

INSULET CORP  
Form 10-K  
February 28, 2013  
Table of Contents

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**Form 10-K**

(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, 2012
- 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)*

<b>Delaware</b> <i>(State or Other Jurisdiction of Incorporation or Organization)</i>	<b>04-3523891</b> <i>(I.R.S. Employer Identification No.)</i>
<b>9 Oak Park Drive</b> <b>Bedford, Massachusetts</b> <i>(Address of Principal Executive Offices)</i>	<b>01730</b> <i>(Zip Code)</i>
<b>Registrant's telephone number, including area code:</b>	

**(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**

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

## Edgar Filing: INSULET CORP - Form 10-K

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, 2012 was approximately \$956.9 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 21, 2013:

Title of Class	Shares Outstanding
Common Stock, \$0.001 Par Value Per Share	53,104,565
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, 2012. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

**Table of Contents****INSULET CORPORATION**

	<b>Page</b>
Explanatory Note	
<b>PART I</b>	
<b>Item 1.</b> <u>Business</u>	1
<b>Item 1A.</b> <u>Risk Factors</u>	13
<b>Item 1B.</b> <u>Unresolved Staff Comments</u>	34
<b>Item 2.</b> <u>Properties</u>	34
<b>Item 3.</b> <u>Legal Proceedings</u>	35
<b>Item 4.</b> <u>Mine Safety Disclosures</u>	35
<b>PART II</b>	
<b>Item 5.</b> <u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	36
<b>Item 6.</b> <u>Selected Financial Data</u>	39
<b>Item 7.</b> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	40
<b>Item 7A.</b> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	60
<b>Item 8.</b> <u>Financial Statements and Supplementary Data</u>	60
<b>Item 9.</b> <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	61
<b>Item 9A.</b> <u>Controls and Procedures</u>	61
<b>Item 9B.</b> <u>Other Information</u>	62
<b>PART III</b>	
<b>Item 10.</b> <u>Directors, Executive Officers and Corporate Governance</u>	64
<b>Item 11.</b> <u>Executive Compensation</u>	64
<b>Item 12.</b> <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	64
<b>Item 13.</b> <u>Certain Relationships and Related Transactions, and Director Independence</u>	65
<b>Item 14.</b> <u>Principal Accounting Fees and Services</u>	65
<b>PART IV</b>	
<b>Item 15.</b> <u>Exhibits and Financial Statement Schedules</u>	65
<u>Signatures</u>	66

**Table of Contents**

**EXPLANATORY NOTE**

On February 28, 2013 we filed an Amendment to our Annual Report on Form 10-K/A for the year ended December 31, 2011, which was originally filed on Form 10-K on February 28, 2012, to reflect a restatement of the fiscal year ended December 31, 2011 and the quarterly periods ended June 30, 2011 and September 30, 2011. Additionally, we filed Amendments to our Quarterly Reports on Forms 10-Q/A, which were originally filed on Forms 10-Q on May 9, 2012, August 8, 2012 and November 8, 2012, to reflect a restatement of the quarterly periods ended March 31, 2012, June 30, 2012, and September 30, 2012. Form 10-K/A and Forms 10-Q/A are known as the Amended Reports.

As discussed in Note 18 to our consolidated financial statements, subsequent to the issuance of the original reports, we and our audit committee concluded that we should restate our consolidated balance sheets at June 30, 2011, September 30, 2011, December 31, 2011, March 31, 2012, June 30, 2012 and September 30, 2012, our consolidated statements of operations for the three and six months ended June 30 2011, the nine months ended September 30, 2011 and the year ended December 31, 2011, consolidated statements of cash flows for the six months ended June 30, 2011, the nine months ended September 30, 2011 and the year ended December 31, 2011 and our consolidated 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 filed these Amended Reports in order to amend our original reports to the extent necessary to reflect the adjustments discussed above.

**Table of Contents**

**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.

---

**Table of Contents**

**PART I**

**ITEM 1. BUSINESS**

**Overview**

We are primarily engaged in the development, manufacturing and sale of our proprietary OmniPod Insulin Management System (the OmniPod System), an innovative, discreet and easy-to-use insulin infusion system for people with insulin-dependent diabetes. The OmniPod System is the only commercially-available insulin infusion system of its kind. The OmniPod System features a unique disposable tubeless OmniPod which is worn on the body for approximately three days at a time and our handheld, wireless Personal Diabetes Manager (PDM). 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.

To support our sales of the OmniPod System, in June 2011, we acquired Neighborhood Holdings, Inc. and its wholly-owned subsidiaries (collectively, Neighborhood Diabetes) in order to expand our full suite diabetes management product offerings and obtain access to a larger number of insulin dependent patients. Through Neighborhood Diabetes, we are able to provide customers with blood glucose testing supplies, insulin pumps, pump supplies and pharmaceuticals and have the ability to process claims as either durable medical equipment or through pharmacy benefits.

The U.S. Food and Drug Administration (FDA) approved the original OmniPod System in January 2005, and we began commercial sale in the United States in October 2005. We received CE Mark approval for the original OmniPod System in April 2009. Since the commercial launch of the OmniPod System, we have progressively expanded our marketing efforts to provide availability of the OmniPod System to patients throughout the entire United States. We have also expanded the availability of the OmniPod System internationally through our partnerships with Ypsomed Distribution AG (Ypsomed) and GlaxoSmithKline Inc. (GSK). In January 2010, we entered into a distribution agreement with Ypsomed pursuant to which Ypsomed became the exclusive distributor of the OmniPod System in multiple countries. 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. Under these distribution agreements, we supply OmniPods and PDMs to Ypsomed and GSK, and they are responsible for the sale to the customer, including distribution, reimbursement and customer support.

Our efforts throughout 2011 and 2012 largely focused on the development and regulatory approval of our next generation OmniPod System. In August 2011 we received CE Mark approval, and in December 2012 we received 510(k) clearance for the next generation OmniPod System by the FDA. The next generation OmniPod System maintains all of the features of the original OmniPod System but is approximately one-third smaller in size and one-quarter lighter in weight.

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, 2012.

---

## **Table of Contents**

### **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, occlusive vascular diseases, 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 continuous infusion through pump therapy, 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. 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.

## **Table of Contents**

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



---

## **Table of Contents**

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.

### **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 key diabetes practitioners, academic medical centers, clinics, people with insulin-dependent diabetes, third-party payors, government agencies and third-party distributors. Our marketing strategy is to build awareness of the benefits of the OmniPod System as well as our high-touch patient model 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 customers. Through both our core OmniPod business as well as our acquisition of Neighborhood Diabetes, we serve more than 100,000 clients with Type 1 and Type 2 diabetes providing them with our proprietary OmniPod System, blood glucose testing supplies, insulin pumps, pump supplies and pharmaceuticals, among other supplies. We have built a strong infrastructure with our reimbursement and billing functions and can provide for adjudication of claims as either durable medical equipment or through pharmacy benefits. Depending on the product sold, and the insurance coverage maintained by the patient, claims are adjudicated under private insurers, Medicaid or Medicare. Our distribution agreements with Ypsomed and GSK provide us with the ability to increase awareness and expand availability of the OmniPod System internationally. Under these agreements, Ypsomed and GSK work with the appropriate agencies to establish a distribution and reimbursement process in each of the countries in which they sell the OmniPod System.

*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 lifestyle benefits provided to its users.

*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.

## **Table of Contents**

*Distributor arrangements.* Our distribution networks include relationships with 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 in 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. 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 ( CPT ) 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 commercial team or CPT 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 CPTs who will conduct customer training at the healthcare 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.

We also use a high-touch service model to supplement our 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 customer initiates an order for our products, our customer support staff assists the customer with completing order forms and collecting additional data as required by his or her insurance provider. Once the order forms are complete, we investigate the customer's insurance coverage and contact the customer to notify them regarding the coverage available under his or her 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. We have built a strong infrastructure in our reimbursement, pharmacy and billing areas to provide for accurate and efficient adjudication of claims as either durable medical equipment or through pharmacy benefits. We believe that our customer support infrastructure enables us to effectively support the growing demand for our product offerings.

Upon approval from the customer, the customer's order is typically shipped to the customer's home. A customer support representative contacts customers to arrange and schedule subsequent shipments of OmniPods

---

## **Table of Contents**

or other supplies, which are typically shipped every month to every three months. In addition, certain patients can be placed on automatic reorder 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 recently approved next generation OmniPod System. The next generation OmniPod maintains the same functionality and features of the original version in a smaller footprint. We are also working on the integration of our OmniPod System with the LifeScan, Inc. ( LifeScan ) OneTouch® blood glucose monitoring technology, the feasibility of enhancing our OmniPod System by incorporating continuous sensing technology into the pod, and the ability to use our OmniPod System as a delivery platform for other pharmaceuticals.

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 continue to work with LifeScan with the goal of submitting the OmniPod System integrated with LifeScan's OneTouch blood glucose monitoring technology for 510(k) clearance from the FDA in 2013.

We believe that the potential uses of our proprietary OmniPod System technology are not limited to the treatment of diabetes. We continue 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 System 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 into 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 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 partially automated manufacturing lines 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 with OmniPods at agreed upon prices per unit pursuant to a rolling forecast that we provide. The current term of the agreement expires in December 2017 and is automatically renewed for one-year terms subsequently. It may be

---

## **Table of Contents**

terminated 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.

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. Our next generation OmniPod was designed to lower the cost of the product further through component sourcing, volume discounts and efficient manufacturing. The cost reductions are important as we strive to achieve profitability. We believe our manufacturing capacity is sufficient to meet our expected 2013 demand for OmniPods.

We purchase certain other diabetes management supplies from manufacturers at contracted rates and supply these products to our customers. Based on market penetration, payor plans and other factors, certain manufacturers provide rebates based on product sold. We record these rebates as a reduction to cost of goods sold as they are earned.

We rely on outside vendors for most of the components, some sub-assemblies, and various services used in the manufacture of the OmniPod System. Many of these suppliers are sole-source suppliers. 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.

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 and distributor, our manufacturing facilities 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, 2012, we had obtained 13 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;

---

## **Table of Contents**

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. In October 2012, Medtronic MiniMed Inc., Medtronic Puerto Rico Operations Co. and MiniMed Distribution Corp. (collectively, Medtronic ) filed a lawsuit in United States District Court for the Central District of California alleging that we have infringed the two patents referenced in their 2007 letter which are owned by Medtronic MiniMed Inc. and licensed to Medtronic Puerto Rico Operations Co. and MiniMed Distribution Corp. Medtronic seeks a declaration that we infringe its patents, equitable relief, including an injunction that would enjoin us from infringing these patents and an unspecified award for monetary damages. The patents referenced by this lawsuit relate to technology that is material to our business. We believe that the OmniPod System does not infringe these patents. 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.

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 that 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.

*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.

Neighborhood Diabetes is a distributor, operating 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 (Assuramed). Neighborhood Diabetes competitors include many profitable and well-established companies that have significantly greater financial, marketing and other resources than we have.

Many of our 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;

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

Edgar Filing: INSULET CORP - Form 10-K

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

## **Table of Contents**

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. These companies are at various stages of development. The companies working in this area of which we are aware include Medtronic, Roche Diagnostics, Asante Solutions, Inc., Phluid Corporation, Johnson & Johnson, Valeritas Inc., Cellnovo Limited, Debiotech S.A., 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.

## **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, 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.

---

## **Table of Contents**

*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;

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, and in August 2011, we received CE Mark approval for our next generation product. 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. We have been distributing the OmniPod System in certain countries in Europe, through Ypsomed, since 2010, and in Canada, through GSK, since 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.





---

**Table of Contents**

*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

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. 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

---

## **Table of Contents**

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.

*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 third-party payors in the United States to establish coverage contracts for the OmniPod System and other diabetes management supplies. 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. Through Neighborhood Diabetes, we have the ability to adjudicate 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 ).

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.

---

## **Table of Contents**

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.

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 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.

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 our sales of certain diabetes testing supplies, the Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bid Program ( the Program ) provides for a phased-in program for competitive bidding on durable medical equipment items, including certain mail-order diabetes testing supplies such as blood glucose testing strips and lancets. In January 2013, as part of the Program, CMS announced new payment amounts, resulting in an average reduction of approximately 72% from the current payment schedule amounts for such diabetes testing supplies. It is expected that this new payment schedule will be effective on July 1, 2013. CMS is expected to announce in spring 2013 the suppliers with whom it will contract to provide these products to Medicare patients. It is unclear at this time if Neighborhood Diabetes will be awarded such a contract. If Neighborhood Diabetes does not receive a contract, it will be unable to provide certain diabetes testing supplies to Medicare patients after the effective date. The implementation of these new payment amounts is expected to negatively impact our operating results in 2013.

### **Employees**

As of December 31, 2012, we had 538 full-time employees. 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, 2012, our gross profit was \$92.3 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, 2012,

**Table of Contents**

2011 and 2010 were \$51.9 million, \$45.8 million and \$61.2 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, 2012, we had an accumulated deficit of \$481.6 million.

*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 allow for volume purchase discounts to reduce our raw material costs and improve absorption of manufacturing overhead costs. 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 have developed our next generation product and continue to focus on reducing its production cost. 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.

---

**Table of Contents**

***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 attained in part 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. 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.

Beginning in 2013, sales of certain medical devices are subject to a 2.3% federal excise tax. We believe, based on advice from our tax advisor, that the sales of our products are exempt from this excise tax. However, if it is subsequently determined that sales of one or more of our products are subject to this excise tax, these tax obligations could materially adversely affect our 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

**Table of Contents**

predict the complete impact of healthcare reform legislation, but it could lead to a decreased demand for 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 2013.



## Edgar Filing: INSULET CORP - Form 10-K

We may in the future seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. In January 2013, we sold 4.7 million shares of our common stock at a price of \$20.75 per share, resulting in net proceeds to us of approximately \$92.8 million. We are using a portion of the net proceeds to fund sales and marketing activities associated with our next generation OmniPod System and to fund product development. 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.

---

## **Table of Contents**

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 Medisize 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. 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.

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 require. Any interruption or delay in obtaining products from our

## Edgar Filing: INSULET CORP - Form 10-K

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.

---

**Table of Contents**

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

The Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bid Program ( the Program ) provides for a phased-in program for competitive bidding on durable medical equipment items, including certain mail-order diabetes testing supplies such as blood glucose testing strips and lancets. In January 2013, as part of the Program, CMS announced new payment amounts, resulting in average reduction of approximately 72% from the current payment schedule amounts for such diabetes testing supplies. It is expected that this new payment schedule will be effective on July 1, 2013. CMS is expected to announce in spring 2013 the suppliers with whom it will contract to provide these products to Medicare patients. It is unclear at this time if Neighborhood Diabetes will be awarded such a contract. If Neighborhood Diabetes does not receive a contract, it will be unable to provide certain diabetes testing supplies to Medicare patients after the effective date. The implementation of these new payment amounts is expected to negatively impact our operating results in 2013.

***If Neighborhood Diabetes does not continue to earn and retain purchase discounts and rebates from manufacturers at current levels, or if it is required to pay sales tax on sales of certain products, our results of operations could be adversely affected.***

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.

We believe that sales of most diabetes supplies are exempt from sales tax in most jurisdictions. However, if it is subsequently determined that sales of one or more of our products are subject to sales tax in such jurisdictions, our obligation to pay such sales taxes could materially adversely affect our financial results.

***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

---

**Table of Contents**

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.

***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 multiple countries including Germany, the United Kingdom, the Netherlands, and Switzerland. We entered into an amendment to the distribution agreement with Ypsomed in April 2012. The amendment expanded the agreement to include additional countries and extended the expiration of the agreement for an additional year. 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. 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;

---

**Table of Contents**

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;

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.

***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.

---

## **Table of Contents**

***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

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.

***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.

Many of our 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;

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.

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.



## Edgar Filing: INSULET CORP - Form 10-K

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. These companies are at various stages of development. The companies of which we are aware working in this area include Medtronic, Roche Diagnostics, Asante Solutions, Inc., Phluid Corporation, Johnson & Johnson, Valeritas Inc., Cellnovo Limited, Debiotech S.A., Novo Nordisk A/S and Abbott Laboratories.

**Table of Contents**

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 (Assuramed). 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. 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.

In January 2013, as part of the Program, CMS announced new payment amounts, resulting in an average reduction of approximately 72% from the current payment schedule amounts for such diabetes testing supplies. It is expected that this new payment schedule will be effective on July 1, 2013. CMS is expected to announce in spring 2013 the suppliers with whom it will contract to provide these products to Medicare patients. It is unclear at this time if Neighborhood Diabetes will be awarded such a contract. If Neighborhood Diabetes does not receive a contract, it will be unable to provide certain diabetes testing supplies to Medicare patients after the effective date. The implementation of these new payment amounts is expected to negatively impact our operating results in 2013.

***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

**Table of Contents**

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. 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 December 2014, with a one-year renewal option. 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 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.

## **Table of Contents**

***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;

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.

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.***

## Edgar Filing: INSULET CORP - Form 10-K

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

---

**Table of Contents**

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 a letter received in March 2007, Medtronic, Inc. invited us to discuss our taking a license to certain Medtronic patents. In October 2012, Medtronic MiniMed Inc., Medtronic Puerto Rico Operations Co. and MiniMed Distribution Corp. (collectively, Medtronic) filed a lawsuit in United States District Court for the Central District of California alleging that we have infringed the two patents referenced in their 2007 letter which are owned by Medtronic MiniMed Inc. and licensed to Medtronic Puerto Rico Operations Co. and MiniMed Distribution Corp. Medtronic seeks a declaration that we infringe its patents, equitable relief, including an injunction that would enjoin us from infringing these patents and an unspecified award for monetary damages. The patents referenced by this lawsuit relate to technology that is material to our business.

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 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.

---

## **Table of Contents**

*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. In December 2012 we received 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;

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

## Edgar Filing: INSULET CORP - Form 10-K

criminal prosecution.

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



---

**Table of Contents**

We entered into a distribution agreement with Ypsomed in January 2010, pursuant to which Ypsomed became the exclusive distributor of the OmniPod System in certain 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.

***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.

---

**Table of Contents**

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 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

---

**Table of Contents**

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 manufacturing lines 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.

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

---

## **Table of Contents**

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 certain 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.

***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.

## **Table of Contents**

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;

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 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

---

**Table of Contents**

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 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 certain 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;



**Table of Contents**

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

issuance of patents to us or our competitors;

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 issued \$143.8 million of 3.75% Convertible Senior Notes in June 2011. 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.***

## Edgar Filing: INSULET CORP - Form 10-K

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.

---

**Table of Contents**

***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 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 79,500 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



**Table of Contents**

with our acquisition of Neighborhood Diabetes, we acquired leases of facilities in Massachusetts of approximately 21,000 square feet, New York of approximately 5,500 square feet and Florida of approximately 1,300 square feet, expiring in June 2013, April 2015 and December 2013, respectively.

**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, 2012.

In a letter received in March 2007, Medtronic, Inc. invited us to discuss our taking a license to certain Medtronic patents. In October 2012, Medtronic MiniMed Inc., Medtronic Puerto Rico Operations Co. and MiniMed Distribution Corp. (collectively, Medtronic ) filed a lawsuit in United States District Court for the Central District of California alleging that we have infringed the two patents referenced in their 2007 letter which are owned by Medtronic MiniMed Inc. and licensed to Medtronic Puerto Rico Operations Co. and MiniMed Distribution Corp. Medtronic seeks a declaration that we infringe its patents, equitable relief, including an injunction that would enjoin us from infringing these patents and an unspecified award for monetary damages. The patents referenced by this lawsuit relate to technology that is material to our business. We believe that the OmniPod System does not infringe these patents. 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, 2012.

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.

	<b>High</b>	<b>Low</b>
<b>Fiscal Year 2011</b>		
First Quarter	\$ 21.09	\$ 15.76
Second Quarter	\$ 22.17	\$ 18.30
Third Quarter	\$ 23.04	\$ 14.85
Fourth Quarter	\$ 18.98	\$ 14.29
<b>Fiscal Year 2012</b>		
First Quarter	\$ 20.98	\$ 18.16
Second Quarter	\$ 21.37	\$ 16.93
Third Quarter	\$ 22.14	\$ 18.72
Fourth Quarter	\$ 22.15	\$ 19.13

As of February 21, 2013, there were approximately 17 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, 2012. 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 5 YEAR CUMULATIVE TOTAL RETURN\***

Among insulet Corp., the NASDAQ Composite index,  
and the NASDAQ Health Care Index

\* \$100 invested on 12/31/07 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

	12/07	12/08	12/09	12/10	12/11	12/12
<b>Insulet Corp.</b>	<b>100.00</b>	<b>32.88</b>	<b>60.82</b>	<b>66.01</b>	<b>80.20</b>	<b>90.37</b>
<b>NASDAQ Composite</b>	<b>100.00</b>	<b>59.03</b>	<b>82.25</b>	<b>97.32</b>	<b>98.63</b>	<b>110.78</b>
<b>NASDAQ Health Care</b>	<b>100.00</b>	<b>80.81</b>	<b>95.16</b>	<b>105.21</b>	<b>113.73</b>	<b>138.96</b>

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, 2012.

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)	3,200,010	\$ 10.33	4,189,332
Equity compensation plans not approved by security holders(2)	190,000	\$ 7.12	
<b>Total(4)</b>	<b>3,390,010</b>	<b>\$ 10.15</b>	<b>4,189,332(3)</b>

- (1) Includes our Amended and Restated 2007 Stock Option and Incentive Plan and our 2000 Stock Option and Incentive Plan. Outstanding restricted stock units convert to common stock without the payment of consideration. As of December 31, 2012 825,068 restricted stock units were outstanding. The weighted-average exercise price of outstanding options and warrants, excluding restricted stock units was \$13.92.
- (2) Consists of two inducement grants of 180,000 shares each to Brian Roberts and Peter Devlin (110,000 of which were exercised during the year ended December 31, 2012 and 60,000 of which were exercised during the year ended December 31, 2011) upon being hired by us in March 2009 and August 2009, respectively. These non-qualified stock option awards were granted outside of our Amended and Restated 2007 Stock Option and Incentive Plan in compliance with Nasdaq Listing Rule 5635, but have similar vesting terms to those stock option awards typically granted under our Amended and Restated 2007 Stock Option and Incentive Plan.
- (3) The maximum number of shares of our common stock that remain available for future issuance under our 2007 Stock Option and Incentive Plan as of December 31, 2012 is 4,189,332 shares, which includes a further increase of 725,000 on January 1, 2012. The amount was increased in May 2012 by 3,775,000 additional shares.
- (4) As of December 31, 2012 825,068 restricted stock units were outstanding. The weighted-average exercise price of outstanding options and warrants, excluding restricted stock units was \$13.41.

For more information relating to our equity compensation plans, see Footnote 14 to our consolidated financial statements.

**Issuer Repurchases of Equity Securities**

We did not repurchase any of our equity securities during the quarter ended December 31, 2012, nor issue any securities that were not registered under Securities Act.

**Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

None.





