, | | | Percent change | September 30, | | | Percent change |
| | 2016 | 2015 | Change | | 2016 | 2015 | Change | |
| Gross profit | \$ 17,019 | \$ 13,516 | \$ 3,503 | 26% | \$ 46,742 | \$ 39,763 | \$ 6,979 | 18% |
| Gross margin | 73.3% | 71.0% | * | 2.3% | 71.0% | 68.7% | * | 2.3% |

* Not applicable

Gross Profit. Gross profit increased \$3.5 million to \$17.0 million for the three months ended September 30, 2016, while gross margin increased by 230 basis points to 73.3%. The gross margin increase was largely driven by manufacturing efficiencies and higher average selling prices across nearly all product lines, as well as a more favorable product mix driven primarily by higher valvulotome and biologic vascular patch sales. These gross margin increases were partially offset by higher sales to China, where we realize comparatively lower gross margins, as well the cost of providing warranty replacements for recalled valvulotome lots. The gross profit increase was a result of higher sales and the improved gross margin.

Gross profit increased \$7.0 million to \$46.7 million for the nine months ended September 30, 2016, while gross margin increased by 230 basis points to 71.0% in the period. The gross margin was favorably impacted by higher average selling prices across nearly all product lines, as well as lower per-unit manufacturing costs of our biologic patch products. These increases were partially offset by higher sales in Europe as well as other non-traditional markets where we sometimes realize lower gross margins than in the United States. The gross profit increase was a result of higher sales and the improved gross margin.

Operating Expenses

Our operating expenses for the three and nine month periods ended September 30, 2016 and 2015 consisted of the following (in thousands):

| (unaudited) | Three months ended | | | | Nine months ended | | | |
|---------------------|--------------------|----------|----------|----------------|-------------------|-----------|----------|----------------|
| | September 30, | | | Percent change | September 30, | | | Percent change |
| | 2016 | 2015 | Change | | 2016 | 2015 | Change | |
| Sales and marketing | \$ 6,541 | \$ 5,489 | \$ 1,052 | 19% | \$ 19,353 | \$ 16,866 | \$ 2,487 | 15% |

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-Q

| | | | | | | | | |
|----------------------------|-----------|-----------|----------|-----|-----------|-----------|----------|------|
| General and administrative | 3,595 | 3,455 | 140 | 4% | 10,343 | 10,375 | (32) | (0%) |
| Research and development | 1,539 | 1,421 | 118 | 8% | 4,619 | 3,904 | 715 | 18% |
| Medical device excise tax | | 190 | (190) | * | | 554 | (554) | * |
| Gain on divestiture | | (360) | 360 | * | | (360) | 360 | * |
| Total | \$ 11,675 | \$ 10,195 | \$ 1,480 | 15% | \$ 34,315 | \$ 31,339 | \$ 2,976 | 9% |

| | Three months ended | | | Nine months ended | | |
|----------------------------|--------------------|----------------|--------|-------------------|----------------|--------|
| | 2016 | 2015 | Change | 2016 | 2015 | Change |
| | % of Net Sales | % of Net Sales | | % of Net Sales | % of Net Sales | |
| Sales and marketing | 28% | 29% | (1%) | 29% | 29% | 0% |
| General and administrative | 15% | 18% | (3%) | 16% | 18% | (2%) |
| Research and development | 7% | 7% | 0% | 7% | 7% | 0% |
| Medical device excise tax | 0% | 1% | (1%) | 0% | 1% | (1%) |
| Gain on divestiture | 0% | (2%) | 2% | 0 | (1%) | 1% |

Sales and marketing. For the three months ended September 30, 2016, sales and marketing expense increased \$1.1 million or 19%, to \$6.5 million. For the nine months ended September 30, 2016, sales and marketing expense increased \$2.5 million or 15% to \$19.4 million. For both comparative periods, the increases were primarily driven by compensation-related expenses and travel, due to an increase in the number of sales representatives from 82 at September 30, 2015 to 91 at September 30, 2016, as well as to increased sales commissions. As a percentage of net sales, sales and marketing expense decreased to 28% for the three months ended September 30, 2016 from 29% in the prior year period. We plan to continue to increase the size of our sales force in 2016, and we expect that selling and marketing expenses will increase commensurately.

