Insulet Corporation

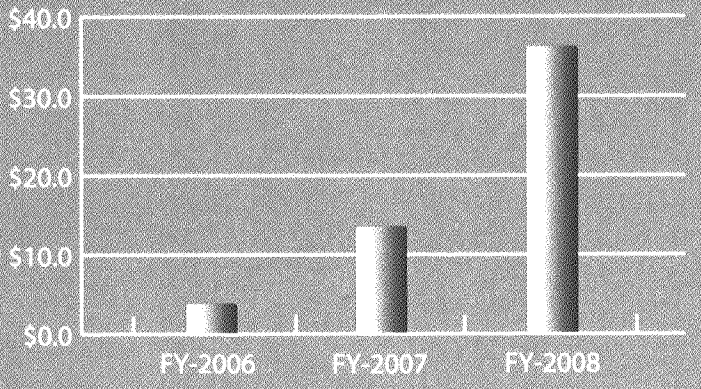
2008 Annual Report

2008 Highlights

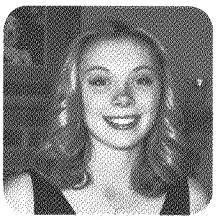
- Achieved 170% annual revenue growth.
- Achieved our first quarter of gross profit.
- Continued strong patient growth and retention.
- More than tripled manufacturing capacity and significantly reduced costs by moving production to China.
- Initiated our first nondiabetes drug delivery project with a pharmaceutical partner.
- Continued studies seeking to demonstrate the clinical superiority of OmniPod and efficacy in alternate applications.

2008 was a year of **170% revenue growth.**

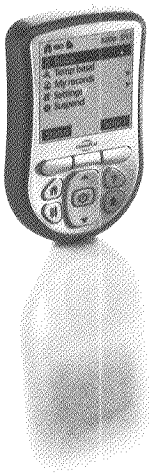
ANNUAL REVENUE ($M)



"Before OmniPod, I felt like the diabetes controlled me. Since I have had OmniPod, **I feel like I am in control of my diabetes.** It changed my life."



SHANNON SMITH
ADA teen ambassador and OmniPod user



OmniPod. Changing lives.

Insulet Corporation was founded to improve the lives of people with diabetes. It is a mission we take seriously. To succeed, we not only need a superior product, we need a viable commercial business. Today, we have both.

In 2008, we saw 170% annual revenue growth, coupled with manufacturing innovations that led to our first quarter of gross profit. We saw expansion into all 50 states and Puerto Rico. We saw solid evidence of superior clinical efficacy—and heartwarming stories of how OmniPod has changed people's lives.

In short, we saw success.

To Our Shareholders,

Since its introduction, the OmniPod® Insulin Management System has changed the way thousands of people live with Type 1 diabetes. It has helped free them from the obstacles that prevented so many people with diabetes from choosing the best possible treatment and living their lives to the fullest. OmniPod enables athletes to fulfill their potential, gives parents peace of mind and allows people with diabetes just to be themselves.

With these advances, commercial success has followed. While we knew the innovation behind the OmniPod System could revolutionize insulin pump therapy, we also knew we had to prove that we could build a viable commercial business. In 2008 we fast-forwarded towards this goal.

OmniPod has changed the face of insulin pump therapy forever.

We put products in the hands of customers—and watched demand grow.

Despite the difficult economic climate, Insulet delivered strong top-line and customer growth in 2008. The Company recorded over $36 million in revenue, a 170% increase compared to 2007; we now have over 10,000 customers using the OmniPod System.

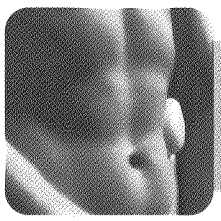
This did not happen by chance.

- We nearly tripled our sales team and began selling OmniPod nationwide.
- We broadened the scope of our marketing initiatives, launching a highly targeted and successful direct-to-consumer (DTC) marketing campaign. Magazine, internet and television advertising in diabetes-specific media, underpinned by direct mail, drove consumers to request the OmniPod Demo Kit. This unique sampling program features a nonworking Pod and virtual PDM, allowing patients to experience OmniPod without waiting to visit their doctor.

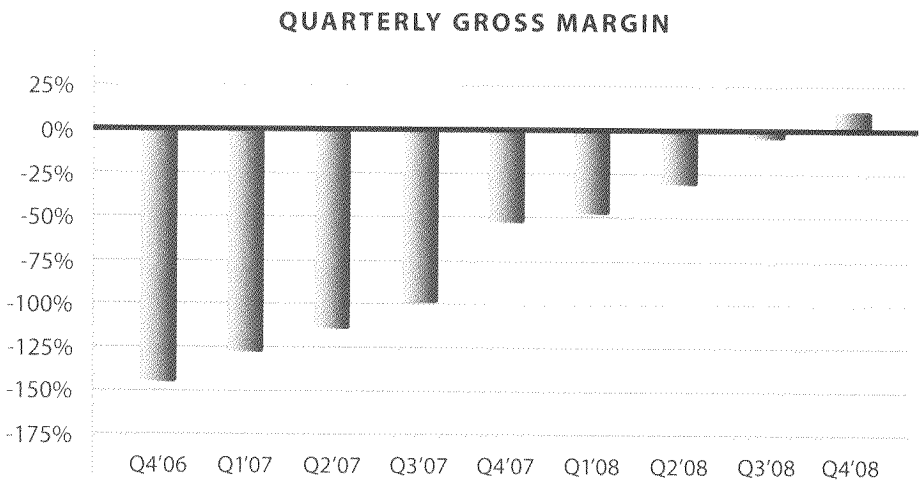
We more than tripled manufacturing capacity while decreasing costs—and saw a gross profit.

At this time last year we were producing 75,000 Pods per month, and hoped to increase output to over 200,000 Pods per month by December 2008. We reached our goal in July. In the third quarter we successfully transitioned our entire manufacturing line to China—with dramatic implications for volume and gross profit.

- Insulet now manufactures more insulin infusion devices in a month than all other insulin pump manufacturers in the world produce in a year.
- Economies of scale combined with cost efficiencies have significantly reduced the cost per Pod—savings that have directly affected our gross profit. At the end of 2007, our gross loss was 54%. In the fourth quarter of 2008, our gross margin was 10%, the first quarter of gross profit in Insulet's history.



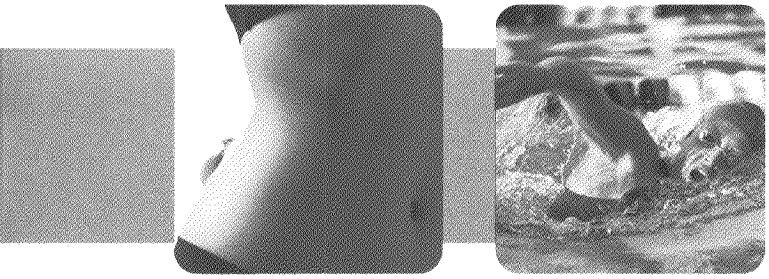
In Q4'08, we achieved our first quarter of **gross profit.**



We are establishing powerful peer-reviewed evidence of OmniPod's clinical superiority over conventional insulin pumps.

Within the medical community, demonstrating that a product is clinically better for patients is paramount. To this end, we are working with key opinion leaders in the field of diabetes to expand the clinical data supporting OmniPod's differentiation and versatility.

- At the 2008 Annual Meeting of the Diabetes Technology Society, Dr. Howard Zisser presented his research on the effect of hydrostatic pressure on expected insulin delivery rates. The study found that OmniPod, with its tubing-free design, delivers more accurate doses of insulin than conventional pumps, whose pumping rates can be impacted by how they're placed on the body relative to their tubing. This is important for people with Type 1 diabetes because variations in insulin delivery make it more difficult to consistently control blood sugar values, which is critically important for proper diabetes management.
- At the recent Advanced Technologies and Treatments for Diabetes conference in Athens, Greece, a team of world-renowned JDRF researchers presented the latest findings from the Artificial Pancreas project; OmniPod is utilized in the majority of the Artificial Pancreas study sites around the globe.
- At the 2008 Annual Meeting of the American Association of Diabetes Educators, The Endocrine Group and the Albany College of Pharmacy of Albany, New York, jointly presented results on a retrospective review of OmniPod users; the study concluded that the OmniPod® Insulin Management System was safe and effective in improving mean A1C values, the standard metric for determining blood sugar control in people with diabetes.
- At the Mountain Diabetes and Endocrine Center in Ashville, North Carolina, Dr. Wendy Lane is conducting the first investigator-initiated clinical trial of the OmniPod System in patients with Type 2 diabetes, a disease affecting 23.6 million Americans.[1] This study uses OmniPod to deliver concentrated U500 insulin to Type 2 patients; it completed enrollment in the third quarter of 2008 and is on track to conclude in 2009. We have received encouraging feedback from Dr. Lane about the early success of this study and OmniPod's ability to control blood sugar in Type 2 diabetes patients.



We are laying the groundwork for Insulet's future expansion—both within the field of diabetes and beyond.

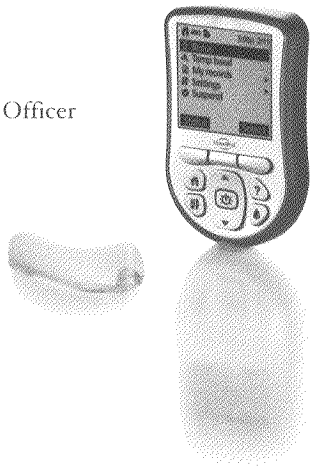
Having established a solid presence in the U.S. diabetes market, we will continue to penetrate it, while laying the groundwork for international expansion and applications beyond diabetes.

- Overseas expansion: In 2008, we filed for a CE mark for OmniPod and began establishing relationships with key opinion leaders in markets around the globe; reception has been strong, and by the end of 2009 we expect to begin selling the OmniPod System in these markets.
- Broader diabetes applications: As noted above, OmniPod's efficacy in controlling blood sugar in Type 2 diabetes is currently under investigation. This application could expand our diabetes market dramatically.
- Innovative applications: In 2008 we took our first concrete step towards expanding applications for OmniPod as a broader drug delivery platform. In partnership with Ferring Pharmaceuticals, we are utilizing the OmniPod System to deliver a women's health treatment. While this initiative is still in development, we believe it will demonstrate OmniPod's efficacy as a platform technology to deliver many drugs that require continuous or frequent infusions; we will continue to pursue these opportunities in 2009.
- Next generation PDM and Pod: We are currently at work on a PDM with a slimmer profile, a large color screen and enhanced data management capabilities. We also have initiated development work to make the Pod even smaller, easier to use and more cost-effective to manufacture.

In 2009, we will continue to drive demand for OmniPod, while further improving our manufacturing efficiency and overall cost structure. In the current economic environment, we are more conscious than ever of our responsibility to deliver value to our shareholders. We believe that with our expanded commercial footprint, our growing base of clinical evidence and our pipeline of future products and markets, we are very well positioned to continue growing our business, while advancing our mission to improve the lives of people living with diabetes.

Thank you to our shareholders, customers and employees for your support and commitment in the past year.

Duane DeSisto
President and Chief Executive Officer



UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2008

☐ **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. ~~000-33589~~ 1-33462

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 **Bedford, Massachusetts**	**01730**
(Address of principal executive offices)	*(Zip code)*

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

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

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

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

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

The aggregate market value of the common stock, without par value, 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, 2008 was approximately $248 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 5, 2009:

Title of Class	Shares Outstanding
Common Stock, $0.001 par value	27,835,393

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, 2008. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

INSULET CORPORATION

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. Forward-looking statements relate to future events or our future financial performance. We generally identify forward looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "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.

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. 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 diabetic 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.

Market Opportunity

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.

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 conventional insulin pumps. Both MDI and CSII therapies are considered intensive insulin management therapies.

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

The OmniPod System

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

- *Discreet, two-part design.* Unlike conventional insulin pumps, the OmniPod System consists of just two discreet, easy-to-use devices that communicate wirelessly: the OmniPod, a small, lightweight, disposable insulin infusion device worn beneath clothing that integrates an infusion set, automated cannula insertion, insulin reservoir, drive mechanism and batteries; and the 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 also 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 will make 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 will help redefine which diabetes patients are appropriate for CSII therapy, enabling healthcare professionals to prescribe CSII therapy to a broader pool of patients.

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

Sales and Marketing

Our sales and marketing effort is focused on generating demand and acceptance of the OmniPod System among healthcare professionals, people with insulin-dependent diabetes and third-party payors. Our marketing strategy is to build awareness for the benefits of the OmniPod System through a wide range of education programs, patient demonstration programs, support materials, media advertisements and events at the national, regional and local levels. In addition, 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.

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 makes CSII therapy easier to recommend. We plan to augment 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 will 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 through our promotional activities. 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, such as television programs and magazines.

Marketing research. In addition to our initiatives focused on healthcare professionals and patients, we also plan to continue evaluating 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 and sales of our products.

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 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 will enable 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 generally 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 focused primarily on increased functionality, design for ease-of-use and reduction of production costs of the OmniPod System. We are also working toward the integration of our existing 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, the SEVEN® System. 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.