**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA**

	2012	2011(4)(5) (Restated)	Year Ended December 31,		2008
			2010	2009	
	(In thousands, except share and per share data)				
<b>Consolidated Statements of Operations Data:</b>					
Revenue	\$ 211,369	\$ 152,255	\$ 96,966	\$ 66,032	\$ 36,059
Cost of revenue	119,033	85,543	53,240	47,735	40,643
Gross profit (loss)	92,336	66,712	43,726	18,297	(4,584)
Operating expenses:					
Research and development	24,359	21,863	16,566	13,231	13,104
General and administrative	51,240	44,083	26,667	26,842	23,750
Sales and marketing	52,708	43,233	34,695	37,583	39,734
Restructuring and impairment of assets(2)			4,431		8,170
Total operating expenses	128,307	109,179	82,359	77,656	84,758
Operating loss	(35,971)	(42,467)	(38,633)	(59,359)	(89,342)
Other expense, net	(15,684)	(14,576)	(22,526)	(12,985)	(5,429)
Income tax benefit (expense)	(212)	11,212			
Net loss	\$ (51,867)	\$ (45,831)	\$ (61,159)	\$ (72,344)	\$ (94,771)
Net loss per share basic and diluted	\$ (1.08)	\$ (0.98)	\$ (1.54)	\$ (2.43)	\$ (3.43)
Weighted-average number of shares used in calculating net loss per share(1)	47,924,324	46,689,880	39,607,899	29,727,106	27,611,003
	2012	2011(4)(5) (Restated)	As of December 31,		2008
			2010	2009	
	(In thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 57,293	\$ 93,955	\$ 113,274	\$ 127,996	\$ 56,663
Working capital	\$ 61,650	\$ 104,640	\$ 123,507	\$ 134,491	\$ 71,531
Total assets	\$ 198,059	\$ 221,322	\$ 156,233	\$ 172,858	\$ 108,233
Current portion of long-term debt	\$ 14,429	\$	\$	\$	\$
Long-term debt(3)	\$ 103,730	\$ 108,540	\$ 69,433	\$ 89,136	\$ 60,172
Other long-term liabilities	\$ 1,867	\$ 2,052	\$ 1,619	\$ 1,999	\$ 2,987
Total stockholders' equity	\$ 44,176	\$ 82,735	\$ 66,231	\$ 61,910	\$ 28,106

(1) In October 2009, we sold 6.9 million shares of common stock to the public. In December 2010, we sold 3.5 million shares of common stock to the public. In June 2011, we issued 1.2 million shares in connection with the acquisition of Neighborhood Diabetes. See Footnote 14 to our consolidated financial statements included in this Annual Report on Form 10-K.

(2) In the year ended December 31, 2008, we recorded an \$8.2 million charge of which \$7.4 million related to the write-down of certain manufacturing equipment which had no future use and \$0.8 million in workforce reduction and related charges. In the year ended

## Edgar Filing: INSULET CORP - Form 10-K

December 31, 2010, we recorded a \$4.4 million non-cash charge related to the write-down of certain manufacturing equipment which had no future use.

- (3) In June 2008, we sold \$85.0 million principal amount of 5.375% Convertible Senior Notes due June 2013 in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933,

---

**Table of Contents**

as amended. In March 2009, we entered into a Facility Agreement of up to \$60 million with certain institutional accredited investors (the Facility Agreement ). We repaid all amounts outstanding under the Facility Agreement in December 2010. In June 2011, we issued \$143.8 million of 3.75% Convertible Notes due June 2016 and repurchased \$70 million in principal of the 5.375% Notes. See Footnote 4 to our consolidated financial statements included in this Annual Report on Form 10-K.

- (4) 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 for an aggregate purchase price of approximately \$37.9 million in cash and \$24.4 million in common stock. Neighborhood Diabetes supplies its customers with blood glucose testing supplies, insulin pumps, pump supplies, pharmaceuticals, and other products for the management and treatment of diabetes. See Footnote 3 to our consolidated financial statements in this Annual Report on Form 10-K.
- (5) Amounts were restated to correct errors in the accounting for income taxes as described in Footnote 18 to our consolidated financial statements in this Annual Report on Form 10-K.

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and analysis should be read in conjunction with the consolidated financial statements and accompanying notes and the other financial information appearing elsewhere in this Annual Report on Form 10-K. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report on Form 10-K, particularly under the heading Risk Factors.*

**Restatement of Previously Issued Financial Statements**

Financial data when presented throughout the MD&A includes the effect of the restatement, as described in Notes 2, 3, 16, 17 and 18 to our consolidated financial statements, of our results for the year ended December 31, 2011, and for the quarterly periods ended June 30, 2011, September 30, 2011, December 31, 2011, March 31, 2012, June 30, 2012, and September 30, 2012.

The following tables summarize the effect of the restatement by major financial statement line item for the three and six months ended June 30, 2011, the nine months ended September 30, 2011 and the year ended December 31, 2011 (in thousands). The restatement resulted in an increase in current deferred tax assets (which are presented as a component of prepaid expenses and other current assets) of \$1.2 million at June 30, 2011 and September 30, 2011 and an increase of \$0.9 million at December 31, 2011, an increase in goodwill of \$11.3 million at June 30, 2011 and September 30, 2011 and \$10.9 million at December 31, 2011, and an increase to non-current deferred tax liabilities (which are presented as a component of other long-term liabilities) of \$1.2 million at June 30, 2011 and September 30, 2011 and \$0.4 million at December 31, 2011. The restatement resulted in an increase in tax benefit of \$11.3 million in the three and six months ended June 30, 2011, the nine months ended September 30, 2011 and the year ended December 31, 2011. The restatement had no effect on any amounts reported in periods prior to the quarter ended June 30, 2011.

**Table of Contents****Consolidated Balance Sheet**

	June 30, 2011		September 30, 2011		December 31, 2011	
	As		As		As	
	Previously Reported (unaudited)	As Restated	Previously Reported (unaudited)	As Restated	Previously Reported	As Restated
Prepaid expenses and other current assets	\$ 4,770	\$ 5,991	\$ 3,653	\$ 4,874	\$ 2,802	\$ 3,652
Total current assets	147,834	149,055	137,857	139,078	131,785	132,635
Goodwill	26,727	38,066	26,164	37,503	26,647	37,536
Total assets	226,190	238,750	215,780	228,340	209,583	221,322
Other long-term liabilities	1,303	2,524	1,260	2,481	1,652	2,052
Total liabilities	132,091	133,312	132,340	133,561	138,187	138,587
Accumulated deficit	(413,122)	(401,783)	(426,684)	(415,345)	(441,023)	(429,684)
Total stockholders equity	94,099	105,438	83,440	94,779	71,396	82,735
Total liabilities and stockholders equity	226,190	238,750	215,780	228,340	209,583	221,322

**Consolidated Statement of Operations**

	Three Months Ended June 30, 2011		Six Months Ended June 30, 2011		Nine Months Ended September 30, 2011		Year Ended December 31, 2011	
	As		As		As		As	
	As Previously Reported (unaudited)	As Restated	Previously Reported (unaudited)	As Restated	Previously Reported (unaudited)	As Restated	Previously Reported	As Restated
Income tax benefit (expense)	\$ 11,339	\$ 11,339	\$ 11,339	\$ 11,339	\$ 11,339	\$ 11,339	\$ (127)	\$ 11,212
Net loss	(19,423)	(8,084)	(29,269)	(17,930)	(42,831)	(31,492)	(57,170)	(45,831)
Net loss per share basic and diluted	(0.42)	(0.17)	(0.64)	(0.39)	(0.92)	(0.68)	(1.22)	(0.98)

**Consolidated Statement of Cash Flows**

	Six Months Ended June 30, 2011		Nine Months Ended September 30, 2011		Year Ended December 31, 2011	
	As		As		As	
	As Previously Reported (unaudited)	As Restated	As Previously Reported (unaudited)	As Restated	As Previously Reported	As Restated
Net loss	\$ (29,269)	\$ (17,930)	\$ (42,831)	\$ (31,492)	\$ (57,170)	\$ (45,831)
Deferred tax provision		(11,339)		(11,339)		(11,289)
Changes in operating assets and liabilities:						
Prepaid expenses and other current assets	(434)	(1,655)	851	(370)	1,703	853
Other long-term liabilities	(316)	905	(359)	862	(417)	383

The restatement had no effect on the previously reported amounts of operating, investing, and financing cash flows in our consolidated statement of cash flows for the six months ended June 30, 2011, the nine months ended September 30, 2011, and the year end December 31, 2011.

The following tables summarize the effect of the restatement by major financial statement line item at March 31, 2012, June 30, 2012, and September 30, 2012 (in thousands). The restatement resulted in an increase in current deferred tax assets (which are presented as a component of prepaid expenses and other current assets) of \$0.9 million at March 31, 2012, June 30, 2012, and September 30, 2012, an increase in goodwill of \$10.9 million at March 31, 2012, June 30, 2012, and September 30, 2012 and an increase in non-current deferred tax liabilities (which are presented as a component of other long-term liabilities) of \$0.4 million at March 31, 2012, June 30, 2012, and September 30, 2012. The restatement had no effect on the consolidated statement of operations during these periods.



**Table of Contents****Consolidated Balance Sheet**

	March 31, 2012		June 30, 2012		September 30, 2012	
	As Previously Reported (unaudited)	As Restated	As Previously Reported (unaudited)	As Restated	As Previously Reported (unaudited)	As Restated
Prepaid expenses and other current assets	\$ 3,463	\$ 4,313	\$ 3,454	\$ 4,304	\$ 4,717	\$ 5,567
Total current assets	127,369	128,219	115,615	116,465	113,394	114,244
Goodwill	26,647	37,536	26,647	37,536	26,647	37,536
Total assets	203,942	215,681	191,940	203,679	191,642	203,381
Other long-term liabilities	1,640	2,040	1,668	2,068	1,670	2,070
Total liabilities	145,064	145,464	144,190	144,590	152,529	152,929
Accumulated deficit	(455,803)	(444,464)	(470,279)	(458,940)	(482,696)	(471,357)
Total stockholders' equity	58,878	70,217	47,750	59,089	39,113	50,452
Total liabilities and stockholders' equity	203,942	215,681	191,940	203,679	191,642	203,381

**Overview**

We are primarily engaged in the development, manufacturing and sale of our proprietary OmniPod Insulin Management System (the OmniPod System), an innovative, discreet and easy-to-use insulin infusion system for people with insulin-dependent diabetes. The OmniPod System is the only commercially-available insulin infusion system of its kind. The OmniPod System features a unique disposable tubeless OmniPod which is worn on the body for approximately three days at a time and our handheld, wireless Personal Diabetes Manager (PDM). 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.

To support our sales of the OmniPod System, in June 2011, we acquired Neighborhood Holdings, Inc. and its wholly-owned subsidiaries (collectively, Neighborhood Diabetes) in order to expand our full suite diabetes management product offerings and obtain access to a larger number of insulin dependent patients. Through Neighborhood Diabetes, we are able to provide customers with blood glucose testing supplies, traditional insulin pumps, pump supplies and pharmaceuticals and have the ability to process claims as either durable medical equipment or through pharmacy benefits.

The U.S. Food and Drug Administration (FDA) approved the original OmniPod System in January 2005, and we began commercial sale in the United States in October 2005. We received CE Mark approval for the original OmniPod System in April 2009. Since the commercial launch of the OmniPod System, we have progressively expanded our marketing efforts to provide availability of the OmniPod System in the entire United States. We have also expanded the availability of the OmniPod System internationally through our partnerships with Ypsomed Distribution AG (Ypsomed) and GlaxoSmithKline Inc. (GSK). In January 2010, we entered into a distribution agreement with Ypsomed pursuant to which Ypsomed became the exclusive distributor of the OmniPod System in multiple countries. 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. Under these distribution agreements, we supply OmniPods and PDMs to Ypsomed and GSK, and they are responsible for the sale to the customer, including distribution, reimbursement and customer support. In August 2011, we received CE Mark approval, and in December 2012, we received 510(k) clearance for our next generation OmniPod System by the FDA.

We sell our proprietary OmniPod System as well as blood glucose testing supplies, traditional insulin pumps, pump supplies, pharmaceuticals and other products for the management and treatment of diabetes to

---

**Table of Contents**

people with diabetes. Through our infrastructure in the reimbursement, billing and collection areas, we are able to provide for adjudication of claims as either durable medical equipment or through pharmacy benefits. Claims are adjudicated under private insurers, Medicaid or Medicare. We are aligning third-party payor contracts to be able to better leverage our cross-selling initiatives. As we expand our sales and marketing focus, increase our manufacturing capacity, expand to additional international markets and broaden our high-touch patient model, we will need to maintain and expand available reimbursement for our product offerings.

Our sales and marketing effort is focused on generating demand and acceptance of the OmniPod System among key diabetes practitioners, academic medical centers, clinics, people with insulin-dependent diabetes, third-party payors, government agencies, and third-party distributors. Our marketing strategy is to build awareness for the benefits of the OmniPod System as well as our high-touch patient model through a wide range of education programs, social networking, patient demonstration programs, support materials, media advertisements and events at the national, regional and local levels. We use third-party distributors to improve our access to managed care and government reimbursement programs, expand our commercial presence and provide access to additional potential patients. Our total revenue was \$211.4 million, \$152.3 million and \$97.0 million for the years ended December 31, 2012, 2011 and 2010, respectively.

As a medical device manufacturer and distributor, reimbursement from third-party payors is an important element of our success. If patients are not adequately reimbursed for the costs of using the OmniPod System or our other diabetes supplies, it will be much more difficult for us to penetrate the market. We continue to negotiate contracts establishing reimbursement for the OmniPod System with national and regional third-party payors. As part of the integration of Neighborhood Diabetes, we are aligning third-party payor contracts, both ours and those of Neighborhood Diabetes, to be able to better leverage our cross-selling initiatives. As we expand our sales and marketing focus, increase our manufacturing capacity, expand to international markets and leverage the Neighborhood Diabetes model, we will need to maintain and expand available reimbursement for our product offerings.

We currently produce the OmniPod System on partially automated manufacturing lines 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 with OmniPods at agreed upon prices per unit pursuant to a rolling forecast that we provide. The current term of the agreement expires in December 2017 and is automatically renewed for one-year terms subsequently. It may be terminated 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.

To achieve profitability, we continue to seek to increase manufacturing volume 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. Our next generation OmniPod was designed to lower the cost of the product further through component sourcing, volume discounts and efficient manufacturing. The cost reductions are important as we strive to achieve profitability. We believe our current manufacturing capacity is sufficient to meet our expected 2013 demand for OmniPods.

We purchase certain other diabetes management supplies from manufacturers at contracted rates and supply these products to our customers. Based on market penetration, payor plans and other factors, certain manufacturers provide rebates based on product sold. We record these rebates as a reduction to cost of goods sold as they are earned.

Since our inception in 2000, we have incurred losses every quarter. In the years ended December 31, 2012, 2011 and 2010, we incurred net losses of \$51.9 million, \$45.8 million and \$61.2 million, respectively. As of December 31, 2012, we had an accumulated deficit of \$481.6 million. We have financed our operations through private placements of debt and equity securities, public offerings of our common stock, issuances of convertible



---

## **Table of Contents**

debt and borrowings under certain other debt agreements. As of December 31, 2012, we had \$158.8 million of convertible debt outstanding. Of the \$158.8 million of convertible debt outstanding, \$15.0 million matures in June 2013 and approximately \$143.8 million matures in June 2016. Since our inception, we have received net proceeds of \$597.0 million from the issuance of redeemable convertible preferred stock, common stock and debt.

Our long-term financial objective is to achieve and sustain profitable growth. Our efforts in the beginning of 2013 will be focused primarily on the production and commercial launch of our next generation OmniPod System as well as the expansion of our customer base in the United States and internationally. We also plan to focus on development projects such as the integration of our OmniPod System with the LifeScan, Inc. ( LifeScan ) OneTouch<sup>®</sup> blood glucose monitoring technology, the feasibility of enhancing our OmniPod System to incorporate continuous sensing technology into the OmniPod System, and the ability to use our OmniPod System as a delivery platform for other pharmaceuticals. Achieving these objectives and increasing our penetration in the United States and international markets is expected to require additional investments in certain personnel and initiatives. We believe that we will continue to incur net losses in the near term in order to achieve these objectives. However, we believe that the accomplishment of our near term objectives will have a positive impact on our financial condition in the future.

In January 2013, we sold 4.7 million shares of our common stock at a price of \$20.75 per share, resulting in net proceeds to us of \$92.8 million. We believe that our cash and cash equivalents, together with the cash to be generated from expected product sales, will be sufficient to meet our projected operating and debt service requirements for the next twelve months.

### **Acquisition of Neighborhood Diabetes**

On June 1, 2011, we acquired all of the outstanding shares of Neighborhood Diabetes, a durable medical equipment distributor specializing in direct to consumer sales of diabetes supplies, including pharmaceuticals, and support services. Neighborhood Diabetes serves more than 60,000 customers with Type 1 and Type 2 diabetes primarily in the northeast and southeast regions of the United States with blood glucose testing supplies, traditional insulin pumps, pump supplies, pharmaceuticals, as well as other products for the management and treatment of diabetes. Neighborhood Diabetes is based in Massachusetts, with additional offices in New York and Florida. At the time of the acquisition, Neighborhood Diabetes employed approximately 200 people across its three locations. The acquisition of Neighborhood Diabetes provides us with full suite diabetes management product offerings, accelerates our sales force expansion, strengthens our back office support capabilities, expands our access to insulin dependent patients, and provides pharmacy adjudication capabilities to drive incremental sales higher. The aggregate purchase price of approximately \$62.4 million consisted of approximately \$37.9 million in cash paid at closing, 1,197,631 shares of our common stock valued at approximately \$24.4 million, or \$20.40 per share based on the closing price of our common stock on the acquisition date, and contingent consideration with a fair value of approximately \$0.1 million. Of the \$37.9 million of cash, \$6.6 million is being held in an escrow account to reimburse us and our affiliates for certain claims for which we are entitled to be indemnified pursuant to the terms of the agreement and plan of merger with Neighborhood Diabetes.

We have accounted for the acquisition of Neighborhood Diabetes as a business combination. Under business combination accounting, the assets and liabilities of Neighborhood Diabetes were recorded as of the acquisition date, at their respective fair values, and consolidated with our results. The excess of the purchase price over the fair value of net assets acquired was recorded as goodwill. The operating results of Neighborhood Diabetes have been included in the consolidated financial statements since June 2011, the period in which the acquisition was completed. The purchase price allocation, including an independent appraisal for intangible assets, has been prepared based on the information that was available to management at the time the consolidated financial statements were prepared. The allocation of the purchase price was finalized during the year ended December 31, 2011.

**Table of Contents**

The purchase price (restated) has been allocated as follows (in thousands):

Cash	\$ 37,855
Common stock	24,432
Contingent consideration obligations	61
 Total allocable purchase price	 \$ 62,348
 Allocation of purchase price:	
Accounts receivable	5,897
Inventories	2,336
Prepaid expenses and other current assets	242
Property and equipment	391
Customer relationships	30,100
Tradenames	2,800
Goodwill	37,536
Other assets	253
Accounts payable	4,109
Accrued expenses	1,700
Deferred tax liabilities	11,339
Other long-term liabilities	59
	 \$ 62,348

In connection with the acquisition of Neighborhood Diabetes, we incurred transaction costs of approximately \$3.2 million, which consisted primarily of banking, legal, accounting and other administrative fees. These costs have been recorded as general and administrative expense in the year ended December 31, 2011.

**Financial Operations Overview**

*Revenue.* We derive most of our revenue from the sale of the OmniPod System and other diabetes related products including blood glucose testing supplies, traditional insulin pumps, pump supplies and other pharmaceuticals to customers and third-party distributors who resell the product to customers. The OmniPod System is comprised of two devices: the OmniPod, a disposable insulin infusion device that the patient wears for up to three days and then replaces; 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 incorporates a blood glucose meter. We received FDA approval for the original OmniPod System in January 2005 and began commercial sale in the U.S. in October 2005. We received CE Mark approval for the original OmniPod System in April 2009. We are currently selling our OmniPod System through our partnership with Ypsomed in multiple countries in Europe and through our partnership with GSK in Canada. In August 2011 we received CE Mark approval and in December 2012 we received 510(k) clearance for the next generation OmniPod System by the FDA.

In June 2011, we entered into 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 term of the Development Agreement, we have and expect to continue to invoice amounts as we meet certain defined deliverable milestones. Revenue on the development agreement is recognized using a proportional performance methodology based on efforts incurred and total payments under the agreement.

As of December 31, 2012 and 2011, we had deferred revenue of \$5.4 million and \$2.7 million, respectively. These amounts primarily include product-related revenue and unrecognized amounts related to the development agreement. For the year ending December 31, 2013, we expect our revenue to continue to increase as we introduce our next generation OmniPod System, leverage our high touch patient model to gain new customers in



## **Table of Contents**

the United States and continue expansion in Europe, Canada, and certain other international markets. Increased revenue will be dependent upon the success of our sales efforts, our ability to produce our next generation OmniPods in sufficient volumes as our patient base grows, the successful launch and transition to our next generation OmniPod System, the impact of competitive bidding on certain durable medical equipment items including mail-order diabetes testing supplies, and other risks and uncertainties.

*Cost of revenue.* Cost of revenue consists primarily of raw material, labor, warranty and overhead costs such as freight, depreciation, and packaging costs, related to the OmniPod System, the cost of products we acquire from third party suppliers, and costs incurred related to the development agreement. Cost of revenue will continue to increase in line with an increase in revenues.

*Research and development.* Research and development expenses consist primarily of personnel costs within our product development, regulatory and clinical functions, and the costs of market studies and product development projects. We expense all research and development costs as incurred. For the year ending December 31, 2013, we expect overall research and development spending to remain consistent with our 2012 spend as we drive cost efficiencies in our next generation OmniPod, work with LifeScan to develop and gain regulatory approval on our PDM integrating LifeScan's OneTouch blood glucose monitoring technology, determine the feasibility of incorporating continuous sensing technology into the pod, and identify uses of our OmniPod System as a delivery platform for other pharmaceuticals.

*General and administrative.* General and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, finance, information technology and human resource functions, as well as legal fees, accounting fees, insurance costs, bad debt expenses, shipping, handling and facilities-related costs. We expect general and administrative expenses to increase slightly in the year ending December 31, 2013 as compared to 2012 to support our overall growth.

*Sales and marketing.* Sales and marketing expenses consist primarily of personnel costs within our sales, marketing, reimbursement support, customer support and training functions, sales commissions paid to our sales representatives and costs associated with participation in medical conferences, physician symposia and promotional activities, including distribution of units used in our demonstration kit programs. We expect sales and marketing expenses to increase in the year ending December 31, 2013 as compared to 2012 as we continue expansion of our sales force to enhance the growth of our existing business as we introduce our next generation product to new and existing customers.

*Restructuring and impairments of assets.* In connection with our efforts to pursue improved gross margins, leverage operational efficiencies and better pursue opportunities for low-cost supplier sourcing of asset costs, we periodically perform an evaluation of our manufacturing processes and review the carrying value of our property and equipment to assess the recoverability of these assets and determine whether impairment may have occurred. As part of this assessment, we review the planned use of the assets as well as the future undiscounted operating cash flows expected to be generated by those assets. If impairment is indicated through this review, the carrying amount of the asset would be reduced to its estimated fair value. This review of manufacturing processes and equipment can result in an impairment of assets based on current net book value and potential future use of the assets.

