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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

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	**04-2825458**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
63 Second Avenue, Burlington, Massachusetts	**01803**
(Address of principal executive offices)	**(Zip Code)**

(781) 221-2266
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒

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

The registrant had 21,838,093 shares of common stock, $.01 par value per share, outstanding as of October 27, 2021.

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Part I. Financial Information

Item 1. Financial Statements

LeMaitre Vascular, Inc.
Consolidated Balance Sheets

	(unaudited) September 30, 2021	December 31, 2020
	(in thousands, except share data)	
Assets		
Current assets:		
Cash and cash equivalents	$ 17,369	$ 26,764
Short-term marketable securities	49,710	214
Accounts receivable, net of allowances of $632 at September 30, 2021 and $623 at December 31, 2020	19,501	19,552
Inventory and other deferred costs	44,326	45,115
Prepaid expenses and other current assets	3,110	2,618
Total current assets	134,016	94,263
Property and equipment, net	16,997	15,036
Right-of-use leased assets	15,664	16,066
Goodwill	65,945	65,945
Other intangibles, net	54,230	58,905
Deferred tax assets	1,627	1,686
Other assets	994	909
Total assets	$ 289,473	$ 252,810
Liabilities and stockholders' equity		
Current liabilities:		
Current portion of long-term debt	$ -	$ 2,500
Revolving line of credit	-	-
Accounts payable	3,137	2,394
Accrued expenses	16,460	17,525
Acquisition-related obligations	616	772
Lease liabilities - short-term	1,901	1,954
Total current liabilities	22,114	25,145
Long-term debt	-	35,532
Lease liabilities - long-term	14,589	14,791
Deferred tax liabilities	122	127
Other long-term liabilities	3,600	4,643
Total liabilities	40,425	80,238
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 23,384,129 shares at September 30, 2021, and 22,061,554 shares at December 31, 2020	234	221
Additional paid-in capital	179,070	114,924
Retained earnings	84,356	70,554
Accumulated other comprehensive loss	(2,636)	(1,525)
Treasury stock, at cost; 1,546,036 shares at September 30, 2021 and 1,538,572 shares at December 31, 2020	(11,976)	(11,602)
Total stockholders' equity	249,048	172,572
Total liabilities and stockholders' equity	$ 289,473	$ 252,810

See accompanying notes to consolidated financial statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(in thousands, except per share data)		(in thousands, except per share data)	
Net sales	$ 38,368	$ 36,416	$ 114,921	$ 91,818
Cost of sales	13,502	13,712	39,495	31,602
Gross profit	24,866	22,704	75,426	60,216
Sales and marketing	6,941	5,157	20,210	17,788
General and administrative	6,004	5,901	18,748	16,425
Research and development	2,848	2,098	8,344	7,230
Gain on sale of building	-	(470)	-	(470)
Total operating expenses	15,793	12,686	47,302	40,973
Income from operations	9,073	10,018	28,124	19,243
Other income (expense):				
Interest income	54	15	56	194
Interest expense	(621)	(665)	(1,693)	(732)
Foreign currency gain (loss)	(72)	10	(105)	(280)
Income before income taxes	8,434	9,378	26,382	18,425
Provision for income taxes	1,930	1,865	5,650	4,238
Net income	$ 6,504	$ 7,513	$ 20,732	$ 14,187
Earnings per share of common stock:				
Basic	$ 0.30	$ 0.37	$ 0.99	$ 0.70
Diluted	$ 0.30	$ 0.37	$ 0.98	$ 0.69
Weighted-average shares outstanding:				
Basic	21,592	20,254	20,920	20,201
Diluted	21,935	20,474	21,251	20,434
Cash dividends declared per common share	$ 0.110	$ 0.095	$ 0.330	$ 0.285

See accompanying notes to consolidated financial statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Net income	$ 6,504	$ 7,513	$ 20,732	$ 14,187
Other comprehensive income (loss):				
Foreign currency translation adjustment, net	(335)	1,142	(1,052)	988
Unrealized gain (loss) on short-term marketable securities	(58)	8	(59)	10
Total other comprehensive income (loss)	(393)	1,150	(1,111)	998
Comprehensive income	$ 6,111	$ 8,663	$ 19,621	$ 15,185

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount				Shares	Amount	
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					220			220
Issuance of common stock for stock options exercised	70,355	1	1,186					1,187
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
Net income				6,504				6,504
Other comprehensive income (loss)					(393)			(393)
Issuance of common stock	1,150,000	12	58,683					58,695
Issuance of common stock for stock options exercised	17,410	-	299					299
Vested restricted stock units	14,941	-	-					-
Stock-based compensation expense			797					797
Repurchase of common stock for net settlement of equity awards						5,223	(286)	(286)
Common stock dividend paid				(2,401)				(2,401)
Balance at September 30, 2021	23,384,129	234	179,070	84,356	(2,636)	1,546,036	(11,976)	249,048

See accompanying notes to consolidated financial statements.

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2019	21,678,927	$ 217	$ 105,934	$ 57,029	$ (4,007)	1,522,035	$ (11,032)	$ 148,141
Net income				3,174				3,174
Other comprehensive income (loss)					(1,518)			(1,518)
Issuance of common stock for stock options exercised	19,141	-	233					233
Vested restricted stock units	4,074	-	-					-
Stock-based compensation expense			779					779
Repurchase of common stock for net settlement of equity awards						1,601	(57)	(57)
Common stock dividend accrued				(1,917)				(1,917)
Balance at March 31, 2020	21,702,142	217	106,946	58,286	(5,525)	1,523,636	(11,089)	148,835
Net income				3,500				3,500
Other comprehensive income					1,366			1,366
Issuance of common stock for stock options exercised	3,000	-	42					42
Vested restricted stock units	192	-	-					-
Stock-based compensation expense			803					803
Common stock dividend paid				(1,917)				(1,917)
Balance at June 30, 2020	21,705,334	217	107,791	59,869	(4,159)	1,523,636	(11,089)	152,629
Net income				7,513				7,513
Other comprehensive income					1,150			1,150
Issuance of common stock for stock options exercised	92,014	1	1,162					1,163
Vested restricted stock units	22,576	-	-					-
Stock-based compensation expense			687					687
Repurchase of common stock for net settlement of equity awards						7,530	(234)	(234)
Common stock dividend paid				(1,925)				(1,925)
Balance at September 30, 2020	21,819,924	$ 218	$ 109,640	$ 65,457	$ (3,009)	1,531,166	$ (11,323)	$ 160,983

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

	For the nine months ended September 30,	
	2021	**2020**
	(in thousands)	
Operating activities		
Net income	$ 20,732	$ 14,187
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	8,186	5,861
Stock-based compensation	2,593	2,269
Fair value adjustment to contingent consideration obligations	(454)	132
Provision for doubtful accounts	136	257
Provision for inventory write-downs	3,016	1,032
Gain on sale of building	-	(470)
Foreign currency transaction loss	322	49
Changes in operating assets and liabilities:		
Accounts receivable	(425)	(1,326)
Inventory and other deferred costs	(2,752)	(3,228)
Prepaid expenses and other assets	(741)	35
Accounts payable and other liabilities	(567)	1,850
Net cash provided by operating activities	30,046	20,648
Investing activities		
Purchases of property and equipment and other assets	(4,276)	(1,767)
Proceeds from sale of building	-	2,023
Payments related to acquisitions	-	(72,627)
Purchases of short-term marketable securities	(49,554)	(2,193)
Proceeds from sales of marketable securities	-	18,000
Net cash used in investing activities	(53,830)	(56,564)
Financing activities		
Payments of deferred acquisition consideration	(401)	(976)
Proceeds from revolving line of credit	-	25,000
Proceeds from issuance of long-term debt	-	40,000
Payments of revolving line of credit	-	(4,000)
Payments of long-term debt	(39,000)	(500)
Payment of deferred debt issuance costs	-	(1,751)
Proceeds from issuance of common stock	61,566	1,437
Purchase of treasury stock for net settlement of equity awards	(374)	(291)
Common stock cash dividend paid	(6,930)	(5,759)
Net cash provided by (used in) financing activities	14,861	53,160
Effect of exchange rate changes on cash and cash equivalents	(472)	249
Net increase in cash and cash equivalents	(9,395)	17,493
Cash and cash equivalents at beginning of period	26,764	11,786
Cash and cash equivalents at end of period	$ 17,369	$ 29,279
Supplemental disclosures of cash flow information (see Note 13)		

