INSULET CORP
Form 10-K
March 20, 2008

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2007

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

Commission File No. 000-33589

INSULET CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**04-3523891**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
9 Oak Park Drive	**01730**
Bedford, Massachusetts	*(Zip code)*
(Address of principal executive offices)	

Registrant s telephone number, including area code:
(781) 457-5000
Securities registered pursuant to Section 12(b) of the Act:

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements

incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer þ	Smaller reporting Company o

(Do not check if a smaller reporting company)

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

The aggregate market value of the common stock, 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, 2007 was approximately $166 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 18, 2008:

Title of Class	**Shares Outstanding**
Common Stock, $0.001 par value	27,531,977

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, 2007. 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, b 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.

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PART I

ITEM 1. *BUSINESS*

Overview

We are a medical device company that develops, manufactures and markets an innovative, discreet and easy-to-use insulin infusion system for people with insulin-dependent diabetes. Our proprietary OmniPod Insulin Management System, 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. We have progressively expanded our marketing efforts from an initial focus in the Eastern United States, as well as some key diabetes practitioners, academic centers and clinics elsewhere in the United States, then to the Midwest and most recently to parts of the Western United States.

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.

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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.

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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 and events at the national, regional and local levels.

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

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that makes diabetes a smaller part of life and strongly promotes the lifestyle benefits afforded by the OmniPod System.

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.

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, 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 benefits. 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 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.

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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.

Additional research and development projects include 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 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. However, there can be no assurance that we will be able to adapt the OmniPod System technology for such 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.

Currently, the sale price of the OmniPod System is not sufficient to cover our direct manufacturing costs. By increasing production volumes of the OmniPod, we will be able to reduce our raw material costs and improve absorption of manufacturing overhead costs. This is important to allow us to achieve profitability.

We are currently producing the OmniPod on a partially automated manufacturing line at our facility in Bedford, Massachusetts. During 2008, we intend to complete the planned automation of this manufacturing line. In addition to the existing manufacturing line in Bedford, we expect to complete construction of a partially automated manufacturing line at a facility in China, operated by a subsidiary of Flextronics International Ltd. The additional manufacturing line in China is expected to be completed during 2008. Pending construction and installation of the remaining automated manufacturing equipment that we plan to use, we are manually performing these steps in the manufacturing process, and this limits our ability to increase our manufacturing capacity and decrease our per unit cost of goods sold, thereby causing us to incur negative gross margins.

We currently purchase a sub-assembly of some of the OmniPod s components from Flextronics. Toward the end of 2008, we intend to purchase complete OmniPods from Flextronics. On January 3, 2007, we entered into an agreement with a subsidiary of Flextronics International Ltd. for the manufacture and supply of a sub-assembly of the chassis for the OmniPods. On October 4, 2007, we expanded the scope of this agreement to cover the manufacture and supply of complete OmniPods. 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. Pursuant to this agreement, we expect to begin purchasing OmniPods

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from Flextronics following the completion of the construction of the partially automated manufacturing line for the OmniPod at one of Flextronics facilities in China. By purchasing OmniPods manufactured by Flextronics in China while continuing to manufacture OmniPods on our manufacturing line in Bedford, we will be able to substantially increase production volumes for the OmniPod and reduce our per unit production cost.

Our OmniPod manufacturing capacity at the end of 2007 was approximately 60,000 OmniPods per month. By completing the planned automation of our existing manufacturing line in Bedford, Massachusetts and by purchasing complete OmniPods from Flextronics, we expect to increase the production capacity of OmniPods to in excess of 200,000 OmniPods per month toward the end of 2008.

Currently, the OmniPod and PDM are assembled and tested in our manufacturing facility in Bedford, Massachusetts. However, 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 a sub-assembly of certain components for the OmniPod, and during 2008 we intend to purchase complete OmniPods from Flextronics. Each of these suppliers is a sole-source supplier. To date, we have not experienced significant disruption of these components and services and we have created safety stocks of our components to address changes in market demand. However, for certain of these components, arrangements for additional or replacement suppliers will take time and result in delays, in part because of the FDA approval process 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, 2007, we had obtained 18 issued United States patents, and had 28 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

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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. (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. The agreement may be terminated by Abbott Diabetes Care, Inc. 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 trademarks INSULET and POD. The INSULET mark is subject to an ongoing opposition proceeding. The POD mark, which has been allowed and for which the opposition period has expired, will be registered upon filing a declaration of use.

Competition

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. The OmniPod System competes with a number of existing insulin delivery devices as well as other methods for the treatment of diabetes. Medtronic MiniMed, a division of Medtronic, Inc., has been the market leader for many years and has the majority share of the conventional insulin pump market in the United States. Other significant suppliers in the United States are Animas Corporation, a division of Johnson & Johnson, and Deltec, a division of Smiths Medical MD, Inc. In October 2006, following the lifting of an FDA ban on the import of Disetronic insulin pumps, Roche Disetronic, a division of Roche Diagnostics, announced its re-entry into the conventional insulin pump market in the United States.

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;

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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 Systems, 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. Existing diabetes-focused pharmaceutical companies, including those marketing or developing inhaled insulin products, include Abbott Laboratories, Eli Lilly and Company, MannKind Corporation, Nektar Therapeutics and Takeda Pharmaceuticals Company Limited.

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 which we are developing which integrates 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

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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

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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.

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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 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.

To date, we have primarily focused on negotiating contracts with third-party payors with a presence in the areas where we have concentrated our initial sales and marketing efforts, which has been on the East Coast, Midwestern and recently parts of the Western regions of the United States. We are continuing to work with additional third-party payors within these areas and, as we expand our sales and marketing focus, in the remainder of the United States to establish coverage contracts. Our coverage contracts with third-party payors typically have a term of between one and three years and set coverage amounts during that term.