Restructuring and impairment of assets is typically based on a review of our manufacturing processes and equipment and may include the difference between the net book value of an asset and the asset's fair value based on our expectation of its potential future use. In addition, restructuring expense may also include workforce reduction and related costs for one-time termination benefits provided to employees who are involuntarily terminated under the terms of a one-time benefit arrangement. Estimates of related costs such as taxes and outplacement services may be provided under the plan. If changes in these estimated services occur, we may be required to record or reverse restructuring expenses associated with these workforce reduction and related costs.

**Table of Contents****Results of Operations for the Fiscal Years Ended December 31, 2012, 2011 and 2010**

The following table presents certain statement of operations information for the years ended December 31, 2012, 2011 and 2010:

	Year Ended December 31, 2011			Year Ended December 31, 2010		
	2012	(Restated)	% Change	(Restated)	2010	% Change
	(Dollar amounts in thousands)					
Revenue	\$ 211,369	\$ 152,255	39%	\$ 152,255	\$ 96,966	57%
Cost of revenue	119,033	85,543	39%	85,543	53,240	61%
Gross profit	92,336	66,712	38%	66,712	43,726	53%
Operating expenses:						
Research and development	24,359	21,863	11%	21,863	16,566	32%
General and administrative	51,240	44,083	16%	44,083	26,667	65%
Sales and marketing	52,708	43,233	22%	43,233	34,695	25%
Restructuring and impairment of assets					4,431	100%
Total operating expenses	128,307	109,179	18%	109,179	82,359	33%
Operating loss	(35,971)	(42,467)	15%	(42,467)	(38,633)	10%
Other expense, net	(15,684)	(14,576)	8%	(14,576)	(22,526)	35%
Income tax benefit (expense)	(212)	11,212	102%	11,212		100%
Net loss	\$ (51,867)	\$ (45,831)	13%	\$ (45,831)	\$ (61,159)	25%

**Comparison of the Years Ended December 31, 2012 and December 31, 2011***Revenue*

Our total revenue was \$211.4 million for the year ended December 31, 2012, as compared to \$152.3 million for the year ended December 31, 2011. The increase in revenue is mainly due to additional revenues generated by our Neighborhood Diabetes business which was acquired in June 2011 and continued adoption of the OmniPod System by patients in the United States and internationally.

*Cost of Revenue*

Cost of revenue was \$119.0 million for the year ended December 31, 2012, as compared to \$85.5 million for the year ended December 31, 2011. The increase is due to higher sales volume in the United States and internationally and higher costs related to lower margin sales by our Neighborhood Diabetes business. These increases were partially offset by lower per-unit costs on the OmniPod System resulting from cost savings on raw materials, volume discounts from our suppliers and increased absorption of manufacturing overhead driven by production volumes.

*Research and Development*

Research and development expense increased \$2.5 million, or 11.4%, to \$24.4 million for the year ended December 31, 2012, as compared to \$21.9 million for the year ended December 31, 2011. This increase was primarily related to an additional \$1.9 million of employee related expenses including stock-based compensation and \$1.5 million of consulting and other services in connection with development and regulatory approval of the next generation OmniPod System. These increases were offset in part by a \$0.8 million reduction in products used for research and development projects.

---

## **Table of Contents**

### *General and Administrative*

General and administrative expense increased \$7.1 million, or 16.2%, to \$51.2 million for the year ended December 31, 2012, as compared to \$44.1 million for the year ended December 31, 2011. The increase was largely due to an additional \$2.3 million of employee related expenses including stock-based compensation, a \$2.1 million increase in amortization expense on the customer relationship and tradename assets related to the June 2011 acquisition of Neighborhood Diabetes, a \$2.6 million increase in administrative and consulting services, a \$1.6 million increase in product shipping expenses due to higher shipment volumes and a \$1.3 million increase related to sales and use tax compliance. These increases were offset in part by \$3.2 million of transaction costs related to the acquisition of Neighborhood Diabetes in June 2011.

### *Sales and Marketing*

Sales and marketing expense increased \$9.5 million, or 21.9%, to \$52.7 million for the year ended December 31, 2012, as compared to \$43.2 million for the year ended December 31, 2011. This increase was largely due to an increase of \$8.8 million in employee related expenses including stock-based compensation as a result of the on-going expansion of our sales force and the acquisition of Neighborhood Diabetes, a \$1.0 million increase for convention fees, and a \$0.5 million increase in additional outside services costs primarily for customer support functions.

### *Other Expense, Net*

Other expense, net mainly consists of interest income and expense. Net interest expense was \$15.7 million for the year ended December 31, 2012, compared to \$14.6 million for the same period in 2011. The increase in net interest expense for the year ended December 31, 2012, is primarily the result of additional interest expense due to an increase in outstanding indebtedness resulting from the issuance of \$143.8 million in principal amount of the 3.75% Notes (as defined below) in June 2011, offset in part by the repurchase of \$70 million in principal amount of the 5.375% Notes (as defined below) in June 2011.

### *Income Tax Benefit (Expense)*

Income tax expense was \$0.2 million for the year ended December 31, 2012 as compared to an income tax benefit of \$11.2 million in the year ended December 31, 2011. Income tax expense is comprised of a current and deferred portion. The current portion in 2012 and 2011 was primarily related to state, local, and foreign taxes and the deferred portion in 2012 primarily related to U.S. Federal and State tax amounts. Income tax benefit in 2011 was generated as a result of the deferred tax liabilities acquired with the Neighborhood Diabetes acquisition. These deferred tax liabilities were used to offset our preexisting deferred tax assets reducing the amount of the valuation allowance required in that period.

### ***Comparison of the Years Ended December 31, 2011 and December 31, 2010***

#### *Revenue*

Our total revenue was \$152.3 million for the year ended December 31, 2011, as compared to \$97.0 million for the year ended December 31, 2010. The increase in revenue is due to continued adoption of the OmniPod System by patients in the United States and internationally, as well as \$35.3 million of revenue related to pharmacy, testing supplies, insulin pumps and pump supplies serviced by Neighborhood Diabetes.

#### *Cost of Revenue*

Cost of revenue was \$85.5 million for the year ended December 31, 2011, as compared to \$53.2 million for the year ended December 31, 2010. The increase is due to higher sales volume and higher costs related to lower margin sales by our Neighborhood Diabetes business. These increases were partially offset by lower per-unit costs on the OmniPod System resulting from cost savings on raw materials, volume discounts from our suppliers and increased production volumes.

---

## **Table of Contents**

### *Research and Development*

Research and development expense increased \$5.3 million, or 32.0%, to \$21.9 million for the year ended December 31, 2011, as compared to \$16.6 million for the year ended December 31, 2010. The increase was primarily related to an increase of \$2.3 million in labor expenses including stock-based compensation, \$1.6 million for products used for research and development purposes, \$0.7 million for depreciation of engineering equipment, and \$0.5 million of outside services in connection with development and regulatory approval of the next generation OmniPod System.

### *General and Administrative*

General and administrative expense increased \$17.4 million, or 65.3%, to \$44.1 million for the year ended December 31, 2011, as compared to \$26.7 million for the year ended December 31, 2010. The increase was largely due to an increase of \$6.6 million of employee related expenses including stock-based compensation. Of the \$6.6 million of increased employee related expenses, \$2.8 million relates to Neighborhood Diabetes. Additionally, we incurred \$3.9 million of amortization expense related to the customer relationship and tradename assets acquired from Neighborhood Diabetes, \$3.2 million of transaction costs related to the acquisition, \$0.9 million of additional bad debt expense related to Neighborhood Diabetes receivables and \$0.9 million for other administrative and consulting services related to the Neighborhood Diabetes business. We also recorded \$1.7 million of additional legal fees mainly related to the BD patent infringement lawsuit.

### *Sales and Marketing*

Sales and marketing expense increased \$8.5 million, or 24.6%, to \$43.2 million for the year ended December 31, 2011, as compared to \$34.7 million for the year ended December 31, 2010. The increase was largely due to an increase of \$5.9 million in employee related expenses including stock-based compensation. Of the \$5.9 million of increased employee related expenses, \$4.5 million relates to Neighborhood Diabetes. Additionally we incurred \$1.1 million of additional outside services costs primarily for customer support functions and \$0.4 million of additional employee travel.

### *Restructuring and Impairment of Assets*

For the year ended December 31, 2010, we recorded a total of \$4.4 million of impairment charges on certain assets. During the year ended December 31, 2010 we determined that certain amounts related to manufacturing equipment for our next generation OmniPod System would not be used in our final product and recorded an impairment charge of approximately \$1.0 million. In addition, we terminated certain other projects related to our existing OmniPod System as we focused primarily on the introduction of our next generation product. As a result, we recorded an impairment charge of approximately \$3.4 million related to this manufacturing equipment and construction in process. We had no restructuring or impairment activity in the year ended December 31, 2011.

### *Other Expense, Net*

Other expense, net mainly consists of interest income and expense. Net interest expense was \$14.6 million for the year ended December 31, 2011, compared to \$22.5 million for the same period in 2010. The decrease in net interest expense is related primarily to the repayment of the Facility Agreement (as defined below) in 2010. We recorded interest expense of \$12.9 million related to the Facility Agreement in 2010, including approximately \$7.0 million for the write off of the debt discount and deferred financing costs. The reduction in interest related to the Facility Agreement was offset by additional cash and non-cash interest expense due to the increase in outstanding indebtedness resulting from the issuance of the \$143.8 million in principal amount 3.75% Notes in June 2011, offset in part by the repurchase of \$70 million in principal amount of the 5.375% Notes in June 2011.

**Table of Contents****Income Tax Benefit (Expense)**

Income tax benefit was \$11.2 million in the year ended December 31, 2011. Income tax benefit was generated as a result of deferred tax liabilities acquired with the Neighborhood Diabetes acquisition. These deferred tax liabilities were used to offset our preexisting deferred tax assets reducing the amount of the valuation allowance required in that period. No income tax benefit or expense was recorded in the year ended December 31, 2010.

**Liquidity and Capital Resources**

We commenced operations in 2000 and to date we have financed our operations primarily through private placements of common and preferred stock, secured indebtedness, public offerings of our common stock and issuances of convertible debt. In June 2011, we acquired all of the outstanding shares of Neighborhood Diabetes. The aggregate purchase price of approximately \$62.4 million included approximately \$37.9 million in cash paid at closing. As of December 31, 2012, we had \$57.3 million in cash and cash equivalents. Additionally, in January 2013, we sold 4.7 million shares of our common stock at a price of \$20.75 per share, resulting in net proceeds to us of \$92.8 million. We believe that our current cash and cash equivalents, together with the cash expected to be generated from sales, will be sufficient to meet our projected operating and debt service requirements for at least the next twelve months.

**Equity**

In December 2010, we issued and sold 3,450,000 shares of our common stock at a price of \$13.27 per share. In connection with the offering, we received total gross proceeds of \$47.8 million, or approximately \$45.4 million in net proceeds after deducting underwriting discounts and offering expenses. Approximately \$33.3 million of the proceeds was used to repay all amounts outstanding under our Facility Agreement with certain institutional accredited investors.

In June 2011, in connection with the acquisition of Neighborhood Diabetes, we issued 1,197,631 shares of our common stock with a value of \$20.40 per share on the issuance date, as partial consideration for the acquisition.

In January 2013, in a public offering, we issued and sold 4,715,000 shares of our common stock at a price of \$20.75 per share. In connection with the offering, we received total gross proceeds of \$97.8 million, or approximately \$92.8 million in net proceeds after deducting underwriting discounts and offering expenses.

**Debt**

At December 31, 2012 and 2011, we had convertible debt and related deferred financing costs on our balance sheet as follows (in thousands):

	As of December 31,	
	2012	2011
Principal amount of the 5.375% Convertible Senior Notes	\$ 15,000	\$ 15,000
Principal amount of the 3.75% Convertible Senior Notes	143,750	143,750
Unamortized discount	(40,591)	(50,210)
Total debt	118,159	108,540
Current portion of long-term debt	14,429	
Long-term debt	\$ 103,730	\$ 108,540
Deferred financing costs	\$ 2,004	\$ 2,597



**Table of Contents**

Interest expense related to the 5.375% Senior Notes (as defined below), the 3.75% Senior Notes (as defined below) and the Facility Agreement (as defined below) was included in interest expense on the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2012	2011	2010
Contractual coupon interest	\$ 6,197	\$ 5,383	\$ 7,203
Accretion of debt discount	9,619	7,213	13,247
Other interest payments		1,991	650
Amortization of debt issuance costs	593	532	1,780
<b>Total interest expense</b>	<b>\$ 16,409</b>	<b>\$ 15,119</b>	<b>\$ 22,880</b>

**5.375% Convertible Senior Notes**

In June 2008, we sold \$85.0 million principal amount of 5.375% Convertible Senior Notes due June 15, 2013 (the 5.375% Notes) in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 5.375% per annum on the principal amount from June 16, 2008, payable semi-annually in arrears in cash on December 15 and June 15 of each year. The 5.375% Notes are convertible into our common stock at an initial conversion rate of 46.8467 shares of common stock per \$1,000 principal amount of the 5.375% Notes, which is equivalent to a conversion price of approximately \$21.35 per share, representing a conversion premium of 34% to the last reported sale price of our common stock on the NASDAQ Global Market on June 10, 2008, subject to adjustment under certain circumstances, at any time beginning on March 15, 2013 or under certain other circumstances and prior to the close of business on the business day immediately preceding the final maturity date of the notes. The 5.375% Notes will be convertible for cash up to their principal amount and shares of our common stock for the remainder of the conversion value in excess of the principal amount.

If a fundamental change, as defined in the Indenture for the 5.375% Notes, occurs at any time prior to maturity, holders of the 5.375% Notes may require us to repurchase their notes in whole or in part for cash equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, including any additional interest to, but excluding, the date of repurchase. If a holder elects to convert their 5.375% Notes upon the occurrence of a make-whole fundamental change, as defined in the Indenture for the 5.375% Notes, the holder may be entitled to receive an additional number of shares of common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option and are set forth in the Indenture to the 5.375% Notes. In no event will the number of shares issuable upon conversion of a note exceed 62.7746 per \$1,000 principal amount (subject to adjustment as described in the Indenture for the 5.375% Notes).

We recorded a debt discount of \$26.9 million to equity to reflect the value of our nonconvertible debt borrowing rate of 14.5% per annum. This debt discount is being amortized as interest expense over the five-year term of the 5.375% Notes. We incurred deferred financing costs related to this offering of approximately \$3.5 million, of which \$1.1 million has been reclassified as an offset to the value of the amount allocated to equity. The remainder is recorded as other assets in the consolidated balance sheet and is being amortized as a component of interest expense over the five-year term of the 5.375% Notes.

In June 2011, in connection with the issuance of \$143.8 million in principal amount of 3.75% Convertible Notes due June 2016 (the 3.75% Notes), we repurchased \$70 million in principal amount of the 5.375% Notes for \$85.1 million, a 21.5% premium on the principal amount. The investors that held the \$70 million in principal amount of repurchased 5.375% Notes purchased \$59.5 million in principal amount of the 3.75% Notes and retained approximately \$13.5 million in principal amount of the remaining 5.375% Notes. The investors combined \$73.0 million in principal amount of convertible debt (\$13.5 million of 5.375% Notes and \$59.5 million of 3.75% Notes) was considered to be a modification of a portion of the 5.375% Notes. See the section entitled 3.75% Convertible Senior Notes below.

---

## **Table of Contents**

Cash interest expense related to the 5.375% Notes was \$0.8 million, \$2.7 million, and \$4.6 million for the years ended December 31, 2012, 2011, and 2010, respectively.

As of December 31, 2012, we included approximately \$14.4 million on our balance sheet in the current portion of long-term debt related to the 5.375% Notes. As of December 31, 2012 the 5.375% Notes have a remaining term of 6 months.

### ***3.75% Convertible Senior Notes***

In June 2011, we sold \$143.8 million principal amount of 3.75% Notes. The interest rate on the notes is 3.75% per annum, payable semi-annually in arrears in cash on December 15 and June 15 of each year. The 3.75% Notes are convertible into our common stock at an initial conversion rate of 38.1749 shares of common stock per \$1,000 principal amount of the 3.75% Notes, which is equivalent to a conversion price of approximately \$26.20 per share, subject to adjustment under certain circumstances. The 3.75% Notes are convertible prior to March 15, 2016 only upon the occurrence of certain circumstances. On and after March 15, 2016 and prior to the close of business on the second scheduled trading day immediately preceding the final maturity date of the 3.75% Notes, the notes may be converted without regard to the occurrence of any such circumstances. The 3.75% Notes and any unpaid interest will be convertible at our option for cash, shares of our common stock or a combination of cash and shares of our common stock for the principal amount. We intend to settle the principal in cash.

We may not redeem the 3.75% Notes prior to June 20, 2014. From June 20, 2014 to June 20, 2015, we may redeem the 3.75% Notes, at our option, in whole or in part only if the last reported sale price per share of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days during a period of 30 consecutive trading days. On and after June 25, 2015, we may redeem the 3.75% Notes, at our option (without regard to such sale price condition), in whole or in part. If a fundamental change, as defined in the Indenture for the 3.75% Notes, occurs at any time prior to maturity, holders of the 3.75% Notes may require us to repurchase their notes in whole or in part for cash equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest. If a holder elects to convert its 3.75% Notes upon the occurrence of a make-whole fundamental change, as defined in the Indenture for the 3.75% Notes, the holder may be entitled to receive an additional number of shares of our common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option and are set forth in the Indenture to the 3.75% Notes. In no event will the number of shares issuable upon conversion of a 3.75% Note exceed 50.5816 per \$1,000 principal amount (subject to adjustment as described in the Indenture for the 3.75% Notes). The 3.75% Notes are unsecured and are equal in right of payment to the 5.375% Notes.

In connection with the issuance of the 3.75% Notes, we repurchased \$70 million in principal amount of the 5.375% Notes for \$85.1 million, a 21.5% premium on the principal amount. The investors that held the \$70 million in principal amount of repurchased 5.375% Notes purchased \$59.5 million in principal amount of the 3.75% Notes and retained approximately \$13.5 million in principal amount of the remaining 5.375% Notes. This transaction was treated as a modification of the existing 5.375% Notes. We accounted for this modification of a portion of the 5.375% Notes separately from the issuance of the remainder of the 3.75% Notes.

Prior to the transaction, the \$70 million principal of repurchased 5.375% Notes had a debt discount of \$10.5 million. This amount remained in debt discount related to the \$73 million in principal amount of modified debt. We recorded additional debt discount of \$15.1 million related to the premium payment in connection with the repurchase and \$0.2 million related to the increase in the value of the conversion feature. The offset to the debt discount related to the value of the conversion feature was recorded as additional paid-in capital. The total debt discount of \$25.8 million related to the modified debt is being amortized as interest expense at the effective rate of 16.5% over the five-year term of the modified debt. We paid transaction fees of approximately \$2.0 million related to the modification, which were recorded as interest expense at the time of the modification.

---

**Table of Contents**

Of the \$143.8 million in principal amount of 3.75% Notes issued in June 2011, \$84.3 million in principal amount was considered to be an issuance of new debt. We recorded a debt discount of \$26.6 million related to the \$84.3 million in principal amount of 3.75% Notes. The debt discount was recorded as additional paid-in capital to reflect the value of our nonconvertible debt borrowing rate of 12.4% per annum. This debt discount is being amortized as interest expense over the five-year term of the 3.75% Notes. We incurred deferred financing costs related to this offering of approximately \$2.8 million, of which \$0.9 million has been recorded as an offset to the value of the amount allocated to equity. The remainder is recorded as other assets in the consolidated balance sheet and is being amortized as a component of interest expense over the five-year term of the 3.75% Notes.

Cash interest expense related to the \$143.8 million in principal amount of 3.75% Notes was \$5.4 million and \$2.7 million in the years ended December 31, 2012 and 2011, respectively. No cash interest was recorded on the 3.75% Notes in the year ended December 31, 2010.

As of December 31, 2012, we included \$103.7 million on our balance sheet in long-term debt related to the 3.75% Notes. As of December 31, 2012, the 3.75% Notes have a remaining term of three and a half years.

***Facility Agreement and Common Stock Warrants***

In March 2009, we entered into a facility agreement with certain institutional accredited investors (the Facility Agreement), pursuant to which the investors agreed to loan us up to \$60 million, subject to the terms and conditions set forth in the Facility Agreement. Total financing costs, including the transaction fee, were \$3.0 million and were amortized as interest expense over the 42 months of the Facility Agreement. In September 2009, we entered into an amendment to the Facility Agreement whereby we repaid the \$27.5 million originally drawn and promptly drew down the remaining \$32.5 million available under the Facility Agreement. The annual interest rate was 8.5%, payable quarterly in arrears. In connection with the amendment to the Facility Agreement, we entered into a securities purchase agreement with the institutional accredited investors whereby we sold 2,855,659 shares of our common stock to the lenders at \$9.63 per share, a \$1.9 million discount based on the closing price of our common stock of \$10.28 on that date. We recorded the \$1.9 million as a debt discount, which was amortized as interest expense over the remaining term of the loan. We received aggregate proceeds of \$27.5 million in connection with the sale of our shares.

In connection with the execution of the Facility Agreement, we issued to the investors fully exercisable warrants to purchase an aggregate of 3.75 million shares of our common stock at an exercise price of \$3.13 per share. The warrants qualified for permanent treatment as equity, and their relative fair value of \$6.1 million on the issuance date was recorded as additional paid-in capital and debt discount. The debt discount was amortized as non-cash interest expense over the term of the loan. As of December 31, 2012, all warrants to acquire 3.75 million shares of our common stock issued in connection with the Facility Agreement were exercised.

In December 2010, we paid \$33.3 million to the lenders, of which \$32.5 million related to principal and \$0.8 million related to interest and prepayment fees, to extinguish this debt. We recorded a non-cash interest charge of \$7.0 million in 2010 related to the write-off of the remaining debt discounts and financing costs included in other assets which were being amortized to interest expense over the term of the debt. At December 31, 2012 and December 31, 2011, there were no amounts related to the Facility Agreement included on our balance sheet.

**Table of Contents****Operating Activities**

The following table sets forth the amounts of cash used in operating activities and net loss for each of the periods indicated:

	Year Ended December 31,		
	2012	2011 (Restated)	2010
	(In thousands)		
Cash used in operating activities	\$ (29,059)	\$ (25,452)	\$ (35,625)
Net loss	\$ (51,867)	\$ (45,831)	\$ (61,159)

Net cash used in operating activities in the years ended December 31, 2012, 2011 and 2010, primarily represents amounts utilized to fund operating losses. The increase of \$3.6 million of cash used in operating activities for the year ended December 31, 2012 as compared to the year ended December 31, 2011 was primarily a result of our net loss of \$51.9 million offset by non-cash expenses of \$34.6 million. Non-cash expenses include non-cash interest, depreciation and amortization, stock-based compensation and bad debt expense. Cash used in operating activities in the year ended December 31, 2012 includes an increase in net accounts receivable of \$13.5 million and an increase of \$3.0 million in inventory. These increases were offset in part by an increase of \$3.0 million in accounts payable, accrued expenses and other liabilities and a \$2.9 million increase in deferred revenue.

