INSULET CORP
Form 10-K
March 10, 2011

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2010

o **TRANSITION REPORTING PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File No. 001-33462

INSULET CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**04-3523891**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
9 Oak Park Drive	**01730**
Bedford, Massachusetts	*(Zip Code)*
(Address of Principal Executive Offices)	

Registrant s telephone number, including area code:
(781) 457-5000

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

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

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

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 o No þ

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 þ No o

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 o No o

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. þ

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 o	Accelerated filer þ	Non-accelerated filer o	Smaller reporting company o

(Do not check if a smaller reporting company)

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

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, 2010 was approximately $570.6 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 March 9, 2011:

Title of Class	**Shares Outstanding**
Common Stock, $0.001 Par Value Per Share Preferred Stock Purchase Rights	45,670,320

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, 2010. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

INSULET CORPORATION

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, anticipates, could, intends, targets, projects, contemplates, predicts, potential or continue or the negative of these terms or other similar 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 a medical device company that develops, manufactures and markets an innovative, discreet and easy-to-use insulin infusion system for people with insulin-dependent diabetes. Our proprietary OmniPod Insulin Management System, or OmniPod System, which consists of our OmniPod disposable insulin infusion device and our handheld, wireless Personal Diabetes Manager, is the only commercially-available insulin infusion system of its kind. Conventional insulin pumps require people with insulin-dependent diabetes to learn to use, manage and wear a number of cumbersome components, including up to 42 inches of tubing. In contrast, the OmniPod System features only two discreet, easy-to-use devices that eliminate the need for a bulky pump, tubing and separate blood glucose meter, provide for virtually pain-free automated cannula insertion, communicate wirelessly and integrate a blood glucose meter. We believe that the OmniPod System s unique proprietary design offers significant lifestyle benefits to people with insulin-dependent diabetes.

The U.S. Food and Drug Administration, or FDA, approved the OmniPod System in January 2005, and we began commercial sale of the OmniPod System in the United States in October 2005. Since the commercial launch of the OmniPod system, we have progressively expanded our marketing efforts from an initial focus in the Eastern United States, to providing availability of the OmniPod System in the entire United States. In January 2010, we entered into a distribution agreement with Ypsomed Distribution AG, or Ypsomed, to become the exclusive distributor of the OmniPod System in eleven countries. Through our partnership with Ypsomed, the OmniPod System is now or will soon be available in seven markets including Germany, the United Kingdom, France, the Netherlands, Sweden, Norway and Switzerland. We expect that Ypsomed will begin distributing the OmniPod System, subject to approved reimbursement, in the other markets under the agreement in 2011 and 2012. In February 2011, we entered into a distribution agreement with GlaxoSmithKline Inc. to become the exclusive distributor of the OmniPod System in Canada. We focus our sales and marketing efforts towards key diabetes practitioners, academic centers and clinics specializing in the treatment of diabetic patients, as well as individual diabetes patients.

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 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, 2010.

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; long-term complications, such as blindness, kidney disease, nervous system disease, amputations, stroke and cardiovascular disease, or death. Hypoglycemia can lead to confusion, loss of consciousness or death.

Table of Contents

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

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

Type 2 diabetes, the more common form of diabetes, is characterized by the body s inability to either properly utilize insulin or produce enough insulin. Historically, Type 2 diabetes has occurred in later adulthood, but its incidence is increasing among the younger population, due primarily to increasing childhood obesity. Initially, many people with Type 2 diabetes attempt to manage their diabetes with improvements in diet, exercise and/or oral medications. As their diabetes advances, some patients progress to multiple drug therapy, which often includes insulin therapy. Recent 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, or CSII, therapy. Patients attempting to control their blood glucose levels tightly to prevent the long-term complications associated with fluctuations in blood glucose levels are at greater risk for overcorrection and the resultant hypoglycemia, which can cause confusion, loss of consciousness or death. As a result, many patients have difficulty managing their diabetes optimally. Additionally, the time spent in managing diabetes, the swings in blood glucose levels and the fear of hypoglycemia can all render diabetes management overwhelming to patients and their families.

Current Insulin Therapy

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

There are three primary types of insulin therapy practiced today: conventional therapy; multiple daily injection, or 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.

Table of Contents

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 Personal Diabetes Manager, or 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 for at least 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 attractive to those people with insulin-dependent diabetes who are frustrated or discouraged by the conventional insulin pumps. 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.

Table of Contents

Sales and Marketing

Our sales and marketing effort is focused on continuing to generate demand and acceptance of the OmniPod System among healthcare professionals, people with insulin-dependent diabetes, third-party payors and third-party distributors. Our marketing strategy is to build awareness for the benefits of the OmniPod System through a wide range of education programs, social networking, patient demonstration programs, support materials, media advertisements, clinical research and events at the national, regional and local levels. We are using third-party distributors within the United States to improve our access to managed care and government reimbursement programs, expand our commercial presence and provide access to additional potential patients. In addition, we entered into a distribution agreement with Ypsomed to become the exclusive distributor of the OmniPod System in eleven countries. As part of our agreement, Ypsomed works with the appropriate agencies to establish a distribution and reimbursement process in each of these countries. Through our partnership with Ypsomed, the OmniPod System is now or will soon be available in seven markets including Germany, The United Kingdom, France, the Netherlands, Sweden, Norway and Switzerland. We expect that Ypsomed will begin distributing the OmniPod System, subject to approved reimbursement, in the other markets under the agreement in 2011 and 2012. In February 2011, we entered into a distribution agreement with GlaxoSmithKline plc. to become the exclusive distributor of the OmniPod System in Canada.

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

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

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

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

Distributor arrangements. We have expanded our distribution networks to 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 to developing a long-term relationship with the patient. We believe that it is crucial for patients to be trained as the

experts in the management of their diabetes. At the same time, we believe that providing reliable and effective customer support reduces patients anxiety and contributes to overall product satisfaction. In order to provide a complete training and customer support solution, we utilize a combination of live training in the office of the healthcare professional, interactive media, as well as online and telephonic support that is available 24 hours a day, 7 days a week.

Training. We believe that the amount of effort required for healthcare professional offices to train patients to use CSII therapy has been a key barrier limiting penetration of this therapy. With the fewest steps

Table of Contents

required to start insulin delivery, compared to conventional insulin pumps, the OmniPod System was designed to be easy to use and to significantly reduce the burden associated with training patients to use CSII therapy.

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

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, billing, telephone and website in order to provide customers with seamless and reliable customer support.

Our customer support staff is proactively involved with both healthcare professionals and patients. When a patient initiates an order for the OmniPod System, our customer support staff assists the patient with completing order forms and collecting additional data as required by the patient s insurance provider. Once the order forms are complete, we investigate the patient s insurance coverage for the OmniPod System and contact the customer to notify them of applicable coverage available under the patient s insurance. We believe it is important from a customer satisfaction perspective, as well as a healthcare professional perspective, that we handle the insurance investigation process accurately, efficiently and promptly, and that we, therefore, are capable of scaling our capacity to meet increasing demand. We also offer healthcare professionals assistance in generating insurance appeals for customers who are denied coverage. We believe that our insurance investigation infrastructure enables us to effectively support the growing demand for the OmniPod System.

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

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

Research and Development

Our current research and development efforts are primarily focused on our next generation OmniPod which reduces both the size of the OmniPod as well as the production costs of the OmniPod System. We are also working toward the integration of our OmniPod System with continuous glucose monitoring technology.

We have agreements with both Abbott Diabetes Care, Inc. and DexCom, Inc. to develop systems that will enable the OmniPod System PDM to receive and display continuous glucose data from Abbott s continuous glucose monitor, the FreeStyle Navigator®, and DexCom s continuous glucose monitor. To date, the FDA has approved, as an adjunct to traditional self-testing, a limited number of continuous glucose monitoring systems, including those manufactured by

Abbott Diabetes Care, Inc., Medtronic, Inc. and DexCom, Inc. All of these products have limited capabilities, and none of them is labeled as a substitute for current blood glucose testing where patients need to draw blood for testing. This means that no continuous glucose monitor, whether currently on the market or pending FDA approval, can be used to determine insulin infusion amounts. It is unknown when, if ever, any continuous glucose monitoring systems will be approved as a replacement for current blood glucose monitors.

Table of Contents

We believe that the potential uses of our proprietary OmniPod System technology are not limited to the treatment of diabetes. We plan to pursue the use of the OmniPod System technology for the delivery of other medications that may be administered subcutaneously in precise and varied doses over an extended period of time. For instance, in June 2008, we announced an agreement with Ferring Pharmaceuticals, of Saint Prex, Switzerland, to develop the OmniPod System for the delivery of a Ferring drug. Under the terms of the agreement with Ferring, Ferring funded the development of a custom version of the OmniPod s Personal Diabetes Manager and, upon completion of the development, agreed to purchase minimum quantities of this custom OmniPod Systems over a five-year period. We received CE mark approval for this custom OmniPod System in September 2009 and began selling the product to Ferring under this arrangement in 2010. To date, revenue under this arrangement has been minimal. 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 highly automated process.

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

To achieve profitability, we seek to continue to increase manufacturing volumes and reduce the per unit production cost for the OmniPod by collaborating with contract manufacturers and reducing the cost of raw materials and sub-assemblies. By increasing production volumes of the OmniPod, we have also been able to improve absorption of manufacturing overhead costs. This, as well as the introduction of our next generation OmniPod are important as we strive to achieve profitability. We believe our manufacturing capacity at the end of 2010 is sufficient to meet our expected 2011 demand for OmniPods.

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

Generally, all outside vendors produce the components to our specifications and in many instances to our designs, and they are audited annually 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 from TÜV America Inc., a Notified Body to the International

Table of Contents

Standards Organization, or ISO, of our quality system standards. These approvals are ISO 13485 standards that include design control requirements. Certain processes utilized in the manufacture and test of our devices have been verified and validated as required by the FDA and other regulatory bodies. As a medical device manufacturer, our manufacturing facility and the facilities of our suppliers and sterilizer are subject to periodic inspection by the FDA, KEMA and certain corresponding state agencies.

Intellectual Property

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

Patents. As of December 31, 2010, we had obtained 20 issued United States patents, and had 6 additional pending U.S. patent applications. We believe it will take up to four years, and possibly longer, for the most recent of these U.S. patent applications to result in issued patents. Our issued U.S. patents expire between 2020 and 2022, assuming we pay all required maintenance fees. We are also seeking patent protection for our proprietary technology in Europe, China, Japan, India and other countries and regions throughout the world. The issued patents and pending patent applications cover, among other things:

the basic architecture of the OmniPod System;

the OmniPod shape memory alloy drive system;

the OmniPod System cannula insertion system; and

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

In 2002, we entered into a development and license agreement with TheraSense, Inc., regarding the incorporation of the FreeStyle blood glucose meter in the PDM. TheraSense was subsequently acquired by Abbott Laboratories and is currently a wholly-owned subsidiary of Abbott Laboratories known as Abbott Diabetes Care, Inc., or Abbott. Under this agreement, we were granted 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 Abbott FreeStyle blood glucose meter for the purpose of making, using and selling the OmniPod System incorporating an Abbott FreeStyle blood glucose meter. In March 2008, we entered into a first amendment of the agreement pursuant to which the term of the original agreement was extended until February 2013, with automatic renewals for subsequent one-year periods thereafter, and the license granted therein was extended to cover Israel as well as the United States. In connection with the execution of the amendment, we received a cash payment from Abbott as an agreement fee. Beginning July 1, 2008, Abbott agreed to pay an amount to us for services we perform in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to a new customer in the United States and Israel. In July 2010, we entered into a second amendment to the agreement whereby the license was extended to cover Canada and certain other countries and Abbott agreed to pay certain amounts over time to us for each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to a new customer in 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.

In a letter received in March 2007, Medtronic, Inc. invited us to discuss our taking a license to certain Medtronic patents. The patents referenced by this letter relate to technology that is material to our business. We have not had any substantive discussions with Medtronic concerning this matter since our receipt of this

Table of Contents

letter. While we believe that the OmniPod System does not infringe these patents, we would consider resolving the matter on reasonable terms. If we are unable to reach agreement with Medtronic, Inc. on this matter, they may sue us for infringement. We believe we would have meritorious defenses to any such suit.

In August 2010, Becton, Dickinson and Company, or 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 of effect of these two actions.

Trademarks. We have registered the trademarks OMNIPOD and the OMNIPOD design with the United States Patent and Trademark Office on the Principal Register. We have applied with the United States Patent and Trademark Office to register the trademark INSULET. The INSULET mark is subject to an ongoing opposition proceeding.

Competition

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, Inc., has been the market leader for many years and has the majority share of the conventional insulin pump market in the United States. Other significant suppliers in the United States are Animas Corporation, a division of Johnson & Johnson and Roche Diagnostics, a division of F. Hoffmann-La Roche, Ltd.

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

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- larger and more established sales forces and distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory approval for products; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

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

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

Table of Contents

Government Regulation

The OmniPod System is a medical device subject to extensive and ongoing regulation by the U.S. Food and Drug Administration, or 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, or 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 exempt.

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 to the FDA s satisfaction the safety and effectiveness of the device. 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.

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;

Table of Contents

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 action 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 our OmniPod System. The CE Mark gives us authorization to distribute the OmniPod System throughout the European Union and in other countries that recognize the CE Mark. In September 2009, we received Health Canada approval to distribute the OmniPod System throughout Canada. In January 2010, we entered into a distribution agreement with Ypsomed to become the exclusive distributor of the OmniPod System in eleven countries, including nine countries in Europe, China and Australia. Ypsomed has or will soon introduce the OmniPod System in seven countries in Europe in 2010 and is expected to introduce it in the remaining markets in 2011 and 2012. In February 2011, we entered into a distribution agreement with GlaxoSmithKline plc to become the exclusive distributor of the OmniPod System in Canada.

Licensure. Several states require that durable medical equipment, or 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. If our educators or we were to be found non-compliant in a given state, we may need to modify our approach to providing education, clinical support and customer service.

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

referral of a person;

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

Table of Contents

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 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. Penalties include fines ranging from $5,500 to $11,000 for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person. At present, we do not receive reimbursement from, or submit claims to, the federal government, although we intend in the future to pursue reimbursement coverage under one or more federal programs, such as Medicare. In any event, we believe that we are in compliance with the federal government s laws and regulations concerning the filing of reimbursement claims.

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

State Fraud and Abuse Provisions. Many states have also adopted some form of anti-kickback and anti-referral laws and false claims act. We believe that we are conforming 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.