General and administrative. For the three months ended September 30, 2016, general and administrative expense increased \$0.1 million or 4% to \$3.6 million. Increases were primarily in compensation related costs and professional services, which were partially offset by a reduction in bad debt expense.

For the nine months ended September 30, 2016, general and administrative expense decreased \$32,000 to \$10.3 million. General and administrative expense decreases were primarily in recruiting costs, professional fees and bad debt expense, which were partially offset by increases in compensation related costs and travel. As a percentage of net sales, general and administrative expense decreased to 16% for the nine months ended September 30, 2016 as compared to 18% for the prior year period.

Research and development. For the three months ended September 30, 2016, research and development expense increased \$0.1 million or 8% to \$1.5 million. Product development expenses were relatively consistent for the comparative quarters, with increases in compensation related expenses and professional services offset by lower spending on supplies and testing. Clinical and regulatory expenses increased \$0.1 million primarily related to compensation costs and professional fees, including costs related to regulatory submission for new products in geographies such as China.

For the nine months ended September 30, 2016, research and development expense increased \$0.7 million or 18%, to \$4.6 million. Product development expenses increased \$0.5 million primarily driven by compensation costs, including costs to support efforts to transition the manufacturing of certain acquired product lines to our Burlington, Massachusetts headquarters. These increases were partially offset by lower spending on supplies and testing. Clinical and regulatory expenses increased \$0.2 million primarily related to compensation costs and professional fees, including costs related to regulatory submission for new products in geographies such as China.

Medical device excise tax. The medical device excise tax was \$0.2 million and \$0.6 million for the three months and nine months ended September 30, 2015, respectively. On December 18, 2015, the Consolidated Appropriations Act of 2016 was signed into law, which suspended the medical device tax for the period beginning January 1, 2016 and ending December 31, 2017.

Income tax expense. We recorded a provision for taxes of \$2.1 million on pre-tax income of \$5.3 million for the three months ended September 30, 2016, compared to \$1.0 million on pre-tax income of \$3.1 million for the three months ended September 30, 2015. We recorded a provision for taxes of \$4.4 million on pre-tax income of \$12.4 million for

the nine months ended September 30, 2016, compared to \$3.1 million on pre-tax income of \$8.3 million for the nine months ended September 30, 2015. Our 2016 provision is based on an estimated annual effective tax rate of 34.8%, comprised of estimated federal and state income taxes of approximately \$3.6 million, as well as foreign income taxes of \$0.8 million. Our income tax expense for the current period varies from the statutory rate amounts mainly due to certain permanent items, offset by lower statutory rates from our foreign entities. Additionally, in the quarter ended September 30, 2016, our provision was increased by discrete items related to a recent federal tax audit, which were partially offset by the benefit of the early adoption of stock based compensation accounting guidance and stock option exercises.

Our 2015 provision was based on the estimated annual effective tax rate of 36.3%, comprised of estimated federal and state income taxes of approximately \$3.8 million, as well as foreign income taxes of \$0.3 million. Our income tax expense for 2015 varied from the statutory rate amounts mainly due to certain permanent items, offset by lower statutory rates from our foreign entities and a discrete item for stock option exercises.

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 for 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 and concluded that as of September 30, 2016, we required a valuation allowance against \$2.2 million of deferred tax assets, principally foreign net operating loss and capital loss carry-forwards. Based on the 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 be higher in 2016 compared to our effective tax rate in 2015, due to certain discrete items included in 2016 including in relation to a recent federal tax audit, an uncertain tax position reserve for certain state credit-carryforwards, and release of certain valuation allowances in the prior year.

Liquidity and Capital Resources

At September 30, 2016, our cash and cash equivalents were \$34.7 million as compared to \$27.5 million at December 31, 2015. Our cash and cash equivalents are highly liquid investments with maturities of 90 days or less at the date of purchase, consist of money market funds, and are stated at cost, which approximates fair value. All of our cash held outside of the United States is available for corporate use, with the exception of \$5.0 million held by subsidiaries in jurisdictions for which earnings are planned to be permanently reinvested.