The decrease of \$10.2 million of cash used in operating activities for the year ended December 31, 2011 compared to the year ended December 31, 2010 was due primarily due to the increase in revenue combined with our ability to maintain lower gross margins as well as cost containment initiatives. Cash used in operating activities in the year ended December 31, 2011 was primarily a result of our net loss of \$45.8 million offset by non-cash expenses of \$17.8 million. Non-cash expenses include non-cash interest, depreciation and amortization, stock-based compensation, deferred tax provision and bad debt expense. Cash used in operating activities in the year ended December 31, 2011 includes an increase in accounts payable and accrued expenses of \$4.7 million, an increase in net accounts receivable of \$3.6 million and a reduction of deferred revenue of \$1.7 million. These increases are mainly attributable to our acquisition of Neighborhood Diabetes and were offset by a decrease in inventory of \$1.9 million.

**Investing and Financing Activities**

The following table sets forth the amounts of cash used in investing activities and cash provided by financing activities for each of the periods indicated:

	Year Ended December 31,		
	2012	2011	2010
	(In thousands)		
Cash used in investing activities	\$ (10,991)	\$ (48,969)	\$ (6,549)
Cash provided by financing activities	\$ 3,388	\$ 55,102	\$ 27,452

Cash used in investing activities in the year ended December 31, 2012 was primarily related to purchases of property and equipment, of which the majority related to the purchase of manufacturing equipment for use in the production of our next generation product. Cash used in investing activities in the year ended December 31, 2011 was primarily related to the acquisition of Neighborhood Diabetes for which we paid \$37.9 million in cash and \$24.4 million in shares of our common stock. In addition, we used approximately \$9.0 million for the purchase of property and equipment primarily related to manufacturing equipment for use in the production of our next generation product. Cash used in investing activities in the year ended December 31, 2010 mainly related to the purchase of property and equipment.

In the year ended December 31, 2012 cash provided by financing activities is mainly related to the net proceeds from the issuance of common stock in connection with the exercise of employee stock options. In the

---

**Table of Contents**

year ended December 31, 2011 cash provided by financing activities related to the net proceeds from the issuance of the 3.75% Notes, offset by the repurchase of \$70 million in principal amount of the 5.375% Notes for \$85.1 million. Cash provided by financing activities in the year ended December 31, 2010 was primarily the result of the sale of 3,450,000 shares of common stock at a price of \$13.27 per share in December 2010 and the exercise of warrants to purchase 3,750,000 shares of common stock at a price of \$3.13 per share, offset by the repayment of all amounts owed under the Facility Agreement.

We lease our facilities in Massachusetts, New York, Florida, and Singapore. These leases are accounted for as operating leases. The leases generally provide for a base rent plus real estate taxes and certain operating expenses related to the leases. We have extended the leases for our facilities in Bedford and Billerica, Massachusetts. Following the extensions, these leases expire in September 2014. The leases for Bedford contain a five-year renewal option and escalating payments over the life of the lease. The leases in Woburn, Singapore, Florida, and New York expire in June 2013, July 2013, December 2013, and April 2015, respectively.

During the year ended December 31, 2012, we terminated a lease for one of our corporate offices spaces in Bedford, Massachusetts. The lease termination resulted in no material impact to the financial statements for the year ended December 31, 2012. During the same period, we entered into a new lease agreement for an additional 26,500 square feet in Bedford, Massachusetts. The lease expires in September 2014 and includes escalating rent payments over its term. Furthermore, during the year ended December 31, 2012, we renewed our lease for our Florida property. The lease expires in December 2013.

Certain of our operating lease agreements contain scheduled rent increases, which are being amortized over the terms of the agreement using the straight-line method and are included in other liabilities in the accompanying balance sheet. We expect to pay rent of \$1.5 million in 2013 and \$1.0 million in 2014.

As a result of the issuance of the 3.75% Notes and the repurchase of \$70 million of the 5.375% Notes in June 2011, we expect to pay cash interest of \$5.8 million in 2013, \$5.4 million in each of 2014 and 2015 and \$2.5 million in 2016. Additionally we expect to repay the \$15 million of the 5.375% Notes in 2013 and the \$143.8 million of the 3.75% Notes in 2016.

During the year ending December 31, 2013, we will be using funds in connection with the development and production of our next generation OmniPod System, expansion of our commercial organization and continued initiatives to increase sales of the OmniPod System in the United States and internationally.

***Shareholder Rights Plan***

In November 2008, our Board of Directors adopted a shareholder rights plan (the *Shareholder's Rights Plan*), as set forth in the Shareholder Rights Agreement between us and the rights agent, the purpose of which is, among other things, to enhance the ability of the Board of Directors to protect shareholder interests and to ensure that shareholders receive fair treatment in the event any coercive takeover attempt of us is made in the future. The Shareholder Rights Plan could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, us or a large block of our common stock.

In connection with the adoption of the Shareholder Rights Plan, our Board of Directors declared a dividend distribution of one preferred stock purchase right (a *Right*) for each outstanding share of common stock to stockholders of record as of the close of business on November 15, 2008. In addition, one Right will automatically attach to each share of common stock issued between November 15, 2008 and the distribution date. The Rights currently are not exercisable and are attached to and trade with the outstanding shares of common stock. Under the Shareholder Rights Plan, the Rights become exercisable if a person or group becomes an *acquiring person* by acquiring 15% or more of the outstanding shares of common stock or if a person or group commences a tender offer that would result in that person or group owning 15% or more of the common stock. If a person or group becomes an *acquiring person*, each holder of a Right (other than the acquiring person) would

**Table of Contents**

be entitled to purchase, at the then-current exercise price, such number of shares of our preferred stock which are equivalent to shares of common stock having a value of twice the exercise price of the Right. If we are acquired in a merger or other business combination transaction after any such event, each holder of a Right would then be entitled to purchase, at the then-current exercise price, shares of the acquiring company's common stock having a value of twice the exercise price of the Right.

**Off-Balance Sheet Arrangements**

As of December 31, 2012, we did not have any off-balance sheet financing arrangements.

**Contractual Obligations**

The following table summarizes our principal contractual obligations as of December 31, 2012. Amounts in thousands:

Contractual Obligations	Total	2013	Payments Due in				Later
			2014	2015	2016	2017	
Operating lease obligations	\$ 2,521	\$ 1,511	\$ 965	\$ 45	\$	\$	
Long-term debt obligations(1)	177,793	20,790	5,391	5,391	146,221		
Purchase obligations for production components	5,206	5,206					
Purchase obligations for capital expenditures	1,616	1,616					
<b>Total contractual obligations</b>	<b>\$ 187,136</b>	<b>\$ 29,123</b>	<b>\$ 6,356</b>	<b>\$ 5,436</b>	<b>\$ 146,221</b>	<b>\$</b>	<b>\$</b>

(1) The interest rate on the convertible debt is 5.375% and 3.75% per annum. We have included future payments of interest on the long-term debt in our obligations.

**Critical Accounting Policies and Estimates**

Our financial statements are based on the selection and application of generally accepted accounting principles, which require us to make estimates and assumptions about future events that affect the amounts reported in our financial statements and the accompanying notes. Future events and their effects cannot be determined with certainty. Therefore, the determination of estimates requires the exercise of judgment. Actual results could differ from those estimates, and any such differences may be material to our financial statements. We believe that the policies set forth below involve a higher degree of judgment and complexity in their application than our other accounting policies and represent the critical accounting policies and estimates used in the preparation of our financial statements. If different assumptions or conditions were to prevail, the results could be materially different from our reported results.

**Revenue Recognition**

We generate nearly all of our revenue from sales of our OmniPod Insulin Management System and other diabetes related products including blood glucose testing supplies, insulin pumps, pump supplies and pharmaceuticals to customers and third-party distributors who resell the products to patients with diabetes.

Revenue recognition requires that persuasive evidence of a sales arrangement exists, delivery of goods occurs through transfer of title and risk and rewards of ownership, the selling price is fixed or determinable and collectibility is reasonably assured. With respect to these criteria:

The evidence of an arrangement generally consists of a physician order form, a patient information form and, if applicable, third-party insurance approval for sales directly to patients or a purchase order for sales to a third-party distributor.

## **Table of Contents**

Transfer of title and risk and rewards of ownership are typically passed to the patient or third-party distributor upon shipment of the products.

The selling prices for all sales are fixed and agreed with the patient or third-party distributor, and if applicable, the patient's third-party insurance provider(s) prior to shipment and are based on established list prices or, in the case of certain third-party insurers, contractually agreed upon prices. Provisions for discounts and rebates to customers are established as a reduction to revenue in the same period the related sales are recorded.

We offer a 45-day right of return for our OmniPod Insulin System sales to new patients, and we defer revenue to reflect estimated sales returns in the same period that the related product sales are recorded. Returns are estimated through a comparison of our historical return data to our related sales. Historical rates of return are adjusted for known or expected changes in the marketplace when appropriate. Historically, sales returns have amounted to approximately 3% of gross product sales. When doubt exists about reasonable assuredness of collectibility from specific customers, we defer revenue from sales of products to those customers until payment is received.

In June 2011, we entered into 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 term of the Development Agreement, we have invoiced and expect to continue to invoice amounts based upon meeting certain defined deliverable milestones. Revenue on the development agreement is recognized using a proportional performance methodology based on efforts incurred and total payments under the agreement.

We had deferred revenue of \$5.4 million as of December 31, 2012. The deferred revenue recorded as of December 31, 2012 was primarily comprised of product-related revenue and unrecognized amounts related to the development agreement.

### ***Restructuring Expense and Impairment of Assets***

In connection with our efforts to pursue improved gross margins, leverage operational efficiencies and better pursue opportunities for low-cost supplier sourcing, we periodically perform an evaluation of our manufacturing processes and review the carrying value of our property and equipment to assess the recoverability of these assets whenever events indicate that impairment may have occurred. As part of this assessment, we review the planned use of the assets as well as the future undiscounted operating cash flows expected to be generated by those assets. If impairment is indicated through this review, the carrying amount of the asset would be reduced to its estimated fair value. This review of manufacturing processes and equipment can result in restructuring activity or an impairment of assets based on current net book value and potential future use of the assets.

Our restructuring expenses may also include workforce reduction and related costs for one-time termination benefits provided to employees who are involuntarily terminated under the terms of a one-time benefit arrangement. We record these one-time termination benefits upon incurring the liability, provided that the employees are notified, the plan is approved by the appropriate level of management, the employees to be terminated and the expected completion date are identified and the benefits the identified employees will be paid are established. Significant changes to the plan are not expected when we record the costs. In recording the workforce reduction and related costs, we estimate related costs such as taxes and outplacement services which may be provided under the plan. If changes in these estimated services occur, we may be required to record or reverse restructuring expenses associated with these workforce reduction and related costs.

---

## **Table of Contents**

### ***Asset Valuation***

Asset valuation includes assessing the recorded value of certain assets, including accounts receivable, inventory and fixed assets. We use a variety of factors to assess valuation, depending upon the asset. Actual results may differ materially from our estimates. Inventories are held at the lower of their cost or market value. We periodically review inventories for potential impairment based on quantities on hand and expectations of future use. Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized over their useful life or the life of the lease, whichever is shorter. We review long-lived assets, including property and equipment and intangibles, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. We also review assets under construction to ensure certainty of their future installation and integration into the manufacturing process. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. We consider various valuation factors, principally planned use of the assets and discounted cash flows, to assess the fair values of long-lived assets.

### ***Income Taxes***

Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect in the years in which the differences are expected to reverse. A valuation allowance is required to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. We review our deferred tax assets for recoverability considering historical profitability, projected future taxable income, and the expected timing of the reversals of existing temporary differences and tax planning strategies.

We follow the provisions of FASB ASC 740-10, *Income Taxes* ( ASC 740-10 ) on accounting for uncertainty in income taxes recognized in our financial statements. ASC 740-10 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In addition, ASC 740-10 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. As of December 31, 2012 we had \$0.1 million of unrecognized tax benefits recorded.

We file federal, state and foreign tax returns. These returns are generally open to examination by the relevant tax authorities from three to four years from the date they are filed. The tax filings relating to our federal and state tax returns are currently open to examination for tax years 2009 through 2011 and 2008 through 2011, respectively. In addition, we have generated tax losses since our inception in 2000. These years may be subject to examination if the losses are carried forward and utilized in future years.

For the year ended December 31, 2012, income tax expense was \$212,000 and was comprised of \$121,000 for the current portion and \$91,000 for the deferred portion. The current portion primarily relates to state, local, and foreign taxes as well as benefit realized for the release of certain reserves. The deferred portion primarily relates to U.S. Federal and State tax amounts.

### ***Stock-Based Compensation***

We account for stock-based compensation under the provisions of FASB ASC 718-10, *Compensation - Stock Compensation* ( ASC 718-10 ). ASC 718-10 requires that all share-based payments to employees, including grants of employee stock options, be recognized in the income statement based on their fair values.

We use the Black-Scholes option pricing model to determine the weighted-average fair value of options granted. We determine the intrinsic value of restricted stock and restricted stock units based on the closing price of our common stock on the date of grant. We recognize the compensation expense of share-based awards on a straight-line basis over the vesting period of the award.



---

## **Table of Contents**

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected life of the awards is estimated based on the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of the awards. The dividend yield assumption is based on company history and the expectation that we will not pay dividends. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest. We evaluate the assumptions used to value the awards on a quarterly basis and if factors change and different assumptions are utilized, stock-based compensation expense may differ significantly from what has been recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense.

In the year ended December 31, 2012 we recorded \$9.9 million of stock-based compensation expense.

### ***Accounts Receivable and Allowance for Doubtful Accounts***

Accounts receivable consist of amounts due from third-party payors, patients, third-party distributors, and government agencies. The allowance for doubtful accounts is recorded at the time the potential collection risk is identified. We estimate our allowance based on historical experience, assessment of specific risk, discussions with individual customers or various assumptions and estimates that are believed to be reasonable under the circumstances. At December 31, 2012 the allowance for doubtful accounts was \$6.6 million. We believe the reserve is adequate to mitigate current collection risk.

### ***Intangibles and Other Long-Lived Assets***

Our finite-lived intangible assets are stated at cost less accumulated amortization. We assess our intangible and other long-lived assets for impairment, whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. We assess the need for an impairment of intangibles and other long-lived assets if the carrying amount of the asset is not recoverable based on its undiscounted future cash flows. Any such impairment loss is measured as the difference between the carrying amount and the fair value of the asset. The estimation of useful lives and expected cash flows requires us to make significant judgments regarding future periods that are subject to some factors outside our control. Changes in these estimates can result in significant revisions to the carrying value of these assets and may result in material charges to the results of operations. The estimated life of the acquired tradename is 15 years. The estimated life of the acquired customer relationships asset is ten years. Intangible assets with determinable estimated lives are amortized over these lives. At December 31, 2012 intangible assets related to the acquisition of Neighborhood Diabetes consisted of \$20.5 million of customer relationships and \$2.5 million of tradenames.

### ***Goodwill***

Goodwill represents the excess of the cost of the acquired Neighborhood Diabetes business over the fair value of identifiable net assets acquired. We perform an assessment of our goodwill for impairment on at least an annual basis or whenever events or changes in circumstances indicate there might be impairment.

Goodwill is evaluated at the reporting unit level. To test for impairment, we compare the carrying value of the reporting unit to its fair value using a discounted cash flow analysis. If the reporting unit's carrying value exceeds its fair value, we record an impairment loss to the extent that the carrying value of goodwill exceeds its implied fair value. We completed our goodwill analysis as of October 1, 2012 and noted no impairment.

### ***Warranty***

We provide a four-year warranty on our PDMs and may replace any OmniPods that do not function in accordance with product specifications. We estimate our warranty at the time the product is shipped based on

---

**Table of Contents**

historical experience and the estimated cost to service the claims. Cost to service the claims reflects the current product cost which has been decreasing over time. As these estimates are based on historical experience, and we continue to introduce new versions of existing products, we also consider the anticipated performance of the product over its warranty period in estimating warranty reserves. At December 31, 2012 the warranty reserve was \$2.0 million.

***Recent Accounting Pronouncements***

In May 2011, the FASB issued ASU No. 2011-04 *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* ( ASU No. 2011-04 ). ASU No. 2011-04 clarifies existing concepts regarding existing fair value principles. The amendments will be effective in fiscal years beginning after December 15, 2011. We adopted the guidance in the first quarter of 2012. The adoption of these amendments did not have a material impact on our financial statements.

In September 2011, the FASB issued ASU No. 2011-08 *Testing Goodwill for Impairment* ( ASU No. 2011-08 ). ASU No. 2011-08 provides guidance on simplifying the impairment testing for goodwill. A company may first assess the qualitative factors to determine whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test on the reporting unit. The amendments will be effective in fiscal years beginning after December 15, 2011, and we adopted the guidance in the first quarter of 2012. The adoption of this guidance did not have a material impact on our financial statements.

In December 2011, the FASB issued ASU No. 2011-11, *Disclosures about Offsetting Assets and Liabilities*. ASU 2011-11 will require disclosure of information about offsetting and related arrangements to enable users of our financial statements to understand the effect of those arrangements on our financial position. The guidance is effective in fiscal years beginning after January 1, 2013. We believe the adoption of ASU No. 2011-11 will have no material impact on our financial statements.

In July 2012, the FASB issued ASU No. 2012-12 *Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment* ( ASU No. 2012-12 ). ASU No. 2012-12 gives a company the option to first assess qualitative factors to determine whether it is more likely-than-not that the indefinitely-lived intangible is impaired. Qualitative factors include related events and circumstances that could affect the significant inputs used in determining the fair value of the indefinite-lived intangible asset. The guidance is effective in fiscal years beginning after September 12, 2012. We believe the adoption of ASU No. 2012-12 will have no material impact on our financial statements.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We do not use derivative financial instruments in our investment portfolio and have no foreign exchange contracts. Our financial instruments consist of cash, cash equivalents, short-term investments, accounts receivable, accounts payable, accrued expenses and long-term obligations. We consider investments that, when purchased, have a remaining maturity of 90 days or less to be cash equivalents. The primary objectives of our investment strategy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. To minimize our exposure to an adverse shift in interest rates, we invest mainly in cash equivalents and maintain an average maturity of six months or less. We do not believe that a 10% change in interest rates would have a material impact on the fair value of our investment portfolio or our interest income.

On December 31, 2012, we had outstanding debt recorded at \$15 million related to our 5.375% Notes and outstanding debt recorded at \$143.8 million related to our 3.75% Notes.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The consolidated financial statements and supplementary data of the Company required in this item are set forth beginning on page F-1 of this Annual Report on Form 10-K.

**Table of Contents****ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES****Disclosure Controls and Procedures**

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2012. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act) means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2012, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at a reasonable assurance level. Specifically, our processes and procedures did not provide for adequate and timely analysis of the appropriate income tax accounting related to our acquisition of Neighborhood Diabetes and our modification of convertible debt in 2011.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting during the three months ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Our internal control system was designed to provide reasonable assurance to our management and the Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (the COSO criteria).

In our Annual Report on Form 10-K for the year ended December 31, 2011, filed on February 28, 2012, management concluded that our internal control over financial reporting was effective as of December 31, 2011. Subsequently, we became aware of a material weakness in our internal control over financial reporting; namely, that we did not maintain effective internal controls over the accuracy of our accounting for income taxes. Specifically, our processes and procedures did not provide for adequate and timely analysis of appropriate income tax accounting related to our acquisition of Neighborhood Diabetes and our modification of convertible debt in 2011.

**Table of Contents**

This material weakness resulted in the amendment to our Annual Report on Form 10-K/A for the year ended December 31, 2011, in order to restate the financial statements for the year ended December 31, 2011, and to restate the financial information for the second, third and fourth quarters of 2011 and the amendments to our Quarterly Reports on Form 10-Q/A to restate the financial information for the first, second and third quarters of 2012. As we have not yet remediated this material weakness, our management has also concluded that our internal control over financial reporting was not effective as of December 31, 2012.

The effectiveness of our internal control over financial reporting as of December 31, 2012 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which appears below.

**ITEM 9B. *OTHER INFORMATION***

None.

---

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

**The Board of Directors and Shareholders of**

**Insulet Corporation**

We have audited Insulet Corporation's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Insulet Corporation's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. Management has identified a material weakness in controls related to the company's accounting for income taxes. We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Insulet Corporation as of December 31, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the 2012 consolidated financial statements, and this report does not affect our report dated February 28, 2013, which expressed an unqualified opinion on those financial statements.

In our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, Insulet Corporation has not maintained effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 28, 2013

---

**Table of Contents**

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Certain information required by this Item 10 relating to our directors, executive officers and corporate governance is incorporated by reference herein from our proxy statement in connection with our 2013 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission (the SEC) not later than 120 days after the close of our year ended December 31, 2012.

**Audit Committee Financial Expert**

The audit committee of our board of directors currently consists of Steven Sobieski (Chairman), Regina Sommer and Daniel Levangie. Our board of directors has determined that each member of the audit committee is independent as that term is defined in the rules of the SEC and the applicable Nasdaq rules. Our board of directors has determined that both Mr. Sobieski and Ms. Sommer qualify as an audit committee financial expert as such term is defined in the rules of the SEC. In making its determination, our board of directors considered the nature and scope of the experiences and responsibilities these members have previously had with reporting companies. Stockholders should understand that this designation is a disclosure requirement of the SEC related to the experience and understanding of the members of the audit committee with respect to certain accounting and auditing matters. The designation does not impose upon any duties, obligations or liability upon the members of the audit committee that are greater than are generally imposed on other members of the audit committee and our board of directors and designation as an audit committee financial expert pursuant to this SEC requirement does not affect the duties, obligations or liability of any other member of the audit committee or the board of directors.

**Code of Ethics**

We have adopted a code of ethics, as defined by regulations promulgated under the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934 as amended, that applies to all of our directors and employees worldwide, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the Code of Business Conduct and Ethics is available at the Corporate Governance section of our website at <http://www.insulet.com>. A copy of the Code of Business Conduct and Ethics may also be obtained, free of charge, upon a request directed to: 9 Oak Park Drive, Bedford, Massachusetts 01730, Attention: Secretary. We intend to disclose any amendment to or waiver of a provision of the Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, by posting such information on our website available at <http://www.insulet.com>.

For more corporate governance information, you are invited to access the Corporate Governance section of our website available at <http://www.insulet.com>.

**ITEM 11. EXECUTIVE COMPENSATION**

Certain information required by this Item 11 relating to remuneration of directors and executive officers and other transactions involving management is incorporated by reference herein from our proxy statement in connection with our 2013 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our year ended December 31, 2012.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Certain information required by this Item 12 relating to security ownership of certain beneficial owners and management is incorporated by reference herein from our proxy statement in connection with our 2013 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission not

**Table of Contents**

later than 120 days after the close of our fiscal year ended December 31, 2012. For information on securities authorized for issuance under equity compensation plans, see the section entitled "Market for Registrant's Common Equity, Related Stockholders Matters, and Issuer Purchases of Equity Securities" in Part II, Item 5. in this Annual Report on Form 10-K.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

Certain information required by this Item 13 relating to certain relationships and related transactions, and director independence is incorporated by reference herein from our proxy statement in connection with our 2013 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our year ended December 31, 2012.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

Certain information required by this Item 14 regarding principal accounting fees and services is set forth under "Principal Accounting Fees and Services" in our proxy statement in connection with our 2013 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our year ended December 31, 2012.