Table of Contents

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

Third-Party Reimbursement

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

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

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

Third-party payors may decline to reimburse for procedures, supplies or services determined not to be medically necessary or reasonable. In a limited number of cases, some third-party payors have declined to reimburse 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 for lower healthcare costs, particularly near-term costs.

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

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

Employees

As of December 31, 2010, we had 310 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.

Table of Contents

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 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, 2010, our gross profit from the manufacture and sale of the OmniPod System was $43.7 million. Although we have achieved a positive gross margin, we still operate at a substantial net loss. Our net losses for the years ended December 31, 2010, 2009 and 2008 were $61.2 million, $72.3 million and $94.8 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, 2010, we had an accumulated deficit of $383.9 million.

We currently rely entirely on sales of our sole product, the OmniPod System, to generate 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 sole product is the OmniPod System, which we introduced to the market in October 2005. We expect to continue to derive substantially all of our revenue from the sale of this product. Accordingly, our ability to generate revenue is entirely 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 ceasing to use the OmniPod System;

competitive pricing and related factors; and

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

Table of Contents

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 our customer orders and manufacturing volume.

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

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 extremely 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 timing, strength or duration of this severe global economic downturn or 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 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 OmniPods and to return to MDI or other less-costly therapies, which would cause our attrition rate to increase. Any decline in new customer orders or increase in our customer attrition rate will reduce our revenue, which in turn will make it more difficult to achieve the per unit cost-savings which are expected to be attained through increases in our manufacturing volume.

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

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

In 2010, the U.S. Congress passed significant reforms to the U.S. healthcare system. Included as part of this new legislation is a 2.3% excise tax on the medical device industry beginning January 1, 2013 that is payable based on revenue, not income. This future excise tax may have a material adverse effect on our

Table of Contents

financial condition and results of operations. In addition, there are provisions that provide for the creation of a new public-private Patient-Centered Outcomes Research Institute tasked with identifying comparative effectiveness research priorities, establishing a research project agenda and contracting with entities to conduct the research in accordance with the agenda. Research findings published by this institute will be publicly disseminated. It is difficult at this time to determine what impact the comparative effectiveness analysis will have on the OmniPod System or our future financial results. 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 OmniPod System 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;
- 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;
- 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 2011.

We may in the future seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. In December 2010, we sold 3.45 million shares of our common stock at a price of $13.27 per share, resulting in net proceeds to us of approximately $45.4 million. We used a portion of the net proceeds to repay amounts outstanding under the Facility Agreement we entered into with certain institutional accredited investors in March 2009, as amended in September 2009 and June 2010 and repaid in December 2010. 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.

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 future 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

Table of Contents

able to develop new products, execute our business plan, take advantage of future opportunities or respond to competitive pressures or unanticipated customer requirements. If any of these events occur, it could adversely affect our business, financial condition and results of operations.

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

We rely on a number of suppliers who manufacture the components of the OmniPods and PDMs. For example, we rely on Phillips Plastic Corporation to manufacture and supply a number of injection molded components of the OmniPod and Freescale Semiconductor, Inc. to manufacture and supply the application specific integrated circuit that is incorporated into the OmniPod. In addition, a subsidiary of Flextronics International Ltd. in China provides the supply of complete OmniPods. We do not have long-term supply agreements with most of our suppliers, and, in many cases, we make our purchases on a purchase order basis. In some other cases, where we do have agreements in place, our agreements with our suppliers can be terminated by either party upon short notice. For example, the term of our agreement with Flextronics is now one year, subject to annual one-year renewals, and may be terminated at any time by either party upon prior written notice given no less than a specified number of days prior to the date of termination. Additionally, our suppliers may encounter problems during manufacturing due to 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 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 U.S. Food and Drug Administration, or 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.

The OmniPod is powered by button cell batteries currently manufactured by Energizer. We have recently learned that these batteries, which contain small amounts of mercury, are subject to statutes enacted in Connecticut, Maine and Rhode Island that prohibit, beginning on July 1, 2011, the sale of both the batteries and products containing the batteries. We are currently assessing both alternative batteries and opportunities to gain permanent or temporary exemptions or exceptions from regulators in these states; however, if we are unable to identify an alternative compliant battery or to gain regulatory relief, we may be unable to sell OmniPods to patients in these states, which may have a material adverse effect on our business, financial condition and results of operation.

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 third-party suppliers, or our

Table of Contents

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.

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

In January 2010, we entered into a 5 year distribution agreement with Ypsomed Distribution AG, or Ypsomed, to become the exclusive distributor of the OmniPod System in eleven countries. Through our partnership with Ypsomed, the OmniPod System is now or will soon be available in seven markets including Germany, The United Kingdom, France, the Netherlands, Sweden, Norway and Switzerland. We expect that Ypsomed will begin distributing the OmniPod System, subject to approved reimbursement, in the other markets under the agreement in 2011 and 2012. In February 2011, we entered into a distribution agreement with GlaxoSmithKline plc to become the exclusive distributor of the OmniPod System in Canada. 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. Moreover, while this agreement will help us expand our global footprint, we will now be exposed to fluctuations in product demand and sales productivity outside the United States as we 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 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 International Ltd. As a result, our business is subject to risks associated with doing business internationally, including:

- political instability and adverse economic conditions;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;
- difficulty in staffing and managing widespread operations;
- difficulties associated with foreign legal systems including increased costs associated with enforcing contractual obligations in foreign jurisdictions;
- changes in foreign currency exchange rates;
- differing protection of intellectual property;
- unexpected changes in regulatory requirements;
- failure to fulfill foreign regulatory requirements on a timely basis or at all to market the OmniPod System or other future products;
- availability of, and changes in, reimbursement within prevailing foreign health care payment systems;

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

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

Table of Contents

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.

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, Inc., has been the market leader for many years and has the majority share of the conventional insulin pump market in the United States. Other significant suppliers in the United States include Animas Corporation, a division of Johnson & Johnson, and Roche Diagnostics, a division of F. Hoffman-La Roche Ltd.

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

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;

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

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

Table of Contents

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

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

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

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

The diabetes treatment market is subject to rapid technological change and product innovation. The OmniPod System is based on our proprietary technology, but a number of companies, medical researchers and existing pharmaceutical companies are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapeutics for the monitoring, treatment and/or prevention of insulin-dependent diabetes. For example, FDA approval of a commercially viable closed-loop system that combines continuous real-time glucose sensing or monitoring and automatic continuous subcutaneous insulin infusion in a manner that delivers appropriate amounts of insulin on a timely basis without patient direction could have a material adverse effect on our revenue and future profitability. We have an agreement with Abbott Diabetes Care, Inc., a global healthcare company that develops continuous glucose monitoring technology, to develop a product that will integrate the receiver portion of Abbott s continuous glucose monitor, the FreeStyle Navigator, with the OmniPod System PDM. The FreeStyle Navigator has recently received FDA approval. We have a similar agreement with DexCom, Inc., a leading provider of continuous glucose monitoring systems for people with diabetes, to develop a product that will integrate the receiver portion of DexCom s continuous glucose monitor with the OmniPod System PDM. Both of these initiatives with Abbott and DexCom have been subject to extensive product development and regulatory delay, and no assurances can be provided that we will ever develop or commercialize an integrated product with either company s continuous glucose monitoring products. Medtronic, Inc. 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.

Table of Contents

If our existing license agreement with Abbott Diabetes Care, Inc. 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 Diabetes Care, Inc., 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. In March 2008 we entered into a first amendment of the agreement pursuant to which the term of the original agreement was extended until February 2013, with automatic renewals for subsequent one-year periods thereafter, and the license granted therein was extended to cover Israel as well as the United States. In July 2010, we entered into a second amendment to the development and license agreement with Abbott. Under the terms of the second amendment, the license was extended to cover Canada and certain other countries and Abbott agreed 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 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, which would require us to acquire rights to or develop an alternative blood glucose meter, incorporate it into the OmniPod System and obtain regulatory approval for the new OmniPod System. Any of these outcomes could have a material adverse effect on our business, financial condition and results of operations.

In addition, Abbott and a number of other major blood glucose monitor manufacturers were sued for patent infringement by Roche Diagnostics pursuant to a complaint dated November 21, 2007. The complaint alleges that the blood glucose monitors currently manufactured by Abbott and others infringe one or more recently-issued Roche patents. Abbott has indemnified us against losses arising from claims of infringement like these and, if our use of the Freestyle blood glucose meter were to be enjoined and Abbott was unable to obtain a license as required by our contract, then we would need to obtain rights to an alternative non-infringing blood glucose meter, incorporate it into the OmniPod System and obtain regulatory approval for the new OmniPod System. Any of these outcomes could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

other parties may challenge patents, patent claims or patent applications licensed or issued to us; and

Table of Contents

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, however, 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.

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

assert claims of infringement;

enforce our patents;

protect our trade secrets or know-how; or

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

Any lawsuits that we initiate could be expensive, take significant time and divert management s attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

Table of Contents

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

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

In addition, in August 2010, Becton, Dickinson and Company, or 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.

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. Each of these processes can be expensive and lengthy, and entail significant user fees, unless exempt. 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,

Table of Contents

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 premarket and postmarket 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

criminal prosecution.

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

In addition, we entered into a distribution agreement with Ypsomed to become our exclusive distributor of the OmniPod system, subject to approved reimbursement, in eleven countries. 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. 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

Table of Contents

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 only 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.

A federal law commonly known as the Medicare/Medicaid anti-kickback law, 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. 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. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or for items or services that were not provided as claimed. 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, these laws are potentially applicable to us. In addition, these laws are potentially applicable to us because we provide reimbursement to healthcare professionals for training patients on the use of the OmniPod System. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be substantial. 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.

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 the Health Insurance Portability and Accountability Act of 1996, or 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.

25

Table of Contents

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, 24/7 customer support and an automatic re-order program for patients. Since we began shipping the OmniPod System in October 2005, we have had a satisfactory customer retention rate; however, we cannot assure you that we will maintain this retention rate in the future. Current uncertainty in global economic conditions, rising unemployment and negative financial news may negatively affect product demand and other related matters. If demand for our products fluctuates as a result of economic conditions or otherwise, our ability to attract and retain customers could be harmed. The failure to retain a high percentage of our customers would negatively impact our revenue growth and may have a material adverse effect on our business, financial condition and results of operations.

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

To help improve, market and sell the OmniPod System, we have sponsored, and expect to continue to sponsor market studies to assess various aspects of its 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.

26

Table of Contents

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

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

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

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

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

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

Since the commercial launch of the OmniPod system, we have progressively expanded our marketing efforts to cover the entire United States, and in 2010 we entered into a distribution agreement with Ypsomed to distribute the OmniPod System in eleven additional countries. 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

Table of Contents

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.

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

Table of Contents

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. We may be forced to take other actions to satisfy our obligations under our indebtedness or we may experience a financial failure.

Our ability to make scheduled payments or to refinance our debt obligations depends on our financial and operating performance, which is subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We cannot assure you that we will maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness, including the 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 eleven countries, and in February 2011, we entered into an exclusive distribution agreement with

GlaxoSmithKline 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.

Table of Contents

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

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

The price of our common stock may be volatile.

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

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

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

volume and timing of orders for the OmniPod System;

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

issuance of patents to us or our competitors;

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.

Table of Contents

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. For the three month period ended December 31, 2010, the average daily trading volume of our common stock on The NASDAQ Global Market has been fewer than 300,000 shares. If our existing stockholders or their distributees sell substantial amounts of our common stock in the public market, the market price of our common stock could decrease significantly. The perception in the public market that our existing stockholders might sell shares of common stock could also depress the trading price of our common stock. In addition, certain stockholders have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

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.

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.

Table of Contents

ITEM 2. ***PROPERTIES***

We lease approximately 63,500 square feet of manufacturing, laboratory and office space in Bedford, Massachusetts under leases expiring in 2014. Additionally, we lease approximately 14,000 square feet of warehousing and manufacturing space in Billerica, Massachusetts under a lease expiring in 2012.

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 financial exposure at December 31, 2010.

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.

Table of Contents

PART II

ITEM 4. ***(REMOVED AND RESERVED)***

ITEM 5. ***MARKET FOR REGISTRANT S COMMON STOCK, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES***

Market Information

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

	High	Low
Fiscal Year 2009		
First Quarter	$ 9.58	$ 2.67
Second Quarter	$ 7.83	$ 3.55
Third Quarter	$ 11.25	$ 6.08
Fourth Quarter	$ 14.40	$ 8.98
Fiscal Year 2010		
First Quarter	$ 16.47	$ 13.06
Second Quarter	$ 15.86	$ 13.21
Third Quarter	$ 15.39	$ 13.22
Fourth Quarter	$ 16.31	$ 12.75

As of December 31, 2010, there were approximately 29 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, 2010. 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 43 Month Cumulative Total Return*
Among Insulet Corp., The NASDAQ Composite Index
And The NASDAQ Health Care Index

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

	5/07	6/07	9/07	12/07	3/08	6/08	9/08	12/08
Insulet Corp.	100.00	88.97	136.28	147.12	90.23	98.56	87.22	48.37
NASDAQ Composite	100.00	103.54	108.35	106.47	91.12	92.14	82.09	63.00
NASDAQ Health Care	100.00	97.70	104.28	102.13	95.78	95.50	98.10	83.99
	3/09	6/09	9/09	12/09	3/10	6/10	9/10	12/10
Insulet Corp.	25.69	48.25	70.36	89.47	94.55	94.30	88.60	97.12
NASDAQ Composite	61.18	73.54	85.18	91.48	96.67	85.17	96.07	107.54
NASDAQ Health Care	76.90	86.12	96.03	97.90	107.31	93.16	100.70	106.85

The material in this performance graph is not soliciting material, is not deemed filed with the SEC, and is not incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, 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, 2010.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders(1)	2,721,221	$ 9.03	1,021,097
Equity compensation plans not approved by security holders(2)	360,000	$ 6.71	
Total	3,081,221	$ 8.76	1,021,097(3)

(1) Includes our 2007 Stock Option and Incentive Plan and our 2000 Stock Option and Incentive Plan.

(2) Consists of two inducement grants of 180,000 shares each to Brian Roberts and Peter Devlin upon being hired by us in March 2009 and August 2009, respectively. These non-qualified stock option awards were granted outside of our 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 2007 Stock Option and Incentive Plan.

(3) The maximum number of shares of our common stock that are authorized for issuance under our 2007 Stock Option and Incentive Plan as of December 31, 2010 is 1,021,097 shares, which includes an increase of 725,000 on January 1, 2010. The amount will be increased on January 1, 2011 and January 1, 2012, by a number of shares equal to 3% of the number of shares of our common stock outstanding as of the immediately preceding December 31, up to the maximum increase of 725,000 additional shares per year.