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. 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 will fund development of a custom version of the OmniPod's Personal Diabetes Manager and, upon completion of the development, will agree to purchase minimum quantities of the OmniPod Systems over a five year period, beginning in 2009. 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. To manufacture sufficient volumes of the OmniPod, each of which is worn for up to three days and then replaced, and to achieve a low per unit production cost, 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 entered into on January 3, 2007 and revised on October 4, 2007. 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 to Flextronics. The initial term of the agreement is three years from January 3, 2007, with automatic one-year renewals. The agreement may be terminated at any time by either party upon prior written notice given no less than a specified number of days prior to the date of termination. The specified number of days is intended to provide the parties with sufficient time to make alternative arrangements in the event of termination. By purchasing OmniPods manufactured by Flextronics in China, we have been able to substantially increase production volumes for the OmniPod and, as a result, reduce our per unit production cost. We also produce certain sub-assemblies for the OmniPod as well as maintain packaging operations in our facility in Bedford, Massachusetts.

To achieve profitability, we are seeking to increase manufacturing volume 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. Prior to June 30, 2008, the sale price of the OmniPod System was not sufficient to cover our production costs. During the third quarter, we incurred production costs for the OmniPod which were lower than its selling price, primarily due to increased production volumes of the OmniPod, which improved absorption of manufacturing overhead costs and reduced our raw material costs, and we have consequently been able to achieve positive gross margin on sales of our OmniPod System. Our OmniPod manufacturing capacity at the end of 2008 was in excess of 250,000 OmniPods per month.

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. In addition, Flextronics currently supplies complete OmniPods. 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 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 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 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, 2008, we had obtained 18 issued United States patents, and had 18 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.

On January 23, 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. On March 3, 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. 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 dated March 13, 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 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.

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, Deltec, a division of Smiths Medical MD, Inc., 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;
- established distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory approval 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 Medingo, Nilimedix, Sensile Medical, M2 Medical, Phluid Corporation, Seattle Medical, Starbridge Medical Systems, Novo Nordisk A/S and Abbott Laboratories.

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

Government Regulation

The OmniPod System is a medical device subject to extensive and ongoing regulation by the 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. We expect that the product under development by us, integrating continuous glucose monitoring capability with our existing OmniPod System would require a PMA. Both of these 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;
- 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, 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 two FDA inspections of our facility. Both inspections resulted in identification of minor items for correction, some of which were immediately resolved, and we expect that our corrective actions for the remaining items will be satisfactorily reviewed by the FDA during its next inspection.

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.

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
- 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.

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

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 U.S. 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.

Employees

As of December 31, 2008, we had 294 full-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe that our employee relations are good.

ITEM 1A. *RISK FACTORS*

Set forth below are certain risk factors that could harm our business, results of operations and financial condition. You should carefully read the following risk factors, together with the financial statements, related notes and other information contained 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 fiscal year ended December 31, 2008, our gross loss from the manufacture and sale of the OmniPod System was $4.6 million. Although we have recently achieved a positive gross margin, we still operate at a substantial net loss. Our net losses for 2008, 2007 and 2006 were $92.8 million, $53.5 million and $36.2 million, respectively. The extent of our future operating losses and the timing of profitability are highly uncertain, and we may never achieve or sustain profitability. We have incurred a significant net loss since our inception, and as of December 31, 2008, we had an accumulated deficit of $248.4 million.

We currently rely entirely on sales of our sole product, the OmniPod System, to generate revenues. 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 derive substantially all of our revenue from the sale of this product. Accordingly, our ability to generate revenues 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 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;
- competitive pricing and related factors; and
- results of clinical studies relating to the OmniPod System or our competitors' products.

If any of these events occurs, our ability to generate revenues 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. Our manufacturing capacity at the end of 2008 was in excess of 250,000 OmniPods per month. We believe we can increase production levels on our existing manufacturing line by, among other actions, running an additional shift to the extent warranted by increased orders. 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. The occurrence of one or more factors that negatively impact our sales of the OmniPod System 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 is currently undergoing unprecedented turmoil amid stock market volatility, difficulties in the financial services sector, tightening of the credit markets, softness in the housing markets, concerns of inflation and deflation, reduced corporate profits and capital spending, significant job losses, reduced consumer spending, and continuing economic uncertainties. The 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 employee-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 revenues, 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 revenues.

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:

- revenues generated by sales of the OmniPod System and any other future products that we may develop;
- costs associated with adding further manufacturing capacity;
- costs associated with expanding our sales and marketing efforts;
- 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, including the net proceeds from our public and private offerings and draw downs on our up to $60 million credit facility, 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 2009.

We may in the future seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. 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.

The facility agreement we entered into on March 13, 2009 with certain institutional accredited investors, contains restrictions on our ability to incur certain indebtedness without the prior consent of our lenders. In addition, our ability to complete the debt financing discussed above and raise additional capital may be adversely impacted by current economic conditions, including the effects of the recent disruptions to the credit and financial markets in the U.S. 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 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, we expanded the scope of our existing contract manufacturing agreement with a subsidiary of Flextronics International Ltd. in China to

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

We may not be able to quickly establish additional or replacement 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 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 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 on a partially automated manufacturing line 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:

- changes in foreign currency exchange rates;
- instability in the political or 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;
- differing protection of intellectual property; and
- unexpected changes in regulatory requirements.

In particular, our future success will depend in large part on our ability to anticipate and effectively manage these and other risks associated with doing business in China. 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. As of December 31, 2008, we had entered into 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. Currently, we believe that the coding verification for Medicare reimbursement of the OmniPod System is inappropriate and we are therefore in the process of seeking appropriate coding verification. As a result, we have focused our efforts in establishing reimbursement for the OmniPod System by negotiating contracts with private insurers. Failure to secure or retain adequate coverage or reimbursement for the OmniPod System by third-party payors 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 are Animas Corporation, a division of Johnson & Johnson, Deltec, a division of Smiths Medical MD, Inc. 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.

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.

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 revenues 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 revenues 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, currently marketed as the SEVEN System, with the OmniPod System PDM. Medtronic, Inc. has developed an FDA-approved product combining continuous glucose sensing and CSII therapy and if we fail to do so, we may be at a significant competitive disadvantage, which could negatively impact our business. In addition, the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure or improve the treatment of diabetes. Any technological breakthroughs in diabetes monitoring, treatment or prevention could render the OmniPod System obsolete, which may have a material adverse effect on our business, financial condition and results of operations.

If our existing license agreement with Abbott 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. On March 3, 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. 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
- 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. 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.

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 revenues increase, 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 dated March 13, 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. We believe we would have meritorious defenses to any such suit. Any litigation, regardless of its outcome, would likely result in the expenditure of significant financial resources and the diversion of management's time and resources. In addition, litigation in which we are accused of infringement 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 and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenues 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. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our reputation, business, financial condition or results of operations.

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.

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, 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. 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.

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

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

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

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

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 revenues. 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 revenues 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 intend 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 intend 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 revenues 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 revenues.

If we expand, or attempt to expand, into foreign markets, we will be affected by new business risks that may adversely impact our business, financial condition and results of operations.

If we expand, or attempt to expand, into foreign markets, we will be subject to new business risks, including:

- 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 countries;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign partners, distributors or sales or marketing agents;
- limited protection for intellectual property rights in some countries;
- difficulty in collecting accounts receivable and longer collection periods;
- costs of enforcing contractual obligations in foreign jurisdictions;
- recessions in economies outside of the United States;
- political instability and unexpected changes in diplomatic and trade relationships;
- currency exchange rate fluctuations; and
- potentially adverse tax consequences.

If we are successful in introducing our current or future products into foreign markets, we will be affected by these additional business risks, which may adversely impact our business, financial condition and results of operations. In addition, expansion into foreign markets imposes additional burdens on our executive and administrative personnel, research and sales departments and general managerial resources. 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.

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 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 our 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 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 the entire United States. As we expand our sales internationally, we will need to obtain reimbursement agreements with government agencies or private third-party payors in those countries. Failure to obtain such agreements would limit our ability to successfully penetrate those foreign markets. In addition, the geographic expansion of our business will require additional manufacturing capacity to supply those markets as well as additional sales and marketing resources.

We expect to continue to increase our manufacturing capacity, our personnel and the scope of our U.S. and international sales and marketing efforts. This growth, as well as any other growth that we may experience in the future, will provide challenges to our organization and may strain our management and operations. In order to manage future growth, we will be required to improve existing, and implement new, management systems, sales and marketing efforts and distribution channels. We will need to manage our relation 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
- 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, including our 5.375% Convertible Senior Notes due June 15, 2013, and 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, including the $85.0 million in indebtedness incurred in connection with the sale in June 2008 of 5.375% Convertible Senior Notes due June 15, 2013. 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 revenues. 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. In addition, we currently utilize a limited number of domestic distributors. As part of our growth plan, we intend to increase the number of distributors we utilize to distribute our OmniPod System. 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 even decline, and our ability to grow our business could be adversely affected. Distributors that are in the business of selling other medical products may not devote a sufficient level of resources and support required to generate awareness of our products and grow or maintain product sales. If our distributors are unwilling or unable to market and sell our products, or if they do not perform to our expectations, we could experience delayed or reduced market acceptance and sales of our products.

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

As a public company, we are required to maintain internal control over financial reporting and our management is required to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year. Additionally, we are required to disclose in our Annual Reports on Form 10-K our management's assessment of the effectiveness of our internal control over financial reporting and a registered public accounting firm's attestation report on this assessment. If we are not successful in establishing 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 often 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. During 2008, our stock price has experienced volatility, with the closing price of our common stock on the NASDAQ Global Market having ranged from $25.87 on January 9, 2008 to $3.21 on November 20, 2008. These broad market and industry factors could materially and adversely affect the market price of our stock, regardless of our actual operating performance.

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

We have been a public company only since May 2007. For the three month period ended December 31, 2008, the average daily trading volume of our common stock on The NASDAQ Global Market has been fewer than 372,000 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, including the holders of the warrants to purchase 3.75 million shares of our common stock issued in connection with the March 13, 2009 facility agreement, have rights, subject to some conditions, to require us to file registration statements covering their share 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 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.

In addition, 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 acquirors 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.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

None.

ITEM 2. *PROPERTIES*

We lease approximately 63,500 square feet of manufacturing, laboratory and office space in Bedford, Massachusetts under leases expiring in 2010 and 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*

None.

ITEM 4. *SUBMISSION OF MATTERS TO A VOTE OF SECURITIES HOLDERS.*

None.

PART II

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

Market Information

Our common stock has been listed on The NASDAQ Global Market under the trading symbol "PODD" since our initial public offering on May 15, 2007. Prior to that time, there was no public market for our common stock. 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.

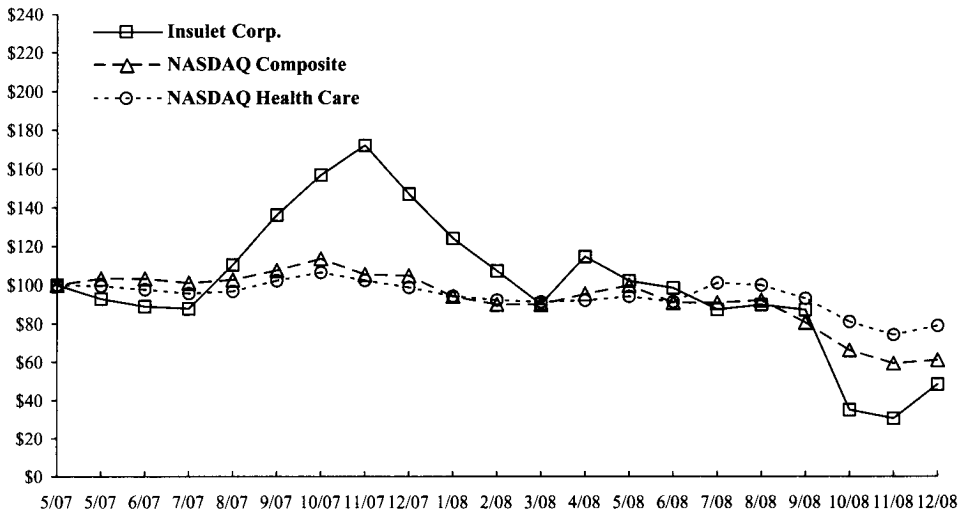
	High	Low
Fiscal Year 2007		
Second Quarter (commencing May 15, 2007)	$15.96	$13.84
Third Quarter	$22.60	$13.68
Fourth Quarter	$27.46	$21.25
Fiscal Year 2008		
First Quarter	$25.87	$12.79
Second Quarter	$20.17	$14.39
Third Quarter	$16.93	$13.00
Fourth Quarter	$13.32	$ 3.21

As of December 31, 2008, there were approximately 49 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.

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, 2008. 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 19 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 & 4/30/07 in index-including reinvestment of dividends.
Fiscal year ending December 31.

	5/15/2007	5/31/2007	6/30/2007	7/31/2007	8/31/2007	9/30/2007	10/31/2007	11/30/2007	12/31/2007
Insulet Corp.	100.00	92.86	88.97	87.84	110.40	136.28	156.89	172.06	147.12
NASDAQ Composite	100.00	103.27	103.23	101.07	102.69	107.57	113.58	105.42	104.81
NASDAQ Health Care	100.00	99.50	97.69	95.72	96.83	102.29	106.48	102.43	98.87

	1/31/2008	2/29/2008	3/31/2008	4/30/2008	5/31/2008	6/30/2008	7/31/2008	8/31/2008	9/30/2008	10/31/2008	11/30/2008	12/31/2008
Insulet Corp.	124.12	107.33	90.23	114.72	102.13	98.56	87.41	89.85	87.22	35.09	30.64	48.37
NASDAQ Composite	94.21	90.09	90.07	95.51	99.83	90.99	90.94	92.19	80.75	66.21	59.27	61.06
NASDAQ Health Care	94.35	92.36	91.38	92.16	94.17	91.42	101.09	99.98	93.11	81.09	74.32	79.02

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.

