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

Form 8-K

Current Report
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 25, 2021

LeMaitre Vascular, Inc.

(Exact name of registrant as specified in its charter)

Commission File Number: 001-33092

Delaware	**04-2825458**
(State or other jurisdiction of incorporation)	**(IRS Employer Identification No.)**

63 Second Avenue
Burlington, MA 01803
(Address of principal executive offices, including zip code)

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by checkmark whether the company is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (240.12c-2 of this chapter).

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. ☐

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

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

Item 2.02. Results of Operations and Financial Condition.

On February 25, 2021, LeMaitre Vascular, Inc. (the "Company") issued a press release regarding its preliminary financial and operational results for the quarter ended December 31, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Report.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

The Company is providing the following regulatory update.

Due to the abrupt exit by its prior notified body (NB) from medical device CE marking, the Company needed six CE marks to be reissued. In Q3 2020, the Company engaged two additional NBs to accelerate the CE marking process. In February 2021, one of these NBs, SGS, issued a CE mark for LifeSpan, issued an Annex II certificate and successfully closed its audit of the Company's quality management system. In light of these actions, the Company now expects SGS will issue three additional CE marks by May 2021 for FlexCel carotid shunts, Pruitt F3 carotid shunts and AnastoClips. The Company continues to pursue the other two CE marks for XenoSure and AlboGraft in hopes that they will issue by May 2021.

Devices representing 99% of Q4 2020 sales in Europe/Middle East/Africa (EMEA) are currently available to EMEA hospitals through valid CE marks (58% of EMEA sales), temporary country-specific derogations (22% of EMEA sales), or sufficient CE-marked inventory (19% of EMEA sales). EMEA sales accounted for 29% of the Company's worldwide sales and 26% of its gross profit in Q4 2020.

Separately, the Company's quality management system was audited by one of its NBs, TUV SUD, in Q4 2020 as part of the XenoSure/AlboGraft CE marking process, and that audit remains open. Approximately 20% of the findings in that audit have been accepted by TUV SUD, and the Company is currently engaged in a dialog with TUV SUD to try to resolve the outstanding findings. Issuance of CE marks for XenoSure and AlboGraft depends on a successful audit closure as well as product approvals. Together, XenoSure and AlboGraft accounted for 22% of EMEA sales in Q4 2020. Retention of other CE marks previously issued by TUV SUD might also depend on a successful audit closure, representing 42% of sales.

Simultaneously, TUV SUD audited the Company for the purposes of issuance of a Medical Device Single Audit Program (MDSAP) certificate. In January, TUV SUD determined not to issue this certificate. However, LeMaitre promptly engaged SGS to undertake a new MDSAP audit. The in-person part of the new audit ended on February 25, 2021, with a recommendation for approval. As a result, LeMaitre expects successful issuance of an MDSAP certificate by March 15, 2021. The Company does not expect any sales impact in any geography from its MDSAP inactive status, and MDSAP status does not apply to European regulatory approvals.

If any or all of the CE marks referred to above are not reissued, or if the Q4 2020 TUV open audit is not successfully closed, then the Company could lose its ability to sell some of its devices. The Company believes it can partially mitigate the impact of these potential issues through a combination of supplementary inventory production, additional/extended derogations, and engaging new NBs.

Forward-Looking Statements

This report contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Statements in this report regarding the Company's business that are not historical facts may be "forward-looking statements" that involve risks and uncertainties. Forward-looking statements are based on management's current, preliminary expectations and are subject to risks and uncertainties that could cause actual results to differ from the results expected, including, but not limited to, the status of our global regulatory approvals and compliance with foreign regulatory requirements to market and sell our products outside the United States; the duration of the lapse in CE mark approval for certain of our devices; the closure of an audit by one of our notified bodies in support of the issuance and/or maintenance of CE marks covering certain of our products or the failure of such audit to be successfully closed; the duration and severity of the impact of COVID-19 on the global economy, our customers, our suppliers and our company; the risk of significant fluctuations in our quarterly and annual results due to numerous factors; the risk that assumptions about the market for the Company's products and the productivity of the Company's direct sales force and distributors may not be correct; the risk that we may not be able to maintain our recent levels of profitability; the risk that the Company may not realize the anticipated benefits of its strategic activities; risks related to the integration of acquisition targets; the acceleration or deceleration of product growth rates; risks related to product demand and market acceptance of the Company's products and pricing; the risk that a recall of our products could result in significant costs or negative publicity; the risk that the Company is not successful in transitioning to a direct-selling model in new territories and other risks and uncertainties included under the heading "Risk Factors" in our most recent Annual Report on Form 10-K, as updated by our subsequent filings with the SEC, which are all available on the Company's investor relations website at http://www.lemaitre.com and on the SEC's website at http://www.sec.gov. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. The Company undertakes no obligation to update publicly any forward-looking statements to reflect new information, events, or circumstances after the date they were made, or to reflect the occurrence of unanticipated events.