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Notes to Consolidated Financial Statements
September 30, 2021
(unaudited)

1. Organization and Basis for Presentation

Description of Business

Unless the context requires otherwise, references to LeMaitre Vascular, we, our, and us refer to LeMaitre Vascular, Inc. and our subsidiaries. We develop, manufacture, and market medical devices and implants used primarily in the field of vascular surgery. We 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; Saint-Etienne, France; Hereford, England; Kensington, Australia; Tokyo, Japan; Shanghai, China; and Singapore.

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting only of normal, recurring adjustments considered necessary for a fair presentation of the results of these interim periods have been included. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Actual results may differ from these estimates. Our estimates and assumptions, including those related to bad debts, inventories, intangible assets, sales returns and discounts, share-based compensation, and income taxes are updated as appropriate. The results for the nine months ended September 30, 2021 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, 2020, including the notes thereto, included in our Form 10-K filed with the Securities and Exchange Commission (SEC) on March 12, 2021.

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 to unaudited consolidated financial statements. Due to the COVID-19 pandemic, there is heightened volatility and uncertainty in customer demand and the worldwide economy in general. The magnitude and duration of any impact on our revenues and operations from COVID-19 is uncertain and cannot be reasonably estimated at this time. 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 November 4, 2021, 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 recognize 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 Vascular 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 September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	($ in thousands)		($ in thousands)	
Americas	$ 25,299	$ 24,184	$ 76,327	$ 57,462
Europe, Middle East and Africa	10,535	10,039	31,200	28,339
Asia Pacific	2,534	2,193	7,394	6,017
Total	$ 38,368	$ 36,416	$ 114,921	$ 91,818

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

In December 2019, the FASB issued ASU 2019-12 Income Taxes (Topic 740), which simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740, as well as clarifying and amending other areas of existing GAAP under Topic 740. The new standard was effective for us beginning January 1, 2021. The adoption of this standard did not have a material impact on our financial statements.

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 within and without the United States, and may be subject to audits from various tax authorities. Management’s judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities, liabilities for uncertain tax positions, and any valuation allowance recorded against our net deferred tax assets. We will monitor the realizability of our deferred tax assets and adjust the valuation allowance accordingly.

Our policy is to classify interest and penalties related to unrecognized tax benefits as income tax expense. Our 2021 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 discrete stock option exercises. Our 2020 income tax expense varied from the statutory rate mainly due to the generation of federal and state tax credits, permanent items, and different statutory rates from our foreign subsidiaries.

We have reviewed the tax positions taken, or to be taken, in our tax returns for all tax years currently open to examination by a taxing authority. As of September 30, 2021, the gross amount of unrecognized tax benefits exclusive of interest and penalties was $787,000. 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 2028. A reconciliation of beginning and ending amount of our unrecognized tax benefits is as follows:

	Nine months ended September 30, 2021
	(in thousands)
Unrecognized tax benefits as of December 31, 2020	$ 820
Additions for tax positions of current year	-
Additions/adjustments for tax positions of prior years	(33)
Reductions for settlements with taxing authorities	-
Reductions for lapses of the applicable statutes of limitations	-
Unrecognized tax benefits as of September 30, 2021	$ 787

As of September 30, 2021, a summary of the tax years that remain subject to examination in our taxing jurisdictions is as follows:

United States	2017 and forward
Foreign	2014 and forward

Cash paid for income taxes was $7.5 million and $3.7 million for the nine month periods ended September 30, 2021 and September 30, 2020, respectively.

3. Inventories and Other Deferred Costs

Inventories and other deferred costs consist of the following:

	September 30, 2021	December 31, 2020
	(in thousands)	
Raw materials	$ 4,688	$ 5,044
Work-in-process	10,589	6,004
Finished products	23,521	28,117
Other deferred costs	5,528	5,950
Total inventory and other deferred costs	$ 44,326	$ 45,115

We had inventory on consignment at customer sites of $2.0 million and $2.1 million at September 30, 2021 and December 31, 2020, respectively.

Other deferred costs relate to our RestoreFlow allograft offering and 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 United States federal law, human tissues cannot be bought or sold. Therefore, the vascular and cardiac tissues we preserve are not held as inventory, and the costs we incur to procure and process them 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 companies' 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 and services, consolidation of manufacturing facilities, and the leveraging of our existing administrative infrastructure.

The fair market valuations associated with these transactions fall within Level 3 of the fair value hierarchy, due to the use of significant unobservable inputs to determine fair value. The fair value measurements were calculated using unobservable inputs, primarily using the income approach, specifically the discounted cash flow method. The amount and timing of future cash flows within our analysis was based on our due diligence models, most recent operational budgets, long-range strategic plans and other estimates. Our assumptions associated with these Level 3 valuations are discussed below and in Note 13 to these financial statements.

Artegraft Biologic Grafts

On June 22, 2020, we entered into an Asset Purchase Agreement (Artegraft APA) to acquire the bovine carotid artery graft business from Artegraft, Inc., which, subsequent to the closing, changed its 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 carotid artery grafts (the 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 is to be held until December 31, 2021 to cover any potential claims against LeMaitre or Artegraft, Inc., after which it will be 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;
- $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, as well as the time value of money until payment.

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.

	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
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 (years)
	(in thousands)	
Customer relationships	$ 20,310	15.0
Intellectual property	16,449	10.0
Non-compete agreement	104	5.0
Tradenames	2,193	10.0
Total intangible assets	$ 39,056	

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

CardioCel and VascuCel Biologic Patches

On October 11, 2019 (the Closing Date), we entered into an asset purchase agreement (Admedus APA) to acquire the biologic patch business assets and a related technology license from Admedus Ltd (now known as Anteris Technologies Ltd) and various of its subsidiaries (collectively, Admedus). The biologic patch business consists of the CardioCel and VascuCel product lines, which are manufactured in a manner intended to reduce the risk of calcification. The products are sold worldwide. On the same date, the parties entered into a Transition Services Agreement (TSA) under which Admedus will manufacture and supply LeMaitre with inventory for a period of up to three years, unless extended in writing by both parties. In August 2021, the term of this arrangement was extended through July 11, 2023.

