GLOBUS MEDICAL INC
Form 8-K
October 15, 2013

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): September 27, 2013

GLOBUS MEDICAL, INC.
(Exact name of registrant as specified in charter)

DELAWARE	001-35621	04-3744954
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2560 GENERAL ARMISTEAD AVENUE, AUDUBON, PA 19403
(Address of principal executive offices) (Zip Code)
(610) 930-1800
(Registrant's telephone number, including area code)

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:

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

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

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

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

Item 8.01. Other Events.

On September 27, 2013, Globus Medical, Inc. (the "Company") received a warning letter, dated September 26, 2013, from the U.S. Food and Drug Administration (the "FDA") following an inspection by the FDA at the Company's Audubon, PA facility.

In the warning letter, the FDA cited deficiencies in the response letter sent by the Company to the FDA following the Form 483, List of Investigational Observations, which was delivered to the Company in connection with the inspection that occurred from May 7, 2013 until June 4, 2013. These deficiencies relate to the Company's MicroFuse® Putty manufactured between October 25, 2012 and December 20, 2012, and mechanical testing of the Company's MicroFuse® Putty, procedures to control environmental conditions in a clean room at the Company's facility, and internal procedures for medical device reporting. The warning letter does not restrict the Company's ability to manufacture or seek 510(k) clearance of products.

The Company is currently addressing the deficiencies cited by the FDA in the warning letter and intends to work expeditiously to address each of the outstanding issues. The Company believes that the FDA's concerns set forth in the warning letter can be resolved without a material impact to the Company's financial results. However, the Company cannot give any assurances that the FDA will be satisfied with its response to the warning letter or its proposed resolution of the outstanding issues.

This Form 8-K may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are forward-looking statements. We have tried to identify forward-looking statements by using words such as "believe," "may," "might," "could," "will," "aim," "estimate," "continue," "anticipate," "intend," "expect," "plan" and similar words. These forward-looking statem based on our current assumptions, expectations and estimates of future events and trends. Forward-looking statements are only predictions and are subject to many risks, uncertainties and other factors that may affect our businesses and operations and could cause actual results to differ materially from those predicted. These risks and uncertainties include, but are not limited to, risks related to regulatory approvals, the effects of FDA regulatory requirements, and our ability to address issues raised by FDA inspections adequately and on a timely basis without a resulting recall of product or interruption of manufacturing or shipment of products. Forward-looking statements contained in this Form 8-K should be considered in light of these factors and those factors discussed from time to time in the Company's public reports filed with the Securities and Exchange Commission, such as those discussed under the heading, "Risk Factors," in the Company's most recent annual report on Form 10-K and those discussed in other documents the Company with the Securities and Exchange Commission. Given these risks and uncertainties, readers are cautioned not to place undue reliance on any forward-looking statements. Forward-looking statements contained in this Form 8-K speak only as of the date of this Form 8-K. We undertake no obligation to update any forward-looking statements as a result of new information, events or circumstances or other factors arising or coming to our attention after the date hereof.

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.

GLOBUS MEDICAL, INC.
(Registrant)

Dated: October 15, 2013

/s/ ANTHONY L. WILLIAMS

Anthony L. Williams
Vice President,
Corporate Counsel and Secretary