INSULET CORP
Form 10-K/A
February 28, 2019
Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K/A
(Amendment No. 1)
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number 001-33462
INSULET CORPORATION
(Exact name of Registrant as specified in its charter)

Delaware	04-3523891
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. 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
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $0.001 Par Value Per Share	The NASDAQ Stock Market, LLC

Securities registered pursuant to Section 12(g) of the Act:
None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No ¨
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer x Accelerated filer o Non-accelerated filer o Smaller reporting company o
(Do not check if a smaller reporting company)

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The aggregate market value of the common stock held by non-affiliates of the registrant computed by reference to the last reported sale price of the Common Stock as reported on The NASDAQ Global Market on June 30, 2018 was approximately $5.0 billion.

The number of shares outstanding of each of the registrant's classes of common stock as of February 20, 2019:

Title of Class	Shares Outstanding
Common Stock, $0.001 Par Value Per Share	59,278,993

Table of Contents

Explanatory Note

This Amendment No. 1 (this “Amendment”) amends the Annual Report on Form 10-K of Insulet Corporation (the "Company") for the year ended December 31, 2018, filed with the Securities and Exchange Commission on February 26, 2019 (the “Original Filing”). The sole purpose of this Amendment is to amend Part II, Item 7 (Management's Discussion and Analysis of Financial Condition and Results of Operations), to correct the final sentence of the second paragraph (the “Corrected Sentence”) under the heading “Liquidity and Capital Resources,” which relates to the Company’s expected capital expenditures for 2019 as compared to 2018. The Corrected Sentence clarifies that the Company currently expects capital expenditures in 2019 to be relatively consistent with 2018.

For ease of reference, the entire text of Part II, Item 7 is included in this Amendment, though the Corrected Sentence is the sole change to the disclosure contained in the Original Filing.

TABLE OF CONTENTS

Table of Contents

PART II

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Executive Level Overview

We are primarily engaged in the development, manufacturing and sale of our proprietary Omnipod System, an innovative, discreet and easy-to-use continuous insulin delivery system for people with insulin-dependent diabetes. There are two primary types of insulin therapy practiced today: MDI therapy using syringes or insulin pens; and pump therapy using insulin pumps. Insulin pumps are used to perform continuous subcutaneous insulin infusion, or insulin pump therapy, and typically use a programmable device and an infusion set to administer insulin into the person's body. Insulin pump therapy has been shown to provide people with insulin-dependent diabetes with numerous advantages relative to MDI therapy. We estimate that approximately one-third of the Type 1 diabetes population in the United States and less than one fifth of the Type 1 diabetes population outside of the United States use insulin pump therapy. An even smaller portion of the Type 2 diabetes population in the United States who are insulin-dependent use insulin pump therapy. The Omnipod System features a small, lightweight, self-adhesive disposable tubeless Omnipod device which is worn on the body for approximately three days at a time and its wireless companion, the handheld PDM. The Omnipod System, which features two discreet, easy-to-use devices, communicates wirelessly, provides for virtually pain-free automated cannula insertion and eliminates the need for traditional MDI therapy or the use of traditional pump and tubing. We believe that the Omnipod System's unique proprietary design and features allow people with insulin-dependent diabetes to manage their diabetes with unprecedented freedom, comfort, convenience, and ease.

We began commercial sale of the Omnipod in the United States in 2005. We sell the Omnipod through direct sales to customers or through our distribution partners. The Omnipod is currently available in multiple countries in Europe, as well as Canada and Israel. On July 1, 2018 we assumed all commercial activities (including, among other things, distribution, sales, marketing, training and support) for our Omnipod System across Europe following the expiration of our prior distribution agreement with our former European Distributor on June 30, 2018.

In addition to the diabetes market space, we have partnered with pharmaceutical and biotechnology companies to tailor the Omnipod System technology platform for the delivery of subcutaneous drugs across other therapeutic areas. The majority of our drug delivery revenue currently consists of sales of pods used in Amgen's Neulasta Onpro kit, an innovative delivery system for Amgen's white blood cell booster to help reduce the risk of infection during intense chemotherapy.

We have substantially completed the construction of a highly-automated manufacturing facility in Acton, Massachusetts, with planned production out of the facility beginning in the first half of 2019. The facility also serves as our global headquarters. We expect that, following start up related activities, the new facility will allow us to lower our manufacturing costs, increase supply redundancy, add capacity closer to our largest customer base and support growth. From the purchase of this facility in late 2016 through December 31, 2018, capital expenditures for the construction of the Acton facility and related equipment purchases have been approximately $193 million. In 2019, we expect to invest additional capital in this facility to support our growth funded by our existing cash and investments.