Under the Admedus APA we agreed to pay Admedus a total of up to $15.3 million for the purchase of substantially all of its biologic patch business assets, other than specifically identified excluded assets, plus $8.0 million for the technology license. The acquired assets (in combination with the license) included inventory, intellectual property, permits and approvals, data and records, and customer and supplier information, as well as a small amount of machinery and equipment. At closing, $14.2 million of the purchase price was paid to Admedus. Shortly thereafter another $0.3 million was paid in connection with delivery of audited financial statements of the acquired business to LeMaitre. Additional payments of $0.7 million are due within 15 days of the first and third anniversaries of the closing date; the first payment was made in October 2020. Additional contingent consideration was or may be payable as follows:

- $2.5 million if revenues in the first 12-month period following the Closing Date exceed $20 million, or, $1.2 million if revenues in the first 12-month period following the Closing Date exceed $15 million (this milestone was not met and accordingly no payment was made);
- $2.5 million if revenues in the second 12-month period following the Closing Date exceed $30 million, or, $1.2 million if revenues in the second 12-month period following the Closing Date exceed $22.5 million (this milestone was not met and accordingly no payment was made);
- $0.5 million if, by the first anniversary of the Closing Date, Admedus extends the shelf life of the products from 36 months to at least 60 months (this milestone was not met and accordingly no payment was made); and
- $2.0 million within 15 days following LeMaitre’s receipt of a CE mark under MDR regulations on all acquired products (the Third Holdback Amount).

This contingent consideration of $7.5 million was initially valued in total at $2.0 million and is being re-measured each reporting period until the payment requirement ends, with any adjustments reported in income from operations.

During the quarter ended September 30, 2021, the Company entered into an amendment to the Admedus APA. Under the amendment, the Third Holdback Amount, less a deduction for certain expenses incurred by LeMaitre in order to achieve CE mark certification, will be paid as follows: 75% within 15 days following LeMaitre’s receipt of a CE mark under MDR regulations for CardioCel products, and 25% within 15 days following LeMaitre’s receipt of a CE mark under MDR regulations for VascuCel products. During the quarter ended September 30, 2021 we recorded a reduction to the liability of $0.5 million, with the offset recorded in income from operations, to reflect our estimate of costs to be deducted from the Third Holdback Amount in connection with this amendment.

During the quarter ended September 30, 2020, we recorded a $1.3 million adjustment to goodwill with an offsetting adjustment to deferred income taxes to reflect the difference between book basis and tax basis of the technology license. The following table summarizes the purchase price allocation:

	Allocated Fair Value
	(in thousands)
Inventory and other	$ 1,343
Deferred tax assets	1,345
Intangible assets	8,725
Goodwill	5,999
Purchase price	$ 17,412

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	**Weighted Average Useful Life (years)**
	(in thousands)	
Customer relationships	$ 5,562	12.0
Intellectual property	2,335	8.0
Non-compete agreement	361	5.0
Tradenames	467	8.0
Total intangible assets	$ 8,725	

The weighted-average amortization period of the acquired intangible assets was 10.4 years.

Tru-Incise Valve Cutter

On July 12, 2019 (the Closing Date), we entered into an agreement with UreSil, LLC to purchase the remaining assets of their Tru-Incise valve cutter business (since rebranded as Eze-Sit), including distribution rights in the United States. We also entered into a TSA under which UreSil, LLC continued to manufacture the acquired products for us for a specified time, until we transitioned the full manufacturing process to our Burlington, Massachusetts facilities. This manufacturing transfer is now complete.

The purchase price for the acquired assets, which included inventory, machinery and equipment, intellectual property, and customer and supplier information, was $8.0 million. Of this amount, $6.8 million was paid on the Closing Date, with three follow-on payments of $0.4 million each due on the first, second and third anniversaries of the Closing Date. The deferred amounts totaling $1.2 million were recorded at an acquisition-date fair value of $1.1 million using a discount rate of 4.19% to reflect the time value of money between the acquisition date and the payment due dates. There are no contingencies associated with these holdback payments, although they may be reduced for certain post-closing claims. The first payment was made without adjustment in July 2020. The second payment was made without adjustment in July 2021.

The following table summarizes the purchase price allocation:

	Allocated Fair Value
	(in thousands)
Inventory	$ 276
Equipment and supplies	70
Intangible assets	4,844
Goodwill	2,748
Purchase price	$ 7,938

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	**Weighted Average Useful Life (years)**
	(in thousands)	
Customer relationships	$ 3,945	13.0
Intellectual property	563	7.0
Non-compete agreement	233	5.0
Tradenames	103	7.0
Total intangible assets	$ 4,844	

The weighted-average amortization period of the acquired intangible assets was 11.8 years.

5. Goodwill and Other Intangible Assets

There was no change to goodwill during the nine months ended September 30, 2021. Other intangible assets consist of the following:

	September 30, 2021			**December 31, 2020**		
	Gross Carrying Value	**Accumulated Amortization**	**Net Carrying Value**	**Gross Carrying Value**	**Accumulated Amortization**	**Net Carrying Value**
	(in thousands)					
Product technology and intellectual property	$ 29,951	$ 10,167	$ 19,784	$ 29,951	$ 7,947	$ 22,004
Trademarks, tradenames and licenses	4,000	1,398	2,602	4,000	1,094	2,906
Customer relationships	38,525	7,352	31,173	38,525	5,424	33,101
Other intangible assets	1,767	1,096	671	1,767	873	894
Total identifiable intangible assets	$ 74,243	$ 20,013	$ 54,230	$ 74,243	$ 15,338	$ 58,905

These intangible assets are being amortized over their useful lives ranging from two to 16 years. The weighted-average amortization period for these intangibles as of September 30, 2021 is 12.1 years. Amortization expense is included in general and administrative expense and was as follows for the periods indicated.

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Amortization expense	$ 1,547	$ 1,681	$ 4,675	$ 3,409

We estimate that amortization expense for the remainder of 2021 and for each of the five succeeding fiscal years will be as follows:

	Year ended December 31,					
	2021	2022	2023	2024	2025	2026
	(in thousands)					
Amortization expense	$ 1,505	$ 5,975	$ 5,902	$ 5,706	$ 5,467	$ 5,001

6. 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, 2020, we made scheduled principal payments on the term loan of $1.0 million and repaid the revolving line of credit in full. During the nine months ended September 30, 2021, we made scheduled principal payments on the term loan of $1.0 million, and repaid the loan in full. Cash paid for interest during the nine months ended September 30, 2021 was $0.9 million.

Under the terms of the agreement, the loans bear 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 is 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.

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 are or 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 three months ended September 30, 2021, in connection with prepaying the term loan in full, we expensed the remaining unamortized transaction costs allocated to the term loan of $0.6 million. The issuance costs allocated to the revolver of $0.5 million as of September 30, 2021 will continue to be amortized on a straight-line basis as the line of credit is still available to us.

The term of the revolving line of credit is five years, with all outstanding amounts due on June 22, 2025. As of September 30, 2021, we had no borrowings outstanding under our revolving line of credit.

Because the revolving line of credit is still available to us, we must comply with various financial and non-financial covenants, which are set forth in the Credit Agreement governing the credit facility. The primary financial covenant consists of a maximum consolidated leverage ratio. The lenders are entitled to accelerate repayment of the loans and terminate the revolving credit commitment upon the occurrence of any of various events of default as described in the Credit Agreement. We were in compliance with the covenants as of September 30, 2021. Borrowings under the secured credit facility are secured by 100% of the stock of our domestic subsidiaries, portions of the stock of certain of our foreign subsidiaries, and substantially all of our and our subsidiaries' other property and assets, in each case subject to various exceptions.

We are required to make mandatory prepayments of any revolving credit loans in various amounts if we have Excess Cash Flow (as defined in the Credit Agreement, and commencing in respect of our fiscal year ending December 31, 2021), if we make certain sales of assets outside the ordinary course of business above certain thresholds or if we suffer certain property loss events above certain thresholds.