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 decided to focus our initial efforts in establishing reimbursement for the OmniPod System on negotiating 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

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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, 2007, we had 247 full-time employees. None of our employees is 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, are currently selling the OmniPod System at a loss 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 and we are currently not able to manufacture and sell the OmniPod System at a cost and in volumes sufficient to allow us to achieve profitability. For the fiscal year ended December 31, 2007, our gross loss from the manufacture and sale of the OmniPod System was $12.4 million. 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, including a net loss of $53.5 million for the fiscal year ended December 31, 2007. As of December 31, 2007, we had an accumulated deficit of $155.6 million. As we have grown our business, our net loss has increased each quarter and we expect our rate of loss to continue to increase on a quarterly basis into 2008 as we expand our commercial infrastructure.

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;

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

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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 through the successful implementation of our automated manufacturing strategy and our plan to purchase complete OmniPods manufactured in China.

Currently, the sale price of the OmniPod System is not sufficient to cover our direct manufacturing costs. We are in the process of completing the construction, testing and installation of automated manufacturing equipment to be used in the assembly of the OmniPod in order to increase our manufacturing volume. Increased volumes will allow for volume purchase discounts to reduce our raw material costs and improve absorption of manufacturing overhead costs. During 2008, we expect to complete the planned automation of our existing manufacturing line at our facility in Bedford, Massachusetts. Pending construction and installation of the remaining automated manufacturing equipment that we plan to use, we are manually performing these steps in the manufacturing process, which limits our ability to increase our manufacturing capacity and decrease our per unit cost of goods sold, thereby causing us to incur negative gross margins. In addition, we expect that during 2008, construction of a partially automated manufacturing line will be completed at a facility in China operated by a subsidiary of Flextronics International Ltd. We cannot assure you that we will successfully complete the planned automation of our existing manufacturing line or subsequent lines in the future, complete construction of the partially automated line in China or otherwise reduce the per unit cost of manufacturing the OmniPod. Failure to do so would limit our production capacity and our ability to reduce raw material and manufacturing overhead costs. If we are unable to reduce raw material and manufacturing overhead costs through volume purchase discounts and increased production capacity, our ability to achieve profitability will be severely constrained.

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, Freescale Semiconductor, Inc. to manufacture and supply the application specific integrated circuit that is incorporated into the OmniPod and a subsidiary of Flextronics International Ltd. to manufacture a sub-assembly of some of the OmniPod s components. Each of these suppliers is a sole-source supplier. In addition, we have recently expanded the scope of our existing contract manufacturing agreement with a subsidiary of Flextronics International Ltd. in China to cover 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

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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 of the United States. For example, on January 3, 2007, we entered into a non-exclusive contract manufacturing agreement with a subsidiary of Flextronics International Ltd. for the supply of a sub-assembly of some of the OmniPod s components. In the second quarter of 2007, we received initial shipments of OmniPod sub-assemblies from Flextronics under the agreement. On October 4, 2007, we expanded the scope of that agreement to cover the production of complete OmniPods. During 2008, we expect to complete the construction of a partially automated manufacturing line at a facility in China operated by Flextronics. As a result, our business will become increasingly 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, as the number of OmniPods manufactured in China increases, 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.

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

We expect that sales of the OmniPod System will be limited unless a substantial portion of the sales price of the OmniPod System is paid for by third-party payors, including private insurance companies, health maintenance organizations, preferred provider organizations and other managed care providers. As of December 31, 2007, we had entered into contracts establishing reimbursement for the OmniPod System with national and regional third-party payors covering an estimated 146 million lives. These contracts provide reimbursement in each of the 38 states in which we currently market the OmniPod System. While we anticipate entering into additional contracts with other third-party payors doing business in these states, 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 decided to focus our initial 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, and Deltec, a division of Smiths Medical MD, Inc. In October 2006, following the lifting of an FDA ban on the import of Disetronic insulin pumps, Roche Disetronic, a division of Roche Diagnostics, announced its re-entry into the conventional insulin pump market in the United States.

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

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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, there is an inhaled insulin product that was recently introduced by Pfizer Inc., and other diabetes-focused pharmaceutical companies, including Abbott Laboratories, Eli Lilly and Company, MannKind Corporation, Nektar Therapeutics 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 is currently pending FDA approval and is not available on the market. 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

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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.

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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

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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. 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;

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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

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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. 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.

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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 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

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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 currently conducted at a single location and any disruption at our facility could increase our expenses.

Substantially all of our operations are currently conducted at a single location in Bedford, 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 manufacturing equipment or 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 manufacturing facility or our other property, or to any of our suppliers, 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, especially Duane DeSisto, our President and Chief Executive Officer, and Carsten Boess, our Chief Financial Officer. Our success will depend on our ability to retain our current management and to attract and retain qualified personnel in the future, including clinicians, engineers and other highly skilled personnel. Competition for senior management personnel, as well as clinicians and engineers, is intense and there can be no assurances that we will be able to retain our personnel. The loss of the services of Mr. DeSisto, Mr. Boess, certain other 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.

We have progressively expanded our marketing efforts from an initial focus in the Eastern United States, as well as with some key diabetes practitioners, academic centers and clinics elsewhere in the United States, then to the Midwestern and most recently to parts of the Western region. As we expand our sales into the balance of the United States and internationally, we will need to obtain coverage contracts with additional third-party payors in those areas. Failure to obtain such contracts would limit our ability to successfully penetrate those areas. 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 significantly increase our manufacturing capacity, our personnel and the scope of our sales and marketing efforts on a phased basis into the rest of the United States and internationally. 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 oversee

the construction and operation of a manufacturing line by Flextronics in China and 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 the planned automation of our existing line as well as subsequent lines in the future. A transition to new suppliers may result in

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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.

Our future capital needs are uncertain and we may need to raise additional funds in the future, and these funds may not be available on acceptable terms or at all.

We believe that our current cash and cash equivalents together with our short-term investments and the cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements for at least the next 12 months. However, we may seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. 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.