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, 2008.

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)	2,996,584	$9.47	603,954
Equity compensation plans not approved by security holders(2)	—	—	—
Total	2,996,584	$9.47	603,954

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

(2) There are no equity compensation plans in place not approved by shareholders.

(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, 2008 is 603,954 shares, which includes increases of 725,000 and 600,000 on January 1, 2008, and May 8, 2008, respectively. The amount will be increased on January 1, 2009, and on each January 1 thereafter through 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 10 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, 2008, nor issue any securities that were not registered under Securities Act of 1933.

Use of Proceeds

On May 14, 2007, our registration statements on Form S-1 (Registration Nos. 333-140694 and 333-142952), as amended, were declared effective for our initial public offering, pursuant to which we offered and sold 8,365,000 shares of common stock and received net proceeds of approximately $113.4 million, after deducting underwriting discounts and offering commissions of approximately $8.8 million and other offering costs of approximately $3.3 million. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any affiliates of ours. All of the shares of common stock issued pursuant to the registration statements were sold at a price to the public of $15.00 per share. The managing underwriters were J.P. Morgan Securities Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Thomas Weisel Partners LLC and Leerink Swann & Co., Inc.

As of December 31, 2008, we have used all of the net proceeds we received from our initial public offering for working capital and other general corporate purposes, including financing our growth, the expansion of our OmniPod production capacity, the continued expansion of our sales and marketing activities and the funding of our research and development efforts. There has been no material change in the planned use of proceeds from our initial public offering as described in the final prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b).

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. *SELECTED FINANCIAL DATA*

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except share and per share data)				
Consolidated Statements of Operations Data:					
Revenue(1)	$ 36,059	$ 13,372	$ 3,663	$ 50	$ —
Cost of revenue	40,643	25,733	15,660	1,530	—
Gross loss	(4,584)	(12,361)	(11,997)	(1,480)	—
Operating expenses:					
Research and development	13,104	10,391	8,094	10,764	9,026
General and administrative	23,750	13,922	8,389	5,490	3,950
Sales and marketing	39,734	16,141	6,165	3,771	1,177
Restructuring and impairment of assets	8,170	1,027	—	—	—
Total operating expenses(2)	84,758	41,481	22,648	20,025	14,153
Operating loss	(89,342)	(53,842)	(34,645)	(21,505)	(14,153)
Other income (expense), net	(3,449)	377	(460)	(131)	332
Change in value of preferred stock warrant liability	—	(74)	(845)	—	
Net loss	(92,791)	(53,539)	(35,950)	(21,636)	(13,821)
Accretion of redeemable convertible preferred stock	—	—	(222)	—	(64)
Net loss attributable to common shareholders	$ (92,791)	$ (53,539)	$ (36,172)	$ (21,636)	$ (13,885)
Net loss per share basic and diluted	$ (3.36)	$ (3.21)	$ (99.72)	$ (70.95)	$ (47.86)
Weighted-average number of shares used in calculating net loss per share(3)	27,611,003	16,688,418	362,750	304,962	290,140

	As of December 31,				
	2008	2007	2006	2005	2004
			(In thousands)		
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 56,663	$ 94,588	$ 33,231	$ 7,660	$23,999
Working capital	$ 71,531	$ 87,723	$ 785	$ 5,168	$22,151
Total assets	$109,229	$130,741	$ 57,140	$ 16,792	$27,121
Current debt	$ —	$ 10,671	$ 29,222	$ 1,479	$ 11
Long-term debt, net of current portion(4)	$ 85,000	$ 16,006	$ —	$ 8,302	$ —
Other long-term liabilities	$ 2,987	$ 1,431	$ 316	$ 315	$ —
Redeemable convertible preferred stock	$ —	$ —	$ 119,509	$ 69,500	$69,500
Total stockholders' (deficit) equity	$ 4,274	$ 92,275	$(101,765)	$(66,091)	$44,509

(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.

(2) Effective January 1, 2006, we adopted FASB Statement No. 123(R), *Share-Based Payment.* In accordance with the provision of Statement 123(R), we recognized expenses of $3.4 million in 2008, $1.5 million in

2007 and $0.3 million in 2006. See Note 10 to our consolidated financial statements included in this Annual Report on Form 10-K.

(3) In connection with our initial public offering of common stock in May 2007, we sold 8.4 million shares of common stock and 17.4 million redeemable convertible preferred stock converted into shares of common stock.

(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. See Note 8 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.

From inception through the year ended December 31, 2005, we devoted substantially all of our efforts to designing and developing the OmniPod System, raising capital and recruiting personnel. As a result, we were considered a development stage company pursuant to Statement of Financial Accounting Standards, or SFAS, No. 7, *Accounting and Reporting by Development Stage Enterprises*, through December 31, 2005. The year 2006 was the first year during which we were an operating company and were no longer in the development stage. In October 2005, we shipped our first commercial OmniPod System. Since October 2005, in order to align the demand for the OmniPod System with our capacity to manufacture the OmniPod, 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. We focus our sales towards key diabetes practitioners, academic centers and clinics specializing in the treatment of diabetic patients. Our total revenues were $36.1 million, $13.4 million and $3.7 million for the years ended December 31, 2008, 2007 and 2006, respectively.

During 2008, construction was completed 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 entered into on January 3, 2007 and revised on October 4, 2007. 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 to Flextronics. The initial term of the agreement is three years from January 3, 2007, with automatic one-year renewals. 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 were able to substantially increase production volumes for the OmniPod and reduce our per unit production cost. We also produce certain sub-assemblies for the OmniPod as well as maintain packaging operations at our facility in Bedford, Massachusetts.

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, and we believe that substantially all of the units sold have been reimbursed by third-party payors, subject to applicable deductible and co-payment amounts. 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, 2008, 2007 and 2006, we incurred net losses of $92.8 million, $53.5 million and $36.2 million, respectively. As of December 31, 2008, we had an accumulated deficit of $248.4 million. We have financed our operations through the private placement of equity securities, public offerings of our common stock as well as a private placement of our convertible debt. As of December 31, 2008, we had $85.0 million of convertible debt outstanding. Since inception, we have received net proceeds of $327.0 million from the issuance of redeemable convertible preferred stock, common stock and convertible debt.

In May 2007, in our initial public offering, we issued and sold 7,700,000 shares of common stock to the public at a price of $15.00 per share. In June 2007, we issued and sold an additional 665,000 shares of common stock to the public at a price of $15.00 per share pursuant to the underwriters' partial exercise of their over-allotment option. In connection with the initial public offering, including the partial exercise of the over-allotment option, we received total gross proceeds of $125.5 million, or approximately $113.4 million of net proceeds after deducting underwriting discounts and offering expenses.

In November 2007, in a public offering of 4,898,398 shares of our common stock at a price to the public of $23.25 per share by certain of our stockholders, we issued and sold an additional 459,759 shares of common stock at the public offering price pursuant to the underwriters' exercise of their over-allotment option. In connection with the public offering, we received total gross proceeds of $10.7 million, or approximately $9.2 million in net proceeds after deducting underwriting discounts and offering expenses. We did not receive any proceeds from the sale of shares by the selling stockholders.

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. In connection with the private placement of our convertible debt, we received total gross proceeds of $85.0 million, or approximately $81.5 million in net proceeds after deducting the initial purchasers' discounts and offering expenses.

On March 13, 2009, we entered into a facility agreement with certain institutional accredited investors, pursuant to which the investors agreed to loan up to $60 million, subject to the terms and conditions set forth in the Facility Agreement. Following the initial disbursement of $27.5 million within fifteen business days of March 13, 2009, we may, but are not required to, draw down on the facility in $6.5 million increments at any time until November 2010 provided that we meet certain financial milestones. While we can not provide assurance that we will meet any or all of these financial milestones, based upon current estimates and assumptions, we expect to be able, at our discretion, to draw down at least an additional $26.0 million under this facility. Upon execution of this facility agreement, we issued to the lenders warrants to purchase an aggregate of 3.75 million shares of our common stock at an exercise price of $3.13 per share in connection with the initial $27.5 million draw down from the facility. As noted above, pursuant to the facility agreement, we have the right to request from the lenders one or more cash disbursements in the minimum amount of $6.5 million per disbursement, and each such disbursement will be accompanied by the issuance to the lenders of warrants to purchase an aggregate of 0.3 million shares of common stock, at an exercise price equal to 120% of the average volume weighted average price of our common stock on the fifteen consecutive trading days beginning with the date following receipt by the lenders of the disbursement request. If we, in our discretion, draw down the entire $60.0 million credit facility, we will have issued warrants to purchase a total of 5.25 million shares of our common stock. See Note 14 for a summary of this financing.

Our long-term financial objective is to achieve and sustain profitable growth. Our efforts for 2009 will be focused primarily on continuing to reduce our per-unit production costs, expanding sales to domestic and international markets and reducing our spending on manufacturing overhead and operating expenses. The continued expansion of our manufacturing capacity will help us to achieve lower material costs due to volume purchase discounts and improved absorption of manufacturing overhead costs, reducing our cost of revenue as a percentage of revenue. 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 market and enter certain international markets. We believe that we will continue to incur net losses in the near term in order to achieve these objectives, particularly in light of the recession in the United States and the slowdown of economic growth in the rest of the world which is creating a challenging near term business environment. 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, including the net proceeds from our public and private offerings and draw downs on our up to $60 million credit facility, 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 2009.

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 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 incurred interest expense of approximately $2.8 million for the year ended December 31, 2008, related to the 5.375% Notes. We incurred deferred financing costs related to this offering of approximately $3.5 million, which are recorded in the condensed consolidated balance sheet and are being amortized as a component of interest expense over the five year term of the notes.

We received net proceeds of approximately $81.5 million from this offering. Approximately $23.2 million of the net proceeds from this offering was used to repay and terminate our 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. We are using the remainder for general corporate purposes. We incurred interest expense of approximately $1.5 million, $3.2 million and

$1.8 million on the term loan for the years ended December 31, 2008, 2007 and 2006 respectively. The term loan was subject to a loan origination fee of $0.9 million, which was recorded in the condensed consolidated balance sheet and was being 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, 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. We 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, we 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 unamortized warrants to purchase common stock, was recognized as a $1.5 million loss from early extinguishment of the term loan.

In connection with the adoption of FSP APB 14-1 in the first quarter of 2009, we will reclassify a portion of the debt related to the 5.375% Notes to equity. We anticipate that the reclassification of approximately $20 to $30 million of long-term debt to equity will result in approximately $3 to $5 million in additional non-cash interest expense during 2009.

Financial Operations Overview

Revenues. Revenues are recognized in accordance with Securities and Exchange Staff Accounting Bulletin No. 104, or SAB 104, and Statement of Financial Accounting Standards No. 48, *Revenue Recognition when the Right of Return Exists*, or SFAS 48. We derive most of our revenues 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. Revenues are derived from the sale to new customers or third-party distributors of OmniPods and Starter Kits, which include the PDM, two OmniPods, 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. During the years ended December 31, 2008, 2007 and 2006, materially all of our revenues were derived from sales within the United States.

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 an amount for services performed by us in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to a new customer. We recognize the revenue related to this portion of the Abbott agreement at the time the revenue is recognized on the sale of the PDM to the patient. In the year ended December 31, 2008, we recognized $2.5 million of revenue, related to the amended Abbott agreement. There was no impact to cost of revenue related to this agreement.

Prior to January 1, 2008, we deferred recognition of revenue from the OmniPods and Starter Kit shipped as part of a customer's initial shipment for 45 days during which time the items could be returned and completely refunded. Effective for shipments made after December 31, 2007, we have deferred revenue based on estimated returns, assessment of collectibility and the transfer of risk and title. If we had continued to defer all initial shipments until the 45-day right of return had expired, deferred revenue as of December 31, 2008 would have been larger by approximately $1.4 million. As of December 31, 2008 and 2007, the balance of deferred revenue was $4.0 million and $1.4 million, respectively, which includes the current portion of deferred revenue related to the agreement fee received under the first amendment to our development agreement with Abbott.

For the year ending December 31, 2009, we expect our revenues to increase. We expect our OmniPod sales and production to grow. Our OmniPod manufacturing capacity at the end of 2008 was in excess of 250,000 OmniPods per month. Additionally, increased revenues will be dependent upon the success of our sales efforts and subject to many risk and uncertainties.

Cost of revenues. Cost of revenues consists primarily of raw material, labor, warranty and overhead costs related to the OmniPod System. Cost of revenues also includes depreciation, freight and packaging costs.

The increase in our OmniPod manufacturing production, as well as increased use of contract manufacturers, is expected to reduce the per-unit cost of manufacturing the OmniPods by allowing us to spread our fixed and semi-fixed overhead costs over a greater number of units. However, if sales volumes do not increase, then the average cost of revenues per OmniPod may not decrease and we may incur gross losses.

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 2009, we expect overall research and development spending to be in line with current levels in order to support our current research and development efforts, which are focused primarily on increased functionality, design for ease of use and reduction of production cost, as well as developing a new OmniPod System that incorporates continuous glucose monitoring technology.

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, 2009, we expect sales and marketing expenses to decrease as a percentage of sales compared to 2008 as we continue to align our sales and marketing efforts with our business needs.

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 be at a similar level in 2009 compared to 2008.

Restructuring expenses 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 restructuring activity or an impairment of assets based on current net book value and potential future use of the assets. We recorded asset impairment charges of $7.4 million and $1.0 million in the years ended December 31, 2008 and 2007, respectively.

