INVACARE CORP
Form 8-K
December 20, 2012

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 20, 2012

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 20, 2012, Invacare Corporation (the “Company”) announced that it has reached an agreement on the terms of a consent decree of injunction with the United States Food and Drug Administration (the “FDA”). The consent decree, which is subject to approval by the United States District Court for the Northern District of Ohio (the “Court”), relates to previously announced inspectional observations at the Company's corporate facility and its Taylor Street wheelchair manufacturing facility, both located in Elyria, Ohio. The terms of the consent decree, set forth in more detail below, limit production and certain design activities at the two Elyria facilities until they are certified as in compliance with FDA regulations by an independent, third-party expert and subsequently approved by the FDA. All other worldwide manufacturing facilities within the Company remain in full operation.

Pending the Court's approval, the terms of the consent decree include an injunction limiting the Company's Taylor Street facility and corporate facilities in Elyria, Ohio from conducting activities related to the manufacture and distribution of custom power and manual wheelchairs, wheelchair components and wheelchair sub-assemblies at or from the Taylor Street facility. The consent decree also temporarily limits design activities related to wheelchairs and power beds that take place at the Elyria facilities. The Company may continue to fulfill orders that are already in its order fulfillment systems at the time of the Court's approval of the consent decree, as long as the applicable healthcare provider completes a form certifying that he or she is aware of the decree and would still like the Company to fulfill the order. Additionally, the Company may manufacture and distribute a patient's replacement chair and/or seating system when a patient requests the same or newer version of his or her product and the patient's clinician submits a verification of medical necessity form that acknowledges the existence of the consent decree. The Company also may continue to manufacture and distribute power wheelchairs or seating systems from the Taylor Street facility if a clinician determines during the course of a clinical evaluation that the product is medically necessary for a particular patient's needs which cannot be addressed by another manufacturer's product, and the patient's clinician and physician complete and submit a verification of medical necessity form. Other exemptions from the injunction exist to allow for ongoing service, repair and warranty replacement of products already in use, as long as the provider completes a form certifying that he or she is aware of the consent decree and the parts and components will be used only for service or repair of Invacare wheelchairs already in use.

In order to resume full operations at the impacted Elyria sites, the Company must successfully complete a third-party expert certification audit that will be followed by an FDA inspection. The audit will review and certify the Company's compliance with the FDA's Quality System Regulation at the Taylor Street and corporate facilities. The audit is divided into three separate reports, which will allow the Company to resume certain activities on a serial basis while it continues to bring the remaining aspects of its quality system into compliance. First, the third-party expert will inspect the qualification and validation procedures and documentation for equipment and processes at the Taylor Street facility and submit a report to the FDA. Once the FDA has reviewed the report and notified the Company that it appears to be in compliance, which may or may not require an FDA inspection, the Company will be permitted to resume the manufacturing of components and parts at the Taylor Street facility for further manufacture of devices produced by other Company facilities. Second, the third party expert will review the Company's design control systems at the corporate and Taylor Street facilities. Once the FDA has reviewed the report and notified the Company that it appears to be in compliance, which may or may not require an FDA inspection, the Company will be able to resume design activities of wheelchairs and power beds at the impacted facilities. Finally, the third party expert will conduct a comprehensive review of the Company's compliance with the FDA's Quality System Regulation at the corporate and Taylor Street facilities, followed by an FDA inspection. Upon receipt of written notification from FDA that the facilities appear to be in compliance, the Company may resume full operations.

A copy of the Company's December 20, 2012 press release announcing the consent decree is attached as Exhibit 99.1, and a copy of the consent decree as filed with the Court is attached as Exhibit 99.2, both of which are incorporated herein by reference. The summary of the press release and the consent decree included herein does not purport to be complete or to contain all of the terms and conditions of the consent decree and is qualified in its entirety by reference to the actual terms of those documents.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated December 20, 2012.
99.2	Consent Decree of Permanent Injunction, as filed with the U.S. District Court for the Northern District of Ohio on December 20, 2012.

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 20, 2012

By: /s/ Anthony C. LaPlaca
Anthony C. LaPlaca
Senior Vice President and General Counsel

Exhibit Index

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