INSULET CORP
Form 424B5
October 30, 2009

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Filed Pursuant to Rule 424(b)(5)
Registration No. 333-158354

Prospectus supplement
(To prospectus dated April 1, 2009)

6,000,000 shares

Common stock

We are offering 6,000,000 shares of common stock.

Our common stock is listed on the NASDAQ Global Market under the symbol PODD. On October 29, 2009, the closing price of our common stock on the NASDAQ Global Market was $10.31 per share.

	Per share	Total
Public offering price	$ 10.250	$ 61,500,000
Underwriting discounts	$ 0.615	$ 3,690,000
Proceeds to Insulet Corporation, before expenses	$ 9.635	$ 57,810,000

We have granted the underwriters an option for a period of up to 30 days from the date of this prospectus supplement to purchase up to 900,000 additional shares of our common stock at the public offering price less the underwriting discounts to cover over-allotments, if any.

Investing in our common shares involves a high degree of risk. See Risk factors beginning on page S-7.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus supplement. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares on or about November 4, 2009.

Sole book-running manager

J.P.Morgan

Co-managers

Canaccord Adams **JMP Securities**

October 29, 2009

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About this prospectus supplement

This document is in two parts. The first part is the prospectus supplement, which describes the specific terms of the securities we are offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into the accompanying prospectus. The second part, the accompanying prospectus, including the documents incorporated by reference, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the Securities and Exchange Commission before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date, for example, a document incorporated by reference into the accompanying prospectus, the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained or incorporated by reference into this prospectus supplement and the accompanying prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement outside the United States. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus is accurate only as of the respective dates of those documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus, including the documents we have referred you to in the section of this prospectus supplement entitled Where You Can Find More Information, before making your investment decision.

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Prospectus supplement summary

This summary highlights certain information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents we incorporate by reference. This summary is not complete and does not contain all of the information that you should consider before investing in our securities. To fully understand this offering and its consequences to you, you should read this entire prospectus supplement and the accompanying prospectus carefully, including the factors described under the headings Risk Factors in this prospectus supplement on page S-7, and the financial statements and other information incorporated by reference into this prospectus supplement and the accompanying prospectus when making an investment decision. Unless the context otherwise requires, all references to we, us, our company or the Company in this prospectus supplement refers to Insulet Corporation, a Delaware corporation, and its wholly-owned subsidiary.

About Insulet Corporation

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

The U.S. Food and Drug Administration, or FDA, approved the OmniPod System in January 2005, and we began commercial sale of the OmniPod System in the United States in October 2005. Since the commercial launch of the OmniPod system, we have progressively expanded our marketing efforts from an initial focus in the Eastern United States, to providing availability of the OmniPod System in the entire United States. We focus our sales and marketing efforts towards key diabetes practitioners, academic centers and clinics specializing in the treatment of diabetic patients, as well as individual diabetic patients.

Recent developments

During the three months ended September 30, 2009, our revenue increased 85% to $18.7 million, compared to $10.1 million for the three months ended September 30, 2008. Gross profit for the three months ended September 30, 2009 was $5.8 million, representing a 31% gross margin, compared to a gross loss of $0.1 million, or a (1%) gross margin, for the three months ended September 30, 2008. Operating loss for the three months ended September 30, 2009 was $13.5 million, a 32% improvement compared to $19.8 million for the three months ended September 30, 2008. Total operating expenses were $19.3 million for the three months ended September 30, 2009, compared to $19.7 million for the three months ended September 30, 2008. Net loss for the three months ended September 30, 2009 was $24.7 million, or $0.88 per share,

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compared to a net loss of $21.7 million, or $0.78 per share, for the three months ended September 30, 2008.

For the nine months ended September 30, 2009, our revenue increased 89% to $45.8 million, compared to $24.2 million for the nine months ended September 30, 2008. Gross profit for the nine months ended September 30, 2009 was $11.0 million, representing a 24% gross margin, compared to a gross loss of $5.8 million, or a (24%) gross margin, for the nine months ended September 30, 2008. Operating loss for the nine months ended September 30, 2009 was $47.4 million compared to $62.0 million for the nine months ended September 30, 2008.