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

The following documents are filed as part of this Form 10-K:

1. *Financial Statements*: Financial Statements are included in "Financial Statements and Supplementary Data" in Part II, Item 8 of this Annual Report on Form 10-K.
2. *Index to Financial Statement Schedules*: Financial Statement Schedules are included in "Financial Statements and Supplementary Data" in Part II, Item 8 of this Annual Report on Form 10-K. Schedules not listed therein are omitted because they are not required or because the required information is given in the consolidated financial statements or notes thereto.
3. *Exhibits*: Exhibits are as set forth in the section entitled "Exhibit Index" which follows the section entitled "Signatures" in this Annual Report on Form 10-K. Exhibits which are incorporated herein by reference can be inspected and copied at the public reference rooms maintained by the SEC in Washington, D.C., New York, New York, and Chicago, Illinois. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. SEC filings are also available to the public from commercial document retrieval services and at the Website maintained by the SEC at <http://www.sec.gov>.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**INSULET CORPORATION**  
(Registrant)

/s/ Duane DeSisto  
Duane DeSisto  
President and Chief Executive Officer

Date: February 28, 2013

/s/ Brian Roberts  
Brian Roberts  
Chief Financial Officer

Date: February 28, 2013

**POWER OF ATTORNEY AND SIGNATURES**

We, the undersigned officers and directors of Insulet Corporation hereby severally constitute and appoint Duane DeSisto and Brian Roberts, and each of them singly, our true and lawful attorneys, with full power to them and each of them singly, to sign for us in our names in the capacities indicated below, on all amendments to this Report, and generally to do all things in our names and on our behalf in such capacities to enable Insulet Corporation to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all requirements of the Securities and Exchange Commission.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities on February 28, 2013.

<b>Signature</b>	<b>Title</b>
/s/ Duane DeSisto	President, Chief Executive Officer and Director
Duane DeSisto	(Principal Executive Officer)
/s/ Brian Roberts	Chief Financial Officer
Brian Roberts	(Principal Financial and Accounting Officer)
/s/ Charles Liamos	Chief Operating Officer and Director
Charles Liamos	
/s/ Sally Crawford	Director
Sally Crawford	



Edgar Filing: INSULET CORP - Form 10-K

/s/ John Fallon

Director

John Fallon

/s/ Daniel Levangie

Director

Daniel Levangie

**Table of Contents**

<b>Signature</b>	<b>Title</b>
/s/ W. Mark Lortz	Director
W. Mark Lortz	
/s/ Steven Sobieski	Director
Steven Sobieski	
/s/ Regina Sommer	Director
Regina Sommer	
/s/ Joseph Zakrzewski	Director
Joseph Zakrzewski	

**Table of Contents****EXHIBIT INDEX**

Listed and indexed below are all Exhibits filed as part of this report.

<b>Number</b>	<b>Description</b>
2.1(20)	Merger Agreement by and among Insulet Corporation, Nectar Acquisition I Corporation, a Delaware corporation and wholly owned subsidiary of Insulet Corporation, and Neighborhood Holdings, Inc., a Delaware corporation, and its subsidiaries dated as of June 1, 2011
3.1(4)	Eighth Amended and Restated Certificate of Incorporation of the Registrant
3.2(4)	Amended and Restated By-laws of the Registrant
4.1(1)	Specimen Stock Certificate
4.2(8)	Indenture, dated June 16, 2008, between Insulet Corporation and Wells Fargo Bank, N.A.
4.3(8)	Registration Rights Agreement, dated as of June 16, 2008, among Insulet Corporation, J.P. Morgan Securities Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated.
4.4(10)	Certificate of Designations, Preferences and Rights of a Series of Preferred Stock of Insulet Corporation classifying and designating the Series A Junior Participating Cumulative Preferred Stock
4.5(10)	Shareholder Rights Agreement, dated as of November 14, 2008, between Insulet Corporation and Registrar and Transfer Company, as Rights Agent
4.6(11)	Form of Warrant to purchase shares of common stock of Insulet Corporation
4.7(12)	Amendment, dated September 25, 2009, to Shareholder Rights Agreement, dated as of November 14, 2008, between Insulet Corporation and Computershare Trust Company, As Rights Agent
4.8(21)	Indenture, dated as of June 29, 2011, between Insulet Corporation and Wells Fargo Bank National Association, as Trustee
4.9(22)	Form of 3.75% Convertible Senior Note due 2016
10.1(2)+	Development and License Agreement between TheraSense, Inc. and Insulet Corporation, dated January 23, 2002
10.2(3)	Lease between William J. Callahan and Insulet Corporation, dated July 15, 2004
10.3(1)	Insulet Corporation 2000 Stock Option and Incentive Plan
10.4(1)	Non-Qualified Stock Option Agreement for Employees under the 2007 Stock Option and Incentive Plan
10.5(1)	Non-Qualified Stock Option Agreement for Non-Employee Directors under the 2007 Stock Option and Incentive Plan
10.6(1)	Restricted Stock Award Agreement under the 2007 Stock Option and Incentive Plan
10.7(1)	Incentive Stock Option Agreement under the 2007 Stock Option and Incentive Plan
10.8(1)	Employment Agreement between Duane DeSisto and Insulet Corporation, dated May 4, 2005
10.9(1)	Employment Agreement between Ruthann DePietro and Insulet Corporation, dated February 8, 2006
10.10(3)	Form of Employee Non-Competition and Non-Solicitation Agreement by and between Insulet Corporation and each of its executive officers
10.11(5)+	Master Supply Agreement between Insulet Corporation and Flextronic Marketing (L) Ltd., dated January 3, 2007

**Table of Contents**

<b>Number</b>	<b>Description</b>
10.12(5)+	Addendum to Master Supply Agreement between Insulet Corporation and Flextronic Marketing (L) Ltd., dated October 4, 2007
10.13(6)+	Amendment No. 1 to Development and License Agreement, dated as of March 3, 2008, by and between Abbott Diabetes Care, Inc. (ADC), formerly known as TheraSense, Inc., and Insulet Corporation.
10.14(7)	Executive Severance Plan
10.15(9)	Amended and Restated 2007 Stock Option and Incentive Plan
10.16(13)	Offer Letter by and between Insulet Corporation and Brian Roberts, dated March 2, 2009
10.17(11)	Registration Rights Agreement, dated March 13, 2009, by and among Insulet Corporation and the investors named therein
10.18(11)	Security Agreement, dated March 13, 2009, by and among Insulet Corporation and the secured parties named therein
10.19(14)	Securities Purchase Agreement, dated September 25, 2009, by and between Insulet Corporation and certain investors named therein
10.20(15)	Offer Letter by and between Insulet Corporation and Peter Devlin, dated July 16, 2009
10.21(16)	Insulet Corporation Amended and Restated 2007 Employee Stock Purchase Plan
10.22(17)	Second Amendment to Facility Agreement, dated June 17, 2010, by and between Insulet Corporation and the lenders named therein.
10.23(18)+	Distribution Agreement dated January 4, 2010 by and between Insulet Corporation and Ypsomed Distribution AG
10.24(19)+	Amendment No. 2 to Development and License Agreement, dated as of June 30, 2010, by and between ADC formerly known as TheraSense, Inc., and Insulet Corporation
10.25(23)	Offer Letter by and between Insulet Corporation and Paul Lucidi, dated May 11, 2010
10.26(24)	Offer Letter by and between Insulet Corporation and Charles Lamos
10.26(25)	Amendment No. 1 to Distribution Agreement dated April 10, 2012 by and between Insulet Corporation and Ypsomed Distribution AG
10.26(25)	Amendment No. 3 to Development and License Agreement, dated as of April 5, 2011 by and between ADC and Insulet Coproration
10.26(25)	Amendment No. 4 to Development and License Agreement, dated as of March 29, 2012 by and between ADC and Insulet Coproration
10.26(26)	Amendment No. 5 to Development and License Agreement, dated as of June 21, 2012 by and between ADC and Insulet Coproration
12.1(27)	Insulet Corporation Statement Regarding Computation of Ratios of Earnings to Fixed Charges
21.1	Subsidiaries of the Registrant
23.1	Consent of Independent Registered Public Accounting Firm (Ernst & Young LLP)
24.1	Power of Attorney (included on signature page)
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Executive Officer.
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Financial Officer.

**Table of Contents**

<b>Number</b>	<b>Description</b>
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Chief Executive Officer and Chief Financial Officer.
101**	The following materials from Insulet Corporation's Annual Report on Form 10-K for the year ended December 31, 2012 formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets; (ii) the Consolidated Statements of Operations; (iii) the Consolidated Statements of Changes in Stockholders' Equity; (iv) the Consolidated Statements of Cash Flows

\* This certification shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that Section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

\*\* As provided in Rule 406T of Regulation S-T, this information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933, as amended, and Section 18 of the Securities Exchange Act of 1934, as amended.

+ Confidential treatment granted as to certain portions of this exhibit.

- (1) Incorporated by reference to Amendment No. 2 to our Registration Statement on Form S-1 (File No. 333-140694) filed April 25, 2007
- (2) Incorporated by reference to Amendment No. 3 to our Registration Statement on Form S-1 (File No. 333-140694) filed May 8, 2007
- (3) Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-140694) filed February 14, 2007
- (4) Incorporated by reference to our Registration Statement on Form S-8 (No. 333-144636) filed July 17, 2007
- (5) Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-146810) filed October 19, 2007
- (6) Incorporated by reference to our Current Report on Form 8-K, filed March 5, 2008
- (7) Incorporated by reference to our Current Report on Form 8-K, filed May 14, 2008
- (8) Incorporated by reference to our Current Report on Form 8-K, filed June 20, 2008
- (9) Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 13, 2008
- (10) Incorporated by reference to our Form 8-A, filed November 20, 2008

## Edgar Filing: INSULET CORP - Form 10-K

- (11) Incorporated by reference to our Current Report on Form 8-K, filed March 16, 2009
- (12) Incorporated by reference to our Current Report on Form 8-A/A, filed September 28, 2009
- (13) Incorporated by reference to our Current Report on Form 8-K, filed March 5, 2009
- (14) Incorporated by reference to our Current Report on Form 8-K, filed September 28, 2009
- (15) Incorporated by reference to our Annual Report on Form 10-K, filed March 9, 2009
- (16) Incorporated by reference to our Quarterly Report on Form 10-Q, filed May 7, 2010
- (17) Incorporated by reference to our Current Report on Form 8-K, filed June 21, 2010
- (18) Incorporated by reference to our Quarterly Report on Form 10-Q/A, filed November 19, 2010
- (19) Incorporated by reference to our Quarterly Report on Form 10-Q/A, filed November 19, 2010
- (20) Incorporated by reference to our Current Report on Form 8-K, filed June 7, 2011
- (21) Incorporated by reference to our Current Report on Form 8-K, filed July 5, 2011
- (22) Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 8, 2009
- (23) Incorporated by reference to our Annual Report on Form 10-K, filed March 10, 2011
- (24) Incorporated by reference to our Current Report on Form 8-K, filed January 10, 2011
- (25) Incorporated by reference to our Quarterly Report on Form 10-Q, filed May 9, 2012
- (26) Incorporated by reference to our Quarterly Report Form 10-Q, filed August 8, 2012
- (27) Incorporated by reference to our Registration Statement on Form S-3, filed June 22, 2011

**Table of Contents**

**Index to Consolidated Financial Statements**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011</u>	F-3
<u>Consolidated Statements of Operations for the Years Ended December 31, 2012, 2011 and 2010</u>	F-4
<u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2012, 2011 and 2010</u>	F-5
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2012, 2011 and 2010</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7
Supporting Financial Statement Schedule:	
<u>Schedule II - Valuation and Qualifying Accounts</u>	F-36

F-1

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of

Insulet Corporation

We have audited the accompanying consolidated balance sheets of Insulet Corporation as of December 31, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Insulet Corporation at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 18 to the consolidated financial statements, the accompanying consolidated balance sheet as of December 31, 2011, and the related consolidated statements of operations, stockholder's equity, and cash flows for the year ended December 31, 2011 have been restated to correct errors in the accounting for income taxes.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Insulet Corporation's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2013, expressed an adverse opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 28, 2013



**Table of Contents**

**INSULET CORPORATION**  
**CONSOLIDATED BALANCE SHEETS**

	As of December 31, 2012 (In thousands, except share and per share data)	As of December 31, 2011 (Restated)
<b>ASSETS</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 57,293	\$ 93,955
Accounts receivable, net	33,294	23,190
Inventories	14,867	11,838
Prepaid expenses and other current assets	4,482	3,652
Total current assets	109,936	132,635
Property and equipment, net	25,422	19,422
Intangible assets, net	22,963	29,002
Goodwill	37,536	37,536
Other assets	2,202	2,727
Total assets	\$ 198,059	\$ 221,322
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 9,361	\$ 11,418
Accrued expenses	19,026	13,064
Deferred revenue	5,445	2,582
Current portion of long-term debt	14,429	
Other current liabilities	25	931
Total current liabilities	48,286	27,995
Long-term debt	103,730	108,540
Other long-term liabilities	1,867	2,052
Total liabilities	153,883	138,587
Commitment and contingencies (Note 13)		
<b>Stockholders Equity</b>		
Preferred stock, \$.001 par value:		
Authorized: 5,000,000 shares at December 31, 2012 and 2011.		
Issued and outstanding: zero shares at December 31, 2012 and 2011.		
Common stock, \$.001 par value:		
Authorized: 100,000,000 shares at December 31, 2012 and 2011.		
Issued and outstanding: 48,359,063 and 47,504,131 shares at December 31, 2012 and 2011.	48	48
Additional paid-in capital	525,679	512,371
Accumulated deficit	(481,551)	(429,684)
Total stockholders equity	44,176	82,735
Total liabilities and stockholders equity	\$ 198,059	\$ 221,322

Edgar Filing: INSULET CORP - Form 10-K

See accompanying notes

F-3

**Table of Contents**

**INSULET CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2012	2011 (Restated)	2010
	(In thousands, except share and per share data)		
Revenue	\$ 211,369	\$ 152,255	\$ 96,966
Cost of revenue	119,033	85,543	53,240
Gross profit	92,336	66,712	43,726
Operating expenses:			
Research and development	24,359	21,863	16,566
General and administrative	51,240	44,083	26,667
Sales and marketing	52,708	43,233	34,695
Restructuring and impairment of assets			4,431
Total operating expenses	128,307	109,179	82,359
Operating loss	(35,971)	(42,467)	(38,633)
Interest income	110	139	168
Interest expense	(15,794)	(14,715)	(22,694)
Other expense, net	(15,684)	(14,576)	(22,526)
Loss before income taxes	(51,655)	(57,043)	(61,159)
Income tax benefit (expense)	(212)	11,212	
Net loss	\$ (51,867)	\$ (45,831)	\$ (61,159)
Net loss per share basic and diluted	\$ (1.08)	\$ (0.98)	\$ (1.54)
Weighted-average number of shares used in calculating net loss per share	47,924,324	46,689,880	39,607,899

See accompanying notes

**Table of Contents****INSULET CORPORATION****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**

(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount			
Balance at December 31, 2009	37,755,254	\$ 39	\$ 384,565	\$ (322,694)	\$ 61,910
Exercise of options to purchase common stock	470,561		3,040		3,040
Issuance for employee stock purchase plan	15,024		229		229
Stock-based compensation expense			5,025		5,025
Issuance of common stock, net of offering costs of \$2.3	3,450,000	3	45,446		45,449
Exercise of warrants to purchase common stock	3,750,000	3	11,734		11,737
Net loss				(61,159)	(61,159)
Balance at December 31, 2010	45,440,839	\$ 45	\$ 450,039	\$ (383,853)	\$ 66,231
Exercise of options to purchase common stock	743,341	1	5,241		5,242
Issuance for employee stock purchase plan	12,429		253		253
Stock-based compensation expense			7,683		7,683
Restricted stock units vested, net of shares withheld for taxes	109,891		(946)		(946)
Issuance of common stock for acquisition, net of transaction	1,197,631	2	24,186		24,188
Allocation of fair value of convertible debt to equity			25,915		25,915
Net loss (Restated)				(45,831)	(45,831)
Balance at December 31, 2011 (Restated)	47,504,131	\$ 48	\$ 512,371	\$ (429,684)	\$ 82,735
Exercise of options to purchase common stock	676,819		4,592		4,592
Issuance for employee stock purchase plan	18,346		392		392
Stock-based compensation expense			9,862		9,862
Restricted stock units vested, net of shares withheld for taxes	159,767		(1,538)		(1,538)
Net loss				(51,867)	(51,867)
Balance at December 31, 2012	48,359,063	\$ 48	\$ 525,679	\$ (481,551)	\$ 44,176

See accompanying notes

**Table of Contents****INSULET CORPORATION****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December 31,		
	2012	2011 (Restated)	2010
	(In thousands)		
<b>Cash flows from operating activities</b>			
Net loss	\$ (51,867)	\$ (45,831)	\$ (61,159)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	11,030	8,503	5,077
Non-cash interest expense	10,212	9,736	15,044
Stock-based compensation expense	9,920	7,734	5,064
Provision for bad debts	3,409	3,165	3,317
Restructuring and impairment of assets			4,432
Deferred tax provision		(11,289)	
Changes in operating assets and liabilities:			
Accounts receivable	(13,513)	(3,617)	(5,196)
Inventories	(3,029)	1,879	(1,343)
Deferred revenue	2,863	(1,665)	277
Prepaid expenses and other assets	(898)	853	381
Accounts payable, accrued expenses, and other liabilities	2,999	4,697	(1,139)
Other long-term liabilities	(185)	383	(380)
Net cash used in operating activities	(29,059)	(25,452)	(35,625)
<b>Cash flows from investing activities</b>			
Purchases of property and equipment	(10,991)	(11,114)	(6,549)
Acquisition of Neighborhood Diabetes		(37,855)	
Net cash used in investing activities	(10,991)	(48,969)	(6,549)
<b>Cash flows from financing activities</b>			
Proceeds from issuance of long-term debt		138,783	
Payment of transaction fees related to the credit facility amendment			(468)
Payments to retire long-term debt		(88,195)	(32,500)
Proceeds from exercise of warrants			11,737
Proceeds from issuance of common stock	4,927	5,460	48,683
Payment of withholding taxes in connection with vesting of restricted stock units	(1,539)	(946)	
Net cash provided by financing activities	3,388	55,102	27,452
Net decrease in cash and cash equivalents	(36,662)	(19,319)	(14,722)
Cash and cash equivalents, beginning of year	93,955	113,274	127,996
Cash and cash equivalents, end of year	\$ 57,293	\$ 93,955	\$ 113,274
<b>Supplemental disclosure of cash flow information</b>			
Cash paid for interest	\$ 6,197	\$ 5,173	\$ 8,087
Cash paid for taxes	\$ 11	\$ 263	\$ 11
<b>Non-cash financing activities</b>			
Issuance of common stock for the acquisition of Neighborhood Diabetes	\$	\$ 24,432	\$

See accompanying notes



---

**Table of Contents**

**INSULET CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Years ended December 31, 2012, 2011 and 2010**

**1. Nature of the Business**

The Company is primarily engaged in the development, manufacturing and sale of its proprietary OmniPod Insulin Management System (the OmniPod System), an innovative, discreet and easy-to-use insulin infusion system for people with insulin-dependent diabetes. The OmniPod System is the only commercially-available insulin infusion system of its kind. The OmniPod System features a unique disposable tubeless OmniPod which is worn on the body for approximately three days at a time and the handheld, wireless Personal Diabetes Manager (PDM). 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. The Company believes that the OmniPod System's unique proprietary design offers significant lifestyle benefits to people with insulin-dependent diabetes.

To support the sales of the OmniPod System, in June 2011, the Company acquired Neighborhood Holdings, Inc. and its wholly-owned subsidiaries (collectively, Neighborhood Diabetes) in order to expand the Company's full suite diabetes management product offerings and obtain access to a larger number of insulin dependent patients. Through Neighborhood Diabetes, the Company is able to provide customers with blood glucose testing supplies, traditional insulin pumps, pump supplies and pharmaceuticals and has the ability to process claims as either durable medical equipment or through pharmacy benefits.

The U.S. Food and Drug Administration (FDA) approved the original OmniPod System in January 2005, and the Company began commercial sale in the United States in October 2005. The Company received CE Mark approval for the original OmniPod System in April 2009.

The Company has also expanded the availability of the OmniPod System internationally through its partnership with Ypsomed Distribution AG (Ypsomed) and GlaxoSmithKline (GSK). In January 2010, the Company entered into a distribution agreement with Ypsomed pursuant to which Ypsomed became the exclusive distributor of the OmniPod System in multiple countries. In February 2011, the Company entered into a distribution agreement with GSK pursuant to which GSK became the exclusive distributor of the OmniPod System in Canada. The Company has focused its efforts through 2011 and 2012 on the development and regulatory approval of its next generation OmniPod System. In August 2011, the Company received CE Mark approval, and in December 2012, the Company received 510(k) clearance for the next generation OmniPod System by the FDA.

**2. Summary of Significant Accounting Policies**

***Restatement of Previously Issued Financial Statements***

As discussed below and further described in Note 18, the Company restated its financial results for the three and six months ended June 30, 2011, the three and nine months ended September 30, 2011, the year ended December 31, 2011, the three months ended March 31, 2012, the three and six months ended June 30, 2012, and the three and nine months ended September 30, 2012 to correct errors in the accounting for income taxes.

In June 2011, the Company 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, the Company recognized net deferred tax liabilities of \$11.3 million. The Company also reduced its preexisting valuation allowance and goodwill, accordingly, through purchase accounting. Upon subsequent review, the Company determined that the \$11.3 million reduction of its preexisting valuation allowance should have been reported as

---

**Table of Contents**

**INSULET CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

an income tax benefit and not as an adjustment to goodwill. The Company has corrected its statement of operations with respect to the income tax benefit generated as a result of the change in the valuation allowance.

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

The restatement resulted in an increase in current deferred tax assets (which are presented as a component of prepaid expenses and other current assets) of \$1.2 million at June 30, 2011 and September 30, 2011 and \$0.9 million at December 31, 2011, an increase in goodwill of \$11.3 million at June 30, 2011 and September 30, 2011 and \$10.9 million at December 31, 2011, and an increase in non-current deferred tax liabilities (which are presented as a component of other long-term liabilities) of \$1.2 million at June 30, 2011 and September 30, 2011 and \$0.4 million at December 31, 2011. The restatement also resulted in an increase in tax benefit of \$11.3 million in the three and six months ended June 30, 2011, the nine months ended September 30, 2011, and the year ended December 31, 2011. The restatement had no effect on amounts reported in periods prior to the quarter ended June 30, 2011.

The restatement resulted in an increase in current deferred tax assets (which are presented as a component of prepaid and expenses and other current assets) of \$0.9 million at March 31, 2012, June 30, 2012 and September 30, 2012, an increase in goodwill of \$10.9 million at March 31, 2012, June 30, 2012 and September 30, 2012, and an increase in non-current deferred tax liabilities (which are presented as a component of other long-term liabilities) of \$0.4 million at March 31, 2012, June 30, 2012, and September 30, 2012.

***Use of Estimates in Preparation of Financial Statements***

The preparation of financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expense during the reporting periods. The most significant estimates used in these financial statements include the valuation of stock-based compensation expense, accounts receivable, inventories, deferred revenue, and equity instruments, the lives of property and equipment and intangible assets, as well as warranty and doubtful accounts allowance reserve calculations. Actual results may differ from those estimates.

***Principles of Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All material intercompany balances and transactions have been eliminated in consolidation.

***Reclassifications***

Certain previously reported amounts have been reclassified to conform to the current year presentation.