As a result of these factors, we may need to raise additional funds, and these funds may not be available on favorable terms, or at all. Furthermore, 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. If we cannot raise funds on acceptable terms, we may not be able to enhance the OmniPod System or 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 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;

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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.

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Our credit and security agreement contains restrictions and covenants that may limit our operating flexibility and which, if violated, could result in the acceleration of the amounts due under this agreement.

On December 27, 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. This term loan is secured by all of our assets other than our intellectual property. The credit and security agreement imposes certain limitations on us, including limitations on our ability to do the following, subject to certain exceptions:

transfer all or any part of our businesses or properties, other than transfers done in the ordinary course of business;

engage in any business other than the business of designing, manufacturing, distributing and selling drug delivery devices and providing associated services or a reasonably related business;

merge or consolidate with or into any other business organization;

suffer or permit a change of control;

incur additional indebtedness;

incur liens with respect to any of our properties;

pay dividends or make any other distribution or payment on account of or in redemption, retirement or purchase of any capital stock;

directly or indirectly acquire or own, or make any investment in, any entity;

directly or indirectly enter into or permit to exist any transaction with any of our affiliates except transactions that are on terms that are no less favorable to us than would be obtained in an arm s length transaction with a non-affiliate;

acquire any assets other than in the ordinary course of business;

incur any liability for rental payments except in the ordinary course of business; or

enter into any sale and leaseback transaction.

Additionally, under the agreement, we must complete construction of a second manufacturing line for the OmniPods by March 31, 2009, which deadline may be extended to June 30, 2009 in specified circumstances. Complying with these restrictions and covenants may make it more difficult for us to successfully execute our business strategy and compete against companies who are not subject to similar restrictions and covenants. Additionally, if we violate any of these restrictions or covenants, our lenders under this agreement may accelerate all of our outstanding indebtedness and other amounts due under the credit and security agreement and, if we do not pay these amounts, proceed against the collateral securing these obligations.

We will incur increased costs as a result of our compliance with laws and regulations affecting public companies.

The laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted thereunder by the Securities and Exchange Commission, or SEC, will result in increased costs to us as a

publicly-traded company. As a public company, we are required to comply with many of these rules and regulations, and will be required to comply with additional rules and regulations in the future. For example, we are evaluating our internal controls systems in order to allow us to report on, and our independent registered public accounting firm to attest to, our internal controls, as required by Section 404 of the Sarbanes-Oxley Act. While we anticipate being able to fully implement the requirements relating to internal controls and all other aspects of Section 404 in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations. In addition, these efforts will divert management s time and attention away from our business in order to

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ensure compliance with these regulatory requirements. This diversion of management s time and attention may have a material adverse effect on our business, financial condition and results of operations.

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, after an initial transition period, we will be required to maintain internal control over financial reporting and our management will be required to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year. Additionally, we will be 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.

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, 2007, the average daily trading volume of our common stock on The NASDAQ Global Market has been fewer than 188,000 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

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in the public market that our existing stockholders might sell shares of common stock could also depress the trading price of our common stock.

A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities.

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 53,000 square feet of manufacturing, laboratory and office space in Bedford, Massachusetts under a lease expiring in 2009. 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.

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PART II

ITEM 5 *MARKET FOR THE 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

As of December 31, 2007, there were approximately 77 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.

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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, 2007. The historical stock price performance of our common stock shown in the performance graph below is not necessarily indicative of future stock price performance.

Insulet vs. NASDAQ Composite and NASDAQ Health Care Indices
Comparison of Seven Month Cumulative Total Return

* $100 invested on May 15, 2007 or April 30, 2007 in index - including reinvestment of dividends.

	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
et Corp.	$ 100.00	92.86	88.97	87.84	110.40	136.28	156.89	172.06	14
DAQ Composite	$ 100.00	103.30	103.25	101.01	102.70	107.57	113.61	105.54	10
DAQ Health	$ 100.00	99.59	97.82	95.77	97.02	102.56	107.06	102.92	9

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.

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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, 2007.

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)	2,754,725	$ 7.00	124,832
Equity compensation plans not approved by security holders(2)			
Total	2,754,725	$ 7.00	124,832

(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, 2007 is 124,832 shares, which 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 9 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, 2007, 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, 2007, we have used approximately $30 million of the net proceeds we received from our initial public offering for working capital and other general corporate purposes, including the 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. Pending such usage, we have invested the net proceeds in short-term, interest-bearing investment-grade securities. 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.

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

	Year Ended December 31,				
	2007	**2006**	**2005**	**2004**	**2003**
	(In thousands, except share and per share data)				
Consolidated Statements of Operations Data:					
Revenue(1)	$ 13,372	$ 3,663	$ 50	$	$
Cost of revenue	25,733	15,660	1,530		
Gross loss	(12,361)	(11,997)	(1,480)		
Operating expenses:					
Research and development	10,391	8,094	10,764	9,026	8,659
General and administrative	13,922	8,389	5,490	3,950	2,809
Sales and marketing	16,141	6,165	3,771	1,177	546
Impairment of assets	1,027				
Total operating expenses(2)	41,481	22,648	20,025	14,153	12,014
Operating loss	(53,842)	(34,645)	(21,505)	(14,153)	(12,014)
Other income (expense), net	377	(460)	(131)	332	73
Change in value of preferred stock warrant liability	(74)	(845)			
Net loss	(53,539)	(35,950)	(21,636)	(13,821)	(11,941)
Accretion of redeemable convertible preferred stock		(222)		(64)	(77)
Net loss attributable to common shareholders	$ (53,539)	$ (36,172)	$ (21,636)	$ (13,885)	$ (12,018)
Net loss per share basic and diluted	$ (3.21)	$ (99.72)	$ (70.95)	$ (47.86)	$ (44.16)
Weighted-average number of shares used in calculating net loss per share(3)	16,688,418	362,750	304,962	290,140	272,118