For more information relating to our equity compensation plans, see Note 11 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, 2010, nor issue any securities that were not registered under Securities Act of 1933.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Table of Contents

ITEM 6. ***SELECTED FINANCIAL DATA***

	Year Ended December 31,				
	2010	**2009**	**2008**	**2007**	**2006**
	(In thousands, except share and per share data)				
Consolidated Statements of Operations Data:					
Revenue(1)	$ 96,966	$ 66,032	$ 36,059	$ 13,372	$ 3,663
Cost of revenue	53,240	47,735	40,643	25,733	15,660
Gross profit (loss)	43,726	18,297	(4,584)	(12,361)	(11,997)
Operating expenses:					
Research and development	16,566	13,231	13,104	10,391	8,094
General and administrative	26,667	26,842	23,750	13,922	8,389
Sales and marketing	34,695	37,583	39,734	16,141	6,165
Restructuring and impairment of assets(3)	4,431		8,170	1,027	
Total operating expenses	82,359	77,656	84,758	41,481	22,648
Operating loss	(38,633)	(59,359)	(89,342)	(53,842)	(34,645)
Other income (expense), net	(22,526)	(12,985)	(5,429)	377	(460)
Change in value of preferred stock warrant liability				(74)	(845)
Net loss	(61,159)	(72,344)	(94,771)	(53,539)	(35,950)
Accretion of redeemable convertible preferred stock					(222)
Net loss attributable to common shareholders	$ (61,159)	$ (72,344)	$ (94,771)	$ (53,539)	$ (36,172)
Net loss per share basic and diluted	$ (1.54)	$ (2.43)	$ (3.43)	$ (3.21)	$ (99.72)
Weighted-average number of shares used in calculating net loss per share(2)	39,607,899	29,727,106	27,611,003	16,688,418	362,750

	As of December 31,				
	2010	**2009**	**2008**	**2007**	**2006**
	(In thousands)				

Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 113,274	$ 127,996	$ 56,663	$ 94,588	$ 33,231
Working capital	$ 123,507	$ 134,491	$ 71,531	$ 87,723	$ 785
Total assets	$ 156,233	$ 172,858	$ 108,233	$ 130,741	$ 57,140
Current debt	$	$	$	$ 10,671	$ 29,222
Long-term debt(4)	$ 69,433	$ 89,136	$ 60,172	$ 16,006	$
Other long-term liabilities	$ 1,619	$ 1,999	$ 2,987	$ 1,431	$ 316
Redeemable convertible preferred stock	$	$	$	$	$ 119,509
Total stockholders equity (deficit)	$ 66,231	$ 61,910	$ 28,106	$ 92,275	$ (101,765)

(1) We commercially launched the OmniPod Insulin Management System in October 2005. See Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K.

Table of Contents

(2) In connection with our initial public offering of common stock in May 2007, we sold 8.4 million shares of common stock and converted 45.8 million shares of redeemable convertible preferred stock converted into 17.4 million shares of common stock. In October 2009, we sold 6.9 million shares of common stock to the public, and in December 2010, we sold 3.5 million shares of common stock to the public. See Note 11 to our consolidated financial statement included in this Annual Report on Form 10-K.

(3) In the year ended December 31, 2007, we recorded a $1.0 million non-cash charge for the write-down of certain manufacturing equipment which had no future use. 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 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.

(4) In June 2008, we sold $85.0 million principal amount of 5.375% Convertible Senior Notes due June 15, 2013 in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. In March 2009, we entered into a Facility Agreement of up to $60 million with certain institutional accredited investors. We repaid all amounts outstanding under the Facility Agreement in December 2010. See Notes 8 and 9 to our consolidated financial statements included 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.

Overview

We are a medical device company that develops, manufactures and markets an insulin infusion system for people with insulin-dependent diabetes. Our proprietary OmniPod Insulin Management System consists of our OmniPod disposable insulin infusion device and our handheld, wireless Personal Diabetes Manager.

The US Food and Drug Administration, or FDA, approved the OmniPod System in January 2005. In October 2005, we shipped our first commercial OmniPod System. We have progressively expanded our marketing efforts from an initial focus in the Eastern United States to having availability of the OmniPod System in the entire United States. In January 2010, we entered into a five-year exclusive distribution agreement with Ypsomed Distribution AG, or Ypsomed, which intends to distribute and sell our OmniPod System in eleven countries, subject to approved reimbursement. Through our partnership with Ypsomed, the OmniPod System is now or will soon be available in seven markets including Germany, The United Kingdom, France, the Netherlands, Sweden, Norway and Switzerland. We expect that Ypsomed will begin distribution of the OmniPod System, subject to approved reimbursement, in the other markets under the agreement in 2011 and 2012. In February 2011, we entered into a distribution agreement with GlaxoSmithKline Inc. to become the exclusive distributor of the OmniPod System in Canada. We focus our sales towards key diabetes practitioners, academic centers and clinics specializing in the treatment of diabetes patients, as well as individual diabetes patients. Our total revenue was $97.0 million, $66.0 million and $36.1 million for the years ended December 31, 2010, 2009 and 2008, respectively.

We currently produce the OmniPod on a partially automated manufacturing line at a facility in China operated by a subsidiary of Flextronics International Ltd. We purchase complete OmniPods pursuant to our agreement with Flextronics. Under the agreement, Flextronics has agreed to supply us, as a non-exclusive supplier, with OmniPods at agreed upon prices per unit pursuant to a rolling 12-month forecast that we provide. The agreement may be terminated at any time by either party upon prior written notice given no less

Table of Contents

than a specified number of days prior to the date of termination. The specified number of days is intended to provide the parties with sufficient time to make alternative arrangements in the event of termination. By purchasing OmniPods manufactured by Flextronics in China, we have been able to substantially increase production volumes for the OmniPod and reduce our per unit production cost.

To achieve profitability, we 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. This, as well as the introduction of our next generation OmniPod, are important as we strive to achieve profitability. We believe our manufacturing capacity at the end of 2010 is sufficient to meet our expected 2011 demand for OmniPods.

Our sales and marketing effort is focused on generating demand and acceptance of the OmniPod System among healthcare professionals, people with insulin-dependent diabetes, third-party payors and third-party distributors. Our marketing strategy is to build awareness for the benefits of the OmniPod System 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 are using 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.

As a medical device company, 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, 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 we expand our sales and marketing focus, increase our manufacturing capacity and expand to international markets, we will need to maintain and expand available reimbursement for the OmniPod System.

Since our inception in 2000, we have incurred losses every quarter. In the years ended December 31, 2010, 2009 and 2008, we incurred net losses of $61.2 million, $72.3 million and $94.8 million, respectively. As of December 31, 2010, we had an accumulated deficit of $383.9 million. We have financed our operations through the private placement of debt and equity securities, public offerings of our common stock, a private placement of our convertible debt and borrowings under certain debt agreements. As of December 31, 2010, we had $85.0 million of convertible debt outstanding. In December 2010, we fully repaid $32.5 million of outstanding debt relating to the facility agreement entered into in March 2009 and amended in September 2009 and June 2010. Since inception, we have received net proceeds of $538.7 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 for 2011 will be focused primarily on the development, production and regulatory approval of our next generation OmniPod System, the continued reduction in our per-unit production costs on our existing product and the expansion of sales through international markets. Achieving these objectives is expected to require additional investments in certain personnel and initiatives to allow for us to increase our market penetration in the United States and international markets. 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.

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 through at least the end of 2011.

Financial Operations Overview

Revenue. We derive nearly all of our revenue from the sale of the OmniPod System directly to patients and third-party distributors who resell the product to diabetes patients. 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 Personal Diabetes Manager, or 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. Revenue is derived from the sale to new

Table of Contents

customers or third-party distributors of OmniPods and Starter Kits, which include the PDM, the OmniPod System User Guide and our Interactive Training CD, and from the subsequent sales of OmniPods to existing customers. Customers generally order a three-month supply of OmniPods. In January 2010, we entered into a five-year exclusive distribution agreement with Ypsomed which intends to distribute and sell the OmniPod System, subject to approved reimbursement, in eleven countries. Through our partnership with Ypsomed, the OmniPod System is now or will soon be available in seven markets including Germany, The United Kingdom, France, the Netherlands, Sweden, Norway and Switzerland. We expect that Ypsomed will begin distributing the OmniPod System, subject to approved reimbursement, in the other markets under the agreement in 2011 and 2012. In addition, in February 2011, we entered into a distribution agreement with GlaxoSmithKline Inc. to become the exclusive distributor of the OmniPod System in Canada.

In March 2008, we received a cash payment from Abbott Diabetes Care, Inc. (Abbott) for an agreement fee in connection with execution of the first amendment to the development and license agreement with Abbott. We are recognizing the payment as revenue over the 5 year term of the agreement. Under the amended Abbott agreement, beginning July 1, 2008, Abbott agreed to pay us certain amounts for services performed in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to certain customers in the United States and Israel. In July 2010, we entered into a second amendment to the development and license agreement with Abbott. Under the terms of the second amendment, the license was extended to cover Canada and certain other countries and Abbott agreed to pay certain amounts over time to us for services we performed in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to customers in these. We recognize the revenue related to this portion of the Abbott agreement at the time we meet the criteria for revenue recognition, typically at the time of the sale of the PDM to a new patient. In the years ended December 31, 2010 and 2009, we recognized $5.4 million and $7.1 million of revenue, respectively, related to the amended Abbott agreement. The decrease from 2009 is attributable to amounts received from Abbott related to upgrades for existing patients.

As of December 31, 2010 and 2009, we had deferred revenue of $4.8 million and $5.1 million, respectively, which includes product-related revenue as well as the unrecognized portion of the agreement fee related to the Abbott agreement. For the year ending December 31, 2011, we expect our revenue to continue to increase as we gain new customers in the United States and continue expansion in Europe and certain other international markets. Increased revenue will be dependent upon the success of our sales efforts, our ability to produce OmniPods in sufficient volumes and other risks and uncertainties.

Cost of revenue. Cost of revenue consists primarily of raw material, labor, warranty and overhead costs related to the OmniPod System. Cost of revenue also includes depreciation, freight and packaging costs. The increase in our OmniPod production volume, including the production of our next generation OmniPod, together with our ability to gain cost savings on our bill of materials, is expected to reduce the per-unit cost of manufacturing the OmniPods by allowing us to reduce our direct costs and spread our fixed and semi-fixed overhead costs over a greater number of units.

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 fiscal year 2011, we expect overall research and development spending to decrease slightly from 2010 levels as we support our current research and development efforts, which are focused primarily on our next generation Omnipod, as well the integration of our OmniPod System with continuous glucose monitoring technology.

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 2011 compared to 2010 as we continue to drive efficiencies in our administrative functions as we expand our business.

Table of Contents

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. In the year ending December 31, 2011, we expect sales and marketing expenses to increase slightly compared to 2010 to support the growth of our business.

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. Based on estimates of 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.

Results of Operations for the Fiscal Years Ended December 31, 2010, 2009 and 2008

The following table presents certain statement of operations information for the years ended December 31, 2010, 2009 and 2008:

	Year Ended December 31,			Year Ended December 31,		
	2010	2009	% Change	2009	2008	% Change
	(Dollar amounts in thousands)					
Revenue	$ 96,966	$ 66,032	47%	$ 66,032	$ 36,059	83%
Cost of revenue	53,240	47,735	12%	47,735	40,643	17%
Gross profit (loss)	43,726	18,297	139%	18,297	(4,584)	499%
Operating expenses:						
Research and development	16,566	13,231	25%	13,231	13,104	1%
General and administrative	26,667	26,842	1%	26,842	23,750	13%
Sales and marketing	34,695	37,583	8%	37,583	39,734	5%
Restructuring and impairment of assets	4,431		100%		8,170	100%
Total operating expenses	82,359	77,656	6%	77,656	84,758	8%
Operating loss	(38,633)	(59,359)	35%	(59,359)	(89,342)	34%
Other expense, net	(22,526)	(12,985)	73%	(12,985)	(5,429)	139%

Net loss	$ (61,159)	$ (72,344)	15%	$ (72,344)	$ (94,771)	24%

Table of Contents

Comparison of the Years Ended December 31, 2010 and December 31, 2009

Revenue

Our total revenue was $97.0 million for year ended December 31, 2010, as compared to $66.0 million for the year ended December 31, 2009. The increase in revenue is due to the increase in the number of diabetes patients using the OmniPod System including patients being serviced by third-party domestic and international distributors.

Cost of Revenue

Cost of revenue was $53.2 million for the year ended December 31, 2010, as compared to $47.7 million for the year ended December 31, 2009. The increase is due to increased sales volume partially offset by lower per-unit costs. Lower per-unit cost is a result of cost savings on raw materials, volume discounts from our suppliers and increased production volumes. Revenue increased by 46.8% from the year ended December 31, 2009 to the year ended December 31, 2010, while cost of revenue increased by only 11.5% in the same period mainly due to the efficiencies realized in OmniPod per-unit cost.

Research and Development

Research and development expense increased $3.3 million, or 25.2%, to $16.6 million for the year ended December 31, 2010, as compared to $13.2 million for the year ended December 31, 2009, which was primarily related to an increase of $2.8 million of pods and other products used for research and development purposes and $1.4 million of outside services in connection with development of the next generation Omnipod, offset by a $1.2 million decrease in employee-related expenses.

General and Administrative

General and administrative expense decreased $0.2 million, or 1.0%, to $26.7 million for the year ended December 31, 2010, as compared to $26.8 million for the year ended December 31, 2009, which was primarily due to a reduction in bad debt expense of $1.7 million. This decrease was offset by an increase in outside services of $1.2 million mainly related to legal fees and temporary help, and an increase of $0.5 million of employee related expenses primarily associated with increased bonus expenses and stock-based compensation.

Sales and Marketing

Sales and marketing expense decreased $2.9 million, or 7.7%, to $34.7 million for the year ended December 31, 2010, as compared to $37.6 million for the year ended December 31, 2009, which was primarily due to a reduction of $1.7 million in sample costs related to patient demonstration kits, a reduction of $1.1 million in outside services, a reduction of $0.3 million in advertising costs and a reduction of $0.3 million in travel-related costs. These decreases were offset in part by an increase of $0.5 million in employee related expenses, primarily due to additional employees and stock-based compensation expenses.

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, we determined that certain amounts related to manufacturing equipment for our next generation Omnipod 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 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 new restructuring or impairment activity in the year ended December 31, 2009.