7. 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. In addition, our European operations are headquartered at a 16,470 square foot leased facility located in Sulzbach, Germany under a lease which expires in August 2023. This lease contains two five-year renewal options. 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, Italy, Spain and Illinois. 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 September 30, 2021.

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 quarter ended June 30, 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 September 30,		Nine months ended September 30,	
	2021 (in thousands)	2020 (in thousands)	2021 (in thousands)	2020 (in thousands)
Lease cost				
Operating lease cost	$ 588	$ 457	$ 1,682	$ 1,413
Short-term lease cost	123	67	313	123
Total lease cost	$ 711	$ 524	$ 1,995	$ 1,536
Other information				
Cash paid for amounts included in the measurement of operating lease liabilities	$ 725	$ 590	$ 2,106	$ 1,761
Right-of-use assets obtained in exchange for new operating lease liabilities	$ -	$ 96	$ 1,277	$ 2,577
Weighted average remaining lease term - operating leases (in years)			8.4	8.2
Weighted average discount rate - operating leases			4.86%	5.17%

At September 30, 2021, the minimum noncancelable operating lease rental commitments with initial or remaining terms of more than one year are as follows:

Remainder of 2021	$ 724
Year ending December 31,	
2022	2,670
2023	2,332
2024	2,104
2025	2,153
2026	2,155
Thereafter	8,198
Adjustment to net present value as of September 30, 2021	(3,846)
Minimum noncancelable lease liability	$ 16,490

8. Accrued Expenses and Other Long-term Liabilities

Accrued expenses consist of the following:

	September 30, 2021	December 31, 2020
	(in thousands)	
Compensation and related taxes	$ 9,515	$ 8,675
Income and other taxes	1,429	2,394
Professional fees	153	39
Other	5,363	6,417
Total	$ 16,460	$ 17,525

Other long-term liabilities consist of the following:

	September 30, 2021	December 31, 2020
	(in thousands)	
Aquisition-related liabilities	$ 2,708	$ 3,700
Income taxes	756	813
Other	136	130
Total	$ 3,600	$ 4,643

9. Segment and Enterprise-Wide Disclosures

Under Accounting Standards Codification Topic 280, *Segment Reporting*, operating segments are defined as components of an enterprise for which separate, discrete financial information is available and evaluated by the chief operating decision-maker in making decisions on how to allocate resources and assess performance. We view our operations and manage our business as one operating segment. No discrete operating information is prepared by us except for sales by product line and by legal entity for local reporting purposes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
United States	$ 23,313	$ 22,633	$ 70,453	$ 53,168
Germany	3,369	3,384	9,586	9,377
Other countries	11,686	10,399	34,882	29,273
Net Sales	$ 38,368	$ 36,416	$ 114,921	$ 91,818

10. 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, 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 September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Stock option awards	$ 504	$ 455	$ 1,660	$ 1,450
Restricted stock units	293	232	933	819
Total share-based compensation	$ 797	$ 687	$ 2,593	$ 2,269

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Cost of sales	$ 91	$ 68	$ 291	$ 237
Sales and marketing	124	103	412	397
General and administrative	499	451	1,617	1,400
Research and development	83	65	273	235
Total stock-based compensation	$ 797	$ 687	$ 2,593	$ 2,269

We did not grant any options during the nine-month period ended September 30, 2021. During the nine-month period ended September 30, 2020, we granted options for the purchase of 20,000 shares of our common stock. During the nine months ended September 30, 2021 and 2020, we awarded restricted stock units of 1,157 and 2,292, respectively. We issued approximately 173,000 and 141,000 shares of common stock following the exercise or vesting of underlying stock options or restricted stock units during the nine months ended September 30, 2021 and 2020, respectively.

11. Net Income per Share

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(in thousands, except per share data)		(in thousands, except per share data)	
Basic:				
Net income available for common stockholders	$ 6,504	$ 7,513	$ 20,732	$ 14,187
Weighted average shares outstanding	21,592	20,254	20,920	20,201
Basic earnings per share	$ 0.30	$ 0.37	$ 0.99	$ 0.70
Diluted:				
Net income available for common stockholders	$ 6,504	$ 7,513	$ 20,732	$ 14,187
Weighted-average shares outstanding	21,592	20,254	20,920	20,201
Common stock equivalents, if dilutive	343	220	331	233
Shares used in computing diluted earnings per common share	21,935	20,474	21,251	20,434
Diluted earnings per share	$ 0.30	$ 0.37	$ 0.98	$ 0.69
Shares excluded in computing diluted earnings per share as those shares would be anti-dilutive	-	496	1	610

12. Stockholders' Equity

Equity Offering

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.

Share Repurchase Program

On February 23, 2021, our Board of Directors authorized the repurchase of up to $15.0 million of the Company's common stock through transactions on the open market, in privately negotiated purchases or otherwise until February 22, 2022. 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:

Record Date	Payment Date	Per Share Amount	Dividend Payment
			(in thousands)
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
Fiscal Year 2020			
March 3, 2020	March 19, 2020	$ 0.095	$ 1,917
May 20, 2020	June 4, 2020	$ 0.095	$ 1,917
August 27, 2020	September 10, 2020	$ 0.095	$ 1,925
November 19, 2020	December 3, 2020	$ 0.095	$ 1,936

On October 26, 2021, our Board of Directors approved a quarterly cash dividend on our common stock of $0.11 per share payable on December 2, 2021, to stockholders of record at the close of business on November 19, 2021, which will total approximately $2.4 million.

13. Fair Value Measurements

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

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

Level 1 assets being measured at fair value on a recurring basis as of September 30, 2021 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 September 30, 2021.

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 Artegraft biologic graft business. 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 will be 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 statement 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. During the quarter ended September 30, 2021 we recorded a reduction to the liability of $0.5 million, with the offset recorded in income from operations, to reflect our estimate of costs to be deducted from the contingent payment in connection with this amendment.

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 and/or unit sales for the acquired businesses, and management's estimates of the likelihood of obtaining CE marks on the acquired CardioCel and VascuCel products and costs to be incurred by us that would reduce the associated liability.

	Nine months ended September 30,	
	2021	2020
	(in thousands)	
Beginning balance	$ 2,240	$ 1,765
Additions	-	406
Payments	-	-
Change in fair value included in earnings	(508)	39
Ending balance	$ 1,732	$ 2,210

14. Accumulated Other Comprehensive Loss

Changes to our accumulated other comprehensive loss for the nine months ended September 30, 2021 and 2020 consisted primarily of foreign currency translation:

	Nine months ended September 30,	
	2021	2020
	(in thousands)	
Beginning balance	$ (1,525)	$ (4,007)
Other comprehensive income (loss) before reclassifications	(1,111)	998
Amounts reclassified from accumulated other comprehensive loss	-	-
Ending Balance	$ (2,636)	$ (3,009)

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 duration and severity of the impact of COVID-19 on the global economy, our customers, our suppliers and our company; compliance with foreign regulatory requirements to market our products outside the United States; 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, 2020, as filed with the SEC on March 12, 2021. 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, AlboSure, AnastoClip, Artegraft, CardioCel, Omniflow, RestoreFlow, TRIVEX, VascuCel and XenoSure are registered trademarks of LeMaitre Vascular or one of its subsidiaries. This Quarterly Report on Form 10-Q also includes the registered and unregistered trademarks of other persons, which are the property of their respective owners.

