

INSULET CORP
Form 10-K/A
February 28, 2013
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A

(Mark One)

**☐ ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2011

**☐ TRANSITION REPORTING PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File No. 001-33462

INSULET CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

*(State or Other Jurisdiction of
Incorporation or Organization)*

04-3523891

*(I.R.S. Employer
Identification No.)*

9 Oak Park Drive

Bedford, Massachusetts

(Address of Principal Executive Offices)

01730

(Zip Code)

Registrant's telephone number, including area code:

(781) 457-5000

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
Preferred Stock Purchase Rights	The NASDAQ Stock Market, LLC

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

None

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 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

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 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 No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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.

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 Accelerated filer Non-accelerated filer Smaller reporting company
(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

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, 2011 was approximately \$976.1 million. In making such calculation, the registrant does not determine whether any director, officer or other holder of common stock is an affiliate for any other purpose.

The number of shares outstanding of each of the registrant's classes of common stock as of February 22, 2012:

Title of Class	Shares Outstanding
Common Stock, \$0.001 Par Value Per Share	47,578,358
Preferred Stock Purchase Rights	

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2011. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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EXPLANATORY NOTE

We are filing this Amendment to our Annual Report on Form 10-K/A (the Amended Report), which was originally filed on Form 10-K on February 28, 2012 (the Original Report or Annual Report on Form 10-K), to reflect a restatement of our consolidated financial statements.

As discussed in Note 18 to our consolidated financial statements, subsequent to the issuance of the Original Report, we and our audit committee concluded that we should restate our consolidated balance sheet at December 31, 2011, and our consolidated statements of operations, cash flows and changes in stockholders' equity for the year ended December 31, 2011 to correct the following errors:

In June 2011, we acquired all of the outstanding shares of privately-held Neighborhood Diabetes and accounted for the acquisition as a business combination. In connection with the acquisition, we recognized net deferred tax liabilities of \$11.3 million. We also reduced our preexisting valuation allowance and goodwill, accordingly, through purchase accounting. Upon subsequent review, we determined that the \$11.3 million reduction of our preexisting valuation allowance should have been reported as an income tax benefit and not as an adjustment to goodwill. We have corrected our statement of operations with respect to the income tax benefit generated as a result of the change in the valuation allowance.

In June 2011, we modified our outstanding convertible debt. Upon subsequent review, we determined that at the date of the modification we should have recognized approximately \$5.5 million in additional deferred tax liability related to our debt. The recognition of this additional deferred tax liability would have resulted in a corresponding reduction of our preexisting valuation allowance and therefore had no effect on our statement of operations. We have corrected certain balance sheet amounts with respect to the presentation of our deferred tax assets and liabilities.

For reasons discussed above, we are filing this Amended Report in order to amend the following items in Part II of our Original Report to the extent necessary to reflect the adjustments discussed above and make corresponding revisions to our financial data cited elsewhere in this Amended Report:

Item 6. Selected Financial Data

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

Item 8. Financial Statements and Supplementary Data

Item 9A. Controls and Procedures

Other than minor conforming revisions made to Item 1A, none of the remaining Items of our Original Report are amended hereby and are repeated herein solely for the reader's convenience.

In order to preserve the nature and character of the disclosures set forth in the Original Report, except as expressly noted above, this Amended Report speaks as of the date of the filing of the Original Report, February 28, 2012, and we have not updated the disclosures in this Amended Report to speak as of a later date. All information contained in this Amended Report is subject to updating and supplementing as provided in our reports filed with the SEC subsequent to the date of the Original Report.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. Forward-looking statements relate to future events or our future financial performance. We generally identify forward looking statements by terminology such as may, will, should, expects, plans, anticipate, could, intends, targets, projects, contemplates, believes, estimates, predicts, potential or continue or the negative of these terms or words. These statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, results of operations and financial condition. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in Risk Factors in Part 1, Item 1A. of this Annual Report on Form 10-K. Accordingly, you should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events.

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PART I

ITEM 1. BUSINESS

Overview

We are a medical device company that develops, manufactures and markets an innovative, discreet and easy-to-use insulin infusion system for people with insulin-dependent diabetes. Our proprietary OmniPod Insulin Management System (the OmniPod System), which consists of our OmniPod disposable insulin infusion device and our handheld, wireless Personal Diabetes Manager (PDM), is the only commercially-available insulin infusion system of its kind. Conventional insulin pumps require people with insulin-dependent diabetes to learn to use, manage and wear a number of cumbersome components, including up to 42 inches of tubing. In contrast, the OmniPod System features only two discreet, easy-to-use devices that eliminate the need for a bulky pump, tubing and separate blood glucose meter, provides for virtually pain-free automated cannula insertion, communicates wirelessly and integrates a blood glucose meter. We believe that the OmniPod System's unique proprietary design offers significant lifestyle benefits to people with insulin-dependent diabetes.

The U.S. Food and Drug Administration (FDA) approved the OmniPod System in January 2005, and we began commercial sale of the OmniPod System in the United States in October 2005. Since the commercial launch of the OmniPod System, we have progressively expanded our marketing efforts from an initial focus in the Eastern United States, to providing availability of the OmniPod System in the entire United States. In January 2010, we entered into a distribution agreement with Ypsomed Distribution AG (Ypsomed) pursuant to which Ypsomed became the exclusive distributor of the OmniPod System in eleven countries, subject to approved reimbursement. Through our partnership with Ypsomed, the OmniPod System is available in Germany, the United Kingdom, the Netherlands, and Switzerland. In February 2011, we entered into a distribution agreement with GlaxoSmithKline Inc. (GSK) pursuant to which GSK became the exclusive distributor of the OmniPod System in Canada. GSK began distributing the OmniPod System during the third quarter of 2011. We focus our sales and marketing efforts related to the OmniPod System towards key diabetes practitioners, academic centers and clinics specializing in the treatment of diabetic patients, as well as individual diabetes patients.

On June 1, 2011, we completed the acquisition of Neighborhood Holdings, Inc. and its wholly-owned subsidiaries (collectively, Neighborhood Diabetes), a leading durable medical equipment distributor, specializing in direct to consumer sales of diabetes supplies. Neighborhood Diabetes is based in Woburn, Massachusetts with additional facilities in Brooklyn, New York and Orlando, Florida. Neighborhood Diabetes supplies these customers with blood glucose testing supplies, insulin pumps, pump supplies, pharmaceuticals, and other products for the management and treatment of diabetes.

We submitted a Form 510K with the FDA and are currently awaiting approval of our next generation of the OmniPod System. The new OmniPod is approximately one-third smaller in size and one-quarter lighter in weight. In August 2011, we received CE Mark approval for our next generation OmniPod System.

Insulet Corporation is a Delaware corporation formed in 2000. Our principal offices are located at 9 Oak Park Drive, Bedford, Massachusetts 01730, and our telephone number is (781) 457-5000. Our website address is <http://www.insulet.com>. We make available, free of charge, on or through our website, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. The information on our website is not part of this Annual Report on Form 10-K for the year ended December 31, 2011.

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Our Market

Diabetes is a chronic, life-threatening disease for which there is no known cure. Diabetes is caused by the body's inability to produce or effectively utilize the hormone insulin. This inability prevents the body from adequately regulating blood glucose levels. Glucose, the primary source of energy for cells, must be maintained at certain concentrations in the blood in order to permit optimal cell function and health. In people with diabetes, blood glucose levels fluctuate between very high levels, a condition known as hyperglycemia, and very low levels, a condition called hypoglycemia. Hyperglycemia can lead to serious short-term complications, such as confusion, vomiting, dehydration and loss of consciousness and long-term complications, such as blindness, kidney disease, nervous system disease, amputations, stroke and cardiovascular disease, or death. Hypoglycemia can lead to confusion, loss of consciousness or death.

Diabetes is typically classified as either Type 1 or Type 2.

Type 1 diabetes is characterized by the body's nearly complete inability to produce insulin. It is frequently diagnosed during childhood or adolescence. Individuals with Type 1 diabetes require daily insulin therapy, typically administered via injections or conventional insulin pumps, to survive.

Type 2 diabetes, the more common form of diabetes, is characterized by the body's inability to either properly utilize insulin or produce enough insulin. Historically, Type 2 diabetes has occurred in later adulthood, but its incidence is increasing among the younger population, due primarily to increasing childhood obesity. Initially, many people with Type 2 diabetes attempt to manage their diabetes with improvements in diet, exercise and/or oral medications. As their diabetes advances, some patients progress to multiple drug therapy, which often includes insulin therapy. Guidelines, including those published by the American Diabetes Association in 2006, suggest more aggressive treatment for people with Type 2 diabetes, including the early adoption of insulin therapy and more frequent testing. It is now becoming more accepted for insulin therapy to be started earlier in people with Type 2 diabetes, and, in some cases, as part of the initial treatment.

Throughout this Annual Report on Form 10-K, we refer to both Type 1 diabetes and insulin-requiring Type 2 diabetes as insulin-dependent diabetes.

Managing Diabetes

Diabetes Management Challenges

Diabetes is often frustrating and difficult for patients to manage. Blood glucose levels can be affected by the carbohydrate and fat content of meals, exercise, stress, illness or impending illness, hormonal releases, variability in insulin absorption and changes in the effects of insulin on the body. For people with insulin-dependent diabetes, many corrections, consisting of the administration of additional insulin or ingestion of additional carbohydrates, are needed throughout the day in order to maintain blood glucose levels within normal ranges. Achieving this result can be very difficult without multiple daily injections of insulin or the use of continuous subcutaneous insulin infusion (CSII) therapy. Patients attempting to control their blood glucose levels tightly to prevent the long-term complications associated with fluctuations in blood glucose levels are at greater risk for overcorrection and the resultant hypoglycemia, which can cause confusion, loss of consciousness or death. As a result, many patients have difficulty managing their diabetes optimally. Additionally, the time spent in managing diabetes, the swings in blood glucose levels and the fear of hypoglycemia can all render diabetes management overwhelming to patients and their families.

Current Insulin Therapy

People with insulin-dependent diabetes need a continuous supply of insulin, known as basal insulin, to provide for background metabolic needs. In addition to basal insulin, people with insulin-dependent diabetes require supplemental insulin, known as bolus insulin, to compensate for carbohydrates ingested during meals or snacks or for a high blood glucose level.

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There are three primary types of insulin therapy practiced today: conventional therapy; multiple daily injection (MDI) therapy using syringes or insulin pens; and CSII therapy using insulin pumps. Both MDI and CSII therapies are considered intensive insulin management therapies.

Many healthcare professionals believe that intensive insulin management therapies are superior to conventional therapies in delaying the onset and reducing the severity of diabetes-related complications. As a result, we believe that the use of intensive insulin management therapies has significantly expanded over the past decade, and that many Type 1 patients manage their diabetes using an intensive insulin management therapy. A significantly smaller percentage of people with insulin-requiring Type 2 diabetes manage their diabetes using an intensive insulin management therapy.

The OmniPod System

The OmniPod Insulin Management System was specifically designed to provide people with insulin-dependent diabetes with a diabetes management solution which provides significant lifestyle and other benefits and to expand the use of CSII therapy. We believe that the following are important contributors to the success of our OmniPod System:

Discreet, two-part design. Unlike conventional insulin pumps, the OmniPod System consists of just two discreet, easy-to-use devices that communicate wirelessly: the OmniPod, a small, lightweight, disposable insulin infusion device worn beneath clothing that integrates an infusion set, automated cannula insertion, insulin reservoir, drive mechanism and batteries; and the PDM, a handheld device much like a personal digital assistant that wirelessly programs the OmniPod with insulin delivery instructions, assists the patient with diabetes management and integrates a blood glucose meter. The OmniPod will operate up to 72 hours (but no more than 80 hours) after it is first activated. We believe our innovative patented design enables people with insulin-dependent diabetes to experience all of the lifestyle benefits and clinical superiority of CSII therapy in a more discreet and convenient manner than possible with conventional insulin pumps.

No tubing. The OmniPod System's innovative, proprietary design dramatically reduces the size of the insulin delivery mechanism, thereby eliminating the need for the external tubing required by conventional pumps. As a result of this design, the OmniPod can be worn discreetly beneath clothing and patients can move, dress, bathe, sleep and exercise without the encumbrance of the up to 42 inches of tubing required by conventional insulin pumps. In addition to untethering people with insulin-dependent diabetes, the OmniPod System's lack of tubing eliminates interruptions in insulin delivery resulting from kinking, leaking or disconnecting, which leads to more consistent delivery of insulin.

Virtually pain-free automated cannula insertion. The OmniPod is the only CSII therapy device to feature a fully automated, hands-free cannula insertion system. This virtually pain-free insertion system features the world's fastest insertion and the smallest-gauge introducer needle available for insulin infusion systems. Cannula insertion is activated wirelessly using the PDM, so the patient never sees or handles an introducer needle, which we believe promotes consistent insertion, reduces patient anxiety and increases the number of insertion sites available to patients. We believe that the OmniPod's proprietary insertion system is a significant differentiating factor for people with insulin-dependent diabetes who are frustrated with the painful and cumbersome manual insertions required with existing conventional pumps or frequent injections required by MDI therapy.

