

WEST PHARMACEUTICAL SERVICES INC

Form 8-K

February 01, 2019

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 1, 2019

WEST PHARMACEUTICAL SERVICES, INC.

(Exact name of registrant as specified in its charter)

Pennsylvania  
(State or other jurisdiction  
of Incorporation)

1-8036  
(Commission File Number)

23-1210010  
(IRS Employer  
Identification No.)

530 Herman O. West Drive, Exton, PA  
(Address of principal executive offices)

19341-0645  
(Zip Code)

Registrant's telephone number, including area code: 610-594-2900

Not Applicable

(Former name or 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 (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 Rule 405 of the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2).

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 2.02 Results of Operations and Financial Condition

The information set forth in “Item 7.01 Regulation FD Disclosure” is incorporated herein by reference.

## Item 7.01 Regulation FD Disclosure

West has issued a voluntary recall of the Vial2Bag®; Vial2Bag® DC 13 mm; and Vial2Bag® DC 20 mm devices, manufactured by our wholly-owned subsidiary in Israel (previously known as MediMop Medical Projects Ltd.), to all end-user facilities. The recall is due to isolated reports of the prescribed drug dosage being unpredictable or variable when administered with the Vial2Bag DC 13 mm device. With an ongoing internal investigation of the Vial2Bag DC 13 mm device underway, and in an abundance of caution for patient safety, we are recalling the three devices while we continue our root cause analysis. Ensuring the quality of our products and the safety of the patients utilizing them is our top priority. We will continue to work to understand the reports and, in consultation with the United States Food and Drug Administration and other regulatory bodies, work to resupply the market as soon as is reasonably possible.

Before the impact of the ongoing recall, we estimate that full-year 2018 sales of Vial2Bag products would have been less than \$25 million. As stated earlier, we are voluntarily recalling Vial2Bag products that are in inventories at customers and distributors.

The information contained in this Current Report on Form 8-K under Items 2.02 and 7.01 is being furnished pursuant to Item 2.02 and Item 7.01 of Form 8-K and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section. The information contained in this Current Report on Form 8-K under Items 2.02 and 7.01 shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific referencing in such filing.

## Forward-Looking Statements

Certain forward-looking statements are included in this Current Report on Form 8-K. They use such words as “will,” “continue,” “estimate,” “would have been,” and other similar terminology. These statements reflect management’s current expectations regarding future events and operating performance and speak only as of the date of this document. There is no certainty that actual results will be achieved in-line with current expectations. These forward-looking statements involve a number of risks and uncertainties. The following are some of the factors that could cause our actual results to differ materially from those expressed in or underlying our forward-looking statements: our analysis of the root cause of the circumstances relating to the voluntary recall is still underway and we cannot predict the time or expense required to address the issues; our estimates of the impact on our financial results related to the voluntary recall are preliminary and subject to change as we conduct further analysis; the voluntary recall and the related circumstances could subject us to claims or proceedings which may adversely impact our net sales and net income, as well as harm our reputation and customer relationships or distract management from operating our business. This list of important factors is not all inclusive. For a description of certain additional factors that could cause the Company’s future results to differ from those expressed in any such forward-looking statements, see Item 1A, entitled “Risk Factors,” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017 and as revised or supplemented by our quarterly reports on Form 10-Q.

Except as required by law or regulation, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events, or otherwise.



SIGNATURE

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.

WEST PHARMACEUTICAL SERVICES, INC.

/s/ Bernard J. Birkett  
Bernard J. Birkett  
Senior Vice President and Chief Financial Officer

February 1, 2019