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. We recorded workforce related charges of $0.8 million in the year ended December 31, 2008. No workforce related charges were recorded in the year ended December 31, 2007.

Stock based compensation expense. Prior to January 1, 2006, we accounted for our stock-based awards under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations, as permitted by the Financial Accounting Standards Board Statement No. 123, *Accounting for Stock-Based Compensation,* or SFAS 123. Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS Statement No. 123 (revised 2004), *Share-Based Payment,* or SFAS 123R, using the prospective method.

Results of Operations for the Fiscal Years Ended December 31, 2008, 2007 and 2006

The following table presents certain statement of operations information for the years ended December 31, 2008, 2007 and 2006:

	Year Ended December 31,			Year Ended December 31,		
	2008	2007	% Change	2007	2006	% Change
			(Dollar amounts in thousands)			
Revenue	$ 36,059	$ 13,372	170%	$ 13,372	$ 3,663	265%
Cost of revenue	40,643	25,733	58%	25,733	15,660	64%
Gross loss	(4,584)	(12,361)	63%	(12,361)	(11,997)	3%
Operating expenses:						
Research and development	13,104	10,391	26%	10,391	8,094	28%
General and administrative	23,750	13,922	71%	13,922	8,389	66%
Sales and marketing	39,734	16,141	146%	16,141	6,165	162%
Restructuring and impairment of assets	8,170	1,027	696%	1,027	—	—
Total operating expenses	84,758	41,481	104%	41,481	22,648	83%
Operating loss	(89,342)	(53,842)	66%	(53,842)	(34,645)	55%
Other income (expense), net	(3,449)	303	1238%	303	(1,305)	123%
Net loss(1)	$(92,791)	$(53,539)	73%	$(53,539)	$(35,950)	49%

(1) Net loss for the years ended December 31, 2008, 2007 and 2006 includes $3.4 million, $1.5 million and $0.3 million, respectively, for stock based compensation expense attributable to common stockholders as required by SFAS 123R. We adopted SFAS 123R on a prospective basis.

Comparison of the Years Ended December 31, 2008 and December 31, 2007

Revenues

Our total revenues were $36.1 million for year ended December 31, 2008, as compared to $13.4 million for the year ended December 31, 2007. The increase in revenues is due to the increase in the number of diabetes patients using the OmniPod System as well as new relationships with third-party distributors who resell our product to diabetes patients.

Cost of Revenues

Cost of revenues was $40.6 million for the year ended December 31, 2008, as compared to $25.7 million for the year ended December 31, 2007. The increase is due to increased sales volume partially offset by lower per-unit costs. Cost of revenues includes adjustment of inventory to the lower of cost or market and indirect costs. Since the OmniPods were sold at a price below direct manufacturing costs in 2007, the inventory adjustment made as of December 31, 2007 increased cost of revenues by $0.6 million. There was no adjustment made as of December 31, 2008. This is a result of a reduced cost of raw materials and increased volumes which improved the absorption of manufacturing overhead costs. During the third quarter, we incurred production costs for the OmniPod which were lower than its selling price, primarily due to increased production volumes of the OmniPod which improved positive gross margin on sales of our OmniPod system.

Research and Development

Research and development expense increased $2.7 million, or 26.1%, to $13.1 million for the year ended December 31, 2008, as compared to $10.4 million for the year ended December 31, 2007. For the year ended December 31, 2008 the increase in expense was primarily attributable to an increase of $2.4 million in employee related expenses, $0.5 million in consulting services, $0.5 million in tools and supplies, offset by a $0.7 million decrease in prototype and other expenses.

General and Administrative

General and administrative expense increased $9.8 million, or 70.6%, to $23.7 million for the year ended December 31, 2008, as compared to $13.9 million for the year ended December 31, 2007. For the year ended December 31, 2008, the increase in expense was primarily due to an increase of $2.6 million in employee related expenses primarily with respect to the hiring of additional employees, $3.2 million related to allowances for doubtful accounts, $0.5 million in consulting related expenses, $1.3 million in increased depreciation expense, $0.3 million for travel expenses and $0.8 million in increased freight expense.

Sales and Marketing

Sales and marketing expenses increased $23.6 million, or 146.2%, to $39.7 million for the year ended December 31, 2008, as compared to $16.1 million for the year ended December 31, 2007. The increase in expenses for the year ended December 31, 2008, was primarily due to an increase of $11.2 million in employee related expenses resulting from the hiring of additional employees in our sales and marketing departments, $3.8 million in patient demonstration kit units and other supplies, $2.6 million in travel expenses, $3.1 million in marketing consultants which include our external trainers and $1.5 million in printing and tradeshow expenses used to support our selling efforts.

Restructuring and Impairment of Assets

Restructuring expenses and impairment of assets was $8.2 million for the year ended December 31, 2008, compared to $1.0 million for the year ended December 31, 2007. 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 the 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.

Employees terminated were mainly in the manufacturing and quality departments. In addition, certain members of senior management were terminated. This reduction was primarily in response to our successful transition of portions of the manufacturing process to Flextronics as well as on-going alignment of our infrastructure.

During the third quarter of 2008, we successfully transitioned our production of completed OmniPods to the manufacturing line operated by Flextronics. Pursuant to our agreement with Flextronics, Flextronics will supply, as a non-exclusive supplier, OmniPods at agreed upon prices per unit pursuant to a rolling 12-month forecast provided by us. The initial term of the agreement is three years from January 3, 2007, with automatic one-year renewals. 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. We continue to manufacture certain sub-assemblies and maintain packaging operations in our Bedford, Massachusetts facility.

We ceased to use certain assets in our Bedford facility in connection with the transition of manufacturing to Flextronics. We 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 we concluded that the capacity of the manufacturing line operated by Flextronics is considered adequate to meet anticipated demand and quality standards in the future. As we determined that we will no longer use the Bedford equipment on December 1, 2008, we 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.

At December 31, 2008, our accrued restructuring was $0.6 million for final payments of severance and will be utilized during 2009.

The following is a summary of restructuring activity for the year ended December 31, 2008:

	Year Ended December 31, 2008
	Workforce and Related
	(In thousands)
Balance at the beginning of year	$ —
Restructuring expense	758
Utilization	(146)
Balance at the end of the year	$ 612

During the year ended December 31, 2007, we completed the evaluation of an upgrade of our manufacturing processes. The upgrade of our product design and associated manufacturing processes were aimed at achieving lower per-unit costs. As a result, we performed a review of certain production equipment. The review resulted in a non-cash charge of $1.0 million for the write-down of certain impaired assets. The impaired assets, which had no future use, consisted of manufacturing equipment. The impairment charges were recorded following determination of the fair value of cash flows resulting from use of the affected assets, and the carrying value of the assets has been reduced to reflect their fair value.

Other Income (Expense)

Interest income was $1.8 million for the year ended December 31, 2008, as compared to $3.5 million during the year ended December 31, 2007. This represents a decrease of $1.7 million compared to the year ended December 31, 2007, 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 $5.2 million for the year ended December 31, 2008, as compared to $3.2 million for the year ended December 31, 2007. This represents an increase of $2.1 million compared to the year ended December 31, 2007. The increase in interest expense was attributable to higher debt levels under our $30 million debt note and interest on the 5.375% Notes.

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. 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. As a result of the determination of fair value, we recorded other expenses of approximately $0.1 million in the year ended December 31, 2007, as the aggregate fair value of warrants decreased from the value recorded at March 31, 2007. The decrease in fair value was primarily caused by a lower expected life for the warrants, considering the existence of a market for our company's common stock.

Comparison of the Years Ended December 31, 2007 and December 31, 2006

Revenues

Our total revenues were $13.4 million for year ended December 31, 2007, as compared to $3.7 million for the year ended December 31, 2006. The increase in revenues is due to the increase in the number of customers using the OmniPod system.

Cost of Revenues

Cost of revenues was $25.7 million for the year ended December 31, 2007, as compared to $15.7 million for the year ended December 31, 2006. The increase is due to increased sales volume partially offset by lower per-unit costs. Cost of revenues includes adjustment of inventory to the lower of cost or market and indirect costs. Since the OmniPods are sold at a price below direct manufacturing costs, the inventory adjustment made as of December 31, 2007 increased cost of revenues by $0.6 million for the year ended December 31, 2007. This decrease is a result of a reduced cost of raw materials and increased volumes which improved the absorption of manufacturing overhead costs.

Research and Development

Research and development expense increased $2.3 million, or 28.4%, to $10.4 million for the year ended December 31, 2007, as compared to $8.1 million for the year ended December 31, 2006. For the year ended December 31, 2007 the increase in expense was primarily attributable to an increase of $1.1 million in employee related expenses, $0.8 million in consulting services, $0.2 million in travel expenses, and $0.2 million in tools and other expenses.

General and Administrative

General and administrative expense increased $5.5 million, or 66.0%, to $13.9 million for the year ended December 31, 2007, as compared to $8.4 million for the year ended December 31, 2006. For the year ended December 31, 2007, the increase in expense was primarily due to an increase of $2.4 million in employee related expenses primarily with respect to the hiring of additional employees, $1.0 million related to allowances for doubtful accounts, $0.9 million in consulting and legal expenses, $0.6 million in audit related expenses, $0.4 million in increased depreciation expense, $0.3 million for travel expenses, $0.3 million in increased insurance expense, and $0.4 million in other expenses. The increased expenses in 2007 compared to 2006 were partly offset by a reduction of $0.7 million for expenses related to asset disposals.

Sales and Marketing

Sales and marketing expenses increased $10.0 million, or 161.8%, to $16.1 million for the year ended December 31, 2007, as compared to $6.2 million for the year ended December 31, 2006. The increase in expenses for the year ended December 31, 2007, was primarily due to an increase of $4.4 million in employee related expenses resulting from the hiring of additional employees in our sales and marketing departments, $2.4 million in patient demonstration kit units, $1.5 million in travel expenses, $1.0 million in marketing consultants which include our external trainers, $0.3 million in printing and tradeshow expenses used to support our selling efforts, and $0.3 million in other marketing expenses.

Restructuring Expenses and Impairment of Assets

During the year ended December 31, 2007, we completed the evaluation of an upgrade of our manufacturing processes. The upgrade of our product design and associated manufacturing processes were aimed at achieving lower per-unit costs. As a result, we performed a review of certain production equipment. The review resulted in a non-cash charge of $1.0 million for the write-down of certain impaired assets. The impaired assets, which had no future use, consisted of manufacturing equipment. The impairment charges were recorded following determination of the fair value of cash flows resulting from use of the affected assets, and the carrying value of the assets has been reduced to reflect their fair value.

Other Income (Expense)

Interest income was $3.5 million during the year ended December 31, 2007. This represents an increase of $2.2 million compared to the year ended December 31, 2006, caused primarily by higher cash balances. Interest income was earned from cash deposits and short-term interest bearing instruments. Interest expense was $3.2 million during the year ended December 31, 2007. This represents an increase of $1.3 million

compared to the year ended December 31, 2006. The increase in interest expense was attributable to higher debt levels under our $30 million debt note.

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. 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. As a result of the determination of fair value, we recorded other expenses of approximately $0.1 million in the year ended December 31, 2007, as the aggregate fair value of warrants decreased from the value recorded at March 31, 2007. The decrease in fair value was primarily caused by a lower expected life for the warrants, considering the existence of a market for our company's common stock.

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 and our initial public offering of our common stock in May 2007 and a subsequent public offering of our common stock in November 2007. Since inception, we have received net proceeds of $327.0 million from the issuance of redeemable convertible preferred stock, common stock and convertible debt. As of December 31, 2008, we had $56.7 million in cash and cash equivalents.

On March 13, 2009, we entered into a facility agreement with certain institutional accredited investors, pursuant to which the investors agreed to loan up to $60 million, subject to the terms and conditions set forth in the Facility Agreement. Following the initial disbursement of $27.5 million within fifteen business days of March 13, 2009, we may, but are not required to, draw down on the facility in $6.5 million increments at any time until November 2010 provided that we meet certain financial milestones. While we can not provide assurance that we will meet any or all of these financial milestones, based upon current estimates and assumptions, we expect to be able, at our discretion, to draw down at least an additional $26.0 million under this facility. Upon execution of this facility agreement, we issued to the lenders warrants to purchase an aggregate of 3.75 million shares of our common stock at an exercise price of $3.13 per share in connection with the initial $27.5 million draw down from the facility. As noted above, pursuant to the facility agreement, we have the right to request from the lenders one or more cash disbursements in the minimum amount of $6.5 million per disbursement, and each such disbursement will be accompanied by the issuance to the lenders of warrants to purchase an aggregate of 0.3 million shares of common stock, at an exercise price equal to 120% of the average volume weighted average price of our common stock on the fifteen consecutive trading days beginning with the date following receipt by the lenders of the disbursement request. If we, in our discretion, draw down the entire $60.0 million credit facility, we will have issued warrants to purchase a total of 5.25 million shares of our common stock. See Note 14 for a summary of this financing.

We believe that our cash and cash equivalents, including the net proceeds from our public and private offerings and draw downs on our up to $60 million credit facility, 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 lease the end of 2009.

In May 2007, in our initial public offering, we issued and sold 7,700,000 shares of common stock at a price to the public of $15.00 per share. In June 2007, we 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 option. In connection with our initial public offering, including the partial exercise of the over-allotment option, we received total net proceeds of $113.4 million. As of December 31, 2008, we had used all of these proceeds in connection with our efforts to expand our manufacturing capacity, expand our sales and marketing activities and fund our research and development, among other general corporate purposes.