On July 25, 2016, our Board of Directors approved a stock repurchase program under which the Company is authorized to repurchase up to \$5 million of its common stock through transactions on the open market, in privately negotiated purchases or otherwise. This program may be suspended or discontinued at any time, and expires on the earlier of July 25, 2017 or when the authorized aggregate \$5 million repurchase limit is reached. To date we have not made any repurchases under this program.

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 and long-term borrowings, and funds generated from our operations.

We recognized operating income of \$12.4 million for the nine months ended September 30, 2016. For the year ended December 31, 2015, we recognized operating income of \$11.5 million. We expect to fund any increased costs and expenditures from our existing cash and cash equivalents, 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 program;

future acquisition-related payments;

payments associated with U.S income and other taxes;

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

the costs associated with our initiatives to sell direct-to-hospital in new countries;

the costs of obtaining and maintaining FDA and other regulatory clearances of our existing and future products; 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 payments under our quarterly dividend program, repurchase shares of our common stock 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 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 funds from, or establish a revolving credit facility, with 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 and possibly our ability to pay dividends. 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.

Dividends

In February 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 2016 | | | |
| March 21, 2016 | April 4, 2016 | \$ 0.045 | \$ 825 |
| May 25, 2016 | June 8, 2016 | \$ 0.045 | \$ 829 |
| August 22, 2016 | September 2, 2016 | \$ 0.045 | \$ 833 |
| Fiscal Year 2015 | | | |
| March 20, 2015 | April 3, 2015 | \$ 0.040 | \$ 700 |
| May 22, 2015 | June 5, 2015 | \$ 0.040 | \$ 705 |
| August 20, 2015 | September 3, 2015 | \$ 0.040 | \$ 715 |
| November 20, 2015 | December 4, 2015 | \$ 0.040 | \$ 725 |

On October 24, 2016 our Board of Directors approved a quarterly cash dividend on our common stock of \$0.045 per share payable on December 5, 2016 to stockholders of record at the close of business on November 21, 2016, which will total approximately \$0.8 million.

| Nine months ended September 30, | | |
|--|-------------|-------------------|
| (in thousands) | | |
| 2016 | 2015 | Net Change |

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-Q

| | | | |
|-----------------------------------|-----------|-----------|-----------|
| Cash and cash equivalents | \$ 34,650 | \$ 23,629 | \$ 11,021 |
| Cash flows provided by (used in): | | | |
| Operating activities | \$ 12,702 | \$ 7,513 | \$ 5,189 |
| Investing activities | (4,198) | (2,615) | (1,583) |
| Financing activities | (1,535) | 232 | (1,767) |

Cash Flows

Net cash provided by operating activities. Net cash provided by operating activities was \$12.7 million for the nine months ended September 30, 2016, and consisted of \$8.0 million net income, adjusted for non-cash items of \$4.2 million (including depreciation and amortization of \$2.7 million, stock-based compensation of \$1.2 million, and provisions for inventory write-offs and doubtful accounts of \$0.3 million), as well as changes in working capital of \$0.5 million. The net cash used by changes in working capital was driven by increases in accounts payable and other liabilities of \$1.2 million offset by decreases in other current assets of \$0.4 million, inventory of \$0.2 million and accounts receivable of \$0.1 million.

Net cash provided by operating activities was \$7.5 million for the nine months ended September 30, 2015, and consisted of \$5.2 million net income, adjusted for non-cash items of \$4.0 million (including among other items depreciation and amortization of \$2.5 million, stock-based compensation of \$1.1 million, and provision for inventory write-offs of \$0.5 million) and was offset by changes in working capital of \$1.7 million. The net cash used by changes in working capital was driven by increases in accounts receivable of \$1.1 million and prepaid expenses and other assets of \$0.8 million, and was partially offset by increases in accounts payable and other liabilities of \$0.2 million.

Net cash used in investing activities. Net cash used in investing activities was \$4.2 million for nine months ended September 30, 2016, driven by \$2.4 million of cash paid in connection with our acquisition of the ProCol biologic vascular grafts, as well as purchases of property and equipment of \$1.8 million primarily associated with the expansion of our Burlington, Massachusetts headquarter offices.