Easy to train, learn and use. We have designed the OmniPod System to fit within the normal daily routines of patients. The OmniPod System requires the fewest steps to start insulin delivery of all CSII therapies on the market by automating much of the process. In addition, the OmniPod System consists of just two devices, as opposed to up to seven for conventional insulin pumps. We have designed the PDM's user interface to be much more intuitive and user-friendly than those used in conventional insulin pumps. As a result, the OmniPod System is easier for patients to use, which reduces the training burden on healthcare professionals. We believe that the OmniPod System's overall ease of use makes it very

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attractive to those people with insulin-dependent diabetes. We also believe that the OmniPod System's ease of use and substantially lower training burden helps to redefine which diabetes patients are appropriate for CSII therapy, enabling healthcare professionals to prescribe CSII therapy to a broader pool of patients.

Low up-front cost and pay-as-you-go pricing structure. The OmniPod System's unique patented design and proprietary manufacturing process have enabled us to provide CSII therapy at a relatively low up-front investment compared to conventional insulin pumps. While the ongoing cost of OmniPods is greater than the ongoing costs of supplies for conventional insulin pumps, we believe that our pay-as-you-go pricing model significantly reduces the risk of investing in CSII therapy for third-party payors and makes CSII therapy much more accessible for people with insulin-dependent diabetes.

The Neighborhood Diabetes Business

Neighborhood Diabetes is a leading durable medical equipment distributor specializing in direct to consumer sales of diabetes supplies, including our OmniPod System. Based in Woburn, Massachusetts, with additional offices in Brooklyn, New York and Orlando, Florida, Neighborhood Diabetes serves more than 60,000 clients with Type 1 and Type 2 diabetes primarily in the northeast and southeast regions of the country with blood glucose testing supplies, insulin pumps, pump supplies and pharmaceuticals, among other supplies. More than 15,000 of Neighborhood Diabetes clients are insulin dependent with the majority of these clients using MDI therapy.

Neighborhood Diabetes employs approximately 200 people across its three locations. The majority of these employees work in Neighborhood Diabetes' reimbursement, pharmacy, billing and distribution areas. Clients place reorders for diabetes supplies either on monthly or quarterly cycles, depending on insurance coverage, which are then shipped or home delivered to the client. Neighborhood Diabetes has built a strong infrastructure in these areas that provide for adjudication of claims as either durable medical equipment or through pharmacy benefits. Claims are adjudicated under private insurers, Medicaid or Medicare.

Sales and Marketing

Our sales and marketing effort for the OmniPod System is focused on continuing to generate demand and acceptance of the OmniPod System among healthcare professionals, people with insulin-dependent diabetes, third-party payors and third-party distributors. Our marketing strategy is to build awareness of the benefits of the OmniPod System through a wide range of education programs, social networking, patient demonstration programs, support materials, media advertisements, clinical research and events at the national, regional and local levels. We use third-party distributors within the United States to improve our access to managed care and government reimbursement programs, expand our commercial presence and provide access to additional potential patients. In addition, we entered into a distribution agreement with Ypsomed pursuant to which Ypsomed became the exclusive distributor of the OmniPod System in eleven countries. As part of our agreement, Ypsomed works with the appropriate agencies to establish a distribution and reimbursement process in each of these countries. Through our partnership with Ypsomed, the OmniPod System is now available in Germany, the United Kingdom, the Netherlands, and Switzerland. In February 2011, we entered into a distribution agreement with GSK pursuant to which GSK became the exclusive distributor of the OmniPod System in Canada. GSK began distributing the OmniPod System during the third quarter of 2011.

Neighborhood Diabetes delivers a differentiated "high-touch" service model to endocrinologists, insurers and clients, which supplements a comprehensive offering of diabetes management products with education, training and other support services. These services have been demonstrated to improve client adherence to their recommended therapy regimens, resulting in fewer long term complications and reduced costs of care. The value proposition for Neighborhood Diabetes to both doctors and insurers focuses on coupling a high level of client service with demonstrated reductions in overall costs of care for these clients. This sales model has enabled

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Neighborhood Diabetes to drive increased referrals from a growing list of physician offices and insurers. The sales model has also created strong loyalty in its clients as clients enjoy being able to receive all of their diabetes supplies from one supplier.

Healthcare professional focused initiatives. We believe that healthcare professionals play an important role in selecting patients for CSII therapy and educating them about CSII technology options. Our marketing to healthcare professionals focuses on positioning the OmniPod System as an innovative continuous insulin delivery system that should be considered as an alternative to a conventional insulin pump. We augmented our healthcare professional focused marketing efforts with market studies to assess various aspects of the OmniPod System's functionality and relative efficacy, which we believe assist us in generating additional patient demand for the OmniPod System among the insulin-dependent diabetes population.

Patient focused initiatives. We sell the OmniPod System directly to patients through referrals from healthcare professionals and through patient leads generated from our promotional activities and social networking. Our marketing to patients focuses on positioning the OmniPod System as an innovative continuous insulin delivery system that makes diabetes a smaller part of life and strongly promotes the lifestyle benefits afforded by the OmniPod System.

Advertising. We promote the OmniPod System and its benefits through targeted advertising in media outlets directed at diabetic patients, including both internet and traditional media channels.

Marketing research. In addition to our initiatives focused on healthcare professionals and patients, we also evaluate the benefits of the OmniPod System through marketing research efforts to assess certain aspects of the efficacy of the OmniPod System.

Distributor arrangements. Additionally, we have expanded our distribution networks to include relationships with other third-party distributors in order to increase market awareness, improve our access to managed care and government reimbursement programs and provide access to additional potential patients both within and outside of the United States.

Training and Customer Support

Given the chronic nature of diabetes, we believe that thorough training and ongoing customer support are important to developing a long-term relationship with the patient. We believe that it is crucial for patients to be trained as the experts in the management of their diabetes. At the same time, we believe that providing reliable and effective customer support reduces patients' anxiety and contributes to overall product satisfaction. In order to provide a complete training and customer support solution, we utilize a combination of live training in the office of healthcare professionals, interactive media, as well as online and telephonic support that is available 24 hours a day, 7 days a week.

Training. We believe that the amount of effort required for healthcare professional offices to train patients to use CSII therapy has been a key barrier limiting penetration of this therapy. With the fewest steps required to start insulin delivery, compared to conventional insulin pumps, the OmniPod System was designed to be easy to use and to significantly reduce the burden associated with training patients to use CSII therapy.

Our training support for the OmniPod System for healthcare professional offices is tailored to the individual needs of recommending offices. In some cases, we certify office-based healthcare professionals to train patients on the OmniPod System through our Certified Pod Trainer Program. In addition, we may assist them with the first customer training as part of the process of transitioning the ongoing training responsibilities to these healthcare professionals. In other cases, a member of our Certified Pod Trainer consultant group will conduct the patient training for an office that does not have the capability or capacity to offer patient training. We have established a network of Certified Pod Trainers (CPTs) who will conduct customer training at the healthcare

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site. We provide all CPTs with a training kit that includes a methodology and documentation for training patients on effective use of the OmniPod System. We believe the CPT Program is a valuable way for us to develop and maintain relationships with key providers in the marketplace.

Neighborhood Diabetes differentiated high-touch service model supplements its product offering with education, training and other support services. These services have been demonstrated to improve client adherence to their recommended therapy regimens, resulting in fewer long term complications and reduced overall cost of care.

Customer Support. We seek to provide our customers with high quality customer support, from product ordering to insurance investigation, fulfillment and ongoing support. We have integrated our customer support systems with our sales, reimbursement and billing processes and also offer support by telephone and through our website in order to provide customers with seamless and reliable customer support.

Our customer support staff is proactively involved with both healthcare professionals and patients. When a patient initiates an order for the OmniPod System, our customer support staff assists the patient with completing order forms and collecting additional data as required by the patient's insurance provider. Once the order forms are complete, we investigate the patient's insurance coverage for the OmniPod System and contact the customer to notify them regarding the coverage available under the patient's insurance. We believe it is important from a customer satisfaction perspective, as well as a healthcare professional perspective, that we handle the insurance investigation process accurately, efficiently and promptly, and that we, therefore, are capable of scaling our capacity to meet increasing demand. Neighborhood Diabetes has built a strong infrastructure in its reimbursement, pharmacy and billing areas to provide for accurate and efficient adjudication of claims as either durable medical equipment or through pharmacy benefits. We also offer healthcare professionals assistance in generating insurance appeals for customers who are denied coverage. We believe that our insurance investigation infrastructure enables us to effectively support the growing demand for the OmniPod System.

Upon approval from the customer, the customer's order is typically shipped to the customer's home and our customer support staff notifies the provider of the shipment date and reviews training plans with the customer. A customer support representative contacts customers to arrange and schedule subsequent shipments of OmniPods or other supplies, which are typically shipped every month to every three months. In addition, patients can be placed on automatic re-order for OmniPod supplies, simplifying the diabetes management process and preventing patients from experiencing inadvertent supply shortages.

Our third-party distributors, including Ypsomed and GSK, manage and perform the training and customer support activities for their sales of the OmniPod System.

Research and Development

Our current research and development efforts are primarily focused on our next generation OmniPod System which reduces the size of the OmniPod. We are also working toward the integration of our OmniPod System with the LifeScan, Inc. (LifeScan) OneTouch® blood glucose monitoring technology as well as the DexCom, Inc. (DexCom) continuous glucose monitoring technology.

We entered into a non-exclusive agreement with LifeScan to integrate LifeScan's OneTouch® blood glucose monitoring technology into our PDM. Under the terms of the agreement, LifeScan is responsible for providing its glucose monitoring technology to us, and we are responsible for the development, design and regulatory approval of the integrated device.

We have an agreement with DexCom to develop a system that will enable the OmniPod System PDM to receive and display continuous glucose data from DexCom's continuous glucose monitor. We currently expect to integrate our next generation OmniPod System with DexCom's next generation continuous glucose monitor.

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Neither device is currently approved by the FDA. To date, the FDA has approved, as an adjunct to traditional self-testing, a limited number of continuous glucose monitoring systems, including those manufactured by Abbott Diabetes Care, Inc., Medtronic, Inc. and DexCom. All of these products have limited capabilities, and none of them is labeled as a substitute for current blood glucose testing where patients need to draw blood for testing. This means that no continuous glucose monitor, whether currently on the market or pending FDA approval, can be used to determine insulin infusion amounts. It is unknown when, if ever, any continuous glucose monitoring systems will be approved as a replacement for current blood glucose monitors.

We believe that the potential uses of our proprietary OmniPod System technology are not limited to the treatment of diabetes. We plan to pursue the use of the OmniPod System technology for the delivery of other medications that may be administered subcutaneously in precise and varied doses over an extended period of time. For instance, in June 2008, we announced an agreement with Ferring Pharmaceuticals (Ferring) of Saint Prex, Switzerland, to develop the OmniPod System for the delivery of a Ferring drug. Under the terms of the agreement, Ferring funded the development of a custom version of the PDM and, upon completion of the development, agreed to purchase minimum quantities of this custom OmniPod Systems over a five-year period. We received CE mark approval for this custom OmniPod System in September 2009 and began selling the product to Ferring under this arrangement in 2010. To date, revenue under this arrangement has been minimal. In June 2011, we entered in a development agreement with a U.S. based pharmaceutical company (the Development Agreement). Under the Development Agreement, we are required to perform design, development, regulatory and other services to support the pharmaceutical company as it works to obtain regulatory approval to use our drug delivery technology as a delivery method for its pharmaceutical. Over the estimated two-year term of the Development Agreement, we have invoiced and expect to continue to invoice amounts as we meet certain defined deliverable milestones. We continue to work with additional partners on potential alternative uses for our OmniPod System technology. However, there can be no assurance that we will be able to adapt the OmniPod System technology for further uses or successfully compete in new therapeutic areas.

Manufacturing and Quality Assurance

We believe a key contributing factor to the overall attractiveness of the OmniPod System is the disposable OmniPod insulin infusion device. In order to manufacture sufficient volumes and achieve a lower per unit production cost for the OmniPod, each of which is worn for up to three days and then replaced, we have designed the OmniPod to be manufactured through a partially automated process.

We are currently producing the OmniPod on a partially automated manufacturing line at a facility in China, operated by a subsidiary of Flextronics International Ltd. (Flextronics). We purchase complete OmniPods pursuant to our agreement with Flextronics. Under the agreement, Flextronics has agreed to supply us, as a non-exclusive supplier, with OmniPods at agreed upon prices per unit pursuant to a rolling 12-month forecast that we provide. The agreement may be terminated at any time by either party upon prior written notice given no less than a specified number of days prior to the date of termination. The specified number of days is intended to provide the parties with sufficient time to make alternative arrangements in the event of termination. By purchasing OmniPods manufactured by Flextronics in China, we have been able to substantially increase production volumes for the OmniPod and reduce our per unit production cost.

To achieve profitability, we seek to continue to increase manufacturing volumes and reduce the per unit production cost for the OmniPod. By increasing production volumes of the OmniPod, we have been able to reduce our per-unit raw material costs and improve absorption of manufacturing overhead costs. This, as well as the introduction of our next generation OmniPod, are important as we strive to achieve profitability. We believe our manufacturing capacity is sufficient to meet our expected 2012 demand for OmniPods.

