

**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 2, 2019

INSULET CORPORATION

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33462
(Commission
File Number)

04-3523891
(IRS Employer
Identification No.)

100 Nagog Park
Acton, Massachusetts 01720
(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))

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.

Item 2.02. Results of Operations and Financial Condition.

On May 2, 2019, Insulet Corporation (the “Company”) announced its financial results for the first quarter ended March 31, 2019. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated May 2, 2019

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.

May 2, 2019

INSULET CORPORATION

By: /s/ Shacey Petrovic
Chief Executive Officer

Exhibit Index

Exhibit No.	Description
<u>99.1</u>	<u>Press Release dated May 2, 2019</u>

Insulet Reports First Quarter 2019 Revenue of \$159.6 Million, an Increase of 29% Year-Over-Year

Commenced Pod Production at U.S. Manufacturing Facility and Initiated Full U.S. Commercial Launch of Omnipod DASH™

ACTON, Mass.--(BUSINESS WIRE)--May 2, 2019--Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), the global leader in tubeless insulin pump technology with its Omnipod® Insulin Management System (Omnipod System), today announced financial results for the three months ended March 31, 2019.

First Quarter Financial Highlights:

- First quarter revenue of \$159.6 million, up 29%, compared to revenue of \$123.6 million in the prior year, exceeds guidance of \$152 to \$156 million
 - U.S. Omnipod revenue of \$86.1 million, an increase of 23%
 - International Omnipod revenue of \$56.9 million, an increase of 48%
 - Drug Delivery revenue of \$16.6 million, an increase of 11%
- Gross margin of 66.9%, up 550 basis points
- Operating income of \$7.3 million compared to operating break-even in the prior year
- Net income of \$4.4 million, or \$0.07 per diluted share, compared to a net loss of \$6.6 million, or \$(0.11) per share, in the prior year

Recent Strategic Highlights:

- Initiated full U.S. market release for Omnipod DASH™, including expanding pharmacy channel coverage
- Began production on our first highly-automated manufacturing line and officially commemorated the opening of the Company's new worldwide headquarters and manufacturing facility in Massachusetts

"Building on our outstanding performance in 2018, Insulet delivered strong financial results for the first quarter, including robust revenue growth, margin expansion and continued profitability," said Shacey Petrovic, President and Chief Executive Officer. "We are making great progress on many fronts, including the start-up of our highly-automated U.S. manufacturing, our Omnipod DASH full U.S. market release, and the corresponding shift to the pay-as-you-go model. We are particularly proud to have advanced all of these initiatives while driving first quarter revenue growth of 29%."

Ms. Petrovic continued, "Our outstanding performance is a clear indication that we are successfully executing on our strategic plan. We are increasing market access to our products, investing in our pipeline, expanding our global footprint, enhancing our operational capabilities, and creating substantial value for Insulet's shareholders. We are well on our way to delivering our 2021 financial targets of \$1 billion in revenue, 70% gross margin and mid-teens operating margin, reinforcing our confidence in Insulet's prospects for long-term, sustainable and profitable growth."

2019 Outlook:

- For the year ending December 31, 2019, the Company is raising its revenue guidance to a range of \$667 to \$690 million, compared to 2018 revenue of \$563.8 million, representing growth of 18% to 22%. This compares to previous expectations of \$662 to \$687 million, and growth of 17% to 22%. By product line:
 - U.S. Omnipod revenue expectations increased to a range of \$376 to \$385 million, representing growth of 16% to 19% (previously \$373 to \$383 million, and growth of 15% to 18%)
 - International Omnipod revenue expectations increased to a range of \$236 to \$244 million, representing growth of 37% to 42% (previously \$235 to \$244 million, and growth unchanged of 37% to 42%)
 - Drug Delivery revenue expectations increased to a range of \$55 to \$61 million, representing a decline of 11% to 19% (previously \$54 to \$60 million, a decline of 12% to 21%)
- For the quarter ending June 30, 2019, the Company expects revenue in the range of \$160 to \$165 million, compared to second quarter 2018 revenue of \$124.3 million, representing growth of 29% to 33%. By product line, the Company expects:
 - U.S. Omnipod revenue of \$89 to \$91 million, representing growth of 14% to 17%
 - International Omnipod revenue of \$57 to \$59 million, representing growth of 100% to 107%
 - Drug Delivery revenue of \$14 to \$15 million, a decline of 15% to 21%

Future results may be affected by changes in ongoing assumptions and judgments, and may also be affected by non-recurring, unusual or unanticipated charges, expenses or gains.

Conference Call:

Insulet will host a conference call at 4:30 p.m. (Eastern Time) on May 2, 2019 to discuss the financial results and outlook. The link to the live call will be available on the Investor Relations section of the Company's website at <http://investors.insulet.com>, "Events and Presentations", and will be archived for future reference. The call may also be accessed by dialing (844) 831-3022 for domestic callers or (315) 625-6887 for international callers, passcode 8408719.

About Insulet Corporation:

Insulet Corporation (NASDAQ: PDD), headquartered in Massachusetts, is an innovative medical device company dedicated to making the lives of people with diabetes and other conditions easier through the use of its Omnipod product platform. The Omnipod Insulin Management System provides a unique alternative to traditional insulin delivery methods. With its simple, wearable design, the disposable Pod provides up to three days of non-stop insulin delivery, without the need to see or handle a needle. Insulet also leverages the unique design of its Pod by tailoring its Omnipod technology platform for the delivery of non-insulin subcutaneous drugs across other therapeutic areas. For more information, please visit: www.insulet.com and www.myomnipod.com.

