

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM
10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2022

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)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.01 par value per share	LMAT	The Nasdaq Global Market

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 every Interactive Data File required to be submitted 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 such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 21,962,869 shares of common stock, \$.01 par value per share, outstanding as of July 29, 2022.



**LEMAITRE VASCULAR
FORM 10-Q
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Part I. Financial Information

Item 1. Financial Statements

LeMaitre Vascular, Inc.
Consolidated Balance Sheets

	(unaudited) June 30, 2022	December 31, 2021
	(in thousands, except share data)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 20,788	\$ 13,855
Short-term marketable securities	54,895	56,104
Accounts receivable, net of allowances of \$792 at June 30, 2022 and \$679 at December 31, 2021	21,542	19,631
Inventory and other deferred costs	47,192	46,104
Prepaid expenses and other current assets	3,243	4,189
Assets held for sale	826	-
Total current assets	<u>148,486</u>	<u>139,883</u>
Property and equipment, net	15,753	17,059
Right-of-use leased assets	16,290	15,071
Goodwill	65,945	65,945
Other intangibles, net	49,598	52,710
Deferred tax assets	2,369	1,566
Other assets	984	568
Total assets	<u>\$ 299,425</u>	<u>\$ 292,802</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,844	\$ 2,340
Accrued expenses	17,009	16,332
Acquisition-related obligations	1,758	1,271
Lease liabilities - short-term	1,794	1,870
Total current liabilities	<u>23,405</u>	<u>21,813</u>
Lease liabilities - long-term	15,420	14,067
Deferred tax liabilities	64	70
Other long-term liabilities	2,503	2,701
Total liabilities	<u>41,392</u>	<u>38,651</u>
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 23,520,888 shares at June 30, 2022, and 23,477,784 shares at December 31, 2021	235	235
Additional paid-in capital	184,605	181,630
Retained earnings	92,190	88,125
Accumulated other comprehensive loss	(6,444)	(3,435)
Treasury stock, at cost; 1,558,019 shares at June 30, 2022 and 1,554,905 shares at December 31, 2021	(12,553)	(12,404)
Total stockholders' equity	<u>258,033</u>	<u>254,151</u>
Total liabilities and stockholders' equity	<u>\$ 299,425</u>	<u>\$ 292,802</u>

See accompanying notes to consolidated financial statements.

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

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
	(in thousands, except per share data)		(in thousands, except per share data)	
Net sales	\$ 42,108	\$ 40,670	\$ 81,669	\$ 76,553
Cost of sales	14,298	13,909	27,897	25,993
Gross profit	27,810	26,761	53,772	50,560
Sales and marketing	8,242	6,803	16,092	13,269
General and administrative	7,331	6,200	14,583	12,744
Research and development	3,346	2,652	6,278	5,496
Restructuring	3,107	-	3,107	-
Total operating expenses	22,026	15,655	40,060	31,509
Income from operations	5,784	11,106	13,712	19,051
Other income (expense):				
Interest income	167	1	275	2
Interest expense	-	(495)	-	(1,072)
Foreign currency gain (loss)	(403)	(157)	(443)	(33)
Income before income taxes	5,548	10,455	13,544	17,948
Provision for income taxes	2,033	2,156	3,991	3,720
Net income	<u>\$ 3,515</u>	<u>\$ 8,299</u>	<u>\$ 9,553</u>	<u>\$ 14,228</u>
Earnings per share of common stock:				
Basic	<u>\$ 0.16</u>	<u>\$ 0.40</u>	<u>\$ 0.44</u>	<u>\$ 0.69</u>
Diluted	<u>\$ 0.16</u>	<u>\$ 0.40</u>	<u>\$ 0.43</u>	<u>\$ 0.68</u>
Weighted-average shares outstanding:				
Basic	<u>21,958</u>	<u>20,611</u>	<u>21,947</u>	<u>20,579</u>
Diluted	<u>22,129</u>	<u>20,959</u>	<u>22,115</u>	<u>20,900</u>
Cash dividends declared per common share	<u>\$ 0.125</u>	<u>\$ 0.110</u>	<u>\$ 0.250</u>	<u>\$ 0.220</u>

See accompanying notes to consolidated financial statements.

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

	Three months ended		Six months ended	
	June 30,		June 30,	
	2022	2021	2022	2021
	(in thousands)		(in thousands)	
Net income	\$ 3,515	\$ 8,299	\$ 9,553	\$ 14,228
Other comprehensive income (loss):				
Foreign currency translation adjustment, net	(1,226)	220	(1,526)	(717)
Unrealized gain (loss) on short-term marketable securities	(594)	-	(1,483)	(1)
Total other comprehensive income (loss)	(1,820)	220	(3,009)	(718)
Comprehensive income	<u>\$ 1,695</u>	<u>\$ 8,519</u>	<u>\$ 6,544</u>	<u>\$ 13,510</u>

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Consolidated Statements of Stockholders' Equity
(unaudited)

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Retained Earnings</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Treasury Stock</u>		<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>				<u>Shares</u>	<u>Amount</u>	
Balance at December 31, 2021	23,477,784	\$ 235	\$ 181,630	\$ 88,125	\$ (3,435)	1,554,905	\$ (12,404)	\$ 254,151
Net income				6,038				6,038
Other comprehensive income (loss)					(1,189)			(1,189)
Issuance of common stock for stock options exercised	24,917	-	508					508
Vested restricted stock units	7,158	-	-					-
Stock-based compensation expense			1,167					1,167
Repurchase of common stock for net settlement of equity awards						3,016	(145)	(145)
Common stock dividend paid				(2,743)				(2,743)
Balance at March 31, 2022	23,509,859	235	183,305	91,420	(4,624)	1,557,921	(12,549)	257,787
Net income				3,515				3,515
Other comprehensive income (loss)					(1,820)			(1,820)
Issuance of common stock for stock options exercised	10,808	-	164					164
Vested restricted stock units	221	-	-					-
Stock-based compensation expense			1,136					1,136
Repurchase of common stock for net settlement of equity awards						98	(4)	(4)
Common stock dividend paid				(2,745)				(2,745)
Balance at June 30, 2022	23,520,888	\$ 235	\$ 184,605	\$ 92,190	\$ (6,444)	1,558,019	\$ (12,553)	\$ 258,033

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Retained Earnings</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Treasury Stock</u>		<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>				<u>Shares</u>	<u>Amount</u>	
Balance at December 31, 2020	22,061,554	\$ 221	\$ 114,924	\$ 70,554	\$ (1,525)	1,538,572	\$ (11,602)	\$ 172,572
Net income				5,929				5,929
Other comprehensive income (loss)					(938)			(938)
Issuance of common stock for stock options exercised	63,895	-	1,385					1,385
Vested restricted stock units	5,974	-	-					-
Stock-based compensation expense			927					927
Repurchase of common stock for net settlement of equity awards						2,241	(88)	(88)
Common stock dividend paid				(2,262)				(2,262)
Balance at March 31, 2021	22,131,423	221	117,236	74,221	(2,463)	1,540,813	(11,690)	177,525
Net income				8,299				8,299
Other comprehensive income (loss)					220			220
Issuance of common stock for stock options exercised	70,355	1	1,186					1,187
Vested restricted stock units	-	-	-					-
Stock-based compensation expense			869					869
Common stock dividend paid				(2,267)				(2,267)
Balance at June 30, 2021	22,201,778	\$ 222	\$ 119,291	\$ 80,253	\$ (2,243)	1,540,813	\$ (11,690)	\$ 185,833

See accompanying notes to consolidated financial statements.

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

	For the six months ended	
	June 30,	
	2022	2021
	(in thousands)	
Operating activities		
Net income	\$ 9,553	\$ 14,228
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	4,817	5,261
Stock-based compensation	2,303	1,796
Fair value adjustment to contingent consideration obligations	(54)	99
Provision for doubtful accounts	141	133
Provision for inventory write-downs	1,671	2,154
Loss on disposal of property and equipment	95	-
Loss on divestitures	1,954	-
Foreign currency transaction loss	(919)	(14)
Changes in operating assets and liabilities:		
Accounts receivable	(2,610)	(1,486)
Inventory and other deferred costs	(3,536)	(2,044)
Prepaid expenses and other assets	403	447
Accounts payable and other liabilities	141	(4,603)
Net cash provided by operating activities	<u>13,959</u>	<u>15,971</u>
Investing activities		
Purchases of property and equipment and other assets	(1,509)	(2,462)
Net cash used in investing activities	<u>(1,509)</u>	<u>(2,462)</u>
Financing activities		
Payment of long-term debt	-	(16,000)
Proceeds from issuance of common stock	672	2,113
Purchase of treasury stock for net settlement of equity awards	(149)	(88)
Common stock cash dividend paid	(5,488)	(4,529)
Net cash used in financing activities	<u>(4,965)</u>	<u>(18,504)</u>
Effect of exchange rate changes on cash and cash equivalents	(552)	(228)
Net increase (decrease) in cash and cash equivalents	6,933	(5,223)
Cash and cash equivalents at beginning of period	13,855	26,764
Cash and cash equivalents at end of period	<u>\$ 20,788</u>	<u>\$ 21,541</u>

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Notes to Consolidated Financial Statements
June 30, 2022
(unaudited)

1. Organization and Basis for Presentation

Description of Business

Unless the context requires otherwise, references to LeMaitre, 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 also derive revenues from the processing and cryopreservation of human tissues for implantation in patients. We operate in a single segment in which our principal product lines include the following: anastomotic clips, angioscopes, biologic vascular and dialysis grafts, biologic vascular and cardiac patches, carotid shunts, embolectomy catheters, occlusion catheters, radiopaque marking tape, synthetic vascular grafts and valvulotomes. Our offices and production facilities are located in Burlington, Massachusetts; Fox River Grove, Illinois; North Brunswick, New Jersey; Chandler, Arizona; Vaughan, Canada; Sulzbach, Germany; Milan, Italy; Madrid, Spain; Hereford, England; Kensington, Australia; Tokyo, Japan; Shanghai, China; Singapore; and Seoul, Korea.

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting only of normal, recurring adjustments considered necessary for a fair presentation of the results of these interim periods have been included. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Actual results may differ from these estimates. Our estimates and assumptions, including those related to bad debts, inventories, intangible assets, sales returns and discounts, share-based compensation, and income taxes are updated as appropriate. The results for the six months ended June 30, 2022 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, 2021, including the notes thereto, included in our Form 10-K filed with the Securities and Exchange Commission (SEC) on February 28, 2022.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the unaudited consolidated financial statements and accompanying notes. The Company is not aware of any specific event or circumstance that would require an update to its accounting estimates or adjustments to the carrying value of its assets and liabilities as of August 5, 2022, the issuance date of this Quarterly Report on Form 10-Q. Actual results could differ from those estimates.

