

INVACARE CORP
Form 8-K
December 14, 2015

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):
December 9, 2015

INVACARE CORPORATION

(Exact name of Registrant as specified in its charter)

| | | |
|---|--------------------------|--|
| Ohio | 001-15103 | 95-2680965 |
| (State or other Jurisdiction of Incorporation or Organization) | (Commission File Number) | (I.R.S. Employer Identification Number) |

One Invacare Way, P.O. Box 4028, Elyria, Ohio 44036
(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))

Item 8.01. Other Events.

Invacare Corporation (the “Company”) has received Form-483 observations following an inspection of its Corporate Headquarters and Taylor Street manufacturing facility in Elyria, Ohio, by the United States Food and Drug Administration (FDA). The FDA’s inspection included a review of the Company’s compliance with terms of the consent decree, including requirements of the first and second certifications previously reviewed and accepted in 2013.

The Company intends to respond to the FDA's inspectional findings as normally permitted. The Company remains focused on developing a strong enterprise-wide quality culture. It will incorporate the FDA’s observations into its ongoing quality system improvements.

About the Consent Decree

On December 21, 2012, the Company entered into a consent decree of injunction with the FDA related to the Company's Corporate Headquarters and Taylor Street manufacturing facility in Elyria, Ohio. The consent decree limits production at the Taylor Street manufacturing facility to orders meeting certain documentation requirements.

Under the terms of the consent decree, in order to resume full operations at the impacted Elyria facilities, the Company must successfully complete a third-party expert certification audit at the these facilities, which is comprised of three distinct reports that must be submitted to, and accepted by, the FDA. During 2013, the Company completed the first two of the expert certification audits, and the FDA found the results of both to be acceptable. The third expert certification audit is an overall review of the Company's compliance with the FDA's Quality System Regulation (QSR), which governs the manufacture of medical devices, at the impacted Elyria facilities. This audit process is the most comprehensive and challenging of the three expert certification audits, and it encompasses all areas of the Company's Corporate and Taylor Street quality system. After the final certification report is submitted to the FDA, as well as the Company’s own report as to its compliance status together with its responses to any observations in the certification report, the FDA will inspect the Company's Corporate and Taylor Street facilities to determine whether they are in compliance with the QSR and the terms of the consent decree. If the FDA is satisfied with the Company's compliance, the FDA will provide written notification that the Company is permitted to resume full operations at the impacted facilities. The timing of resuming full operations at these facilities cannot be predicted.

For more information about the consent decree, refer to the Company's Form 10-K and 10-Q filings with the Securities and Exchange Commission (SEC).

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.

INVACARE CORPORATION
(Registrant)

Date: December 14, 2015

By: /s/ Robert K. Gudbranson
Name: Robert K. Gudbranson
Title: Senior Vice President and Chief Financial Officer