In November 2007, in a public offering of 4,898,398 shares of our common stock at a price to the public of $23.25 per share by certain of our stockholders, we issued and sold an additional 459,759 shares of common stock at the public offering price pursuant to the underwriters' exercise of their over-allotment option. In connection with the public offering, we received total gross proceeds of $10.7 million, or approximately

$9.2 million in net proceeds after deducting underwriting discounts and offering expenses. We did not receive any proceeds from the sale of shares by the selling stockholders. We used these proceeds in connection with our efforts to expand our manufacturing capacity, expand our sales and marketing activities and fund our research and development, among other general corporate purposes.

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. In connection with the private placement of our convertible debt, we received total gross proceeds of $85.0 million, or approximately $81.5 million in net proceeds after deducting underwriting discounts and offering expenses. We are using these proceeds for general corporate purposes.

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,		
	2008	2007	2006
		(In thousands)	
Cash used in operating activities	$(82,611)	$(50,372)	$(31,820)
Net loss	$(92,791)	$(53,539)	$(35,950)

Net cash used in operating activities primarily represents funds utilized in the development and commercialization of the OmniPod System. The increase of $32.2 million in cash used in operating activities for the year ended December 31, 2008 compared to the year ended December 31, 2007 was due primarily to the growth in our activities that continued to result in a loss, increased net accounts receivable of $6.9 million, partly offset by an increase of $3.1 million in the provision for doubtful accounts, an increase in inventory of $4.3 million and increased prepaids and other current assets of $2.1 million, partially offset by increases in accounts payable and accrued expenses of $3.5 million. The increase in accounts receivable balance is related to increased sales and slower than expected collections. The increase in inventory is a result of improved manufacturing capacity and increased patient count.

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,		
	2008	2007	2006
		(In thousands)	
Cash used in investing activities	$(10,047)	$ (10,089)	$(12,587)
Cash provided by financing activities	$ 54,733	$121,818	$ 69,978

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, 2008, 2007 and 2006. Cash provided by financing activities was primarily generated from our private placement of our convertible debt in 2008, offerings of our common stock in 2007 and from private placement of our preferred stock and secured indebtedness in 2006.

In February 2006, we sold 13,738,661 shares of Series E preferred stock for net proceeds of $49.8 million. In February 2004, we sold 14,669,421 shares of Series D preferred stock for net proceeds of $35.4 million. All of these preferred shares converted into shares of common stock on a 1-for-2.6267 basis upon the closing of our initial public offering.

In June 2005, we entered into a term loan and security agreement with Lighthouse Capital Partners V, L.P. pursuant to which we borrowed $10.0 million. This term loan was secured by all of our assets other than our intellectual property. Our borrowings under the term loan bore interest at a rate of 8% per annum. Interest

was payable on a monthly basis during the term of the loan and beginning on June 1, 2006, we were required to repay the principal in 42 equal monthly installments until the loan matured in December 2009. Upon the prepayment or final maturity of the term loan, we were required to pay the lender an additional amount equal to $1.0 million of the original loan amount. In connection with the term loan, we issued a warrant to the lender to purchase up to 330,579 shares of Series D preferred stock at a purchase price of $2.42 per share. The warrant automatically converted into a warrant to purchase common stock on a 1-for-2.6267 basis at a purchase price of $6.36 per share upon the closing of our initial public offering. The cost of the warrant was being amortized to interest expense over the 54 month life of this term loan. The fair value of the warrant was calculated using the Black-Scholes option pricing model with the following assumptions: seven year expected life risk-free, interest rate of 3.89% and no dividend yield.

In December 2006, we entered into a credit and security agreement with a group of lenders led by Merrill Lynch Capital pursuant to which we borrowed $30.0 million in a term loan. We used $9.5 million of the proceeds from this term loan to repay all remaining amounts owed under the loan with Lighthouse Capital Partners V, L.P. that we had entered into in June 2005. This term loan was secured by all of our assets other than our intellectual property. Our borrowings under the term loan bore interest at a floating rate equal to the LIBOR rate plus 6% per annum. Interest was payable on a monthly basis during the term of the loan and we began repayment of the principal 33 equal monthly installments of $0.9 million in October 2007. In addition, we were subject to loan origination fees amounting to $0.9 million for the costs incurred by the lenders in making the funds available. We capitalized these costs as deferred financing costs. The deferred financing cost was being amortized to interest expense over the entire 42-month life of this term loan. This term loan was subject to acceleration upon the occurrence of any fact, event or circumstance that has resulted or could reasonably be expected to result in a material adverse effect. Consequently, due to our low cash resources, relative to our operating losses, prior to our initial public offering, all of such debt was classified as a current liability at December 31, 2006 in accordance with the provisions set forth by *FASB Technical Bulletin No. 79-3 Subjective Acceleration Clauses in Long-Term Debt Agreements.* In connection with the term loan, we issued seven-year warrants expiring in December 2013 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 upon the closing of our initial public offering.

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, per $1,000 principal amount of the 5.375% Notes, 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 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.

We received net proceeds of approximately $81.5 million from the sale of the 5.375% Notes. On June 16, 2008, we used a portion of the net proceeds to repay the entire outstanding principal balance, plus accrued and unpaid interest, under our existing term loan in the aggregate of approximately $21.8 million in its entirety. Additionally, we paid a prepayment fee related to the term loan of approximately $0.4 million, a termination

fee related to the term loan of $0.9 million, and incurred certain other expenses related to the repayment and termination of the term loan.

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, 2008, we had an outstanding letter of credit which totaled $0.2 million to cover our security deposits for lease obligations. This letter of credit will expire October 30, 2009.

During the year ending December 31, 2009, we will be expending funds in connection with, among other things, our efforts to increase our production capacity and expand our sales and marketing activities to international markets.

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 14, 2008. In addition, one Right will automatically attach to each share of common stock issued between November 14, 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 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, 2008, we did not have any off-balance sheet financing arrangements.

Contractual Obligations

The following table summarizes our principal contractual obligations as of December 31, 2008. Amounts in thousands:

	Payments Due by Period				
Contractual Obligations	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating lease obligations	$ 4,401	$ 841	$ 1,655	$ 1,412	$493
Long-term debt obligations(1)	105,560	4,569	9,138	91,853	—
Purchase obligations for production components	21,493	18,267	3,226	—	—
Total contractual obligations	$131,454	$23,677	$14,019	$93,265	$493

(1) The interest rate on the long-term 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.

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, two OmniPods, 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 is recognized in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements*, or SAB 104, which 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 their receipt 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 have considered the requirements of Emerging Issues Task Force, or EITF, No. 00-21, *Revenue Arrangements with Multiple Deliverables*, when accounting for the OmniPods and Starter Kits. EITF 00-21 requires that 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 have applied Statement of Financial Accounting Standards No. 48, *Revenue Recognition When the Right of Return Exists*, or SFAS No. 48. In accordance with SFAS No. 48, we defer the 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 gross product sales.

Prior to January 1, 2008, we deferred the revenue and related costs of revenue for all initial shipments until the 45-day right of return had lapsed. With the accumulation of approximately 2 years of data for sales and return rates, we concluded that we had sufficient historical data on which to base our estimated returns

from January 1, 2008. If we had continued to defer all initial shipments until the 45-day right of return had expired, deferred revenue as of December 31, 2008 would have been larger by $1.4 million.

When doubt exists about reasonable assuredness of collectibility from specific customers, we defer revenue from sales of products to those customers until payment is received.

In 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 between us and Abbott. We recognize the agreement fee received from Abbott over the 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 us an amount for services performed by us in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to a new customer. We recognize the revenue related to this portion of the Abbott agreement at the time the revenue is recognized on the sale of the PDM to the patient. In the year ended December 31, 2008, we recognized $2.5 million of revenue related to the amended Abbott agreement. There was no impact to cost of revenue related to this agreement.

We recognize subsequent sales of OmniPods upon shipment in accordance with the provisions set forth by SAB 104.

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.

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. 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

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN No. 48, which clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS No. 109. FIN 48 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, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We adopted FIN 48 on January 1, 2007. The adoption of FIN 48 did not have a material impact on our financial position or results of operations. Upon adoption and as of December 31, 2008 and 2007, we have no unrecognized tax benefits recorded.

Stock Based Compensation

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share Based Payment*, or SFAS 123R, which is a revision of Statement No. 123, or SFAS 123, *Accounting for Stock Based Compensation*. SFAS 123R supersedes Accounting Principles Board No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and amends FASB Statement No. 95 *Statement of Cash Flows*. SFAS 123R 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.

SFAS 123R requires nonpublic companies that used the minimum value method in SFAS 123R for either recognition or pro forma disclosures to apply SFAS 123R using the prospective-transition method. As such, we will continue to apply APB 25 in future periods to equity awards outstanding at the date of SFAS 123R adoption that were measured using the minimum value method. In accordance with the requirements of SFAS 123R, we will not present pro forma disclosures for periods prior to the adoption of SFAS 123R, as the estimated fair value of our stock options granted through December 31, 2005 was determined using the minimum value method.

Effective January 1, 2006 with the adoption of SFAS 123R, we elected to use the Black-Scholes option pricing model to determine the weighted-average fair value of options granted. In accordance with SFAS 123R, 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, 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, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation". 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.

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. Until the completion of our initial public offering, these warrants were recorded as "warrants to purchase shares subject to redemption" in current liabilities in accordance with FASB Statement No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity,* or SFAS 150, and FASB Staff Position No. 150-5 *Issuer's Accounting under FASB Statement No. 150 for Freestanding Warrants and Other Similar Instruments on Shares That Are Redeemable*, or FSP 150-5.

Significant terms and fair values of warrants to purchase redeemable convertible preferred 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, 2008	Common Shares as of December 31, 2007	Fair Value as of December 31, 2008	Fair Value as of December 31, 2007
Series E preferred . . .	December 27, 2013	9.56	62,752	62,752	—	—

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 or ending 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.

In the year ended December 31, 2007, Lighthouse Capital Partners V, L.P. exercised their right to convert 125,853 warrants into common stock, resulting in the issuance and purchase of 89,821 shares of our common stock at $6.36 per share. In addition, two members of the group of lenders led by Merrill Lynch Capital exercised their right to convert a total of 31,376 warrants into common stock, resulting in the issuance of 21,376 shares of our common stock.

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.

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. We base our allowance 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.

Recent Accounting Pronouncements

In May 2008, the FASB issued Staff Position Accounting Principles Board 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ("FSP APB 14-1"), which is effective for fiscal years beginning after December 15, 2008. FSP APB 14-1 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. We anticipate that the reclassification of approximately $20 to $30 million of long-term debt to equity under the provisions of FSP APB 14-1 will result in approximately $3 to $5 million in additional interest expense during 2009. We do not anticipate the adoption of FSP APB 14-1 to impact to our cash flows during the year ending December 31, 2009.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ("SFAS 162"). This standard identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the United States. SFAS 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles. We are currently evaluating the potential effect of implementing this standard.

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, 2008, we had outstanding debt recorded at $85.0 million. Changes in interest rates do not affect the value of our debt or interest expense.

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, 2008. 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, 2008, 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 have been no significant changes in our internal control over financial reporting during the quarterly period ended December 31, 2008 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, 2008. 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, 2008, 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, 2008 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.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of
Insulet Corporation

We have audited Insulet Corporation's internal control over financial reporting as of December 31, 2008, 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, 2008, 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, 2008 and 2007 and the related consolidated statements of operations, consolidated statements of redeemable convertible preferred stock and changes in stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2008 and our report dated March 13, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 13, 2009

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 2009 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, 2008.

Audit Committee Financial Expert

The audit committee of our board of directors currently consists of Steven Sobieski (Chairman), Charles Liamos 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 each member of the audit committee qualifies 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 each member has 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 2009 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, 2008.

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 2009 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, 2008. For information on securities authorized for issuance

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 2009 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, 2008.

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 2009 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, 2008.

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 Web site maintained by the SEC at http://www.sec.gov.

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 16, 2009

/s/ Brian Roberts
Brian Roberts
Chief Financial Officer

Date: March 16, 2009

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 16, 2009.

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/ Sally Crawford Sally Crawford	Director
/s/ Gary Eichhorn Gary Eichhorn	Director
/s/ Ross Jaffe, M.D. Ross Jaffe, M.D.	Director
/s/ Charles Liamos Charles Liamos	Director

Signature	Title
/s/ Steven Sobieski Steven Sobieski	Director
/s/ Regina Sommer Regina Sommer	Director
/s/ Joseph Zakrzewski Joseph Zakrzewski	Director

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
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

Number	Description
10.22(9)	Amended and Restated 2007 Stock Option and Incentive Plan
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	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.