	As of December 31,				
	2007	**2006**	**2005**	**2004**	**2003**
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 94,588	$ 33,231	$ 7,660	$ 23,999	$ 4,328

Working capital	$ 87,723	$ 785	$ 5,168	$ 22,151	$ 2,841
Total assets	$ 130,741	$ 57,140	$ 16,792	$ 27,121	$ 4,958
Current debt	$ 10,671	$ 29,222	$ 1,479	$ 11	$ 11
Long-term debt, net of current portion	$ 16,006	$	$ 8,302	$	$
Other long-term liabilities	$ 1,431	$ 316	$ 315	$	$ 11
Redeemable convertible preferred stock	$	$ 119,509	$ 69,500	$ 69,500	$ 34,000
Total stockholders (deficit) equity	$ 92,275	$ (101,765)	$ (66,091)	$ 44,509	$ (30,650)

(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 $1.5 million in 2007 and $0.3 million in 2006. See Note 9 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.

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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.

Since inception and until 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 as well as with some key diabetes practitioners, academic centers and clinics elsewhere in the United States, then to the Midwest and most recently to parts of the Western United States. Our total revenues were $13.4 million and $3.7 million for the years ended December 31, 2007 and 2006, respectively.

Throughout 2007, the expansion of our business was constrained by our capacity to manufacture the OmniPod insulin infusion device, and we devoted significant attention to complete our production capacity of OmniPods. Currently, the sale price of the OmniPod System is not sufficient to cover our direct manufacturing costs. Increasing our production capacity for OmniPods will allow for volume purchase discounts to reduce our raw material costs and improve absorption of manufacturing overhead costs.

During 2008, we expect to complete the planned automation of our existing manufacturing line in Bedford, Massachusetts. Pending construction and installation of the remaining automated manufacturing equipment that we plan to use, we are manually performing certain steps in the manufacturing process, which limits our ability to increase our manufacturing capacity and decrease our per-unit cost of goods sold, thereby causing us to incur negative gross margins. In addition, we expect that during 2008, construction of a partially automated manufacturing line will be completed at a facility in China operated by a subsidiary of Flextronics International Ltd. By the end of 2008, we intend to purchase complete OmniPods from Flextronics. No assurances can be given that we will successfully complete the planned automation of our existing manufacturing line, successfully implement our Asian manufacturing strategy or otherwise reduce the per-unit cost of manufacturing the OmniPod. Failure to do so would limit our production capacity and not allow us to achieve per-unit cost improvements, which could severely constrain our ability to achieve profitability.

Additionally, 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 and increase our manufacturing capacity, 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, 2007, 2006 and 2005, we incurred net losses of $53.5 million, $36.2 million and $21.6 million respectively.

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As of December 31, 2007, we had an accumulated deficit of $155.6 million. We have financed our operations through the private placement of equity securities, secured indebtedness and public offerings of our common stock. As of December 31, 2007, we had secured debt outstanding of $26.7 million. Since inception, we have received net proceeds of $244.1 million from the issuance of redeemable convertible preferred stock and common stock.

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.

Our long-term financial objective is to achieve and sustain profitable growth. Our efforts for 2008 will be focused primarily on expanding our production capacity, reducing our per-unit production costs and expanding our sales and marketing efforts, including reimbursement, customer care, collections, training and product samples for the OmniPod System. The expansion of our manufacturing capacity will allow us to increase production volumes which will help us to achieve lower material costs due to volume purchase discounts and improve the 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 manufacturing and additional hiring of sales and administrative personnel with the goal of increasing our market penetration. We believe that we will continue to incur net losses in the near term in order to achieve these objectives, although we believe that the accomplishment of these combined efforts will have a positive impact on our financial condition in the future.

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 all of our revenues from the sale of the OmniPod System directly to 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 of OmniPods and Starter Kits, which include the PDM, two OmniPods, the OmniPod System User Guide and our Interactive Training CD, and from the follow-on sales of OmniPods to existing customers. Customers generally order a three-month supply of OmniPods. Our first commercial shipment was in October 2005, and we recognized no revenue before this time. During the years ended December 31, 2007, 2006 and 2005, all of our revenues were derived from sales within the United States. For shipments prior to December 1, 2006, we deferred recognition of revenue from the OmniPods and Starter Kit shipped as part of a customer s initial shipment for thirty days during which time the items could be returned and completely refunded. For shipments subsequent to December 1, 2006, we changed prospectively to a forty-five day right of return, and as a result have deferred revenue for forty-five days following customers initial shipment . We had a balance of deferred revenue of $1.4 million as of December 31, 2007.

For the year ending December 31, 2008, we expect our revenues to increase. We expect our OmniPod production capacity to grow as we continue the process of automating our OmniPod manufacturing process

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and receive increased supplies from Flextronics. Our OmniPod manufacturing capacity at the end of 2007 was approximately 60,000 OmniPods per month. By completing the planned automation of our existing manufacturing line in Bedford, Massachusetts and by purchasing complete OmniPods from Flextronics, we expect to increase our production capacity to in excess of 200,000 OmniPods per month toward the end of 2008. However, we are still in the process of designing and testing the custom equipment that we will need in order to automate our OmniPod manufacturing process and our Asian production strategy is still being implemented; accordingly, we cannot be assured that our efforts will be successful or that the expected production increases will be realized. 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 and packaging costs. Currently, the sale price of the OmniPod System is not sufficient to cover the direct manufacturing costs. Accordingly, the book value of our inventory of finished goods has been adjusted down to reflect the the lower of cost or market.

The planned increase in our OmniPod manufacturing capacity 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 or we are not successful in our efforts to automate the OmniPod manufacturing process, then the average cost of revenues per OmniPod may not decrease and we may continue to realize negative gross margins.

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 2008, we expect overall research and development spending to be higher than current levels 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, 2008, we expect sales and marketing expenses to more than double compared to 2007 as we hire additional sales and marketing personnel, incur additional sales commission expense related to sales growth and expand our sales and marketing efforts, which will include the implementation of broader direct-to-consumer marketing programs and the roll-out of our Patient Demonstration Kit Program.

