

GLOBUS MEDICAL INC
Form 8-K
November 13, 2018

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): October 31, 2018

GLOBUS MEDICAL, INC.

(Exact name of registrant as specified in charter)

DELAWARE 001-35621 04-3744954
(State or other jurisdiction (Commission (IRS Employer
of incorporation) File Number) 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 (see General Instruction A.2. below):

☐ 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 check mark whether the registrant is an emerging growth company as defined in 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 (§240.12b-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.

Item 8.01. Other Events.

On October 31, 2018, Globus Medical, Inc. received a warning letter from the U.S. Food and Drug Administration (the “FDA”) resulting from an inspection of the facilities of Human Biologics of Texas, a subsidiary of Globus Medical, located in San Antonio, Texas, in April 2018. The letter describes observed non-conformities to regulations for human cells, tissues, and cellular and tissue-based products relating to one allograft tissue product processed by Human Biologics of Texas and sold to end users by Globus Medical. We take the matters identified in the warning letter seriously, are working diligently to address the FDA’s observations, and intend to respond in the specified time period. We believe that the FDA’s concerns set forth in the warning letter can be resolved without a material impact to our financial results. We cannot, however, give any assurances that the FDA will be satisfied with our response or as to the expected date of the resolution of the matters included in the warning letter. Until the issues cited in the warning letter are resolved to the FDA’s satisfaction, additional legal or regulatory action may be taken without further notice. Any adverse action by the FDA, depending on its magnitude, may restrict us from effectively producing, marketing and selling the product that is the subject matter of the warning letter and could have a material adverse effect on our business, financial condition and results of operations.

Safe Harbor Statements

Statements included in this report other than statements of historical fact are forward-looking statements and may be identified by their use of words such as “believe,” “may,” “might,” “could,” “will,” “aim,” “estimate,” “continue,” “anticipate,” “expect,” “plan” and other similar terms. Particularly, our statements regarding our response to the FDA, our ability to resolve the FDA’s concerns without a material impact on our financial results, and the impact of any further action by the FDA are forward-looking statements. These forward-looking statements are 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: November 13, 2018 /s/ DANIEL T. SCAVILLA

Daniel T. Scavilla
Executive Vice President,
Chief Financial Officer
Chief Commercial Officer