Table of Contents

Other Expense, Net

Interest income was $0.2 million for the years ended December 31, 2010 and 2009. Interest income was earned from cash deposits and short-term interest bearing instruments. Interest expense increased $9.5 million to $22.7 million for the year ended December 31, 2010, as compared to $13.2 million for the year ended December 31, 2009.

The increase in interest expense is primarily due to amortization of the debt discount related to our 5.375% Notes and additional interest associated with the Facility Agreement entered into in March 2009, amended in September 2009 and June 2010 and repaid in December 2010. We recorded interest expense on the 5.375% Notes of $10.0 million in the year ended December 31, 2010. Of the $10.0 million, $4.9 million related to the amortization of the debt discount, $0.5 million related to the amortization of deferred financing costs, and $4.6 million related to interest payments. We recorded approximately $12.9 million of interest expense related to the Facility Agreement in the year ended December 31, 2010. Of the $12.9 million, approximately $3.3 million related to interest payments including a prepayment penalty, $2.6 million related to non-cash charges associated with the amortization of debt discounts and deferred financing costs, and $7.0 million related to the non-cash charges associated with the write-off of the remaining debt discounts and deferred financing costs in connection with the early extinguishment of the debt in December 2010. We recorded interest expense on the 5.375% Notes of $9.4 million in the year ended December 31, 2009. Of the $9.4 million, $4.3 million related to amortization of the debt discount, $0.5 million related to the amortization of deferred financing costs, and $4.6 million related to cash interest. We also recognized interest expense of $4.0 million related to the Facility Agreement in the year ended December 31, 2009. Of the $4.0 million recorded in 2009, approximately $2.5 million related to cash interest and $1.5 million related to non-cash charges associated with the amortization of the debt discount and deferred financing costs.

Comparison of the Years Ended December 31, 2009 and December 31, 2008

Revenue

Our total revenue was $66.0 million for the year ended December 31, 2009, as compared to $36.1 million for year ended December 31, 2008. The increase in revenue is due to the increase in the number of diabetes patients using the OmniPod System as well as relationships with third-party distributors who resell our product to diabetes patients.

Cost of Revenue

Cost of revenue was $47.7 million for the year ended December 31, 2009, as compared to $40.6 million for the year ended December 31, 2008. The increase is due to increased sales volume partially offset by lower per-unit costs. Lower per-unit cost is a result of cost savings on raw materials, volume discounts from our suppliers and increased production volumes. Revenue increased by 83.1% from the year ended December 31, 2008 to the year ended December 31, 2009, while cost of revenue increased by only 17.4% in the same period mainly due to the reduction in cost per OmniPod.

Research and Development

Research and development expense increased $0.1 million, or 1.0%, to $13.2 million for the year ended December 31, 2009, as compared to $13.1 million for the year ended December 31, 2008. For the year ended December 31, 2009, the increase in expense was primarily related to increased severance expense of $0.3 million offset by a $0.2 million decrease in products used for research and development purposes.

General and Administrative

General and administrative expense increased $3.1 million, or 13.0%, to $26.8 million for the year ended December 31, 2009, as compared to $23.8 million for the year ended December 31, 2008. For the year ended December 31, 2009, the increase in expense was primarily due to an increase of $2.2 million in employee related expenses mainly related to increased bonuses of $0.8 million and stock based compensation of

Table of Contents

$0.9 million, an increase of $0.8 million related to allowances for doubtful accounts and an increase of $0.6 million in license fees. These increases were offset by a $0.3 million decrease in depreciation expense and a $0.1 million decrease in freight expense.

Sales and Marketing

Sales and marketing expense decreased $2.2 million, or 5.4%, to $37.6 million for the year ended December 31, 2009, as compared to $39.7 million for the year ended December 31, 2008. The decrease in expense for the year ended December 31, 2009, was primarily due to a $3.5 million reduction in patient demonstration kit units and a reduction of $0.6 million in advertising, promotion and tradeshow expenses used to support our selling efforts. These decreases were offset by an increase of $1.6 million in employee related expenses, primarily due to increasing commissions as a result of our increasing revenue, and a $0.8 million increase in outside services.

Restructuring and Impairment of Assets

We had no restructuring or impairment activity in the year ended December 31, 2009. For the year ended December 31, 2008, our restructuring expenses and impairment of assets was $8.2 million. In the fourth quarter of 2008, we recorded restructuring charges of $8.2 million for the impairment of certain manufacturing equipment no longer in use as well as workforce reduction and related costs. As part of our strategic goal to pursue improved gross margins, leverage operational efficiencies and better pursue opportunities for low-cost supplier sourcing, we transitioned the manufacturing of completed OmniPods to Flextronics International Ltd., located in China. We determined that we would no longer use certain manufacturing equipment located in our Bedford facility. In addition, this transition resulted in a reduction in workforce of approximately 30 employees, mainly in the manufacturing and quality departments. As a result of these actions, we recorded a non-cash charge of $7.4 million related to impairments of assets as well as $0.8 million in workforce and related charges in 2008.

Other Expense, Net

Interest income was $0.2 million for the year ended December 31, 2009, as compared to $1.8 million for the year ended December 31, 2008. This represents a decrease of $1.6 million compared to the year ended December 31, 2008, caused primarily by lower cash balances and interest rates. Interest income was earned from cash deposits and short-term interest bearing instruments. Interest expense was $13.2 million for the year ended December 31, 2009, as compared to $7.2 million for the year ended December 31, 2008. This represents an increase of $6.0 million compared to the year ended December 31, 2008.

The increase in interest expense is primarily a result of additional interest incurred on the 5.375% Notes, the retrospective adoption of FASB ASC 470-20 and interest incurred on the Facility Agreement entered into in March 2009, which was amended in September 2009 and June 2010 and repaid in December 2010. We recorded interest expense on the 5.375% Notes of $8.9 million in the year ended December 31, 2009. Of the $8.9 million, $4.3 million related to amortization of the debt discount and deferred financing costs and $4.6 million related to cash interest. We recorded interest expense on the 5.375% Notes of $4.6 million in the year ended December 31, 2008. Of the $4.6 million, $2.1 million related to amortization of the debt discount and deferred financing costs and $2.5 million related to cash interest. We also recognized interest expense of $4.0 million related to the Facility Agreement in the year ended December 31, 2009. Of the $4.0 million recorded in 2009, approximately $2.5 million related to cash interest and $1.5 million related to amortization of the debt discount and deferred financing costs.

Liquidity and Capital Resources

We commenced operations in 2000, and, to date, we have financed our operations primarily through private placements of our preferred stock, secured indebtedness, the initial public offering of our common stock in May 2007 and subsequent public offerings of our common stock in November 2007, October 2009 and December 2010. Since inception, we have received net proceeds of $538.7 million from the issuance of

Table of Contents

redeemable convertible preferred stock, common stock and debt. As of December 31, 2010, we had $113.3 million in cash and cash equivalents. Our cash equivalents are maintained in money market accounts and are therefore highly liquid. 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 through at least the end of 2011.

Equity

In October 2009, in a public offering we issued and sold 6,900,000 shares of our common stock at a price to the public of $10.25 per share. In connection with the offering, we received total gross proceeds of $70.7 million, or approximately $66.1 million in net proceeds after deducting underwriting discounts and offering expenses.

In December 2010, we issued and sold 3,450,000 shares of our common stock pursuant to an underwriting agreement with Canaccord Genuity 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 Deerfield Partners.

Facility Agreement and Common Stock Warrants

In March 2009, we entered into a Facility Agreement with certain institutional accredited investors, 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. Following the initial disbursement of $27.5 million on March 31, 2009, we could, but were not required to, draw down on the facility in $6.5 million increments at any time until November 2010 provided that we met certain financial performance milestones. In connection with this financing, we paid Deerfield Management Company, L.P., an affiliate of the lead lender, a one-time transaction fee of $1.2 million. Total financing costs, including the transaction fee, were $3.0 million and were being amortized as interest expense over the 42 month term of the Facility Agreement.

In connection with the execution of the Facility Agreement, we issued to the lenders 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. Pursuant to the original terms of the Facility Agreement, we would have been required to issue additional warrants to purchase 1.5 million shares upon drawing down the remaining $32.5 million under the facility. 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.

The amounts initially drawn under the Facility Agreement accrued interest at a rate of 9.75% per annum, and the undrawn amounts under the Facility Agreement accrued interest at a rate of 2.75% per annum. Accrued interest was payable quarterly in cash in arrears.

In September 2009, we entered into an Amendment to the Facility Agreement whereby we repaid the $27.5 million of outstanding debt and promptly drew down the remaining $32.5 million available under the Facility Agreement. The lenders eliminated all future performance milestones associated with the remaining $32.5 million available on the credit facility and reduced the annual interest rate on any borrowed funds to 8.5%. In connection with the Amendment to the Facility Agreement, we entered into a Securities Purchase Agreement with the lenders 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 additional paid-in capital and debt discount and amortized it to 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.

All principal amounts outstanding under the Facility Agreement were payable in September 2012. Any amounts drawn under the Facility Agreement would become immediately due and payable upon (i) an event of default, as defined in the Facility Agreement, in which case the lenders would have the right to require us

Table of Contents

to re-pay 100% of the principal amount of the loan, plus any accrued and unpaid interest thereon, or (ii) the consummation of certain change of control transactions, in which case the lenders would have the right to require us to re-pay 106% of the outstanding principal amount of the loan, plus any accrued and unpaid interest thereon. The amended Facility Agreement also provided for certain prepayment penalties in the event that we repaid the debt prior to its maturity.

In June 2010, we entered into a Second Amendment to the Facility Agreement whereby we paid a $0.5 million amendment fee to the lenders in exchange for the reduction of the prepayment penalties as well as the modification of certain other terms in the Facility Agreement. The fee was recorded as additional debt discount and was being amortized to interest expense over the remaining term of the loan.

All references herein to the Facility Agreement refer to the Facility Agreement entered into in March 2009 and amended in September 2009 and June 2010.

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 the fourth quarter related to the write-off of the remaining debt discount and financing costs included in other assets which were being amortized to interest expense over the term of the debt.

In the year ended December 31, 2010, we recorded approximately $3.3 million of cash interest related to the Facility Agreement, including the prepayment penalty. In addition, in the year ended December 31, 2010, non-cash interest of approximately $9.6 million was recorded. Non-cash interest in the year ended December 31, 2010 consists of amortization and extinguishment of the debt discount from the issuance of warrants and transaction fee in March 2009, amortization of the discount on the shares sold in connection with the amendment in September 2009, amortization of the transaction fee in connection with the amendment in June 2010 and amortization of the issuance costs associated with the debt.

In March 2009, in connection with the execution of the Facility Agreement, we issued to the lenders fully exercisable warrants to purchase an aggregate of 3.75 million shares of common stock at an exercise price of $3.13 per share. Pursuant to the original terms of the Facility Agreement, we would have been required to issue additional warrants to purchase 1.5 million shares upon drawing down the remaining $32.5 million under the facility. In connection with the Amendment to the Facility Agreement in September 2009, the lenders agreed to forego the remaining 1.5 million additional warrants that would have been issued upon future draws. The warrants issued in connection with the Facility Agreement qualified for permanent classification 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.

As of December 31, 2010, all warrants to acquire 3.75 million shares of our common stock issued in connection with the Facility Agreement were exercised.

Convertible Notes and Repayment and Termination of Term Loan

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, beginning December 15, 2008. 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. We do not have the right to redeem any of the 5.375% Notes prior to maturity. If a fundamental change, as defined in the Indenture for the 5.375% Notes, occurs at any time prior to maturity, holders of the

Table of Contents

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 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 for the 5.375% Notes. In no event will the 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 5 year term of the 5.375% Notes.

We incurred interest expense related to the 5.375% Notes of approximately $10.0 million for the year ended December 31, 2010. Of the $10.0 million recorded in the year ended December 31, 2010, approximately $5.4 million relates to amortization of the debt discount and deferred financing costs and $4.6 million relates to cash interest. 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 amount allocated to equity. The remainder is recorded in the consolidated balance sheet and is being amortized as a component of interest expense over the five year term of the notes.

As of December 31, 2010, the outstanding amounts related to the 5.375% Notes of $69.4 million are included in long-term debt in the consolidated balance sheet and reflect the debt discount of $15.6 million. The debt discount represents the difference between our nonconvertible debt borrowing rate and the stated rate on the 5.375% Notes and includes the equity allocation of $25.8 million (which represents $26.9 million less the $1.1 million of allocated financing costs) offset by the accretion of the debt discount through interest expense from the issuance date in 2008 over the 5 year term of the notes. We recorded $4.9 million of interest expense related to the debt discount in the year ended December 31, 2010. As of December 31, 2010, the 5.375% Notes have a remaining life of 2.5 years.

We received net proceeds of approximately $81.5 million from the 5.375% Notes offering. Approximately $23.2 million of the net proceeds from this offering was used to repay and terminate our then-existing term loan, including outstanding principal and accrued and unpaid interest of $21.8 million, a prepayment fee related to the term loan of approximately $0.4 million, a termination fee of $0.9 million and incurred certain other expenses related to the prepayment and termination of the term loan. In connection with this term loan, we issued warrants to the lenders to purchase up to 247,252 shares of Series E preferred stock at a purchase price of $3.64 per share. The warrants automatically converted into warrants to purchase common stock on a 1-for-2.6267 basis at a purchase price of $9.56 per share at the closing of our initial public offering in May 2007. Warrants to purchase 62,752 shares of our common stock remain outstanding at December 31, 2010 and expire on December 27, 2013.

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,		
	2010	2009	2008
	(In thousands)		

Cash used in operating activities	$ (35,625)	$ (49,323)	$ (82,611)
Net loss	$ (61,159)	$ (72,344)	$ (94,771)

Net cash used in operating activities in the years ended December 31, 2010, 2009 and 2008, primarily represents amounts utilized to fund operating losses. The decrease of $13.7 million in cash used in operating activities for the year ended December 31, 2010 compared to the year ended December 31, 2009 was due

Table of Contents

primarily to the increase in revenue combined with our ability to improve gross margins in 2010 and cost containment initiatives implemented as we strive to become profitable. Cash used in operations in the year ended December 31, 2010 is primarily a result of our net loss of $61.2 million offset by non-cash items such as amortization of debt discount and non-cash interest, asset impairment charges, depreciation, stock compensation and bad debt expense. Cash used in operations includes an increase in net accounts receivable of $5.2 million and inventory of $1.3 million and a decrease in accounts payable and accrued expenses of $1.1 million. Amortization increased by $7.7 million in the year ended December 31, 2010, compared to the year ended December 31, 2009, related to the write-off of amounts in connection with the early extinguishment of indebtedness under our Facility Agreement.