Overview

We are a 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 extent, 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 throughout the world, 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 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 are therefore uniquely positioned to 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, and many of our devices are used in elective procedures. Additionally, our sales representatives' access to hospitals and surgeons has been restricted by hospitals or local governments. In some geographies, we have seen restrictions eased, however, the prevalence of COVID-19 variants has resulted in the re-imposition of restrictions in some areas. During 2020 and into 2021, these dynamics resulted in, and we expect will continue to result in, variable and unpredictable sales. In response to the COVID-19 pandemic, we have modified our manufacturing operations in order to adhere to social distancing requirements. In Q2 2020 we also undertook measures to reduce our operating costs, including temporary base salary cuts and a reduction in force of approximately 13% of our full-time employees. However, as sales normalized, we began rehiring personnel in many departments, including our sales force, and we expect to continue adding personnel in the second half of 2021. We ended our temporary base salary cuts on August 31, 2020.

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. 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, vascular, and cardiac and dialysis grafts. In Q3 2021, biologics represented 49% of worldwide sales. We view the biologic device segment favorably, as we believe it contains differentiated and in some cases growing product segments.

On June 22, 2020, we acquired the Artegraft biologic graft business. The results of operations of this business have been included in our results of operations since the date of acquisition.

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 North America, Europe, the United Kingdom, and Asia Pacific;
- 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 September 30, 2021, our sales force was comprised of 92 sales representatives in North America, Europe, the United Kingdom and Asia Pacific, including three export managers. Our worldwide headquarters is located in Burlington, Massachusetts, and we also have North American sales offices in Chandler, Arizona and Vaughan, Canada. Our European headquarters is located in Sulzbach, Germany, with additional sales offices in Milan, Italy; Madrid, Spain; and Hereford, England. Our Asia Pacific headquarters is located in Singapore, with additional sales offices in Tokyo, Japan; Shanghai, China; and Kensington, Australia. In Q3 2021, approximately 94% of our net sales were generated in countries or regions 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, for example the markets for valvulotomes and carotid shunts. In the valvulotome market, 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. 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 also 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 as well as the occasional discontinuance or divestiture of products that are no longer complementary:

- In July 2019, we entered into an agreement with UreSil, LLC to purchase the remaining assets of their valve cutter business, including distribution rights in the United States, for $8.0 million.

- In October 2019, we entered into an agreement with Admedus to purchase the assets of their 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, Inc., to purchase the assets of their biologic graft business for $72.5 million plus additional payments of up to $17.5 million, depending upon 2021 – 2023 unit sales.

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 the United Kingdom, Europe and Canada, in order to terminate their distribution of our biologic patches, 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 biologic grafts. We now sell Artegraft products direct-to-hospital throughout the United States.

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

- In 2019, we launched DuraSure, a biologic patch indicated for closing or repairing dural defects during open neurosurgical procedures.

- In 2020, we launched RestoreFlow cardiac allografts for use in cardiac repair and restoration.

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 September 2018, we acquired the Syntel embolectomy catheter business assets from Applied Medical. We immediately initiated a project to transfer the production to our Burlington facilities. This transfer is now complete.

- In late 2018 and into 2019, we expanded our Burlington biologic clean room in order to transfer the production of our Omniflow II vascular graft from our North Melbourne, Australia facility to Burlington. This transfer is substantially complete, and the North Melbourne facility has been sold.

- 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.

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 nine months ended September 30, 2021 approximately 39% 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 nine months ended September 30, 2021, we estimate that the effects of changes in foreign exchange rates increased our reported sales by approximately $2.4 million, as compared to rates in effect for the nine months ended September 30, 2020.

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 includes primarily costs associated with obtaining and maintaining regulatory approval of our products, principally 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 United States, which include operating losses in certain foreign jurisdictions for certain years depending on tax elections made, and foreign taxes on earnings of our wholly-owned foreign subsidiaries. Our consolidated tax expense is affected by the mix of our taxable income (loss) in the United States and foreign subsidiaries, permanent items, discrete items, unrecognized tax benefits, and amortization of goodwill for United States 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, and many of our devices are used in elective procedures. Additionally, our sales representatives' access to hospitals and surgeons has been restricted by hospitals or local governments. In some geographies, we have seen restrictions eased, however, the prevalence of COVID-19 variants has resulted in the re-imposition of restrictions in some areas. During 2020 and into 2021, these dynamics resulted in, and we expect will continue to result in, variable and unpredictable sales. In particular, in Q3 2021, the delta variant of COVID-19 depressed demand for our products in some geographies. In response to the COVID-19 pandemic, we have modified our manufacturing operations in order to adhere to social distancing requirements. In Q2 2020 we also undertook measures to reduce our operating costs, including temporary base salary cuts and a reduction in force of approximately 13% of our full-time employees. However, as sales normalized, we began rehiring personnel in many departments, including our sales force, and we expect to add personnel in the second half of 2021. We ended our temporary base salary cuts on August 31, 2020.

For reasons 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 nine-month periods ended September 30, 2021 to the three- and nine-month month periods ended September 30, 2020:

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 September 30,			Nine months ended September 30,		
	2021	2020	Percent change	2021	2020	Percent change
	($ in thousands)			($ in thousands)		
Net sales	$ 38,368	$ 36,416	5%	$ 114,921	$ 91,818	25%
Net sales by geography:						
Americas	$ 25,299	$ 24,184	5%	$ 76,327	$ 57,462	33%
Europe, Middle East and Africa	10,535	10,039	5%	31,200	28,339	10%
Asia Pacific	2,534	2,193	16%	7,394	6,017	23%
Total	$ 38,368	$ 36,416	5%	$ 114,921	$ 91,818	25%

As a general matter, the COVID-19 pandemic negatively impacted sales in the 2020 periods more acutely than in the 2021 periods in all geographies, though it still negatively impacted sales in Q3 2021 as compared to Q2 2021.

Net sales. Net sales increased $2.0 million, or 5%, to $38.4 million for the three months ended September 30, 2021, compared to $36.4 million for the three months ended September 30, 2020. The increase was driven primarily by Artegraft bovine grafts, with increased sales of $0.7 million, as well as higher allograft service revenues of $0.6 million. We also had higher valvulotome sales and bovine carotid patch sales of $0.3 million each. We estimate that the weaker U.S. dollar increased net sales by $0.2 million during the three months ended September 30, 2021 as compared to the three months ended September 30, 2020.

Net sales increased $23.1 million, or 25%, to $114.9 million for the nine months ended September 30, 2021, compared to $91.8 million for the nine months ended September 30, 2020. The increase was driven largely by Artegraft bovine grafts, with increased sales of $13.0 million. We also had higher valvulotome sales of $3.2 million, higher carotid shunt and bovine carotid patch sales of $1.6 million each, and higher allografts service revenues of $1.5 million. We estimate that the weaker U.S. dollar increased sales by $2.4 million during the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020.

Direct-to-hospital net sales were 94% of our total net sales for the nine months ended September 30, 2021, and 95% for the nine-month period ended September 30, 2020.

Net sales by geography. Net sales in the Americas increased $1.1 million, or 5%, for the three months ended September 30, 2021 as compared to September 30, 2020. The increase was driven mainly by Artegraft bovine grafts, with increased sales of $0.7 million, as well as higher allograft service revenue of $0.6 million. Offsetting these increases were lower bovine cardiac patch revenues of $0.3 million.