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.

Revenue Recognition

Our revenue is derived primarily from the sale of disposable or implantable devices used during vascular surgery. We sell primarily directly to hospitals and to a lesser extent to distributors, as described below, and, during the periods presented in our consolidated financial statements, entered into consigned inventory arrangements with either hospitals or distributors on a limited basis. We also derive revenues from the processing and cryopreservation of human tissues for implantation in patients. These revenues are recognized when services have been provided and the tissue has been shipped to the customer, provided all other revenue recognition criteria discussed in the succeeding paragraph have been met.

We record revenue under the provisions of ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The core principle of Topic 606 is that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard explains that to achieve the core principle, an entity should take the following actions:

Step 1: Identify the contract with a customer

Step 2: Identify the performance obligations in the contract

Step 3: Determine the transaction price

Step 4: Allocate the transaction price

Step 5: Recognize revenue when or as the entity satisfies a performance obligation

Revenue is recognized when or as a company satisfies a performance obligation by transferring a promised good or service to a customer (which is when the customer obtains control of that good or service). In instances in which shipping and handling activities are performed after a customer takes control of the goods (such as when title passes upon shipment from our dock), we have made the policy election allowed under Topic 606 to account for these activities as fulfillment costs and not as performance obligations.

We generally reference customer purchase orders to determine the existence of a contract. Orders that are not accompanied by a purchase order are confirmed with the customer either in writing or verbally. The purchase orders or similar correspondence, once accepted, identify the performance obligations as well as the transaction price, and otherwise outline the rights and obligations of each party. We allocate the transaction price of each contract among the performance obligations in accordance with the pricing of each item specified on the purchase order, which is in turn based on standalone selling prices per our published price lists. In cases where we discount products or provide certain items free of charge, we allocate the discount proportionately to all performance obligations, unless it can be demonstrated that the discount should be allocated entirely to one or more, but not all, of the performance obligations.

We record revenue, net of allowances for returns and discounts, fees paid to group purchasing organizations, and any sales and value added taxes required to be invoiced, which we have elected to exclude from the measurement of the transaction price as allowed by the standard, at the time of shipment (taking into consideration contractual shipping terms), or in the case of consigned inventory, when it is consumed. Shipment is the point at which control of the product and title passes to our customers, and at which LeMaitre has a present right to receive payment for the goods.

Below is a disaggregation of our revenue by major geographic area, which is among the primary categorizations used by management in evaluating financial performance, for the periods indicated (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
	(\$ in thousands)		(\$ in thousands)	
Americas	\$ 28,854	\$ 27,329	\$ 55,397	\$ 51,028
Europe, Middle East and Africa	10,749	10,803	21,243	20,665
Asia Pacific	2,505	2,538	5,029	4,860
Total	\$ 42,108	\$ 40,670	\$ 81,669	\$ 76,553

We do not carry any contract assets or contract liabilities, as there are generally no unbilled amounts due from customers under contracts for which we have partially satisfied performance obligations, or amounts received from customers for which we have not satisfied performance obligations. We satisfy our performance obligations under revenue contracts within a very short time period from receipt of the orders, and payments from customers are typically received within 30 to 60 days of fulfillment of the orders, except in certain geographies such as Spain and Italy where the payment cycle is customarily longer. Accordingly, there is no significant financing component to our revenue contracts. Additionally, we have elected as a policy that incremental costs (such as commissions) incurred to obtain contracts are expensed as incurred, due to the short-term nature of the contracts.

Customers returning products may be entitled to full or partial credit based on the condition and timing of the return. To be accepted, a returned product must be unopened (if sterile), unadulterated, and undamaged, must have at least 18 months remaining prior to its expiration date, or twelve months for our hospital customers in Europe, and generally be returned within 30 days of shipment. These return policies apply to sales to both hospitals and distributors. The amount of products returned to us, either for exchange or credit, has not been material. Nevertheless, we provide for an allowance for future sales returns based on historical returns experience, which requires judgment. Our cost of replacing defective products has not been material and is accounted for at the time of replacement.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies and are general adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

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 certain 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 inside and outside 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 2022 income tax expense varies from the statutory rate mainly due to the generation of federal and state tax credits, permanent items, different statutory rates from our foreign subsidiaries, and certain foreign losses not benefitted due to a valuation allowance. Our 2021 income tax expense varied from the statutory rate mainly due to the generation of federal and state tax credits, permanent items, different statutory rates from our foreign subsidiaries, and discrete 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 June 30, 2022, the gross amount of unrecognized tax benefits exclusive of interest and penalties was \$702,000. 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 2030. A reconciliation of beginning and ending amount of our unrecognized tax benefits is as follows:

	Six months ended June 30, 2022
	(in thousands)
Unrecognized tax benefits as of December 31, 2021	\$ 768
Additions/adjustments for tax positions of current year	-
Additions/adjustments for tax positions of prior years	(66)
Reductions for settlements with taxing authorities	-
Reductions for lapses of the applicable statutes of limitations	-
Unrecognized tax benefits as of June 30, 2022	<u>\$ 702</u>

As of June 30, 2022, a summary of the tax years that remain subject to examination in our taxing jurisdictions is as follows:

United States	2018 and forward
Foreign	2014 and forward

3. Inventories and Other Deferred Costs

Inventories and other deferred costs consist of the following:

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
	(in thousands)	
Raw materials	\$ 13,434	\$ 5,945
Work-in-process	3,057	9,416
Finished products	25,269	25,286
Other deferred costs	5,432	5,457
Total inventory and other deferred costs	<u>\$ 47,192</u>	<u>\$ 46,104</u>

We had inventory on consignment at customer sites of \$1.8 million and \$2.1 million at June 30, 2022 and December 31, 2021, respectively.

In connection with our RestoreFlow allograft business, other deferred costs include costs incurred for the preservation of human tissues available for shipment, tissues currently in active processing, and tissues held in quarantine pending release to implantable status. By U.S. federal law, human tissues cannot be bought or sold. Therefore, the tissues we preserve are not held as inventory, and the costs we incur to procure and process tissues are instead accumulated and deferred. These costs include fixed and variable overhead costs associated with the cryopreservation process, including primarily direct labor costs, tissue recovery fees, inbound freight charges, indirect materials and facilities costs. General and administrative expenses and selling expenses associated with the provision of these services are expensed as incurred.

4. Acquisitions

Our acquisitions are accounted for using the acquisition method, and the acquired businesses' results have been included in the accompanying consolidated financial statements from their respective dates of acquisition. In each case for the acquisitions disclosed below, pro forma information assuming the acquisition had occurred at the beginning of the earliest period presented is not included, as the impact is immaterial.

Our acquisitions 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 (see Note 15) 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.

Artegraft Biologic Grafts

On June 22, 2020, we entered into an Asset Purchase Agreement (Artegraft APA) to acquire the biologic graft business from Artegraft, Inc., which subsequent to the closing changed their name to Accidentals, Inc. (Artegraft, Inc.). Under the terms of the Artegraft APA, we agreed to pay Artegraft, Inc. a total of up to \$90.0 million for the purchase of substantially all of the assets related to its business of manufacturing, marketing, sale and distribution of bovine grafts (Products) other than specifically identified excluded assets. The acquired assets included inventory, accounts receivable, machinery and equipment, intellectual property, permits and approvals, data and records, and customer and supplier information. At closing, \$72.5 million of the purchase price was paid to Artegraft, Inc. and other parties as specified in the Artegraft APA, including \$7.5 million into an escrow account. The escrow amount was held until December 31, 2021 to cover any potential claims against LeMaitre or Artegraft, Inc. and subsequently was released to Artegraft, Inc. by mutual consent of the parties.

Three earn-out payments of \$5,833,333 each are potentially due to Artegraft, Inc. under the Artegraft APA depending on the achievement of specified revenue targets, as follows:

- \$5.8 million upon final determination that 20,000 units of the Product have been sold to third parties from January 1, 2021 to December 31, 2021 (this milestone was not met and accordingly no payment was made);
- \$5.8 million upon final determination that 24,000 units of the Product have been sold to third parties from January 1, 2022 to December 31, 2022; and
- \$5.8 million upon final determination that 28,800 units of the Product have been sold to third parties from January 1, 2023 to December 31, 2023.

The Artegraft APA includes a catch-up feature on the earn-outs such that, at the end of the three-year period, if the sum of the unit sales for all three years is greater than or equal to 58,240 unit sales (80% of the combined individual-year targets), Artegraft, Inc. will receive a “catch-up payment” in an amount equal to (a) \$17,500,000 times a fraction, the numerator of which is the aggregate number of unit sales for the three-year period, and the denominator of which is 72,800 less (b) any individual-year earn-out previously paid. We recorded this liability at a fair value of \$0.4 million to reflect management’s estimate of the likelihood of achieving these targets at the time of the closing of the acquisition, as well as the time value of money until payment. This amount will be remeasured each quarter during the earn-out period, with any adjustments recorded in income from operations. As of June 30, 2022 the fair value of the liability is \$0.2 million.

On the date of acquisition, the Company allocated the consideration given to the individual assets acquired and the liabilities assumed based on a preliminary estimate of their fair values. During the three months ended September 30, 2020, the Company obtained and considered additional information related to the assets acquired and liabilities assumed, and recorded measurement period adjustments to the allocation of the purchase price. The following table summarizes the purchase price allocation:

	Allocated Fair Value
	(in thousands)
Inventory	\$ 3,859
Accounts receivable	1,789
Equipment and supplies	1,140
Accounts payable and other	(53)
Intangible assets	39,056
Goodwill	27,115
	<hr/>
Purchase price	\$ 72,906

The goodwill results from expected synergies of combining the acquired products and customer information to our existing operations, and is deductible for tax purposes over 15 years.

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

	Allocated Fair Value	Estimated Useful Life
	(in thousands)	
Customer relationships	\$ 20,310	15.0 years
Intellectual property	16,449	10.0 years
Non-compete agreement	104	5.0 years
Tradenames	2,193	10.0 years
	<hr/>	
Total intangible assets	\$ 39,056	

The weighted-average amortization period of the acquired intangible assets was 12.6 years.

5. Divestitures

On April 26, 2022, we committed to a plan to close our St. Etienne, France factory, which supported our LeMaitre Cardial SAS (Cardial) business, in order to streamline manufacturing operations and reduce expenses. The Cardial business consisted of the manufacture of polyester vascular grafts, valvulotomes, surgical glue and selected OEM devices. We acquired the Cardial business in 2018.

On June 30, 2022 we ceased operations at the St. Etienne, France factory and terminated most of the personnel at the site. The closure resulted in a restructuring charge of \$3.1 million for the three and six months ended June 30, 2022. Charges primarily consisted of employment termination costs, impairment of fixed assets and inventory, and third-party costs.