As of September 30, 2009, our cash and cash equivalents totaled $72.7 million, compared to $56.7 million as of December 31, 2008. On September 30, 2009, we repaid the $27.5 million of outstanding debt and borrowed the remaining $32.5 million available under the credit facility we entered into in March 2009. Under the modified agreement, interest accrues on drawn amounts at a rate of 8.5% per annum and the lender agreed to forego the remaining warrants to purchase shares of our common stock that would have been issued upon future draws. In addition, we entered into a securities purchase agreement with the lender whereby we sold 2,855,659 shares of our common stock to the lender at $9.63 per share for aggregate proceeds of $27.5 million on September 30, 2009.

Our corporate information

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.MyOmniPod.com. We do not incorporate the information on, or accessible through, our website into this prospectus supplement or accompanying prospectus, and you should not consider it part of this prospectus supplement or accompanying prospectus.

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The offering

Issuer	Insulet Corporation
Common stock we are offering	6,000,000 shares (or 6,900,000 shares of common stock if the over-allotment option is exercised in full).
Over-allotment option	We have granted the underwriters an option for a period of up to 30 days from the date of this prospectus supplement to purchase up to 900,000 additional shares of common stock at the public offering price less the underwriting discounts to cover over-allotments, if any.
Common stock to be outstanding after this offering	36,789,239 shares (or 37,689,239 shares of common stock if the over-allotment option is exercised in full).
Use of proceeds	We expect to receive net proceeds from this offering of approximately $57.3 million after deducting the underwriting discounts and estimated offering expenses. We intend to use the net proceeds for general corporate purposes, which may include the repayment of certain outstanding debt obligations. See Use of Proceeds on page S-30.
Risk factors	See Risk Factors on page S-7 for a discussion of factors you should consider carefully before making an investment decision.
NASDAQ Global Market symbol	PODD

The number of shares of common stock to be outstanding after this offering is based on 30,789,239 shares outstanding as of September 30, 2009 and excludes:

- 3,627,277 shares of common stock issuable upon the exercise of outstanding stock options as of September 30, 2009 at a weighted average exercise price per share of $8.34;
- 3,812,752 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2009 at a weighted average exercise price per share of $3.24; and
- an aggregate of up to 2,914,721 shares of common stock reserved for future issuance under our 2007 Stock Option and Incentive Plan and our 2007 Employee Stock Purchase Plan.

Unless otherwise indicated, the information in this prospectus supplement assumes that the underwriters will not exercise the over-allotment option granted to them by us.

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Summary consolidated financial data

The summary consolidated financial data as of December 31, 2007 and 2008 and for the years ended December 31, 2006, 2007 and 2008 have been derived from our historical financial statements audited by Ernst & Young LLP, an independent registered public accounting firm, incorporated by reference into this prospectus supplement and the accompanying prospectus. The summary consolidated financial data as of September 30, 2009 and for the nine-month periods ended September 30, 2008 and 2009 have been derived from our unaudited consolidated financial statements incorporated by reference into this prospectus supplement and the accompanying prospectus. These unaudited consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements. In the opinion of management, the unaudited financial data reflect all adjustments, consisting only of normal and recurring adjustments, necessary for a fair statement of the results for those periods. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the full year or any future period. Historical results are not necessarily indicative of the results to be expected in the future. The following summary consolidated financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations, and our consolidated financial statements and the accompanying notes to those consolidated financial statements included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2009 and our Quarterly Report on Form 10-Q filed on October 26, 2009, which are incorporated by reference into this prospectus supplement and the accompanying prospectus.

	Year ended December 31,			Nine months ended September 30,	
(in thousands, except share and per share data)	2006	2007	2008 (restated)	2008 (restated) (unaudited)	2009 (unaudited)
Consolidated Statements of Operations Data:					
Revenue	$ 3,663	$ 13,372	$ 36,059	$ 24,198	$ 45,821
Cost of revenue	15,660	25,733	40,643	29,980	34,858
Gross profit (loss)	(11,997)	(12,361)	(4,584)	(5,782)	10,963
Operating expenses:					
Research and development	8,094	10,391	13,104	9,569	9,880
General and administrative	8,389	13,922	23,750	16,900	19,575
Sales and marketing	6,165	16,141	39,734	29,735	28,905
Restructuring and impairment of assets		1,027	8,170		
Total operating expenses	22,648	41,481	84,758	56,204	58,360
Operating loss	(34,645)	(53,842)	(89,342)	(61,986)	(47,397)
Net interest income (expense)	(460)	377	(5,430)	(3,588)	(17,212)