Net cash used in investing activities was \$2.6 million for the nine months ended September 30, 2015. This use of cash was driven by the Tru-Incise valvulotome acquisition and related distributor buyouts of \$1.3 million, and purchases of property and equipment of \$1.6 million, partially offset by proceeds from the sale of the UnBalloon modeling catheter assets of \$0.4 million.

Net cash used in financing activities. Net cash used in financing activities was \$1.5 million for the nine months ended September 30, 2016, driven primarily by payments of common stock dividends of \$2.5 million, partially offset by proceeds from stock option exercise, net of shares repurchased for taxes, of \$1.2 million. We also made payments related to our prior acquisitions of \$0.2 million.

Net cash provided by financing activities was \$0.2 million for the nine months ended September 30, 2015, driven primarily by proceeds from stock option exercises of \$3.7 million, offset by payments of common stock dividends of \$2.1 million and deferred payments related to the Xenotis acquisition of \$1.1 million.

Contractual obligations. Our principal contractual obligations consist of operating leases and inventory purchase commitments, and have not changed significantly since December 31, 2015 as reported in our Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of September 30, 2016. 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, 2015. There have been no material changes in our critical accounting policies during the nine months ended September 30, 2016. 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, share-based compensation, and income taxes are reviewed on an ongoing basis and updated as appropriate. Actual results may differ from those estimates.

Recent Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board (FASB) issued an accounting standards update, ASU 2016-15, which changes the classification of certain cash receipts and cash payments within the statement of cash flows. The new standard is effective for us beginning January 31, 2018, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

In March 2016, the Financial Accounting Standards Board (FASB) issued a new standard that changes the accounting for certain aspects of share-based payments to employees. The new guidance requires excess tax benefits and tax deficiencies to be recorded in the income statement when the awards vest or are settled. In addition, cash flows related to excess tax benefits will no longer be separately classified as a financing activity apart from other income tax cash flows. The new standard is effective for us beginning January 31, 2017, with early adoption permitted.

We elected to early adopt the new guidance in the third quarter of fiscal year 2016, which required us to reflect any adjustments as of January 1, 2016, the beginning of the annual period that includes the interim period of adoption. The primary impact of adoption was the recognition of \$0.3 million of excess tax benefits in our provision for income taxes rather than paid-in capital for all periods in fiscal year 2016. We recorded this adjustment in the quarter ended September 30, 2016 as it was not material to the earlier periods previously reported. As allowed by the standard, we also made an election to account for award forfeitures as they occur, rather than estimating them at the time of grant. In connection with this election we recorded a cumulative-effect adjustment to beginning retained earnings of \$0.1 million.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

In the ordinary course of conducting business, we are exposed to certain risks associated with potential changes in market conditions. These market risks include changes in currency exchange rates and interest rates which could affect operating results, financial position and cash flows. We manage our exposure to these market risks through our regular operating and financing activities and, if considered appropriate, we may enter into derivative financial instruments such as forward currency exchange contracts, although we have not done so in 2016 or in recent years. There have been no material changes in our quantitative and qualitative market risks since the disclosure in our Annual Report on Form 10-K for the year ended December 31, 2015.

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 September 30, 2016, 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 a result of the material weakness in internal control over financial reporting previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, and as described below, our disclosure controls and procedures were not effective as of September 30, 2016.

Previously Reported Material Weakness

As reported in Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2015, our management concluded that our internal control over financial reporting was not effective as of that date because of a material weakness in our internal controls over financial reporting. We concluded that we had a material weakness because we did not have control activities in revenue recognition that were designed and operating effectively, including controls to validate pricing terms and conditions in our revenue contracts such that the price of a sale is fixed or determinable at the time of shipment for all sales made by the Company. Control activities that were historically in place (i) did not always address relevant risks and (ii) were not performed on all relevant transactions. In addition, the level of precision of the management review controls was not sufficient to identify all potential errors.

Management's Plan for Remediation

Management is in the process of designing and implementing a remediation plan intended to address the control deficiencies which resulted in the material weakness described above. These remediation efforts are underway and include enhancements of automated and management oversight controls to validate pricing terms and conditions, as well as utilizing system security features to ensure segregation of duties for certain key processes. Management will report regularly to the Audit Committee regarding the status of the implementation activities.