As of June 30, 2022, there are assets associated with Cardial that are classified as held for sale. The net assets held for sale represent the St. Etienne, France factory building, building improvements, and land that have met the criteria of “held for sale” accounting, as specified by Accounting Standards Codification (“ASC”) 360, “Property, Plant, and Equipment.” The net assets held for sale are being marketed for sale, and it is the Company’s intention to complete the sales of these assets within the next twelve-months.

6. Goodwill and Other Intangible Assets

There was no change to goodwill during the six months ended June 30, 2022. Other intangible assets consist of the following:

	June 30, 2022			December 31, 2021		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
	(in thousands)					
Product technology and intellectual property	\$ 29,549	\$ 11,914	\$ 17,635	\$ 29,549	\$ 10,473	\$ 19,076
Trademarks, tradenames and licenses	3,647	1,338	2,309	3,647	1,139	2,508
Customer relationships	36,197	7,015	29,182	36,197	5,674	30,523
Other intangible assets	1,461	989	472	1,461	858	603
Total identifiable intangible assets	\$ 70,854	\$ 21,256	\$ 49,598	\$ 70,854	\$ 18,144	\$ 52,710

These assets are being amortized over useful lives ranging from 2 to 16 years. The weighted-average amortization period for these intangibles as of June 30, 2022 is 11.1 years. Amortization expense is included in general and administrative expense and was as follows for the periods indicated.

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
	(in thousands)			
Amortization expense	\$ 1,596	\$ 1,562	\$ 3,112	\$ 3,128

We estimate that amortization expense for the remainder of 2022 and for each of the five succeeding fiscal years will be as follows:

	Year ended December 31,					
	2022	2023	2024	2025	2026	2027
	(in thousands)					
Amortization expense	\$ 3,071	\$ 5,952	\$ 5,629	\$ 5,429	\$ 4,983	\$ 4,706

7. Revolving Line of Credit and Long-term Debt

In connection with the acquisition of the Artegraft biologic graft business, we incurred debt in the amount of \$65 million under a senior secured credit facility with a group of banks. This credit arrangement included a \$25 million revolving credit line that was fully drawn at inception, as well as a \$40 million five-year term loan. During the year ended December 31, 2021, we made scheduled principal payments on the term loan of \$1.0 million, repaid the loan in full, and terminated the credit agreement in accordance with its terms. During the six months ended June 30, 2021, we made scheduled principal payments on the term loan of \$1.0 million and also made additional optional prepayments of \$15.0 million.

Under the terms of the agreement, the loans bore interest at a rate per annum of, at our option, either (i) the Base Rate plus an applicable margin of from 1.25% to 1.75% depending on our consolidated leverage ratio, or (ii) the Eurodollar Rate plus an applicable margin of from 2.25% to 2.75% depending on our consolidated leverage ratio. Base Rate was defined in the credit agreement as a fluctuating rate per annum of the Federal Funds rate plus 0.5% or the prime rate of interest established from time to time by KeyBank National Association. At June 30, 2021, all outstanding borrowings were designated as Eurodollar loans and bore interest of 3.25%.

We incurred debt issuance costs in connection with this credit arrangement of approximately \$1.8 million. These costs were allocated between the revolving line of credit and the term loans, with the portion related to the revolving line of credit of \$0.7 million recorded in other assets on our balance sheet, and the portion allocated to the term loan recorded as a deduction from the amount of the debt. All of these transaction costs were being amortized into interest expense on a straight-line basis as the result would not be materially different from using the interest method, over the five-year term of the arrangement. This resulted in an effective interest rate of approximately 4.2%. During the six months ended June 30, 2021, in connection with making optional prepayments of \$15.0 million on the term loan, we expensed a proportionate amount of the unamortized transaction costs in the amount of \$0.3 million. Cash paid for interest during the six months ended June 30, 2021 was \$0.7 million.

At September 30, 2021, the outstanding balances of both the term loan and the revolver were zero, and in September 2021 we cancelled both loan agreements.

8. Leases

We conduct the majority of our operations in leased facilities, all of which are accounted for as operating leases, as they do not meet the criteria for finance leases. Our principal worldwide executive, distribution, and manufacturing operations are located in five leased facilities with square footage totaling 109,354 in Burlington, Massachusetts. All five Burlington leases expire in December 2030.

Our European operations are headquartered at a 21,410 square foot leased facility located in Sulzbach, Germany. During the quarter ended June 30, 2022 we increased our square footage by 4,940 (from 16,470) and extended the lease through June 2031. This lease contains a five-year renewal option. Additionally, during the quarter ending June 30, 2022, we signed a new sales office/warehouse lease in the Seoul, Korea, which includes 2,300 square feet of office space, and expires in April 2027. Finally, we extended our Singapore lease by one-year and it will expire in June 2023.

Similar to prior quarters, we also lease a facility in Hereford, England which houses our United Kingdom sales and distribution business. During the quarter ended June 30, 2021 we executed an expansion of the Hereford lease under terms substantially similar to the original lease. In connection with our acquisition of the Artegraft biologic graft business, we assumed a 16,732 square foot lease in North Brunswick, New Jersey, which expires in October 2029. In June 2021 we entered into a six-year lease in Milan, Italy which houses a customer service and warehouse facility. This lease contains a six-year renewal option. We also have smaller long-term leased sales, marketing and other facilities located in Arizona, Canada, Australia, Singapore and China, and short-term leases in Japan, Spain and Illinois. The lease in Arizona was extended during the quarter ending June 30, 2022, for an additional three years through August 2025, effective as of August 24, 2022. Our lease in Canada contains a five-year renewal option exercisable in February 2023. Our leases in Germany and Italy are subject to periodic rent increases based on increases in the consumer price index as measured on an annual basis, with such increases applicable to the subsequent twelve months of lease payments. None of our noncancelable lease payments include non-lease components such as maintenance contracts; we generally reimburse the landlord for direct operating costs associated with the leased space. We have no subleases, and there are no residual value guarantees associated with, or restrictive covenants imposed by, any of our leases. There were no assets held under capital leases at June 30, 2022.

We also lease automobiles under operating leases in the United States as well as certain of our international subsidiaries. The terms of these leases are generally three years, with older vehicles replaced by newer vehicles from time to time. During the fiscal year 2021, we entered into a five-year lease for printing equipment.

We account for leases under the provisions of ASU No. 2016-02, *Leases (Topic 842)*, subsequently amended by ASU 2018-11, *Leases (Topic 842): Targeted Improvements*. Under this guidance, we are required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term.

Our most significant judgment involved in determining the amounts to initially record as lease liabilities and right-of-use assets upon initial adoption of this standard, and for leases entered into subsequently, was the selection of a discount rate; because we had no debt as of the adoption of this standard, we had no incremental borrowing rate to reference. We therefore derived an incremental borrowing rate using quotes from potential lenders as the primary inputs, augmented by other available information. The resulting rate selected was 5.25%. We determined that it was appropriate to apply this single rate to our portfolio of leases worldwide, as the lease terms and conditions are substantially similar, and because we believe our subsidiaries would be unable to obtain borrowings on their own without a commitment of parent company support. In connection with the assumption of the Artegraft North Brunswick, New Jersey lease, we used LeMaitre's borrowing rate of 3.5% as of the acquisition date associated with debt incurred to finance the acquisition to value the lease.

Additional information with respect to our leases is as follows:

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
	<u>(in thousands)</u>	<u>(in thousands)</u>	<u>(in thousands)</u>	<u>(in thousands)</u>
Lease cost				
Operating lease cost	\$ 638	\$ 487	\$ 1,163	\$ 1,094
Short-term lease cost	161	126	324	190
Total lease cost	<u>\$ 799</u>	<u>\$ 613</u>	<u>\$ 1,487</u>	<u>\$ 1,284</u>
Other information				
Cash paid for amounts included in the measurement of operating lease liabilities	<u>\$ 810</u>	<u>\$ 633</u>	<u>\$ 1,484</u>	<u>\$ 1,381</u>
Right-of-use assets obtained in exchange for new operating lease liabilities	<u>\$ 2,240</u>	<u>\$ 1,261</u>	<u>\$ 2,381</u>	<u>\$ 1,277</u>
Weighted average remaining lease term - operating leases (in years)			8.2	8.2
Weighted average discount rate - operating leases			4.88%	4.86%

At June 30, 2022, the minimum non-cancelable operating lease rental commitments with initial or remaining terms of more than one year are as follows:

Remainder of 2022	\$ 1,463
Year ending December 31,	
2023	2,602
2024	2,547
2025	2,530
2026	2,489
2027	2,372
Thereafter	6,973
Adjustment to net present value as of June 30, 2022	(3,762)
Minimum noncancelable lease liability	<u>\$ 17,214</u>

9. Accrued Expenses and Other Long-term Liabilities

Accrued expenses consist of the following:

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
	(in thousands)	
Compensation and related taxes	\$ 10,148	\$ 10,236
Income and other taxes	669	551
Professional fees	121	129
Other	6,071	5,416
Total	<u>\$ 17,009</u>	<u>\$ 16,332</u>

Other long-term liabilities consist of the following:

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
	(in thousands)	
Aquisition-related liabilities	\$ 1,664	\$ 1,761
Income taxes	691	799
Other	148	141
Total	<u>\$ 2,503</u>	<u>\$ 2,701</u>

10. Segment and Enterprise-Wide Disclosures

The FASB establishes standards for reporting information regarding operating segments in financial statements. Operating segments are identified as components of an enterprise that engage in business activities for which separate, discrete financial information is available and is regularly reviewed 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 operations by legal entity for local purposes.

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

	<u>Three months ended</u>		<u>Six months ended</u>	
	<u>June 30,</u>		<u>June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
	(in thousands)		(in thousands)	
United States	\$ 26,228	\$ 25,172	\$ 50,492	\$ 47,140
Germany	2,870	3,154	5,861	6,217
Other countries	13,010	12,344	25,316	23,196
Net Sales	<u>\$ 42,108</u>	<u>\$ 40,670</u>	<u>\$ 81,669</u>	<u>\$ 76,553</u>

11. Share-based Compensation

Our Third Amended and Restated 2006 Stock Option and Incentive Plan allows for granting of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, performance-based 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		Six months ended	
	June 30,		June 30,	
	2022	2021	2022	2021
	(in thousands)		(in thousands)	
Stock option awards	\$ 607	\$ 562	\$ 1,226	\$ 1,156
Restricted stock units	391	307	799	640
Performance-based restricted stock units	138	-	278	-
Total share-based compensation	\$ 1,136	\$ 869	\$ 2,303	\$ 1,796

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

	Three months ended		Six months ended	
	June 30,		June 30,	
	2022	2021	2022	2021
	(in thousands)		(in thousands)	
Cost of sales	\$ 135	\$ 100	\$ 273	\$ 200
Sales and marketing	193	119	402	288
General and administrative	695	557	1,407	1,118
Research and development	113	93	221	190
Total stock-based compensation	\$ 1,136	\$ 869	\$ 2,303	\$ 1,796

During the six-month period ended June 30, 2022, we granted options for the purchase of 984 shares of our common stock. We did not grant any options during the six-month period ended June 30, 2021. During the six months ended June 30, 2022 and 2021, we awarded restricted stock units of 320 and 1,157, respectively. We awarded performance-based restricted stock units of 250 during the six months ended June 30, 2022. We did not award any performance-based restricted stock units during the six-month period ended June 30, 2021. We issued approximately 43,000 and 140,000 shares of common stock following the exercise or vesting of underlying stock options or restricted stock units during the six months ended June 30, 2022 and 2021, respectively.

