

LEMAITRE VASCULAR INC
Form 8-K
December 08, 2009

**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): 12/04/2009

LeMaitre Vascular, Inc.

(Exact name of registrant as specified in its charter)

Commission File Number: 001-33092

Delaware
(State or other jurisdiction of
incorporation)

04-2825458
(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))
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Item 8.01. Other Events

In May 2008, the Company submitted an investigational device exemption (IDE) application to the FDA to begin a feasibility study, which the Company calls the ENTRUST Trial, to evaluate the safety of the TAArget Thoracic Stent Graft in the treatment of thoracic aortic aneurysms in the descending aorta. Because the TAArget Thoracic Stent Graft is a "significant risk" device for regulatory purposes, the United States Food and Drug Administration (FDA) must approve the IDE application prior to the start of the ENTRUST Trial. On December 4, 2009, the Company received conditional approval from the FDA to commence the ENTRUST Trial, provided that the Company resolves the issues identified in the conditional approval letter to the FDA's satisfaction. The Company intends to work with the FDA to resolve these issues, although there can be no assurance that the FDA will fully approve the IDE application.

The Company intends to enroll 30 patients at up to four centers. These patients must be followed for at least six months prior to the Company's application to the FDA for an IDE supplement to conduct a pivotal study in support of a potential premarket application (PMA) approval. The primary effectiveness endpoint of the study is based on endoleak occurrence, aneurysm size change, device migration, aneurysm exclusion, and aneurysm rupture as evaluated through six-month follow-up. The primary safety endpoint of the study is based on major adverse event occurrence as evaluated through six-month follow-up. The ENTRUST Trial compares the safety and efficacy of the TAArget Thoracic Stent Graft against open surgical thoracic aorta repair.

Forward-Looking Statements

This Current Report on Form 8-K contains forward looking statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to the enrollment in the ENTRUST Trial, the likelihood that the ENTRUST study will successfully meet its endpoints and the possibility of receiving approval for the sale of the TAArget Thoracic Stent Graft in the United States. Although the Company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, these forward-looking statements are neither promises nor guarantees. There can be no assurance that the results of the ENTRUST Trial will support an IDE supplement or a PMA or that the FDA will approve the TAArget Thoracic Stent Graft for sale the United States. The Company's business is subject to significant risks and uncertainties and there can be no assurance that its actual results will not differ materially from its expectations. These risks and uncertainties include, among others: the risk that the results of the Company's ENTRUST Trial will be unfavorable; the risk that these results, even if favorable, will not be accepted by the FDA or other relevant agencies and the device will not be approved for sale in the relevant timeframe, if at all; risks associated with the Company's ability to successfully commercialize its TAArget Thoracic Stent Graft in the United States if the device is approved for use in the United States; and other risk factors that are discussed in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission. The forward-looking statements made in this Current Report on Form 8-K are made only as of the date hereof and the Company disclaims any intention or responsibility for updating predictions or expectations contained in this release.

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 hereunto duly authorized.

LeMaitre Vascular, Inc.

Date: December 08, 2009

By: /s/ Aaron M. Grossman

Aaron M. Grossman
Secretary