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* 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

(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 Form 8-A, filed November 20, 2008

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

The Board of Directors
Insulet Corporation

We have audited the accompanying consolidated balance sheets of Insulet Corporation, as of December 31, 2008 and 2007, and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements 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, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2007, the Company adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Insulet Corporation's internal control over financial reporting as of December 31, 2008, 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 13, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 13, 2009

INSULET CORPORATION

CONSOLIDATED BALANCE SHEETS

	As of December 31, 2008	As of December 31, 2007
	(In thousands, except share and per share data)	
ASSETS		
Current Assets		
Cash and cash equivalents	$ 56,663	$ 94,588
Accounts receivable, net	11,938	4,783
Inventories	16,870	7,990
Prepaid expenses and other current assets	3,028	1,391
Total current assets	88,499	108,752
Property and equipment, net	17,564	21,304
Other assets	3,166	685
Total assets	$ 109,229	$ 130,741
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 7,291	$ 4,544
Accrued expenses	7,300	4,464
Deferred revenue	2,377	1,350
Current portion of long-term debt	—	10,671
Total current liabilities	16,968	21,029
Long-term debt, net of current portion	85,000	16,006
Other long-term liabilities	2,987	1,431
Total liabilities	104,955	38,466
Stockholders' equity		
Preferred stock, $.001 par value:		
Authorized: 5,000,000 shares at December 31, 2008 and 2007		
Issued: zero shares at December 31, 2008 and 2007	—	—
Common stock, $.001 par value:		
Authorized: 100,000,000 shares at December 31, 2008 and 2007		
Issued: 27,778,921 and 27,223,820 shares at December 31, 2008 and 2007, respectively	29	28
Additional paid-in capital	252,615	247,835
Accumulated deficit	(248,370)	(155,579)
Subscription receivable	—	(9)
Total stockholders' equity	4,274	92,275
Total liabilities and stockholders' equity	$ 109,229	$ 130,741

See accompanying notes

INSULET CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2008	2007	2006
	(In thousands, except share and per share data)		
Revenue	$ 36,059	$ 13,372	$ 3,663
Cost of revenue	40,643	25,733	15,660
Gross loss	(4,584)	(12,361)	(11,997)
Operating expenses:			
Research and development	13,104	10,391	8,094
General and administrative	23,750	13,922	8,389
Sales and marketing	39,734	16,141	6,165
Restructuring and impairment of assets	8,170	1,027	—
Total operating expenses	84,758	41,481	22,648
Operating loss	(89,342)	(53,842)	(34,645)
Interest income	1,795	3,537	1,378
Interest expense	(5,244)	(3,160)	(1,838)
Net interest income (expense)	(3,449)	377	(460)
Change in value of preferred stock warrant liability	—	(74)	(845)
Net loss	(92,791)	(53,539)	(35,950)
Accretion of redeemable convertible preferred stock	—	—	(222)
Net loss attributable to common shareholders	$ (92,791)	$ (53,539)	$ (36,172)
Net loss per share basic and diluted	$ (3.36)	$ (3.21)	$ (99.72)
Weighted-average number of shares used in calculating net loss per share	27,611,003	16,688,418	362,750

See accompanying notes

INSULET CORPORATION

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Series D Warrant	Series E Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Deferred	Subscription	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Compensation	Receivable	(Deficit)
	(In thousands, except for share data)																	
Balance at December 31, 2005	1,000,000	1,000	5,945,946	11,000	10,476,191	22,000	14,669,421	35,500	251	—	—	311,508	$ 1	$ 28	$ (66,058)	$(32)	$(30)	$ (66,091)
Issuance of Series E Convertible Preferred Stock, net accretion of redeemable convertible preferred stock	—	—	—	—	—	—	—	—	—	13,738,661	49,787	—	—	—	—	—	—	—
Accretion of redeemable convertible preferred stock	—	—	—	—	—	—	—	—	—	—	222	—	—	(222)	—	—	—	(222)
Series D Warrant — Adoption of FAS 150-5	—	—	—	—	—	—	—	—	(251)	—	—	—	—	—	—	—	—	—
Exercise of options to purchase common stock	—	—	—	—	—	—	—	—	—	—	—	145,568	—	180	—	—	11	191
Deferred compensation expense related to stock options issued to nonemployees	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(32)	(32)	—	—
Compensation expense related to stock options issued to employees	—	—	—	—	—	—	—	—	—	—	—	—	—	307	—	—	—	307
Net loss															(35,950)			(35,950)
Balance at December 31, 2006	1,000,000	$ 1,000	5,945,946	$ 11,000	10,476,191	$ 22,000	14,669,421	$ 35,500	$ —	13,738,661	$ 50,009	457,076	$ 1	$ 293	$(102,040)	$ —	$(19)	$(101,765)
Exercise of options to purchase common stock	—	—	—	—	—	—	—	—	—	—	—	380,190	—	886	—	—	10	896
Issuance for employee stock purchase plan	—	—	—	—	—	—	—	—	—	—	—	2,789	—	66	—	—	—	66
Exercise of warrant to purchase common stock	—	—	—	—	—	—	—	—	—	—	—	111,197	—	150	—	—	—	150
Compensation expense related to stock options issued to employees	—	—	—	—	—	—	—	—	—	—	—	—	—	1,520	—	—	—	1,520
Conversion of preferred stock to common stock	(1,000,000)	(1,000)	(5,945,946)	(11,000)	(10,476,191)	(22,000)	(14,669,421)	(35,500)	—	(13,738,661)	(50,009)	17,447,809	18	119,491	—	—	—	119,509
Issuance of common stock, net of offering costs of $3.3 million	—	—	—	—	—	—	—	—	—	—	—	8,824,759	9	123,424	—	—	—	123,433
Conversion of warrants to purchase preferred stock to warrants to purchase common stock	—	—	—	—	—	—	—	—	—	—	—	—	—	2,005	—	—	—	2,005
Net loss															(53,539)			(53,539)
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
Compensation expense related to stock options issued to employees	—	—	—	—	—	—	—	—	—	—	—	—	—	3,352	—	—	—	3,352
Net loss															(92,791)			(92,791)
Balance at December 31, 2008	—	—	—	—	—	—	—	—	—	—	—	27,778,921	$29	$252,615	$(248,370)	$ —	$ —	$ 4,274

See accompanying notes

INSULET CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2008	2007	2006
		(In thousands)	
Cash flows from operating activities			
Net loss	$(92,791)	$ (53,539)	$(35,950)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	6,375	4,681	2,421
Amortization of debt discount	596	239	219
Redeemable convertible preferred stock warrant expense	—	74	845
Stock compensation expense	3,368	1,520	307
Provision for bad debts	4,264	1,120	149
Restructuring and impairment of assets	8,170	1,103	771
Non cash interest expense	1,034	(57)	57
Changes in operating assets and liabilities:			
Accounts receivable	(11,419)	(4,486)	(1,426)
Inventory	(8,880)	(4,600)	(2,526)
Prepaids and other current assets	(1,637)	436	(1,358)
Other assets	1	(409)	(221)
Accounts payable and accrued expenses	4,825	1,365	4,723
Other long term liabilities	2,456	1,115	1
Deferred revenue	1,027	1,066	168
Net cash used in operating activities	(82,611)	(50,372)	(31,820)
Cash flows from investing activities			
Purchases of property and equipment	(10,047)	(10,089)	(13,137)
Decrease in restricted cash	—	—	550
Net cash used in investing activities	(10,047)	(10,089)	(12,587)
Cash flows from financing activities			
Proceeds from sale of Series E preferred stock, net of issuance cost	—	—	49,787
Proceeds from issuance of debt	81,484	—	30,000
Principal payments of long term debt	(5,454)	(2,727)	(10,000)
Repayment of long-term debt	(22,719)	—	—
Proceeds from payment of subscription receivable	9	10	11
Proceeds from issuance of common stock, net of offering expenses	1,413	124,535	180
Net cash provided by financing activities	54,733	121,818	69,978
Net increase (decrease) in cash and cash equivalents	(37,925)	61,357	25,571
Cash and cash equivalents, beginning of year	94,588	33,231	7,660
Cash and cash equivalents, end of period	$ 56,663	$ 94,588	$ 33,231
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 4,018	$ 3,154	$ 1,760
Non-cash financing activities			
Accretion of redeemable convertible preferred stock	$ —	$ —	$ 222
Conversion of preferred stock to common stock upon initial public offering	$ —	$119,509	$ —

See accompanying notes

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 and marketing the OmniPod Insulin Management System. The Company was considered a development stage company pursuant to Statement of Financial Accounting Standards ("SFAS") No. 7, *Accounting and Reporting by Development Stage Enterprises*, through December 31, 2005. The year 2006 was the first year during which the Company was an operating company and was no longer in the development stage. 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. In May 2007, the Company completed an initial public offering of its common stock.

Liquidity

The Company commenced operations in 2000 and had an accumulated deficit of $248.4 million as of December 31, 2008. The Company incurred a net loss of $92.8 million in 2008, net loss of $53.5 million in 2007, and net loss of $36.2 million in 2006. The Company's operating results for future periods are subject to numerous uncertainties, and it cannot assure you that it will not continue to experience net losses for the foreseeable future. Although its revenue has grown in recent years, it may be unable to sustain such growth rates if there are adverse changes in market or economic conditions. If the Company is not able to increase revenue and/or reduce its costs, it may not be able to achieve profitability.

At December 31, 2008, cash and cash equivalents totaled approximately $56.7 million. Historically, the Company has consumed cash from operations. During 2008, the Company consumed cash from operations of approximately $82.6 million, with the rate of cash consumption declining in the third and fourth quarters. Historically, the Company has addressed its liquidity requirements through public and private offerings of debt and equity. As of December 31, 2008, the Company had approximately $71.5 million in working capital. Although the Company expects its operating performance to improve in future periods, it anticipates that the recession in the United States and the slowdown of economic growth in the rest of the world may create a more challenging business environment for it in the near term.

On March 13, 2009, the Company entered into a facility agreement with certain institutional accredited investors, pursuant to which the investors agreed to loan up to $60 million, subject to the terms and conditions set forth in the Facility Agreement. Following the initial disbursement of $27.5 million within fifteen business days of March 13, 2009, the Company may, but is not required to, draw down on the facility in $6.5 million increments at any time until November 2010 provided that the Company meets certain financial milestones. While the Company can not provide assurance that it will meet any or all of these financial milestones, based upon current estimates and assumptions, it expects to be able, at its discretion, to draw down at least an additional $26.0 million under this facility. Upon execution of this facility agreement, the Company issued to the lenders warrants to purchase an aggregate of 3.75 million shares of its common stock at an exercise price of $3.13 per share in connection with the initial $27.5 million draw down from the facility. As noted above, pursuant to the Facility Agreement, the Company has the right to request from the lenders one or more cash disbursements in the minimum amount of $6.5 million per disbursement, and each such disbursement will be accompanied by the issuance to the lenders of warrants to purchase an aggregate of 0.3 million shares of common stock, at an exercise price equal to 120% of the average volume weighted average price of its common stock on the fifteen consecutive trading days beginning with the date following receipt by the lenders of the disbursement request. If the Company, in its discretion, draws down the entire $60.0 million credit

facility, the Company will have issued warrants to purchase a total of 5.25 million shares of its common stock. See Note 14 for a summary of this financing.

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 subsidiary, Sub-Q Solutions, Inc. All material intercompany balances and transactions have been eliminated in consolidation. To date there has been minimal activity in Sub-Q Solutions, Inc.

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.

Fair Value of Financial Instruments

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 notes payable 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, 2008 and 2007.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable consist of amounts due from third-party payors and patients. In estimating whether accounts receivable can be collected, the Company performs evaluations of customers and continuously monitors collections and payments and estimates an allowance for doubtful accounts based on the aging of the underlying invoices, experience to date and any specific collection issues that have been identified.

Bad debt expense for the years ended December 31, 2008, 2007 and 2006 amounted to $4.3 million, $1.1 million and $0.1 million, respectively. There were $1.6 million, $0.1 million and $0 write-offs or other

adjustments to the allowance for doubtful accounts during the years ended December 31, 2008, 2007 and 2006, respectively. Allowance for doubtful accounts totaled $3.8 million and $1.2 million as of December 31, 2008 and 2007, respectively.

Inventories

Inventories are stated 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, 2008, and at market value at December 31, 2007, as the Company sold the OmniPod at a loss in 2007. 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 evaluates inventory valuation on a quarterly basis for obsolete or slow-moving items.

Property & 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.

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.

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, two OmniPods, the OmniPod System User Guide and the OmniPod System Interactive Training CD. Subsequent sales to existing customers typically consist of additional OmniPods.

Revenue is recognized in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements* ("SAB 104"), which 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 their receipt 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 has considered the requirements of Emerging Issues Task Force 00-21, *Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"), when accounting for the OmniPods and Starter Kits. EITF 00-21 requires the Company to assess 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, in accordance with SFAS No. 48, *Revenue Recognition When the Right of Return Exists*, the Company 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 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 gross product sales.

Prior to January 1, 2008, the Company deferred the revenue and related costs of revenue for all initial shipments until the 45-day right of return had lapsed. With the accumulation of approximately 2 years of data for sales and return rates, the Company concluded that it had sufficient historical data on which to base its estimated returns from January 1, 2008. If the Company had continued to defer all initial shipments until the 45-day right of return had expired, deferred revenue as of December 31, 2008, would have been larger by $1.4 million.

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 a new customer. The Company recognizes the revenue related to this portion of the Abbott agreement at the time the revenue is recognized on the sale of the PDM to the patient. In the year ended December 31, 2008, the Company recognized $2.5 million of revenue related to the amended Abbott agreement. There was no impact to cost of revenue related to this agreement.

The Company had deferred revenue of $4.0 million and $1.4 million as of December 31, 2008 and 2007, respectively. The deferred revenue recorded was comprised of product-related revenue as well as the non-amortized 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 one accredited financial institution.

Although revenues are recognized from shipments directly to patients, the majority of shipments are billed to third party insurance payors. For the year ended December 31, 2008, the two largest third party payors accounted for 7% and 4% of gross accounts receivable balances. For the year ended December 31, 2007, the two largest third party payors accounted for 8% and 4% of gross accounts receivable balances.

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 personnel employed with sales and marketing activities, outside marketing expenses including commercial product samples and advertising expenses.

