

GLOBUS MEDICAL INC
Form 8-K
May 17, 2017

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): May 17, 2017 (May 15, 2017)

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:

☐ 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 May 15, 2017, Globus Medical, Inc. (“Globus” or the “Company”) received a letter from the Food & Drug Administration (“FDA”) informing us that the Company had not sufficiently addressed the FDA’s questions regarding the Company’s 510(k) submission for the ExcelsiusGPSSM robotic guidance and navigation system (“ExcelsiusGPSSM”) within the FDA review period required for clearance under the rules governing the 510(k) process. Consequently, the Company intends to file a revised 510(k) submission for ExcelsiusGPSTM in an expedited fashion. We remain confident in our ability to adequately satisfy all of the issues identified by the FDA. Globus had previously estimated that it was likely to receive FDA clearance to market ExcelsiusGPSTM in the second calendar quarter of 2017. In light of the FDA correspondence, the Company no longer anticipates obtaining FDA clearance for ExcelsiusGPSTM during the second calendar quarter.

The Company reaffirms guidance for full year 2017 sales of \$625 million and non-GAAP fully diluted earnings per share of \$1.27.

Cautionary Note Concerning Forward-Looking Statements

This Current Report on Form 8-K contains 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 included in this Form 8-K other than statements of historical fact are forward-looking statements and may be identified by their use of words such as “anticipate,” “intend,” “expect,” “remain confident,” “reaffirms guidance” and other similar terms. 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, factors affecting our quarterly results, demand for our products, our ability to compete successfully (including without limitation our ability to convince surgeons to use our products and our ability to attract and retain sales and other personnel), our ability to rapidly develop and introduce new products, our ability to develop and execute on successful business strategies, our ability to comply with laws and regulations that are or may become applicable to our businesses, our ability to safeguard our intellectual property, our success in defending legal proceedings brought against us, trends in the medical device industry, general economic conditions, and other risks. For a discussion of these and other risks, uncertainties and other factors that could affect our results, you should refer to the disclosure contained in our most recent annual report on Form 10-K filed with the Securities and Exchange Commission, including the sections labeled “Risk Factors” and “Cautionary Note Concerning Forward-Looking Statements,” and in our Forms 10-Q, Forms 8-K and other filings with the Securities and Exchange Commission. These documents are available at www.sec.gov. Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for us to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. 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 filing. 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: May 17, 2017 /s/ DANIEL T. SCAVILLA

Daniel T. Scavilla
Senior Vice President,
Chief Financial Officer