We rely on outside vendors for most of the components, some sub-assemblies, and various services used in the manufacture of the OmniPod System. For example, we rely on Phillips Plastic Corporation to manufacture

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and supply a number of injection molded components of the OmniPod and on Freescale Semiconductor, Inc. to manufacture and supply the application specific integrated circuit that is incorporated into the OmniPod. Each of these suppliers is a sole-source supplier. To date, we have not experienced significant disruption in the delivery of these components and services. For certain of these components, arrangements with additional or replacement suppliers will take time and result in delays, in part because of the vendor qualification process required under FDA regulations and because of the custom nature of various parts we design. Any interruption or delay in the supply of components or services, or our inability to obtain components from alternate sources at acceptable prices in a timely manner, could harm our business, financial condition and results of operations.

Generally, all outside vendors produce the components to our specifications and in many instances to our designs, and they are audited periodically by our Quality Assurance Department to ensure conformity with the specifications, policies and procedures for our devices. Our Quality Assurance Department also inspects and tests our devices at various steps in the manufacturing cycle to facilitate compliance with our devices' stringent specifications. We have received approval of our quality systems standards from DEKRA Certification B. V., Arnhem, The Netherlands, an accredited Notified Body for CE Marking and the International Standards Organization (ISO). Certain processes utilized in the manufacture and test of our devices have been verified and validated as required by the FDA and other regulatory bodies. As a medical device manufacturer, our manufacturing facility and the facilities of our suppliers and sterilizer are subject to periodic inspection by the FDA, KEMA and certain corresponding state agencies.

Intellectual Property

We believe that to maintain a competitive advantage, we must develop and preserve the proprietary aspect of our technologies. We rely on a combination of copyright, patent, trademark, trade secret and other intellectual property laws, non-disclosure agreements and other measures to protect our proprietary rights. Currently, we require our employees, consultants and advisors to execute non-disclosure agreements in connection with their employment, consulting or advisory relationships with us, where appropriate. We also require our employees, consultants and advisors who we expect to work on our current or future products to agree to disclose and assign to us all inventions conceived during the work day, developed using our property or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of the OmniPod System or to obtain and use information that we regard as proprietary.

Patents. As of December 31, 2011, we had obtained 20 issued United States patents, and had 6 additional pending U.S. patent applications. We believe it will take up to four years, and possibly longer, for the most recent of these U.S. patent applications to result in issued patents. Our issued U.S. patents expire between 2020 and 2022, assuming we pay all required maintenance fees. We are also seeking patent protection for our proprietary technology in Europe, China, Japan, India and other countries and regions throughout the world. The issued patents and pending patent applications cover, among other things:

the basic architecture of the OmniPod System;

the OmniPod shape memory alloy drive system;

the OmniPod System cannula insertion system; and

various novel aspects of the OmniPod System and potential next generation OmniPod Systems.

In a letter received in March 2007, Medtronic, Inc. (Medtronic) invited us to discuss our taking a license to certain Medtronic patents. The patents referenced by this letter relate to technology that is material to our business. We have not had any substantive discussions with Medtronic concerning this matter since our receipt of this letter. While we believe that the OmniPod System does not infringe these patents, we would consider resolving the matter on reasonable terms. If we are unable to reach agreement with Medtronic, Inc. on this matter, they may sue us for infringement. We believe we would have meritorious defenses to any such suit.

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In August 2010, Becton, Dickinson and Company (BD) filed a lawsuit in the United States District Court in the State of New Jersey against us alleging that the OmniPod System infringes three of its patents. BD seeks a declaration that we have infringed its patents, equitable relief, including an injunction that would enjoin us from infringing these patents, and an unspecified award for monetary damages. We believe that the OmniPod System does not infringe these patents and we believe that we have meritorious defenses to this lawsuit. We do not expect that this litigation or the letter from Medtronic will have a material adverse impact on our financial position or results of operations; however, litigation is inherently uncertain and there can be no assurance as to the ultimate outcome or effect of these two actions.

Trademarks. We have registered the trademarks INSULET, OMNIPOD and the OMNIPOD design with the United States Patent and Trademark Office on the Principal Register.

Competition

The medical device industry is intensely competitive, subject to rapid change and is significantly affected by new product introductions and other market activities of industry participants. The OmniPod System competes with a number of existing insulin delivery devices as well as other methods for the treatment of diabetes. Medtronic MiniMed, a division of Medtronic has been the market leader for many years and has the majority share of the conventional insulin pump market in the United States. Other significant suppliers in the United States are Animas Corporation, a division of Johnson & Johnson and Roche Diagnostics, a division of F. Hoffmann-La Roche, Ltd.

All of these competitors are large, well-capitalized companies with significantly more market share and resources than we have. They are able to spend aggressively on product development, marketing, sales and other product initiatives. Many of these competitors have:

significantly greater name recognition;

established relations with healthcare professionals, customers and third-party payors;

larger and more established sales forces and distribution networks;

additional lines of products and the ability to offer rebates or bundle products to offer higher discounts or other incentives to gain a competitive advantage;

greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory approval for products; and

greater financial and human resources for product development, sales and marketing and patent litigation.

In addition to the established insulin pump competitors a number of companies (including current competitors) are working to develop and market new insulin patch pumps or multi channel pump devices (insulin and glucagon). These companies are at various stages of development. The companies working in this area of which we are aware include Medtronic, Roche Diagnostics, Spring Health Solutions Ltd., Sensile Medical AG, Asante Solutions, Inc., Phluid Corporation, Calibra Medical, Inc., Valeritas Inc., Starbridge Systems Ltd., Novo Nordisk A/S and Abbott Laboratories.

The OmniPod System and conventional insulin pumps, both of which provide CSII therapy, also face competition from conventional and MDI therapy, both of which are substantially less expensive than CSII therapy, as well as from newer methods for the treatment of diabetes, such as inhaled insulin.

Neighborhood Diabetes operates in the diabetes testing supply and insulin pump and pump supply market. Competition among distributors in this market is significant. Neighborhood Diabetes competes with a wide variety of market participants, including national, regional and local distributors such as Liberty Medical Supply Inc., CCS Medical, Simplex Healthcare, Inc. and Edgepark Medical Supplies. Neighborhood

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Diabetes competitors include many profitable and well-established companies that have significantly greater financial, marketing and other resources than we have.

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Government Regulation

The OmniPod System is a medical device subject to extensive and ongoing regulation by the FDA and other regulatory bodies. FDA regulations govern product design and development, pre-clinical and clinical testing, manufacturing, labeling, storage, pre-market clearance or approval, advertising and promotion, and sales and distribution.

FDA's Pre-Market Clearance and Approval Requirements. Unless an exemption applies, each medical device we seek to commercially distribute in the United States will require either a prior 510(k) clearance or a pre-market approval, (PMA) from the FDA. We have obtained 510(k) clearance for the OmniPod System. Both the 510(k) clearance and PMA processes can be expensive and lengthy and entail significant user fees, unless an exemption is available.

In order to obtain pre-market approval and, in some cases, a 510(k) clearance, a product sponsor must conduct well controlled clinical trials designed to test the safety and effectiveness of the product. Conducting clinical trials generally entails a long, costly and uncertain process that is subject to delays and failure at any stage. The data obtained from clinical trials may be inadequate to support approval or clearance of a submission. In addition, the occurrence of unexpected findings in connection with clinical trials may prevent or delay obtaining approval or clearance. If we conduct clinical trials, they may be delayed or halted, or be inadequate to support approval or clearance.

510(k) Clearance. To obtain 510(k) clearance for any of our potential future devices (or for certain modifications to devices that have received 510(k) clearance), we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a pre-amendment device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA application. The FDA's 510(k) clearance pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer. After a medical device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a significant change in its intended use, requires a new 510(k) clearance.

PMA. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device or device in commercial distribution before May 28, 1976 for which PMAs have not been required, generally require a PMA before they can be commercially distributed. A PMA application must be supported by extensive data, including technical, pre-clinical, clinical trials, manufacturing and labeling to demonstrate the safety and effectiveness of the device to the FDA's satisfaction. After a PMA application is complete and the FDA begins an in-depth review of the submitted information, which generally takes between one and three years, but may take significantly longer. After any pre-market approval, a new pre-market approval application or application supplement may be required in the event of modifications to the device, its labeling, intended use or indication or its manufacturing process. In addition, any PMA approval may be conditioned upon the manufacturer conducting post-market surveillance and testing.

Ongoing Regulation by FDA. Even after a device receives clearance or approval and is placed on the market, numerous regulatory requirements apply. These include:

establishment registration and device listing;

quality system regulation, which requires manufacturers, including third party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses, and other requirements related to promotional activities;

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medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;

corrections and removals reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug and Cosmetic Act that may present a risk to health; and

post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Failure to comply with applicable regulatory requirements can result in enforcement actions by the FDA and other regulatory agencies, which may include any of the following sanctions: fines, injunctions, civil or criminal penalties, recall or seizure of our current or future products, operating restrictions, partial suspension or total shutdown of production, refusing our request for 510(k) clearance or PMA approval of new products, rescinding previously granted 510(k) clearances or withdrawing previously granted PMA approvals.

We are subject to announced and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of our subcontractors. If, as a result of these inspections, the FDA determines that our equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may seek civil, criminal or administrative sanctions and/or remedies against us, including the suspension of our manufacturing operations. Since approval of the OmniPod System, we have been subject to FDA inspections of our facility on multiple occasions.

International sales of medical devices are subject to foreign government regulations, which may vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. There is a trend towards harmonization of quality system standards among the European Union, United States, Canada and various other industrialized countries. In April 2009, we received CE Mark approval for the current version of our OmniPod System. In August 2011, we received CE Mark approval for our next generation OmniPod System. The CE Mark gives us authorization to distribute the OmniPod System throughout the European Union and in other countries that recognize the CE Mark. In September 2009, we received Health Canada approval to distribute the current version of the OmniPod System throughout Canada. In January 2010, we entered into a distribution agreement with Ypsomed pursuant to which Ypsomed became the exclusive distributor of the OmniPod System in eleven countries, including nine countries in Europe, China and Australia. Ypsomed has introduced the OmniPod System in Germany, the United Kingdom, the Netherlands, and Switzerland. In February 2011, we entered into a distribution agreement with GSK pursuant to which GSK became the exclusive distributor of the OmniPod System in Canada. GSK began distributing the OmniPod System during the third quarter of 2011.

Licensure. Several states require that durable medical equipment (DME) providers be licensed in order to sell products to patients in that state. Certain of these states require that DME providers maintain an in-state location. Although we believe we are in compliance with all applicable state regulations regarding licensure requirements, if we were found to be noncompliant, we could lose our licensure in that state, which could prohibit us from selling our current or future products to patients in that state. In addition, we are subject to certain state laws regarding professional licensure. We believe that our certified diabetes educators are in compliance with all such state laws. However, if our educators or we were to be found non-compliant in a given state, we may need to modify our approach to providing education, clinical support and customer service.

Federal Anti-Kickback and Self-Referral Laws. The Federal Anti-Kickback Statute prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce the:

referral of a person;

furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid or other governmental programs; or

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purchase, lease, or order of, or the arrangement or recommendation of the purchasing, leasing, or ordering of any item or service reimbursable under Medicare, Medicaid or other governmental programs.

We provide the initial training to patients necessary for appropriate use of the OmniPod System either through our own diabetes educators or by contracting with outside diabetes educators that have completed a Certified Pod Trainer training course. Outside diabetes educators are reimbursed for their services at fair market value. Although we believe that these arrangements do not violate the law, regulatory authorities may determine otherwise, especially as enforcement of this law historically has been a high priority for the federal government. In addition, because we may provide some coding and billing information to purchasers of the OmniPod System, and because we cannot assure that the government will regard any billing errors that may be made as inadvertent, the federal anti-kickback legislation may apply to us. Noncompliance with the federal anti-kickback legislation can result in exclusion from Medicare, Medicaid or other governmental programs, restrictions on our ability to operate in certain jurisdictions, as well as civil and criminal penalties, any of which could have an adverse effect on our business and results of operations.

Federal law also includes a provision commonly known as the Stark Law, which prohibits a physician from referring Medicare or Medicaid patients to an entity providing designated health services, including a company that furnishes durable medical equipment, in which the physician has an ownership or investment interest or with which the physician has entered into a compensation arrangement. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a noncompliant arrangement, civil penalties, and exclusion from Medicare, Medicaid or other governmental programs. Although we believe that we have structured our provider arrangements to comply with current Stark Law requirements, these arrangements may not expressly meet the requirements for applicable exceptions from the law.

Additionally, as some of these laws are still evolving, we lack definitive guidance as to the application of certain key aspects of these laws as they relate to our arrangements with providers with respect to patient training. We cannot predict the final form that these regulations will take or the effect that the final regulations will have on us. As a result, our provider and training arrangements may ultimately be found to be not in compliance with applicable federal law.

Federal False Claims Act. The Federal False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. In addition, amendments in 1986 to the Federal False Claims Act have made it easier for private parties to bring qui tam whistleblower lawsuits against companies under the Federal False Claims Act. Penalties include fines ranging from \$5,500 to \$11,000 for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person. At present, we do not receive reimbursement from, or submit claims to, the federal government, although we intend in the future to pursue reimbursement coverage under one or more federal programs, such as Medicare. In any event, we believe that we are in compliance with the federal government's laws and regulations concerning the filing of reimbursement claims.

Civil Monetary Penalties Law. The Federal Civil Monetary Penalties Law prohibits the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance can result in civil money penalties of up to \$10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs. We believe that our arrangements comply with the requirements of the Federal Civil Monetary Penalties Law.