Segment Reporting

SFAS No. 131, *Disclosure about Segments of an Enterprise and Related Information*, establishes standards for reporting information about operating segments in annual financial statements and in interim financial reports issued to stockholders. 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

In June 2006, the Financial Accounting Standards Board, or FASB, issued FASB Interpretation, or FIN, No. 48, *Accounting for Uncertainty in Income Taxes*, which clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS No. 109. FIN 48 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, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006.

The Company adopted FIN 48 on January 1, 2007. The adoption of FIN 48 did not have a material impact on the Company's financial position or results of operations. Upon adoption and as of December 31, 2008, the Company had no 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.

The Company recognizes estimated interest and penalties for uncertain tax positions in income tax expense. Upon adoption and as of December 31, 2008 and 2007, the Company had no interest and penalty accrual or expense.

Stock Based Compensation

Effective January 1, 2006, the Company adopted SFAS No. 123 (revised 2004), *Share Based Payment*, or SFAS 123R, which is a revision of Statement No. 123 ("SFAS 123") *Accounting for Stock Based Compensation*. SFAS 123R supersedes Accounting Principles Board ("APB") No. 25, *Accounting for Stock Issued to Employees* ("APB 25"), and amends FASB Statement No. 95 *Statement of Cash Flows*. SFAS 123R 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. Pro forma disclosure is no longer an alternative.

SFAS 123R requires nonpublic companies that used the minimum value method in SFAS 123R for either recognition or pro forma disclosures to apply SFAS 123R using the prospective-transition method. As such, the Company will continue to apply APB 25 in future periods to equity awards outstanding at the date of SFAS 123R's adoption that were measured using the minimum value method.

Effective January 1, 2006 with the adoption of SFAS 123R, the Company elected to use the Black-Scholes option pricing model to determine the weighted-average fair value of options granted. In accordance with SFAS 123R, 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 (AICPA) in the AICPA Technical Practice Aid, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation", or the AICPA Practice Aid. To that end, 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 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 10 for a summary of the stock option activity under our stock based employee compensation plan.

Recent Accounting Pronouncements

In May 2008, the FASB issued Staff Position Accounting Principles Board 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ("FSP APB 14-1"), which is effective for fiscal years beginning after December 15, 2008. FSP APB 14-1 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. The Company anticipates that the reclassification of approximately $20 to $30 million of long-term debt to equity under the provisions of FSP APB 14-1 will result in approximately $3 to $5 million in additional interest expense during 2009. The Company does not anticipate the adoption of FSP APB 14-1 to impact to its cash flows during the year ending December 31, 2009.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ("SFAS 162"). This standard identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the United States. SFAS 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. The Company is currently evaluating the potential effect of implementing this standard.

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.

Employees terminated were mainly in the manufacturing and quality departments. In addition, certain members of senior management were terminated. This reduction was primarily in response to the successful transition of portions of the manufacturing process to Flextronics as well as on-going alignment of the Company's infrastructure.

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 will supply, as a non-exclusive supplier, OmniPods at agreed upon prices per unit pursuant to a rolling 12-month forecast provided by the Company. The initial term of the agreement is three years from January 3, 2007, with automatic one-year renewals. 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 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. During the fourth quarter the Company concluded that the capacity of the manufacturing line operated by Flextronics is considered adequate to meet anticipated demand and quality standards in the future. As the Company determined that it will 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.

At December 31, 2008, the Company's accrued expense for restructuring was $0.6 million for final payments of severance and will be utilized during 2009.

The following is a summary of restructuring activity for the year ended December 31, 2008:

	Year Ended December 31, 2008
	Workforce and Related
	(In thousands)
Balance at the beginning of year	$ —
Restructuring expense	758
Utilization	(146)
Balance at the end of the year	$ 612

Impairment of Property and Equipment

During the year ended December 31, 2007, the Company completed the evaluation of an upgrade of its manufacturing processes, and as a result, the Company performed a review of certain production equipment. The review resulted in a non-cash charge of $1.0 million for the write-down of certain impaired assets. The impaired assets, which had no future use, consisted of manufacturing equipment. The impairment charges were recorded following determination of the fair value of cash flows resulting from use of the affected assets, and the carrying value of the assets was reduced to reflect their fair value.

4. Net Loss Per Share

Basic net loss per share is computed by dividing net loss attributable to common stockholders 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. None of these shares were vested at December 31, 2008. In the years ended December 31, 2007 and 2006, there were no vested or unvested restricted common shares. Diluted net loss per share is computed using the weighted average number of common shares outstanding and, when dilutive, potential common share equivalents 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, 2008, 2007 and 2006, all potential common shares have been excluded from the computation of the dilutive net loss per share for all periods presented because the effect would have been antidilutive. Upon the closing of the initial public offering of the Company's common stock in May 2007, all redeemable convertible preferred stock converted to common stock. Potential common share equivalents consist of the following:

	Year Ended December 31,		
	2008	2007	2006
Series A redeemable convertible preferred stock	—	—	380,705
Series B redeemable convertible preferred stock	—	—	2,263,651
Series C redeemable convertible preferred stock	—	—	3,988,337
Series D redeemable convertible preferred stock	—	—	5,584,722
Series E redeemable convertible preferred stock	—	—	5,230,376
Convertible debt	3,981,969	—	—
Unvested restricted common shares	4,000	—	—
Outstanding options and ESPP	2,933,832	2,341,844	2,318,250
Outstanding warrants	62,752	62,752	219,981
Total	6,982,553	2,404,596	19,986,022

5. Inventories

Inventories consist of the following:

	As of December 31,	
	2008	2007
	(In thousands)	
Raw materials	$ 3,518	$2,994
Work-in-process	997	1,583
Finished goods	12,355	3,413
	$16,870	$7,990

Inventory was adjusted by $0.6 million as of December 31, 2007, to reflect values at the lower of cost or market. There was no adjustment recorded to inventory as of December 31, 2008. At December 31, 2008 and 2007, 0% and 43% , respectively, of the finished goods inventory was valued below the Company's cost. The Company's production process has a high degree of fixed costs and due to the early stage of market acceptance for its products, sales and production volumes may vary significantly from one period to another. Prior to June 30, 2008, sales and production volumes were not adequate to result in per-unit costs that were lower than the current market price for the OmniPod. During the third quarter of 2008, the Company began presenting its inventory of completed OmniPods at cost, as the cost to produce OmniPods was lower than the Company's selling price.

6. Property and Equipment

Property and equipment consist of the following:

	Estimated Useful Life (Years)	As of December 31,	
		2008	2007
		(In thousands)	
Machinery and equipment	5	$13,834	$16,874
Construction in process		2,252	5,475
Computers	3	2,220	1,602
Software	3	3,788	1,972
Leasehold improvement	*	2,186	1,901
Office furniture and fixtures	5	1,607	791
Total property and equipment		$25,887	$28,615
Less: Accumulated depreciation		(8,323)	(7,311)
Total		$17,564	$21,304

* Lesser of term of lease or useful life of asset.

Depreciation expense related to property and equipment was $6.4 million, $4.7 million and $2.4 million for the years ended December 31, 2008, 2007 and 2006, respectively. The Company recorded $0.4 million and $0.7 million of capitalized interest for the years ended December 31, 2008 and 2007, respectively. The Company did not capitalize interest in the year ended December 31, 2006.

Construction in process 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,	
	2008	2007
	(In thousands)	
Employee compensation and related items	$3,402	$2,025
Professional services	441	369
Interest expense	190	255
Warranty reserve	885	435
Training	344	168
Other	2,038	1,212
Total accrued expenses	$7,300	$4,464

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,	
	2008	2007
	(In thousands)	
Balance at the beginning of year	$ 865	$ 193
Warranty expense	3,865	1,898
Warranty claims settled	(2,462)	(1,226)
Balance at the end of the year	$ 2,268	$ 865
Composition of balance:		
Short-term	885	435
Long-term	1,383	430
Total warranty balance	$ 2,268	$ 865

8. Convertible Notes and Repayment and Termination of Term Loan

Loan and Security Agreements

In June 2005, the Company entered into a $10.0 million term loan and security agreement with Lighthouse Capital Partners V, L.P. Interest on this term loan was charged at a rate of 8%. This term loan required only interest payments through June 1, 2006. After that date, the principal and interest was payable ratably over 42 months. At the end of the amortization period of the term loan, the Company was obligated to make a final payment of $1.0 million, which was being amortized as interest expense over the life of the loan. Upon payment of the term loan in December 2006, the remaining unamortized balance of the final $1.0 million payment was recognized as interest expense.

In connection with this term loan, the Company issued a warrant to the lender to purchase up to 330,579 shares of Series D preferred stock. The Company recorded the $0.3 million fair value of the warrant

as a discount to the term loan. The cost of the warrant was being amortized to interest expense over the 54-month life of this term loan. The remaining balance of the discount was expensed upon payment of the term loan in December 2006.

In December 2006, the Company entered into a credit and security agreement with a group of lenders led by Merrill Lynch Capital pursuant to which the Company borrowed $30.0 million in a term loan. The Company used $9.5 million of the proceeds from this term loan to repay all amounts owed under the term loan with Lighthouse Capital Partners V, L.P. This term loan was secured by all the assets of the Company other than its intellectual property. The borrowings under the term loan bore interest at a floating rate equal to the LIBOR rate plus 6% per annum. Interest was payable on a monthly basis during the term of the loan and, on October 1, 2007, the Company began the repayment of principal in 33 equal monthly installments of $0.9 million. This term loan was also subject to a loan origination fee amounting to $0.9 million. The Company capitalized these costs as deferred financing costs as of December 31, 2006. The deferred cost asset was being amortized to interest expense over the 42-month life of this term loan. This term loan was subject to acceleration upon the occurrence of any fact, event or circumstance that has resulted or could reasonably be expected to result in a material adverse effect. Consequently, such debt was classified as a current liability at December 31, 2006 in accordance with the provisions set forth by *FASB Technical Bulletin No. 79-3 Subjective Acceleration Clause in Long-Term Debt Agreements.*

In connection with this term loan, the Company issued warrants to the lenders to purchase up to 247,252 of Series E preferred stock. The Company recorded the $0.8 million fair value of the warrants as a discount to the term loan. The value of the warrants was being amortized to interest expense over the 42-month life of this 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 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 incurred interest expense of approximately $2.8 million for the year ended December 31, 2008, related to the 5.375% Notes. The Company incurred deferred financing costs related to this offering of approximately $3.5 million, which are recorded in the condensed consolidated balance sheet and are being amortized as a component of interest expense over the five year term of the notes.

The Company received net proceeds of approximately $81.5 million from this offering. Approximately $23.2 million of the proceeds from this offering was used to repay and terminate the Company's 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 intends in using the remainder for general corporate purposes. The Company incurred interest expense of approximately $1.5 million, $3.2 million and $1.8 million for the years ended December 31, 2008, 2007 and 2006, respectively, related to the term loan. The term loan was subject to a loan origination fee of $0.9 million, which was recorded in the condensed 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 unamortized warrants to purchase common stock, was recognized as a $1.5 million loss from early extinguishment of the term loan.

In connection with the adoption of FSP APB 14-1 in the first quarter of 2009, the Company will reclassify a portion of the debt related to the 5.375% Notes to equity. The Company anticipates that the reclassification of approximately $20 to $30 million of long-term debt to equity will result in approximately $3 to $5 million in additional non-cash interest expense during 2009.

Warrants

In connection with the term loans 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 Statement No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity* and FASB Staff Position No. 150-5 *Issuer's Accounting under FASB Statement No. 150 for Freestanding Warrants and Other Similar Instruments on Shares That Are Redeemable (FSP-150")*.

Significant terms and fair values of warrants to purchase common stock are as follows (in thousands except share and per share data), and reflect the conversion ratio of 2.6267 redeemable convertible preferred shares for each common share:

Stock	Expiration Date	Exercise Price per Share	Common Shares as of December 31, 2008	Common Shares as of December 31, 2007	Fair Value as of December 31, 2008	Fair Value as of December 31, 2007
Series E preferred . . .	December 27, 2013	9.56	62,752	62,752	—	—

The Company recorded $0.8 million as the fair value of the warrants for Series E preferred stock 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 and, as a result, are no longer subject to FSP 150-5 for periods ended or ending 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. No periodic fair value adjustments will be made in future periods.

9. 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 February 2008, the Company entered into a non-cancelable lease for additional office space in Bedford, Massachusetts. The lease expires in September 2010 and provides a renewal option of five years and escalating payments over the life of the lease. In March 2008, the Company extended the lease of its Bedford, Massachusetts headquarters facility containing research and development and manufacturing space. Following the extension, the lease expires in September 2014. The lease is non-cancelable and contains 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 Technical Bulletin 88-1, *Issues Relating to Accounting for Leases*, and FASB Technical Bulletin 85-3, *Accounting for Operating Leases with Scheduled Rent Increases*, in accounting for these lease provisions.

The Company leases its corporate offices under long-term, noncancelable leases with a five-year renewal option. The Company leases its warehouse facility under a long-term, cancelable lease with a five-year renewal option. The aggregate future minimum lease payments of these leases as of December 31, 2008, is as follows (in thousands):

Year	Minimum Lease Payments
2009	$ 841
2010	900
2011	755
2012	755
2013	657
Thereafter	493
Total	$4,401

Rent expense of approximately $0.8 million, $0.5 million and $0.9 million was charged to operations as of December 31, 2008, 2007 and 2006, 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. Deferred rent was $0.1 million and $0.2 million as of December 31, 2008 and 2007, respectively.

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.