Change in value of preferred stock warrant liability	(845)	(74)			
Net loss	(35,950)	(53,539)	(94,772)	(65,574)	(64,609)
Accretion of redeemable convertible preferred stock	(222)				
Net loss attributable to common shareholders	$ (36,172)	$ (53,539)	$ (94,772)	$ (65,574)	$ (64,609)
Net loss per share basic and diluted(1)	$ (99.72)	$ (3.21)	$ (3.43)	$ (2.38)	$ (2.32)
Weighted-average number of shares used in calculating net loss per share	362,750	16,688,418	27,611,003	27,560,258	27,894,775

(1) See note 4 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2008 for an explanation of the method used to calculate basic and diluted net loss per common share.

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(in thousands)	As of December 31, 2007	2008 (restated)	As of September 30, 2009 (unaudited)
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 94,588	$ 56,663	$ 72,694
Working capital	$ 87,723	$ 71,531	$ 81,574
Total assets	$ 130,741	$ 108,233	$ 117,128
Current debt	$ 10,671	$	$
Long-term debt, net of current portion	$ 16,006	$ 60,172	$ 95,902
Other long-term liabilities	$ 1,431	$ 2,987	$ 2,706
Total stockholders equity	$ 92,275	$ 28,106	$ 303

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Cautionary note regarding forward-looking statements

This prospectus supplement contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements regarding our or our management s expectations, hopes, beliefs, intentions or strategies regarding the future. We may, in some cases, use words such as anticipate, believe, could, estimate, expect, intend, may, plan, projec would or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and are including this statement for purposes of complying with those safe harbor provisions. Forward-looking statements in this prospectus supplement may include, for example, statements about:

- our estimates regarding revenues, expenses, capital requirements and needs for additional financing;
- our manufacturing capacity in future periods;
- our ability to reduce the per unit production cost of the OmniPod;
- our ability to raise additional funds in the future;
- our research, development, commercialization, and other activities and projected expenditures;
- our ability to obtain regulatory approvals for any future products;
- our intellectual property position;
- our cash needs;
- our plans to pursue the use of the OmniPod System technology for the delivery of drugs other than insulin;
- the implementation of our business strategies, including our manufacturing strategies and the expansion of our international sales and marketing efforts; and
- our financial performance.

The forward-looking statements contained in this prospectus supplement are based on current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section entitled Risk Factors. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

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Risk factors

An investment in our common stock involves risks. You should consider carefully the risks described below together with all of the other information included in this prospectus supplement, the accompanying prospectus, and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus, before making any investment decisions regarding our securities. If any of these risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline, and you may lose all or part of your investment.

Risks related to our business

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

Since our inception in 2000, we have incurred losses every quarter. We began commercial sales of the OmniPod System in October 2005. Beginning in the second half of 2008, we have been able to manufacture and sell the OmniPod System at a cost and in volumes sufficient to allow us to achieve a positive gross margin. For the nine months ended September 30, 2009, our gross profit from the manufacture and sale of the OmniPod System was $11.0 million. Although we have achieved a positive gross margin, we still operate at a substantial net loss. Our net losses for the nine months ended September 2009, and the years ended December 31, 2008 and 2007 were $64.6 million, $94.8 million and $53.5 million, respectively. The extent of our future operating losses and the timing of profitability are highly uncertain, and we may never achieve or sustain profitability. We have incurred a significant net loss since our inception, and, as of September 30, 2009, we had an accumulated deficit of $315.0 million.