State Fraud and Abuse Provisions. Many states have also adopted some form of anti-kickback and anti-referral laws and a false claims act. We believe that we are in conformance to such laws. Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

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Administrative Simplification of the Health Insurance Portability and Accountability Act of 1996. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated the adoption of standards for the exchange of electronic health information in an effort to encourage overall administrative simplification and enhance the effectiveness and efficiency of the healthcare industry. Ensuring privacy and security of patient information is one of the key factors driving the legislation. We believe we are in substantial compliance with the applicable HIPAA regulations.

Third-Party Reimbursement

In the United States, our products are generally reimbursed by third-party payors and we bill those payors for products provided to patients. Our fulfillment and reimbursement systems are fully integrated such that product is generally shipped only after confirmation of a physician's valid statement of medical necessity and current health insurance information. We maintain an insurance benefits investigation department which works to simplify and expedite claims processing and to assist patients in obtaining third-party reimbursement.

We continue to work with additional third-party payors in the United States to establish coverage contracts for the OmniPod System. Our coverage contracts with third-party payors typically have a term of between one and three years and set coverage amounts during that term. Typically, coverage contracts will automatically renew for specified incremental periods upon expiration, unless one of the parties terminates the contract.

We are an approved Medicare provider and current Medicare coverage for CSII therapy does exist. However, existing Medicare coverage for CSII therapy is based on the pricing structure developed for conventional insulin pumps. We believe that the coding verification for Medicare reimbursement of the OmniPod System is inappropriate. We continue to seek appropriate coding verification for Medicare reimbursement. As a result, we have decided to focus our principal efforts in establishing reimbursement for the OmniPod System on negotiating coverage contracts with private insurers.

Third-party payors may decline to reimburse for procedures, supplies or services determined not to be medically necessary or reasonable. In a limited number of cases, some third-party payors have declined to reimburse us for a particular patient because such patient failed to meet its criteria, most often because the patient already received reimbursement for an insulin pump from that payor within the warranty period, which is generally four years, or because the patient did not meet their medical criteria for an insulin infusion device. Common medical criteria for third-party payors approving reimbursement for CSII therapy include a patient having elevated A1c levels, a history of recurring hypoglycemia, fluctuations in blood glucose levels prior to meals or upon waking or severe glycemic variability. We try to deter and reverse decisions denying reimbursement through education. Although our efforts are usually successful, such reimbursement may become less likely in the future as pressure increases to lower healthcare costs, particularly near-term costs.

There is widespread concern that healthcare market initiatives in the United States may lead third-party payors to decline or further limit reimbursement. The extent to which third-party payors may determine that use of the OmniPod System will save costs or will at least be cost effective is highly uncertain, and it is possible, especially for diabetes, that they will merely focus on the lower initial costs associated with injection therapy or will otherwise limit reimbursement for insulin infusion systems or other products we develop. Because of uncertainties regarding the possible healthcare reform measures that could be proposed in the future and initiatives to reduce costs by private payors, we cannot predict whether reimbursement for our current or future products will be affected or, if affected, the extent of any effect. The unavailability of third-party coverage or the inadequacy of reimbursement for our current or future products would adversely affect our business, financial condition and results of operations.

As part of our distribution agreement with Ypsomed, Ypsomed is establishing appropriate reimbursement contracts with third-party payors in countries in which it distributes the OmniPod System prior to distributing the OmniPod System in each country.

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Neighborhood Diabetes has built a strong infrastructure in the reimbursement, billing and collection areas that provide for adjudication of claims as either durable medical equipment or through pharmacy benefits. Claims are adjudicated under private insurers, Medicaid or Medicare. Neighborhood Diabetes' business model requires collaboration with physicians, medical device manufacturers, pharmaceutical distributors, private insurers and public insurers such as The Center for Medicare & Medicaid Services (CMS), who we collectively refer to as partners. Neighborhood Diabetes' net sales are primarily generated from distributing diabetes supplies and pharmaceuticals pursuant to agreements with its partners.

Neighborhood Diabetes derives a significant amount of its revenue from Medicare reimbursement. Medicare reimbursement rates are reset annually by CMS and are typically subject to downward pressure. CMS is able to reset reimbursement rates and terminate contracts at will. Participation in the Medicare program requires strict compliance to a complex set of regulatory requirements. Neighborhood Diabetes has been subject to in the past and continues to be subject to CMS audits to ensure compliance with these requirements.

Relative to Neighborhood Diabetes' diabetes testing supplies business, the Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bid Program (the Program) provides for a phased-in program for competitive bidding on certain durable medical equipment items, including mail-order diabetes testing supplies. The Program is expected to create a limited single pay amount for diabetes testing supplies. CMS implementation of a national mail-order competitive bid program is not expected until at least 2013; however, it is expected to further reduce the reimbursement rates of these products.

Employees

As of December 31, 2011, we had 576 full-time employees, including over 200 employees from our acquisition of Neighborhood Diabetes. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe that our employee relations are good.

ITEM 1A. RISK FACTORS

An investment in our common stock involves risks. You should consider carefully the risks described below together with all of the other information included in this Annual Report on Form 10-K. This Annual Report on Form 10-K contains forward-looking statements that contain risks and uncertainties. Please refer to the section entitled "Cautionary Note Regarding Forward-Looking Statements" on page 1 of this Annual Report on Form 10-K in connection with your consideration of the risk factors and other important factors that may affect future results described below.

Risks Relating to Our Business

We have incurred significant operating losses since inception and cannot assure you that we will achieve profitability.

Since our inception in 2000, we have incurred operating losses every quarter. We began commercial sales of the OmniPod System in October 2005. Beginning in the second half of 2008, we have been able to manufacture and sell the OmniPod System at a cost and in volumes sufficient to allow us to achieve a positive gross margin. For the year ended December 31, 2011, our gross profit was \$66.7 million. Although we have achieved a positive gross margin, we still operate at a substantial net loss. Our net losses for the years ended December 31, 2011, 2010 and 2009 were \$45.8 million, \$61.2 million and \$72.3 million, respectively. The extent of our future operating losses and the timing of profitability are highly uncertain, and we may never achieve or sustain profitability. We have incurred a significant net loss since our inception and, as of December 31, 2011, we had an accumulated deficit of \$429.7 million.

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We currently rely on sales of the OmniPod System to generate most our revenue. The failure of the OmniPod System to achieve and maintain significant market acceptance or any factors that negatively impact sales of this product will adversely affect our business, financial condition and results of operations.

Our main product is the OmniPod System, which we introduced to the market in October 2005. We expect to continue to derive a significant portion of our revenue from the sale of this product. Accordingly, our ability to generate revenue is highly reliant on our ability to market and sell the devices that comprise the OmniPod System. Our sales of the OmniPod System may be negatively impacted by many factors, including:

the failure of the OmniPod System to achieve wide acceptance among opinion leaders in the diabetes treatment community, insulin-prescribing physicians, third-party payors and people with insulin-dependent diabetes;

manufacturing problems;

actual or perceived quality problems;

changes in reimbursement rates or policies relating to the OmniPod System by third-party payors;

claims that any portion of the OmniPod System infringes on patent rights or other intellectual property rights owned by other parties;

adverse regulatory or legal actions relating to the OmniPod System;

damage, destruction or loss of any of our automated assembly units;

conversion of patient referrals to actual sales of the OmniPod System;

collection of receivables from our customers;

attrition rates of customers who cease using the OmniPod System;

competitive pricing and related factors; and

results of clinical studies relating to the OmniPod System or our competitors' products.

If any of these events occurs, our ability to generate revenue could be significantly reduced.

Our ability to achieve profitability from a current net loss level will depend on our ability to reduce the per unit cost of producing the OmniPod by increasing customer orders, increasing manufacturing volume and reducing raw material and overhead costs per OmniPod.

Currently, the gross profit from the sale of the OmniPod System is not sufficient to cover our operating expenses. To achieve profitability, we need to, among other things, reduce the per unit cost of the OmniPod. This can be achieved by increasing our manufacturing volume, which will

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allow for volume purchase discounts to reduce our raw material costs and improve absorption of manufacturing overhead costs. During 2008, we completed construction of a partially automated manufacturing line at a facility in China operated by a subsidiary of Flextronics International Ltd. If we are unable to reduce raw material and manufacturing overhead costs through volume purchase discounts and increased production capacity, our ability to achieve profitability will be severely constrained. Any increase in manufacturing volumes must be supported by a concomitant increase in customer orders. In addition, we are in the process of developing our next generation product. Further, each OmniPod contains limited amounts of silver and other precious metals, the costs of which have risen over the recent past. The occurrence of one or more factors that negatively impact the manufacturing or sales of the OmniPod System or delay the introduction of our next generation product or increase our raw material costs may prevent us from achieving our desired increase in manufacturing volume, which would prevent us from attaining profitability.

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Adverse changes in general economic conditions in the United States could adversely affect us.

We are subject to the risks arising from adverse changes in general economic market conditions. The U.S. economy remains sluggish as it seeks to recover from a severe recession and unprecedented turmoil. The U.S. economy continues to suffer from market volatility, difficulties in the financial services sector, tight credit markets, softness in the housing markets, concerns of inflation, increases in the cost of commodities such as silver and gold, reduced corporate profits and capital spending, significant job losses, reduced consumer spending, and continuing economic uncertainties. The economic turmoil and the uncertainty about future economic conditions could negatively impact our current and prospective customers, adversely affect the financial ability of health insurers to pay claims, adversely impact our expenses and ability to obtain financing of our operations, cause delays or other problems with key suppliers and increase the risk of counterparty failures. We cannot predict the strength or duration of this global economic downturn or the subsequent recovery.

Healthcare spending in the United States has been, and is expected to continue to be, negatively affected by these recessionary trends. For example, patients who have lost their jobs or healthcare coverage may no longer be covered by an employer-sponsored health insurance plan and patients reducing their overall spending may eliminate purchases requiring co-payments. Since the sale of the OmniPod System to a new patient is generally dependent on the availability of third-party reimbursement and normally requires the patient to make a significant co-payment, the impacts of the recession on our potential customers may reduce the referrals generated by our sales force and thereby reduce our customer orders. Similarly, the impacts of the recession on our existing patients may cause some of them to cease purchasing the OmniPod System and to return to MDI or other less-costly therapies, which would cause our attrition rate to increase. Any decline in new customer orders or increase in our customer attrition rate will reduce our revenue, which in turn will make it more difficult to achieve the per unit cost-savings which are expected to be attained through increases in our manufacturing volume.

The severe recession has impacted the financial stability of many private health insurers. As a result, it has been reported that some insurers are scrutinizing claims more rigorously and delaying or denying reimbursement more often. Since the sale of the OmniPod System is generally dependent on the availability of third-party reimbursement, any delay or decline in such reimbursement will adversely affect our revenue.

Healthcare reform legislation could adversely affect our revenue and financial condition.

During the past several years, the U.S. healthcare industry has been subject to an increase in governmental regulation at both the federal and state levels. Efforts to control healthcare costs, including prescription drug costs, are underway at the federal and state government levels. Included as part of this new legislation is a 2.3% excise tax on the medical device industry beginning January 1, 2013 that is payable based on revenue, not income. This future excise tax may have a material adverse effect on our financial condition and results of operations. In addition, there are provisions that provide for the creation of a new public-private Patient-Centered Outcomes Research Institute tasked with identifying comparative effectiveness research priorities, establishing a research project agenda and contracting with entities to conduct the research in accordance with the agenda. Research findings published by this institute will be publicly disseminated. It is difficult at this time to determine what impact the comparative effectiveness analysis will have on the OmniPod System or our future financial results.

The recently enacted healthcare reform legislation, along with associated proposed and interim final rule-making, may have an adverse impact on Neighborhood Diabetes business. For example, the federal Retiree Drug Subsidy is less valuable to Neighborhood Diabetes clients due to the change in tax treatment of the subsidy. As a result, Neighborhood Diabetes clients may choose to drop or limit retiree prescription drug coverage. Further, private plan sponsors may react to the new laws and the uncertainty surrounding them by reducing, foregoing or delaying engaging Neighborhood Diabetes to distribute products. We cannot accurately predict the complete impact of healthcare reform legislation, but it could lead to a decreased demand for

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Neighborhood Diabetes distribution services and other outcomes that could adversely impact Neighborhood Diabetes business and financial results, which in turn could materially and adversely impact our business and financial results.

In addition, the healthcare reform legislation significantly increased regulation of managed care plans and decreased reimbursement to Medicare managed care and fee-for-service programs. Some of these initiatives purport to, among other things, require that health plan members have greater access to drugs not included on a plan's formulary. Moreover, to alleviate budget shortfalls, states have reduced or frozen payments to Medicaid managed care plans.

There may in the future be additional changes in government policy, including additional modifications to the recently-adopted healthcare reform bill, that could increase our cost of doing business and negatively impact our ability to sell our products and achieve profitability.

We may need to raise additional funds in the future, and these funds may not be available on acceptable terms or at all.

Our capital requirements will depend on many factors, including:

revenue generated by sales of the our current products and any other future products that we may develop;

costs associated with adding further manufacturing capacity, including capacity to manufacture our next-generation product;

costs associated with expanding our sales and marketing efforts in the United States and internationally;

expenses we incur in manufacturing and selling the OmniPod System and selling our products;

costs of developing new products or technologies and enhancements to the OmniPod System;

the cost of obtaining and maintaining FDA approval or clearance of our current or future products;

costs associated with any expansion;

the cost of complying with regulatory requirements;

costs associated with capital expenditures;

costs associated with litigation; and

the number and timing of any acquisitions or other strategic transactions.

