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): May 26, 2026

INSULET CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	001-33462	04-3523891
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

100 Nagog Park		
Acton	Massachusetts	01720
(Address of principal executive offices)		(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 Par Value Per Share	PODD	The NASDAQ Stock Market, LLC

Item 7.01 Regulation FD Disclosure

On May 26, 2026, Insulet Corporation (the "Company") issued a press release announcing a voluntary Medical Device Correction for specific lots of Omnipod® products due to a manufacturing issue identified through ongoing product monitoring. A copy of the press release is furnished herewith.

This action is separate from the Company's March 12, 2026 voluntary Medical Device Correction.

The two actions involved different manufacturing processes, both of which were related to cannula tears associated with cannula handling at the Company's Acton, Massachusetts facility. In both cases, the Company identified the cause and implemented corrective actions designed to prevent recurrence. All product in scope of this correction was manufactured before the enhanced quality controls implemented in connection with the prior action were put in place.

Approximately 7 million Pods are included in scope, of which approximately 60% have been consumed or expired. Based on its current assessment, the Company does not anticipate disruption to customer shipments, product availability or new customer starts.

While it is too early to ascertain the exact cost of this voluntary medical device correction, the Company expects to incur up to $50 million of costs associated with this correction in 2026, which will be excluded from adjusted results. Accordingly, the Company does not expect an impact to its long-term growth profile and is not changing its previously issued 2026 guidance as a result of this voluntary action.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability of that section. The information in this Current Report shall not be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing or document.

Forward-Looking Statements

This current report on Form 8-K includes certain forward-looking statements within the meaning of the Private Litigation Securities Reform Act of 1995, as amended. Forward-looking statements relate to future events, including statements concerning the Company's plans or expectations regarding any voluntary medical device correction, effects of any voluntary medical device correction on the Company's business, operations, and financial performance or guidance, and expected costs of any voluntary medical device correction, and involve known and unknown risks, uncertainties and other factors, many of which are beyond the Company's control, that may cause the actual results, performance or achievements of the Company to be materially different from its current expectations, assumptions, plans, guidance, estimates and projections, including (but not limited to) the financial, operational, and reputational impact and costs of any voluntary medical device correction, future actions by the FDA and other regulatory bodies, the possibility that any voluntary medical device correction could subject the Company to disputes, claims or proceedings that may adversely affect its business and financial operation and other factors detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including those discussed under "Risk Factors" in the Company's Form 10-K for the year ended December 31, 2025. The Company encourages you to consider all of these risks, uncertainties and other factors carefully in evaluating the forward-looking statements contained in this report. The forward-looking statements made in this report are made only as of the date of this report, and the Company undertakes no obligation to update them to reflect subsequent events or circumstances except as required by applicable law.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

No.	Exhibit
99.1	Press Release dated May 26, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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

May 26, 2026

By: /s/ John W. Kapples
Name: John W. Kapples
Title: Senior Vice President, General Counsel

Exhibit 99.1

Insulet Initiates Voluntary Medical Device Correction for Certain Omnipod® Pods in the U.S. and Affected International Markets

ACTON, Mass., May 26, 2026 -- Insulet Corporation, Inc. (NASDAQ: PODD) ("Insulet" or the "Company") today announced a voluntary Medical Device Correction for specific lots of Omnipod® 5, Omnipod DASH®, and Omnipod® Insulin Management System (Omnipod Eros) Pods due to a manufacturing issue, identified through ongoing product monitoring, that could result in insulin under-delivery.

This action is separate from the voluntary Medical Device Correction issued on March 12, 2026 affecting certain Omnipod® 5 Pods in the U.S. and includes certain Pod lots distributed in the U.S. and affected international markets. Pods not included in the affected lots remain safe to use.

Insulet identified that some Pods from specific lots may have a small tear in the tubing (cannula) just above the skin, between the Pod and the point where the cannula enters the body. If this occurs, insulin may leak outside of the Pod instead of being fully delivered into the body as intended, potentially leading to under-delivery of insulin.

Individuals using an affected Pod may notice wetness on their skin or Pod adhesive or detect the smell of insulin. However, in some cases, this issue may be difficult to detect and go unnoticed.

If insulin is not delivered properly, users may experience high blood glucose levels due to under-delivery of insulin. In the most severe cases, prolonged and persistent high blood glucose levels can lead to diabetic ketoacidosis (DKA), a serious medical condition that requires prompt medical treatment and can be life-threatening if not treated.

Approximately 7 million Pods are included within the scope of this action, approximately 60% of which have been consumed or are expired. The Pods affected by this correction represent approximately 8.5% of 2025 global Omnipod Pod production. Globally, there have been 24 reports of serious adverse events associated with high blood glucose levels, including hospitalization and DKA. There have been no deaths reported.

This issue does **not** affect continuous glucose monitoring (CGM) systems or CGM readings.

The issue was identified through the company's ongoing product monitoring.

Insulet has identified the cause of this manufacturing issue and implemented corrective actions designed to prevent recurrence. In addition, the Company has further strengthened its in-process monitoring and quality controls designed to detect cannula tears of this nature.

Insulet is communicating proactively with affected customers and providing clear instructions to help them identify affected lots, discontinue use of impacted Pods, and obtain replacement Pods at no cost. The Company has sufficient supply available to replace affected Pods and does not anticipate any disruption to product availability.

The U.S. Food and Drug Administration (FDA) and all other relevant regulatory authorities have been notified of this action.

Important Information for Omnipod® Pod Users

Customers should visit Check Pod Lot (www.omnipod.com/mdc/check-pod-lot) to confirm whether their Pod lot number is included in this voluntary Medical Device Correction and request replacement Pods at no cost. A full list of affected lots is available on this site.

If a Pod from an affected lot is currently in use, customers should discontinue use and replace it with a Pod from an unaffected lot.

Customers in the U.S. who have questions or need assistance may contact Insulet Product Support at 1-800-641-2049 (available 24/7) or use the live agent chat at www.omnipod.com/current-podders.

Customers outside the U.S. should visit www.omnipod.com and click the banner at the top of the page for more information.

Forward-Looking Statement:

This press release includes certain forward-looking statements within the meaning of the Private Litigation Securities Reform Act of 1995, as amended. Forward-looking statements relate to future events, including statements concerning the Company's plans or expectations regarding any voluntary medical device correction and effects of any voluntary medical device correction on the Company's business, operations, and financial performance or guidance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond the Company's control, that may cause the actual results, performance or achievements of the Company to be materially different from its current expectations, assumptions, plans, guidance, estimates and projections, including (but not limited to) the financial, operational, and reputational impact and costs of any voluntary medical device correction, future actions by the FDA and other regulatory bodies, the possibility that any voluntary medical device correction could subject the Company to disputes, claims or proceedings that may adversely affect its business and financial operation and other factors detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including those discussed under "Risk Factors" in the Company's Form 10-K for the year ended December 31, 2025. The Company encourages you to consider all of these risks, uncertainties and other factors carefully in evaluating the forward-looking statements contained in this press release. The forward-looking statements made in this press release are made only as of the date of this press release, and the Company undertakes no obligation to update them to reflect subsequent events or circumstances except as required by applicable law.

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