12. Net Income per Share

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

	Three months ended		Six months ended	
	June 30,		June 30,	
	2022	2021	2022	2021
	(in thousands, except per share data)		(in thousands, except per share data)	
Basic:				
Net income available for common stockholders	\$ 3,515	\$ 8,299	\$ 9,553	\$ 14,228
Weighted average shares outstanding	21,958	20,611	21,947	20,579
Basic earnings per share	\$ 0.16	\$ 0.40	\$ 0.44	\$ 0.69
Diluted:				
Net income available for common stockholders	\$ 3,515	\$ 8,299	\$ 9,553	\$ 14,228
Weighted-average shares outstanding	21,958	20,611	21,947	20,579
Common stock equivalents, if dilutive	171	348	168	321
Shares used in computing diluted earnings per common share	22,129	20,959	22,115	20,900
Diluted earnings per share	\$ 0.16	\$ 0.40	\$ 0.43	\$ 0.68
Shares excluded in computing diluted earnings per share as those shares would be anti-dilutive	328	-	390	152

13. Stockholders' Equity***Share Repurchase Program***

On February 22, 2022, our Board of Directors authorized the repurchase of up to \$20.0 million of the Company's common stock through transactions on the open market, in privately negotiated purchases or otherwise until February 22, 2023. The repurchase program may be suspended or discontinued at any time. To date we have not made any 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:

<u>Record Date</u>	<u>Payment Date</u>	<u>Per Share Amount</u>	<u>Dividend Payment</u> (in thousands)
Fiscal Year 2022			
March 8, 2022	March 24, 2022	\$ 0.125	\$ 2,743
May 17, 2022	June 2, 2022	\$ 0.125	\$ 2,745
Fiscal Year 2021			
March 9, 2021	March 25, 2021	\$ 0.110	\$ 2,262
May 19, 2021	June 3, 2021	\$ 0.110	\$ 2,267
August 26, 2021	September 9, 2021	\$ 0.110	\$ 2,401
November 19, 2021	December 2, 2021	\$ 0.110	\$ 2,405

On July 26, 2022, our Board of Directors approved a quarterly cash dividend on our common stock of \$0.125 per share payable on September 8, 2022, to stockholders of record at the close of business on August 25, 2022.

14. Supplemental Cash Flow Information

	For the six months ended	
	June 30,	
	<u>2022</u>	<u>2021</u>
	(in thousands)	
Cash paid for income taxes, net	\$ 3,991	\$ 6,236

15. Fair Value Measurements

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

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

Level 1 assets being measured at fair value on a recurring basis as of June 30, 2022 included our short-term investment and short-duration bond mutual fund accounts.

We had no Level 2 assets being measured at fair value on a recurring basis as of June 30, 2022.

As discussed in Note 4, several of our acquisition-related assets and liabilities have been measured using Level 3 techniques. During 2020 we recorded a contingent liability associated with our acquisition of the bovine graft business from Artegraft. The agreement requires us to make potential additional payments to Artegraft of up to \$17.5 million depending on the achievement of certain unit sales milestones during the first three calendar years following the acquisition. We recorded this liability at a fair value of \$0.4 million to reflect management's estimate of the likelihood of achieving these targets at the time of the Closing, as well as the time value of money until payment. This amount is being remeasured each quarter during the earn-out period, with any adjustments recorded in income from operations.

During 2019, we recorded contingent liabilities associated with our acquisition of the Admedus biologic patch business. The agreement includes the potential for us to pay up to \$7.8 million of additional consideration beyond payments made to date, with \$0.3 million contingent upon the delivery of audited financial statements of the acquired business to us; \$2.0 million contingent on LeMaitre's success in obtaining CE marks under MDR regulations on the acquired products, \$0.5 million contingent upon Admedus' success in extending the shelf life of the acquired products as specified in the agreement, and another \$5.0 million contingent on the achievement of specified levels of revenues in the first 12 and 24 months following the acquisition date. This additional contingent consideration was initially valued in total at \$2.3 million and is being re-measured each reporting period until the payment requirement ends, with any adjustments reported in income from operations. The contingent payment related to the delivery of audited financial statements of the business was paid in November 2019 upon satisfaction of the deliverable. The contingent payments related to Admedus' extending the shelf life of the acquired products and achieving the revenue targets during the first 12 and 24 month periods following the acquisition were not met, and the portion of the liabilities related to these items was adjusted through income from operations. The agreement was amended in August 2021 such that the contingent payment of \$2.0 million potentially due upon LeMaitre Vascular's success in obtaining CE marks under MDR regulations on the acquired products may be reduced for certain costs incurred by LeMaitre in achieving the CE marks.

The following table provides a rollforward of the fair value of these liabilities, as determined by Level 3 unobservable inputs including management's forecast of future revenues for the acquired businesses, as well as, management's estimates of the likelihood of achieving the other specified criteria:

	Six months ended June 30,	
	2022	2021
	(in thousands)	
Beginning balance	\$ 1,492	\$ 2,240
Additions	-	-
Payments	-	-
Change in fair value included in earnings	27	61
Ending balance	<u>\$ 1,519</u>	<u>\$ 2,301</u>

16. Accumulated Other Comprehensive Loss

Changes to our accumulated other comprehensive loss for the six months ended June 30, 2022 and 2021 consisted primarily of foreign currency translation and unrealized losses on short-term marketable securities:

	Six months ended	
	June 30,	
	2022	2021
	(in thousands)	
Beginning balance	\$ (3,435)	\$ (1,525)
Other comprehensive income (loss) before reclassifications	(3,009)	(718)
Ending Balance	<u>\$ (6,444)</u>	<u>\$ (2,243)</u>

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 U.S. Private Securities Litigation Reform Act of 1995) that involve substantial risks and uncertainties, particularly risks related to the regulatory environment, our common stock, fluctuations in our quarterly and annual results, our ability to successfully integrate acquisitions into our business, and risks related to our business and industry generally, such as risks inherent in the process of developing and commercializing products and services that are safe and effective for use in the peripheral vascular disease market. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future net sales, gross margin expectations, 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. No forward-looking statement can be guaranteed and actual results may vary materially from those projected in the forward-looking statements. We intend to take advantage of the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995 regarding our forward-looking statements, and are including this sentence for the express purpose of enabling us to use the protections of the safe harbor with respect to all forward-looking statements. These risks and uncertainties include, but are not limited to: the status of our global regulatory approvals and compliance with regulatory requirements to market and sell our products both in the US and outside of the US; the duration and severity of the impact of COVID-19 on the global economy, our customers, our suppliers and our company; the risk of significant fluctuations in our quarterly and annual results due to numerous factors; 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; the risk that we may not be able to maintain our recent levels of profitability; the risk that the Company may not realize the anticipated benefits of its strategic activities; risks related to the integration of acquisition targets; the acceleration or deceleration of product growth rates; risks related to product demand and market acceptance of the Company’s products and pricing; the risk that a recall of our products could result in significant costs or negative publicity; 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, 2021, as filed with the SEC on February 28, 2022. 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, AlboGraft, AnastoClip, Artegraft, CardioCel, Omniflow, RestoreFlow, VasculCel 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

LeMaitre Vascular is a global provider of medical devices and human tissue cryopreservation services largely used in the treatment of peripheral vascular disease, end-stage renal disease, and to a lesser extent cardiovascular disease. We develop, manufacture, and market vascular devices to address the needs of vascular surgeons and, to a lesser degree, other specialties such as cardiac surgeons, general surgeons and neurosurgeons. Our diversified portfolio of devices consists of brand name products that are used in arteries and veins and are well known to vascular surgeons. Our principal product offerings are sold globally, primarily in the United States, Europe, the United Kingdom, Canada and Asia Pacific. We estimate that the annual worldwide market for peripheral vascular devices exceeds \$5 billion, within which we estimate that the market for our products is approximately \$750 million. We have grown our business using a simple three-pronged strategy: 1) pursuing a focused call point, 2) competing for sales of low-rivalry, niche products, and 3) expanding our worldwide direct sales force while acquiring and, to a lesser extent, developing complementary devices. We have used acquisitions as a primary means of further penetrating the peripheral vascular device market, and we expect to continue to pursue this strategy in the future. We currently manufacture most of our products in our Burlington, Massachusetts headquarters.

Our products and services 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, vascular surgeons can perform both open surgical and minimally invasive endovascular procedures, and therefore can provide a wider range of treatment options to their patients. More recently, however, we have begun to explore adjacent market customers, or non-vascular surgeon customers, who can be served by our vascular device technologies, such as cardiac surgeons and neurosurgeons.

Since March 2020, the COVID-19 pandemic has significantly impacted the markets for our products as well as our business. In response to COVID-19, many hospitals limited elective procedures in response to the onset of the pandemic and then periodically when infection rates have increased. Many of our devices are used in elective procedures. Additionally, our sales representatives' access to hospitals and surgeons has periodically been restricted by hospitals or local governments. More recently, however, in many geographies we have seen restrictions eased, although the prevalence of COVID-19 variants has not always resulted in the re-opening of hospital access. During 2020 and into 2022, these dynamics resulted in, and we expect will continue to result in, variable and unpredictable sales.

Our principal product lines include the following: anastomotic clips, biologic vascular and dialysis grafts, biologic vascular and cardiac patches, carotid shunts, embolectomy catheters, occlusion catheters, radiopaque marking tape, synthetic vascular grafts, and valvulotomes. Through our RestoreFlow allografts business, we also provide services related to the processing and cryopreservation of human vascular and cardiac tissue.

Our principal biologic offerings include vascular and cardiac patches as well as vascular and dialysis grafts. In Q2 2022, biologics represented 50% of worldwide sales. We view the biologic device offerings favorably, as we believe they represent differentiated and in some cases growing product segments.

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:

- adding complementary products through acquisitions;
- growing our direct sales force in the United States, Europe, the United Kingdom, Canada and Asia Pacific, including replacing a distributor with our sales personnel;
- introducing our products into new territories upon receipt of regulatory approvals or registrations in these territories;
- consolidating and automating product manufacturing at our Burlington, Massachusetts facilities, and
- updating existing products and introducing new products through research and development.