We believe that our current cash and cash equivalents, together with the cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements through at least the end of 2012.

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We may in the future seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. In December 2010, we sold 3.45 million shares of our common stock at a price of \$13.27 per share, resulting in net proceeds to us of approximately \$45.4 million. We used a portion of the net proceeds to repay amounts outstanding under the Facility Agreement we entered into with certain institutional accredited investors in March 2009, as amended in September 2009 and June 2010 and repaid in December 2010. In addition, in June 2011 we issued \$143.8 million of our 3.75% Convertible Senior Notes and repurchased \$70 million of our outstanding 5.375% Convertible Senior Notes. The 3.75% Convertible Senior Notes will mature in June 2016 and the remaining 5.375% Senior Convertible Notes will mature in June 2013. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies, or grant licenses on terms that are not favorable to us.

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Our ability to raise additional capital may be adversely impacted by current economic conditions, including the effects of the continued disruptions to the credit and financial markets in the United States and worldwide. As a result of these and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on terms favorable to us or our stockholders.

If we are unable to raise additional capital due to these or other factors, we may need to further manage our operational expenses to reflect these external factors, including potentially curtailing our planned development activities. If we cannot raise additional funds in the future on acceptable terms, we may not be able to develop new products, execute our business plan, take advantage of future opportunities or respond to competitive pressures or unanticipated customer requirements. If any of these events occur, it could adversely affect our business, financial condition and results of operations.

We are dependent upon third-party suppliers, making us vulnerable to supply problems and price fluctuations.

We rely on a number of suppliers who manufacture the components of the OmniPods and PDMs. For example, we rely on Phillips Plastic Corporation to manufacture and supply a number of injection molded components of the OmniPod and Freescale Semiconductor, Inc. to manufacture and supply the application specific integrated circuit that is incorporated into the OmniPod. In addition, a subsidiary of Flextronics in China provides the supply of complete OmniPods. We do not have long-term supply agreements with most of our suppliers, and, in many cases, we make our purchases on a purchase order basis. In some other cases, where we do have agreements in place, our agreements with our suppliers can be terminated by either party upon short notice. For example, the term of our agreement with Flextronics is now one year, subject to annual one-year renewals, and may be terminated at any time by either party upon prior written notice given no less than a specified number of days prior to the date of termination. Additionally, our suppliers may encounter problems during manufacturing for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;

we may not be able to obtain an adequate supply in a timely manner or on commercially reasonable terms;

our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of the OmniPod System or cause delays in shipment;

we may have difficulty locating and qualifying alternative suppliers for our sole-source supplies;

switching components may require product redesign and submission to the FDA of a 510(k) supplement;

our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver products to us in a timely manner;

the occurrence of a fire, natural disaster or other catastrophe, impacting one or more of our suppliers, may affect their ability to deliver products to us in a timely manner; and

our suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

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We may not be able to quickly establish additional or alternative suppliers, particularly for our sole-source suppliers, in part because of the FDA approval process and because of the custom nature of various parts we

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require. Any interruption or delay in obtaining products from our third-party suppliers, or our inability to obtain products from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competing products.

If Neighborhood Diabetes does not continue to earn and retain purchase discounts and rebates from manufacturers at current levels, gross margins may decline, which could adversely affect our business and results of operations.

Neighborhood Diabetes has contractual relationships with product device manufacturers, pharmaceutical manufacturers and wholesalers that provide Neighborhood Diabetes with purchase discounts and rebates on products distributed by Neighborhood Diabetes and drugs dispensed from Neighborhood Diabetes mail-order pharmacies. These discounts and rebates are generally passed on to payors in the form of lower contracted reimbursement rates. Manufacturer rebates often depend on Neighborhood Diabetes ability to meet contractual market share or other requirements.

Neighborhood Diabetes payor partners often have contractual rights relating to their formulary structure, and while Neighborhood Diabetes programs aim to maximize savings to payors, they are often making specific choices regarding which products and drugs to place on their formularies. Neighborhood Diabetes profitability may be impacted by these payor decisions. In addition, the pharmaceutical industry (both manufacturers of brand-name drugs, as well as generic drugs) continues to consolidate and this may impact Neighborhood Diabetes drug purchasing costs and profitability.

Changes in existing federal or state laws or regulations, or in their interpretation by courts and agencies or the adoption of new laws or regulations (such as the Patient Protection and Affordable Care Act enacted on March 23, 2010), relating to patent term extensions, purchase discount and rebate arrangements with manufacturers, as well as some of the other services Neighborhood Diabetes provides to manufacturers, could also reduce the discounts or rebates Neighborhood Diabetes receives and adversely impact its business, financial condition, liquidity and operating results, which in turn could materially and adversely affect our business and results of operations.

Neighborhood Diabetes business is dependent on its relationships with a limited number of suppliers and health plans. As such, the loss of one or more of these relationships could significantly impact our ability to sustain and/or improve our financial performance.

Neighborhood Diabetes derives a significant percentage of its net sales and profitability from its relationships with a limited number of suppliers and payors. Neighborhood Diabetes agreements with its suppliers and payors may be short-term and cancelable by either party without cause on 30 to 365 days prior notice. These agreements may limit Neighborhood Diabetes ability to provide distribution services for competing products during the term of the agreement and allow the supplier to distribute through channels other than Neighborhood Diabetes. Further, certain of these agreements allow pricing and other terms of these relationships to be periodically adjusted for changing market conditions or required service levels. A termination or modification to any of these relationships could have a material adverse effect on Neighborhood Diabetes business, financial condition and results of operations, which in turn could have a material and adverse effect on our business and results of operations.

Neighborhood Diabetes has received a significant percentage of its historical net sales from Medicare reimbursement. Medicare reimbursement rates are reset annually by CMS and are typically subject to downward pressure. Furthermore, CMS is able to reset reimbursement rates and terminate contracts at will. In addition, participation in the Medicare program requires strict compliance to a complex set of regulatory requirements. Failure by Neighborhood Diabetes to meet those requirements could result in the loss of the ability to participate as a Medicare supplier, which could have an adverse effect on our business and results of operations.

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Our financial condition or results of operations may be adversely affected by international business risks.

In January 2010, we entered into a five-year distribution agreement with Ypsomed to become the exclusive distributor of the OmniPod System in eleven countries. Through our partnership with Ypsomed, the OmniPod System is now available in Germany, the United Kingdom, the Netherlands, and Switzerland. Ypsomed's introduction of the OmniPod System in certain countries has been delayed due to a number of factors. Future delays would likely result in reduced purchases by Ypsomed, which would adversely affect our revenue. In February 2011, we entered into a distribution agreement with GSK to become the exclusive distributor of the OmniPod System in Canada. GSK began distributing the OmniPod System during the third quarter of 2011. Moreover, while these agreements will help us expand our global footprint, we will now be exposed to fluctuations in product demand and sales productivity outside the United States and will have to manage the risks associated with market acceptance of the OmniPod System in foreign countries. Our efforts to introduce our current or future products into foreign markets may not be successful, in which case we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for expansion into foreign markets could exceed the results of operations generated from this expansion. We do not have control over Ypsomed's or GSK's operational and financial condition, and we will have increased foreign regulatory and export requirements.

In addition, in order to reduce our cost of goods sold and increase our production capacity, we increasingly rely on third-party suppliers located outside the United States. For example, currently all of our OmniPods are manufactured at a facility in China operated by Flextronics. As a result, our business is subject to risks associated with doing business internationally, including:

political instability and adverse economic conditions;

trade protection measures, such as tariff increases, and import and export licensing and control requirements;

potentially negative consequences from changes in tax laws;

difficulty in staffing and managing widespread operations;

difficulties associated with foreign legal systems including increased costs associated with enforcing contractual obligations in foreign jurisdictions;

changes in foreign currency exchange rates;

differing protection of intellectual property;

unexpected changes in regulatory requirements;

failure to fulfill foreign regulatory requirements on a timely basis or at all to market the OmniPod System or other future products;

availability of, and changes in, reimbursement within prevailing foreign health care payment systems;

adapting to the differing laws and regulations, business and clinical practices, and patient preferences in foreign markets;

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difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign partners, distributors or sales or marketing agents; and

difficulty in collecting accounts receivable and longer collection periods.

In addition, expansion into foreign markets imposes additional burdens on our executive and administrative personnel, research and sales departments and general management resources. Our future success will depend in large part on our ability to anticipate and effectively manage these and other risks associated with doing business outside of the United States. Any of these factors may have a material adverse effect on our production capacity and, consequently, our business, financial condition and results of operations.

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Failure to secure or retain adequate coverage or reimbursement for the OmniPod System by third-party payors could adversely affect our business, financial condition and results of operations.

We expect that sales of the OmniPod System will be limited unless a substantial portion of the sales price of the OmniPod System is paid for by third-party payors, including private insurance companies, health maintenance organizations, preferred provider organizations and other managed care providers. We currently have contracts establishing reimbursement for the OmniPod System with national and regional third-party payors which provide reimbursement for patients residing in all 50 states. While we anticipate entering into additional contracts with other third-party payors, we cannot assure you that we will be successful in doing so. In addition, these contracts can generally be terminated by the third-party payor without cause. Also, healthcare market initiatives in the United States may lead third-party payors to decline or reduce reimbursement for the OmniPod System. Moreover, compliance with administrative procedures or requirements of third-party payors may result in delays in processing approvals by those payors for patients to obtain coverage for the use of the OmniPod System. We are an approved Medicare provider and current Medicare coverage for CSII therapy does exist. However, existing Medicare coverage for CSII therapy is based on the pricing structure developed for conventional insulin pumps. We believe that the coding verification for Medicare reimbursement of the OmniPod System is inappropriate and we have been in the process for several years in seeking appropriate coding verification. No assurance can be provided that we will ever obtain appropriate coding verification for Medicare reimbursement of the OmniPod System. As a result, we have focused our efforts in establishing reimbursement for the OmniPod System by negotiating contracts with private insurers. In addition, as we expand our sales and marketing efforts outside of the United States, we face additional risks associated with obtaining and maintaining reimbursement from foreign health care payment systems on a timely basis or at all. Failure to secure or retain adequate coverage or reimbursement for the OmniPod System by third-party payors, including Medicare, could have a material adverse effect on our business, financial condition and results of operations.

Failure to retain key payor partners and their members, either as a result of economic conditions, increased competition or other factors, could result in significantly decreased revenues and decreased profitability of the Neighborhood Diabetes business.

If several of Neighborhood Diabetes' payor partners terminate, cancel or do not renew their agreements with Neighborhood Diabetes or stop contracting with Neighborhood Diabetes for some of the products Neighborhood Diabetes provides because they accept a competing proposal or for any other reason, and Neighborhood Diabetes is not successful in generating new sales with comparable operating margins to replace the lost business, Neighborhood Diabetes' revenues and results of operations could suffer, which in turn could materially and adversely affect our revenues and results of operations.

Certain revenues from diabetes testing supplies and Neighborhood Diabetes' Medicare Part D offerings expose Neighborhood Diabetes to increased billing, cash application and credit risks. Additionally, current economic conditions may expose Neighborhood Diabetes to increased credit risk.

Net sales from Neighborhood Diabetes' distribution of diabetes testing supplies depend on the continued availability of reimbursement by government and private insurance plans. The government's Medicare regulations are complex and, as a result, the billing and collection process is time-consuming and typically involves the submission of claims to multiple payors whose payment of such claims may be contingent upon the payment of another payor. Because of the coordination with multiple payors and the complexity in determining reimbursable amounts, these accounts receivable have higher risk in collecting the full amounts due and applying the associated payments.

The Medicare Part D product offerings that Neighborhood Diabetes distributes require premium payments from members for receipt of ongoing benefit, as well as amounts due from CMS. As a result of the demographics of the consumers covered under these programs and the complexity of the calculations, as well as the potential magnitude and timing of settlement for amounts due from CMS, these accounts receivable are subject to heightened billing and realization risk.

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Additionally, Neighborhood Diabetes may be subject to increased credit risk associated with state and local government agencies experiencing increased fiscal challenges. As a result of these aforementioned risks, Neighborhood Diabetes may be required to record bad debt expenses, which could materially and adversely affect our results of operations and liquidity.

The implementation of a national-mail order competitive bid program by CMS could negatively affect Neighborhood Diabetes operating results.

Relative to Neighborhood Diabetes diabetes testing supplies business, the Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bid Program (the Program) provides for a phased-in program for competitive bidding on certain durable medical equipment items, including mail-order diabetes testing supplies. In July 2010, as part of the Program, CMS announced new single payment amounts for diabetes testing supplies, which averaged 56% off the current fee schedule amounts for such supplies under round one. The new limited single pay amounts impact a limited number of geographic areas. Neighborhood Diabetes bid was not aligned with these single payment amounts. In November 2010, CMS announced the names of the winners for round one, for which reimbursement rates became effective January 2011 for the limited number of geographic areas. Although Neighborhood Diabetes will not be a contracted supplier in the competitively bid areas, round one of the Program affects a small portion of Neighborhood Diabetes base membership. However, Congressional action has provided CMS with additional authority to use pricing information gathered during the Program for purposes of establishing reimbursement rates in geographic areas not subject to competitive bidding. CMS also announced in November 2010 some general parameters relating to a national mail-order competitive bid program. While CMS implementation of a national mail-order competitive bid program is not expected until at least 2013, if such a program is implemented and, depending upon the level of reduction in reimbursement rates of the final bid program, Neighborhood Diabetes operating results could be materially and adversely affected, which in turn could materially and adversely affect our operating results.