***Certain Risks and Uncertainties***

The Company is subject to risks common to companies in the medical device industry, including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, reliance on third party manufacturers, protection of proprietary technology, and compliance with regulatory requirements.



---

**Table of Contents**

**INSULET CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Fair Value Measurements***

The Company adopted the Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( ASC ) 820, *Fair Value Measurements and Disclosures* ( ASC 820 ) related to the fair value measurement of certain of its assets and liabilities. ASC 820 defines fair value as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. FASB ASC 820 also describes three levels of inputs that may be used to measure the fair value:

Level 1 quoted prices in active markets for identical assets or liabilities

Level 2 observable inputs other than quoted prices in active markets for identical assets or liabilities

Level 3 unobservable inputs in which there is little or no market data available, which require the reporting entity to develop its own assumptions

The only assets and liabilities subject to fair value measurement standards at December 31, 2012 and 2011 are cash equivalents, including money market accounts, and long-term debt which are based on Level 1 inputs.

Certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and other liabilities are carried at cost, which approximates their fair value because of the short-term maturity of these financial instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, the carrying value of the Company's long-term debt and capital lease obligations approximates their fair values.

***Cash and Cash Equivalents***

For the purposes of the financial statement classification, the Company considers all highly liquid investment instruments with original maturities of 90 days or less, when purchased, to be cash equivalents. Cash equivalents consist of money market accounts and are carried at cost which approximates their fair value. Outstanding letters of credit, principally relating to security deposits for lease obligations, totaled \$0.1 million at December 31, 2012 and 2011.

***Accounts Receivable and Allowance for Doubtful Accounts***

Accounts receivable consist of amounts due from third-party payors, patients, third-party distributors, and government agencies. The allowance for doubtful accounts is recorded at the time potential collection risk is identified. The Company estimates its allowance based on historical experience, assessment of specific risk, discussions with individual customers and various assumptions and estimates that are believed to be reasonable under the circumstances.

***Inventories***

Inventories are held at the lower of cost or market, determined under the first-in, first-out method. Inventory has been recorded at cost at December 31, 2012 and 2011. Work in process is calculated based upon a build up in the stage of completion using estimated labor inputs for each stage in production. The Company periodically reviews inventories for potential impairment based on quantities on hand and expectations of future use.

***Property and Equipment***

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized over their useful life or the life of the



---

**Table of Contents**

**INSULET CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

lease, whichever is shorter. Assets capitalized under capital leases are amortized in accordance with the respective class of owned assets and the amortization is included with depreciation expense. Maintenance and repair costs are expensed as incurred.

***Intangibles and Other Long-Lived Assets***

The Company's finite-lived intangible assets are stated at cost less accumulated amortization. The Company assesses its intangible and other long-lived assets for impairment whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. The Company recognizes an impairment loss for intangibles and other finite-lived assets if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows. Any such impairment loss is measured as the difference between the carrying amount and the fair value of the asset. The estimation of useful lives and expected cash flows requires the Company to make significant judgments regarding future periods that are subject to some factors outside its control. Changes in these estimates can result in significant revisions to the carrying value of these assets and may result in material charges to the results of operations. The estimated life of the acquired tradename asset is 15 years. The estimated useful life of the acquired customer relationship asset is 10 years. Intangible assets with determinable estimated lives are amortized over these lives. At December 31, 2012 intangible assets related to the acquisition of Neighborhood Diabetes consisted of \$20.5 million of customer relationships and \$2.5 million of tradenames.

***Goodwill***

Goodwill represents the excess of the cost of an acquired business over the fair value of identifiable net assets acquired. The Company performs an assessment of its goodwill for impairment on at least an annual basis or whenever events or changes in circumstances indicate there might be impairment.

Goodwill is evaluated at the reporting unit level. To test for impairment, the Company compares the carrying value of the reporting unit to its fair value using a discounted cash flow analysis. If the reporting unit's carrying value exceeds its fair value, the Company would record an impairment loss to the extent that the carrying value of goodwill exceeds its implied fair value. The Company completed its goodwill analysis as of October 1, 2012 and noted no impairment.

***Warranty***

The Company provides a four-year warranty on its PDMs and may replace any OmniPods that do not function in accordance with product specifications. The Company estimates its warranty at the time the product is shipped based on historical experience and the estimated cost to service the claims. Cost to service the claims reflects the current product cost which has been decreasing over time. As these estimates are based on historical experience, and the Company continues to introduce new products and new versions of existing products, the Company also considers the anticipated performance of the product over its warranty period in estimating warranty reserves.

***Restructuring Expenses and Impairment of Assets***

In connection with its efforts to pursue improved gross margins, leverage operational efficiencies and better pursue opportunities for low-cost supplier sourcing, the Company periodically performs an evaluation of its manufacturing processes and reviews the carrying value of its property and equipment to assess the recoverability of these assets whenever events indicate that impairment may have occurred. As part of this assessment, the Company reviews the future undiscounted operating cash flows expected to be generated by

---

**Table of Contents**

**INSULET CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

those assets. If impairment is indicated through this review, the carrying amount of the asset would be reduced to its estimated fair value. This review of manufacturing processes and equipment can result in restructuring activity or an impairment of assets based on current net book value and potential future use of the assets.

The Company's restructuring expenses may also include workforce reduction and related costs for one-time termination benefits provided to employees who are involuntarily terminated under the terms of a one-time benefit arrangement. The Company records these one-time termination benefits upon incurring the liability, provided that the employees are notified, the plan is approved by the appropriate level of management, the employees to be terminated and the expected completion date are identified, and the benefits the identified employees will be paid are established. Significant changes to the plan are not expected when the Company records the costs. In recording the workforce reduction and related costs, the Company estimates related costs such as taxes and outplacement services which may be provided under the plan. If changes in these estimated services occur, the Company may be required to record or reverse restructuring expenses associated with these workforce reduction and related costs.

***Revenue Recognition***

The Company generates nearly all of its revenue from sales of its OmniPod System and other diabetes related products including blood glucose testing supplies, traditional insulin pumps, pump supplies and pharmaceuticals to customers and third-party distributors who resell the products to patients with diabetes.

Revenue recognition requires that persuasive evidence of a sales arrangement exists, delivery of goods occurs through transfer of title and risk and rewards of ownership, the selling price is fixed or determinable and collectibility is reasonably assured. With respect to these criteria:

The evidence of an arrangement generally consists of a physician order form, a patient information form and, if applicable, third-party insurance approval for sales directly to patients or a purchase order for sales to a third-party distributor.

Transfer of title and risk and rewards of ownership are passed to the patient or third-party distributor upon shipment of the products.

The selling prices for all sales are fixed and agreed with the patient or third-party distributor and, if applicable, the patient's third-party insurance provider(s) prior to shipment and are based on established list prices or, in the case of certain third-party insurers, contractually agreed upon prices. Provisions for discounts and rebates to customers are established as a reduction to revenue in the same period the related sales are recorded.

The Company offers a 45-day right of return for its OmniPod System sales to new patients, and defers revenue to reflect estimated sales returns in the same period that the related product sales are recorded. Returns are estimated through a comparison of the Company's historical return data to its related sales. Historical rates of return are adjusted for known or expected changes in the marketplace when appropriate. When doubt exists about reasonable assuredness of collectibility from specific customers, the Company defers revenue from sales of products to those customers until payment is received.

In June 2011, the Company entered into a development agreement with a U.S. based pharmaceutical company (the Development Agreement). Under the Development Agreement, the Company is required to perform design, development, regulatory, and other services to support the pharmaceutical company as it works to obtain regulatory approval to use the Company's drug delivery technology as a delivery method for its pharmaceutical. Over the term of the Development Agreement, the Company has and will continue to invoice amounts based upon meeting certain defined deliverable milestones. Revenue on the development agreement is recognized using a proportional performance methodology based on efforts incurred and total payments under the agreement.



**Table of Contents**

**INSULET CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company deferred revenue of \$5.4 million and \$2.7 million as of December 31, 2012 and 2011, respectively. The deferred revenue recorded was primarily comprised of product-related revenue and unrecognized amounts related to the development agreement.

***Shipping and Handling Costs***

The Company does not typically charge its customers for shipping and handling costs associated with shipping its product to its customers. These shipping and handling costs are included in general and administrative expenses.

***Concentration of Credit Risk***

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents. The Company maintains the majority of its cash with two accredited financial institutions.

The Company purchases complete OmniPods from Flextronics International Ltd., its single source supplier. As of December 31, 2012 and 2011, liabilities from one vendor represented approximately 19% and 12% of the combined balance of accounts payable and accrued expenses, respectively.

***Research and Development Expenses***

The Company's research and development expenses consist of engineering, product development, quality assurance, clinical and regulatory expenses. These expenses are primarily related to employee compensation, including salary, benefits and stock-based compensation. The Company also incurs expenses related to consulting fees, materials and supplies, and clinical studies, including data management and associated travel expenses. Research and development costs are expensed as incurred.

***General and Administrative Expenses***

General and administrative expenses are primarily comprised of salaries and benefits associated with finance, legal and other administrative personnel, overhead and occupancy costs, outside legal costs, and other general and administrative costs.

***Sales and Marketing Expenses***

Sales and marketing expenses are primarily comprised of salaries and benefits associated with sales and marketing personnel, outside marketing expenses including commercial product samples, tradeshows and advertising expenses.

***Segment Reporting***

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision-maker, or decision making group, in deciding how to allocate resources to an individual segment and in assessing performance of the segment. The Company's current product offering consists of diabetes supplies, including the OmniPod System as well as other diabetes related products and supplies such as blood glucose testing supplies, traditional insulin pumps, pump supplies, and pharmaceuticals. The Company's current product offering is marketed to a single customer type, people with diabetes. As the Company sells a single product type, management operates the business as a single entity.

---

**Table of Contents**

**INSULET CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Income Taxes***

Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect in the years in which the differences are expected to reverse. A valuation allowance is required to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company reviews its deferred tax assets for recoverability considering historical profitability, projected future taxable income, and the expected timing of the reversals of existing temporary differences and tax planning strategies.

The Company follows the provisions of FASB ASC 740-10, *Income Taxes* ( ASC 740-10 ) on accounting for uncertainty in income taxes recognized in its financial statements. ASC 740-10 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In addition, ASC 740-10 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company had unrecognized tax benefits of \$0.1 million and \$0.2 million as of December 31, 2012, and 2011, respectively.

The Company files federal, state and foreign tax returns. These returns are generally open to examination by the relevant tax authorities from three to four years from the date they are filed. The tax filings relating to the Company's federal and state tax returns are currently open to examination for tax years 2009 through 2011 and 2008 through 2011, respectively. In addition, the Company has generated tax losses since its inception in 2000. These years may be subject to examination if the losses are carried forward and utilized in future years.

The Company recognizes estimated interest and penalties for uncertain tax positions in income tax expense. As of December 31, 2012 and 2011, interest and tax penalties were immaterial to the financial statements.

For the year ended December 31, 2012, income tax expense was comprised of \$121,000 for the current portion and \$91,000 for the deferred portion. For the year ended December 31, 2011, income taxes were comprised of an expense of \$77,000 for the current portion and a benefit of \$11.3 million for the deferred portion. The current portion in the years ended December 31, 2012 and 2011 primarily relates to state, local, and foreign taxes. The deferred portion in the year ended December 31, 2012 primarily relates to the U.S. Federal and State tax amounts. The deferred portion in the year ended December 31, 2011 primarily relates to deferred tax liabilities acquired with the Neighborhood Diabetes acquisition. These deferred tax liabilities were used to offset the Company's preexisting deferred tax assets reducing the amount of the valuation allowance required in that period. The Company recorded no income tax benefit or expense in the year ended December 31, 2010.

***Stock-Based Compensation***

The Company accounts for stock-based compensation under the provisions of FASB ASC 718-10, *Compensation - Stock Compensation* ( ASC 718-10 ). ASC 718-10 requires all share-based payments to employees, including grants of employee stock options and restricted stock units, to be recognized in the income statement based on their fair values.

The Company uses the Black-Scholes option pricing model to determine the weighted-average fair value of options granted. The Company determines the intrinsic value of restricted stock and restricted stock units based on the closing price of its common stock on the date of grant. The Company recognizes the compensation expense of share-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the stock price and a number of assumptions, including expected volatility, expected life, risk-free

---

**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

interest rate and expected dividends. The expected life of the awards is estimated based on the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of the awards. The dividend yield assumption is based on Company history and the expectation of paying no dividends. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest. The Company evaluates the assumptions used to value the awards on a quarterly basis and if factors change and different assumptions are utilized, stock-based compensation expense may differ significantly from what has been recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, the Company may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense.

In the years ended December 31, 2012, 2011, and 2010, the Company recorded \$9.9 million, \$7.7 million, and \$5.0 million of stock-based compensation expense, respectively.

See Footnote 14 for a summary of the stock option activity under the Company's stock-based employee compensation plan.

***Recent Accounting Pronouncements***

In May 2011, the FASB issued ASU No. 2011-04 *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (ASU No. 2011-04). ASU No. 2011-04 clarifies existing concepts regarding existing fair value principles. The amendments are effective in fiscal years beginning after December 15, 2011. The Company adopted the guidance in the first quarter of 2012. The adoption of these amendments did not have a material impact on the Company's financial statements.

In September 2011, the FASB issued ASU No. 2011-08 *Testing Goodwill for Impairment* (ASU No. 2011-08). ASU No. 2011-08 provides guidance on simplifying the impairment testing for goodwill. A company may first assess the qualitative factors to determine whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test on the reporting unit. The guidance is effective in fiscal years beginning after December 15, 2011, and the Company adopted the guidance in the first quarter of 2012. The adoption of this guidance did not have a material impact on the Company's financial statements.

In December 2011, the FASB issued ASU No. 2011-11, *Disclosures about Offsetting Assets and Liabilities*. ASU 2011-11 will require disclosure of information about offsetting and related arrangements to enable users of the Company's financial statements to understand the effect of those arrangements on its financial position. The guidance is effective in fiscal years beginning after January 1, 2013. The Company believes the adoption of ASU No. 2011-11 will have no material impact on its financial statements.

In July 2012, the FASB issued ASU No. 2012-02 *Intangibles - Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment* (ASU No. 2012-02). ASU No. 2012-02 gives a company the option to first assess qualitative factors to determine whether it is more-likely-than-not that the indefinite-lived intangible is impaired. Qualitative factors include related events and circumstances that could affect the significant inputs used in determining the fair value of the indefinite-lived intangible asset. The guidance is effective in fiscal years beginning after September 15, 2012. The Company believes the adoption of ASU No. 2012-02 will have no material impact on its financial statements.



**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. Acquisition of Neighborhood Diabetes**

In June 2011, the Company acquired all of the outstanding shares of privately-held Neighborhood Diabetes, a durable medical equipment distributor specializing in direct to consumer sales of diabetes supplies, including pharmaceuticals, and support services. Neighborhood Diabetes serves more than 60,000 customers with Type 1 and Type 2 diabetes primarily in the northeast and southeast regions of the United States with blood glucose testing supplies, traditional insulin pumps, pump supplies, pharmaceuticals, as well as other products for the management and treatment of diabetes. Neighborhood Diabetes is based in Massachusetts, with additional offices in New York and Florida. At the time of the acquisition, Neighborhood Diabetes employed approximately 200 people across its three locations. The acquisition of Neighborhood Diabetes provides the Company with full suite diabetes management product offerings, accelerates the Company's sales force expansion, strengthens the Company's back office support capabilities, expands the Company's access to insulin dependent patients, and provides pharmacy adjudication capabilities to drive incremental sales higher. The aggregate purchase price of approximately \$62.4 million consisted of approximately \$37.9 million in cash paid at closing, 1,197,631 shares of the Company's common stock valued at approximately \$24.4 million, or \$20.40 per share based on the closing price of the Company's common stock on the acquisition date, and contingent consideration with a fair value of approximately \$0.1 million. Of the \$37.9 million of cash, \$6.6 million is being held in an escrow account to reimburse the Company and its affiliates for certain claims for which the Company is entitled to be indemnified pursuant to the terms of the agreement and plan of merger with Neighborhood Diabetes.

The Company has accounted for the acquisition of Neighborhood Diabetes as a business combination. Under business combination accounting, the assets and liabilities of Neighborhood Diabetes were recorded as of the acquisition date, at their respective fair values, and consolidated with the Company's results. The excess of the purchase price over the fair value of net assets acquired was recorded as goodwill. The operating results of Neighborhood Diabetes have been included in the consolidated financial statements since June 2011, the period in which the acquisition was completed. The purchase price allocation, including an independent appraisal for intangible assets, has been prepared based on the information that was available to management at the time the consolidated financial statements were prepared. The allocation of the purchase price was finalized during the year ended December 31, 2011.

The purchase price (restated) has been allocated as follows (in thousands):

Cash	\$ 37,855
Common stock	24,432
Contingent consideration obligations	61
 Total allocable purchase price	 \$ 62,348
 Allocation of purchase price:	
Accounts receivable	5,897
Inventories	2,336
Prepaid expenses and other current assets	242
Property and equipment	391
Customer relationships	30,100
Tradenames	2,800
Goodwill	37,536
Other assets	253
Accounts payable	4,109
Accrued expenses	1,700
Deferred tax liabilities	11,339
Other long-term liabilities	59
	 \$ 62,348



**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company incurred transaction costs of approximately \$3.2 million, which consisted primarily of banking, legal, accounting and other administrative fees. These costs have been recorded as general and administrative expense in the year ended December 31, 2011.

**4. Debt**

At December 31, 2012 and 2011, the Company had outstanding convertible debt and related deferred financing costs on its balance sheet as follows (in thousands):

	As of December 31,	
	2012	2011
Principal amount of the 5.375% Convertible Senior Notes	\$ 15,000	\$ 15,000
Principal amount of the 3.75% Convertible Senior Notes	143,750	143,750
Unamortized discount	(40,591)	(50,210)
<b>Total debt</b>	<b>118,159</b>	<b>108,540</b>
Current portion of long-term debt	14,429	
Long-term debt	\$ 103,730	\$ 108,540
Deferred financing costs	\$ 2,004	\$ 2,597

Interest expense related to the 5.375% Senior Notes (as defined below), the 3.75% Senior Notes (as defined below) and the Facility Agreement (as defined below) was included in interest expense on the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2012	2011	2010
Contractual coupon interest	\$ 6,197	\$ 5,383	\$ 7,203
Accretion of debt discount	9,619	7,213	13,247
Other interest payments		1,991	650
Amortization of debt issuance costs	593	532	1,780
<b>Total interest expense</b>	<b>\$ 16,409</b>	<b>\$ 15,119</b>	<b>\$ 22,880</b>

The Company expects to pay cash interest of \$5.8 million in 2013, \$5.4 million in each of 2014 and 2015, and \$2.5 million in 2016. Additionally, \$15 million related to the 5.375% Notes is due to the holders in 2013 and \$143.8 million related to the 3.75% Notes is due to the holders in 2016.

**5.375% Convertible Senior Notes**

In June 2008, the Company sold \$85.0 million principal amount of 5.375% Convertible Senior Notes due June 15, 2013 (the "5.375% Notes") in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 5.375% per annum on the principal amount from June 16, 2008, payable semi-annually in arrears in cash on December 15 and June 15 of each year. The 5.375% Notes are convertible into the Company's common stock at an initial conversion rate of 46.8467 shares of common stock per \$1,000 principal amount of the 5.375% Notes, which is equivalent to a conversion price of approximately \$21.35 per share, representing a conversion premium of 34% to the last reported sale price of the Company's common stock on the NASDAQ Global Market on

Edgar Filing: INSULET CORP - Form 10-K

June 10, 2008, subject to adjustment under certain circumstances, at any time beginning on March 15, 2013 or under certain other

F-16

**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

circumstances and prior to the close of business on the business day immediately preceding the final maturity date of the notes. The 5.375% Notes will be convertible for cash up to its principal amount and shares of the Company's common stock for the remainder of the conversion value in excess of the principal amount.

If a fundamental change, as defined in the Indenture for the 5.375% Notes, occurs at any time prior to maturity, holders of the 5.375% Notes may require the Company to repurchase their notes in whole or in part for cash equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, including any additional interest to, but excluding, the date of repurchase. If a holder elects to convert its 5.375% Notes upon the occurrence of a make-whole fundamental change, as defined in the Indenture for the 5.375% Notes, the holder may be entitled to receive an additional number of shares of common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option and are set forth in the Indenture to the 5.375% Notes. In no event will the number of shares issuable upon conversion of a note exceed 62.7746 per \$1,000 principal amount (subject to adjustment as described in the Indenture for the 5.375% Notes).

The Company recorded a debt discount of \$26.9 million to equity to reflect the value of its nonconvertible debt borrowing rate of 14.5% per annum. This debt discount is being amortized as interest expense over the five-year term of the 5.375% Notes. The Company incurred deferred financing costs related to this offering of approximately \$3.5 million, of which \$1.1 million has been reclassified as an offset to the value of the amount allocated to equity. The remainder is recorded as other assets in the consolidated balance sheet and is being amortized as non-cash interest expense over the five-year term of the 5.375% Notes.

In June 2011, in connection with the issuance of \$143.8 million in principal amount of 3.75% Convertible Notes due June 15, 2016 (the 3.75% Notes), the Company repurchased \$70 million in principal amount of the 5.375% Notes for \$85.1 million, a 21.5% premium on the principal amount. The investors that held the \$70 million in principal amount of repurchased 5.375% Notes purchased \$59.5 million in principal amount of the 3.75% Notes and retained approximately \$13.5 million in principal amount of the remaining 5.375% Notes. The investors' combined \$73.0 million in principal amount of convertible debt (\$13.5 million of 5.375% Notes and \$59.5 million of 3.75% Notes) was considered to be a modification of a portion of the 5.375% Notes. See the section entitled "3.75% Convertible Senior Notes" below for additional detail on the modification accounting.

Cash interest expense related to the 5.375% Notes was \$0.8 million, \$2.7 million, and \$4.6 million for the years ended December 31, 2012, 2011, and 2010, respectively.

As of December 31, 2012, the Company included approximately \$14.4 million on its balance sheet in the current portion of long-term debt related to the 5.375% Notes. As of December 31, 2012 the 5.375% Notes have a remaining term of 6 months.

**3.75% Convertible Senior Notes**

In June 2011, the Company sold \$143.8 million principal amount of 3.75% Notes. The interest rate on the notes is 3.75% per annum, payable semi-annually in arrears in cash on December 15 and June 15 of each year. The 3.75% Notes are convertible into the Company's common stock at an initial conversion rate of 38.1749 shares of common stock per \$1,000 principal amount of the 3.75% Notes, which is equivalent to a conversion price of approximately \$26.20 per share, subject to adjustment under certain circumstances. The 3.75% Notes are convertible prior to March 15, 2016 only upon the occurrence of certain circumstances. On and after March 15, 2016 and prior to the close of business on the second scheduled trading day immediately preceding the final maturity date of the 3.75% Notes, the notes may be converted without regard to the occurrence of any such

**Table of Contents**

**INSULET CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

circumstances. The 3.75% Notes and any unpaid interest will be convertible at the Company's option for cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock for the principal amount. The Company intends to settle the principal in cash.