10. Equity

On April 12, 2007, the Company's Board of Directors approved a 1-for-2.6267 reverse stock split of the Company's common stock, which was executed on May 10, 2007. All share and per share amounts of common and preferred stock in the accompanying consolidated financial statements have been restated for all periods to give retroactive effect to the stock split.

On May 18, 2007, the Company issued and sold 7,700,000 shares of common stock at a price to the public of $15.00 per share. On June 12, 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 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.

On October 29, 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 of 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 the year ended December 31, 2007, 157,229 warrants to purchase common stock issued in relation to the Company's term loan were exercised, resulting in the issuance of 111,197 common shares. In addition, 532,763 and 380,192 common shares were issued related to exercises of employee stock options in the years ended December 31, 2008 and 2007, respectively.

Redeemable Convertible Preferred Stock Conversion

Upon the closing of the initial public offering of the Company's common stock, all redeemable convertible preferred stock converted to common stock.

Stock Option Plans

On May 18, 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 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 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, 2008, 603,954 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 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 ($)	Aggregate Intrinsic Value ($)
Balance, December 31, 2005	2,097,192	2.27	
Granted	441,391	6.62	
Exercised	(145,568)	1.23	1,109,488(1)
Canceled	(74,765)	2.89	
Balance, December 31, 2006	2,318,250	3.29	
Granted	810,306	15.32	
Exercised	(380,192)	2.34	7,689,142(1)
Canceled	(56,391)	8.37	
Balance, December 31, 2007	2,691,973	6.94	
Granted	1,114,349	13.87	
Exercised	(532,763)	2.32	7,938,993(1)
Canceled	(339,727)	15.02	
Balance, December 31, 2008	2,933,832	9.47	6,080,097(2)
Vested, December 31, 2008	1,457,846	5.44	5,166,176(2)
Vested and expected to vest, December 31, 2008(3)	2,432,396		

(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.

(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, 2008, and the exercise price of the underlying options.

(3) Represents the number of vested options as of December 31, 2008, plus the number of unvested options expected to vest as of December 31, 2008, based on the unvested options outstanding at December 31, 2008, adjusted for the estimated forfeiture rate of 16%.

The options outstanding and currently exercisable by exercise price at December 31, 2008 are as follows:

	Options Outstanding			Options Exercisable	
Exercise prices ($)	Number of Options (#)	Weighted Average Exercise Price($)	Weighted Average Remaining Contractual Life (Years)	Number of Options (#)	Weighted Average Exercise Price($)
0.26 - 1.19	225,733	$ 1.06	3.39	225,733	$ 1.06
1.20 - 2.84	345,929	2.55	4.85	345,719	2.55
2.85 - 4.86	472,552	3.71	5.99	435,092	3.70
4.87 - 8.04	581,123	6.28	8.43	171,491	7.17
8.05 - 11.64	215,287	11.57	7.58	110,788	11.56
11.65 - 14.12	113,682	13.47	7.80	48,032	13.35
14.13 - 15.00	276,008	14.74	7.34	89,550	14.75
15.01 - 23.40	703,518	18.74	8.86	31,441	23.30
Total	2,933,832		7.15	1,457,846	

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.

2007 Employee Stock Purchase Plan

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

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

The Company will make one or more offerings each year to employees to purchase stock under the 2007 ESPP. The first offering began on the date of the closing of our initial public offering and ended on December 31, 2007. Subsequent offerings will 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 our 2007 Employee Stock Purchase Plan 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.

For the years ended December 31, 2008 and 2007 the Company issued 18,338 and 2,789 shares of common stock, respectively, to employees participating in the 2007 ESPP. The Company recorded $29,000 and $10,000 of stock-based compensation expense for the years ended December 31, 2008 and 2007, respectively.

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 in exchange for $0.001 per share. 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, 448 vested on January 4, 2009, and the remaining vest ratably on a quarterly basis thereafter for a period of 2 years. The shares were valued at approximately $32,000 at their grant date, and the Company will recognize the compensation expense over the two year vesting period. No significant stock-based compensation expense related to the restricted stock was recognized in the year ended December 31, 2008.

The total fair value of the restricted shares at December 31, 2008 was approximately $32,000, which was unrecognized as of December 31, 2008. The stock-based compensation cost is expected to be recognized over a weighted average period of 2 years.

The following table summarizes the status of the Company's restricted shares since December 31, 2007:

	Number of Shares	Weighted Average Fair Value
Balance, December 31, 2007	—	$ —
Granted	4,000	8.04
Vested	—	—
Forfeited	—	—
Balance, December 31, 2008	4,000	$8.04

Stock-based Compensation Associated with Awards for Employees

Employee Stock-based Awards Prior to January 1, 2006

Compensation costs for employee stock options granted prior to January 1, 2006, the date the Company adopted SFAS 123R, were accounted for using the intrinsic-value method of accounting as prescribed by APB No. 25, as permitted by SFAS 123. Under APB No. 25, compensation expense for employee stock options is based on the excess, if any, of the fair market value of the Company's common stock over the option exercise price on the measurement date, which is typically the date of grant. All options granted were intended to be exercisable at a price per share not less than fair market value of the shares of the Company's stock underlying those options on their respective dates of grant. The board of directors determined these fair market

values in good faith based on the best information available to the board of directors and Company's management at the time of grant.

Employee Stock-Based Awards Granted On or Subsequent to January 1, 2006

Effective January 1, 2006, the Company adopted SFAS 123R, using the prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards made to the Company's employees, directors and consultants. The Company's financial statements as of and for the year ended December 31, 2006 reflect the impact of SFAS 123R. Stock-based compensation expense recognized is based on the value of the portion of stock-based awards that is ultimately expected to vest. Stock-based compensation expense recognized in the Company's statements of operations during the year ended December 31, 2006 includes compensation expense for stock-based awards based on the fair value estimated in accordance with the provisions of SFAS 123R. The Company attributes the value of stock-based compensation to expense using the straight-line method, which was previously used for its pro forma information required under SFAS 123.

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 our 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,		
	2008	2007	2006
Risk-free interest rate	1.71% - 3.30%	3.62 - 5.10%	4.29 - 5.19%
Expected term (in years)	6.25	6.25	6.25
Dividend yield	0	0	0
Expected volatility	52% - 61%	67%	71%

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. SFAS 123R also requires the Company to estimate forfeitures at the time of grant, and revise those estimates 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, 2008, 2007 and 2006 was $7.15, $9.99 and $2.04, respectively. Employee stock-based compensation expense under

SFAS 123R recognized in the year ended December 31, 2008, 2007 and 2006 was $3.4 million, $1.5 million and $0.3 million, respectively, and was calculated based on awards ultimately expected to vest. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. At December 31, 2008, the amount of stock-based compensation capitalized as part of inventory was not material.

At December 31, 2008, the Company had $11.1 million of total unrecognized compensation expense under SFAS 123R that will be recognized over a weighted-average period of 1.4 years.

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 14, 2008. In addition, one Right will automatically attach to each share of common stock issued between November 14, 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.

11. 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 2003, 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 $0.2 million, $0.1 million and $0.1 million for the years ended December 31, 2008, 2007 and 2006, respectively.

12. Income Taxes

The Company accounts for income taxes under FAS 109 *Accounting for Income Taxes* (FAS 109). 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,	
	2008	2007
Tax at U.S. statutory rate	(34.00)%	(34.00)%
State taxes, net of federal benefit	(5.61)	(5.61)
Tax credits	(0.88)	(1.97)
Change in valuation allowance	39.09	39.10
Other	1.40	2.48
	0.00%	0.00%

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,	
	2008	2007
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 85,397	$ 51,886
Start up expenditures	4,540	5,632
Tax credits	4,707	3,885
Depreciation	—	42
Gain/loss on impairments	2,936	—
Bad debt	1,505	479
Other	1,663	2,387
Deferred tax liabilities:		
Prepaids	(527)	(461)
Depreciation	(101)	—
	100,120	63,850
Valuation allowance	(100,120)	(63,850)
	$ —	$ —

FAS 109 requires a valuation allowance 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 $100.1 million valuation allowance at December 31, 2008, 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, 2007, because realization of any future tax benefit was not sufficiently assured.

At December 31, 2008, the Company had approximately $215.2 million and $4.7 million of federal 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 state tax purposes. At December 31, 2007, the Company had approximately $131.0 million and $3.9 million of federal 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.

13. Quarterly Data (Unaudited)

Upon the closing of the initial public offering of the Company's common stock, all redeemable convertible preferred stock converted to common stock, affecting the number of common shares used to calculate net loss per share.

	2008 Quarters Ended			
	December 31	September 30	June 30	March 31
	(In thousands, except per share data)			
Revenue	$ 11,861	$ 10,110	$ 7,417	$ 6,671
Gross margin (loss)	$ 1,198	$ (87)	$ (2,368)	$ (3,327)
Net loss	$(28,283)	$(20,752)	$(23,882)	$(19,874)
Net loss per share	$ (1.02)	$ (0.75)	$ (0.87)	$ (0.73)

	2007 Quarters Ended			
	December 31	September 30	June 30	March 31
	(In thousands, except per share data)			
Revenue	$ 4,361	$ 3,791	$ 3,212	$ 2,008
Gross loss	$ (2,318)	$ (3,792)	$ (3,687)	$ (2,564)
Net loss	$(15,668)	$(13,639)	$(12,672)	$(11,560)
Net loss per share	$ (0.59)	$ (0.52)	$ (0.99)	$ (23.86)

Net loss in the quarter ended December 31, 2008, includes the impact of restructuring and impairment related charges of $8.2 million. Net loss in the quarter ended September 30, 2007, includes the impact of impairment related charges of $1.0 million. See Note 3 for a description of the restructuring and impairment charges.

14. Subsequent Event

Facility Agreement

On March 13, 2009, the Company entered into a facility agreement with certain institutional accredited investors, pursuant to which the investors agreed to loan up to $60 million, subject to the terms and conditions set forth in the Facility Agreement. Following the initial disbursement of $27.5 million within fifteen business days of March 13, 2009, the Company may, but is not required to, draw down on the facility in $6.5 million increments at any time until November 2010 provided that the Company meets certain financial milestones. While the Company can not provide assurance that it will meet any or all of these financial milestones, based upon current estimates and assumptions, it expects to be able, at its discretion, to draw down at least an additional $26.0 million under this facility.

Any amounts drawn under the Facility Agreement accrue interest at a rate of 9.75% per annum, and any undrawn amounts under the Facility Agreement accrue interest at a rate of 2.75% per annum. Accrued interest is payable quarterly in cash in arrears beginning on June 1, 2009. The Company has the right to prepay any amounts owed without penalty unless the prepayment is in connection with a major transaction. The Company shall repay the Lenders any principal amount outstanding under the Facility Agreement in September 2012.

Additionally, any amounts drawn under the Facility Agreement may 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.

Warrants

In connection with the execution of the Facility Agreement, the Company issued to the Lenders warrants to purchase an aggregate of 3.75 million shares of common stock of the Company at an exercise price of $3.13 per share. Pursuant to the Facility Agreement, the Company has the right to request from the Lenders one or more cash disbursements in the minimum amount of $6.5 million per disbursement. Each disbursement shall be accompanied by the issuance to the Lenders of warrants to purchase an aggregate of 0.3 million shares of common stock, at an exercise price equal to 120% of the average volume weighted average price of the Company's common stock on the fifteen consecutive trading days beginning with the date following receipt by the Lenders of the disbursement request. If the Company, in its discretion, draws down the entire $60 million credit facility, the Company will have issued warrants to purchase a total of 5.25 million shares of its common stock.

Each warrant issued under the Facility Agreement expires six years from the date of its issuance. The warrants contain certain limitations that prevent the holder from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by it to exceed 9.98% of the total number of shares of Company common stock then issued and outstanding.

Registration Rights Agreement

In connection with the Financing, the Company entered into a Registration Rights Agreement with the Lenders obligating the Company to register for resale the shares of the common stock issuable upon the exercise of the Warrants on a registration statement on Form S-3 to be filed with the Securities and Exchange Commission within twenty days after the issuance date of the Warrants.

Security Agreement

In connection with the Financing, the Company entered into a Security Agreement with the Lenders, pursuant to which, as security for the Company's repayment obligations under the Facility Agreement, the Company granted to the Lenders a security interest in its accounts, receivables, equipment, intellectual property and other general intangibles, inventory, investment property, and all proceeds and products thereof.

Board of Directors

Sally Crawford
Healthcare Consultant and Director, Hologic, Inc., EXACT Sciences, Inc., CombinatoRx, Inc. and Universal American

Duane DeSisto
President, Chief Executive Officer and Director, Insulet Corporation

Gary Eichhorn
President, Eichhorn Group, LLC

Ross Jaffe, M.D.
Managing Director, Versant Ventures

Charles Liamos
Partner, MedVenture Associates

Steven Sobieski
Chief Financial Officer and Vice President, Finance and Administration, LifeCell Corporation

Regina Sommer
Director, ING Direct, Soundbite Communications and Wright Express Corporation

Joseph Zakrzewski
Chief Executive Officer, Xcellerex, Inc.

Executive Officers

Duane DeSisto
President and Chief Executive Officer

Brian Roberts
Chief Financial Officer

Luis Malave
Chief Operating Officer

William Arthur
Vice President, Business Development

Lars Boesgaard
Vice President, Finance

Carsten Boess
Vice President, International

Robert Campbell
Vice President, Clinical Services & Research

Ruthann DePietro
Vice President, Quality & Regulatory Affairs

R. Anthony Diehl, Esq.
General Counsel

John Garibotto
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David Howe
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