Our ability to execute on these opportunities on a timely basis, or at all, may be impacted by the COVID-19 pandemic, the duration and severity of which are uncertain.

We sell our products and services primarily through a direct sales force. As of June 30, 2022, our sales force was comprised of 111 sales representatives in North America, Europe, the United Kingdom and Asia Pacific, including two export managers. Our worldwide headquarters is located in Burlington, Massachusetts, and we also have sales offices in Chandler, Arizona and Vaughan, Canada. Our European headquarters is located in Sulzbach, Germany, and we also have sales offices in Milan, Italy; Madrid, Spain; and Hereford, England. Our Asia Pacific headquarters is located in Singapore, and we also have sales offices in Tokyo, Japan; Shanghai, China; Kensington, Australia; and Seoul, Korea. During the current quarter, approximately 95% of our net sales were generated in territories in which we employ direct sales representatives. We also sell our products in other countries through distributors.

Historically we have experienced success in lower-rivalry niche segments. In the valvulotome market, for example, our highly differentiated devices have historically allowed us to increase our selling prices while maintaining unit share. In contrast, we have experienced less success in highly competitive markets such as the polyester vascular graft market, where we face competition from larger companies with greater resources and lower per unit costs. While we believe these challenging market dynamics can be mitigated by our relationships with vascular surgeons, there can be no assurance that we will succeed in highly competitive markets.

We have also experienced success in international markets, such as Europe, where we have a significant sales force, and sometimes offer comparatively lower average selling prices. If we continue to seek growth opportunities outside of North America, we may experience downward pressure on our gross margin.

Our strategy for growing our business includes the acquisition of complementary product lines and companies.

- In July 2019, we entered into an agreement with UreSil, LLC to purchase the remaining assets of their Eze-Sit valve cutter business, including U.S. distribution rights, for \$8.0 million.
- In October 2019, we entered into an agreement with Admedus to purchase the assets of their CardioCel biologic patch business for \$15.5 million plus additional payments of up to \$7.8 million, depending upon the satisfaction of certain contingencies.
- In June 2020, we entered into an agreement with Artegraft to purchase the assets of their bovine graft business for \$72.5 million plus additional payments of up to \$17.5 million, depending upon 2021 – 2023 unit sales.

Occasionally we discontinue or divest products or product lines that are no longer complementary to our business or that are not commercially viable.

- During 2021, we made decisions to wind down or discontinue TRIVEX powered phlebectomy systems, remote endarterectomy devices and surgical glue. These product lines totaled approximately \$2.2 million in 2021 revenues.
- During 2022, we made the decision to wind down the ProCol graft, AlboSure polyester patch and Latis graft cleaning catheter product lines. These products totaled approximately \$0.9 million in 2021 revenues.

From time to time we may undertake SKU reductions and transition sales to other SKUs or products with similar features. For example, in 2022, we decided to initiate the transition of sales of our Syntel spring tip catheter to our NovaSil catheter. Any of these actions may result in inventory write-offs and temporary or permanent negative impacts to our sales, gross margin and customer relationships.

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 into our direct sales organization:

- During 2020, we entered into definitive agreements with, or participated with Admedus in concluding agreements with, several former Admedus distributors in Europe and Canada, in order to terminate their distribution of our acquired bovine cardiac and vascular patch products, and we began selling direct-to-hospital in those geographies. The termination fees totaled approximately \$0.1 million.
- During 2020, we participated with Artegraft in concluding agreements with several of their former U.S. distributors in order to terminate their distribution of our bovine graft products. We now sell Artegraft products direct-to-hospital throughout the United States.
- In May 2022, we entered into a distribution transition agreement with our Korean distributor in order to sell products directly in Korea and dissolve the existing distribution arrangement. We expect to begin selling direct-to-hospital in Korea in January 2023. The distribution termination fees will total approximately \$0.5 million.

We also rely, to a much lesser extent, on internal product development efforts to bring differentiated technology and next-generation products to market:

- In 2020, we launched RestoreFlow cardiac allografts for use in cardiac repair and restoration.
- In March 2022, we received U.S. FDA clearance to market PhasTIPP, a portable powered phlebotomy device used to remove varicose veins in the leg.

In addition to our sales growth strategies, we have also executed on several operational initiatives designed to consolidate manufacturing into our Burlington facilities. We expect these plant consolidations will result in improved control over production quality as well as reduced costs. Our most recent manufacturing transfers included:

- In October 2019, we acquired the biologic patch business assets from Admedus. In July 2020, we initiated a project to transfer the production of these devices to our Burlington facilities. We expect this transfer to be complete in 2023.
- In June 2022, we closed our St. Etienne, France factory in order to streamline manufacturing operations and to reduce expenses. The Cardial business consisted of the manufacturing of polyester vascular grafts, valvulotomes, surgical glue and select OEM devices. We expect to transition Cardial graft sales to our Burlington-manufactured AlboGraft product for additional cost savings and improved margins. We acquired the Cardial business in 2018.

Our execution of these initiatives may affect the comparability of our financial results and may cause fluctuations from period to period as we incur related process engineering and other charges.

Fluctuations in the exchange rates between the U.S. dollar and foreign currencies, primarily the Euro, affect our financial results. For the six months ended June 30, 2022 approximately 38% of our sales took place outside the U.S., largely in currencies other than the U.S. dollar. We expect foreign currencies will represent a significant percentage of future sales. Selling, marketing, and administrative costs related to these sales are also denominated in foreign currencies, thereby partially mitigating our bottom-line exposure to exchange rate fluctuations. However, 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 record less revenue in U.S. dollars than we did before the exchange rate changed. For the six months ended June 30, 2022, we estimate that the effects of changes in foreign exchange rates decreased our reported sales by approximately \$2.5 million, as compared to rates in effect for the six months ended June 30, 2021.

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 and services, 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 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 the majority 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, sales meetings, attendance at vascular congresses, 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 salaries, stock based compensation, legal and accounting fees, information technology expense, intangible asset amortization expense and insurance expense.

Research and development. Research and development expense primarily includes costs associated with obtaining and maintaining regulatory approval of our products, salaries, laboratory testing and supply costs. It also includes costs associated with the design and execution of clinical studies, costs to register, maintain, and defend our intellectual property, and costs to transfer the manufacturing of acquired product lines to our Burlington facility. Also included are costs associated with the design, development, testing and enhancement of new or existing products.

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 U.S., which include operating losses or profits 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 U.S. and foreign subsidiaries, permanent items, discrete items, unrecognized tax benefits, and amortization of goodwill for U.S. tax reporting purposes.

Results of Operations

Since March 2020, the COVID-19 pandemic has significantly impacted the markets for our products as well as our business. In response to COVID-19, many hospitals limited elective procedures at the onset of the pandemic and then periodically over the last two years when infection rates have increased. Many of our devices are used in elective procedures. Additionally, our sales representatives' access to hospitals and surgeons has periodically been restricted by hospitals or local governments. More recently, in many geographies we have seen restrictions eased, although the prevalence of COVID-19 variants has not always resulted in the re-opening of hospital access. During 2020 and into 2022, these dynamics resulted in, and we expect will continue to result in, variable and unpredictable sales.

As described above, our results could be materially impacted in the near term. These financial statements and management's discussion and analysis of financial condition and results of operations should be read in that context.

Comparison of the three- and six-month periods ended June 30, 2022 to the three- and six-month periods ended June 30, 2021:

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

(unaudited)	Three months ended June 30,			Six months ended June 30,		
	2022	2021	Percent change	2022	2021	Percent change
	(\$ in thousands)			(\$ in thousands)		
Net sales	\$ 42,108	\$ 40,670	4%	\$ 81,669	\$ 76,553	7%
Net sales by geography:						
Americas	\$ 28,854	\$ 27,329	6%	\$ 55,397	\$ 51,028	9%
Europe, Middle East and Africa	10,749	10,803	(0%)	21,243	20,665	3%
Asia Pacific	2,505	2,538	(1%)	5,029	4,860	3%
Total	<u>\$ 42,108</u>	<u>\$ 40,670</u>	<u>4%</u>	<u>\$ 81,669</u>	<u>\$ 76,553</u>	<u>7%</u>

Net sales. Net sales increased by \$1.4 million, or 4%, to \$42.1 million for the three months ended June 30, 2022, compared to \$40.7 million for the three months ended June 30, 2021. The increase was driven primarily by an increase in carotid patch sales of \$0.9 million, allograft preservation services of \$0.7 million, and bovine graft sales of \$0.6 million. Additionally, shunt and valvulotome sales increased by \$0.2 million and \$0.1 million, respectively. We estimate that the stronger U.S. dollar decreased net sales by \$1.7 million during the three months ended June 30, 2022 as compared to the three months ended June 30, 2021.

Net sales increased by \$5.1 million, or 7%, to \$81.7 million for the six months ended June 30, 2022, compared to \$76.6 million for the six months ended June 30, 2021. The increase was driven primarily by an increase in carotid patch sales of \$1.6 million, bovine graft sales of \$1.6 million and allograft preservation services of \$1.4 million. Additionally, shunt and valvulotome sales increased by \$0.9 million and \$0.5 million, respectively. We estimate that the stronger U.S. dollar decreased net sales by \$2.5 million during the six months ended June 30, 2022 as compared to the six months ended June 30, 2021.

Direct-to-hospital net sales were 95% of our total net sales for the six months ended June 30, 2022 and June 30, 2021.

Net sales by geography. Net sales in the Americas increased \$1.5 million, or 6%, for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021. The increase was driven primarily by increased allograft preservation services of \$0.6 million, increased bovine graft sales of \$0.6 million, and increased shunt sales of \$0.3 million.

Net sales in the Americas increased \$4.4 million, or 9%, for the six months ended June 30, 2022 as compared to the six months ended June 30, 2021. The increase was driven primarily by increased bovine graft sales of \$1.6 million, increased allograft preservation services of \$1.2 million, and increased shunt sales of \$0.5 million. Additionally, valvulotome and carotid patch sales both increased by \$0.4 million, respectively.

EMEA net sales decreased \$0.1 million, or 0.5%, for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021. The decrease was driven primarily by decreased ovine graft sales of \$0.4 million largely due to the lack of a CE mark for Burlington produced devices, and decreased surgical glue sales of \$0.2 million, as surgical glue sales were discontinued during the most recent period. The decreased sales were offset by increased carotid patch sales of \$0.4 million, and increased valvulotome sales of \$0.2 million.

