

AMERISOURCEBERGEN CORP

Form 8-K

November 06, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): November 6, 2018

AmerisourceBergen Corporation

(Exact name of registrant as specified in its charter)

Delaware

1-16671

(State or other jurisdiction of

(Commission File Number)

incorporation)

23-3079390

(IRS

Employer

Identification

No.)

1300 Morris Drive

Chesterbrook, PA 19087

(Address of principal executive offices, including Zip Code)

(610) 727-7000

(Registrant's telephone number, including area code)

Not Applicable

(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))

Indicate by check mark whether the registrant is an emerging growth company 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 7.01. Regulation FD Disclosure.

AmerisourceBergen Corporation (the "Company") today provided the following update regarding its subsidiary PharMEDium.

Following inspections of PharMEDium's 503B outsourcing facilities by the U.S. Food and Drug Administration (FDA) in the first and second quarters of fiscal 2018 and in response to observations in the FDA's Form 483 reports, PharMEDium has taken and is continuing to take corrective actions across its facilities. As previously disclosed, among other actions, PharMEDium voluntarily suspended production activities in December 2017 at its largest compounding facility located in Memphis, Tennessee pending execution of certain remedial measures.

PharMEDium's actions have included deployment of third party compliance monitors at all locations and, in response to feedback from the FDA, engagement of independent current good manufacturing practices experts to audit the Memphis facility. As previously disclosed, the independent audit report was submitted to the FDA on September 5, 2018 and PharMEDium submitted its evaluation of the audit report and its planned actions with respect thereto to the FDA on September 6, 2018.

Prior and subsequent to the Company's Form 8-K filed on September 5, 2018, PharMEDium has been engaged in active communications with the FDA (which, since November 1, 2018, also have included the Consumer Protection Branch of the Civil Division of the U.S. Department of Justice (DOJ)) about its remedial actions and FDA concerns, and has committed that it will not restart commercial operations at its Memphis, Tennessee facility pending further feedback from the FDA and DOJ. PharMEDium anticipates further communications with the FDA and the DOJ regarding FDA concerns at the Memphis, Tennessee facility and PharMEDium's other facilities. PharMEDium's priority is to demonstrate conclusively to the FDA its commitment to patient safety and to compliant aseptic compounding practices consistent with Section 503B of the Federal Food, Drug and Cosmetic Act. Currently, PharMEDium cannot determine when the FDA will consider its observations to be fully resolved, whether the FDA will impose additional requirements as a condition to the resumption of compounding for commercial distribution at the Memphis facility or whether the DOJ will initiate any enforcement actions on behalf of FDA against PharMEDium, which could include filing of a civil complaint, entry of a consent decree, or imposition of other penalties.

The Company's top priority remains patient safety and the Company is dedicated to achieving full regulatory compliance. There is compelling patient need and significant market demand for safe and effective compounded sterile preparation products. PharMEDium remains committed to being the market leader in quality and the trusted partner to its customers for their outsourced compounded sterile preparation needs.

Cautionary Note Regarding Forward-Looking Statements

Certain of the statements contained in this Current Report on Form 8-K are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Words such as "expect," "likely," "outlook," "forecast," "would," "could," "should," "can," "project," "intend," "plan," "continue," "s track," "believe," "seek," "estimate," "anticipate," "may," "possible," "assume," variations of such words, and similar expressions intended to identify such forward-looking statements. These statements are based on management's current expectations and are subject to uncertainty and change in circumstances. These statements are not guarantees of future performance and are based on assumptions that could prove incorrect or could cause actual results to vary materially from those indicated. Among the factors that could cause actual results to differ materially from those projected, anticipated, or implied are the following: unfavorable trends in brand and generic pharmaceutical pricing, including in rate or frequency of price inflation or deflation; competition and industry consolidation of both customers and suppliers resulting in increasing pressure to reduce prices for our products and services; changes in pharmaceutical

market growth rates; changes in the United States healthcare and regulatory environment, including changes that could impact prescription drug reimbursement under Medicare and Medicaid; increasing governmental regulations regarding the pharmaceutical supply channel and pharmaceutical compounding; declining reimbursement rates for pharmaceuticals; federal and state government enforcement initiatives to detect and prevent suspicious orders of controlled substances and the diversion of controlled substances; increased public concern over the abuse of opioid medications; prosecution or suit by federal, state and other governmental entities of alleged violations of laws and regulations regarding controlled substances, and any related disputes, including shareholder derivative lawsuits; increased federal scrutiny and litigation, including qui tam litigation, for alleged violations of laws and regulations governing the marketing, sale, purchase and/or dispensing of pharmaceutical products or services, and associated reserves and costs; material adverse resolution of pending legal proceedings; the retention of key customer or supplier relationships under less favorable economics or the adverse resolution of any contract or other dispute with customers or suppliers; changes to customer or supplier payment terms; risks associated with the strategic, long-term relationship between Walgreens Boots Alliance, Inc. and the Company, including principally with respect to the pharmaceutical distribution agreement and/or the global generic purchasing services arrangement; changes in tax laws or

legislative initiatives that could adversely affect the Company's tax positions and/or the Company's tax liabilities or adverse resolution of challenges to the Company's tax positions; regulatory action in connection with the production, labeling or packaging of products compounded by our compounded sterile preparations (CSP) business; suspension of production of CSPs, including continued suspension at our Memphis facility; managing foreign expansion, including non-compliance with the U.S. Foreign Corrupt Practices Act, anti-bribery laws and economic sanctions and import laws and regulations; financial market volatility and disruption; substantial defaults in payment, material reduction in purchases by or the loss, bankruptcy or insolvency of a major customer; the loss, bankruptcy or insolvency of a major supplier; changes to the customer or supplier mix; malfunction, failure or breach of sophisticated information systems to operate as designed; risks generally associated with data privacy regulation and the international transfer of personal data; natural disasters or other unexpected events that affect the Company's operations; the impairment of goodwill or other intangible assets (including with respect to foreign operations), resulting in a charge to earnings; the acquisition of businesses that do not perform as expected, or that are difficult to integrate or control, including the integration of H. D. Smith and PharMEDium, or the inability to capture all of the anticipated synergies related thereto or to capture the anticipated synergies within the expected time period; the effects of disruption from the transactions on the respective businesses of the Company and H. D. Smith and the fact that the transactions may make it more difficult to establish or maintain relationships with employees, suppliers, customers and other business partners; the disruption of the Company's cash flow and ability to return value to its stockholders in accordance with its past practices; interest rate and foreign currency exchange rate fluctuations; declining economic conditions in the United States and abroad; and other economic, business, competitive, legal, tax, regulatory and/or operational factors affecting the Company's business generally. Certain additional factors that management believes could cause actual outcomes and results to differ materially from those described in forward-looking statements are set forth (i) in Item 1A (Risk Factors) in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2017 and elsewhere in that report and (ii) in other reports filed by the Company pursuant to the Securities Exchange Act.

Regulation FD Disclosure

The information in this Current Report on Form 8-K is being furnished to the U.S. Securities and Exchange Commission and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section. This information shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

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.

AMERISOURCEBERGEN CORPORATION

Date: November 6, 2018 By: /s/ John G. Chou

Name: John G. Chou

Title: Executive Vice President and Chief Legal & Business Officer