The Company may not redeem the 3.75% Notes prior to June 20, 2014. From June 20, 2014 to June 20, 2015 the Company may redeem the 3.75% Notes, at its option, in whole or in part only if the last reported sale price per share of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days during a period of 30 consecutive trading days. On and after June 25, 2015, the Company may redeem the 3.75% Notes, at its option (without regard to such sale price condition), in whole or in part. If a fundamental change, as defined in the Indenture for the 3.75% Notes, occurs at any time prior to maturity, holders of the 3.75% Notes may require the Company to repurchase their notes in whole or in part for cash equal to 100% of the principal amount of the 3.75% Notes to be repurchased, plus accrued and unpaid interest. If a holder elects to convert its 3.75% Notes upon the occurrence of a make-whole fundamental change, as defined in the Indenture for the 3.75% Notes, the holder may be entitled to receive an additional number of shares of the Company's common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option and are set forth in the Indenture to the 3.75% Notes. In no event will the number of shares issuable upon conversion of a note exceed 50.5816 per \$1,000 principal amount (subject to adjustment as described in the Indenture for the 3.75% Notes). The 3.75% Notes are unsecured and are equal in right of payment to the 5.375% Notes.

The Company identified certain features related to a portion of the 3.75% Notes, including the holders' ability to require the Company to repurchase their notes and the higher interest payments required in an event of default, which are considered embedded derivatives and should be bifurcated and accounted for at fair value. The Company assesses the value of each of these embedded derivatives at each balance sheet date. At December 31, 2012, the Company separately accounted for and determined that these derivatives had de minimus value.

In connection with the issuance of the 3.75% Notes, the Company repurchased \$70 million in principal amount of the 5.375% Notes for \$85.1 million, a 21.5% premium on the principal amount. The investors that held the \$70 million in principal amount of repurchased 5.375% Notes purchased \$59.5 million in principal amount of the 3.75% Notes and retained approximately \$13.5 million in principal amount of the remaining 5.375% Notes. This transaction was treated as a modification of a portion of the 5.375% Notes. The Company accounted for this modification of existing debt separately from the issuance of the remainder of the 3.75% Notes.

Prior to the transaction, the \$70 million in principal amount of repurchased 5.375% Notes had a debt discount of \$10.5 million. This amount remained in debt discount related to the \$73 million in principal amount of modified debt. The Company recorded additional debt discount of \$15.1 million related to the premium payment in connection with the repurchase and \$0.2 million related to the increase in the value of the conversion feature. The portion of the debt discount related to the value of the conversion feature was recorded as additional paid-in capital. The total debt discount of \$25.8 million related to the modified debt is being amortized as non-cash interest expense at the effective rate of 16.5% over the five year term of the modified debt. The Company paid transaction fees of approximately \$2.0 million related to the modification, which were recorded as interest expense at the time of the modification.

Of the \$143.8 million in principal amount of 3.75% Notes issued in June 2011, \$84.3 million in principal amount was considered to be an issuance of new debt. The Company recorded a debt discount of \$26.6 million related to the \$84.3 million in principal amount of 3.75% Notes. The debt discount was recorded as additional paid-in capital to reflect the value of its nonconvertible debt borrowing rate of 12.4% per annum. This debt discount is being amortized as non-cash interest expense over the five year term of the 3.75% Notes. The

---

**Table of Contents**

**INSULET CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Company incurred deferred financing costs related to this offering of approximately \$2.8 million, of which \$0.9 million has been reclassified as an offset to the value of the amount allocated to equity. The remainder is recorded as other assets in the consolidated balance sheet and is being amortized as non-cash interest expense over the five year term of the 3.75% Notes.

Cash interest expense related to the \$143.8 million in principal amount of 3.75% Notes was \$5.4 million and \$2.7 million in the years ended December 31, 2012 and 2011, respectively. No cash interest was recorded on the 3.75% Notes in the year ended December 31, 2010.

As of December 31, 2012, the Company included \$103.7 million on its balance sheet in long-term debt related to the 3.75% Notes. As of December 31, 2012, the 3.75% Notes have a remaining term of three and a half years.

***Facility Agreement and Common Stock Warrants***

In March 2009, the Company entered into a facility agreement with certain institutional accredited investors (the Facility Agreement), pursuant to which the investors agreed to loan the Company up to \$60 million, subject to the terms and conditions set forth in the Facility Agreement. Total financing costs, including the transaction fee, were \$3.0 million and were amortized as interest expense over the 42 months of the Facility Agreement. In September 2009, the Company entered into an amendment to the Facility Agreement whereby the Company repaid the \$27.5 million originally drawn and promptly drew down the remaining \$32.5 million available under the Facility Agreement. The annual interest rate was 8.5%, payable quarterly in arrears. In connection with the amendment to the Facility Agreement, the Company entered into a securities purchase agreement with the institutional accredited investors whereby the Company sold 2,855,659 shares of its common stock to the such investors at \$9.63 per share, a \$1.9 million discount based on the closing price of the Company's common stock of \$10.28 on that date. The Company recorded the \$1.9 million as a debt discount, which was amortized as interest expense over the remaining term of the loan. The Company received aggregate proceeds of \$27.5 million in connection with the sale of its shares.

In connection with the execution of the Facility Agreement, the Company issued to the investors fully exercisable warrants to purchase an aggregate of 3.75 million shares of common stock of the Company at an exercise price of \$3.13 per share. The warrants qualified for permanent treatment as equity, and their relative fair value of \$6.1 million on the issuance date was recorded as additional paid-in capital and debt discount. The debt discount was amortized as non-cash interest expense over the term of the loan. As of December 31, 2012, all warrants to acquire 3.75 million shares of the Company's common stock issued in connection with the Facility Agreement were exercised.

In December 2010, the Company paid \$33.3 million to the lenders, of which \$32.5 million related to principal and \$0.8 million related to interest and prepayment fees, to extinguish this debt. The Company recorded a non-cash interest charge of \$7.0 million in 2010 related to the write-off of the remaining debt discounts and financing costs included in other assets which were being amortized to interest expense over the term of the debt. At December 31, 2012 and December 31, 2011, there were no amounts related to the Facility Agreement included on the Company's balance sheet.

**5. Net Loss Per Share**

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period, excluding unvested restricted common shares. Diluted net loss per share is computed using the weighted average number of common shares outstanding and, when dilutive, potential common share equivalents (using options, restricted stock units, and warrants (using the treasury-stock method), and potential common shares from convertible securities (using the if-converted method)). Because the Company reported a net

**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

loss for the years ended December 31, 2012, 2011 and 2010, all potential common shares have been excluded from the computation of the diluted net loss per share for all periods presented because the effect would have been antidilutive. Potential dilutive common share equivalents consist of the following:

	Year Ended December 31,		
	2012	2011	2010
5.375% Convertible Senior Notes	702,701	702,701	3,981,969
3.75% Convertible Senior Notes	5,487,642	5,487,642	
Unvested restricted common shares			444
Unvested restricted stock units	825,068	603,882	355,999
Outstanding options	2,502,190	2,814,591	3,018,469
Outstanding warrants	62,752	62,752	62,752
<b>Total dilutive common shares</b>	<b>9,580,353</b>	<b>9,671,568</b>	<b>7,419,633</b>

**6. Accounts Receivable**

Accounts receivable consist of amounts due from third-party payors, patients, third-party distributors and government agencies. The Company records an allowance for doubtful accounts at the time potential collection risk is identified. The Company estimates its allowance based on historical experience, assessment of specific risk, discussions with individual customers or various assumptions and estimates that are believed to be reasonable under the circumstances. The Company believes the reserve is adequate to mitigate current collection risk.

As of December 31, 2012, accounts receivable from two customers represented approximately 18% and 11% of gross accounts receivable, respectively. No customers represented more than 10% of gross accounts receivable as of December 31, 2011.

The components of accounts receivable are as follows:

	As of December 31,	
	2012	2011
	(In thousands)	
Trade receivables	\$ 39,921	\$ 30,211
Allowance for doubtful accounts	(6,627)	(7,021)
<b>Total accounts receivable</b>	<b>\$ 33,294</b>	<b>\$ 23,190</b>

Bad debt expense for the years ended December 31, 2012, 2011 and 2010 amounted to \$3.4 million, \$3.2 million, and \$3.3 million, respectively.

**7. Inventories**

Inventories consist of the following:



Edgar Filing: INSULET CORP - Form 10-K

	As of December 31,	
	2012	2011
	(In thousands)	
Raw materials	\$ 1,487	\$ 3,528
Work-in-process	1,595	359
Finished goods	11,785	7,951
Total inventories	\$ 14,867	\$ 11,838

F-20

**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. Property and Equipment**

Property and equipment consist of the following:

	Estimated Useful Life (Years)	As of December 31,	
		2012	2011
		(In thousands)	
Machinery and equipment	2-5	\$ 28,879	\$ 15,908
Lab equipment	2	1,481	1,481
Computers	3	3,558	3,373
Software	3	4,670	4,486
Office furniture and fixtures	3-5	2,045	1,853
Leasehold improvement	*	2,899	2,648
Construction in process		9,817	12,606
Total property and equipment		\$ 53,349	\$ 42,355
Less: Accumulated depreciation		(27,927)	(22,933)
Total property and equipment		\$ 25,422	\$ 19,422

\* Lesser of lease term or useful life of asset

Depreciation expense related to property and equipment was \$5.0 million, \$4.6 million, and \$5.1 million for the years ended December 31, 2012, 2011 and 2010, respectively. The Company recorded \$0.6 million, \$0.4 million, and \$0.2 million of capitalized interest for the years ended December 31, 2012, 2011 and 2010, respectively.

Construction in process mainly consists of machinery and equipment in the process of being constructed for use in the Company's next generation product manufacturing lines. Depreciation on the machinery and equipment does not begin until the machinery and equipment are installed and integrated into the manufacturing process.

**9. Other Intangible Assets**

Other intangible assets consist of the following (in thousands):

	As of December 31, 2012	
	2012	2011
Customer relationships	\$ 30,100	\$ 30,100
Tradename	2,800	2,800

## Edgar Filing: INSULET CORP - Form 10-K

Total intangible assets	\$ 32,900	\$ 32,900
Less: Accumulated amortization	(9,937)	(3,898)
Total other intangible assest	\$ 22,963	\$ 29,002

The Company recorded \$32.9 million of other intangible assets in the year ended December 31, 2011 as a result of the acquisition of Neighborhood Diabetes (see Footnote 3 for further description). The Company determined that the estimated useful life of the customer relationships asset is ten years and is amortizing the asset over the estimated period of use. The Company determined that the estimated useful life of the tradename is

F-21

**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

15 years and is amortizing the asset over that period on a straight-line basis. Accumulated amortization on the customer relationships asset was \$9.6 million and \$3.8 million as of December 31, 2012 and 2011, respectively. Accumulated amortization on the tradename asset was \$0.3 million and \$0.1 million as of December 31, 2012 and 2011, respectively. The amortization expense related to other intangible assets was approximately \$6.0 and \$3.9 million for the years ended December 31, 2012 and 2011, respectively. No amortization expense was recorded in any year prior to the year ended December 31, 2011.

Amortization expense expected for the next five years is as follows (in thousands):

Year Ending December 31,	Amortization Expense		
	Customer Relationships	Tradename	Total
2013	\$ 4,736	\$ 187	\$ 4,923
2014	3,790	187	3,977
2015	3,064	187	3,251
2016	2,478	187	2,665
2017	2,003	187	2,190

As of December 31, 2012, the weighted average amortization period of the Company's intangible assets is approximately ten years.

**10. Goodwill**

The Company follows the provisions of FASB ASC Topic 350-20, *Intangibles - Goodwill and Other* (ASC 350-20). ASC 350-20 requires companies to use the purchase method of accounting for all business combinations initiated after June 2001, and establishes specific criteria for the recognition of intangible assets separately from goodwill. Goodwill and indefinite-lived intangible assets are not amortized and are tested for impairment at least annually. In accordance with ASC 350-20, the Company tests goodwill for impairment on an annual basis or whenever events and circumstances indicate there might be an impairment. The Company's goodwill arose in connection with the acquisition of Neighborhood Diabetes in June 2011. No goodwill impairment loss was recorded in the year ended December 31, 2012.

**11. Accrued Expenses**

Accrued expenses consist of the following:

	As of	
	December 31, 2012	December 31, 2011
	(In thousands)	
Employee compensation and related items	\$ 6,789	\$ 6,141
Professional and consulting services	2,069	2,813
Sales and use tax	3,965	247
Supplier charges	1,752	1,009
Interest expense	258	258
Warranty reserve	863	940
Training	455	377
Other	2,875	1,279

Edgar Filing: INSULET CORP - Form 10-K

Total accrued expenses	\$ 19,026	\$ 13,064
------------------------	-----------	-----------

F-22

**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Product Warranty Costs***

The Company provides a four-year warranty on its PDMs and may replace any OmniPods that do not function in accordance with product specifications. Warranty expense is recorded in the period that shipment occurs. The expense is based on historical experience and the estimated cost to service the claims. A reconciliation of the changes in the Company's product warranty liability is as follows:

	<b>Year Ended December 31,</b>	
	<b>2012</b>	<b>2011</b>
	<b>(In thousands)</b>	
Balance at the beginning of year	\$ 1,960	\$ 1,873
Warranty expense	2,666	3,071
Warranty claims settled	(2,634)	(2,984)
Balance at the end of the year	\$ 1,992	\$ 1,960
Composition of balance:		
Short-term	\$ 863	\$ 940
Long-term	1,129	1,020
Total warranty balance	\$ 1,992	\$ 1,960

**12. Restructuring Expenses and Impairment of Assets**

During the year ended December 31, 2010, the Company determined that certain amounts related to manufacturing equipment for its next generation OmniPod would not be used in the final product, and the Company recorded an impairment charge of approximately \$1.0 million. In addition, the Company terminated certain other projects related to its existing OmniPod as the Company focused primarily on the introduction of its next generation product. As a result, the Company recorded an impairment charge of approximately \$3.4 million related to this manufacturing equipment and construction in process. The Company had no restructuring or impairment activity in the years ended December 31, 2012 and 2011.

**13. Commitments and Contingencies*****Operating Leases***

The Company leases its facilities in Massachusetts, New York, Florida, and Singapore. The Company's leases are accounted for as operating leases. The leases generally provide for a base rent plus real estate taxes and certain operating expenses related to the leases. The Company has extended the leases of its facilities in Bedford and Billerica, Massachusetts. Following the extensions, these leases expire in September 2014. The lease space in Bedford contain a five-year renewal option and escalating payments over the life of the lease. The leases in Woburn, Singapore, Florida, and New York expire in June 2013, July 2013, December 2013, and April 2015, respectively.

During the year ended December 31, 2012, the Company terminated a lease for one of its corporate offices spaces in Bedford, Massachusetts. The lease termination resulted in no material impact to the financial statements for the year ended December 31, 2012. During the same period, the Company entered into a new lease agreement for an additional 26,500 square feet in Bedford, Massachusetts. The lease expires in September 2014 and includes escalating rent payments over its term. Furthermore, during the year ended December 31, 2012, the Company renewed its

lease for its Florida property. The lease now expires in December 2013.

F-23

**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Certain of the Company's operating lease agreements contain scheduled rent increases, which are being amortized over the terms of the agreement using the straight-line method and are included in other liabilities in the accompanying balance sheet. The Company has considered FASB ASC 840-20, *Leases* in accounting for these lease provisions. The Company leases its corporate offices under long-term leases with a five-year renewal option. The Company leases its warehouse facility under a long-term lease with a five-year renewal option. The aggregate future minimum lease payments of these leases as of December 31, 2012, are as follows (in thousands):

Year Ending December 31,	Minimum Lease Payments
2013	\$ 1,511
2014	965
2015	45
Thereafter	
<b>Total</b>	<b>\$ 2,521</b>

Rent expense of approximately \$1.7 million, \$1.3 million, and \$0.9 million was charged to operations in the years ended December 31, 2012, 2011 and 2010, respectively. The deferred rent had a de minimus value for the years ended December 31, 2012 and 2011.

***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 the Company alleging that the OmniPod System infringes three of its patents. BD seeks a declaration that the Company has infringed its patents, equitable relief, including an injunction that would enjoin the Company from infringing these patents, and an unspecified award for monetary damages. The Company believes that the OmniPod System does not infringe these patents. The Company expects that this litigation will not have a material adverse impact on its financial position or results of operations. The Company believes it has 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. The Company does not believe it has any material financial exposure at December 31, 2012.

In a letter received in March 2007, Medtronic, Inc. invited the Company to discuss its taking a license to certain Medtronic patents. In October 2012, Medtronic MiniMed Inc., Medtronic Puerto Rico Operations Co. and MiniMed Distribution Corp. (collectively, Medtronic) filed a lawsuit in United States District Court for the Central District of California alleging that the Company infringes the two patents referenced in their 2007 letter which are owned by Medtronic MiniMed Inc. and licensed to Medtronic Puerto Rico Operations Co. and MiniMed Distribution Corp. Medtronic seeks a declaration that the Company has infringed its patents, equitable relief, including an injunction that would enjoin the Company from infringing these patents and as unspecified award for monetary damages. The patents referenced by this lawsuit relate to technology that is material to the Company's business. The Company believes that the OmniPod System does not infringe these patents. The Company believes it has 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. The Company does not believe it has any material financial exposure at December 31, 2012.

***Indemnifications***

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these



---

**Table of Contents**

**INSULET CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date under such indemnification obligations and the Company has a director and officer insurance policy that enables it to recover a portion of any amounts paid for future claims.

At December 31, 2012, the Company is subject to an on-going sales and use tax audit by the Massachusetts Department of Revenue related to Neighborhood Diabetes for a period prior to the acquisition. Under the Merger Agreement, the Company has been indemnified by the former stockholders of Neighborhood Diabetes for any liability resulting from or related to any tax attributable to pre-acquisition periods. The Company has recorded a contingent liability in current liabilities and a corresponding indemnification asset in current assets related to the estimated sales tax payable to the state of Massachusetts for the period under audit.

**14. Equity**

In March 2009, in connection with the Facility Agreement entered into with certain institutional accredited investors, the Company issued warrants to purchase 3,750,000 shares of its common stock at an exercise price of \$3.13 per share. The warrants were exercised in the year ended December 31, 2010 and the Company received approximately \$11.7 million in proceeds.

In December 2010, in a public offering, the Company issued and sold 3,450,000 shares of its common stock at a price of \$13.27 per share. In connection with the offering, the Company received total gross proceeds of \$47.8 million, or approximately \$45.4 million in net proceeds after deducting underwriting discounts and offering expenses.

In June 2011, in connection with the acquisition of Neighborhood Diabetes, the Company issued 1,197,631 shares of its common stock at a price of \$20.40 per share, as partial consideration for the acquisition.

In January 2013, in a public offering, the Company issued and sold 4,715,000 shares of its common stock at a price of \$20.75 per share. In connection with the offering, the Company received total gross proceeds of \$97.8 million, or approximately \$92.8 million in net proceeds after deducting underwriting discounts and offering expenses.

The Company grants share-based awards to employees in the form of options to purchase the Company's common stock, the ability to purchase stock at a discounted price under the employee stock purchase plan and restricted stock units. Stock-based compensation expense related to share-based awards recognized in the years ended December 31, 2012, 2011 and 2010 was \$9.9 million, \$7.7 million, and \$5.0 million, respectively, and was calculated based on awards ultimately expected to vest. At December 31, 2012, the Company had \$21.6 million of total unrecognized compensation expense related to unvested stock options and restricted stock units.

***Stock Options***

In May 2007, upon the closing of the Company's initial public offering, the Company's 2007 Stock Option and Incentive Plan (the 2007 Plan) became effective and the Company's Board of Directors determined not to make any further grants under the Company's 2000 Stock Option and Incentive Plan. Under the 2007 Plan,

**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

awards may be granted to persons who are, at the time of grant, employees, officers, non-employee directors or key persons (including consultants and prospective employees) of the Company. The 2007 Plan provides for the granting of stock options, restricted stock units, stock appreciation rights, deferred stock awards, restricted stock, unrestricted stock, cash-based awards, performance share awards or dividend equivalent rights. Options granted under the 2007 Plan generally vest over a period of four years and expire ten years from the date of grant. The Company had originally reserved 535,000 shares of common stock for issuance under the 2007 Plan in which the amount was increased on each January 1 through January 1, 2012 by 725,000 shares. The 2007 Plan was amended and restated in November 2008 and May 2012 to provide for the issuance of additional shares and changes to certain other provisions. In May 2012, shares available for grant under the 2007 Plan were increased by 3,775,000 shares. At December 31, 2012, 4,189,332 shares remain available for future issuance under the 2007 Plan.

Under the Company's 2000 Stock Option and Incentive Plan (the 2000 Plan), options could be granted to persons who were, at the time of grant, employees, officers, or directors of, or consultants or advisors to, the Company. The 2000 Plan provided for the granting of non-statutory stock options, incentive stock options, stock bonuses, and rights to acquire restricted stock. The option price at the date of grant was determined by the Board of Directors and, in the case of incentive stock options, could not be less than the fair market value of the common stock at the date of grant, as determined by the Board of Directors. Options granted under the 2000 Plan generally vest over a period of four years and expire 10 years from the date of grant. The provisions of the 2000 Plan limit the exercise of incentive stock options. At the time of grant, options are typically immediately exercisable, but subject to restrictions. The restrictions generally lapse over a period of four years.

Activity under the Company's Stock Option Plans:

	Number of Options(#)	Weighted Average Exercise Price(\$)	Aggregate Intrinsic Value(\$) (In thousands)
Balance, December 31, 2011	2,814,591	\$ 11.02	
Granted	485,970	19.33	
Exercised	(676,819)	6.98	\$ 9,019(1)
Canceled	(121,552)	15.44	
<b>Balance, December 31, 2012</b>	<b>2,502,190</b>	<b>\$ 13.51</b>	<b>\$ 19,463</b>
Vested, December 31, 2012	1,539,729	\$ 11.06	\$ 15,763(2)
Vested and expected to vest, December 31, 2012(3)	2,154,495		\$ 17,957(2)

- (1) The aggregate intrinsic value was calculated based on the positive difference between the estimated fair value of the Company's common stock as of the date of exercise and the exercise price of the underlying options. The aggregate intrinsic value of options exercised in the years ended December 31, 2012, 2011 and 2010, was \$9.0 million, \$8.8 million and \$3.8 million, respectively.
- (2) The aggregate intrinsic value was calculated based on the positive difference between the estimated fair value of the Company's common stock as of December 31, 2012, and the exercise price of the underlying options.
- (3) Represents the number of vested options as of December 31, 2012, plus the number of unvested options expected to vest as of December 31, 2012, based on the unvested options outstanding at December 31, 2012, adjusted for the estimated forfeiture rate of 16%.



**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

At December 31, 2012, there were 2,502,190 options outstanding with a weighted average exercise price of \$13.51 and a weighted average remaining contractual life of 6.8 years. At December 31, 2012, there were 1,539,729 options exercisable with a weighted average exercise price of \$11.06 and a weighted average remaining contractual life of 5.7 years.

The Company recognizes compensation expense for all share-based payment awards made to its employees, directors and consultants. Stock-based compensation expense recognized is based on the value of the portion of stock-based awards that is ultimately expected to vest. The Company recognizes the value of stock-based compensation in operating expense using the straight-line method.