General and administrative. General and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, finance, information technology and human resource functions, as well as legal fees, accounting fees, insurance costs, bad debt expenses, shipping, handling and facilities-related costs. We expect general and administrative expenses to increase as we increase personnel to support our planned expansion.

Stock based compensation expense. Prior to January 1, 2006, we accounted for our stock option plan 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 and therefore we have not restated our financial results for prior periods.

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Results of Operations for the Fiscal Years Ended December 31, 2007, 2006 and 2005

The following table presents certain statement of operations information for the years ended December 31, 2007, 2006 and 2005:

	Year Ended December 31,			Year Ended December 31,		
	2007	2006	% Change	2006	2005	% Change
	(Dollar amounts in thousands)					
Revenue	$ 13,372	$ 3,663	265%	$ 3,663	$ 50	7226%
Cost of revenue	25,733	15,660	64%	15,660	1,530	924%
Gross loss	(12,361)	(11,997)	3%	(11,997)	(1,480)	711%
Operating expenses:						
Research and development	10,391	8,094	28%	8,094	10,764	(25)%
General and administrative	13,922	8,389	66%	8,389	5,490	53%
Sales and marketing	16,141	6,165	162%	6,165	3,771	63%
Impairment of assets	1,027					
Total operating expenses	41,481	22,648	83%	22,648	20,025	13%
Operating loss	(53,842)	(34,645)	55%	(34,645)	(21,505)	61%
Other income (expense), net	303	(1,305)		(1,305)	(131)	896%
Net loss(1)	$ (53,539)	$ (35,950)	49%	$ (35,950)	$ (21,636)	66%

(1) Net loss for the years ended December 31, 2007 and 2006 include $1,520,000 and $307,000, respectively, for stock based compensation expense attributable to common stockholders as required by SFAS 123R. We adopted SFAS 123R on a prospective basis, and as a result previous periods are not restated.

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 $625,000 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%, 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, $829,000 in consulting services, $190,000 in travel expenses, and $206,000 in tools and other expenses.

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General and Administrative

General and administrative expense increased $5.5 million, or 66%, 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, $971,000 related to allowances for doubtful accounts, $905,000 in consulting and legal expenses, $581,000 in audit related expenses, $402,000 in increased depreciation expense, $334,000 for travel expenses, $277,000 in increased insurance expense, and $384,000 in other expenses. The increased expenses in 2007 compared to 2006 were partly offset by a reduction of $706,000 for expenses related to asset disposals.

Sales and Marketing

Sales and marketing expenses increased $10.0 million, or 162%, 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, $341,000 in printing and tradeshow expenses used to support our selling efforts, and $332,000 in other marketing expenses.

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 $1,027,000 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 $3,537,000 during the year ended December 31, 2007. This represents an increase of $2,159,000 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 $3,160,000 during the year ended December 31, 2007. This represents an increase of $1,322,000 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 $2,005,000, 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 $74,000 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, 2006 and December 31, 2005

Revenues

Our total revenues were $3.7 million for the year ended December 31, 2006 as compared to $50,000 for the year ended December 31, 2005. We did not begin commercial shipment of the OmniPod System until October 2005; therefore, we only had three months of sales in 2005.

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Cost of Revenues

Cost of revenues for the year ended December 31, 2006 was $15.7 million as compared to $1.5 million for the year ended December 31, 2005. The increase is due to the increased sales volume. Cost of revenues include inventory write down and indirect costs. Since the OmniPods are sold at a price below direct manufacturing costs, inventory was adjusted down $1.5 million as of December 31, 2006 to reflect values at the lower of cost or market. Stock based compensation expense for the year ended December 31, 2006 allocated to cost of revenues was $22,000.

Research and Development

Research and development expense decreased $2.7 million, or 24.8%, to $8.1 million for the year ended December 31, 2006 from $10.8 million for the year ended December 31, 2005. The decrease in research and development expense was attributable to a reduction of $990,000 in employee related expenses, $835,000 in consulting expenses, which was attributable to the reduced need for design services in 2006, $689,000 in temporary employees, $294,000 in tools and services and an increase of $88,000 for stock based compensation expense.

General and Administrative

General and administrative expenses increased $2.9 million, or 52.8%, to $8.4 million for the year ended December 31, 2006 from $5.5 million for the year ended December 31, 2005. The increase in expenses was primarily due to an increase of $1.3 million in employee compensation and benefit costs, $521,000 in consulting expenses, $170,000 in stock based compensation expense and $149,000 in bad debt expense, as well as an expense of $771,000 related to the disposal of equipment.

Sales and Marketing

Sales and marketing expenses increased $2.4 million, or 63.5%, to $6.2 million for the year ended December 31, 2006 from $3.8 million for the same period in 2005. The increase in expenses was primarily due to an increase of $1.1 million in employee compensation and benefit costs resulting from the hiring of fifteen additional employees in our sales and marketing department, $677,000 in demonstration kit units, $480,000 in marketing consultants, $466,000 in travel, printing and tradeshow expenses used to support our selling efforts and $27,000 of stock based compensation expense, offset by a reduction in market research expenses of $360,000.

Other Income (Expense)

Interest income was $1.4 million and $505,000 during the years ended December 31, 2006 and 2005, respectively. This represents an increase of $873,000. Interest income was earned from investments in cash and cash equivalents. Interest income increased primarily due to higher combined average cash and cash equivalents resulting from the issuance of Series E preferred stock in February 2006. Interest expense was $1.8 million and $636,000 during the years ended December 31, 2006 and 2005, respectively. This represents an increase of $1.2 million. The increase in interest expense was primarily attributable to the interest expense on the $10.0 million loan from Lighthouse Capital Partners V, L.P. that we borrowed in June 2005 including the amortization of the discount associated with the warrant issued in connection with the term loan. In addition, we recorded $845,000 of other expense for the year ended December 31, 2006 to reflect any increases in the estimated fair value of the warrants, which resulted from our adoption of Financial Accounting Standards Board Staff Position 150-5.

