

INVACARE CORP
Form 8-K
September 25, 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):
September 20, 2017

INVACARE CORPORATION

(Exact name of Registrant as specified in its charter)
Ohio 001-15103 95-2680965
(State or other Jurisdiction of (Commission File Number) (I.R.S. Employer
Incorporation or Organization) Identification Number)

One Invacare Way, Elyria, Ohio 44035
(Address of principal executive offices, including zip code)

(440) 329-6000
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, 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

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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 September 20, 2017, Alber GmbH, a wholly owned subsidiary of Invacare Corporation (the “company”), received a warning letter from the United States Food and Drug Administration (FDA). The warning letter requires completion of corrective actions to address the FDA Form 483 observations following an inspection of Alber’s facility in Albstadt, Germany in May 2017. As a consequence of the warning letter, Alber Twion Power Assist devices will not be imported into the United States until all findings are corrected to FDA's satisfaction. Although the company does not expect this action to have a significant impact on its financial results, it takes FDA’s observations very seriously and is working diligently to address these observations and respond to FDA’s warning letter in a timely manner.

This Current Report on Form 8-K contains forward-looking statements within the meaning of the “Safe Harbor” provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are those that describe future outcomes or expectations that are usually identified by words such as “will,” “should,” “could,” “plan,” “intend,” “expect,” “continue,” “forecast,” “believe,” and “anticipate” and include, for example, any statement made regarding the company's future results. Actual results may differ materially as a result of various risks and uncertainties, including the company’s inability to remediate, or delays in the remediation of, the violations noted in the FDA’s warning letter, and any resultant delays in the removal of the import suspension relating to the impacted products; additional regulatory actions or proceedings or the company's further failure to comply with regulatory requirements or receive regulatory clearance or approval for the company's products or operations; and those other risks and uncertainties expressed in the cautionary statements and risk factors in the company’s annual report on Form 10-K, quarterly reports on Form 10-Q and other filings with the Securities and Exchange Commission. The company may not be able to predict and may have little or no control over many factors or events that may influence its future results and, except as required by law, shall have no obligation to update any forward-looking statements.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INVACARE CORPORATION
(Registrant)

Date: September 25, 2017 By: /s/ Robert K. Gudbranson
Name: Robert K. Gudbranson
Title: Senior Vice President and
Chief Financial Officer