Forward-Looking Statement:

The 2019 financial results contained in this news release are subject to finalization in connection with the preparation of the Company's Form 10-Q for the quarter ended March 31, 2019. This press release contains forward-looking statements concerning Insulet's expectations, anticipations, intentions, beliefs or strategies regarding the future. These forward-looking statements are based on its current expectations and beliefs concerning future developments and their potential effects on Insulet. There can be no assurance that future developments affecting Insulet will be those that it has anticipated.

These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Insulet's control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: risks associated with the Company's dependence on its principal product platform, the Omnipod System; risks associated with the Company's ability to design, develop, manufacture and commercialize future products; Insulet's ability to reduce production costs and increase customer orders and manufacturing volumes; adverse changes in general economic conditions; impact of healthcare reform laws; Insulet's ability to raise additional funds in the future on acceptable terms or at all; potential supply problems or price fluctuations with sole source or third-party suppliers on which Insulet is dependent; the potential establishment of a competitive bid program for conventional insulin pumps; failure by Insulet to retain supplier pricing discounts and achieve satisfactory gross margins; failure by Insulet to retain key supplier and payor partners; international business risks; Insulet's inability to effectively operate the Company's business in Europe following the expiration of its distribution agreement with its European distributor on June 30, 2018; regulatory, commercial and logistics risks associated with the Company selling its products in Europe in light of the uncertainty related to the timing and terms of the separation of the United Kingdom from the European Union (Brexit); Insulet's inability to secure and retain adequate coverage or reimbursement from third-party payors for the Omnipod System or future products and potential adverse changes in reimbursement rates or policies relating to the Omnipod System or future products; failure to retain key payor partners and their members; potential adverse effects resulting from competition; technological change and product innovation adversely affecting the Company's business; potential changes to or termination of Insulet's license to incorporate a blood glucose meter into the Omnipod System or its inability to enter into new license or other agreements with respect to the Omnipod System's current or future features; challenges to the future development of our non-insulin drug delivery business; Insulet's ability to protect its intellectual property and other proprietary rights; conflicts with the intellectual property of third parties, including claims that Insulet's current or future products infringe or misappropriate the proprietary rights of others; adverse regulatory or legal actions relating to the Omnipod System or future products; failure of Insulet's contract manufacturers or component suppliers to comply with FDA's quality system regulations; the potential violation of international, federal or state laws prohibiting "kickbacks" or protecting the confidentiality of patient health information or other protected personal information, or any challenge to or investigation into Insulet's practices under these laws; product liability lawsuits that may be brought against Insulet; reduced retention rates of our customer base; unfavorable results of clinical studies relating to the Omnipod System or future products, or the products of Insulet's competitors; potential future publication of articles or announcement of positions by diabetes associations or other organizations that are unfavorable to the Omnipod System; the concentration of substantially all of Insulet's manufacturing operations at a single location in China and substantially all of Insulet's inventory at a single location in Massachusetts; Insulet's ability to attract and retain personnel; Insulet's ability to manage its growth; fluctuations in quarterly results of operations; risks associated with potential future acquisitions or investments in new businesses; Insulet's ability to generate sufficient cash to service all of its indebtedness; the expansion of Insulet's distribution network; Insulet's ability to successfully maintain effective internal control over financial reporting; the volatility of the trading price of Insulet's common stock; risks related to future sales of its common stock or the conversion of any of the Convertible Senior Notes; potential limitations on Insulet's ability to use its net operating loss carryforwards; anti-takeover provisions in its organizational documents; and other risks and uncertainties described in its Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission in February 2019 in the section entitled "Risk Factors," and in its other filings from time to time with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of its assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Insulet undertakes no obligation to publicly update or revise any forward-looking statements.

INSULET CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
(Unaudited) (In thousands, except per share data)	2019	2018
Revenue	\$ 159,555	\$ 123,578
Cost of revenue	52,859	47,763
Gross profit	106,696	75,815
Operating expenses:		
Research and development	31,954	20,267
Sales and marketing	41,616	33,049
General and administrative	25,861	22,499
Total operating expenses	99,431	75,815
Operating income	7,265	—
Interest expense and other, net	2,561	6,236
Income (loss) before income taxes	4,704	(6,236)
Income tax expense	326	333
Net income (loss)	\$ 4,378	\$ (6,569)
Net income (loss) per share:		
Basic	\$ 0.07	\$ (0.11)
Diluted	\$ 0.07	\$ —
Basic weighted-average number of shares outstanding	59,355	58,483
Diluted weighted-average number of shares outstanding	61,148	58,483

INSULET CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)
(In thousands)

	March 31,	December 31,
	2019	2018
ASSETS		
Cash, cash equivalents and short-term investments	\$ 316,374	\$ 288,946
Accounts receivable and unbilled receivable	78,158	76,672
Inventories	73,822	71,414
Prepaid expenses and other current assets	28,028	24,254
Total current assets	496,382	461,286
Long-term investments	76,789	140,784
Property and equipment, net	299,605	258,379
Goodwill and intangible assets, net	51,178	50,029
Other assets	28,658	18,266
Total assets	<u>\$ 952,612</u>	<u>\$ 928,744</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	\$ 26,833	\$ 25,500
Accrued expenses and other current liabilities	87,140	90,157
Total current liabilities	113,973	115,657
Convertible debt, net	599,601	591,978
Other long-term liabilities	15,408	9,010
Total liabilities	728,982	716,645
Stockholders' Equity	223,630	212,099
Total liabilities and stockholders' equity	<u>\$ 952,612</u>	<u>\$ 928,744</u>

CONTACT:

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