We face competition from numerous competitors, most of whom have far greater resources than we have, which may make it more difficult for us to achieve significant market penetration and which may allow them to develop additional products for the treatment of diabetes that compete with the OmniPod System.

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. The OmniPod System competes with a number of existing insulin delivery devices as well as other methods for the treatment of diabetes. Medtronic MiniMed, a division of Medtronic has been the market leader for many years and has the majority share of the conventional insulin pump market in the United States. Other significant suppliers in the United States include Animas Corporation, a division of Johnson & Johnson, and Roche Diagnostics, a division of F. Hoffman-La Roche Ltd.

All of these competitors are large, well-capitalized companies with significantly more market share and resources than we have. As a consequence, they are able to spend more aggressively on product development, marketing, sales and other product initiatives than we can. Many of these competitors have:

significantly greater name recognition;

established relations with healthcare professionals, customers and third-party payors;

larger and more established distribution networks;

additional lines of products and the ability to offer rebates or bundle products to offer higher discounts or other incentives to gain a competitive advantage;

greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory approval; and

greater financial and human resources for product development, sales and marketing and patent litigation.

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We also compete with MDI therapy, which is substantially less expensive than CSII therapy. MDI therapy has been made more effective by the introduction of long-acting insulin analogs by both sanofi-aventis and Novo Nordisk A/S. While we believe that CSII therapy, in general, and the OmniPod System, in particular, have significant competitive and clinical advantages over traditional MDI therapy, improvements in the effectiveness of MDI therapy may result in fewer people with insulin-dependent diabetes converting from MDI therapy to CSII therapy than we expect and may result in negative price pressure.

In addition to the established insulin pump competitors, a number of companies (including current competitors) are working to develop and market new insulin patch pumps or multi channel pump devices (insulin and glucagon). These companies are at various stages of development. The companies of which we are aware working in this area include Medtronic, Roche Diagnostics, Spring Health Solutions Ltd., Sensile Medical AG, Asante Solutions, Inc., Phluid Corporation, Calibra Medical, Inc., Valeritas Inc., Starbridge Systems Ltd., Novo Nordisk A/S and Abbott Laboratories.

Our current competitors or other companies may at any time develop additional products for the treatment of diabetes. For example, other diabetes-focused pharmaceutical companies, including Abbott Laboratories, Eli Lilly and Company, Novo Nordisk A/S and Takeda Pharmaceuticals Company Limited, are developing similar products. All of these competitors are large, well-capitalized companies with significantly greater product development resources than us. If an existing or future competitor develops a product that competes with or is superior to the OmniPod System, our revenue may decline. In addition, some of our competitors may compete by changing their pricing model or by lowering the price of their insulin delivery systems or ancillary supplies. If these competitors' products were to gain acceptance by healthcare professionals, people with insulin-dependent diabetes or third-party payors, a downward pressure on prices could result. If prices were to fall, we may not improve our gross margins or sales growth sufficiently to achieve profitability.

Competition among distributors in the diabetes testing supply and insulin pump and pump supply market, as well as the broader healthcare industry, is significant and could impair Neighborhood Diabetes' ability to attract and retain clients.

Competition among distributors in the diabetes testing supply and insulin pump and pump supply market, which Neighborhood Diabetes serves, is significant. Neighborhood Diabetes competes with a wide variety of market participants, including national, regional and local distributors such as Liberty Medical Supply Inc., CCS Medical, Simplex Healthcare, Inc. and Edgepark Medical Supplies. Neighborhood Diabetes competitors include many profitable and well-established companies that have significantly greater financial, marketing and other resources than we have.

Neighborhood Diabetes competes primarily on the basis of its high touch service model, which we believe distinguishes it from other market participants. To attract new clients and retain existing clients, Neighborhood Diabetes must continually provide quality services to its clients and assist healthcare providers and insurers with managing their costs. We cannot be sure that Neighborhood Diabetes will continue to remain competitive, nor can we be sure that we will be able to market Neighborhood Diabetes' distribution capabilities and services to clients successfully.

Part of Neighborhood Diabetes' ability to remain profitably competitive in winning and retaining business relies on its ability to maintain reimbursement rates and product supply costs in ranges that produce a positive sales margin. Decreased competition among product manufacturers and payors may impact Neighborhood Diabetes' ability to achieve favorable terms. Neighborhood Diabetes' largest payor partner, the Medicare Program, represents a significant portion of Neighborhood Diabetes' net sales. Medicare reimbursement rates are reset annually by CMS and are typically subject to downward pressure. Significant reimbursement decreases by Medicare without a corresponding ability to secure lower supply costs could materially and adversely affect operations.

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Consolidation of payor entities within the markets Neighborhood Diabetes serves, as well as the consolidation of competitors, or suppliers could impair Neighborhood Diabetes' ability to attract and retain clients.

Technological breakthroughs in diabetes monitoring, treatment or prevention could render the OmniPod System obsolete.

The diabetes treatment market is subject to rapid technological change and product innovation. The OmniPod System is based on our proprietary technology, but a number of companies, medical researchers and existing pharmaceutical companies are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapeutics for the monitoring, treatment and/or prevention of insulin-dependent diabetes. For example, FDA approval of a commercially viable closed-loop system that combines continuous real-time glucose sensing or monitoring and automatic continuous subcutaneous insulin infusion in a manner that delivers appropriate amounts of insulin on a timely basis without patient direction could have a material adverse effect on our revenue and future profitability. We have an agreement with DexCom, a leading provider of continuous glucose monitoring systems for people with diabetes, to develop a product that will integrate the receiver portion of DexCom's continuous glucose monitor with the OmniPod System PDM. This initiative with DexCom has been subject to extensive product development and regulatory delay, and no assurances can be provided that we will ever develop or commercialize an integrated product with DexCom's continuous glucose monitoring products. Medtronic has developed an FDA-approved product combining continuous glucose sensing and CSII therapy and if we fail to do so or are delayed in doing so, we may be at a competitive disadvantage, which could negatively impact our business. In addition, the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure or improve the treatment of diabetes. Any technological breakthroughs in diabetes monitoring, treatment or prevention could render the OmniPod System obsolete, which may have a material adverse effect on our business, financial condition and results of operations.

If our existing license agreement with Abbott is terminated or we fail to enter into new license agreements allowing us to incorporate a blood glucose meter into the OmniPod System, our business may be materially adversely impacted.

Our rights to incorporate the FreeStyle blood glucose meter into the OmniPod System are governed by a development and license agreement with Abbott as the successor to TheraSense, Inc. This agreement provides us with a non-exclusive, fully paid, non-transferable and non-sublicensable license in the United States under patents and other relevant technical information relating to the FreeStyle blood glucose meter during the term of the agreement. As amended, this agreement runs through February 2013, with automatic renewals for subsequent one-year periods thereafter. The license granted under the agreement covers the United States, Canada, and Israel and certain other countries and Abbott is obligated to pay certain amounts over time to us for services performed in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to customers in most of these countries. The agreement may be terminated by Abbott if it discontinues its FreeStyle blood glucose meter or test strips or by either party if the other party is acquired by a competitor of the first party or materially breaches its obligations under the agreement. Termination of this agreement could require us to either remove the blood glucose meter from PDMs to be sold in the future, which would impair the functionality of the OmniPod System, or attempt to incorporate an alternative blood glucose meter into the PDM, either of which would require significant development and regulatory activities that might not be completed in time to prevent an interruption in the availability of the OmniPod System to our customers, which could have a material adverse effect on our business, financial condition and results of operations.

We entered into a non-exclusive agreement with LifeScan, Inc. (LifeScan) to integrate LifeScan's OneTouch blood glucose monitoring technology into our PDM. Under the terms of the agreement, LifeScan will provide its glucose monitoring technology to us, and we are responsible for the development, design and approval of the integrated device. The initial term of the agreement ends in 2017. The agreement also contains an exclusivity option that may be exercised, at our discretion, upon commercialization of the integrated PDM. This

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option would make LifeScan the exclusive blood glucose monitoring technology integrated into our PDM and provide for additional compensation payments to be paid by LifeScan to us. However, if we are unable to complete the development and regulatory process so that we can begin marketing and selling our PDM with an integrated LifeScan meter before we are required to cease marketing and selling our PDM with an integrated Abbott meter, there could be an interruption in the payments we receive related to the sale of our PDM with an integrated blood glucose meter, which could have a material adverse effect on our business, financial condition and results of operations.

In the future, we may need additional licenses to intellectual property owned by third parties in order to commercialize new products. If we cannot obtain these additional licenses, we may not be able to develop or commercialize these future products. Our rights to use technologies licensed to us by third parties are not entirely within our control, and we may not be able to continue selling the OmniPod System or sell future products without these technologies.

The patent rights on which we rely to protect the intellectual property underlying the OmniPod System may not be adequate, which could enable third parties to use our technology and would harm our continued ability to compete in the market.

Our success will depend in part on our continued ability to develop or acquire commercially-valuable patent rights and to protect these rights adequately. Our patent position is generally uncertain and involves complex legal and factual questions. The risks and uncertainties that we face with respect to our patents and other related rights include the following:

the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;

the claims of any patents that are issued may not provide meaningful protection;

we may not be able to develop additional proprietary technologies that are patentable; and

other companies may design around technologies we have patented, licensed or developed.

We also may not be able to protect our patent rights effectively in some foreign countries. For a variety of reasons, we may decide not to file for patent protection. Our patent rights underlying the OmniPod System may not be adequate, and our competitors or customers may design around our proprietary technologies or independently develop similar or alternative technologies or products that are equal or superior to ours without infringing on any of our patent rights. In addition, the patents licensed or issued to us may not provide a competitive advantage. The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

Other rights and measures we have taken to protect our intellectual property may not be adequate, which would harm our ability to compete in the market.

In addition to patents, we rely on a combination of trade secrets, copyright and trademark laws, confidentiality, non-disclosure and assignment of invention agreements and other contractual provisions and technical measures to protect our intellectual property rights. Despite these measures, any of our intellectual property rights could be challenged, invalidated, circumvented or misappropriated. While we currently require employees, consultants and other third parties to enter into confidentiality, non-disclosure or assignment of invention agreements, or a combination thereof where appropriate, any of the following could still occur:

the agreements may be breached;

we may have inadequate remedies for any breach;

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trade secrets and other proprietary information could be disclosed to our competitors; or

others may independently develop substantially equivalent or superior proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

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If, for any of the above reasons, our intellectual property is disclosed or misappropriated, it would harm our ability to protect our rights and have a material adverse effect on our business, financial condition and results of operations.

We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in the medical device industry are generally uncertain. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

assert claims of infringement;

enforce our patents;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of others.

Any lawsuits that we initiate could be expensive, take significant time and divert management's attention from other business concerns.

Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing.

Additionally, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

Claims that our current or future products infringe or misappropriate the proprietary rights of others could adversely affect our ability to sell those products and cause us to incur additional costs.

Substantial litigation over intellectual property rights exists in the medical device industry. We expect that we could be increasingly subject to third-party infringement claims as our revenue increases, the number of competitors grows and the functionality of products and technology in different industry segments overlaps. Third parties may currently have, or may eventually be issued, patents on which our current or future products or technologies may infringe. For example, we are aware of certain patents and patent applications owned by our competitors that cover different aspects of insulin infusion and the related devices. Any of these third parties might make a claim of infringement against us. In particular, Medtronic in a letter we received in March 2007, invited us to discuss our taking a license to certain Medtronic patents. The patents referenced by this letter relate to technology that is material to our business. We have not had any substantive discussions with Medtronic concerning this matter since our receipt of this letter.

In addition, in August 2010, BD filed a lawsuit in the United States District Court in the State of New Jersey against us alleging that the OmniPod System infringes three of its patents. BD seeks a declaration that we have infringed its patents, equitable relief, including an injunction that would enjoin us from infringing these patents, and an unspecified award for monetary damages. This litigation, regardless of its outcome, will likely result in the expenditure of significant financial resources and the diversion of management's time and resources. In addition, this litigation may cause negative publicity, adversely impact prospective customers, cause product shipment delays, prohibit us from manufacturing, marketing or selling our current or future products, require us to develop non-infringing technology, make substantial payments to third parties or enter into royalty or license agreements, which may not be available on acceptable terms or at all. If a successful claim of infringement were made against us in this litigation and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenue may decrease substantially and we could be

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exposed to significant liability. A court could enter orders that temporarily, preliminarily or permanently enjoin us or our customers from making, using, selling, offering to sell or importing our current or future products, or could enter an order mandating that we undertake certain remedial activities.

We are subject to extensive regulation by the U.S. Food and Drug Administration, which could restrict the sales and marketing of the OmniPod System and could cause us to incur significant costs. In addition, we may become subject to additional foreign regulation as we increase our efforts to sell the OmniPod System outside of the United States.