Item 9.01. Financial Statements and Exhibits.

The following exhibits are furnished or filed as part of this Report, as applicable:

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press release issued by LeMaitre Vascular, Inc. on February 25, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Exhibit Index

Exhibit No.	Description
99.1	Press release issued by LeMaitre Vascular, Inc. on February 25, 2021.

Signature(s)

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 hereunto duly authorized.

LeMaitre Vascular, Inc.

Date: February 25, 2021

By: Joseph P. Pellegrino, Jr.
/s/ JOSEPH P. PELLEGRINO, JR.
Joseph P. Pellegrino, Jr.
Chief Financial Officer

Exhibit 99.1

LeMaitre Q4 2020 Financial Results

BURLINGTON, MA, February 25, 2021 - LeMaitre (Nasdaq:LMAT), a provider of vascular devices, implants and services, today reported Q4 2020 results and announced an $0.11/share quarterly dividend.

Q4 2020 Results

- Sales of $37.5mm, +24% (+3% organic) vs. Q4 2019
- Op. income of $9.5mm, +94%
- Op. margin of 25%
- Net income of $7.0mm, +52%
- Earnings of $0.34 per diluted share, +51%
- EBITDA of $11.9mm, +84%
- Debt paid down $21.5mm to $39.0mm

The Company posted sales growth in the Americas (+35%), Asia/Pac (+12%) and Europe/Middle East/Africa (+9%). The three recent acquisitions (Artegraft, CardioCel and Eze-Sit) led growth in Q4 2020. By product, biologic grafts, valvulotomes and embolectomy catheters drove sales.

Gross margin decreased to 65.0% in Q4 2020 (vs. 66.0% in Q4 2019) primarily due to recent acquisitions and factory transitions.

Operating expenses decreased 1% to $14.9mm in Q4 2020 (vs. $15.0mm). The decline was driven by COVID-related cost-cuts as well as reduced travel and surgeon congresses.

Chairman & CEO George LeMaitre said “For Q4, record sales combined with expense control to produce healthy bottom-line results and an improved balance sheet. For 2020 we reported 10% sales growth and 36% op. income growth. 2021 marks a decade of yearly dividend growth at LeMaitre.”

Business Outlook

	Guidance
Q1 2021 Sales	$33.8mm - $36.8mm (Midpoint:+16%)
Q1 2021 Gross Margin	66.7%
Q1 2021 Operating Income	$6.8mm - $8.8mm (Midpoint:+79%)
Q1 2021 Earnings Per Share	$0.24 - $0.31 (Midpoint: +78%)

Quarterly Dividend

On February 23, 2021, the Company's Board of Directors approved a quarterly dividend of $0.11/share of common stock. The dividend will be paid on March 25, 2021 to shareholders of record on March 9, 2021.

Share Repurchase Program

On February 23, 2021, the Company's Board of Directors authorized the repurchase of up to $15.0mm of the Company’s common stock. The repurchase program may be suspended or discontinued at any time and will conclude on February 22, 2022, unless extended by the Board.

Conference Call Reminder

Management will conduct a conference call at 5:00 p.m. ET today. The conference call will be broadcast live over the Internet. Individuals interested in listening to the webcast can log on to the Company's website at www.lemaitre.com/investor. The conference call may also be accessed by dialing 844-239-5284 (+1 512-961-6497 for international callers), using passcode 8429679. For individuals unable to join the live conference call, a replay will be available on the Company's website.

A reconciliation of GAAP to non-GAAP results is included in the tables attached to this release.

About LeMaitre Vascular

LeMaitre is a provider of devices, implants and services for the treatment of peripheral vascular disease, a condition that affects more than 200 million people worldwide. The Company develops, manufactures and markets disposable and implantable vascular devices to address the needs of its core customer, the vascular surgeon.