EMEA net sales increased \$0.6 million, or 3%, for the six months ended June 30, 2022 as compared to the six months ended June 30, 2021. The increase was driven primarily by increased carotid patch sales of \$0.8 million, increased shunt sales of \$0.5 million, and increased valvulotome sales of \$0.3 million. The increased sales were partial offset by decreased ovine graft sales of \$0.6 million largely due to the lack of a CE mark for Burlington-produced devices, and decreased surgical glue sales of \$0.3 million.

Asia Pacific net sales decreased \$33,000, or 1%, for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021. The decrease was driven primarily by decreased occlusion catheter sales of \$0.1 million, decreased shunt sales of \$0.1 million, and decreased valvulotome sales of \$0.1 million. The decreased sales were offset by increased carotid patch sales of \$0.2 million.

Asia Pacific net sales increased \$0.2 million, or 3%, for the six months ended June 30, 2022 as compared to the six months ended June 30, 2021. The increase was driven primarily by increased carotid patch sales of \$0.4 million offset by decreased shunt sales of \$0.1 million.

The following table sets forth the change in our gross profit and gross margin for the periods indicated:

(unaudited)	Three months ended June 30,				Six months ended June 30,			
	2022	2021	Change	Percent change	2022	2021	Change	Percent change
	(\$ in thousands)				(\$ in thousands)			
Gross profit	\$ 27,810	\$ 26,761	\$ 1,049	4%	\$ 53,772	\$ 50,560	\$ 3,212	6%
Gross margin	66.0%	65.8%	0.2%	*	65.8%	66.0%	(0.2%)	*

*Not applicable

Gross Profit. Gross profit increased \$1.0 million, or 4%, to \$27.8 million for the three months ended June 30, 2022, and gross margin increased 20 basis points to 66.0% in the period. The increase in gross profit was driven primarily by increased sales from carotid patch, allograft, and bovine grafts. The increase in gross margin was driven primarily by increased manufacturing efficiencies, lower charges for excess and obsolete inventory, and increased bovine graft sales which carry comparatively higher gross margins, partially offset by unfavorable changes in foreign currency exchange rates.

Gross profit increased \$3.2 million, or 6%, to \$53.8 million for the six months ended June 30, 2022, and gross margin decreased 20 basis points to 65.8% in the period. The increase in gross profit was driven primarily by increased sales from carotid patch, bovine graft, and allografts. The decrease in the gross margin was driven primarily by an increase in labor costs, unfavorable product mix, including higher sales of comparatively low margin polyester grafts, unfavorable changes in foreign currency exchange rates and manufacturing inefficiencies largely related to bovine carotid patches.

Operating Expenses

The following tables set forth changes in our operating expenses for the periods indicated and the change between the specified periods expressed as a percentage increase or decrease:

(unaudited)	Three months ended June 30,				Six months ended June 30,			
	2022	2021	\$ Change	Percent change	2022	2021	\$ Change	Percent change
Sales and marketing	\$ 8,242	\$ 6,803	\$ 1,439	21%	\$ 16,092	\$ 13,269	\$ 2,823	21%
General and administrative	7,331	6,200	1,131	18%	14,583	12,744	1,839	14%
Research and development	3,346	2,652	694	26%	6,278	5,496	782	14%
Restructuring	3,107	-	3,107	*	3,107	-	3,107	*
Total	\$ 22,026	\$ 15,655	\$ 6,371	41%	\$ 40,060	\$ 31,509	\$ 8,551	27%

	Three months ended June 30,			Six months ended June 30,		
	2022 % of Net Sales	2021 % of Net Sales	Change	2022 % of Net Sales	2021 % of Net Sales	Change
Sales and marketing	20%	17%	3%	20%	17%	3%
General and administrative	17%	15%	2%	18%	17%	1%
Research and development	8%	7%	1%	8%	7%	1%
Restructuring	7%	0%	7%	4%	0%	4%

* Not a meaningful percentage relationship.

Sales and marketing. For the three months ended June 30, 2022, sales and marketing expense increased 21% to \$8.2 million. The increase was driven primarily by higher salaries and related expenses of \$1.1 million, including higher commissions of approximately \$0.3 million. The number of sales reps increased from 88 to 111 from June 30, 2021 to June 30, 2022. We also added 2 additional regional sales managers during this time. Travel and related expenses were also higher by \$0.2 million. Expense reduction programs implemented during the second quarter of 2020 through the fourth quarter of 2021 in response to the COVID-19 global pandemic, including a reduction in force, lowered expenses for the three months ended June 30, 2021. We have since rehired in many areas, including our sales force. As a percentage of net sales, sales and marketing expense increased to 20% for the three months ended June 30, 2022, up from 17% in the prior period.

For the six months ended June 30, 2022, sales and marketing expense increased 21% to \$16.1 million. The increase was driven by higher salaries and related expenses of \$2.2 million, including higher commissions of approximately \$0.7 million. Travel and related expenses were also higher by \$0.4 million. As a percentage of net sales, sales and marketing expense increased to 20% for the six months ended June 30, 2022, up from 17% in the prior period.

General and administrative. For the three months ended June 30, 2022, general and administrative expenses increased 18% to \$7.3 million. The increase was driven primarily by higher salaries and related expenses of \$0.6 million, as well as an increase in personnel. Outside services expense also increased by \$0.4 million. As a percentage of sales, general and administrative expense increased to 17% for the three months ended June 30, 2022, up from 15% in the prior period.

For the six months ended June 30, 2022, general and administrative expenses increased 14% to \$14.6 million. The increase was driven primarily by higher salaries and related expenses of \$1.3 million, as well as an increase in personnel. Outside services expense also increased by \$0.4 million. As a percentage of net sales, general and administrative expense increased to 18% for the six months ended June 30, 2022, up from 17% in the prior period.

Research and development. For the three months ended June 30, 2022, research and development expense increased 26% to \$3.3 million. The increase was driven primarily by higher salaries and related expenses of \$0.2 million, as well as an increase in personnel. Outside services and testing also increased by \$0.5 million due to higher consulting and third-party costs associated with regulatory approvals, as well as testing related to our biologic products. As a percentage of sales, total research and development expense increased to 8% for the three months ended June 30, 2022, from 7% in the prior period.

For the six months ended June 30, 2022, research and development expenses increased 14% to \$6.3 million. The increase was driven primarily by higher salaries and related expenses of \$0.6 million, as well as an increase in personnel. Outside services and testing also increased by \$0.2 million. As a percentage of net sales, total research and development expense increased to 8% for the six months ended June 30, 2022, from 7% in the prior period.

Restructuring. For the three and six months ended June 30, 2022, restructuring expense was \$3.1 million. On June 30, 2022 we ceased operations at the St. Etienne, France factory and terminated most of the personnel at the site. The closure resulted in a restructuring charge of \$3.1 million for the three and six months ended June 30, 2022. Charges primarily consisted of employment termination costs, impairment of fixed assets and inventory, and third-party costs. Total costs associated with the closure are expected to be approximately \$3.5 million.

Income tax expense. We recorded a tax provision of \$2.0 million on pre-tax income of \$5.5 million for the three months ended June 30, 2022, compared to a \$2.2 million tax provision on pre-tax income of \$10.5 million for the three months ended June 30, 2021. We recorded a tax provision of \$4.0 million on pre-tax income of \$13.5 million for the six months ended June 30, 2022, compared to a tax provision of \$3.7 million on pre-tax income of \$17.9 million for the six months ended June 30, 2021. Our effective income tax rate was 36.7% and 29.5% for the three and six month periods ended June 30, 2022. Generally, income tax provisions for interim periods are based on an estimated annual income tax rate, adjusted for discrete tax items, with any changes affecting the estimated annual effective tax rate recorded in the interim period in which the change occurs. There is an exception to the estimated annual income tax rate calculation when there are losses in a jurisdiction that have a valuation allowance. The Company incurred losses in 2022 that are not benefitted in connection with the closure of the St. Etienne, France factory. Accordingly, the company has removed the pre-tax losses of its French subsidiary to calculate the annual effective tax rate. As such, our tax expense for the current period is based on an estimated annual effective tax rate of 24.6%, adjusted in the applicable quarterly periods for discrete stock option exercises and other discrete items. Our income tax expense for the current period varies from the statutory rate mainly due to federal and state tax credits, permanent items, different statutory rates from our foreign entities, and certain foreign losses not benefitted due to a valuation allowance. When the French subsidiary's ordinary pre-tax loss is removed, our effective income tax rate is 23.7% and 24.1% for the three and six month periods ended June 30, 2022. As noted above, the effective income tax rate on unadjusted pre-tax income of \$5.5 million and \$13.5 million for the three and six month periods ended June 30, 2022, results in effective tax rates of 36.7% and 29.5% for the three and six month periods ended June 30, 2022, respectively. The primary factors affecting the Company's recalculated effective tax rate for the three and six month periods ended June 30, 2022, were certain foreign losses not benefitted due to a valuation allowance.

Our effective income tax rate was 20.6% and 20.7% for the three and six month periods ended June 30, 2021. Our 2021 provision was based on the estimated annual effective tax rate of 24.1%, adjusted in the applicable quarterly period for discrete stock option exercises and other discrete items. Our income tax expense for the six month period ended June 30, 2021 varied from the statutory rate mainly due to federal and state tax credits, permanent items, different 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 our tax reserves reflect the probable outcome of known contingencies.

We assess the likelihood that our deferred tax assets will be realized through future taxable income and record a valuation allowance to reduce gross deferred tax assets to an amount that we believe is more likely than not to be realized. As of June 30, 2022, we have provided a valuation allowance of \$2.5 million for deferred tax assets primarily related to Australian net operating loss and capital loss carry forwards, Massachusetts tax credit carry forwards, and France (Cardial) net operating loss carry forwards that are not expected to be realized.

Liquidity and Capital Resources

At June 30, 2022, our cash and cash equivalents were \$20.8 million as compared to \$13.9 million at December 31, 2021. We also had \$54.9 million in short-term marketable securities as of June 30, 2022 and \$56.1 million as of December 31, 2021. Our cash and cash equivalents are highly liquid investments with maturities of 90 days or less at the date of purchase, and consist primarily of operating bank accounts. Our short-term marketable securities consist of a managed income mutual fund investing mainly in short-term investment grade, U.S.-dollar denominated fixed and floating-rate debt, and a short-duration bond fund. As of June 30, 2022 our short-term marketable securities reflected an unrealized loss of \$1.8 million as a result of increasing market interest rates.

On July 16, 2021, we closed an offering of 1,000,000 shares of our common stock, \$0.01 par value per share, at a price to the public of \$54.50 per share less underwriting discounts. The net proceeds, after deducting the underwriting discounts and other offering expenses, were approximately \$51.0 million. We used a portion of the proceeds from the offering to repay our outstanding debt. We plan to use the remaining proceeds for general corporate purposes, including working capital needs and capital expenditures, dividend payments, deferred payments related to prior acquisitions, and the funding of future acquisitions. On August 4, 2021, the underwriters purchased an additional 150,000 shares pursuant to an option granted to them in connection with the offering described above. The net proceeds to the Company, after deducting underwriting discounts and other offering expenses, were approximately \$7.6 million. We plan to use the proceeds for general corporate purposes.