We sell medical devices that are subject to extensive regulation by the FDA. These regulations relate to manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance or pre-market approval from the FDA, unless an exemption applies. We may be required to obtain a new 510(k) clearance or pre-market approval for significant post-market modifications to the OmniPod System. For example, we are currently awaiting 510(k) clearance for our next generation OmniPod System. Obtaining 510(k) clearance or pre-market approval for medical devices can be expensive and lengthy, and entail significant user fees, unless an exemption is available. The FDA's process for obtaining 510(k) clearance usually takes three to twelve months, but it can last longer. The process for obtaining pre-market approval is much more costly and uncertain and it generally takes from one to three years, or longer, from the time the application is filed with the FDA.

Medical devices may be marketed only for the indications for which they are approved or cleared. We have obtained 510(k) clearance for the current clinical applications for which we market our OmniPod System, which includes the use of U-100, which is a common form of insulin. However, our clearances can be revoked if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k) clearances or pre-market approvals for new products or for modifications to, or additional indications for, the OmniPod System in a timely fashion or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices.

We also are subject to numerous post-marketing regulatory requirements, which include quality system regulations related to the manufacturing of our devices, labeling regulations and medical device reporting regulations, which require us to report to the FDA if our devices cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. In addition, these regulatory requirements may change in the future in a way that adversely affects us. For instance, the FDA is in the process of reviewing the 510(k) approval process and criteria and has announced initiatives to improve the current pre-market and post-market regulatory processes and requirements associated with infusion pumps and other home use medical devices. As part of this effort, the FDA is reviewing the adverse event reporting and recall processes for insulin pumps. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA, which may include any of the following sanctions:

untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

customer notification, or orders for repair, replacement or refunds;

voluntary or mandatory recall or seizure of our current or future products;

administrative detention by the FDA of medical devices believed to be adulterated or misbranded;

imposing operating restrictions, suspension or shutdown of production;

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refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses or modifications to the OmniPod System;

rescinding 510(k) clearance or suspending or withdrawing pre-market approvals that have already been granted; and

criminal prosecution.

The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

We entered into a distribution agreement with Ypsomed pursuant to which Ypsomed became the exclusive distributor of the OmniPod System, subject to approved reimbursement, in eleven countries. In addition, in February 2011, we entered into a distribution agreement with GSK pursuant to which GSK became the exclusive distributor of the OmniPod System in Canada. By distributing our product outside of the United States we may be required to comply with additional foreign regulatory requirements. For example, in April 2009, we received CE Mark approval for our OmniPod System and in August 2011, we received CE Mark approval of our next generation OmniPod System. The CE Mark gives us authorization to distribute the OmniPod System throughout the European Union and in other countries that recognize the CE Mark. Additionally, in September 2009, we received Health Canada approval to distribute the OmniPod System throughout Canada. As we expand our sales efforts internationally, we may need to obtain additional foreign approval certifications.

If we, our contract manufacturers or our component suppliers fail to comply with the FDA's quality system regulations, the manufacturing and distribution of our devices could be interrupted, and our product sales and operating results could suffer.

We, our contract manufacturers and our component suppliers are required to comply with the FDA's quality system regulations, which is a complex regulatory framework that covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces its quality system regulations through periodic unannounced inspections. We cannot assure you that our facilities or our contract manufacturers' or component suppliers' facilities would pass any future quality system inspection. If our or any of our contract manufacturers' or component suppliers' facilities fails a quality system inspection, the manufacturing or distribution of our devices could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse quality system inspection could force a suspension or shutdown of our packaging and labeling operations or the manufacturing operations of our contract manufacturers, or a recall of our devices. If any of these events occurs, we may not be able to provide our customers with the quantity of OmniPods they require on a timely basis, our reputation could be harmed and we could lose customers, any or all of which may have a material adverse effect on our business, financial condition and results of operations.

Our current or future products are subject to recalls even after receiving FDA clearance or approval, which would harm our reputation, business and financial results.

The FDA and similar governmental bodies in other countries have the authority to require the recall of our current or future products if we or our contract manufacturers fail to comply with relevant regulations pertaining to manufacturing practices, labeling, advertising or promotional activities, or if new information is obtained concerning the safety or efficacy of these products. A government-mandated recall could occur if the FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death. A voluntary recall by us could occur as a result of manufacturing defects, labeling deficiencies, packaging defects or other failures to comply with applicable regulations. Any recall would divert management attention and financial resources and harm our reputation with customers. A recall involving the OmniPod System would be particularly harmful to our business, financial condition and results of operations because it is currently our principal product.

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We are subject to federal and state laws prohibiting kickbacks and false or fraudulent claims, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

The federal anti-kickback statute and several similar state laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services and impose civil and criminal penalties for noncompliance that can be substantial. These laws constrain our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of medical devices. We conduct various marketing and product training activities that involve making payments to healthcare providers and entities. While we believe that our activities are compliant with all applicable laws, even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could have a material adverse effect on our business, financial condition and results of operations.

We participate in federal and state programs such as Medicare and Medicaid, under which we are subject to numerous state and federal laws and regulations regulating reimbursement and intended to prevent fraud and abuse. Medicare and Medicaid regulations are complex and may require management's interpretation. Our compliance with Medicare and Medicaid regulations may be reviewed by federal or state agencies, including the United States Department of Health and Human Services' Office of the Inspector General (OIG), CMS, and the Department of Justice. To ensure compliance with Medicare, Medicaid and other regulations, government agencies conduct periodic audits of us to ensure compliance with various supplier standards and billing requirements.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. If we are found to be in violation of the privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

Product liability suits, whether or not meritorious, could be brought against us due to an alleged defective product or for the misuse of our devices. These suits could result in expensive and time-consuming litigation, payment of substantial damages, and an increase in our insurance rates.

If our current or future products are defectively designed or manufactured, contain defective components or are misused, or if someone claims any of the foregoing, whether or not meritorious, we may become subject to substantial and costly litigation. Misusing our devices or failing to adhere to the operating guidelines of the OmniPod System could cause significant harm to patients, including death. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. While we believe that we are reasonably insured against these risks, we may not have sufficient insurance coverage for all future claims. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm

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our reputation in the industry and could reduce revenue. Product liability claims in excess of our insurance coverage would be paid out of cash reserves harming our financial condition and adversely affecting our results of operations.

Our ability to grow our revenue depends in part on our retaining a high percentage of our customer base.

A key to driving our revenue growth is the retention of a high percentage of our customers. We have developed retention programs aimed at both the healthcare professionals and the patients, which include appeals assistance, patient training, customer support and an automatic re-order program for patients. We have had a satisfactory customer retention rate; however, we cannot assure you that we will maintain this retention rate in the future. Current uncertainty in global economic conditions, rising unemployment and negative financial news may negatively affect product demand and other related matters. If demand for our products fluctuates as a result of economic conditions or otherwise, our ability to attract and retain customers could be harmed. The failure to retain a high percentage of our customers would negatively impact our revenue growth and may have a material adverse effect on our business, financial condition and results of operations.

We have sponsored, and expect to continue to sponsor market studies seeking to demonstrate certain aspects of the efficacy of the OmniPod System, which may fail to produce favorable results.

To help improve, market and sell the OmniPod System, we have sponsored, and expect to continue to sponsor market studies to assess various aspects of the OmniPod System's functionality and its relative efficacy. The data obtained from the studies may be unfavorable to the OmniPod System or may be inadequate to support satisfactory conclusions. In addition, in the future we may sponsor clinical trials to assess certain aspects of the efficacy of the OmniPod System. If future clinical trials fail to support the efficacy of our current or future products, our sales may be adversely affected and we may lose an opportunity to secure clinical preference from prescribing clinicians, which may have a material adverse effect on our business, financial condition and results of operations.

If future clinical studies or other articles are published, or diabetes associations or other organizations announce positions that are unfavorable to the OmniPod System, our sales efforts and revenue may be negatively affected.

Future clinical studies or other articles regarding our existing products or any competing products may be published that either support a claim, or are perceived to support a claim, that a competitor's product is clinically more effective or easier to use than the OmniPod System or that the OmniPod System is not as effective or easy to use as we claim. Additionally, diabetes associations or other organizations that may be viewed as authoritative could endorse products or methods that compete with the OmniPod System or otherwise announce positions that are unfavorable to the OmniPod System. Any of these events may negatively affect our sales efforts and result in decreased revenue.

Substantially all of our operations related to the OmniPod System are conducted at a single location and substantially all of our OmniPod System inventory is held at a single location. Any disruption at either of these locations could increase our expenses.

Substantially all of our manufacturing of complete OmniPods is currently conducted at a single location on a manufacturing line owned by us at a facility located in China, operated by a subsidiary of Flextronics. We take precautions to ensure that Flextronics safeguards our assets, including insurance and health and safety protocols. However, a natural or other disaster, such as a fire or flood, could cause substantial delays in our operations, damage or destroy our manufacturing equipment, and cause us to incur additional expenses. The insurance we maintain may not be adequate to cover our losses in any particular case. With or without insurance, damage to our manufacturing equipment, or to any of our suppliers, may have a material adverse effect on our business, financial condition and results of operations.

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In addition, substantially all of our OmniPod System inventory is held at a single location in Billerica, Massachusetts. We take precautions to safeguard our facility, including insurance, health and safety protocols and off-site storage of computer data. However, a natural or other disaster, such as a fire or flood, could cause substantial delays in our operations, damage or destroy our inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods and other natural disasters may not be adequate to cover our losses in any particular case. With or without insurance, damage to our facility or our other property, due to fire, flood or other natural disaster or casualty event may have a material adverse effect on our business, financial condition and results of operations.

Our success will depend on our ability to attract and retain personnel.

We have benefited substantially from the leadership and performance of our senior management. Our success will depend on our ability to retain our current management and to attract and retain qualified personnel in the future, including clinicians, engineers and other highly skilled personnel. Competition for senior management personnel, as well as clinicians and engineers, is intense and there can be no assurances that we will be able to retain our personnel. The loss of the services of certain members of our senior management, clinicians or engineers could prevent or delay the implementation and completion of our objectives, or divert management's attention to seeking a qualified replacement.

Additionally, the sale and after-sale support of the OmniPod System is logistically complex, requiring us to maintain an extensive infrastructure of field sales personnel, diabetes educators, customer support, insurance specialists, and billing and collections personnel. We face considerable challenges in recruiting, training, managing, motivating and retaining these teams, including managing geographically dispersed efforts. If we fail to maintain and grow an adequate pool of trained and motivated personnel, our reputation could suffer and our financial position could be adversely affected.

If we do not effectively manage our growth, our business resources may become strained, we may not be able to deliver the OmniPod System in a timely manner and our results of operations may be adversely affected.

Since the commercial launch of the OmniPod System, we have progressively expanded our marketing efforts to cover the entire United States. In addition, in 2010 we entered into a distribution agreement with Ypsomed to distribute the OmniPod System in eleven additional countries. In February 2011, we entered into a distribution agreement with GSK to distribute the OmniPod System in Canada. As we continue to expand our sales internationally, we will need to obtain regulatory approvals and reimbursement agreements with government agencies or private third-party payors in those countries. Failure to obtain such agreements would limit our ability to successfully penetrate those foreign markets. In addition, the geographic expansion of our business will require additional manufacturing capacity to supply those markets as well as additional sales and marketing resources.

We expect to continue to increase our manufacturing capacity, our personnel and the scope of our U.S. and international sales and marketing efforts. This growth, as well as any other growth that we may experience in the future, will provide challenges to our organization and may strain our management and operations. In order to manage future growth, we will be required to improve existing, and implement new, management systems, sales and marketing efforts and distribution channels. We will need to manage our relationship with Flextronics going forward. We may also need to partner with additional third-party suppliers to manufacture certain components of the OmniPod System and complete additional manufacturing lines in the future. A transition to new suppliers may result in additional costs or delays. We may misjudge the amount of time or resources that will be required to effectively manage any anticipated or unanticipated growth in our business or we may not be able to manufacture sufficient inventory or attract, hire and retain sufficient personnel to meet our needs. If we cannot scale our business appropriately, maintain control over expenses or otherwise adapt to anticipated and unanticipated growth, our business resources may become strained, we may not be able to deliver the OmniPod System in a timely manner and our results of operations may be adversely affected.

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We may experience significant fluctuations in our quarterly results of operations.

The fluctuations in our quarterly results of operations have resulted, and will continue to result, from numerous factors, including:

delays in shipping due to capacity constraints;

practices of health insurance companies and other third-party payors with respect to reimbursement for our current or future products;

market acceptance of the OmniPod System;

our ability to manufacture the OmniPod efficiently;

timing of regulatory approvals and clearances;

new product introductions;

competition; and

timing of research and development expenditures.

These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. In particular, if our quarterly results of operations fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. We believe the quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

If we choose to acquire or invest in new businesses, products or technologies, instead of developing them ourselves, these acquisitions or investments could disrupt our business and could result in the use of significant amounts of equity, cash or a combination of both.

From time to time we may seek to acquire or invest in new businesses, products or technologies, instead of developing them ourselves. Acquisitions and investments involve numerous risks, including:

the inability to complete the acquisition or investment;

disruption of our ongoing businesses and diversion of management attention;

difficulties in integrating the acquired entities, products or technologies;

risks associated with acquiring intellectual property;

difficulties in operating the acquired business profitably;

the inability to achieve anticipated synergies, cost savings or growth;

potential loss of key employees, particularly those of the acquired business;

difficulties in transitioning and maintaining key customer, distributor and supplier relationships;

risks associated with entering markets in which we have no or limited prior experience; and

unanticipated costs.