In December 2006, we repaid the remaining balance of the term loan from Lighthouse Capital Partners in full with a portion of the proceeds from a $30.0 million term loan from a group of lenders led by Merrill Lynch Capital. See Liquidity and Capital Resources.

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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. As of December 31, 2007, we had recorded $26.7 million of secured debt outstanding. Since inception, we have received net proceeds of $244.1 million from the issuance of redeemable convertible preferred stock and common stock. As of December 31, 2007, we had $94.6 million in cash and cash equivalents. We believe that our current cash and cash equivalents, including the net proceeds from our public offerings, together with our short-term investments and the cash to be generated from expected product sales, will be sufficient to meet our projected operating and debt service requirements for at least the next twelve months.

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. We intend to use 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.

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,		
	2007	2006	2005
		(In thousands)	
Cash used in operating activities	$ (50,372)	$ (31,820)	$ (20,321)
Net loss	$ (53,539)	$ (35,950)	$ (21,636)

Net cash used in operating activities primarily represents funds utilized in the development and commercialization of the OmniPod System. The increase of $18.6 million in cash used in operating activities for the year ended December 31, 2007 compared to the year ended December 31, 2006 was due primarily to the growth in our activities that continued to result in a loss, increased net accounts receivable of $4.5 million, partly offset by increased provision for doubtful accounts, and an increase in inventory of $4.6 million, partially offset by increases in accounts payable and accrued expenses of $1.4 million. The increase in accounts receivable balance was related to increased sales and slower than expected collections.

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,		
	2007	2006	2005
	(In thousands)		
Cash used in investing activities	$ (10,089)	$ (12,587)	$ (6,022)
Cash provided by financing activities	$ 121,818	$ 69,978	$ 10,004

Cash used in investing activities was primarily for the purchase of fixed assets for use in the development and manufacturing of the OmniPod System. Cash provided by financing activities was primarily generated from our offerings of our common stock in 2007 and from private placement of our preferred stock and secured indebtedness in 2005 and 2006.

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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.

On June 2, 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.

On December 27, 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 is secured by all of our assets other than our intellectual property. Our borrowings under the term loan bear interest at a floating rate equal to the LIBOR rate plus 6% per annum. Interest is payable on a monthly basis during the term of the loan and we began repayment of the principal 33 equal monthly installments of $909,091 in October 2007. In addition, we are subject to loan origination fees amounting to $900,000 for the costs incurred by the lenders in making the funds available. We have capitalized these costs as deferred financing costs. The deferred financing cost is being amortized to interest expense over the entire 42-month life of this term loan. This term loan is 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. At December 31, 2007, the term loan principal was presented with its current and non-current components separately, based on its stated repayment schedule, as a result of the significant increase in our cash reserves following the initial public offering of our common stock in May 2007.

The credit and security agreement contains limitations, subject to certain exceptions, on, among other things, our ability to incur additional indebtedness or liens, make dividends or distributions to our stockholders, repurchase shares of our stock, acquire or dispose of any assets other than in the ordinary course of business, make investments in other entities, merge or consolidate with another entity or engage in a change of control, a new business or a non-arms length transaction with one of our affiliates. Additionally, under the agreement, we are obligated to complete construction of a second OmniPod manufacturing line by March 31, 2009, which deadline may be extended to June 30, 2009 in specified circumstances. If we are not in compliance with these covenants, breach any representation or warranty in the credit and security agreement, default in any payment due under the credit and security agreement or related promissory notes or any other indebtedness above a specified amount, fail to discharge a judgment against us above a specified amount, cease to be solvent or experience other insolvency related events, then the administrative

agent may declare all of the amounts owed under the term loan immediately due and payable.

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We lease our facilities, which are accounted for as operating leases. The lease of our Bedford facility generally provides for a base rent plus real estate taxes and certain operating expenses related to the lease. We entered into a new lease for our Bedford facility in 2004 which contains renewal options, escalating payments and leasehold allowances over the life of the lease. As of December 31, 2007, we had an outstanding letter of credit which totaled $200,000 to cover our security deposits for lease obligations. This letter of credit will expire October 30, 2009.

During the year ending December 31, 2008, we will be expending funds in connection with, among other things, our efforts to expand our automated manufacturing process and increase our production capacity, and expand our sales and marketing activities.

Off-Balance Sheet Arrangements

As of December 31, 2007, we did not have any off-balance sheet financing arrangements.

Contractual Obligations

The following table summarizes our principal contractual obligations as of December 31, 2007. As of December 31, 2007, we did not have contractual obligations for any payments due in 2013 or beyond. 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	$ 1,371	$ 598	$ 577	$ 196	$
Long-term debt obligations(1)(2)	31,880	13,312	18,568		
Purchase obligations for production components	16,260	16,260			
Purchase obligations for capital expenditures	2,456	2,456			
Total contractual obligations	$ 51,967	$ 32,626	$ 19,145	$ 196	$

(1) The long-term obligation amounts in the above table differ from the related carrying amounts on the Consolidated Balance Sheet as of December 31, 2007 due to the recording of $835,000 fair value of the warrants for Series E preferred stock as a discount to the term loan. The costs of the warrants are being amortized to interest expense over the 42-month life of this term loan.

(2) The interest rate on the term loan is variable and set at LIBOR rate plus 6% per annum, We have estimated future payments based on the interest rate applied in periods prior to December 31, 2007.

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 revenue from sales of our OmniPod Insulin Management System to diabetes patients. The initial sale to a new customer typically includes OmniPods and a Starter Kit, which include the PDM, two

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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 (we changed from a 30-day right of return effective for shipments prior to December 1, 2006). 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.