Net sales in the Americas increased $18.9 million, or 33%, for the nine months ended September 30, 2021 as compared to September 30, 2020. The increase was driven mainly by Artegraft bovine grafts, with increased sales of $13.0 million. We also had higher valvulotome sales of $1.9 million, higher allografts service revenues of $1.5 million, higher bovine carotid patch sales of $1.3 million and higher carotid shunt sales of $1.0 million. Offsetting these increases were lower bovine cardiac patch revenues of $0.3 million. Revenues from all other products increase $0.5 million on a net basis.

EMEA net sales increased $0.5 million, or 5%, for the three months ended September 30, 2021 as compared to September 30, 2020. Higher sales of valvulotomes led the growth, with increased sales of $0.4 million. Bovine cardiac patch sales increased by $0.2 million.

EMEA net sales increased $2.9 million, or 10%, for the nine months ended September 30, 2021 as compared to September 30, 2020. The increase was driven by higher valvulotome sales of $1.2 million, as well as higher carotid shunt, embolectomy catheter and bovine cardiac patch sales, all with increases of $0.5 million. Ovine graft sales were higher by $0.4 million. These increases were offset in part by a decrease in sales of bovine carotid patches of $0.5 million.

In May 2021, our CE mark certifications were reinstated for five products. However, we also simultaneously received a change in CE mark requirements for certain bovine carotid patches and polyester grafts. For bovine carotid patches, only bovine pericardium sourced from certain of our suppliers are permitted to be sold under the new CE mark, which is causing our production costs to increase, and our gross margin to decrease. The company is pursuing a path to reinstate an additional lower-cost supplier, although no assurance can be given.

Asia Pacific net sales increased $0.3 million, or 16%, for the three months ended September 30, 2021 as compared to September 30, 2020, with bovine carotid patch sales increasing $0.3 million. Embolectomy catheter and ePTFE graft sales each increased by $0.1 million. These and other product sales increases were in part offset by lower sales of TRIVEX powered phlebectomy systems of $0.1 million.

Asia Pacific net sales increased $1.4 million, or 23%, for the nine months ended September 30, 2021 as compared to September 30, 2020, with bovine carotid patch sales increasing $0.8 million, and embolectomy catheter sales and ePTFE graft sales each increasing $0.1 million. These and other product sales increases were partially offset by lower sales of TRIVEX powered phlebectomy systems of $0.2 million.

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

(unaudited)	Three months ended September 30,				Nine months ended September 30,			
	2021	2020	Change	Percent change	2021	2020	Change	Percent change
	($ in thousands)				($ in thousands)			
Gross profit	$ 24,866	$ 22,704	$ 2,162	10%	$ 75,426	$ 60,216	$ 15,210	25%
Gross margin	64.8%	62.3%	2.5%	*	65.6%	65.6%	0.0%	*

*Not applicable

Gross Profit. Gross profit increased $2.1 million, or 10%, to $24.9 million for the three months ended September 30, 2021, and gross margin increased 250 basis points to 64.8% in the period. The increase in gross profit and the gross margin were driven primarily by the impact in the prior period of purchase accounting from the Artegraft bovine graft acquisition that is no longer applicable in the current period. Higher Artegraft and valvulotome sales in the current period also contributed to the gross margin increase, as these products carry comparatively higher gross margins. These favorable impacts were partly offset by manufacturing inefficiencies and higher excess and obsolescence expense in the current period.

Gross profit increased $15.2 million, or 25%, to $75.4 million for the nine months ended September 30, 2021, with gross margin unchanged for the two comparative periods. The increase in gross profit was driven partly by the impact in the prior period of purchase accounting from the Artegraft bovine graft acquisition. This favorable impact was partly offset by manufacturing inefficiencies and higher excess and obsolescence expense in the current period.

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 September 30,				Nine months ended September 30,			
	2021	2020	$ Change	Percent change	2021	2020	$ Change	Percent change
Sales and marketing	$ 6,941	$ 5,157	$ 1,784	35%	$ 20,210	$ 17,788	$ 2,422	14%
General and administrative	6,004	5,901	103	2%	18,748	16,425	2,323	14%
Research and development	2,848	2,098	750	36%	8,344	7,230	1,114	15%
Gain on sale of building	-	(470)	470	*	-	(470)	470	*
Total	$ 15,793	$ 12,686	$ 3,107	24%	$ 47,302	$ 40,973	$ 6,329	15%

	Three months ended September 30,			Nine months ended September 30,		
	2021 % of Net Sales	2020 % of Net Sales	Change	2021 % of Net Sales	2020 % of Net Sales	Change
Sales and marketing	18%	14%	4%	18%	19%	(1%)
General and administrative	16%	16%	(0%)	16%	18%	(2%)
Research and development	7%	6%	1%	7%	8%	(1%)
Gain on sale of building	0%	(1%)	1%	0%	(1%)	1%

* Not a meaningful percentage relationship.

Sales and marketing. For the three months ended September 30, 2021, sales and marketing expense increased 35% to $6.9 million. The increase was driven primarily by higher salaries and related expenses of $1.5 million, including higher commissions of approximately $0.4 million and higher recruiting costs of $0.3 million. Travel and related expenses were also higher by $0.2 million. Expense reduction programs implemented during the second quarter of 2020 in response to the COVID-19 global pandemic, including a reduction in force, lowered expenses for the three months ended September 30, 2020. Since the pandemic has abated, we have begun rehiring in most positions, including our sales force. As a percentage of net sales, sales and marketing expense increased to 18% for the three months ended September 30, 2021 from 14% in the prior period.

For the nine months ended September 30, 2021, sales and marketing expense increased 14% to $20.2 million. The increase was driven by higher salaries and related expenses of $2.5 million, including higher commissions due to increased sales, as well as higher recruiting costs. These increases were offset in part by lower travel and related expenses, including our annual sales meeting held each January, which took place virtually in 2021. As a percentage of net sales, sales and marketing expense decreased to 18% for the nine months ended September 30, 2021 from 19% in the prior period.

General and administrative. For the three months ended September 30, 2021, general and administrative expenses increased 2% to $6.0 million. Compensation and related expenses were higher by $0.6 million, as salaries were reinstated in September 2020 and personnel were rehired following the April 2020 reduction in force. Offsetting this increase was a gain recognized in the current period from an amendment of a contingent purchase obligation associated with our 2019 Admedus biologic patch acquisition. As a percentage of sales, general and administrative expense was unchanged at 16% for three month periods ended September 30, 2021 and 2020.

For the nine months ended September 30, 2021, general and administrative expenses increased 14% to $18.7 million. The increase was primarily due to higher compensation and related expenses, as salaries were reinstated in September 2020 and personnel were rehired following the April 2020 reduction in force. We also had higher insurance costs, banking fees and professional fees. As a percentage of sales, general and administrative expense decreased to 16% for the nine months ended September 30, 2021, from 18% in the prior period.

Research and development. For the three months ended September 30, 2021, research and development expense increased $0.8 million, or 36%, to $2.8 million. Product development and process engineering expenses together increased $0.4 million or 57%, in large part due to projects related to the manufacturing transfer of acquired products to our Burlington facilities. Clinical and regulatory expenses increased $0.3 million, or 23%, driven by higher compensation and other costs incurred in connection with reinstating or maintaining regulatory approvals, especially in Europe. As a percentage of sales, total research and development expense increased to 7% for the three months ended September 30, 2021, from 6% in the prior period. Product development expenses was unchanged at 1% of sales for the three month periods ended September 30, 2021 and 2020.

