INVACARE CORP
Form 8-K
December 23, 2013

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 23, 2013

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 December 23, 2013, Invacare Corporation (the “Company”) announced that, while it has made significant progress on the final third-party expert certification audit relating to the quality systems at its corporate and Taylor Street manufacturing facilities in Elyria, Ohio, it has recently received additional input from the third-party expert. This input has clarified that some additional work is required in a few particular areas before the final certification report can be provided to the United States Food and Drug Administration (FDA). The final third-party certification audit is a comprehensive review of the Company's compliance with the FDA's Quality System Regulation (QSR) at the impacted Elyria facilities. The Company has already completed two third-party expert certification audits, and the FDA has found the results of both to be acceptable. In the first two audits, the third-party expert certified that the Company's equipment and process validation procedures and its design control systems were compliant with the FDA's QSR.

At a meeting on Friday, December 20th, the third-party expert indicated that its remaining observations from the final certification audit are largely focused on the sustainable compliance of the Company’s updated complaint and risk review processes. As part of the remediation, the Company conducted a comprehensive overhaul of its complaint handling system. This change has led to an increase in the backlog of complaints, as the updated procedure now requires the funneling of all sources of complaint data through one system. The launch of this new process initially outpaced the Company’s ability to add and train new associates to thoroughly address and conduct standard investigations of complaint data. This backlog, combined with the breadth of Invacare’s product offerings and the complexity associated with its highly configurable medical devices, provided a challenge to the Company’s ability to investigate and close complaints in a timely manner, classify and code the issues when complaint data provided to the Company is not complete and demonstrate consistent use of the risk review process.

The new comprehensive complaint handling system has been operating for several months, and the Company has been closing significantly more complaints than are opened. The Company has added additional contractors to further expedite clearing the backlog in order to achieve and demonstrate sustainable improvement.

The Company is formalizing an action plan to address the observations of the third-party expert, who the Company would expect to return in February to commence their re-audit of the quality system. While the Company is disappointed that the final certification report is not ready to be filed, the Company has made significant progress in our quality systems improvements over the past two years. Notwithstanding the Company's extension of the timeline resulting from the complexities of this process, the fact remains that the Company's associates have done an incredible amount of work. The Company remains fully committed to meeting the expectations of the Company's third-party auditor and ultimately the FDA, so the Company can return to full operations at he Company's corporate and Taylor Street manufacturing facilities.

At this point, the Company cannot predict the timing of the completion of the third-party’s final certification report. However, when the expert's final certification report is completed and submitted to the FDA, along with the Company’s own report as to its compliance as well as 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 FDA's QSR. The FDA has the authority to reinspect these facilities at any time. Once 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 Company issued a press release relating to the announcement on December 23, 2013, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated December 23, 2013.

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 23, 2013

By: /s/ Robert K. Gudbranson

Robert K. Gudbranson
Senior Vice President and Chief Financial Officer

Exhibit Index

Exhibit Number	Description
99.1	Press Release, dated December 23, 2013