Transfer of title and risk and rewards of ownership are passed to the patient upon shipment from us.

The selling prices for all sales are fixed and agreed with the patient, 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.

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 and the right of return has expired.

We 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 and, to the extent allowed, all related costs of all initial shipments until the right of return has lapsed. We had deferred revenue of $1,350,000 and $284,000 as of December 31, 2007 and December 31, 2006, respectively.

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

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 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

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did not have a material impact on our financial position or results of operations. Upon adoption and as of December 31, 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.

Prior to January 1, 2006, we accounted for employee stock based compensation in accordance with the provisions of APB 25 and FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation an Interpretation of APB No. 25*, and complied with the disclosure provisions of SFAS 123, and related SFAS No. 148, *Accounting for Stock-Based Compensation Transaction and Disclosure*. Under APB 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of the stock and the exercise price of the option. The stock based compensation is amortized using the straight-line method over the vesting period.

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 will 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 in 2006 and thereafter 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

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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 and a group of lenders led by Merrill Lynch Capital, we issued warrants to the lenders to purchase shares of its 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* 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, 2007	Common Shares as of December 31, 2006	Fair Value as of December 31, 2007	Fair Value as of December 31, 2006
Series D preferred	June 2, 2012	$ 6.36		125,853	$	$ 1,096
Series E preferred	December 27, 2013	9.56	62,752	94,128		835
Total			62,752	219,981	$	$ 1,931

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 $835,000 fair value of the warrants for Series E preferred stock as a discount to the term loan. The value of the warrants is being amortized to interest expense over the 42-month life of this term loan.

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 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 $2,005,000, 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.

Allowance for doubtful accounts

Accounts receivable consist of amounts due from third-party payors and patients. 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.

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Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157. This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007, and for interim periods within those fiscal years. We will be required to adopt SFAS 157 in the first quarter of 2008. We are currently evaluating the requirements of SFAS 157 and have not yet determined the impact on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement 115*, or SFAS 159, which permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 is effective as of the beginning of an entity s first fiscal year that begins after November 15, 2007. We are currently evaluating the requirements of SFAS 159 and have not yet determined the impact on our consolidated financial statements.

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

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

On December 31, 2007, we had outstanding debt recorded at $26.7 million. Changes in interest rates do not affect the value of our debt. However, interest expense incurred on our outstanding debt will be affected because the term loan bears interest at a floating rate equal to the LIBOR rate plus 6% per annum. An increase of 1% to the interest rate will result in approximately $0.3 million additional interest payments over the remainder of the loan s term.

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(I). ***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, 2007. 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,

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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, 2007, 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.

Internal Control over Financial Information

This Annual Report on Form 10-K does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of the company s registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarterly period ended December 31, 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

None.

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 2008 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, 2007.

Audit Committee Financial Expert

The audit committee of our board of directors currently consists of Steven Sobieski (Chairman), Charles Liamos and Alison de Bord. 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 Messrs. Sobieski and Liamos each qualify as an audit committee financial expert as such term is defined in the rules of the SEC. In making its determination, our board of directors considered the nature and scope of the experiences and responsibilities Messrs. Sobieski and Liamos each 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 Messrs. Sobieski and Liamos with respect to certain accounting and auditing matters. The designation does not impose upon any duties, obligations or liability upon Messrs. Sobieski and Liamos 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

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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 2008 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, 2007.

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 2008 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, 2007. 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 2008 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, 2007.

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 2008 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, 2007.

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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.

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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 20, 2008

/s/ Carsten Boess
Carsten Boess
Chief Financial Officer

Date: March 20, 2008

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 20, 2008.

Signature	Title
/s/ Duane DeSisto Duane DeSisto	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ Carsten Boess Carsten Boess	Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ Alison de Bord Alison de Bord	Director
/s/ Gary Eichhorn Gary Eichhorn	Director
/s/ Ross Jaffe, M.D. Ross Jaffe, M.D.	Director

/s/ Charles Liamos	Director
Charles Liamos	
/s/ Gordie Nye	Director
Gordie Nye	
/s/ Jonathan Silverstein	Director
Jonathan Silverstein	
/s/ Steven Sobieski	Director
Steven Sobieski	

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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
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
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.

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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, 2007 and 2006, and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders deficit, and cash flows for each of the three years ended December 31, 2007. 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. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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 financial position of Insulet Corporation at December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the consolidated financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standard No. 123R, Share Based Payments . As also discussed in Note 1 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.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 11, 2008

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INSULET CORPORATION

CONSOLIDATED BALANCE SHEETS

	As of December 31, 2007	As of December 31, 2006
	(In thousands, except share data)	
ASSETS		
Currents Assets		
Cash	$ 94,588	$ 33,231
Accounts receivable, net	4,783	1,417
Inventories	7,990	3,390
Prepaid expenses and other current assets	1,391	1,827
Total current assets	108,752	39,865
Property and equipment, net	21,304	16,999
Other assets	685	276
Total assets	$ 130,741	$ 57,140
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
Currents Liabilities		
Accounts payable	$ 4,544	$ 3,450
Accrued expenses	4,464	4,193
Deferred revenue	1,350	284
Current portion of long-term debt	10,671	29,222
Preferred stock warrant liability		1,931
Total current liabilities	21,029	39,080
Long-term debt, net of current portion	16,006	
Other long-term liabilities	1,431	316
Total liabilities	38,466	39,396
Redeemable convertible preferred stock, $0.001 par value:		
Authorized: zero and 46,408,050 shares at December 31, 2007 and 2006, respectively		
Issued and outstanding Series A: zero and 1,000,000 shares stated at liquidation and redemption value at December 31, 2007 and 2006, respectively		1,000
Issued and outstanding Series B: zero and 5,945,946 shares stated at liquidation and redemption value at December 31, 2007 and 2006, respectively		11,000
		22,000