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,		
	2010	**2009**	**2008**
		(In thousands)	
Cash used in investing activities	$ (6,549)	$ (3,140)	$ (10,047)
Cash provided by financing activities	$ 27,452	$ 123,796	$ 54,733

Cash used in investing activities was primarily for the purchase of fixed assets for use in the development and manufacturing of the OmniPod System in the years ended December 31, 2010, 2009 and 2008. 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. Cash provided by financing activities in the year ended December 31, 2009, was primarily generated from the net proceeds from the Facility Agreement entered into in March 2009, amended in September 2009 and June 2010 and repaid in December 2010, the sale of common shares in connection with the amendment in September 2009 and the sale of 6,900,000 shares of common stock at a price to the public of $10.25 per share in October 2009. Cash provided by financing activities in the year ended December 31, 2008 was primarily a result of the private placement of our convertible debt in 2008.

We lease our facilities, which are accounted for as operating leases. The leases of our facilities in Bedford and Billerica, Massachusetts, generally provide for a base rent plus real estate taxes and certain operating expenses related to the lease. All operating leases contain renewal options and escalating payments over the life of the lease. As of December 31, 2010, we had an outstanding letter of credit which totaled $0.2 million to cover our security deposits for lease obligations.

During the year ending December 31, 2011, we will be expending funds in connection with development, production and regulatory approval of our next generation OmniPod System 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, 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 Board s ability 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

Table of Contents

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 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 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, 2010, we did not have any off-balance sheet financing arrangements.

Contractual Obligations

The following table summarizes our principal contractual obligations as of December 31, 2010. Amounts in thousands:

		Payments Due in					
Contractual Obligations	**Total**	**2011**	**2012**	**2013**	**2014**	**2015**	**Later**
Operating lease obligations	$ 2,660	$ 755	$ 755	$ 657	$ 493	$	
Long-term debt obligations(1)	96,232	4,569	4,569	87,094			
Purchase obligations for production components	10,721	10,721					
Purchase obligations for capital expenditures	3,174	3,174					
Total contractual obligations	$ 112,787	$ 19,219	$ 5,324	$ 87,751	$ 493	$	$

(1) The interest rate on the convertible debt is 5.375% 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 may 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.

We adopted the Financial Accounting Standard Board Accounting Standards Codification in the year ended December 31, 2009. The FASB Accounting Standards Codification (Codification) has become the single source of

authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in accordance with GAAP. All existing accounting standard documents are superseded by the Codification and any accounting literature not included in the Codification will not be authoritative. However, rules and interpretive releases of the Securities and Exchange Commission (SEC) issued under the authority of federal securities laws will continue to be sources of authoritative GAAP for SEC registrants. All references made to GAAP in our consolidated financial statements now use the new Codification numbering system. The Codification does not change or alter existing GAAP and, therefore, did not have a material impact on our consolidated financial statements.

Table of Contents

Revenue Recognition

We generate nearly all of our revenue from sales of our OmniPod Insulin Management System to diabetes patients or third-party distributors who resell the product to diabetes patients. The initial sale to a new customer typically includes OmniPods and a Starter Kit, which include the PDM, the OmniPod System User Guide and the OmniPod System Interactive Training CD. We offer a 45-day right of return for our Starter Kits sales. Subsequent sales to existing customers typically consist of additional OmniPods.

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 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 assess whether the different elements qualify for separate accounting. We recognize revenue for the initial shipment to a patient or other third party once all elements have been delivered.

We offer a 45-day right of return for our Starter Kits sales, 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 historical return data to their 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 initial sales to new customers.

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.

Restructuring Expense and Impairment of Assets

As part of 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 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

FASB ASC 740-10, *Income Taxes,* clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements. FASB 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, FASB ASC 740-10 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. As of December 31, 2010, we had $0.2 million of unrecognized tax benefits recorded. As of December 31, 2009, we had $0.1 million of unrecognized tax benefits recorded.

Stock Based Compensation

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

We have continued to apply the minimum value method in future periods to equity awards outstanding that were originally measured using this method. 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.

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. Because our initial public offering was completed in May 2007, we do not have sufficient history of market prices of our common stock, and as such we estimate volatility in accordance with Securities and Exchange Commission s Staff Accounting Bulletin No. 107, *Share-Based Payment* , or SAB 107, using historical volatilities of comparable public entities. The expected life of the awards is estimated based on the SEC Shortcut Approach as defined in SAB 107, which is 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 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.

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,

Table of Contents

we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense.

Prior to April 1, 2006, the exercise prices for options granted were set by our board of directors based upon guidance set forth by the American Institute of Certified Public Accountants in the AICPA Technical Practice Aid. To that end, the board considered a number of factors in determining the option price, including the following factors: (1) prices for our preferred stock, which we had sold to outside investors in arms-length transactions, and the rights, preferences and privileges of our preferred stock and common stock in the Series A through Series E financing, (2) obtaining FDA 510(k) clearance, (3) launching the OmniPod System and (4) achievement of budgeted revenue and results.

In connection with the preparation of the financial statements for our initial public offering, we retrospectively estimated the fair value of our common stock based upon several factors, including the following: (1) operating and financial performance, (2) progress and milestones attained in the business, (3) past sales of convertible preferred stock, (4) the results of the retrospective independent valuations, and (5) the expected valuation obtained in an initial public offering. We believe this to have been a reasonable methodology based on the factors above and based on several arm s length transactions involving our stock supportive of the results produced by this valuation methodology.

In the years ended December 31, 2010, 2009, and 2008, we recorded $5.0 million, $4.2 million and $3.4 million of stock based compensation expense, respectively.

Warrants

In connection with the term loans with Lighthouse Capital Partners in 2005 and a group of lenders led by Merrill Lynch Capital in 2006, we issued warrants to the lenders to purchase shares of our redeemable convertible preferred stock. Upon the closing of our initial public offering in May 2007, all outstanding warrants to purchase shares of our preferred stock were converted into warrants to purchase shares of our common stock on a 1-for-2.6267 basis at a purchase price of $9.56 per share and, as a result, are no longer be subject to FSP 150-5 for periods ended on or after that date. The aggregate fair value of these warrants as of May 18, 2007, determined to be $2.0 million, was reclassified from liabilities to additional paid-in capital, a component of stockholders equity, and we have ceased to record any related periodic fair value adjustments.

We recorded $0.8 million fair value of the warrants for Series E preferred stock as a discount to the term loan with Merrill Lynch Capital. The value of the warrants was being amortized to interest expense over the 42-month life of this term loan. Upon repayment and termination of the term loan in June 2008, we recognized approximately $0.5 million as interest expense for the unamortized balance of the warrants fair value.

In connection with the $27.5 million initial disbursement related to the execution of the Facility Agreement in March 2009, we issued to the lenders fully exercisable warrants to purchase an aggregate of 3.75 million shares of common stock at an exercise price of $3.13 per share. We recorded $6.1 million fair value as additional paid-in capital and debt discount and were amortizing this amount to interest expense over the term of the loan. In the year ended December 31, 2010, these warrants were exercised to purchase 3,750,000 shares of our common stock. We received proceeds of $11.7 million in connection with the warrant exercise. Significant terms and fair values of warrants to purchase common stock are as follows (in thousands except share and per share data):

Stock	Expiration Date	Exercise Price per Share	Common Shares as of December 31, 2010	Common Shares as of December 31, 2009	Fair Value as of December 31, 2010	Fair Value as of December 31, 2009

Common Stock	December 27, 2013	$	9.56	62,752	62,752

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable consist of amounts due from third-party payors, patients and third-party distributors. We account for doubtful accounts using the allowance method. The allowances for doubtful accounts are recorded in the period in which the revenue is recorded or at the time the potential collection risk is identified.

Table of Contents

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, 2010 and 2009, the allowance for doubtful accounts was $5.4 million and $7.2 million, respectively. We believe the reserve is adequate to mitigate current collection risk.

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 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 products and 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, 2010 and 2009, the warranty reserve was $1.9 million.

Recent Accounting Pronouncements

In April 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-17 thereby amending FASB ASC 605 for revenue recognition related to the milestone method of revenue recognition. ASU No. 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development arrangements. A company may make an accounting policy election to use the milestone method of revenue recognition for transactions within the scope of the amendments. The amendments will be effective in fiscal years beginning on or after June 15, 2010. We will adopt the amendments on January 1, 2011 on a prospective basis. We believe the adoption of ASU No. 2010-17 will have no material effect on our financial statements.

In October 2009, the FASB issued ASU No. 2009-13 (formerly Emerging Issues Task Force, or EITF, No. 08-1) on ASC 605 for revenue recognition related to multiple-deliverable revenue arrangements. ASU No. 2009-13 provides amendments to the existing criteria for separating consideration in multiple-deliverable arrangements. The amendments establish a selling price hierarchy for determining the selling price of a deliverable, eliminate the residual method of allocation of arrangement consideration to all deliverables and require the use of the relative selling price method in the allocation of arrangement consideration to all deliverables, require the determination of the best estimate of a selling price in a consistent manner, and significantly expand the disclosures related to the multiple-deliverable revenue arrangements. The amendments will be effective in fiscal years beginning on or after June 15, 2010, and early adoption is permitted. We will adopt the amendments on January 1, 2011 on a prospective basis. We believe the adoption of ASU No. 2009-13 will have no material effect 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 short-term investments 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, 2010, we had outstanding debt recorded at $69.4 million related to our 5.375% Notes. As the interest rate on the 5.375% Notes is fixed, changes in interest rates do not affect the value of our debt or interest expense.

Table of Contents

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.

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, 2010. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under 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 SEC 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, 2010, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended December 31, 2010 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, 2010. 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).

Based on our assessment we believe that, as of December 31, 2010, our internal control over financial reporting is effective based on those criteria. The effectiveness of our internal control over financial reporting as of December 31,

2010 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, 2010, 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.

In our opinion, Insulet Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the COSO criteria.

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, 2010 and 2009 and the related consolidated statements of operations, statements of changes in stockholders equity and statements of cash flows for each of the three years in the period ended December 31, 2010 and our report dated March 10, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 10, 2011

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 2011 annual meeting of stockholders, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2010.

Audit Committee Financial Expert

The audit committee of our board of directors currently consists of Steven Sobieski (Chairman), Sally Crawford and Regina Sommer. 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 Exchange Act, 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 2011 annual meeting of stockholders, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2010.

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 2011 annual meeting of stockholders, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2010. For information on securities authorized for issuance

Table of Contents

under equity compensation plans, see the section entitled Market for Registrant s Common Equity and Related Stockholders Matters 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 2011 annual meeting of stockholders, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2010.

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 2011 annual meeting of stockholders, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2010.

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: March 10, 2011

/s/ Brian Roberts
Brian Roberts
Chief Financial Officer

Date: March 10, 2011

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, all amendments to this reports, 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 March 10, 2011.

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

Sally Crawford

/s/ Ross Jaffe, M.D. Director

Ross Jaffe, M.D.

Table of Contents

Signature	Title
/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.

Number	Description
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
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(3)	Credit and Security Agreement by and among Insulet Corporation, Sub-Q Solutions, Inc., the lenders party thereto and Merrill Lynch Capital, as Administrative Agent, dated as of December 27, 2006
10.4(1)	Insulet Corporation 2000 Stock Option and Incentive Plan
10.7(1)	Insulet Corporation 2007 Stock Option and Incentive Plan
10.8(1)	Non-Qualified Stock Option Agreement for Employees under the 2007 Stock Option and Incentive Plan
10.9(1)	Non-Qualified Stock Option Agreement for Non-Employee Directors under the 2007 Stock Option and Incentive Plan
10.10(1)	Restricted Stock Award Agreement under the 2007 Stock Option and Incentive Plan
10.11(1)	Incentive Stock Option Agreement under the 2007 Stock Option and Incentive Plan
10.12(1)	Insulet Corporation 2007 Employee Stock Purchase Plan
10.13(1)	Employment Agreement between Duane DeSisto and Insulet Corporation, dated May 4, 2005
10.14(1)	Employment Agreement between Carsten Boess and Insulet Corporation, dated May 9, 2006
10.15(1)	Employment Agreement between Ruthann DePietro and Insulet Corporation, dated February 8, 2006
10.16(3)	Form of Employee Non-Competition and Non-Solicitation Agreement by and between Insulet Corporation and each of its executive officers
10.17(5)+	Master Supply Agreement between Insulet Corporation and Flextronic Marketing (L) Ltd., dated January 3, 2007
10.18(5)+	Addendum to Master Supply Agreement between Insulet Corporation and Flextronic Marketing (L) Ltd., dated October 4, 2007
10.19(6)+	Amendment No. 1 to Development and License Agreement, dated as of March 3, 2008, by and between Abbott Diabetes Care, Inc., formerly known as TheraSense, Inc., and Insulet Corporation.
10.20(7)	Amendment to the Company s 2007 Stock Option and Incentive Plan.
10.21(7)	Executive Severance Plan

59

Table of Contents

Number	Description
10.22(9)	Amended and Restated 2007 Stock Option and Incentive Plan
10.23(13)	Offer Letter by and between Insulet Corporation and Brian Roberts, dated March 2, 2009
10.24(11)	Facility Agreement, dated March 13, 2009, by and among Insulet Corporation and the lenders named therein
10.25(11)	Registration Rights Agreement, dated March 13, 2009, by and among Insulet Corporation and the investors named therein
10.26(11)	Security Agreement, dated March 13, 2009, by and among Insulet Corporation and the secured parties named therein
10.27(14)	Securities Purchase Agreement, dated September 25, 2009, by and between Insulet Corporation and certain investors named therein
10.28(14)	Amendment to Facility Agreement, dated September 25, 2009, by and between Insulet Corporation and the lenders named therein
10.29(15)	Offer Letter by and between Insulet Corporation and Peter Devlin, dated July 16, 2009
10.30(16)	Insulet Corporation Amended and Restated 2007 Employee Stock Purchase Plan
10.31(17)	Second Amendment to Facility Agreement, dated June 17, 2010, by and between Insulet Corporation and the lenders named therein.
10.32(18)+	Distribution Agreement dated January 4, 2010 by and between Insulet Corporation and Ypsomed Distribution AG
10.33(19)+	Amendment No. 2 to Development and License Agreement, dated as of June 30, 2010, by and between Abbott Diabetes Care, Inc., formerly known as TheraSense, Inc., and Insulet Corporation
10.34	Offer Letter by and between Insulet Corporation and Paul Lucidi, dated May 11, 2010.
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.
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.

* 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.