For more information about the Company, please visit http://www.lemaitre.com.

Use of Non-GAAP Financial Measures

LeMaitre Vascular management believes that in order to better understand the Company's short-term and long-term financial trends, investors may wish to consider certain non-GAAP financial measures as a supplement to financial performance measures prepared in accordance with GAAP. Non-GAAP financial measures are not based on a comprehensive set of accounting rules or principles and do not have standardized meanings. These non-GAAP measures result from facts and circumstances that may vary in frequency and/or impact on continuing operations. Non-GAAP measures should be considered in addition to, and not as a substitute for, financial performance measures in accordance with GAAP. In addition to the description provided below, reconciliation of GAAP to non-GAAP results is provided in the financial statement tables included in this press release.

In this press release, the Company has reported non-GAAP sales growth percentages after adjusting for the impact of foreign currency exchange, business development transactions, and/or other events as well as EBITDA or earnings before interest, taxes, depreciation and amortization. The Company refers to the calculation of non-GAAP sales growth percentages as "organic." The Company analyzes non-GAAP sales on a constant currency basis, net of acquisitions and other non-recurring events, and EBITDA to better measure the comparability of results between periods. Because changes in foreign currency exchange rates have a non-operating impact on net sales, and acquisitions, divestitures, product discontinuations, and other strategic transactions are episodic in nature and are highly variable to the reported sales results, the Company believes that evaluating growth in sales on a constant currency basis net of such transactions provides an additional and meaningful assessment of sales to management. The Company believes that evaluating EBITDA provides an approximation of the cash generating ability of its operations.

Forward-Looking Statements

The Company's current financial results, as discussed in this release, are preliminary and unaudited, and subject to adjustment. This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Statements in this press release regarding the Company's business that are not historical facts may be "forward-looking statements" that involve risks and uncertainties. Forward-looking statements are based on management's current, preliminary expectations and are subject to risks and uncertainties that could cause actual results to differ from the results expected, including, but not limited to, the status of our global regulatory approvals and compliance with foreign regulatory requirements to market and sell our products outside the United States; the duration of the lapse in CE mark approval for certain of our devices; the closure of an audit by one of our notified bodies in support of the issuance and/or maintenance of CE marks covering certain of our products or the failure of such audit to be successfully closed; the duration and severity of the impact of COVID-19 on the global economy, our customers, our suppliers and our company; the risk of significant fluctuations in our quarterly and annual results due to numerous factors; the risk that assumptions about the market for the Company’s products and the productivity of the Company’s direct sales force and distributors may not be correct; the risk that we may not be able to maintain our recent levels of profitability; the risk that the Company may not realize the anticipated benefits of its strategic activities; risks related to the integration of acquisition targets; the acceleration or deceleration of product growth rates; risks related to product demand and market acceptance of the Company’s products and pricing; the risk that a recall of our products could result in significant costs or negative publicity; the risk that the Company is not successful in transitioning to a direct-selling model in new territories and other risks and uncertainties included under the heading "Risk Factors" in our most recent Annual Report on Form 10-K, as updated by our subsequent filings with the SEC, which are all available on the Company's investor relations website at http://www.lemaitre.com and on the SEC's website at http://www.sec.gov. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. The Company undertakes no obligation to update publicly any forward-looking statements to reflect new information, events, or circumstances after the date they were made, or to reflect the occurrence of unanticipated events.

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LEMAITRE VASCULAR, INC (NASDAQ: LMAT)
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands)

	December 31, 2020 (unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 26,764	$ 11,786
Short-term marketable securities	214	20,895
Accounts receivable, net	19,552	16,572
Inventory and other deferred costs	45,115	39,527
Prepaid expenses and other current assets	2,618	3,312
Total current assets	94,263	92,092
Property and equipment, net	15,036	14,854
Right-of-use leased assets	16,066	15,208
Goodwill	65,945	39,951
Other intangibles, net	58,905	24,893
Deferred tax assets	1,686	1,084
Other assets	909	259
Total assets	$ 252,810	$ 188,341
Liabilities and stockholders' equity		
Current liabilities:		
Current portion of long-term debt	$ 2,500	$ -
Accounts payable	2,394	2,604
Accrued expenses	17,525	14,014
Acquisition-related obligations	772	2,476
Lease liabilities - short-term	1,954	1,757
Total current liabilities	25,145	20,851
Long-term debt	35,532	-
Lease liabilities - long-term	14,791	13,955
Deferred tax liabilities	127	1,179
Other long-term liabilities	4,643	4,215
Total liabilities	80,238	40,200
Stockholders' equity		
Common stock	221	217
Additional paid-in capital	114,924	105,934
Retained earnings	70,554	57,029
Accumulated other comprehensive loss	(1,525)	(4,007)
Treasury stock	(11,602)	(11,032)
Total stockholders' equity	172,572	148,141
Total liabilities and stockholders' equity	$ 252,810	$ 188,341

