MEDTRONIC MINIMED

Company Overview

Medtronic MiniMed, the world leader in insulin pump therapy and continuous glucose monitoring technology, designs, manufactures and markets advanced systems for the treatment of diabetes. The company’s vision is to improve the lives of people with diabetes by providing integrated systems to enhance and simplify diabetes management. Diabetes-related supplies and data management systems are also part of the company's current broad-based product offerings. The company’s ultimate goal is to create an artificial pancreas, designed to automatically regulate insulin delivery using an insulin pump, a continuous glucose monitoring system and a mathematical control algorithm.

Founded more than 20 years ago, the company’s core business is insulin pump therapy for people using insulin to treat diabetes. For many diabetes patients, an insulin pump can enable tighter blood sugar control than any other insulin delivery method. Studies show that for many people living with diabetes, maintaining blood sugar levels within a near-normal range can improve health and extend life. With a pump, diabetes patients can live a more flexible lifestyle, free from the rigid meal, exercise and sleep schedules required by injection therapy. Diabetes patients can eat what they want, when they want, and manually adjust insulin delivery to account for changes in diet, lifestyle and blood glucose levels.

Medtronic MiniMed offers responsive customer service, assisting pump users with insurance paperwork, billing, training for pump initiation and ordering supplies. In addition, Medtronic MiniMed provides ongoing educational support for physicians and diabetes patients. Nationwide educational programs are also provided for diabetes patients and the healthcare community.

Products

Insulin Pump Therapy

Medtronic MiniMed manufactures and supports a variety of insulin infusion pumps. The company’s wireless diabetes management systems automate the exchange of blood sugar values between a meter and a pump, while recommending proper insulin dosages to patients. The company offers a variety of disposable infusion sets used with pump therapy, which customers typically change every two to three days.

Through the company’s Paradigm Pathway Program, Paradigm pump users can upgrade their current pump to receive new technology features, as they become available, for an affordable fee. This marks the first time in the history of pump therapy that pump users can protect themselves against near-term technology obsolescence. The Paradigm Pathway Program enables customers to remain at the forefront of technology for years to come. Separate Pathway programs are available for Paradigm 512 and 712 insulin pump users.

Physician-Use Continuous Glucose Monitoring System: CGMS® System Gold™

CGMS System Gold, the second-generation enhancement of the CGMS system, is a state-of-the-art evaluation tool used to track blood glucose patterns in people with diabetes. It provides physicians with unmatched insight into glycemic patterns. The uniquely comprehensive information provided by CGMS...
System Gold can identify unhealthy blood glucose fluctuations and trends in diabetes patients, which otherwise can go undetected with standard HbA1c tests and fingerstick measurements. Comprehensive information provided by CGMS System Gold enables healthcare professionals and their patients to work together to make therapy, dietary and lifestyle adjustments with the goal of improving diabetes management.

CGMS System Gold provides up to 288 glucose measurements every 24 hours – 72 times more data than patients testing their blood sugars four times a day would obtain. In fact, the CGMS System Gold sensor is the only continuous glucose sensor that can measure blood glucose values for up to 72 hours while patients go about their normal activities. The CGMS System Gold sensor is typically inserted into the subcutaneous tissue of the abdominal area and worn for a period of one to three days. A Holter-style monitor stores continuous glucose sensor data measured by the sensor at five-minute intervals. This data can be downloaded into a computer and analyzed retrospectively by a healthcare professional.

**Patient-Use Continuous Glucose Monitoring System: The Guardian™ System**

The Guardian system is an “alarm device” designed to alert users to potentially dangerous fluctuations in blood sugar levels. The Guardian system incorporates the same glucose sensor technology as CGMS System Gold. Comprehensive data stored in the monitor can be downloaded to a personal computer for retrospective analysis. Parents with small children, adults with diabetes who have lost their ability to detect oncoming hypoglycemia, and any diabetes patient who desires optimal control, can benefit from this system.

**General Medication Pump**

The company is also committed to treating medical conditions other than diabetes through the use of its General Medication Pump. This pump is currently being used to deliver the drug Remodulin™* for the treatment of Primary Pulmonary Hypertension. Medtronic MiniMed continues to evaluate opportunities for using the General Medication Pump with macromolecules, such as proteins and peptides, and drugs with short half-lives, to treat cancer, cardiovascular disease, diabetes, and other disease states.

**Discrete Glucose Meter**

In 2003, Medtronic MiniMed entered into an alliance with Becton Dickinson (BD) to distribute a co-branded version of the BD Logic™ blood glucose monitor and test strips in its direct-to-consumer distribution channel. The companies are also sharing intellectual property to co-develop and distribute integrated systems to simplify and improve diabetes management. The first integrated system developed through this partnership is expected to utilize wireless communication to automatically send a glucose value from a state-of-the-art glucose meter¹ to a future generation Paradigm pump.¹

**Products of the Future**

**Continuous Glucose Monitoring System: The Guardian™ 2 system**

In addition to the Guardian system, the company intends to introduce the Guardian 2 system, designed to display real-time glucose readings to help patients improve their diabetes management.

**Data Management Systems**¹

In addition to the company’s current software programs, which allow patients and healthcare providers to download and view pertinent diabetes management information from a personal computer, the company is developing a web-based diabetes data management system (DDMS). This system is expected to increase access and utilization of important diabetes management data.

**Pre-filled Reservoirs**¹

¹Investigational device only. Not yet cleared by the FDA
A pre-filled reservoir is being designed to provide greater convenience to customers. Currently, to fill a new reservoir, pump users must manually transfer insulin from a standard vial into a disposable reservoir. Medtronic MiniMed pump users typically change their disposable reservoirs and infusion sets every two to three days.

*A registered trademark of United Therapeutics.

**Implantable Pump**

The Medtronic MiniMed 2007 System, designed to more closely mimic the function of a normal pancreas, offers potential treatment advantages to diabetes patients who have difficulty maintaining consistent glucose control. The implantable pump is designed to deliver short, frequent pulses of insulin into the peritoneal cavity, where it can be more rapidly and predictably absorbed versus in the subcutaneous tissue. Worldwide, more than 350 people currently wear an implantable pump as participants in clinical research studies or through compassionate-use programs. The Model 2007 implantable pump received approval for distribution in the European Union in February 2000 and bears the CE mark. In 2003, AFSSAPS, the French regulatory authority, approved the highly concentrated insulin used with the implantable pump in France.

**Artificial Pancreas**

To create an artificial pancreas, the company intends to develop semi-automated and closed-loop systems that have the potential to automatically regulate insulin delivery for diabetes patients.

* _Semi-Automated System_

In a semi-automated system, continuous glucose readings are recorded by a sensor and incorporated in a mathematical algorithm for the purpose of proactively suggesting insulin dosage to diabetes patients. The patient must confirm the recommended dose before insulin is infused through either an external or implantable insulin pump. The continuous glucose sensor is periodically calibrated with blood glucose meter readings.

* _Closed-Loop System_

In a closed-loop system, continuous glucose readings are recorded by a sensor and incorporated in an algorithm to calculate insulin dosages, which are automatically infused by either an external or implantable insulin pump.

**Workforce and Operations**

Medtronic MiniMed employs approximately 2,300 people worldwide. Customer support (sales processing, insurance verification, clinical services, billing and collections), marketing, research and development, and manufacturing are located at its corporate headquarters in Northridge, California. International headquarters are located in Tolochenaz, Switzerland.

Any statements made about the company's anticipated regulatory approvals are forward-looking statements subject to risks and uncertainties such as those described in the company's Annual Report on Form 10-K for the year ended April 25, 2003. Actual results may differ materially from anticipated results.