\+ 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

Table of Contents

(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

(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

Table of Contents

Index to Consolidated Financial Statements

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, 2010 and 2009, and the related consolidated statements of operations, statements of changes in stockholders equity, and statements of cash flows for each of the three years in the period ended December 31, 2010. 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, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the financial statement schedule, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set forth therein.

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, 2010, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 10, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 10, 2011

Table of Contents

INSULET CORPORATION

CONSOLIDATED BALANCE SHEETS

	As of December 31, 2010	As of December 31, 2009
	(In thousands, except share and per share data)	
ASSETS		
Current Assets		
Cash and cash equivalents	$ 113,274	$ 127,996
Accounts receivable, net	16,841	14,962
Inventories	11,430	10,086
Prepaid expenses and other current assets	912	1,260
Total current assets	142,457	154,304
Property and equipment, net	12,522	15,482
Other assets	1,254	3,072
Total assets	$ 156,233	$ 172,858
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities		
Accounts payable	$ 4,895	$ 5,870
Accrued expenses	9,808	9,973
Deferred revenue	4,247	3,970
Total current liabilities	18,950	19,813
Long-term debt	69,433	89,136
Other long-term liabilities	1,619	1,999
Total liabilities	90,002	110,948
Stockholders Equity		
Preferred stock, $.001 par value:		
Authorized: 5,000,000 shares at December 31, 2010 and 2009.		
Issued: zero shares at December 31, 2010 and 2009		
Common stock, $.001 par value:		
Authorized: 100,000,000 shares at December 31, 2010 and 2009.		
Issued: 45,440,839 and 37,755,254 shares at December 31, 2010 and 2009, respectively	45	39
Additional paid-in capital	450,039	384,565
Accumulated deficit	(383,853)	(322,694)
Total stockholders equity	66,231	61,910

Total liabilities and stockholders equity	$ 156,233	$ 172,858

See accompanying notes

Table of Contents

INSULET CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2010	2009	2008
	(In thousands, except share and per share data)		
Revenue	$ 96,966	$ 66,032	$ 36,059
Cost of revenue	53,240	47,735	40,643
Gross profit (loss)	43,726	18,297	(4,584)
Operating expenses:			
Research and development	16,566	13,231	13,104
General and administrative	26,667	26,842	23,750
Sales and marketing	34,695	37,583	39,734
Restructuring and impairment of assets	4,431		8,170
Total operating expenses	82,359	77,656	84,758
Operating loss	(38,633)	(59,359)	(89,342)
Interest income	168	241	1,795
Interest expense	(22,694)	(13,226)	(7,224)
Net loss	$ (61,159)	$ (72,344)	$ (94,771)
Net loss per share basic and diluted	$ (1.54)	$ (2.43)	$ (3.43)
Weighted-average number of shares used in calculating net loss per share	39,607,899	29,727,106	27,611,003

See accompanying notes

Table of Contents

INSULET CORPORATION

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Subscription Receivable	Total Stockholders Equity
Balance at December 31, 2007	27,223,820	$ 28	$ 247,835	$ (155,579)	$ (9)	$ 92,275
Exercise of options to purchase common stock	532,763	1	1,237		9	1,247
Issuance for employee stock purchase plan	18,338		190			190
Issuance of restricted stock	4,000		1			1
Stock based compensation expense			3,352			3,352
Allocation of fair value of convertible debt to equity			25,812			25,812
Net loss				(94,771)		(94,771)
Balance at December 31, 2008	27,778,921	$ 29	$ 278,427	$ (250,350)	$	$ 28,106
Exercise of options to purchase common stock	191,232		577			577
Issuance for employee stock purchase plan	29,442		273			273
Stock based compensation expense			4,161			4,161
Issuance of common stock, net of offering costs of $4.6 million	9,755,659	10	95,454			95,464
Issuance of warrants in connection with debt			5,673			5,673
Net loss				(72,344)		(72,344)
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 million	3,450,000	3	45,446			45,449
	3,750,000	3	11,734			11,737

Exercise of warrants to purchase common stock						
Net loss				(61,159)		(61,159)
Balance at December 31, 2010	45,440,839	$ 45	$ 450,039	$ (383,853)	$	$ 66,231

See accompanying notes

Table of Contents

INSULET CORPORATION

CONSOLIDATED STATEMENT OF CASH FLOWS

	Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Cash flows from operating activities			
Net loss	$ (61,159)	$ (72,344)	$ (94,771)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	5,077	5,222	6,375
Amortization of debt discount	13,265	5,585	2,693
Stock based compensation expense	5,064	4,202	3,368
Provision for bad debts	3,317	5,020	4,264
Restructuring and impairment of assets	4,432		8,170
Non cash interest expense	1,779	677	916
Changes in operating assets and liabilities:			
Accounts receivable	(5,196)	(6,972)	(12,491)
Inventories	(1,343)	5,843	(8,880)
Prepaid expenses and other current assets	348	696	(565)
Other assets	33	(50)	2
Accounts payable and accrued expenses	(1,139)	1,487	4,825
Other long term liabilities	(380)	(282)	2,456
Deferred revenue	277	1,593	1,027
Net cash used in operating activities	(35,625)	(49,323)	(82,611)
Cash flows from investing activities			
Purchases of property and equipment	(6,549)	(3,140)	(10,047)
Net cash used in investing activities	(6,549)	(3,140)	(10,047)
Cash flows from financing activities			
Net proceeds from issuance of debt	(468)	56,879	81,484
Principal payments of long term debt	(32,500)	(27,500)	(28,173)
Proceeds from payment of subscription receivable			9
Proceeds from exercise of warrants	11,737		
Proceeds from issuance of common stock	48,683	94,417	1,413
Net cash provided by financing activities	27,452	123,796	54,733
Net increase (decrease) in cash and cash equivalents	(14,722)	71,333	(37,925)
Cash and cash equivalents, beginning of year	127,996	56,663	94,588
Cash and cash equivalents, end of year	$ 113,274	$ 127,996	$ 56,663
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 8,087	$ 6,823	$ 4,018

Cash paid for taxes	$ 11	$	$
Non-cash financing activities			
Allocation of fair value of warrants from net proceeds from issuance of Facility Agreement	$	$ 6,065	$

See accompanying notes

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years ended December 31, 2010, 2009 and 2008

1. Nature of the Business

Insulet Corporation (the Company) is principally engaged in the development, manufacture and marketing of an insulin infusion system for people with insulin-dependent diabetes. The Company was incorporated in Delaware in 2000 and has its corporate headquarters in Bedford, Massachusetts. Since inception, the Company has devoted substantially all of its efforts to designing, developing, manufacturing and marketing the OmniPod Insulin Management System (OmniPod), which consists of the OmniPod disposable insulin infusion device and the handheld, wireless Personal Diabetes Manager (PDM). The Company commercially launched the OmniPod Insulin Management System in August 2005 after receiving FDA 510(k) approval in January 2005. The first commercial product was shipped in October 2005.

The Company adopted the Financial Accounting Standard Board Accounting Standards Codification in the year ended December 31, 2009. The FASB Accounting Standards Codification (Codification) has become the single source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in accordance with GAAP. All existing accounting standard documents are superseded by the Codification and any accounting literature not included in the Codification will not be authoritative. However, rules and interpretive releases of the Securities and Exchange Commission (SEC) issued under the authority of federal securities laws will continue to be sources of authoritative GAAP for SEC registrants. All references made to GAAP in the Company s consolidated financial statements now use the new Codification numbering system. The Codification does not change or alter existing GAAP and, therefore, did not have a material impact on its consolidated financial statements.

2. Summary of Significant Accounting Policies

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 inventories, accounts receivable, equity instruments, the lives of property and equipment, 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 FASB ASC 820, Fair Value Measurements and Disclosures related to the fair value measurement of certain of its assets and liabilities. FASB 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, 2010 and 2009 are cash equivalents 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 approximate 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 ninety days or less, when purchased, to be cash equivalents. Cash equivalents consist of money market accounts and are carried at cost. This approximates their fair values. Outstanding letters of credit, principally relating to security deposits for lease obligations, totaled $0.2 million at December 31, 2010 and 2009.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable consist of amounts due from third-party payors, patients and third-party distributors. The Company accounts for doubtful accounts using the allowance method. The allowances for doubtful accounts are recorded in the period in which the revenue is recorded or 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.

The components of accounts receivable are as follows:

As of

	December 31, 2010	2009
	(In thousands)	
Trade receivables	$ 22,273	$ 22,152
Allowance for doubtful accounts	(5,432)	(7,190)
	$ 16,841	$ 14,962

Bad debt expense for the years ended December 31, 2010, 2009 and 2008 amounted to $3.3 million, $5.0 million, and $4.3 million, respectively.

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Inventories

Inventories are held at the lower of cost or market, determined under the first-in, first-out (FIFO) method. Inventory has been recorded at cost at December 31, 2010 and 2009. Work in process is calculated based upon a build up in the stage of completion using estimated labor inputs for each stage in production. Costs for Personal Diabetes Managers (PDMs) and OmniPods include raw material, labor and manufacturing overhead. 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 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.

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 of asset costs, 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 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 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.

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenue Recognition

The Company generates nearly all of its revenue from sales of its OmniPod Insulin Management System to diabetes patients and third-party distributors who resell the product to diabetes patients. The initial sale to a new customer typically includes OmniPods and a Starter Kit, which is comprised of the PDM, the OmniPod System User Guide and the OmniPod System Interactive Training CD. Subsequent sales to existing customers typically consist of additional OmniPods.

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 assesses whether the different elements qualify for separate accounting. The Company recognizes revenue for the initial shipment to a patient or other third party once all elements have been delivered.

The Company offers a 45-day right of return for its Starter Kits sales, and it 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. Historically, sales returns have amounted to approximately 3% of initial sales to new customers.

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 March 2008, the Company received a cash payment from Abbott Diabetes Care, Inc. (Abbott) for an agreement fee in connection with execution of the first amendment to the development and license agreement between the Company and Abbott. The Company recognizes the agreement fee from Abbott over the initial 5-year term of the agreement, and the non-current portion of the agreement fee is included in other long-term liabilities. Under the amended Abbott agreement, beginning July 1, 2008, Abbott agreed to pay an amount to the Company for services performed by Insulet in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to certain customers. In July 2010, the Company entered into a second amendment to the development and license agreement with Abbott. Under the terms of the second amendment Abbott agreed to pay certain amounts to the Company for services performed in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to

customers in certain additional territories. The Company recognizes the revenue related to this portion of the Abbott agreement at the time it meets the criteria for revenue recognition, typically at the time the revenue is recognized on the sale of the PDM to the patient. In the years ended December 31, 2010 and 2009, the Company recognized $5.4 million and $7.1 million, respectively, of revenue related to the amended Abbott agreement. The decrease from 2009 is attributable to amounts received from Abbott related to PDM upgrades for existing patients. There was no impact to cost of revenue related to this agreement.

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company had deferred revenue of $4.8 million and $5.1 million as of December 31, 2010 and 2009, respectively. The deferred revenue recorded was comprised of product-related revenue as well as the unrecognized portion of the agreement fee related to the Abbott agreement.

Shipping and Handling Costs

The Company does not 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.

Although revenue is recognized from shipments directly to patients or third-party distributors, the majority of shipments are billed to third-party insurance payors. There were no third-party payors that accounted for more than 10% of gross accounts receivable at December 31, 2010 or 2009.

Research and Development Expenses

The Company s research and development expenses consist of engineering, product development, quality assurance, clinical function and regulatory expenses. These expenses are primarily related to employee compensation, including salary, benefits and stock-based compensation. The Company also incurs expense related to consulting fees, materials and supplies, and marketing 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 personnel employed with sales and marketing activities, outside marketing expenses including commercial product samples 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. In light of the Company s current product offering, and other considerations, management has determined that the primary form of internal reporting is aligned with the offering of the OmniPod System. Therefore, the Company believes that it operates in one

segment.

Income Taxes

FASB ASC 740-10, *Income Taxes,* clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements. FASB 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

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

taken in a tax return. In addition, FASB ASC 740-10 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. As of December 31, 2010, the Company had $0.2 million of unrecognized tax benefits. As of December 31, 2009, the Company has $0.1 million of unrecognized tax benefits recorded.

The Company files federal and state tax returns. The Company has accumulated significant losses since its inception in 2000. Since the net operating losses may potentially be utilized in future years to reduce taxable income, all of the Company s tax years remain open to examination by the major taxing jurisdictions to which the Company is subject.

Stock Based Compensation

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

The Company continues to apply the minimum value method in future periods to equity awards outstanding that were originally measured using this method. 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 interest rate and expected dividends. As the Company s initial public offering was completed in May 2007, it does not have a history of market prices of its common stock, and as such estimates volatility in accordance with Securities and Exchange Commission s Staff Accounting Bulletin No. 107, *Share-Based Payment* (SAB 107), using historical volatilities of similar public entities. The expected life of the awards is estimated based on the SEC Shortcut Approach as defined in SAB 107*,* which is 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 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.

Prior to April 1, 2006, the exercise prices for options granted were set by the Company s board of directors based upon guidance set forth by the American Institute of Certified Public Accountants. The board considered a number of factors in determining the option price, including the following factors: (1) prices for the Company s preferred stock, which the Company had sold to outside investors in arms-length transactions, and the rights, preferences and privileges of the Company s preferred stock and common stock in the Series A through Series E financing, (2) obtaining FDA 510(k) clearance, (3) launching the OmniPod System and (4) achievement of budgeted revenue and results.

The Company retrospectively estimated the fair value of its common stock based upon several factors, including the following factors: (1) operating and financial performance, (2) progress and milestones attained

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

in the business, (3) past sales of convertible preferred stock, (4) the results of the retrospective independent valuations, and (5) the expected valuation obtained in an initial public offering. The Company believes this to have been a reasonable methodology based on the factors above and based on several arm s-length transactions involving the Company s stock supportive of the results produced by this valuation methodology.

See Note 11 for a summary of the stock option activity under the Company s stock-based employee compensation plan.

Recent Accounting Pronouncements

In April 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-17 thereby amending FASB ASC 605 for revenue recognition related to the milestone method of revenue recognition. ASU No. 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development arrangements. A company may make an accounting policy election to use the milestone method of revenue recognition for transactions within the scope of the amendments. The amendments will be effective in fiscal years beginning on or after June 15, 2010. The Company will adopt the amendments on January 1, 2011 on a prospective basis. The Company believes the adoption of ASU No. 2010-17 will have no material effect on its financial statements.