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

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

- the failure of the OmniPod System to achieve wide acceptance among opinion leaders in the diabetes treatment community, insulin-prescribing physicians, third-party payors and people with insulin-dependent diabetes;
- manufacturing problems;
- actual or perceived quality problems;
- changes in reimbursement rates or policies relating to the OmniPod System by third-party payors;

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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;

attrition rates of customers ceasing to use the OmniPod System;

competitive pricing and related factors; and

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

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

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

Currently, the gross profit from the sale of the OmniPod System is not sufficient to cover our operating expenses. To achieve profitability, we need to, among other things, reduce the per unit cost of the OmniPod. This can be achieved by increasing our manufacturing volume, which will allow for volume purchase discounts to reduce our raw material costs and improve absorption of manufacturing overhead costs. During 2008, we completed construction of a partially automated manufacturing line at a facility in China operated by a subsidiary of Flextronics International Ltd. Our manufacturing capacity at September 30, 2009 was in excess of 300,000 OmniPods per month. If we are unable to reduce raw material and manufacturing overhead costs through volume purchase discounts and increased production capacity, our ability to achieve profitability will be severely constrained. Any increase in manufacturing volumes must be supported by a concomitant increase in customer orders. The occurrence of one or more factors that negatively impact our sales of the OmniPod System may prevent us from achieving our desired increase in manufacturing volume, which would prevent us from attaining profitability.

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

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

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

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

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

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs. Recently, President Obama and members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. healthcare reform and a number of bills have been proposed in Congress. A leading proposal includes an excise tax on the medical device industry that would be payable based on revenue, not income. In addition, recent legislation and many of these proposed bills include funding to assess the comparative effectiveness of medical devices. It is unclear what impact the excise tax proposal or the comparative effectiveness analysis would have on the OmniPod System or our financial results. The ultimate content or timing of any future healthcare reform legislation, and its impact on medical device companies such as us, is impossible to predict. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may have a material adverse effect on our financial condition and results of operations.

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

Our capital requirements will depend on many factors, including:

- revenues generated by sales of the OmniPod System and any other future products that we may develop;
- costs associated with adding further manufacturing capacity;

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

expenses we incur in manufacturing and selling the OmniPod System;

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

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

costs associated with any expansion;

costs associated with capital expenditures;

costs associated with litigation; and

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

We believe that our current cash and cash equivalents, including the net proceeds from this offering, together with the cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements through at least the end of 2010.

We may in the future seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies, or grant licenses on terms that are not favorable to us.

The facility agreement we entered into on March 13, 2009, as amended on September 25, 2009, with certain institutional accredited investors, contains restrictions on our ability to incur certain indebtedness without the prior consent of our lenders. In addition, our ability to raise additional capital may be adversely impacted by current economic conditions, including the effects of the recent disruptions to the credit and financial markets in the United States and worldwide. As a result of these and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain future additional capital on terms favorable to us or our stockholders.

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

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

We rely on a number of suppliers who manufacture the components of the OmniPods and PDMs. For example, we rely on Phillips Plastic Corporation to manufacture and supply a number of injection molded components of the OmniPod and Freescale Semiconductor, Inc. to

manufacture and supply the application specific integrated circuit that is incorporated into the OmniPod. In addition, we expanded the scope of our existing contract manufacturing agreement with a subsidiary of Flextronics International Ltd. in China to provide the supply of complete OmniPods. We do not have long-term supply agreements with most of our suppliers, and, in many cases, we make our purchases on a purchase order basis. In some other cases, where we do have agreements in place, our agreements with our suppliers can be terminated by either party upon short notice. For example, the initial term of our agreement with Flextronics is three years from January 3, 2007, with automatic one-year renewals, and may be terminated at any time by either party upon prior written notice given no less than a specified number of days prior to the date of termination. Additionally, our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers needs higher priority than ours;
- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of the OmniPod System or cause delays in shipment;
- we may have difficulty locating and qualifying alternative suppliers for our sole-source supplies;
- switching components may require product redesign and submission to the U.S. Food and Drug Administration, or FDA, of a 510(k) supplement;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver products to us in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

We may not be able to quickly establish additional or replacement suppliers, particularly for our sole-source suppliers, in part because of the FDA approval process and because of the custom nature of various parts we require. Any interruption or delay in obtaining products from our third-party suppliers, or our inability to obtain products from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competing products.

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

In order to reduce our cost of goods sold and increase our production capacity, we increasingly rely on third-party suppliers located outside the United States. For example, currently all of our OmniPods are manufactured on a partially automated manufacturing line at a facility in China

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operated by Flextronics International Ltd. As a result, our business is subject to risks associated with doing business internationally, including:

- 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;
- changes in foreign currency exchange rates;
- difficulties associated with foreign legal systems;
- differing protection of intellectual property; and
- unexpected changes in regulatory requirements.