For the nine months ended September 30, 2021, research and development expense increased $1.1 million, or 15%, to $8.3 million. Product development and process engineering expenses decreased $0.3 million, or 8%, in large part due to the completion of certain manufacturing transfer projects. Clinical and regulatory expenses increased $1.4 million, or 38%, driven by higher compensation expenses as well as consulting and other costs incurred in connection with reinstating or maintaining regulatory approvals, especially in Europe. As a percentage of sales, total research and development expense decreased to 7% for the nine months ended September 30, 2021, from 8% in the prior period. Product development expenses decreased to 1% of sales for the nine months ended September 30, 2021, from 2% in the prior period.

Gain on sale of building. During the first quarter of 2020, in connection with our planned manufacturing transfer of our Omniflow II ovine biologic graft to Burlington, management committed to a plan to sell our land and building located in North Melbourne, Australia. The sale was completed in September 2020. We recognized a gain on the sale during the three months ending September 30, 2020, net of applicable sales taxes and administrative costs, of $0.5 million.

***Income tax expense*.** We recorded a tax provision of $1.9 million on pre-tax income of $8.4 million for the three months ended September 30, 2021, compared to a $1.9 million tax provision on pre-tax income of $9.4 million for the three months ended September 30, 2020. We recorded a tax provision of $5.6 million on pre-tax income of $26.4 million for the nine months ended September 30, 2021, compared to $4.2 million on pre-tax income of $18.4 million for the nine months ended September 30, 2020.

Our effective income tax rate was 22.6% and 21.3% for the three- and nine-month periods ended September 30, 2021. Our tax expense for the current period is based on an estimated annual effective tax rate of 24.3%, 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 a discrete item for stock option exercises.

Our effective income tax rate was 19.9% and 23.0% for the three- and nine-month periods ended September 30, 2020. Our 2020 provision was based on an estimated annual effective tax rate of 25.0%, adjusted in the applicable quarterly period for discrete stock option exercises and other discrete items. Our income tax expense for 2020 varied from the statutory rate mainly due to federal and state tax credits, permanent items, and different statutory rates from our foreign entities.

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 we believe is more likely than not to be realized. As of September 30, 2021, we have provided a valuation allowance of $1.8 million for deferred tax assets primarily related to Australian net operating loss and capital loss carry forwards and Massachusetts tax credit carry forwards that are not expected to be realized.

Liquidity and Capital Resources

At September 30, 2021, our cash and cash equivalents were $17.4 million as compared to $26.8 million at December 31, 2020. We also had $49.7 million in short-term marketable securities as of September 30, 2021 and $0.2 million as of December 31, 2020. 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. All of our cash held outside of the United States is available for corporate use, with the exception of $3.4 million held by subsidiaries in jurisdictions for which earnings are planned to be permanently reinvested.

On July 16, 2021, we closed an offering of 1,000,0000 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 23, 2021, our Board of Directors authorized the repurchase of up to $15.0 million of the Company's common stock through transactions on the open market, in privately negotiated purchases or otherwise until February 22, 2022. 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 bear 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.

The term of the revolving line of credit is five years and allows re-borrowing up to $25 million during the term, with all outstanding amounts due on June 22, 2025. The revolving line of credit is currently undrawn and available for future drawdowns.

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 $28.1 million for the nine months ended September 30, 2021. For the year ended December 31, 2020, we had operating income of $28.8 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;
- payments for interest and principle on our long-term debt and revolving line of credit;
- the costs associated with expanding our manufacturing, marketing, sales, and distribution efforts;
- the costs associated with our initiatives to sell direct-to-hospital in new countries;
- the costs of obtaining and maintaining FDA and other regulatory clearances 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, repay outstanding debt, 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 access our available revolving credit facility. 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:

Record Date	Payment Date	Per Share Amount	Dividend Payment
			(in thousands)
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
Fiscal Year 2020			
March 3, 2020	March 19, 2020	$ 0.095	$ 1,917
May 20, 2020	June 4, 2020	$ 0.095	$ 1,917
August 27, 2020	September 10, 2020	$ 0.095	$ 1,925
November 19, 2020	December 3, 2020	$ 0.095	$ 1,936

On October 26, 2021, our Board of Directors approved a quarterly cash dividend on our common stock of $0.11 per share payable on December 2, 2021, to stockholders of record at the close of business on November 19, 2021, which will total approximately $2.4 million.

Cash Flows

	Nine months ended September 30,		
	(in thousands)		
	2021	2020	Net Change
Cash and cash equivalents	$ 17,369	$ 29,279	$ (11,910)
Cash flows provided by (used in):			
Operating activities	$ 30,046	$ 20,648	$ 9,398
Investing activities	(53,830)	(56,564)	2,734
Financing activities	14,861	53,160	(38,299)

Net cash provided by operating activities. Net cash provided by operating activities was $30.0 million for the nine months ended September 30, 2021, consisting of $20.7 million in net income, adjustments for non-cash or non-operating items of $13.8 million (including primarily depreciation and amortization of $8.2 million, stock-based compensation of $2.6 million, provisions for inventory write-offs and doubtful accounts of $3.2 million), and also a net use of working capital of $4.5 million. The net cash used for working capital was driven by an increase in inventory and other deferred costs of $2.8 million, an increase in prepaid expenses and other assets of $0.7 million, payments of accounts payable and accrued liabilities of $0.6 million, and an increase in accounts receivable of $0.4 million.

Net cash provided by operating activities was $20.6 million for the nine months ended September 30, 2020, consisting of $14.2 million in net income, adjustments for non-cash or non-operating items of $9.1 million (including depreciation and amortization of $5.9 million, stock-based compensation of $2.3 million, provisions for inventory write-offs and doubtful accounts of $1.0 million and $0.3 million, respectively, and a gain on the sale of a building of $0.5 million) and also a net use of working capital of $2.7 million. The net cash used for working capital was driven by an increase in inventory and other deferred costs of $3.2 million and an increase in receivable of $1.3 million. These cash uses were offset by an increase in accounts payable and accrued liabilities of $1.9 million.

Net cash used in investing activities. Net cash used in investing activities was $53.8 million for the nine months ended September 30, 2021, consisting of purchases of marketable securities of $49.6 million and expenditures on equipment and technology of $4.3 million.

Net cash used in investing activities was $56.6 million for the nine months ended September 30, 2020, including acquisition-related payments of $72.6 million primarily associated with the purchase of the Artegraft biologic graft business and expenditures on equipment and technology of $1.2 million, offset by net sales and purchases of marketable securities of $15.8 million and proceeds from the sale of the North Melbourne, Australia building of $2.0 million.

Net cash provided by financing activities. Net cash provided by financing activities was $14.9 million for the nine months ended September 30, 2021. Sources of cash included primarily net proceeds from an equity offering of $58.7 million and proceeds from stock option exercises of $2.5 million, net of shares repurchased to cover employee payroll taxes. These sources of cash were offset by payments made on our long-term debt of $39.0 million, dividend payments of $6.9 million and deferred payments for acquisitions of $0.4 million.

Net cash provided by financing activities was $53.2 million for the nine months ended September 30, 2020, consisting primarily of borrowings of $63.2 million net of debt issuance costs incurred and proceeds from stock option exercises of $1.2 million, net of shares repurchased to cover employee payroll taxes. These increases to cash were partly offset by the payment of dividends of $5.8 million, payments of debt of $4.5 million and deferred payments for acquisitions of 1.0 million.

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, 2020. There have been no material changes in our critical accounting policies during the nine months ended September 30, 2021. 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 2021 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, 2020.

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 September 30, 2021 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 nine months ended September 30, 2021 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 October 29, 2021, 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, 2020, 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, 2020.