In October 2009, the FASB issued ASU No. 2009-13 (formerly Emerging Issues Task Force, or EITF, No. 08-1) on ASC 605 for revenue recognition related to multiple-deliverable revenue arrangements. ASU No. 2009-13 provides amendments to the existing criteria for separating consideration in multiple-deliverable arrangements. The amendments establish a selling price hierarchy for determining the selling price of a deliverable, eliminate the residual method of allocation of arrangement consideration to all deliverables and require the use of the relative selling price method in the allocation of arrangement consideration to all deliverables, require the determination of the best estimate of a selling price in a consistent manner, and significantly expand the disclosures related to the multiple-deliverable revenue arrangements. The amendments will be effective in fiscal years beginning on or after June 15, 2010, and early adoption is permitted. The Company will adopt the amendments on January 1, 2011 on a prospective basis. The Company believe the adoption of ASU No. 2009-13 will have no material effect on its financial statements.

3. Restructuring Expenses and Impairments of Assets

Restructuring Expenses

In December 2008, the Company recorded restructuring charges of $8.2 million for the impairment of certain manufacturing equipment no longer in use as well as workforce reduction and related costs. As part of the Company s strategic goal to pursue improved gross margins, leverage operational efficiencies and better pursue opportunities for low-cost supplier sourcing, the Company transitioned the manufacturing of completed OmniPods to Flextronics International Ltd., located in China. The Company determined that it would no longer use certain manufacturing equipment located in its Bedford facility. In addition, this transition resulted in a reduction in workforce of approximately 30 employees, mainly in the manufacturing and quality departments. As a result of these actions, the Company recorded a non-cash charge of $7.4 million related to impairments of assets and $0.8 million in workforce and related charges. The Company took no restructuring actions in 2010.

During the third quarter of 2008, the Company successfully transitioned its production of completed OmniPods to the manufacturing line operated by Flextronics. Pursuant to the Company s agreement with Flextronics, Flextronics supplies, as a non-exclusive supplier, OmniPods at agreed upon prices per unit pursuant to a rolling 12-month forecast provided by the Company. The agreement may be terminated at any time by either party upon prior written notice given no less than a specified number of days prior to the date

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

of termination. The Company continues to manufacture certain sub-assemblies and maintain packaging operations in its Bedford, Massachusetts facility.

The Company ceased to use certain assets in its Bedford facility, in connection with the transition of manufacturing to Flextronics. The Company continued to evaluate Flextronics ability to manufacture completed OmniPods against the rolling forecast as well as anticipated capacity and demand throughout the fourth quarter of 2008. During the fourth quarter of 2008 the Company concluded that the capacity of the manufacturing line operated by Flextronics was adequate to meet anticipated demand and quality standards in the future. As the Company determined that it would no longer use the Bedford equipment on December 1, 2008, the Company recorded an impairment charge for the remaining net book value of the assets of $7.4 million on that date. The equipment has no expected salvage value as it is highly customized equipment that can only be used for the manufacture of OmniPods.

In September 2009, the Company recorded a charge to operating expenses of $0.6 million for workforce reduction and related costs as part of the Company s continued focus on aligning the Company s infrastructure. This focus resulted in a reduction of workforce of approximately 30 employees throughout the organization, including certain members of senior management. As the reduction was not considered a restricting the related costs remain in the specific operating expense lines. At December 31, 2010, the Company has no accrued severance related to the workforce reduction.

During the year, 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 new restructuring or impairment activity in the year ended December 31, 2009.

At December 31, 2008, the Company s accrued expense for restructuring was $0.6 million for final payments of severance which were fully utilized during 2009. The Company had no accrued restructuring at December 31, 2010.

4. 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. During the year ended December 31, 2008, the Company issued 4,000 shares of restricted common stock. The restricted common stock vests over 2 years. At December 31, 2010, 3,556 shares were vested and 444 shares were unvested. At December 31, 2009 1,780 shares were vested and 2,220 shares were unvested. At December 31, 2008, 4,000 shares of restricted common stock were unvested. During the year ended December 31, 2010, the Company issued 399,999 restricted stock units to employees. The restricted stock units vest over 3 years. During the year ended December 31, 2010, 44,000 shares were forfeited and 355,999 shares remain unvested at December 31, 2010. Diluted net loss per share is computed using the weighted average number of common shares outstanding and, when dilutive, potential common share equivalents from options 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 loss for the years ended December 31, 2010, 2009 and 2008, all potential common shares have been excluded from the computation of the diluted net loss per share for all

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

periods presented because the effect would have been antidilutive. Potential common share equivalents consist of the following:

	Year Ended December 31,		
	2010	2009	2008
Convertible debt	3,981,969	3,981,969	3,981,969
Unvested restricted common shares	444	2,220	4,000
Unvested restricted stock units	355,999		
Outstanding options and ESPP	3,018,469	3,542,590	2,933,832
Outstanding warrants	62,752	3,812,752	62,752
Total	7,419,633	11,339,531	6,982,553

5. Inventories

Inventories consist of the following:

	As of December 31,	
	2010	2009
	(In thousands)	
Raw materials	$ 1,892	$ 1,657
Work-in-process	2,378	496
Finished goods	7,160	7,933
	$ 11,430	$ 10,086

The Company is currently producing the OmniPod on a partially automated manufacturing line at a facility in China, operated by a subsidiary of Flextronics International Ltd. The Company produces certain sub-assemblies for the OmniPod as well as maintains packaging operations in its facility in Bedford, Massachusetts. The Company purchases complete OmniPods from Flextronics. Inventories of finished goods were held at cost at December 31, 2010 and 2009.

6. Property and Equipment

Property and equipment consist of the following:

	Estimated	As of

	Useful Life (Years)	December 31, 2010	2009
		(In thousands)	
Machinery and equipment	3-5	$ 15,260	$ 16,019
Lab equipment	2	1,341	
Construction in process		3,550	2,705
Computers	3	2,673	2,405
Software	3	4,172	3,987
Leasehold improvement	*	2,252	2,247
Office furniture and fixtures	5	1,642	1,664
Total property and equipment		$ 30,890	$ 29,027
Less: Accumulated depreciation		(18,368)	(13,545)
Total		$ 12,522	$ 15,482

* Lesser of lease or useful life of asset

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Depreciation expense related to property and equipment was $5.1 million, $5.2 million, and $6.4 million for the years ended December 31, 2010, 2009 and 2008, respectively. The Company recorded $0.2 million, $0.1 million, and $0.4 million of capitalized interest for the years ended December 31, 2010, 2009 and 2008, respectively.

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

7. Accrued Expenses

Accrued expenses consist of the following:

	As of December 31,	
	2010	2009
	(In thousands)	
Employee compensation and related items	$ 4,481	$ 4,552
Professional and consulting services	1,627	1,571
Interest expense	190	425
Warranty reserve	880	928
Training	436	384
Other	2,194	2,113
Total accrued expenses	$ 9,808	$ 9,973

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:

	Year Ended December 31,	
	2010	2009
	(In thousands)	
Balance at the beginning of year	$ 1,820	$ 2,268
Warranty expense	2,082	3,373
Warranty claims settled	(2,029)	(3,821)

Balance at the end of the year	$ 1,873	$ 1,820
Composition of balance:		
Short-term	880	928
Long-term	993	892
Total warranty balance	$ 1,873	$ 1,820

8. Facility Agreement and Common Stock Warrants

In March 2009, the Company entered into a Facility Agreement with certain institutional investors, 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. Following the initial disbursement of $27.5 million on March 31,

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2009, the Company could, but was not required to, draw down on the facility in $6.5 million increments at any time until November 2010, provided that the Company met certain financial performance milestones. In connection with this financing, the Company paid Deerfield Management Company, L.P., an affiliate of the lead lender, a one-time transaction fee of $1.2 million. Total financing costs, including the transaction fee, were $3.0 million and were being amortized as interest expense over the 42 month term of the Facility Agreement.

In connection with the execution of the Facility Agreement, the Company issued to the lenders fully exercisable warrants to purchase an aggregate of 3.75 million shares of the Company s common stock at an exercise price of $3.13 per share. Pursuant to the original terms of the Facility Agreement, the Company would have been required to issue additional warrants to purchase 1.5 million shares upon drawing down the remaining $32.5 million under the facility. 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.

The amounts initially drawn under the Facility Agreement accrued interest at a rate of 9.75% per annum, and the undrawn amounts under the Facility Agreement accrued interest at a rate of 2.75% per annum. Accrued interest was payable quarterly in cash in arrears.

In September 2009, the Company entered into an Amendment to the Facility Agreement whereby the Company repaid the $27.5 million of outstanding debt and at that time drew down the remaining $32.5 million available under the Facility Agreement. The lenders eliminated all future performance milestones associated with the remaining $32.5 million available on the credit facility and reduced the annual interest rate on any borrowed funds to 8.5%. In connection with the Amendment to the Facility Agreement, the Company entered into a Securities Purchase Agreement with the lenders whereby the Company sold 2,855,659 shares of the Company s common stock to the lenders 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 additional paid-in capital and debt discount and amortized it to 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.

All principal amounts outstanding under the Facility Agreement were payable in September 2012. Any amounts drawn under the Facility Agreement would become immediately due and payable upon (i) an event of default, as defined in the Facility Agreement, in which case the lenders would have the right to require the Company to re-pay 100% of the principal amount of the loan, plus any accrued and unpaid interest thereon, or (ii) the consummation of certain change of control transactions, in which case the lenders would have the right to require the Company to re-pay 106% of the outstanding principal amount of the loan, plus any accrued and unpaid interest thereon. The amended Facility Agreement also provided for certain prepayment penalties in the event that the Company repaid the debt prior to its maturity.

In June 2010, the Company entered into a Second Amendment to the Facility Agreement whereby the Company paid a $0.5 million amendment fee to the lenders in exchange for the reduction of the prepayment penalties as well as the modification of certain other terms in the Facility Agreement. The fee was recorded as additional debt discount and was being amortized to interest expense over the remaining term of the loan.

All references herein to the Facility Agreement refer to the Facility Agreement entered into in March 2009 and amended in September 2009 and June 2010 and repaid in December 2010.

Because the consummation of certain change of control transactions would result in the payment of a premium of the outstanding principal, the premium feature was a derivative that was required to be bifurcated from the host debt instrument and recorded at fair value at each quarter end. As a prepayment penalty would be paid by the Company in the event that the Company repaid the debt prior to maturity, the prepayment penalty was also considered a derivative. The prepayment penalty did not meet the criteria to be accounted for separately. Any changes in fair value of the premium feature would be recorded as interest expense. The

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

difference between the face value of the outstanding principal on the Facility Agreement and the amount remaining after the bifurcation would be recorded as a discount to be amortized over the term of the Facility Agreement.

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 the fourth quarter 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.

In the year ended December 31, 2010, the Company recorded approximately $3.3 million of cash interest related to the Facility Agreement, including the prepayment penalty, compared to $2.5 million for the year ended December 31, 2009. In addition, in the year ended December 31, 2010, non-cash interest of approximately $9.6 million was recorded, compared to $1.5 million for the year ended December 31, 2009. Non-cash interest in the year ended December 31, 2010 consisted of amortization and extinguishment of the debt discount from the issuance of warrants and transaction fee in March 2009, amortization of the discount on the shares sold in connection with the amendment in September 2009, amortization of the transaction fee in connection with the amendment in June 2010 and amortization of the issuance costs associated with the debt. Non-cash interest in the year ended December 31, 2009 consisted of amortization of the debt discount from the issuance of warrants and transaction fee in March 2009, amortization of the discount on the shares sold in connection with the amendment in September 2009 and amortization of the issuance costs associated with the debt.

As of December 31, 2010, all warrants to acquire 3.75 million shares of the Company s common stock issued in connection with the Facility Agreement were exercised.

9. Convertible Notes and Repayment and Termination of Term Loan

Convertible 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, beginning December 15, 2008. 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 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 the Company s common stock for the remainder of the conversion value in excess of the principal amount. The Company does not have the right to redeem any of the 5.375% Notes prior to maturity. 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

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 adopted certain provisions of FASB ASC 470-20, *Debt with Conversion and Other Options,* on January 1, 2009. FASB ASC 470-20 clarifies that convertible debt instruments that may be settled in cash upon conversion should be separated between the liability and equity components in a manner that will reflect the entity s nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. FASB ASC 470-20 was applied retrospectively to all periods presented. Accordingly, 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 beginning June 15, 2008 over the 5 year term of the 5.375% Notes.

The Company incurred interest expense of approximately $10.0 million and $9.4 million for the years ended December 31, 2010 and 2009, respectively, related to the 5.375% Notes. Of the $10.0 million recorded in the year ended December 31, 2010, approximately $4.9 million relates to amortization of the debt discount, $0.5 million relates to the amortization of deferred financing costs, and $4.6 million relates to cash interest. Of the $9.4 million recorded in the year ended December 31, 2009, approximately $4.3 million relates to amortization of the debt discount, $0.5 million relates to the amortization of deferred financing costs, and $4.6 million relates to cash interest. 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 amount allocated to equity. The remainder is recorded in the consolidated balance sheet and is being amortized as a component of interest expense over the five year term of the notes.

As of December 31, 2010, the outstanding amounts related to the 5.375% Notes of $69.4 million are included in long-term debt in the consolidated balance sheet and reflect the debt discount of $15.6 million. As of December 31, 2009, the outstanding amounts related to the 5.375% Notes of $64.5 million are included in long-term debt and reflect the debt discount of $20.5 million. The debt discount includes the equity allocation of $25.8 million (which represents $26.9 million less the $1.1 million of allocated financing costs) offset by the accretion of the debt discount through interest expense from the issuance date in 2008 over the 5 year term of the notes. The Company recorded $5.0 million of interest expense related to the debt discount in the year ended December 31, 2010. As of December 31, 2010, the 5.375% Notes have a remaining life of 2.5 years.

The Company received net proceeds of approximately $81.5 million from the debt offering. Approximately $23.2 million of the proceeds from this offering was used to repay and terminate the Company s then-existing term loan, including outstanding principal and accrued and unpaid interest of $21.8 million, a prepayment fee related to the term loan of approximately $0.4 million and a termination fee of $0.9 million. The Company is using the remainder for general corporate purposes. The Company incurred interest expense of approximately $1.5 million on the term loan prior to its termination in the year ended December 31, 2008. The Company incurred no interest on the term loan in the years ended December 31, 2010 and December 31, 2009. The term loan was subject to a loan origination fee of $0.9 million, which was recorded in the consolidated balance sheet and was amortized as a component of interest expense over the term of the loan. The remaining balance of deferred financing costs of approximately $0.6 million was written off at the repayment and termination date. In connection with this term loan, the Company issued warrants to the lenders to purchase up to 247,252 shares of Series E preferred stock at a purchase price of $3.64 per share. The warrants automatically converted into warrants to purchase common stock on a 1-for-2.6267 basis at a purchase price of $9.56 per share at the closing of the Company s initial public offering in May 2007. The Company recorded the $0.8 million fair value of the warrants as a discount to the term loan. Upon repayment and termination of the term

loan, the Company recognized approximately $0.5 million as interest expense for the unamortized balance of the warrants fair value. The difference between the amount paid, including the prepayment fee, and the carrying value of the term loan, including the remaining deferred financing costs and

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

unamortized warrants to purchase common stock, was recognized as a $1.5 million loss from early extinguishment of the term loan.