LEMAITRE VASCULAR, INC (NASDAQ: LMAT)
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(amounts in thousands, except per share amounts)
(unaudited)

	For the three months ended		For the year ended	
	December 31, 2020	**December 31, 2019**	**December 31, 2020**	**December 31, 2019**
Net sales	$ 37,548	$ 30,170	$ 129,366	$ 117,232
Cost of sales	13,146	10,262	44,748	37,379
Gross profit	24,402	19,908	84,618	79,853
Operating expenses:				
Sales and marketing	5,912	7,452	23,700	30,339
General and administrative	6,076	5,029	22,501	19,055
Research and development	2,869	2,499	10,099	9,276
Gain on sale of building	-	-	(470)	-
Total operating expenses	14,857	14,980	55,830	58,670
Income from operations	9,545	4,928	28,788	21,183
Other income:				
Interest expense	(579)	-	(1,310)	-
Other income (loss), net	(35)	260	(122)	496
Income before income taxes	8,931	5,188	27,356	21,679
Provision for income taxes	1,898	575	6,136	3,745
Net income	$ 7,033	4,613	$ 21,220	17,934
Earnings per share of common stock				
Basic	$ 0.35	0.23	$ 1.05	0.91
Diluted	$ 0.34	0.23	$ 1.04	0.88
Weighted - average shares outstanding:				
Basic	20,380	20,054	20,246	19,813
Diluted	20,621	20,484	20,479	20,326
Cash dividends declared per common share	$ 0.095	0.085	$ 0.380	0.340

LEMAITRE VASCULAR, INC (NASDAQ: LMAT)
SELECTED NET SALES INFORMATION
(amounts in thousands)
(unaudited)

	For the three months ended				For the year ended			
	December 31, 2020		December 31, 2019		December 31, 2020		December 31, 2019	
	$	%	$	%	$	%	$	%
Net Sales by Geography								
Americas	$ 24,008	64%	$ 17,775	59%	$ 81,470	63%	$ 69,359	59%
Europe/Middle East/Africa	10,854	29%	10,001	33%	39,193	30%	39,480	34%
Asia/Pacific Rim	2,686	7%	2,394	8%	8,703	7%	8,393	7%
Total Net Sales	$ 37,548	100%	$ 30,170	100%	$ 129,366	100%	$ 117,232	100%

LEMAITRE VASCULAR, INC (NASDAQ: LMAT)
NON-GAAP FINANCIAL MEASURES
(amounts in thousands)
(unaudited)

Reconciliation between GAAP and Non-GAAP sales growth:			
For the three months ended December 31, 2020			
Net sales as reported	$ 37,548		
Impact of currency exchange rate fluctuations	(792)		
Net impact of acquisitions excluding currency	(5,705)		
Adjusted net sales		$ 31,051	
For the three months ended December 31, 2019			
Net sales as reported	$ 30,170		
Adjusted net sales		$ 30,170	
Adjusted net sales increase for the three months ended December 31, 2020		$ 881	3%

Reconciliation between GAAP and non-GAAP debt outstanding:			
As of December 31, 2020			
Debt as reported	$ 38,032		
Add back unamortized deferred financing costs	968		
Adjusted debt outstanding		$ 39,000	

	For the three months ended		For the year ended	
	December 31, 2020	December 31, 2019	December 31, 2020	December 31, 2019
Reconciliation between GAAP and Non-GAAP EBITDA				
Net income as reported	$ 7,033	$ 4,613	$ 21,220	$ 17,934
Interest (income) expense, net	565	(123)	1,103	(698)
Amortization and depreciation expense	2,447	1,441	8,224	5,416
Provision for income taxes	1,898	575	6,136	3,745
EBITDA	$ 11,943	$ 6,506	$ 36,683	$ 26,397
EBITDA percentage increase		84%		39%