On February 22, 2022, our Board of Directors authorized the repurchase of up to \$20.0 million of the Company's common stock through transactions on the open market, in privately negotiated purchases or otherwise until February 22, 2023. The repurchase program may be suspended or discontinued at any time. To date we have not made any repurchases under this program.

In June 2020, in connection with the Artegraft acquisition, we incurred debt of \$65 million including a five-year revolving line of credit of \$25 million and a five-year term loan of \$40 million. The loans bore interest at either the Base Rate as defined in the agreement plus an applicable margin of 1.25% to 1.75% depending on our consolidated leverage ratio, or the Eurodollar Rate plus an applicable margin of 2.25% to 2.75% depending on our consolidated leverage ratio. In July 2021 we repaid the balance under the term loan, plus accrued interest, in full.

In November 2021, we terminated the credit agreement, including the revolving line of credit, as permitted under the original agreement.

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 \$13.7 million for the six months ended June 30, 2022. For the year ended December 31, 2021, we had operating income of \$36.4 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 and services;
- payments associated with potential future quarterly cash dividends to our common stockholders;
- future acquisition-related payments;
- payments associated with 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 U.S. FDA and other regulatory clearances for our existing and future products;
- the costs associated with obtaining European MDR clearances for our existing and future products;
- the number, timing, and nature of acquisitions, divestitures and other strategic transactions, and
- potential future share repurchases.

Our cash balances may decrease as we continue to use cash to fund our operations, make acquisitions, pay dividends, 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 take out a loan. The sale of additional equity and debt securities may result in dilution to our stockholders, as was the case with our July 2021 equity offering. 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:

<u>Record Date</u>	<u>Payment Date</u>	<u>Per Share Amount</u>	<u>Dividend Payment</u> (in thousands)
Fiscal Year 2022			
March 8, 2022	March 24, 2022	\$ 0.125	\$ 2,743
May 17, 2022	June 2, 2022	\$ 0.125	\$ 2,745
Fiscal Year 2021			
March 9, 2021	March 25, 2021	\$ 0.110	\$ 2,262
May 19, 2021	June 3, 2021	\$ 0.110	\$ 2,267
August 26, 2021	September 9, 2021	\$ 0.110	\$ 2,401
November 19, 2021	December 2, 2021	\$ 0.110	\$ 2,405

On July 26, 2022 our Board of Directors approved a quarterly cash dividend on our common stock of \$0.125 per share payable on September 8, 2022, to stockholders of record at the close of business on August 25, 2022.

Cash Flows

	<u>Six months ended June 30,</u> (in thousands)		
	<u>2022</u>	<u>2021</u>	<u>Net Change</u>
Cash and cash equivalents	\$ 20,788	\$ 21,541	\$ (753)
Cash flows provided by (used in):			
Operating activities	\$ 13,959	\$ 15,971	\$ (2,012)
Investing activities	(1,509)	(2,462)	953
Financing activities	(4,965)	(18,504)	13,539

Net cash provided by operating activities. Net cash provided by operating activities was \$14.0 million for the six months ended June 30, 2022, consisting of \$9.6 million in net income, adjustments for non-cash or non-operating items of \$10.0 million (including primarily depreciation and amortization of \$4.8 million, stock-based compensation of \$2.3 million, provisions for inventory write-offs and doubtful accounts of \$1.8 million, and loss on divestiture of \$2.0 million), and also a net use of working capital of \$5.6 million. The net cash used for working capital was driven by an increase in inventory and other deferred costs of \$3.5 million and an increase in accounts receivable of \$2.6 million. These cash uses were offset by a decrease in prepaid expenses and other assets of \$0.4 million and increase of accounts payable of \$0.1 million.

Net cash provided by operating activities was \$16.0 million for the six months ended June 30, 2021, consisting of \$14.2 million in net income, adjustments for non-cash or non-operating items of \$9.4 million (including depreciation and amortization of \$5.3 million, stock-based compensation of \$1.8 million, provisions for inventory write-offs and doubtful accounts of \$2.3 million), and also a net use of working capital of \$7.6 million. The net cash used for working capital was driven by payments of accounts payable and accrued liabilities of \$4.6 million, an increase in inventory and other deferred costs of \$2.0 million and an increase in accounts receivable of \$1.5 million. These cash uses were offset by a decrease in prepaid expenses and other assets of \$0.5 million.

Net cash used in investing activities. Net cash used in investing activities was \$1.5 million for the six months ended June 30, 2022, consisting of expenditures on equipment and technology.

Net cash used in investing activities was \$2.5 million for the six months ended June 30, 2021, consisting of expenditures on equipment and technology.

Net cash used in financing activities. Net cash used in financing activities was \$5.0 million for the six months ended June 30, 2022, consisting primarily of a dividend payment of \$5.5 million. This use of cash was partly offset by proceeds from stock option exercises of \$0.5 million, net of shares repurchased to cover employee payroll taxes.

Net cash used in financing activities was \$18.5 million for the six months ended June 30, 2021, consisting primarily of payments made on our long-term debt of \$16.0 million and dividend payments of \$4.5 million. These uses of cash were partly offset by proceeds from stock option exercises of \$2.0 million, net of shares repurchased to cover employee payroll taxes.

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, 2021. There have been no material changes in our critical accounting policies during the six months ended June 30, 2022. 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 revenue recognition, inventory valuation, valuation of intangible assets and goodwill, contingent consideration and income taxes are reviewed on an ongoing basis and updated as appropriate. Actual results may differ from those estimates.

Recent Accounting Pronouncements

A summary of recent accounting pronouncements that may impact our financial statements upon adoption in future periods can be found in Note 1 to our financial statements included under Part 1, Item 1 of this Quarterly Report on Form 10-Q.

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 2022 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, 2021.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and Chief Financial Officer, is responsible for our disclosure controls and procedures pursuant to Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified under SEC rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. We design our disclosure controls and procedures to ensure, at reasonable assurance levels, that such information is timely recorded, processed, summarized and reported, and then accumulated and communicated appropriately.

Based on an evaluation of our disclosure controls and procedures as of June 30, 2022 our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at reasonable assurance levels.

Changes in Internal Control

There have been no changes in our internal control over financial reporting for the six months ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Internal Controls

Notwithstanding the foregoing, 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 based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any system will succeed in achieving its stated goals under all potential future conditions. Over time, 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, contracts, intellectual property and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of August 5, 2022, 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, 2021, which could materially affect our business, financial condition, or future results. The risk factors below supplement and update the risk factors and information discussed in our Annual Report on Form 10-K for the year ended December 31, 2021.

Our business is subject to complex, costly, and burdensome regulations. We could be subject to significant penalties if we fail to comply.

The production and marketing of our products and services and our ongoing research and development are subject to extensive regulation and review by numerous governmental authorities both in the U.S. and abroad. U.S. and foreign regulations applicable to medical devices and human tissues are wide-ranging and govern, among other things, the testing, marketing, and premarket clearance or approval of new medical devices and services related to human tissue, as applicable, in addition to regulating manufacturing and processing practices, reporting, promotion and advertising, importing and exporting, labeling, and record-keeping procedures.

Our failure to comply with applicable regulatory requirements could result in governmental agencies or a court taking action, including any of the following:

- issuing public warning letters to us;
- imposing fines and penalties on us;
- issuing an injunction preventing us from manufacturing, processing, selling or distributing our products;
- bringing civil or criminal charges against us;
- delaying the introduction of our new products into the market;
- ordering a recall of, or detaining or seizing, our products or cryopreserved human tissue; or
- withdrawing or denying approvals or clearances for our products.

If any or all of the foregoing were to occur, our business, results of operations, and brand could be materially adversely affected.

If we or some of our suppliers fail to comply with the FDA’s Quality System Regulation and other applicable requirements, our manufacturing or processing operations could be disrupted, our sales and profitability could suffer, and we may become subject to a wide variety of FDA enforcement actions.

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with all regulatory requirements. If the FDA finds that we have failed to comply with any regulatory requirements, it can institute a wide variety of enforcement actions, including, but not limited to, warning letters, fines and penalties, injunctions, civil or criminal charges, mandatory recalls, and withdrawal of clearances to sell products.

We and some of our suppliers must comply with the FDA’s Quality System Regulation, which governs the methods used in, and the facilities and controls used for, the design, testing, manufacture, control, quality assurance, installation, servicing, labeling, packaging, storage, and shipping of medical devices. Our Fox River Grove operations must comply with the FDA’s current Good Tissue Practices, which are the FDA regulatory requirements for the processing of human tissue. The FDA enforces its regulations through pre-announced and unannounced inspections. We have been, and anticipate in the future being, subject to such inspections by the FDA and other regulatory bodies. The timing and scope of future audits is unknown and it is possible, despite our efforts to ensure that our quality systems and the operation of our manufacturing facilities remain in compliance with U.S. and non-U.S. regulatory requirements, that audits may result in one or more unsatisfactory results. If we or one of our suppliers fails an inspection, or if a corrective action plan adopted by us or one of our suppliers is not sufficient, the FDA may bring an enforcement action against us, and our operations could be disrupted and our manufacturing delayed. For example, the FDA concluded a six week inspection of our Burlington facilities in June 2022. The inspection, which primarily focused on the manufacturing activities for our XenoSure biologic patch, yielded five FDA Form 483 observations with numerous examples cited by the FDA in support. Notwithstanding the FDA’s observations, based on our controls and empirical evidence, we believe that our products remain safe and effective for their intended use. We responded to the FDA with an extensive corrective action plan, and we have begun to address their findings. However, there can be no assurance that the FDA will be satisfied with our proposed actions or risk mitigation activities. As a result, the FDA may choose to take enforcement action against our firm, including by issuing a warning letter to us, requesting or mandating a recall of certain lots of our XenoSure patches or taking any of the other enforcement actions described above. If the FDA were to issue a warning letter to us, it could trigger additional audits by regulators from other geographies, consume additional internal and financial resources, interrupt our operations and have a material adverse impact on our business, results of operations and brand.

We participate in the Medical Device Single Audit (MDSAP) program, which allows manufacturers to undergo a universal quality system audit that is accepted in the United States, Japan, Australia, Canada and Brazil in lieu of individual routine audits by each regulator. Maintenance of this certification is a requirement to maintain sales in certain geographies including Canada. Failure to maintain this certification in good standing could result in suspension of our sales efforts in Canada or the other geographies.