Warrants

In connection with the term loan with Lighthouse Capital Partners and a group of lenders led by Merrill Lynch Capital, the Company issued warrants to the lenders to purchase shares of its redeemable convertible preferred stock. Prior to the Company s initial public offering, these warrants were recorded as warrants to purchase shares subject to redemption in current liabilities in accordance with FASB ASC 480-10, *Distinguishing Liabilities from Equity*.

All outstanding warrants to purchase shares of the Company s preferred stock were converted into warrants to purchase shares of its common stock on a 1-for-2.6267 basis at a purchase price of $9.56 per share. As of December 31, 2010, warrants to purchase 62,752 shares of the Company s common stock remained outstanding at an exercise price per share of $9.56. These warrants will expire on December 27, 2013. The Company recorded $0.8 million as the fair value of the warrants issued in connection with the term loan as a discount to the term loan. The fair value of the warrants was being amortized to interest expense over the 42-month life of the term loan. Upon repayment and termination of the term loan, the Company recognized approximately $0.5 million as interest expense for the unamortized balance of the warrants fair value.

Upon the closing of the Company s initial public offering on May 18, 2007, all outstanding warrants to purchase shares of the Company s preferred stock were converted into warrants to purchase shares of common stock. The aggregate fair value of these warrants as of May 18, 2007, determined to be $2.0 million, was reclassified from liabilities to additional paid-in capital, a component of stockholders equity. No periodic fair value adjustments will be made in future periods.

10. Commitments and Contingencies

Operating Leases

The Company leases its facilities, which 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. In 2008, the Company extended the lease of its Bedford, Massachusetts headquarters facility containing research and development and manufacturing space, and in 2010 the Company extended the lease of its additional office space in Bedford. Following the extensions, the leases expire in September 2014. The leases contain a five year renewal option and escalating payments over the life of the lease. The Company also leases warehouse facilities in Billerica, Massachusetts. This lease expires in December 2012.

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.

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2010, are as follows (in thousands):

Year		Minimum Lease Payments
2011		755
2012		755
2013		657
2014		493
2015		
Thereafter		
Total	$	2,660

Rent expense of approximately $0.9 million, $0.8 million, and $0.8 million was charged to operations in the years ended December 31, 2010, 2009 and 2008, respectively. 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 long-term liabilities in the accompanying consolidated balance sheet. There was no deferred rent for the years ended December 31, 2010 and December 31, 2009.

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 does not expect this litigation to 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 financial exposure at December 31, 2010.

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 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 and the Company has a director and officer insurance policy that enables it to recover a portion of any amounts paid for future claims.

11. Equity

In May 2007, the Company issued and sold 7,700,000 shares of common stock at a price to the public of $15.00 per share. In June 2007, the Company issued and sold an additional 665,000 shares of common stock at a price to the public of $15.00 per share pursuant to the underwriters partial exercise of their over-allotment

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

option. In connection with the initial public offering, the Company received total gross proceeds of $125.5 million, or approximately $113.4 million in net proceeds after deducting underwriting discounts and offering expenses.

In October 2007, in a public offering of 4,898,398 shares of the Company s common stock at a price to the public of $23.25 per share by certain of its stockholders, the Company issued and sold 459,759 shares of common stock which were purchasable by the underwriters upon their exercise of a 30-day over-allotment option granted to the underwriters by the Company. The Company did not receive any of the proceeds from the sale of shares of its common stock by the selling stockholders. Upon the closing of the sale of these shares, the Company received net proceeds of approximately $9.2 million.

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 connection with the Amendment to the Facility Agreement in September 2009, the Company entered into a Securities Purchase Agreement with the lenders whereby the Company sold 2,855,659 shares of its common stock to the lenders at $9.63 per share. The Company received aggregate proceeds of $27.5 million in connection with the sale of those shares.

In October 2009, in a public offering, the Company issued and sold 6,000,000 shares of its common stock at a price to the public of $10.25 per share. In November 2009, the Company issued and sold an additional 900,000 shares of common stock to the public at a price of $10.25 per share pursuant to the underwriters exercise of their over-allotment option. In connection with the offering, the Company received total gross proceeds of $70.7 million, or approximately $66.1 million in net proceeds after deducting underwriting discounts and offering expenses.

In December 2010, in a public offering, the Company issued and sold 3,000,000 shares of its common stock at a price of $13.27 per share. The Company issued and sold an additional 450,000 shares of common stock at a price of $13.27 per share pursuant to the underwriters exercise of their over-allotment option. 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.

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, 2010, 2009 and 2008 was $5.0 million, $4.2 million, and $3.4 million, respectively, and was calculated based on awards ultimately expected to vest. At December 31, 2010, the amount of stock-based compensation capitalized as part of inventory was not material. At December 31, 2010, the Company had $10.8 million of total unrecognized compensation expense.

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, 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, 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, which amount will be increased on each January 1 through January 1, 2012, by a number of shares

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

equal to the lesser of 3% of the number of shares of common stock of the Company outstanding as of the immediately preceding December 31, or 725,000 shares. In addition, in May 2008, shares available for grant under the 2007 Plan were increased by 600,000 shares. At December 31, 2010, 1,021,097 options were available for future grants.

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, 2009	3,542,590	$ 8.36	
Granted	345,000	14.85	
Exercised	(470,561)	6.46	$ 3,848(1)
Canceled	(398,560)	13.29	
Balance, December 31, 2010	3,018,469	8.74	21,508(2)
Vested, December 31, 2010	1,876,259	7.85	15,143(2)
Vested and expected to vest, December 31, 2010(3)	2,584,886		18,992(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, 2010, 2009 and 2008, was $3.8 million, $1.1 million and $7.9 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, 2010, and the exercise price of the underlying options.

(3) Represents the number of vested options as of December 31, 2010, plus the number of unvested options expected to vest as of December 31, 2010, based on the unvested options outstanding at December 31, 2010, adjusted for

the estimated forfeiture rate of 16%.

At the time of grant, options granted under the 2000 Plan are typically immediately exercisable, but subject to restrictions. Therefore, under the 2000 Plan, the number of options exercisable is greater than the number of options vested until all options are fully vested. At December 31, 2010, there were 3,018,469 options outstanding with a weighted average exercise price of $8.74 and a weighted average remaining contractual life of 6.8 years. At December 31, 2010, there were 1,884,365 options exercisable with a weighted average exercise price of $7.88 and a weighted average remaining contractual life of 5.8 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

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the portion of stock-based awards that is ultimately expected to vest. The Company recognizes the value of stock-based compensation to 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,		
	2010	**2009**	**2008**
Risk-free interest rate	1.47 - 3.05%	1.80-2.80%	1.71 - 3.30%
Expected term (in years)	6.25	6.25	6.25
Dividend yield	0	0	0
Expected volatility	71 - 78%	71 - 76%	52 - 61%

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. The Company determines volatility based on an analysis of comparable companies.

Expected term. The expected term of stock options represents the period the stock options are expected to remain outstanding and is based on the SEC Shortcut Approach as defined in SAB 107, *Share-Based Payments* , which is 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 year ended December 31, 2010, 2009 and 2008 was $9.92, $4.52, and $7.15, respectively. Employee stock-based compensation expense related to stock options recognized in the year ended December 31, 2010, 2009 and 2008 was $4.0 million, $4.2 million, and $3.4 million, respectively, and was calculated based on awards ultimately expected to vest. At December 31, 2010, the amount of stock-based compensation capitalized as part of inventory was not material.

At December 31, 2010, the Company had $6.5 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.

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.

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 will 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 shares 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 for any reason.

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

The Company issued 15,024 shares of common stock in 2010, 29,442 shares of common stock in 2009, and 18,338 shares of common stock in 2008 to employees participating in the 2007 ESPP. The Company recorded $34,000, $41,000 and $29,000 of stock-based compensation expense related to the 2007 ESPP for the years ended December 31, 2010, 2009 and 2008, respectively.

Restricted Stock Units

In the year ended December 31, 2010, the Company awarded 399,999 restricted stock units to certain employees. The restricted stock units were granted under the Company s 2007 Stock Option and Incentive Plan (the 2007 Plan) and vest annually over three years from the grant date. The restricted stock units granted have a weighted average fair value of $14.99 based on the closing price of the Company s common stock on the date of grant with a weighted average remaining contractual term of 9.2 years. The restricted stock units were valued at approximately $6.0 million at their grant dates, and the Company is recognizing the compensation expense of the restricted stock units expected to vest over the three year vesting period. Approximately $1.0 million of stock-based compensation expense related to the vesting of restricted stock units was recognized in the year ended December 31, 2010, and approximately $4.3 million of the fair value of the restricted stock units remained unrecognized as of December 31, 2010. Under the terms of the award, the Company will issue shares of common stock on each of the vesting dates. None of the restricted stock units awarded to employees vested during the year ended December 31, 2010.

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes the status of the Company s restricted stock units:

	Number of Shares	Weighted Average Fair Value
Balance, December 31, 2009		$
Granted	399,999	14.99
Vested		
Forfeited	(44,000)	15.03
Balance, December 31, 2010	355,999	$ 14.99

Stock-based Compensation Associated with Awards for Non-Employees

Restricted Stock Awards for Non-Employees

During the year ended December 31, 2008, the Company granted 4,000 shares of restricted common stock from the 2007 Plan to a non-employee. The restricted shares 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. The intrinsic value of these shares was measured using the closing price on the date of grant. Of the shares awarded, 1,776 shares of restricted stock vested in the year ended December 31, 2010, 1,780 shares of restricted stock vested in the year ended December 31, 2009 and the remaining 444 unvested shares will vest in 2011. The shares were valued at approximately $32,000 at their grant date, and the Company is recognizing the compensation expense over the two year vesting period. Approximately $17,000 and $15,000 of stock-based compensation expense related to the vesting of restricted stock was recognized in the years ended December 31, 2010 and 2009, respectively.

The total fair value of the restricted shares at December 31, 2010 was approximately $32,000. The stock-based compensation cost is being recognized over a weighted average period of 2 years.

The following table summarizes the status of the Company s restricted shares:

	Number of Shares	Weighted Average Fair Value
Balance, December 31, 2009	2,220	$ 8.04
Granted		
Vested	(1,776)	8.04
Forfeited		
Balance, December 31, 2010	444	$ 8.04

Shareholder Rights Plan

In November 2008, the Board of Directors of the Company adopted a 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 Board s ability 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

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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.

12. Defined Contribution Plan

The Insulet 401(k) Retirement 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, from 1% to 20% of their compensation. The Company has the option of making both matching contributions and discretionary profit-sharing contributions to the plan. During 2010, the Company offered a discretionary match of 25% of the first 4% 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). The total amount contributed by the Company was $0.1 million, $0.1 million, and $0.2 million for the years ended December 31, 2010, 2009 and 2008, respectively.

13. Income Taxes

The Company accounts for income taxes under FASB 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.

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

	Year Ended December 31,	
	2010	2009
Tax at U.S. statutory rate	(34.00)%	(34.00)%
State taxes, net of federal benefit	(3.48)	(5.33)
Tax credits	(0.80)	0.18
State apportionment	7.98	
Change in valuation allowance	27.14	41.52
Other	3.16	(2.37)
	%	%

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 purposes and the amounts used for income tax purposes. Significant components of the Company s deferred tax assets (liabilities) consisted of the following:

	Year Ended December 31,	
	2010	2009
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 125,814	$ 113,462
Start up expenditures	2,422	3,424
Tax credits	6,172	5,685
Gain/loss on impairments	4,066	2,915
Bad debt	2,032	2,828
Other	5,018	2,576
Deferred tax liabilities:		
Prepaids	(270)	(231)
Depreciation	(1,401)	(1,157)
Amortization of debt discount	(5,825)	(8,070)
	138,028	121,432
Valuation allowance	$ (138,028)	$ (121,432)
	$	$

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 $138.0 million valuation allowance at December 31, 2010, is necessary to reduce the deferred tax assets to the amount that will more likely than not be realized. The Company also provided a valuation allowance for the full amount of its net deferred tax asset for the year ended December 31, 2009, because realization of any future tax benefit was not sufficiently assured. In the year ended December 31, 2010, the Company s valuation allowance increased by $16.6 million from the balance at December 31, 2009 of $121.4 million.

At December 31, 2010, the Company had approximately $324.1 million, $15.5 million and $6.2 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 for federal tax purposes and began to expire in 2005 for state tax purposes. At December 31, 2009, the Company had approximately $280.1 million, $18.2 million and $5.7 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 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.

Table of Contents

INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. Quarterly Data (Unaudited)

	2009 Quarters Ended			
	December 31	September 30	June 30	March 31
	(In thousands, except per share data)			
Revenue	$ 20,211	$ 18,735	$ 14,617	$ 12,469
Gross profit	$ 7,334	$ 5,799	$ 3,169	$ 1,995
Net loss	$ (15,538)	$ (16,922)	$ (20,239)	$ (19,645)
Net loss per share	$ (0.44)	$ (0.60)	$ (0.73)	$ (0.71)

	2010 Quarters Ended			
	December 31	September 30	June 30	March 31
	(In thousands, except per share data)			
Revenue	$ 27,767	$ 25,455	$ 22,937	$ 20,807
Gross profit	$ 13,826	$ 11,629	$ 9,886	$ 8,385
Net loss	$ (20,858)	$ (12,100)	$ (13,711)	$ (14,491)
Net loss per share	$ (0.50)	$ (0.30)	$ (0.36)	$ (0.38)

Table of Contents

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

The following table sets forth activities in our accounts receivable reserve accounts:

Classifications	Balance Beginning of Period	Additions Charged to Costs and Expenses	Deductions	Balance At End of Period
		(In thousands)		
Year Ended December 31, 2010				
Allowance for doubtful accounts	$ 7,190	$ 3,317	$ 5,075	$ 5,432
Year Ended December 31, 2009				
Allowance for doubtful accounts	$ 3,800	$ 5,020	$ 1,630	$ 7,190
Year Ended December 31, 2008				
Allowance for doubtful accounts	$ 1,209	$ 4,264	$ 1,673	$ 3,800