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options. The determination of the fair value of stock-based payment awards on the date of grant using a pricing model is affected by the Company's stock price as well as assumptions regarding a number of complex and subjective variables. The estimated grant date fair values of the employee stock options were calculated using the Black-Scholes option pricing model, based on the following assumptions:

	Year Ended December 31,		
	2012	2011	2010
Risk-free interest rate	0.80% - 1.16%	1.16% - 2.61%	1.47% - 3.05%
Expected term (in years)	6.25	6.25	6.25
Dividend yield	-	-	-
Expected volatility	67% - 71%	72% - 76%	71% - 78%

*Risk-free interest rate.* The risk-free interest rate is based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

*Expected volatility.* Expected volatility measures the amount that a stock price has fluctuated or is expected to fluctuate during a period.

*Expected term.* The expected term of stock options represents the period the stock options are expected to remain outstanding and is based on the midpoint between the vesting date and the end of the contractual term.

*Dividend yield.* The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and, therefore, used an expected dividend yield of zero in the valuation model.

*Forfeitures.* Forfeitures are estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. If the Company's actual forfeiture rate is materially different from its estimate, the stock-based compensation expense could be significantly different from what the Company has recorded in the current period.

The weighted average grant date fair value of options granted for the years ended December 31, 2012, 2011 and 2010 was \$12.04, \$11.75, and \$9.92, respectively. Employee stock-based compensation expense related to stock options recognized in the years ended December 31, 2012, 2011 and 2010 was \$4.8 million, \$4.4 million, and \$4.0 million, respectively, and was calculated based on awards ultimately expected to vest.

At December 31, 2012, the Company had \$9.3 million of total unrecognized compensation expense related to stock options under FASB ASC 718-10 that will be recognized over a weighted-average period of 1.2 years.

---

**Table of Contents**

**INSULET CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***2007 Employee Stock Purchase Plan***

The 2007 Employee Stock Purchase Plan ( 2007 ESPP ) was adopted by the Board of Directors and approved by stockholders in April 2007 and became effective upon the closing of the initial public offering in May 2007. The 2007 ESPP authorizes the issuance of up to a total of 380,000 shares of common stock to participating employees.

All employees who have been employed by the Company for at least six months and whose customary employment is for more than 20 hours a week are eligible to participate in the 2007 ESPP. Any employee who owns 5% or more of the voting power or value of shares of the Company s common stock is not eligible to purchase shares under the 2007 ESPP.

The Company will make one or more offerings each year to employees to purchase stock under the 2007 ESPP. Offerings usually begin on each January 1 and July 1 and continue for six-month periods, referred to as offering periods. Each employee eligible to participate on the date of the closing of the initial public offering was automatically deemed to be a participant in the initial offering period.

Each employee who is a participant in the Company s 2007 ESPP may purchase shares by authorizing payroll deductions of up to 10% of his or her cash compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase common stock on the last business day of the offering period at a price equal to 85% of the fair market value of the common stock on the last day of the offering period. Under applicable tax rules, an employee may purchase no more than \$25,000 worth of common stock, valued at the start of the purchase period, under the 2007 ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee s rights under the 2007 ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with the Company for any reason.

The 2007 ESPP may be terminated or amended by the Board of Directors at any time. An amendment to increase the number of shares of common stock that is authorized under the 2007 ESPP and certain other amendments require the approval of stockholders.

The Company issued 18,346 shares of common stock in 2012, 12,429 shares of common stock in 2011, and 15,024 shares of common stock in 2010 to employees participating in the 2007 ESPP. The Company recorded \$59,000, \$38,000 and \$34,000 of stock-based compensation expense related to the 2007 ESPP for the years ended December 31, 2012, 2011 and 2010, respectively.

***Restricted Stock Units***

In the year ended December 31, 2012, the Company awarded 498,739 restricted stock units to certain employees. The restricted stock units were granted under the 2007 Plan and vest annually over three to four years from the grant date. The restricted stock units granted have a weighted average fair value of \$19.12 per share based on the closing price of the Company s common stock on the date of grant. The restricted stock units were valued at approximately \$9.5 million at their grant dates, and the Company recognizes the compensation expense of the restricted stock units expected to vest over the three to four year vesting period. Approximately \$5.1 million, \$3.3 million and \$1.0 million of stock-based compensation expense related to the vesting of restricted stock units was recognized in the years ended December 31, 2012, 2011 and 2010, respectively. Approximately \$12.3 million of the fair value of the restricted stock units remained unrecognized as of

**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

December 31, 2012 and will be recognized over a weighted average period of 1.3 years. Under the terms of the award, the Company will issue shares of common stock on each of the vesting dates. The following table summarizes the status of the Company's restricted stock units:

	Number of Shares (#)	Weighted Average Fair Value (\$)
Balance, December 31, 2011	603,882	\$ 17.12
Granted	498,739	19.12
Vested	(238,134)	16.72
Forfeited	(39,419)	17.86
Balance, December 31, 2012	825,068	\$ 18.40

***Stock-based Compensation Associated with Awards for Non-Employees******Restricted Common Stock***

During the year ended December 31, 2008, the Company awarded 4,000 shares of restricted common stock to a non-employee. The shares of restricted common stock were granted under the 2007 Plan and vested over two years. The shares of restricted common stock granted had a weighted average fair value of \$8.04 based on the closing price of the Company's common stock on the date of grant. Of the shares awarded, 444 shares of restricted stock vested in the year ended December 31, 2011 and 1,776 shares of restricted stock vested in the year ended December 31, 2010. The shares were valued at approximately \$32,000 at their grant date, and the Company recognized the compensation expense over the two-year vesting period.

***Shareholder Rights Plan***

In November 2008, the Board of Directors of the Company adopted a shareholder rights plan (the Shareholder Rights Plan), as set forth in the Shareholder Rights Agreement between the Company and the rights agent, the purpose of which is, among other things, to enhance the ability of the Board of Directors to protect shareholder interests and to ensure that shareholders receive fair treatment in the event any coercive takeover attempt of the Company is made in the future. The Shareholder Rights Plan could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, the Company or a large block of the Company's common stock.

In connection with the adoption of the Shareholder Rights Plan, the Board of Directors of the Company declared a dividend distribution of one preferred stock purchase right (a Right) for each outstanding share of common stock to stockholders of record as of the close of business on November 15, 2008. In addition, one Right will automatically attach to each share of common stock issued between November 15, 2008 and the distribution date. The Rights currently are not exercisable and are attached to and trade with the outstanding shares of common stock. Under the Shareholder Rights Plan, the Rights become exercisable if a person or group becomes an acquiring person by acquiring 15% or more of the outstanding shares of common stock or if a person or group commences a tender offer that would result in that person or group owning 15% or more of the common stock. If a person or group becomes an acquiring person, each holder of a Right (other than the acquiring person) would be entitled to purchase, at the then-current exercise price, such number of shares of the Company's preferred stock which are equivalent to shares of common stock having a value of twice the exercise price of the Right. If the Company is acquired in a merger or other business combination transaction after any such event, each holder of a Right would then be entitled to purchase, at the then-current exercise price, shares of the acquiring company's common stock having a value of twice the exercise price of the Right.

**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****15. Defined Contribution Plan**

The Insulet 401(k) Retirement Plan (the "401(k) Plan") is a defined contribution plan in the form of a qualified 401(k) plan, in which substantially all employees are eligible to participate upon the first day of the month following 30 days of service. Eligible employees may elect to contribute, subject to certain IRS limits, up to 20% of their compensation. The Company has the option of making both matching contributions and discretionary profit-sharing contributions to the 401(k) Plan. During 2010, the Company offered a discretionary match of 25% for the first 4% of an employee's salary that was contributed to the 401(k) Plan. During 2011 and 2012, the Company offered a discretionary match of 50% for the first 6% of an employee's salary that was contributed to the 401(k) Plan. The Company match vests over a four-year period (25% per year). In connection with the acquisition of Neighborhood Diabetes, the Company adopted the legacy Neighborhood Diabetes 401(k) plan. During the year ended December 31, 2012, all employees participating in the legacy Neighborhood Diabetes 401(k) plan were moved to the Company's plan. The total amount contributed by the Company under the 401(k) Plan and the adopted Neighborhood 401(k) Plan was \$1.0 million, \$0.7 million, and \$0.1 million for the years ended December 31, 2012, 2011 and 2010, respectively.

**16. Income Taxes**

The Company accounts for income taxes under ASC 740-10. Deferred income tax assets and liabilities are determined based upon differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

Income tax benefit (expense) consists of the following (in thousands):

	Year Ended December 31,		
	2012	2011 (Restated)	2010
Current	\$ (121)	\$ (77)	\$
Deferred	(91)	11,289	
<b>Total income tax benefit (expense)</b>	<b>\$ (212)</b>	<b>\$ 11,212</b>	<b>\$</b>

For the years ended December 31, 2012 and 2011 the current portion of income tax expense primarily related to state, local, and foreign taxes. For the year ended December 31, 2012, the deferred portion of tax expense primarily related to the U.S. Federal and State amounts. For the year ended December 31, 2011, income tax benefit resulted from a change in the valuation allowance for preexisting deferred tax assets as a result of the Neighborhood Diabetes acquisition and current tax expense primarily related to state and local taxes. For the year ended December 31, 2010 there was no income tax benefit or expense.

A reconciliation of income tax benefit (expense) at the statutory federal income tax rate as reflected in the financial statements is as follows:

	Year Ended December 31,		
	2012	2011 (Restated)	2010
Tax at U.S. statutory rate	34.00%	34.00%	34.00%
State taxes, net of federal benefit	(1.18)	(1.88)	3.48
Tax credits	0.50	2.07	0.80
State apportionment			(7.98)
Change in valuation allowance	(32.34)	(11.65)	(27.14)

Edgar Filing: INSULET CORP - Form 10-K

Other	(1.38)	(2.88)	(3.16)
Effective income tax rate	(0.40)%	19.66%	%

F-30



**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amounts used for income tax purposes as well as federal and state net operating losses and tax credit carryforwards. Significant components of the Company's deferred tax assets (liabilities) consists of the following:

	Year Ended December 31,	
	2012	2011 (Restated)
	(In thousands)	
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 151,818	\$ 141,000
Start up expenditures	2,020	2,142
Tax credits	7,608	7,352
Bad debt	2,602	2,589
Depreciation & amortization	2,357	1,988
Other	4,661	4,040
<b>Total deferred tax assets</b>	<b>\$ 171,066</b>	<b>\$ 159,111</b>
<b>Deferred tax liabilities:</b>		
Prepays	(169)	(657)
Amortization of acquired intangibles	(9,015)	(10,696)
Amortization of debt discount	(15,955)	(18,535)
Goodwill	(139)	(48)
<b>Total deferred tax liabilities</b>	<b>\$ (25,278)</b>	<b>\$ (29,936)</b>
<b>Valuation allowance</b>	<b>\$ (145,927)</b>	<b>\$ (129,223)</b>
<b>Net deferred tax liabilities</b>	<b>\$ (139)</b>	<b>\$ (48)</b>

A valuation allowance is required to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of the available evidence, both positive and negative, the Company has determined that a \$145.9 million valuation allowance at December 31, 2012 is necessary to reduce the deferred tax assets to the amount that will more likely than not be realized. The Company provided a valuation allowance for the full amount of its net deferred tax asset for the years ended December 31, 2012 and 2011 because realization of any future tax benefit was not sufficiently assured. In the year ended December 31, 2012, the Company's valuation allowance increased by \$16.7 million to \$145.9 million from the balance at December 31, 2011 of \$129.2 million. The change in the valuation allowance is primarily attributable to the deferred tax liabilities related to the Neighborhood Diabetes acquisition and the additional deferred tax liabilities related to the modification of the debt, offset by an increase in net operating loss carryforwards.

In the future, the Company will generate additional deferred tax assets and liabilities related to its amortization of acquired intangible assets for tax purposes because these long-lived intangible assets are not amortized for financial reporting purposes. The tax amortization in future years will give rise to a temporary difference, and a tax liability, which will only reverse at the time of ultimate sale or further impairment of the underlying intangible assets. Due to the uncertain timing of this reversal, the temporary difference cannot be considered as a source of future taxable income for purposes of determining a valuation allowance; therefore, the tax liability cannot be used to offset the deferred tax asset related to the net operating loss carryforward for tax purposes that will be generated by the same amortization.

At December 31, 2012 and 2011, the Company included \$0.5 million and \$0.9 million, respectively, of current deferred tax assets in prepaid expenses and other current assets and \$0.7 million and \$0.9 million, respectively, of non-current deferred tax liabilities in other long-term

liabilities on its balance sheet.

F-31

**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

At December 31, 2012, the Company had approximately \$404.4 million, \$282.8 million and \$7.6 million of federal net operating loss carryforwards, state net operating loss carryforwards and research and development and other tax credits, respectively, that if not utilized, will begin to expire in 2020 and will continue to expire through 2032 for federal tax purposes and began to expire in 2005 and will continue to expire through 2032 for state tax purposes. At December 31, 2011, the Company had approximately \$372.3 million, \$277.5 million and \$7.4 million of federal net operating loss carryforwards, state net operating loss carryforwards and research and development and other tax credits, respectively. The utilization of such net operating loss carryforwards and the realization of tax benefits in future years depends predominantly upon having taxable income. Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership may result in a limitation on the amount of net operating loss carryforwards and tax credit carryforwards which may be used in future years. As there were significant issuances of Series C, Series D and Series E redeemable convertible preferred stock in 2003, 2005 and 2006, respectively, to mostly new investors, it is probable that there will be a yearly limitation placed on the amount of net operating loss and tax credit carryforwards available for use in future years.

The Company had \$0.1 million and \$0.2 million of unrecognized tax benefits at December 31, 2012 and 2011, respectively. Unrecognized tax benefits represent tax positions for which reserves have been established. Unrecognized state benefits and interest related to unrecognized tax benefits are reflected net of applicable tax benefits. The Company expects its uncertain tax positions will reduce by approximately \$0.1 million over the next twelve months.

The Company currently intends to reinvest the total amount of its unremitted earnings in the local international jurisdiction or to repatriate the earnings only when tax-effective. As such, the Company has not provided for U.S. Federal income taxes on the unremitted earnings of its international subsidiary.

**17. Quarterly Data (Unaudited)**

	December 31	2012 Quarters ended		March 31 (Restated)
		September 30 (Restated)	June 30 (Restated)	
		(In thousands, except per share data)		
Revenue	\$ 57,828	\$ 54,752	\$ 51,035	\$ 47,754
Gross profit	\$ 25,319	\$ 24,390	\$ 22,331	\$ 20,296
Net loss	\$ (10,194)	\$ (12,417)	\$ (14,476)	\$ (14,780)
Net loss per share	\$ (0.21)	\$ (0.26)	\$ (0.30)	\$ (0.31)

	December 31 (Restated)	2011 Quarters ended		March 31
		September 30 (Restated)	June 30 (Restated)	
		(In thousands, except per share data)		
Revenue	\$ 47,192	\$ 44,594	\$ 32,211	\$ 28,258
Gross profit	\$ 20,080	\$ 18,561	\$ 14,538	\$ 13,533
Net loss	\$ (14,337)	\$ (13,562)	\$ (8,084)	\$ (9,848)
Net loss per share	\$ (0.30)	\$ (0.29)	\$ (0.17)	\$ (0.22)

As further described in Note 18, the Company restated its financial results for the second, third, and fourth quarters of the year ended December 31, 2011 to correct errors in the accounting for income taxes. The following tables summarize the effect of the restatement by major financial statement line item in the three and six months ended June 30, 2011 and the nine months ended September 30, 2011 (in thousands). The restatement had no effect on any amounts reported in periods prior to the quarter ended June 30, 2011.



**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The restatement resulted in an increase in current deferred tax assets (which are presented as a component of prepaid expenses and other current assets) of \$1.2 million at June 30, 2011 and September 30, 2011, an increase in goodwill of \$11.3 million at June 30, 2011 and September 30, 2011 and an increase in non-current deferred tax liabilities (which are presented as a component of other long-term liabilities) of \$1.2 million at June 30, 2011 and September 30, 2011. The restatement also resulted in an increase in tax benefit of \$11.3 million in the three and six months ended June 30, 2011 and the nine months ended September 30, 2011.

**Consolidated Balance Sheet**

	June 30, 2011		September 30, 2011	
	As Previously Reported	As Restated (unaudited)	As Previously Reported	As Restated (unaudited)
Prepaid expenses and other current assets	\$ 4,770	\$ 5,991	\$ 3,653	\$ 4,874
Total current assets	147,834	149,055	137,857	139,078
Goodwill	26,727	38,066	26,164	37,503
Total assets	226,190	238,750	215,780	228,340
Other long-term liabilities	1,303	2,524	1,260	2,481
Total liabilities	132,091	133,312	132,340	133,561
Accumulated deficit	(413,122)	(401,783)	(426,684)	(415,345)
Total stockholders' equity	94,099	105,438	83,440	94,779
Total liabilities and stockholders' equity	226,190	238,750	215,780	228,340

**Consolidated Statement of Operations**

	Three Months Ended June 30, 2011		Six Months Ended June 30, 2011		Nine Months Ended September 30, 2011	
	As Previously Reported	As Restated (unaudited)	As Previously Reported	As Restated (unaudited)	As Previously Reported	As Restated (unaudited)
Income tax benefit (expense)	\$	\$ 11,339	\$	\$ 11,339	\$	\$ 11,339
Net loss	(19,423)	(8,084)	(29,269)	(17,930)	(42,831)	(31,492)
Net loss per share basic and diluted	(0.42)	(0.17)	(0.64)	(0.39)	(0.92)	(0.68)

**Consolidated Statement of Cash Flows**

	Six Months Ended June 30, 2011		Nine Months Ended September 30, 2011	
	As Previously Reported	As Restated (unaudited)	As Previously Reported	As Restated (unaudited)
Net loss	\$ (29,269)	\$ (17,930)	\$ (42,831)	\$ (31,492)
Deferred tax provision		(11,339)		(11,339)
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(434)	(1,655)	851	(370)
Other long-term liabilities	(316)	905	(359)	862

## Edgar Filing: INSULET CORP - Form 10-K

The restatement had no effect on the previously reported amounts of operating, investing, and financing cash flows in the Company's consolidated statement of cash flows for the six months ended June 30, 2011 and the nine months ended September 30, 2011.

The following tables summarize the effect of the restatement by major financial statement line item at March 31, 2012, June 30, 2012, and September 30, 2012 (in thousands). The restatement resulted in an increase

F-33

**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

in current deferred tax assets (which are presented as a component of prepaid expenses and other current assets) of \$0.9 million at March 31, 2012, June 30, 2012, and September 30, 2012, an increase in goodwill of \$10.9 million at March 31, 2012, June 30, 2012, and September 30, 2012 and an increase in non-current deferred tax liabilities (which are presented as a component of other long-term liabilities) of \$0.4 million at March 31, 2012, June 30, 2012, and September 30, 2012. The restatement had no effect on the consolidated statement of operations or cash flows during these periods.

**Consolidated Balance Sheet**

	March 31, 2012		June 30, 2012		September 30, 2012	
	As Previously Reported	As Restated (unaudited)	As Previously Reported	As Restated (unaudited)	As Previously Reported	As Restated (unaudited)
Prepaid expenses and other current assets	\$ 3,463	\$ 4,313	\$ 3,454	\$ 4,304	\$ 4,717	\$ 5,567
Total current assets	127,369	128,219	115,615	116,465	113,394	114,244
Goodwill	26,647	37,536	26,647	37,536	26,647	37,536
Total assets	203,942	215,681	191,940	203,679	191,642	203,381
Other long-term liabilities	1,640	2,040	1,668	2,068	1,670	2,070
Total liabilities	145,064	145,464	144,190	144,590	152,529	152,929
Accumulated deficit	(455,803)	(444,464)	(470,279)	(458,940)	(482,696)	(471,357)
Total stockholders' equity	58,878	70,217	47,750	59,089	39,113	50,452
Total liabilities and stockholders' equity	203,942	215,681	191,940	203,679	191,642	203,381

**18. Restatement of Previously Issued Financial Statements**

Subsequent to the issuance of the Company's Annual Report on Form 10-K for the year ended December 31, 2011, the Company and its audit committee concluded that it should restate its consolidated balance sheet at December 31, 2011, and its 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, the Company 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, the Company recognized net deferred tax liabilities of \$11.3 million. The Company also reduced its preexisting valuation allowance and goodwill, accordingly, through purchase accounting. Upon subsequent review, the Company determined that the \$11.3 million reduction of its preexisting valuation allowance should have been reported as an income tax benefit and not as an adjustment to goodwill. The Company has corrected its statement of operations with respect to the income tax benefit generated as a result of the acquired deferred tax liabilities.

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

The following tables summarize the effect of the restatement by major financial statement line item for the year ended December 31, 2011 (in thousands). The restatement resulted in an increase in current deferred tax

**Table of Contents****INSULET CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

assets (which are presented as a component of prepaid expenses and other current assets) of \$0.9 million at December 31, 2011, an increase in goodwill of \$10.9 million at December 31, 2011, and an increase to non-current deferred tax liabilities (which are presented as a component of other long-term liabilities) of \$0.4 million at December 31, 2011. The restatement resulted in an increase in tax benefit of \$11.3 million in the year ended December 31, 2011.

**Consolidated Balance Sheet**

	December 31, 2011	
	As Previously Reported	As Restated
Prepaid expenses and other current assets	\$ 2,802	\$ 3,652
Total current assets	131,785	132,635
Goodwill	26,647	37,536
Total assets	209,583	221,322
Other long-term liabilities	1,652	2,052
Total liabilities	138,187	138,587
Accumulated deficit	(441,023)	(429,684)
Total stockholders' equity	71,396	82,735
Total liabilities and stockholders' equity	209,583	221,322

**Consolidated Statement of Operations**

	Year Ended December 31, 2011	
	As Previously Reported	As Restated
Income tax benefit (expense)	\$ (127)	\$ 11,212
Net loss	(57,170)	(45,831)
Net loss per share basic and diluted	(1.22)	(0.98)

**Consolidated Statement of Cash Flows**

	Year Ended December 31, 2011	
	As Previously Reported	As Restated
Net loss	\$ (57,170)	\$ (45,831)
Deferred tax provision		(11,289)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,703	853
Other long-term liabilities	(417)	383

The restatement had no effect on the previously reported amounts of operating, investing, and financing cash flows in the Company's consolidated statement of cash flows for the year ended December 31, 2011.

Financial information included in the accompanying financial statements and the notes thereto reflect the effects of the corrections described above.





**Table of Contents****SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS**

The following table sets forth activities in our accounts receivable reserve and deferred tax valuation allowance accounts:

Classifications	Balance Beginning of Period	Additions Charged to Costs and Expenses	Deductions	Balance End of Period
	(In thousands)			
<b>Year Ended December 31, 2012</b>				
Allowance for doubtful accounts	\$ 7,021	\$ 3,409	\$ 3,803	\$ 6,627
Deferred tax valuation allowance	\$ 129,223	\$ 20,972	\$ 4,268	\$ 145,927
<b>Year Ended December 31, 2011</b>				
Allowance for doubtful accounts	\$ 5,432	\$ 3,165	\$ 1,576	\$ 7,021
Deferred tax valuation allowance	\$ 138,028	\$ 27,047	\$ 35,852	\$ 129,223
<b>Year Ended December 31, 2010</b>				
Allowance for doubtful accounts	\$ 7,190	\$ 3,317	\$ 5,075	\$ 5,432
Deferred tax valuation allowance	\$ 121,432	\$ 23,937	\$ 7,341	\$ 138,028