INSULET CORP
Form 8-K
June 10, 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): June 10, 2015 (June 8, 2015)
INSULET CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	001-33462	04-3523891
(State or Other Jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

600 Technology Park Drive
Suite 200
Billerica, Massachusetts 01821
(Address of Principal Executive Offices, including Zip Code)
Registrant's telephone number, including area code: (978) 600-7000
Not Applicable
(Former Name or Former Address, 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.

On June 8, 2015, Insulet Corporation (the Company) received a warning letter from the U.S. Food and Drug Administration (FDA) relating to observations noted during its March 2015 inspection of the Company's facility located in Billerica, MA. The issue noted in the warning letter relates to the Company's release of certain lots of EROS OmniPods that did not conform to final acceptance criteria. The lots identified in the warning letter were manufactured in mid-2013 and the first half of 2014.

On April 16, 2015, the Company submitted a response letter to a Form FDA 483, List of Inspectional Observations, received on March 27, 2015. In the June 2015 warning letter, the FDA stated that the corrective action plans implemented by the Company as referenced in its April response letter should address this issue. The FDA requests a description of the corrective actions and verification when complete, as well as information to demonstrate that the corrective actions have been effective. Insulet is required to respond within 15 days.

The Company takes these matters seriously and is committed to complying with all applicable laws, regulations and rules in connection with the manufacturing, sale and marketing of its products. The Company intends to respond to the issue raised in the FDA's letter within 15 days and is committed to resolving this issue with the FDA.

The Company believes this matter will not have an adverse impact on its ongoing business and operations.

Item 9.01. Financial Statement and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	FDA Warning Letter dated June 5, 2015, received by the Company on June 8, 2015

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Current Report on Form 8-K to be signed on its behalf by the undersigned thereunto duly authorized.

INSULET CORPORATION

June 10, 2015

By: /s/ Michael L. Levitz
Chief Financial Officer