If we do not comply with international regulatory requirements to market our products outside the United States 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 continue to 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 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 have received CE marks under the MDD to sell most of our products after managing a reinstatement process for those CE marks since 2020. A summary table of the reinstated or abandoned CE marks is provided below.

Product	Notified Body	Regulatory Status	Expiration Date
XenoSure	TUV SUD	CE Marked	May, 2024
AlboGraft	TUV SUD	CE Marked	May, 2024
Pruitt Aortic Occlusion Catheter	TUV SUD	Expired	n/a
AnastoClip	SGS	CE Marked	May, 2024
Flexcel	SGS	CE Marked	May, 2024
Pruitt Carotid Shunts	SGS	CE Marked	May, 2024
LifeSpan	SGS	CE Marked	May, 2024
AlboSure	SGS	Expired*	n/a
Surgical Glue	BSI	Abandoned*	n/a

*CE mark no longer being pursued under MDD and no filing will be made under MDR.

As part of the CE mark reinstatement of XenoSure, our new Notified Body required us to limit the indications for use to vascular-only. As a result, we lost our ability to promote the XenoSure device for cardiac and neuro procedures in Europe. We estimate that the removed indications account for roughly $1.0 million of annual sales. Additionally, the governing Notified Body also restricted our sourcing of raw tissue to two of our three tissue suppliers. While our existing suppliers have pledged to meet our demand for tissue supply over time, there can be no assurance that they will meet or sustain those higher levels of demand. If they cannot meet our demand for tissue supply, our ability to supply conforming XenoSure devices 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 gross margin for XenoSure tissue sold in Europe may be impacted. The Company is pursuing a path to reinstate the third supplier, although no assurances can be given.

As a result of the previous CE mark lapses, and the subsequent re-initiation of CE marked production with new limits on suppliers, we have begun experiencing backorders related to some of these products and our revenues are being impacted. Although there were no backorders for these products as of September 30, 2021, the backorders approximated $0.2 million as of June 30, 2021. To partially mitigate the potential impact of certain of these backorders, we have sought extension to our existing temporary exemptions, or derogations, in certain European countries from the requirement to apply CE marks to XenoSure and AlboGraft while we continue to restock our warehouses with CE marked products. We have received extensions to those exemptions in a limited number of countries, although nearly all have expired as of the date of this report. Where customers are not satisfied with this authorization status, they have in some cases decided to stop using our product and/or use a competing product and may continue to do so in the future, which could impact our revenues. If we are unsuccessful rapidly building and distributing our stock of these CE marked products, our revenues could be further impacted and our business could be harmed.

Additionally, the CE mark for our Omniflow II graft is currently being transferred to our Burlington headquarters due to our discontinuation of operations in North Melbourne, Australia in June 2020. While the MDD CE mark has been secured, the startup validation activities have been delayed and as a result, Burlington-built product is not yet available for sale on the European market. We expect that the inventory of the majority of such products held by our European subsidiary will only be sufficient to supply customers until partly through Q1 2022, based on historical sales, and as a result, we may go into backorder for Omniflow II until the validation activities are approved by our Notified Body. If the approval of these validation activities for Omniflow II is materially delayed or withheld, our European revenues could be impacted and our business could be harmed.

In April 2017, the EU adopted new regulations for medical devices, the MDR, which replace the MDD and now apply beginning 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 in order to obtain approval to renew the CE marks on certain of our products. Until recently, our preparation of filings under the MDR has been delayed due to our work on the other CE mark matters described above. If we fail to obtain new CE marks on these products or our other products 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. For example, under the new CE mark issued for XenoSure by TUV SUD, 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. 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. Additionally, significant changes to our devices may trigger a requirement to file for an MDR CE mark earlier than expected, which could result in supply chain delays. For example, in March, 2020, we learned that a chemical used in our latex formulation was obsoleted. As a result, we must submit our new latex formulation to one of our Notified Bodies for review and acceptance under our F3 shunt MDD CE mark, which we expect to do in Q1 2022. If the Notified Body determines that the change is significant under the rules of the MDD, it will require us to file a new MDR CE mark application, which could result in significant delays to instituting the change and thus maintaining adequate inventory levels of our F3 shunts.

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.

Supply chain disruptions could adversely impact our operations and financial condition.

Global supply chains have been disrupted as a result of the COVID-19 pandemic. Accordingly, the availability of raw materials and components used in the manufacture of our products may be adversely impacted. Additionally, even when we are able to source such materials and components, they may cost more and may only be available on a delayed basis. Higher materials and component costs could adversely affect our margins if we are unable to pass such costs along to customers in the form of price increases. Delays in receipt of materials and components could also interrupt our production and cause us to go into backorder on certain of our products, further exacerbating the global supply chain disruption.

If we are unable to expand our product and service offerings, we may not achieve our growth objectives and our results of operations could suffer.

Treatment of peripheral vascular and cardiovascular disease includes both open vascular surgery and minimally invasive endovascular procedures, and most of our products are used primarily or exclusively in open surgery procedures. We market and sell our products primarily to vascular surgeons. We estimate that in 2020 over 90% of our sales were from devices used in open surgery.

A core component of our growth strategy is the acquisition of complementary product lines, principally in the open vascular surgery space. The number of appropriately sized targets in the open vascular surgery space is limited, and if we are unable to execute on our acquisition strategy (or we do not expand the scope of our acquisition strategy), growth of our sales may be inhibited.

We may not be able to compete effectively unless we can keep pace with existing or new products, services and technologies in the vascular device market and the minimally invasive endovascular procedure segment, in particular. Our success in developing and commercializing new products and new versions of our existing products and services, or acquiring new products, is affected by our ability to:

- recognize in a timely manner new market trends and customer needs;
- identify products or services that address those trends or needs;
- identify suitable acquisition targets in the open vascular surgery space and execute on the acquisition of such targets;
- obtain regulatory clearance or approval of new products and technologies;
- successfully develop cost-effective manufacturing processes for such products;
- commercially introduce such products, services and technologies; and
- achieve market acceptance.

If we are unable to expand our product or service offerings, whether through internal development or by acquisition, we may not achieve our growth objectives and our results of operations as well as our stock price could suffer.

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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

Period	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
July 1, 2021 through July 31, 2021	5,223	$ 54.76	N/A	N/A
August 1, 2021 through August 31, 2021	-		N/A	N/A
September 1, 2021 through September 30, 2021	-		N/A	N/A
Total	5,223	$ 54.76	N/A	N/A

Item 5. Other Information

On July 23, 2021, our Board of Directors approved changes to the Company's director compensation policy, which is incorporated by reference into this report as Exhibit 10.3.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
2.1	Amendment No. 1 to Asset Purchase Agreement dated October 11, 2019 between the Registrant and Admedus Ltd (now known as Anteris Technologies Ltd) and certain of its subsidiaries.	8-K	9-1-21	001-33092	
10.1	Underwriting Agreement, dated as of July 13, 2021, among LeMaitre Vascular, Inc. and Jefferies LLC and Stifel, Nicolaus & Company, Incorporated, as representatives for the underwriters named therein.	8-K	7-16-21	001-33092	
10.2†	Eighth Amended and Restated Equity Award Grant Policy	8-K	7-9-21	001-33092	
10.3	Director Compensation Policy	10-Q	8-5-21	001-33092	
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15 d-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 November 4, 2021.

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

EXHIBIT 31.1

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: November 4, 2021

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: November 4, 2021

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 September 30, 2021 (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)
November 4, 2021

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 September 30, 2021 (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)
November 4, 2021