Issued and outstanding Series C: zero and 10,476,191 shares stated at liquidation and redemption value at December 31, 2007 and 2006, respectively		
Issued and outstanding Series D: zero and 14,669,421 shares stated at liquidation and redemption value at December 31, 2007 and 2006, respectively		35,500
Issued and outstanding Series E: zero and 13,738,661 shares stated at liquidation and redemption value at December 31, 2007 and 2006, respectively		50,009
Stockholders equity (deficit)		
Preferred stock, $.001 par value: Authorized 5,000,000 and zero shares at December 31, 2007 and 2006, respectively. Issued and outstanding zero shares at December 31, 2007 and 2006, respectively		
Common stock, $.001 par value:		
Authorized: 100,000,000 and 65,000,000 shares authorized at December 31, 2007 and 2006, respectively		
Issued: 27,223,820 and 457,076 shares at December 31, 2007 and 2006, respectively	28	1
Additional paid-in capital	247,835	293
Accumulated deficit	(155,579)	(102,040)
Subscription receivable	(9)	(19)
Total stockholders equity (deficit)	92,275	(101,765)
Total liabilities and stockholders equity (deficit)	$ 130,741	$ 57,140

See accompanying notes

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INSULET CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2007	2006	2005
	(In thousands, except share and per share data)		
Revenue	$ 13,372	$ 3,663	$ 50
Cost of revenue	25,733	15,660	1,530
Gross loss	(12,361)	(11,997)	(1,480)
Operating expenses:			
Research and development	10,391	8,094	10,764
General and administrative	13,922	8,389	5,490
Sales and marketing	16,141	6,165	3,771
Impairment of assets	1,027		
Total operating expenses	41,481	22,648	20,025
Operating loss	(53,842)	(34,645)	(21,505)
Interest income	3,537	1,378	505
Interest expense	(3,160)	(1,838)	(636)
Net interest income (expense)	377	(460)	(131)
Change in value of preferred stock warrant liability	(74)	(845)	
Net loss	(53,539)	(35,950)	(21,636)
Accretion of redeemable convertible preferred stock		(222)	
Net loss attributable to common shareholders	$ (53,539)	$ (36,172)	$ (21,636)
Net loss per share basic and diluted	$ (3.21)	$ (99.72)	$ (70.95)
Weighted-average number of shares used in calculating net loss per share	16,688,418	362,750	304,962

See accompanying notes

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INSULET CORPORATION

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND CHANGES IN STOCKHOLDERS DEFICIT

ible	Series C Convertible		Series D Convertible			Series E Convertible			
	Preferred Stock		Preferred Stock		Series D Warrant	Preferred Stock		Common Stock	
nount	Shares	Amount	Shares	Amount	Amount	Shares	Amount	Shares	Amou
	(In thousands, except for share data)								
11,000	10,476,191	22,000	14,669,421	35,500				296,599	
								14,909	
					251				
11,000	10,476,191	22,000	14,669,421	35,500	251			311,508	

							13,738,661	49,787			
								222			
						(251)					
										145,568	
11,000	10,476,191	$	22,000	14,669,421	$ 35,500	$	13,738,661	$ 50,009	457,076	$	
										380,190	
										2,789	
										111,197	

11,000)	(10,476,191)	(22,000)	(14,669,421)	(35,500)		(13,738,661)	(50,009)	17,447,809	1
								8,824,759	
								27,223,820	$ 2

See accompanying notes

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INSULET CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2007	2006	2005
	(In thousands)		
Cash flows from operating activities			
Net loss	$ (53,539)	$ (35,950)	$ (21,636)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	4,681	2,421	1,203
Amortization of debt discount	239	219	33
Redeemable convertible preferred stock warrant expense	74	845	
Stock compensation expense	1,520	307	39
Provision for bad debts	1,120	149	14
Loss on impairment and disposal of assets	1,103	771	
Non cash interest expense	(57)	57	
Changes in operating assets and liabilities:			
Accounts receivable	(4,486)	(1,426)	(154)
Inventory	(4,600)	(2,526)	(864)
Prepaids and other current assets	436	(1,358)	(187)
Other assets	(409)	(221)	(1)
Accounts payable and accrued expenses	1,365	4,723	801
Other long term liabilities	1,115	1	315
Deferred revenue	1,066	168	116
Net cash used in operating activities	(50,372)	(31,820)	(20,321)
Cash flows from investing activities			
Purchases of property and equipment	(10,089)	(13,137)	(5,472)
Decrease (increase) in restricted cash		550	(550)
Net cash used in investing activities	(10,089)	(12,587)	(6,022)
Cash flows from financing activities			
Proceeds from sale of Series E preferred stock, net of issuance cost		49,787	
Proceeds from issuance of debt		30,000	10,000
Principal payments of long term debt	(2,727)	(10,000)	
Proceeds from payment of subscription receivable	10	11	
Principal payments under capital lease			(11)
Proceeds from issuance of common stock, net of offering expenses	124,535	180	15
Net cash provided by financing activities	121,818	69,978	10,004
Net increase (decrease) in cash and cash equivalents	61,357	25,571	(16,339)
Cash and cash equivalents, beginning of year	33,231	7,660	23,999

Cash and cash equivalents, end of period	$ 94,588	$ 33,231	$ 7,660
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 3,154	$ 1,760	$ 473
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

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INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Years ended December 31, 2007, 2006 and 2005

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.

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 no 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.

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INSULET CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Outstanding letters of credit, principally relating to security deposits for lease obligations, totaled $200,000 at December 31, 2007 and 2006, respectively.

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, 2007, 2006 and 2005 amounted to $1,120,000, $149,000, $14,000, respectively. There were $74,000 and $0, and $0 write-offs or other adjustments to the allowance for doubtful accounts during the years ended December 31, 2007, 2006, and 2005, respectively. Allowance for doubtful accounts totaled $1,209,000 and $163,000 as of December 31, 2007 and 2006, 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 market value for all periods presented as the Company currently sells the OmniPod at a loss. 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