Changes in Internal Control

Other than as described under Management's Plan for Remediation, there have been no changes in our internal control over financial reporting for the nine months ended September 30, 2016, 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 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 employment, product liability, commercial arrangements,

intellectual property and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of November 4, 2016, that management believes would have a material adverse effect on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

In addition to the information set forth in this report, you should consider the risks and uncertainties discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2015, which could materially affect our business, financial condition, or future results. Except as contained in the two paragraphs below, there have been no substantive changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, which was filed with the Securities and Exchange Commission on March 10, 2016.

If we are unable to retain customers who switched to our product during the pendency of the Baxter safety alert/recall or if we are unable to meet product demand, then we may not realize the expected incremental sales of our XenoSure biologic patch.

On June 24, 2016, Baxter Healthcare Corporation (Baxter) issued a safety alert requesting that hospitals discontinue and quarantine the use of certain lots of its Vascu-Guard peripheral vascular patches. On August 11, 2016, Baxter began releasing newly manufactured lots to fulfill orders while continuing their investigation related to the safety alert. We experienced higher than normal XenoSure biologic patch sales in Q3 2016, of which approximately \$1.4 million was attributable to the Baxter safety alert/recall. We believe that we will retain approximately \$500,000 of the increased patch sales in Q4 2016. If we are unable to retain customers who switched to our product, then our XenoSure biologic patch sales could be materially lower than expected and our results of operations could be adversely affected. Additionally, if we are unable to maintain or further increase an elevated level of production or if demand exceeds our expectations, then we may be unable to timely satisfy customer orders for these products and we could forgo revenue opportunities, potentially lose market share and damage new and existing customer relationships, all of which could adversely affect our business and results of operations.

Even after our products have received marketing approval or clearance, our products may be subject to product recalls or product approvals and clearances could be withdrawn or suspended 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, suspended 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 or suspension of any of our product approvals by any single regulatory agency will not precipitate one or more additional regulatory agencies from also withdrawing or suspending approval of any such product.

In the event that any of our products proves to be defective, we can voluntarily recall, or the FDA or foreign equivalent could require us to implement a recall of or prohibit the sale of, any of our products. For example, in Q3 2016, we voluntarily recalled certain lots of our HYDRO LeMaitre valvulotome due to an issue with the product's closure mechanism. We were able to address the issue quickly and we believe the recall, affecting approximately

4,500 units, will be substantially complete by December 31, 2016. While the affected lots remain on recall, we have continued to sell unaffected lots and we will be able to rework returned valvulotomes at minimal expense. Though we have taken corrective action to address the issue, there can be no assurance that there will not be a recurrence or that other problems related to our HYDRO LeMaitre valvulotome will not develop in the future.

Additionally, if someone is harmed by a malfunction or a product defect, we may experience product liability claims for such defects. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital and may harm our reputation and financial results. Future recalls or claims could also result in significant costs to us and significant adverse publicity, which could harm our ability to market our products in the future.

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

None.

Issuer Purchases of Equity Securities

None.

Item 6. Exhibits

| Exhibit Number | Exhibit Description | Incorporated by Reference | | | Filed Herewith |
|---------------------------|--|----------------------------------|-------------|---------------|---------------------------|
| | | Form | Date | Number | |
| 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 63 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 63 of Title 18 of the United States Code (18 U.S.C. §1350).* | | | | X |
| 101.INS | XBRL Instance Document. | | | | X |
| 101.SCH | XBRL Taxonomy Extension Schema Document. | | | | X |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document. | | | | X |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document. | | | | X |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document. | | | | X |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document. | | | | X |

* 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on November 4, 2016.

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

EXHIBIT INDEX

| Exhibit Number | Exhibit Description | Incorporated by Reference | | | Filed Herewith |
|---------------------------|--|----------------------------------|-------------|---------------|---------------------------|
| | | Form | Date | Number | |
| 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 63 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 63 of Title 18 of the United States Code (18 U.S.C. §1350).* | | | | X |
| 101.INS | XBRL Instance Document. | | | | X |
| 101.SCH | XBRL Taxonomy Extension Schema Document. | | | | X |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document. | | | | X |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document. | | | | X |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document. | | | | X |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document. | | | | X |

* 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.