In addition, any future acquisitions or investments may result in one or more of the following:

dilutive issuances of equity securities, which may be sold at a discount to market price;

the use of significant amounts of cash;

the incurrence of debt;

the assumption of significant liabilities;

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increased operating costs or reduced earnings;

financing obtained on unfavorable terms;

large one-time expenses; and

the creation of certain intangible assets, including goodwill, the write-down of which in future periods may result in significant charges to earnings.

Any of these factors could materially harm our stock price, business, financial condition and results of operations.

We will incur significant transaction, integration and other costs in connection with the acquisition of Neighborhood Diabetes and these costs may exceed the realized benefits, if any, of the synergies and efficiencies from the acquisition.

We incurred significant transaction costs related to the acquisition of Neighborhood Diabetes. In addition, we have incurred and will continue to incur integration costs as we integrate the Neighborhood Diabetes business with our own. Financial, managerial and operational challenges of the Neighborhood Diabetes acquisition may include:

disruption of our ongoing businesses and diversion of management attention;

difficulties in integrating Neighborhood Diabetes products and technologies;

risks associated with acquiring intellectual property;

difficulties in operating Neighborhood Diabetes profitably;

the inability to achieve anticipated synergies, cost savings or growth;

potential loss of key employees, particularly those of Neighborhood Diabetes;

difficulties in transitioning and maintaining key customer, distributor and supplier relationships;

risks associated with entering markets in which we have no or limited prior experience;

unanticipated costs, and

potential disputes with the sellers of Neighborhood Diabetes.

No assurances can be given that the expected benefit of synergies and efficiencies of the acquisition of Neighborhood Diabetes will exceed the transaction and integration costs and the costs associated with these potential financial, managerial and operational challenges, or that expected

benefits and synergies and efficiencies will be achieved in the near term or at all.

We may not be able to generate sufficient cash to service all of our indebtedness, which currently consists of our 5.375% Convertible Senior Notes due June 15, 2013 and our 3.75% Convertible Senior Notes due June 15, 2016. We may be forced to take other actions to satisfy our obligations under our indebtedness or we may experience a financial failure.

Our ability to make scheduled payments or to refinance our debt obligations depends on our financial and operating performance, which is subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We cannot assure you that we will maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness, including the 5.375% Convertible Senior Notes and the 3.75% Convertible Senior Notes. We cannot assure you that we would be able to take any of these actions, that these

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actions would be successful and permit us to meet our scheduled debt service obligations or that these actions would be permitted under the terms of our future debt agreements. In the absence of sufficient operating results and resources, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations. We may not be able to consummate those dispositions or obtain sufficient proceeds from those dispositions to meet our debt service and other obligations then due.

We need to expand our distribution network to maintain and grow our business and revenue. If we fail to expand and maintain an effective sales force or successfully develop our relationship with distributors, our business, prospects and brand may be materially and adversely affected.

We currently promote, market and sell the majority of our OmniPod Systems through our own direct sales force. We currently utilize a limited number of domestic distributors to augment our sales efforts. In addition, in January 2010 we entered into an exclusive distribution agreement with Ypsomed to promote, advertise, distribute and sell the OmniPod System in eleven countries, and in February 2011, we entered into an exclusive distribution agreement with GSK to promote, advertise, distribute and sell the OmniPod System in Canada. We cannot assure you that we will be able to successfully develop our relationships with third-party distributors. If we fail to do so, our sales could fail to grow or could decline, and our ability to grow our business could be adversely affected. Distributors that are in the business of selling other medical products may not devote a sufficient level of resources and support required to generate awareness of our products and grow or maintain product sales. If our distributors are unwilling or unable to market and sell our products, or if they do not perform to our expectations, we could experience delayed or reduced market acceptance and sales of our products.

If we are unable to successfully maintain effective internal control over financial reporting, investors may lose confidence in our reported financial information and our stock price and our business may be adversely impacted.

As a public company, we are required to maintain internal control over financial reporting and our management is required to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year. Additionally, we are required to disclose in our Annual Reports on Form 10-K our management's assessment of the effectiveness of our internal control over financial reporting and a registered public accounting firm's attestation report on this assessment. If we are not successful in maintaining effective internal control over financial reporting, there could be inaccuracies or omissions in the consolidated financial information we are required to file with the Securities and Exchange Commission. Additionally, even if there are no inaccuracies or omissions, we will be required to publicly disclose the conclusion of our management that our internal control over financial reporting or disclosure controls and procedures are not effective. These events could cause investors to lose confidence in our reported financial information, adversely impact our stock price, result in increased costs to remediate any deficiencies, attract regulatory scrutiny or lawsuits that could be costly to resolve and distract management's attention, limit our ability to access the capital markets or cause our stock to be delisted from The NASDAQ Global Market or any other securities exchange on which it is then listed.

The price of our common stock may be volatile.

There has been a public market for our common stock only since our initial public offering in May 2007. The market price of our common stock is affected by a number of factors, including:

failure to maintain and increase production capacity and reduce per unit production costs;

changes in the availability of third-party reimbursement in the United States or other countries;

volume and timing of orders for the OmniPod System;

developments in administrative proceedings or litigation related to intellectual property rights;

issuance of patents to us or our competitors;

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the announcement of new products or product enhancements by us or our competitors;

the announcement of technological or medical innovations in the treatment or diagnosis of diabetes;

changes in governmental regulations or in the status of our regulatory approvals or applications;

developments in our industry;

publication of clinical studies relating to the OmniPod System or a competitor's product;

quarterly variations in our or our competitors' results of operations;

changes in earnings estimates or recommendations by securities analysts; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

At times, the fluctuations in the market price of our common stock have been unrelated or disproportionate to our operating performance. These forces reached unprecedented levels in the second half of 2008, resulting in the bankruptcy or acquisition of, or government assistance to, several major domestic and international financial institutions and a material decline in economic conditions. In particular, the U.S. equity markets experienced significant price and volume fluctuations that have affected the market prices of equity securities of many technology companies. Broad market and industry factors such as these could materially and adversely affect the market price of our stock, regardless of our actual operating performance.

Future sales of shares of our common stock in the public market, or the perception that such sales may occur, may depress our stock price.

We have been a public company only since May 2007. Since becoming a public company, the average daily trading volume of our common stock on The NASDAQ Global Market has been approximately 300,000 shares.

In addition to our outstanding shares of common stock, we have recently issued \$143.8 million of 3.75% Convertible Senior Notes. Additionally, there are \$15 million of our 5.375% Convertible Senior Notes outstanding. A substantial number of shares of our common stock could potentially be issued upon the conversion of these Convertible Senior Notes. The issuance of substantial amounts of common stock underlying the Convertible Senior Notes, or the perception that such issuance may occur, could adversely affect the market price of our common stock.

Furthermore, the price of our common stock also could be affected by possible sales of our common stock by investors who view the Convertible Senior Notes as a more attractive means of equity participation in us and by hedging or arbitrage trading activity that we expect will develop involving our common stock. A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities.

Conversion of any of our 3.75% Convertible Senior Notes or 5.375% Convertible Senior Notes may dilute the ownership interest of existing stockholders.

The conversion of some or all of the 3.75% Convertible Senior Notes or the 5.375% Convertible Senior Notes may dilute the ownership interests of existing stockholders. Any sales in the public market of any of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the anticipated conversion of the Convertible Senior Notes into a combination of cash and shares of our common stock could depress the price of our common stock.

Our ability to use net operating loss carryforwards may be subject to limitation.

Section 382 of the U.S. Internal Revenue Code of 1986, as amended, imposes an annual limit on the amount of net operating loss carryforwards that may be used to offset taxable income when a corporation has undergone

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significant changes in its stock ownership or equity structure. Our ability to use net operating losses may be limited by prior changes in our ownership, and may be further limited by the issuance of common stock in connection with the conversion of our Convertible Senior Notes, or by the consummation of other transactions. As a result, if we earn net taxable income, our ability to use net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liabilities for we have.

Anti-takeover provisions in our organizational documents, our shareholder rights plan and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of our common stock;

provide for a classified board of directors, with each director serving a staggered three-year term;

prohibit our stockholders from filling board vacancies, calling special stockholder meetings or taking action by written consent;

provide for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors; and

require advance written notice of stockholder proposals and director nominations.

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender offer or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

In addition, in November 2008, our board of directors adopted a shareholder rights plan, implementing what is commonly known as a poison pill. This poison pill significantly increases the costs that would be incurred by an unwanted third party acquirer if such party owns or announces its intent to commence a tender offer for more than 15% of our outstanding common stock or otherwise triggers the poison pill by exceeding the applicable stock ownership threshold. The existence of this poison pill could delay, deter or prevent a takeover of us.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease approximately 63,500 square feet of manufacturing, laboratory and office space in Bedford, Massachusetts under leases expiring in 2014. Additionally, we lease approximately 14,000 square feet of warehousing and manufacturing space in Billerica, Massachusetts under a lease expiring in 2014. In connection with our acquisition of Neighborhood Diabetes, we acquired leases of facilities in Woburn, Massachusetts of approximately 21,000 square feet, Brooklyn, New York of approximately 5,500 square feet and Orlando, Florida of approximately 1,300 square feet, expiring in June 2013, April 2015 and September 2012, respectively.

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ITEM 3. LEGAL PROCEEDINGS

In August 2010, Becton, Dickinson and Company (BD) filed a lawsuit in the United States District Court in the State of New Jersey against us alleging that the OmniPod System infringes three of its patents. BD seeks a declaration that we have infringed its patents, equitable relief, including an injunction that would enjoin us from infringing these patents, and an unspecified award for monetary damages. We believe that the OmniPod System does not infringe these patents. We do not expect this litigation to have a material adverse impact on our financial position or results of operations. We believe we have meritorious defenses to this lawsuit; however, litigation is inherently uncertain and there can be no assurance as to the ultimate outcome or effect of this action. We do not believe we have any material financial exposure at December 31, 2011.

We are, from time to time, involved in the normal course of business in various legal proceedings, including intellectual property, contract employment and product liability suits. Although we are unable to quantify the exact financial impact of any of these matters, we believe that none of these currently pending matters will have an outcome material to our financial condition or business.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

Table of Contents**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON STOCK, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Information**

Our common stock has been listed on The NASDAQ Global Market under the trading symbol **PODD** since our initial public offering on May 15, 2007. The following table sets forth the high and low closing sales prices of our common stock, as reported by The NASDAQ Global Market, for each of the periods listed.

	High	Low
Fiscal Year 2010		
First Quarter	\$ 16.47	\$ 13.06
Second Quarter	\$ 15.86	\$ 13.21
Third Quarter	\$ 15.39	\$ 13.22
Fourth Quarter	\$ 16.31	\$ 12.75
Fiscal Year 2011		
First Quarter	\$ 21.09	\$ 15.76
Second Quarter	\$ 22.17	\$ 18.30
Third Quarter	\$ 23.04	\$ 14.85
Fourth Quarter	\$ 18.98	\$ 14.29

As of February 22, 2012, there were approximately 26 registered holders of record of our common stock. The number of beneficial stockholders of our shares is greater than the number of stockholders of record.

Table of Contents**Performance Graph**

The chart set forth below shows the value of an investment of \$100 on May 15, 2007 in each of Insulet Corporation common stock, the NASDAQ Composite Index, and the NASDAQ Health Care Index. All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices and are calculated as of December 31, 2011. The historical stock price performance of our common stock shown in the performance graph below is not necessarily indicative of future stock price performance.

Comparison of 55 Month Cumulative Total Return*

Among Insulet Corp., The NASDAQ Composite Index

And The NASDAQ Health Care Index

* \$100 invested on 5/15/07 in stock or 4/30/07 in index, including reinvestment of dividends.
Fiscal year ending December 31.

	5/07	6/07	9/07	12/07	3/08	6/08	9/08	12/08	3/09	6/09
Insulet Corp.	100.00	88.97	136.28	147.12	90.23	98.56	87.22	48.37	25.69	48.25
NASDAQ Composite	100.00	103.50	107.85	105.41	90.44	90.99	81.50	62.76	60.80	73.08
NASDAQ Health Care	100.00	97.59	105.12	102.07	95.72	95.54	97.42	83.86	76.97	87.40
	9/09	12/09	3/10	6/10	9/10	12/10	3/11	6/11	9/11	12/11
Insulet Corp.	70.36	89.47	94.55	94.30	88.60	97.12	129.20	138.91	95.61	117.98
NASDAQ Composite	84.77	91.00	96.26	85.02	95.69	107.16	112.59	112.43	97.84	105.93
NASDAQ Health Care	98.04	100.53	110.63	95.41	102.01	108.68	115.49	121.05	102.47	113.10

The material in this performance graph is not soliciting material, is not deemed filed with the Securities and Exchange Commission (SEC) and is not incorporated by reference in any filing of Insulet Corporation under the Securities Act of 1933, as amended (the Securities Act) or the Exchange Act of 1934, as amended, whether made on, before or after the date of this filing and irrespective of any general incorporation language in such filing.

Dividend Policy

We currently intend to retain future earnings for the development, operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

Table of Contents**Securities Authorized For Issuance Under Equity Compensation Plans**

The following table sets forth information regarding securities authorized for issuance under our equity compensation plans as of December 31, 2011.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders(1)	2,577,343	\$ 11.52	669,707
Equity compensation plans not approved by security holders(2)	300,000		