We are also subject to the FDA's general prohibition against promoting our products for unapproved or off-label uses and to the medical device reporting regulations that require us to report to the FDA if our products may have caused or contributed to a death or serious injury, or if our device malfunctions and a recurrence of the malfunction would likely result in a death or serious injury. We must also file reports with the FDA of some device corrections and removals, and we must adhere to the FDA's rules on labeling and promotion. If we fail to comply with these or other FDA requirements or fail to take adequate corrective action in response to any significant compliance issue raised by the FDA, the FDA can take significant enforcement actions, which could harm our business, results of operations, and our reputation.

In addition, most other countries, such as Japan, require us to comply with manufacturing and quality assurance standards for medical devices that are similar to those in force in the U.S. before marketing and selling our products in those countries. If we fail to comply, we would lose our ability to market and sell our products in those foreign countries.

If we do not comply with international regulatory requirements to market our products outside the United States or are required to modify our operations or products as a result of such requirements, our business will be harmed.

Sales of medical devices outside the United States are subject to international regulatory requirements that vary from country to country. These requirements and the amount of time required for approval may differ from our experiences with the U.S. FDA. In some countries, we rely on our international distributors to obtain premarket approvals, complete product registrations, comply with clinical trial requirements, and complete those steps that are customarily taken in the applicable jurisdictions to comply with governmental and quasi-governmental regulation. In the future, we expect to continue to rely on distributors in this manner in those countries where we market and sell our products through them. Failure to satisfy these foreign regulations would impact our ability to sell our products in these countries and could cause our business to suffer. There can be no assurance that we will be able to obtain or maintain the required regulatory approvals in these countries.

Our products are currently regulated in the European Union (EU) and the United Kingdom under the European Medical Devices Directive (93/42/EC as amended by 2007/47/EC) (MDD) and the European Medical Device Regulation (2017/745) (MDR). In order to market our medical devices in the EU, we are required to obtain CE marks, which denote conformity to the essential requirements of the MDD or MDR, and manufacturers of higher-risk devices generally must use a "Notified Body"—an appointed independent third party to assess conformity. We currently use three Notified Bodies for our various products. We have received CE marks under the MDD to sell most of our products after managing a reinstatement process for those CE marks in 2020 and 2021.

In April 2017, the EU adopted new regulations for medical devices, the MDR, which replace the MDD and which took effect as of May 26, 2021. Our products will eventually be fully subject to the MDR, which requires all of our products, regardless of classification, to obtain a new CE mark in accordance with the new, more stringent standards under the MDR. As a condition to CE mark approval, clinical evidence will be required for Class III and implantable devices. As our Notified Bodies transition from MDD to MDR, they have begun to impose more rigorous requirements on us. Until recently, our preparation of filings under the MDR had been delayed due to our work on the MDD CE mark reinstatement referred to above. As a result, we may not receive CE marks under MDR on a timely basis, which could lead to backorders if we have not placed sufficient inventory on the EU market before our CE mark under MDD expires in order to bridge any gap between such CE mark and a new CE mark under MDR. For example, the arrangement under which Admedus agreed to manufacture and supply us with CardioCel and VasculCel inventory expires on July 11, 2023, and we may not receive a CE mark under MDR for such products until Q2 2024. If we are unable to procure sufficient inventory to cover such gap period, then we could encounter backorders in CardioCel and VasculCel until receipt of CE marks under MDR for such products in 2024. If we fail to obtain new CE marks under the MDR in a timely manner, or at all, future sales of our products in the EU could be adversely impacted.

There can be no assurance that we will be able to obtain or maintain MDR CE marks for our existing products, and obtaining CE marks may involve a significant amount of time and expense, stringent clinical and preclinical testing, or modification of our products and could result in limitations being placed on the use of our products in order to obtain approval. These types of more stringent restrictions on our products as they transition to MDR could impact sales of our products and/or their gross margins could be adversely impacted. For example, under the MDD CE mark issued for XenoSure in 2021, the indications for its use no longer include neuro or cardiac applications, indications for which the product was previously approved. Additionally, only XenoSure made from bovine pericardium sourced from certain of our suppliers is permitted to be sold under the new CE mark. While our existing suppliers are meeting our demand for tissue supply, there can be no assurance that they will meet or sustain higher levels of demand in the future. If they cannot meet our demand for tissue supply, our ability to supply conforming XenoSure devices to our EMEA customers may be impacted and our sales may suffer. Additionally, the tissue from the two approved tissue suppliers is significantly more expensive than that sourced from the third supplier. As a result, our EMEA gross margin for XenoSure has been negatively impacted. The Company is pursuing a path to reinstate the third supplier, although no assurances can be given.

Additionally, significant changes to our devices may trigger a requirement to file for an MDR CE mark earlier than expected, which could result in backorders. For example, in March 2020, we learned that a chemical used in our latex formulation was obsoleted. As a result, we submitted our new latex formulation to one of our Notified Bodies for review and acceptance under our Class III Pruitt F3 shunt MDD CE mark. Our Notified Body determined that the change is significant under the rules of the Class III MDD and as such we cannot implement that change under the Class III MDD rules. We filed for an MDR CE mark on that device in Q4 2021, and we currently await the results of our MDR review. We anticipate approval for that device in Q4 2022, though no assurance can be given as to timing or result. We believe inventory for our Pruitt F3 shunt will likely only be sufficient to supply customers until the end of Q3 2022, based on historical sales, and as a result, we may begin to experience backorders for the Pruitt F3 shunt while we await approval by our Notified Body. If we fail to obtain a new CE mark under MDR on this product in a timely manner, or at all, future sales of this product in the EU could be adversely impacted, though we could pursue mitigation strategies, including country-by-country derogations.

As a result of the United Kingdom's exit from the EU, the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) has announced that devices marketed in the U.K. will require U.K. Conformity Assessed (UKCA) marks certified by a U.K. approved Notified Body following the expiration of a transition period. During the transition period, CE marking will continue to be recognized in the U.K. and certificates issued by EU-recognized Notified Bodies will continue to be valid in the U.K. market. The MHRA previously indicated that the transition period would remain in effect until June 30, 2023. On June 26, 2022, the MHRA announced its intention to establish a transitional arrangement that would extend this deadline and allow medical devices with valid MDD CE marks to continue to be sold in the U.K. until the expiration of such CE marks. For all of our CE marked products except CardioCel and VascuCel, this would result in an extension of the transition period until May 25, 2024. Following such date (and in the case of CardioCel and VascuCel, following August 13, 2023), our devices marketed in the U.K. will require U.K. Conformity Assessed (UKCA) marks certified by a U.K. approved Notified Body. We intend to seek such marks for our products currently sold on the U.K. market. If we fail to obtain UKCA marks in a timely manner, or at all, future sales of our products in the U.K. could be adversely impacted.

Failure to receive or maintain CE mark approval would prohibit us from selling these products in the EU or the U.K., and would require significant delays in obtaining individual country approvals. If we do not receive or maintain these approvals, our business could be harmed. Maintaining a CE mark is contingent upon our continued compliance with applicable European medical device requirements, including limitations on advertising and promotion of medical devices and requirements governing the handling of adverse events. As highlighted above, there can be no assurance that we will be successful in obtaining, retaining or maintaining the CE mark for any of our current products. In particular, adverse event reporting requirements in the EU and the U.K. mandate that we report incidents which led or could have led to death or serious deterioration in health. Under certain circumstances, we could be required to or could voluntarily initiate a recall or removal of our product from the market in order to address product deficiencies or malfunctions. Any recall of our products may harm our reputation with customers and divert managerial and financial resources.

Our facilities are subject to periodic inspection by numerous regulatory authorities, including governmental agencies and Notified Bodies, and we must demonstrate compliance with the applicable medical devices regulations. Any failure by us to comply with regulatory requirements may entail our taking corrective action, such as modification of our policies and procedures. In addition, we may be required to cease all or part of our operations for some period of time until we can demonstrate that appropriate steps have been taken. There can be no assurance that we will be found in compliance with such standards in future audits.

We also pursue registrations in other jurisdictions in which we sell our devices directly, such as Japan and China. In 2015, the China Food and Drug Administration (NMPA) significantly increased the application fees for product registrations and imposed additional requirements for obtaining product approval, which includes requirements for conducting clinical trials to support the registration application process on newly introduced products in China. As a result, we may not seek registration for certain products where the cost is not justified. Any delay in product registrations could have a negative impact on our results of operations.

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

None.

Issuer Purchases of Equity Securities

Period	Issuer Purchases of Equity Securities			
	Total Number of Shares (or Units) Purchased (1)	Average Price Paid Per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Program	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that may yet be Purchased under the Plans or Program
April 1, 2022 through April 30, 2022	33	\$ 47.85	N/A	N/A
May 1, 2022 through May 31, 2022	65	\$ 39.05	N/A	N/A
June 1, 2022 through June 30, 2022	-	\$ -	N/A	N/A
Total	98	\$ 41.79	N/A	N/A

(1) For the three months ended June 30, 2022, we repurchased 98 shares of our common stock to satisfy employees' obligations with respect to minimum statutory withholding taxes in connection with the vesting of restricted stock units.

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	Inline XBRL Instance Document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				X

†Indicates a management contract or any compensatory plan, contract, or arrangement.

*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 August 5, 2022.

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 and Director

CERTIFICATION

I, George W. LeMaitre, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of LeMaitre Vascular, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ George W. LeMaitre

George W. LeMaitre
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: August 5, 2022

EXHIBIT 31.2

CERTIFICATION

I, Joseph P. Pellegrino, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of LeMaitre Vascular, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Joseph P. Pellegrino, Jr.

Joseph P. Pellegrino, Jr.

Chief Financial Officer and Director

(Principal Accounting and Financial Officer)

Date: August 5, 2022

EXHIBIT 32.1

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “*Exchange Act*”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), George W. LeMaitre, Chairman and Chief Executive Officer of LeMaitre Vascular, Inc. (the “*Company*”), certifies to the best of his knowledge that:

- (1) The Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2022 (the “*Report*”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is being provided pursuant to 18 U.S.C. § 1350 and is not deemed to be a part of the Report, nor is it to deemed to be “filed” for any purpose whatsoever.

/s/ George W. LeMaitre

George W. LeMaitre
Chairman and Chief Executive Officer
(Principal Executive Officer)
August 5, 2022

EXHIBIT 32.2

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “*Exchange Act*”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Joseph P. Pellegrino, Jr., Chief Financial Officer of LeMaitre Vascular, Inc. (the “*Company*”), certifies to the best of his knowledge that:

- (1) The Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2022 (the “*Report*”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is being provided pursuant to 18 U.S.C. § 1350 and is not deemed to be a part of the Report, nor is it to deemed to be “filed” for any purpose whatsoever.

/s/ Joseph P. Pellegrino, Jr.

Joseph P. Pellegrino, Jr.

Chief Financial Officer and Director

(Principal Accounting and Financial Officer)

August 5, 2022