In January 2018, we announced that the Centers for Medicare & Medicaid Services ("CMS") has issued guidance clarifying that Medicare Part D Plan Sponsors may provide coverage for products such as the Omnipod System under the Medicare Part D (prescription drug) program. We have been securing coverage with Medicare Part D carriers to ensure beneficiaries living with diabetes have access to the Omnipod System. Securing Medicare Part D coverage also provides us with a direct pathway to increased Medicaid coverage at the state level, as many state-run Medicaid programs follow CMS prescription drug guidance to determine coverage. This allows access for lower-income individuals and families on Medicaid for whom Omnipod currently is not a covered option. In April 2018, we also significantly increased our market access when we secured in-network coverage of Omnipod with United Healthcare, the largest commercial payer in the United States.

In June 2018, the FDA provided clearance for the commercial distribution of our DASH ™ System, which is our next-generation digital mobile Omnipod platform, featuring a secured Bluetooth enabled Pod and PDM with a touch screen color user interface supported by smartphone connectivity. We commenced a U.S. limited commercial release

of Omnipod DASH ™ in the third quarter of 2018 prior to a U.S. full market launch in the first half of 2019.

2018 Revenue Results:

- Total revenue of $563.8 million
- U.S. Omnipod revenue of $323.5 million, a 19% increase year over year
- International Omnipod revenue of $172.0 million, a 43% increase year over year
- Drug Delivery revenue of $68.3 million, a 5% decrease year over year

Table of Contents

Our long-term financial objective is to sustain profitable growth. We expect our efforts in 2019 to focus primarily on commissioning our U.S. manufacturing facility, commencing a U.S. full market release of Omnipod DASH, continuing our product development efforts, and continuing to work with Medicare, Medicaid and commercial payors and intermediaries to expand access. Achieving these objectives is expected to require additional investments in certain initiatives and personnel, as well as enhancements to our supply chain operation capacity, efficiency and effectiveness.

Components of Financial Operations

Revenue. We derive the majority of our revenue from global sales of the Omnipod System. We also sell devices based on the Omnipod System technology to global pharmaceutical and biotechnology companies for the delivery of their drugs across therapeutic areas.

Cost of revenue. Cost of revenue consists primarily of raw material, labor, warranty, inventory scrap and excess and obsolescence adjustments, and overhead costs such as freight-in and depreciation and the cost of products we acquire from third party suppliers.

Research and development. Research and development expenses consist primarily of personnel costs, license fees and outside service expenses within our product development, regulatory and clinical functions and well as innovations related to our global supply chain and manufacturing process. Research and development expenses also include engineering and operational costs, such as training and start up activities, associated with our newly constructed U.S. manufacturing facility. We generally expense research and development costs as incurred.

Sales and marketing. Sales and marketing expenses consist primarily of personnel costs within our sales, marketing, reimbursement support and customer care functions, as well as sales commissions paid to our sales representatives, costs associated with promotional activities and participation in industry trade shows. Commission costs that are direct and incremental to obtaining a new customer are capitalized and amortized to sales and marketing expense over the expected period of benefit.

General and administrative. General and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, finance, legal, information technology and human resource functions, as well as legal fees, accounting fees, insurance costs, bad debt expenses, shipping, handling and facilities-related costs including depreciation of office facility-related property and equipment.

Table of Contents

Results of Operations

This section discusses our consolidated results of operations for 2018 compared to 2017, as well as 2017 compared to 2016, and should be read in conjunction with the consolidated financial statements and accompanying notes included under Item 8 of this Form 10-K.

TABLE 1: RESULTS OF OPERATIONS

	Years Ended December 31,				Years Ended December 31,			
			Change				Change	
(In Thousands)	2018	2017	$	%	2017	2016	$	%
Revenue								
U.S. Omnipod	$323,528	$271,597	$51,931	19 %	$271,597	$229,785	$41,812	18 %
International Omnipod	172,020	119,953	52,067	43 %	119,953	71,889	48,064	67 %
Drug Delivery	68,275	72,218	(3,943)	(5)%	72,218	65,315	6,903	11 %
Total Revenue	563,823	463,768	100,055	22 %	463,768	366,989	96,779	26 %
Cost of revenue	193,655	186,599	7,056	4 %	186,599	155,903	30,696	20 %
Gross profit	370,168	277,169	92,999	34 %	277,169	211,086	66,083	31 %
Gross margin	65.7 %	59.8 %			59.8 %	57.5 %		
Operating expenses:								
Research and development	88,606	74,452	14,154	19 %	74,452	55,710	18,742	34 %
Sales and marketing	142,321	121,617	20,704	17 %	121,617	94,483	27,134	29 %
General and administrative	111,818	88,487	23,331	26 %	88,487	71,597	16,890	24 %
Total operating expenses	342,745	284,556	58,189	20 %	284,556	221,790	62,766	28 %
Operating income (loss)	27,423	(7,387)	34,810					