INVACARE CORP
Form 8-K
June 08, 2016

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):
June 7, 2016

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)

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(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))

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Item 8.01. Other Events.

On June 7, 2016, Invacare Corporation (the "Company") received a letter from the United States Food and Drug Administration (the "FDA"). The letter was provided in follow up to the FDA's 2015 inspection of the Corporate and Taylor Street facilities in Elyria, Ohio, which included the matters covered by the first and second expert certification reports previously accepted in 2013, as well as the Form-483 observations issued by the FDA in December 2015 following the inspection (the "2015 Form-483"), and the Company's subsequent responses to the observations submitted to the FDA.

To satisfy FDA's design control requirements, the Agency has outlined additional steps the Company must take. In particular, the FDA has clarified its requirement for the Company to complete the remediation of certain design history files (DHFs) referenced in the 2015 Form-483 and in the consent decree. Before the Company can design any new Taylor Street wheelchair devices, the specified DHFs must be completed, then recertified by the Company's third-party expert, whose updated report must be accepted by the FDA. The FDA also has clarified that its acceptance of the expert's updated report on these DHFs is a prerequisite to proceeding further with the third certification process. The Company appreciates the clarity from the FDA's feedback, which is aligned with work already underway. The information received from the FDA provides helpful additional guidance and clarification for the actions needed to progress to the next phase of the certification process. The Company remains focused on developing a strong enterprise-wide quality culture as part of its long-term transformation. Without minimizing the FDA's feedback, the Company does not expect it to materially impact its anticipated financial results during this transformation.

Forward-Looking Statements

This Form 8-K contains forward-looking statements within the meaning of the "Safe Harbor" provisions of the Private Securities Litigation Reform Act of 1995. Terms such as "will," "should," "could," "plan," "intend," "expect," "continue," "be and "anticipate," as well as similar comments, denote forward-looking statements that are subject to inherent uncertainties that are difficult to predict. Actual results and events may differ significantly from those expressed or anticipated as a result of risks and uncertainties, which include, but are not limited to, the following: compliance costs, limitations on the production and/or distribution of the company's products, inability to bid on or win certain contracts, unabsorbed capacity utilization, including fixed costs and overhead, or other adverse effects of the company's consent decree of injunction with the U.S. Food and Drug Administration (FDA); any circumstances or developments that might delay or adversely impact the completion and acceptance of an updated second expert certification audit report, the FDA's acceptance of the third, most comprehensive expert certification audit report, FDA's acceptance of the company's own written report as required by the consent decree, or FDA's inspection of the company's quality systems at the Elyria, Ohio, facilities impacted by the consent decree, including any possible failure to comply with the consent decree or FDA regulations, requirement to perform additional remediation activities or further resultant delays in receipt of the written notification to resume operations; regulatory proceedings or the company's failure to comply with regulatory requirements or receive regulatory clearance or approval for the company's products or operations in the United States or abroad; adverse effects of regulatory or governmental inspections of company facilities at any time and governmental enforcement actions; product liability or warranty claims; product recalls, including more extensive recall experience than expected; the failure or refusal of customers or healthcare professionals to sign verification of medical necessity (VMN) documentation or other certification forms required by the exceptions to the FDA consent decree; possible adverse effects of being leveraged, including interest rate or event of default risks; exchange rate fluctuations, particularly in light of the relative importance of the company's foreign

operations to its overall financial performance; legal actions, including adverse judgments or settlements of litigation or claims in excess of available insurance limits; adverse changes in government and other third-party payor reimbursement levels and practices both in the U.S. and in other countries (such as, for example, more extensive pre-payment reviews and post-payment audits by payors, or the continuing roll out of the Medicare National Competitive Bidding program); impacts of the U.S. Affordable Care Act of 2010 (such as, for example, the impact on the company of the excise tax on certain medical devices, and the company's ability to successfully offset such impact); ineffective cost reduction and restructuring efforts or inability to realize anticipated cost savings or achieve desired efficiencies from such efforts; delays, disruptions or excessive costs incurred in facility closures or consolidations; interest rate or tax rate fluctuations; additional tax expense or additional tax exposures could affect the company's future profitability and cash flow; inability to design, manufacture, distribute and achieve market acceptance of new products with greater functionality or lower costs or new product platforms that deliver the anticipated benefits; consolidation of health care providers; lower cost imports; uncollectible accounts receivable; difficulties in implementing/upgrading Enterprise Resource Planning systems; risk of cybersecurity attack, data breach or data loss and/or delays in or inability to recover or restore data and IT systems; risks inherent in managing and operating businesses in many different foreign jurisdictions; decreased availability or increased costs of materials which could increase the company's costs of producing or acquiring the company's products, including possible increases in commodity costs or freight costs; heightened vulnerability to a hostile takeover attempt; provisions of Ohio law or in the company's debt agreements, charter documents or other agreements that may prevent or delay a change in control, as well as the risks described from time to time in the company's reports as filed with the Securities and Exchange Commission. Except to the extent required by law, the company does not undertake and specifically declines any obligation to review or update any forward-looking statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments or otherwise.

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: June 8, 2016 By: /s/ Anthony C. LaPlaca
Name: Anthony C. LaPlaca
Title: Senior Vice President, General Counsel and Secretary